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

4 June 2008
[9-08]

FINAL ASSESSMENT REPORT

APPLICATION A610

MAXIMUM RESIDUE LIMITS (JULY, AUGUST 2007)

For information on matters relating to this Assessment Report or the assessment process generally, please refer to: http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

Application A610 seeks to amend maximum residue limits (MRLs) for agricultural and veterinary chemicals in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* (the Code). Notifications from the Australian Pesticides and Veterinary Medicines Authority (APVMA) received prior to 1 October 2007 are routinely batched and processed as an Application to update the Code in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

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.

The Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food[1] 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 will be exploring alternative options for regulating chemical residues in food.

There are no MRLs for antibiotic residues in this Application.

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 submissions were received from WTO members.

FSANZ decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) (as was in force prior to 1 July 2007), not to invite public submissions in relation to the Application prior to making a Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only. FSANZ considered submissions on the Initial / Draft Assessment Report to assist in making a Final Assessment.

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1 http://www.health.gov.au/internet/wcms/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/$File/pol-g-line-reg-res.pdf accessed 12 March 2008.

Purpose

The purpose of this Application is to update the Code with current MRLs for agricultural and veterinary chemicals in use in Australia. 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.

Decision

FSANZ has made an assessment and approves the draft variations to Standard 1.4.2 – Maximum Residue Limits.

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 Application.

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

- FSANZ has undertaken a regulation impact assessment and concluded that the 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 enforcement agencies.

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

Consultation

FSANZ has now completed the assessment of Application A610 and held a single round of public consultation under section 36 of the FSANZ Act (as was in force prior to 1 July 2007.) 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 Australian State and Territory food law.

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INTRODUCTION

Notifications were received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 8 and 20 August 2007 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 non-antibiotic agricultural and veterinary chemicals with the MRLs in the APVMA MRL Standard.

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 producers, importers and compliance agencies by maintaining current MRLs in the Code.

FSANZ will not agree to adopt MRLs into the Code where dietary exposure to residues of a chemical presents a risk to public health and safety. In assessing this risk, FSANZ reviews dietary exposure assessments in accordance with internationally accepted practices and procedures.

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 and to allow for future developments in methods of analysis that could lead to a lowering of this limit.

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. Background

1.1 Current Standard

The APVMA has approved the use of the agricultural and veterinary chemical products associated with the MRLs in this Application, and made amendments to the MRL Standard accordingly. Consequently there are discrepancies between the potential residues associated with the use of the relevant agricultural and/or veterinary chemicals and the MRLs in Standard 1.4.2.

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 people, animals 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 Applications

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. FSANZ reviews information provided by the APVMA 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 (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.

Appropriate toxicology, residue, animal transfer, processing and metabolism studies were 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 MRLs for the commodities as outlined in this Application.

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

1.4 Summary of Proposed Variations to Standard 1.4.2

Amendments under consideration in Application A610:

- adding temporary MRLs including some at the LOQ for certain foods for imidacloprid, iprodione, methabenzthiazuron and prothioconazole;

- adding MRLs for certain foods including some at the LOQ for abamectin, acibenzolar-S-methyl, cloquintocet-mexyl, iprodione, milbemectin, pyraflufen-ethyl and trinexapac-ethyl;

- increasing MRLs for certain foods for dimethomorph and trinexapac-ethyl; and

- decreasing MRLs for certain foods including some to the LOQ for methabenzthiazuron.

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**.

In considering the issues associated with MRLs it should be noted that 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.

1.5 Antibiotic MRLs

There are no MRLs for antibiotic[2] residues in this Application.

1.6 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.

[2] An antibiotic is a substance that inhibits or inactivates the growth of microorganisms such as bacteria.

New Zealand MRLs are discussed further in section 10.6 of this Report.

2. 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. Changes to Australian MRLs reflect the changing patterns of agricultural and veterinary chemicals available to farmers. These changes include the development of new products or crop uses, granting or expiry of temporary permissions and the withdrawal of older products following review.

3. Objectives

In assessing this Application, 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. The APVMA has already established MRLs under its legislation, and now seeks to have the relevant amendments made in the Code.

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

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

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

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

The Ministerial Council has endorsed a Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food[3], which has now been provided to FSANZ. In consultation with stakeholders, FSANZ will explore alternative options for regulating chemical residues in food. To ensure appropriate consultation, this process will take some time to complete.

[3] http://www.health.gov.au/internet/wcms/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/$File/pol-g-line-reg-res.pdf accessed 12 March 2008.

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

4. Assessment Approach

FSANZ's primary role in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential residues in treated food do not present public health and safety concerns.

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code Act 1994* (Ag Vet Code Act) requires the APVMA to be satisfied that there will not be any appreciable risk to the consumer, to the person handling, applying or administering the chemical, to the environment, to the target crop or animal or to trade in an agricultural commodity.

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 represent a risk to public health and safety. In assessing this risk, FSANZ reviews dietary exposure assessments conducted by the APVMA in accordance with internationally accepted practices and procedures.

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.

At the risk characterisation step, 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)).

RISK ASSESSMENT

5. Safety Assessment

5.1 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.

5.2 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.

5.3 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.

5.3.1 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.

5.3.2 Acute Dietary Exposure Assessment

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

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

5.3.3 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.

6. Risk Assessment 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.

For this Application, the APVMA has assessed 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 as outlined in this Application.

The OCS has undertaken a toxicological assessment of the chemical products and has established relevant ADIs and where appropriate, an ARfD.

FSANZ has reviewed the dietary exposure assessments submitted by the APVMA as part of this Application and concluded that the residues associated with the 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.

RISK MANAGEMENT

7. Options

7.1 Option 1 – no change to Standard 1.4.2

Option 2 has been arranged into two general sub-options for the purpose of outlining the implications in the benefit cost analysis below.

7.2 Option 2(a) – vary Schedule 1 of Standard 1.4.2 to omit or decrease existing MRLs as proposed

7.3 Option 2(b) – vary Schedule 1 of Standard 1.4.2 to include new or increase existing MRLs as proposed

8. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposed changes, and the potential impacts of any regulatory or non-regulatory provisions. Information from public submissions is needed to make a final assessment of the proposed changes.

8.1 Affected Parties

The parties affected by proposed MRL amendments include:

- domestic and international consumers;
- growers and producers of domestic and export food commodities;
- 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.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – no change to Standard 1.4.2

Importers and consumers may benefit if proposed MRL deletions or reductions are not progressed. 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. Further information provided at Initial / Draft Assessment to assist in identifying implications for imported foods is discussed in section 10 of this Report and the requested MRL variations are outlined in **Attachment 2**.

This option would result in costs to growers and producers of domestic and export food commodities as food containing residues consistent with new or increased MRLs could not legally be sold. Primary producers do not produce food or use chemical products to comply with MRLs. They use chemical products to control pests and diseases in accordance with the prescribed label conditions, and expect that the resulting residues will be acceptable and that legally treated food can be sold legally. If legal use of chemical products results in the production of food that cannot be sold under food legislation then primary producers will incur substantial losses. Major losses for primary producers would in turn impact negatively upon rural and regional communities.

This option may potentially result in costs to importers as food containing residues consistent with new or increased MRLs could not be imported. This option may restrict the opportunity for importers to source safe produce or foods.

This option would allow discrepancies between agricultural and food legislation thereby creating uncertainty, inefficiency and confusion in the enforcement of regulations. This would impact negatively on all affected parties.

8.2.2 Option 2(a) – vary Schedule 1 of Standard 1.4.2 to omit or decrease existing MRLs as proposed

This option may contribute to community confidence that regulatory authorities are maintaining standards to minimise residues in the food supply.

This option may result in costs for importers and consumers as foods containing residues that exceed the new, lower MRLs could not be legally imported or sold to consumers. Any MRL deletions or reductions have the potential to restrict importation of foods and could potentially result in higher food prices and a reduced product range available to consumers. Imported foods and Codex MRLs are addressed in section 10 of this Report.

This option is unlikely to result in any costs for producers as changes in use patterns are made as required, proper use resulting in compliance with proposed MRLs already.

This option is unlikely to result in discernable costs to Australian Government, State and Territory agencies, although there would need to be an awareness of changes in the standards for residues in food.

8.2.3 Option 2(b) – vary Schedule 1 of Standard 1.4.2 to include new or increase existing MRLs as proposed

FSANZ has not identified any health or safety concerns in relation to incorporating the requested new or increased MRLs in the Code. FSANZ does not consider there to be any dietary exposure implications associated with the proposed approval. Progressing this option may contribute to maintaining community confidence in the food supply in relation to residues of agricultural chemicals in the food supply.

This option may result in some benefits to consumers in terms of price and availability of foods if foods with residues consistent with new or increased MRLs can be sold. No additional costs to consumers have been identified.

This option benefits growers and producers of domestic and export food commodities in that food containing residues consistent with new or increased MRLs could be sold.

This option would benefit importers in that food containing residues consistent with new or increased MRLs could be imported.

This option is unlikely to result in significant costs to Australian Government, State and Territory agencies although an awareness of changes in the standards for residues in food would be needed and there may be minimal impacts associated with slight changes to residue monitoring programs.

Achieving further consistency between agricultural and food legislation would minimise compliance costs to primary producers and assist in efficient enforcement of regulations.

8.3 Comparison of Options

In assessing applications, 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 Application A610, there are no options other than a variation to Standard 1.4.2.

FSANZ recommends approving option 2 – to vary Schedule 1 of Standard 1.4.2 to include new, increase, omit or decrease some existing MRLs.

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

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

- The changes would minimise potential costs to primary producers and rural and regional communities in terms of legally permitting the sale of 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(a) may result in compliance costs for importers and industry where there are decreases or deletions of MRLs.

Option 1 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. Also, consequent discrepancies between agricultural and food legislation could have negative impacts on compliance costs for producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

The benefits of progressing option 2 outweigh any associated costs.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

Applications by the APVMA to amend MRLs in the Code do 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 the Application 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.

10. Consultation

FSANZ decided, pursuant to section 36 of the FSANZ Act (as was in force prior to 1 July 2007), to omit inviting public submissions in relation to Application A610 prior to making a Draft Assessment. However, FSANZ invited written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act (as was in force prior to 1 July 2007) and had regard to submissions received.

FSANZ made this decision because it was satisfied that Application A610 raised issues of minor significance or complexity only.

Section 63 of the FSANZ Act (as was in force prior to 1 July 2007) provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for review of the decision not to invite public submissions prior to making a Draft Assessment, may be made to the Administrative Appeals Tribunal.

Public comment was sought on any cost/benefit impacts of the proposed variations, in particular the likely impacts on importation of food if specific variations are advanced; any public health and safety considerations associated with the proposed MRLs; and any other affected parties to this Application.

Submissions were received from the Queensland Government, the NSW Food Authority, the Australian Food and Grocery Council (AFGC), the Country Women's Association of New South Wales (CWA) and the Food Technology Association of Australia Inc. (FTAA). The submissions are summarised at **Attachment 3**.

Submissions from the NSW Food Authority, AFGC and FTAA supported approving options 2(a) and 2(b) to vary the Code in Schedule 1 of Standard 1.4.2 as proposed at Initial / Draft Assessment.

10.1 Issues raised in submissions

10.1.1 Commodity classifications

The Queensland Government supports the progression of the Application providing an issue relating to the 'Goat muscle' entry is adequately addressed.

The submission states that the proposed abamectin MRL entry for 'Goat muscle' should be replaced by a 'Goat meat' MRL. 'Goat muscle' is not a standard commodity name in the Code and other MRLs are set on meat. The Codex MRL for abamectin applies to 'Goat meat'. Furthermore, sampling instructions in Standard 1.6.1 – Microbiological Limits for Food refer to 'meat' and not 'muscle'.

10.1.1.2 FSANZ Evaluation

The APVMA adopted the Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA) approach 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. Codex MRLs for residues of veterinary drugs in food are set using the JECFA approach. The JECFA approach is internationally accepted as best practice for setting MRLs for veterinary chemicals.

As Australian MRLs for veterinary chemicals are now set in accordance with the JECFA approach, the APVMA will notify these MRLs with JECFA commodity classifications to FSANZ for incorporation in the Code. This Application includes consideration of an abamectin MRL for residues arising from a veterinary use notified by the APVMA with a commodity classification consistent with the JECFA approach i.e. 'Goat muscle'. 'Goat muscle' is not currently a standard commodity name in the Code. Existing MRLs for veterinary chemicals in the Code were set in accordance with the JMPR approach used previously. While these remain in the Code there will be inconsistencies among commodity classifications for MRLs for veterinary chemicals. Commodity classifications used for veterinary and agricultural chemicals differ, reflecting the different approaches used to determine MRLs in agricultural as opposed to veterinary situations. Also, commodity names used in Standard 1.4.2 may differ from those used in other parts of the Code.

As a result of the Queensland Government submission FSANZ will continue to consult on the practical implications of including MRLs with the JECFA commodity classifications in the Code. As an interim measure FSANZ has decided to progress the requested abamectin MRL for 'Goat muscle' consulted in at Initial / Draft Assessment. If subsequent issues are identified that may necessitate varying the Standard, these will be considered in a future Proposal and the 'Goat muscle' MRL will be revisited in that context.

FSANZ and the APVMA are currently discussing implementation issues associated with incorporating JECFA commodity classifications in the Code.

10.1.2 Impact on trade of imported foods

The NSW Food Authority (the Authority) supports progression of this Application to Final Assessment, but has suggested that FSANZ adequately investigate the impact of proposed MRL withdrawals on trade of imported foods. The Authority stated that it would not be an appropriate use of limited State and Territory resources to pursue a violation of Standard 1.4.2 due to such withdrawals.

10.1.2.1 FSANZ Evaluation

Foods containing agricultural or veterinary chemical residues must comply with the requirements in Standard 1.4.2. MRL reductions and deletions have the potential to restrict the importation of foods and could potentially result in a reduced product range available to consumers, as foods containing non-permitted residues could not be legally imported or sold in Australia. FSANZ is committed to ensuring that the implications of MRL deletions and reductions are considered. It can be difficult to determine the likely impacts of MRL reductions and deletions and FSANZ relies on public consultation to determine those foods which may be implicated by reductions and deletions. FSANZ publicly advertises and consults on proposed changes to MRLs and lists all amendments on the FSANZ website to assist industry sectors and other interested parties in identifying any impacts of proposed deletions or reductions of specific MRLs. FSANZ also includes details of Codex MRLs in consultation reports on all applications. This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.

At Initial / Draft Assessment, FSANZ requested comment on any possible ramifications of approving the proposed MRLs including issues in relation to differences from international MRLs. The AFGC supported the progression of this Application and noted that it is unaware of any issues concerning the proposed variations for imported food. Following WTO Notification, member nations raised no specific trade impact issues in regard to the proposed variations. On this basis, it is unlikely that there will be impacts on trade of imported foods as a result of variations to the Code through this Application. However, 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.

Submissions including data demonstrating a requirement for certain MRLs to be retained or varied may be made under the current process for considering amendments to the Code. FSANZ considers retaining MRLs proposed for deletion or incorporating MRLs at levels other than those consulted on at Initial / Draft Assessment where this is 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 present public health or safety concerns.

10.1.3 Health and safety

The CWA notes that in view of concerns regarding antibiotic resistance, the CWA would only support the Application on the grounds that rigorous independent scientific testing has already been carried out to prove there are no health or safety concerns.

10.1.3.1 FSANZ Evaluation

There are no MRLs for residues of antibiotic substances in this Application. The Office of Chemical Safety (OCS) and the APVMA have reviewed scientific studies including toxicology, residue, animal transfer, processing and metabolism studies in relation to the chemicals for which MRL variations have been proposed through this Application. The OCS and the APVMA data requirements include stringent criteria concerning rigor and independence of studies evaluated in their assessments.

The Office of Chemical Safety has undertaken a toxicological assessment of each chemical and established reference health standards. These standards are the acceptable daily intake (ADI) and the acute reference dose (ARfD).

The APVMA must be satisfied that there will be no appreciable risk to the consumer, to the person handling, applying or administering the chemical to the environment, to the target crop or animal or to trade in an agricultural commodity. To protect public health and safety, the APVMA independently evaluates the safety and performance of chemicals before registering products. This evaluation includes a dietary exposure assessment where appropriate.

In assessing the public health and safety implications of chemical residues in food, FSANZ considers the dietary exposure from potentially treated foods by comparing 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. The risk assessment methodology is outlined above in section 5 of this Report and the results of the dietary exposure assessments expressed as percentages of the reference health standards are summarised in **Attachment 2**. FSANZ has reviewed the dietary exposure assessments in this Application and identified no health or safety concerns.

10.4 World Trade Organization

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

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.

Application A610 includes requests to vary MRLs in the Code that are addressed in the international Codex standard. MRLs in the Application 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 Application 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 made a submission on this Application.

10.5 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 in Application A610 where there is a corresponding MRL in the international Codex standard.

No submitters raised any issues in relation to specific MRLs differing from Codex or other international standards.

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
Abamectin		
Goat kidney	0.01	Goat, Edible offal of 0.1
Goat liver	0.05	
Goat milk	0.005	0.005
Goat muscle	0.01	Goat meat 0.01
Iprodione		
Carrot	T0.5	10

10.6 New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008

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 proposed variations to MRLs in Application A610 and includes the corresponding MRL in the New Zealand MRL Standards.

Chemical Food	**Proposed MRL** **mg/kg**	**NZ MRL** **mg/kg**
Abamectin		
Goat fat	0.1	Mammalian fats 0.02
Goat kidney	0.01	
Goat liver	0.05	Liver 0.015
Goat milk	0.005	
Goat muscle	0.01	Meat 0.01

Chemical Food	**Proposed MRL** **mg/kg**	**NZ MRL** **mg/kg**
Iprodione Brassica leafy vegetables	15	Leafy vegetables 5
Methabenzthiazuron Leek Shallot Spring onion	T*0.05 T0.2 T0.2	Bulb vegetables *0.05
Milbemectin Strawberry	0.2	*0.02
Prothioconazole Barley	T*0.05	Cereal grains *0.02

10.7 Imported Foods

Internationally, countries set MRLs under their own regulations and according to GAP (Good Agricultural Practice) or GVP (Good Veterinary Practice). 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 deletions and reductions 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. FSANZ will consider retaining MRLs proposed for deletion, or not reducing MRLs where these MRLs are necessary to continue to allow the sale of safe food; and where the MRLs are supported by adequate data or information demonstrating that the residues associated with these MRLs do not raise any public health or safety concerns. Further information on data requirements may be obtained from FSANZ.

To assist in identifying possible impacts on imported foods, FSANZ compiled the following table of foods that have MRLs proposed for deletion or reduction and sought comment on any impacts of these reductions or deletions at Initial / Draft Assessment. No submitters raised any issues in relation to the proposed reduction of the methabenzthiazuron MRL for leek. 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. The draft variations to the Code are at **Attachment 1** and the requested changes are outlined in **Attachment 2**.

Chemical Food
Methabenzthiazuron Leek

CONCLUSION

11. Conclusion and Decision

This Application has been assessed against the considerations provided for in the FSANZ Act. FSANZ recommends approving the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits.

The recommendation is to adopt option 2 to vary MRLs in Schedule 1 of Standard 1.4.2 – Maximum Residue Limits as proposed at Initial / Draft Assessment.

Decision

FSANZ has made an assessment and approves the draft variations to Standard 1.4.2 – Maximum Residue Limits.

11.1 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 Application.
- 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 enforcement agencies.
- The proposed changes are consistent with the FSANZ Act section 18 objectives.

12. 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.

MRL amendments in this Application take effect on gazettal. The MRLs will be subject to existing monitoring arrangements.

ATTACHMENTS

1. Draft Variations to the *Australia New Zealand Food Standards Code*
2. A Summary of Requested MRLs for each Chemical and an Outline of Information Supporting the Requested Variations to the *Australia New Zealand Food Standards Code*
3. Summary of Submissions

Attachment 1

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

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act 2003 and are not subject to disallowance or sunsetting.

To commence: on gazettal

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

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

COLUMN 1	COLUMN 2
ACIBENZOLAR-S-METHYL	ACIBENZOLAR-S-METHYL AND ALL METABOLITES CONTAINING THE BENZO[1,2,3]THIADIAZOLE-7-CARBOXYL MOIETY HYDROLYSED TO BENZO[1,2,3]THIADIAZOLE-7-CARBOXYLIC ACID, EXPRESSED AS ACIBENZOLAR-S-METHYL

[1.2] *inserting in* Schedule 1–

MILBEMECTIN SUM OF MILBEMYCIN MA_3 AND MILBEMYCIN MA_4 AND THEIR PHOTOISOMERS, MILBEMYCIN (Z) 8,9-MA_3 AND (Z) 8,9Z-MA_4	
STRAWBERRY	0.2
PROTHIOCONAZOLE *COMMODITIES OF PLANT ORIGIN*: SUM OF PROTHIOCONAZOLE AND PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE *COMMODITIES OF ANIMAL ORIGIN:* SUM OF PROTHIOCONAZOLE, PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), PROTHIOCONAZOLE-3-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-3-HYDROXYPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL) AND PROTHIOCONAZOLE-4-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-4-HYDROXYPHENYL)-3-(1*H*-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE	
BARLEY	T*0.05
EDIBLE OFFAL (MAMMALIAN)	T*0.05
EGGS	T*0.01
MEAT (MAMMALIAN) (IN THE FAT)	T*0.01
MILKS	T*0.01

POULTRY, EDIBLE OFFAL OF	T*0.05
POULTRY MEAT (IN THE FAT)	T*0.05
WHEAT	T*0.05
PYRAFLUFEN-ETHYL SUM OF PYRAFLUFEN-ETHYL AND ITS ACID METABOLITE (2-CHLORO-5-(4-CHLORO-5-DIFLUOROMETHOXY-1-METHYLPYRAZOL-3-YL)-4-FLUOROPHENOXYACETIC ACID)	
CEREAL GRAINS	*0.02
COTTON SEED	*0.05
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02

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

ABAMECTIN SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
GOAT FAT	0.1
GOAT KIDNEY	0.01
GOAT LIVER	0.05
GOAT MILK	0.005
GOAT MUSCLE	0.01
ACIBENZOLAR-S-METHYL SUM OF ACIBENZOLAR-S-METHYL AND BENZO[1,2,3]THIADIAZOLE-7-CARBOXYLIC ACID METABOLITE, EXPRESSED AS ACIBENZOLAR-S-METHYL	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.005
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
CLOQUINTOCET-MEXYL SUM OF CLOQUINTOCET MEXYL AND 5-CHLORO-8-QUINOLINOXYACETIC ACID, EXPRESSED AS CLOQUINTOCET MEXYL	
RYE	*0.1
TRITICALE	*0.1
IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID	
BURDOCK, GREATER	T0.05
GINGER, JAPANESE	T5
GINGER, ROOT	T0.05
RADISH, JAPANESE	T0.05

TARO	T0.05
YAM BEAN	T0.05
YAMS	T0.05
IPRODIONE IPRODIONE	
BRASSICA LEAFY VEGETABLES	15
CARROT	T0.5
METHABENZTHIAZURON METHABENZTHIAZURON	
SHALLOT	T0.2
SPRING ONION	T0.2
TRINEXAPAC-ETHYL 4-(CYCLOPROPYL-α-HYDROXY-METHYLENE)-3,5-DIOXO-CYCLOHEXANECARBOXYLIC ACID	
EDIBLE OFFAL (MAMMALIAN)	0.05
MEAT (MAMMALIAN)	*0.02
MILKS	*0.005

[1.4] *omitting from* Schedule 1, *under the entries for the following chemicals, the maximum residue limit for the food, substituting –*

ACIBENZOLAR-S-METHYL SUM OF ACIBENZOLAR-S-METHYL AND BENZO[1,2,3]THIADIAZOLE-7-CARBOXYLIC ACID METABOLITE, EXPRESSED AS ACIBENZOLAR-S-METHYL	
COTTON SEED	*0.02
DIMETHOMORPH SUM OF E AND Z ISOMERS OF DIMETHOMORPH	
SHALLOT	0.5
SPRING ONION	2
METHABENZTHIAZURON METHABENZTHIAZURON	
LEEK	T*0.05
TRINEXAPAC-ETHYL 4-(CYCLOPROPYL-α-HYDROXY-METHYLENE)-3,5-DIOXO-CYCLOHEXANECARBOXYLIC ACID	
SUGAR CANE	0.1

Attachment 2

A Summary of Requested MRLs for Each Chemical and an Outline of Information Supporting the Requested Variations to the *Australia New Zealand Food Standards Code*

The Full Evaluation Reports for individual chemicals are available upon request from the relevant Project Coordinator at FSANZ.

NOTES ON TERMS USED IN THE TABLE

ADI – Acceptable Daily Intake - 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 based on all the known facts at the time of the evaluation of the chemical. The ADI is expressed in milligrams of the chemical per kilogram of body weight.

ARfD – Acute Reference Dose - The ARfD 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.

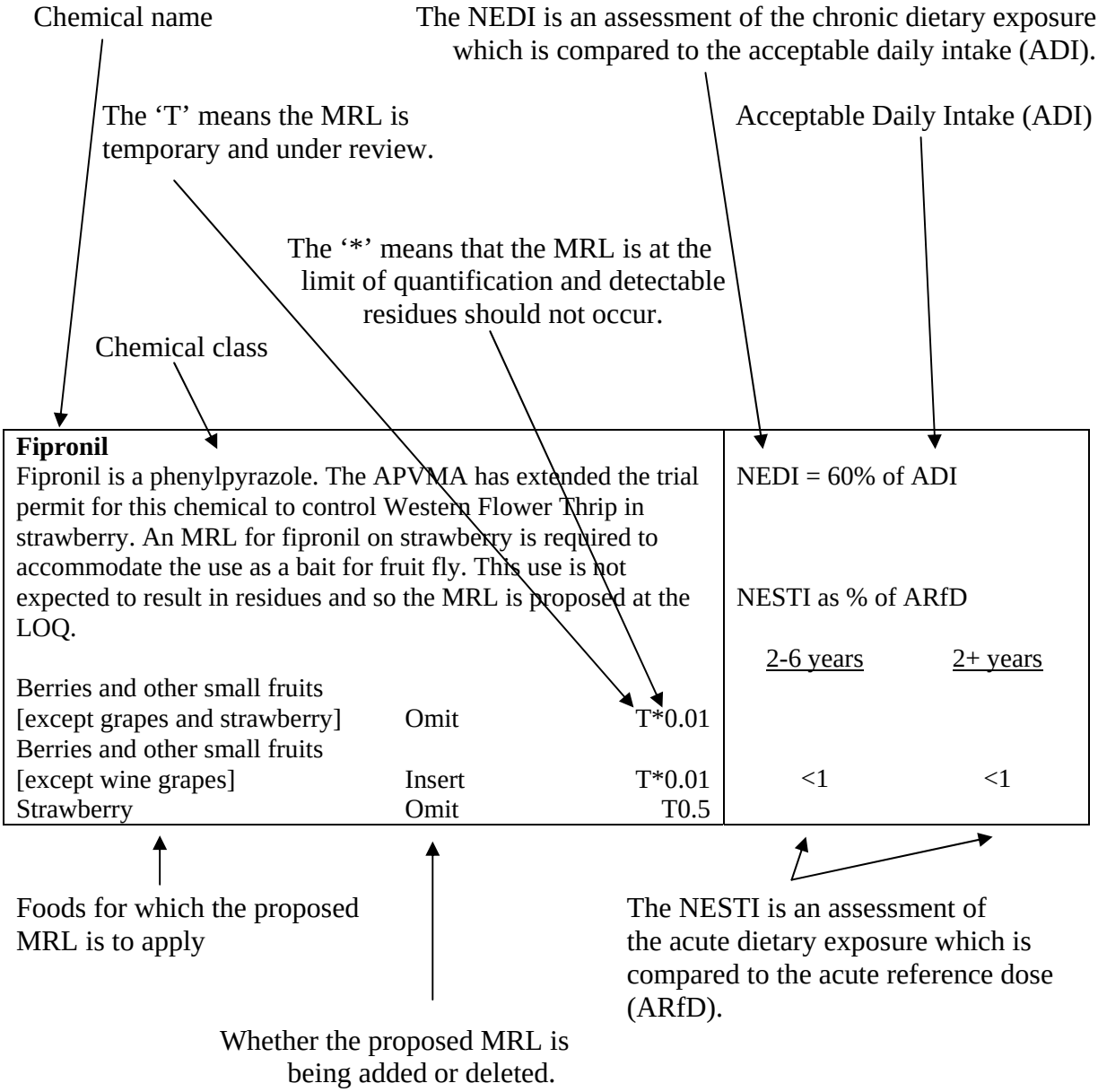
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

NEDI - National Estimated Dietary Intake - The NEDI represents a realistic estimate of chronic dietary exposure and is the preferred calculation. It may incorporate specific 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; the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials to represent pesticide residue levels. In most cases the NEDI is still an overestimation because more specific residue data are often not available and in these cases the MRL is used.

NESTI - National Estimated Short Term Intake - The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated based on consumption of 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. FSANZ has used ARfDs set by the OCS and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 NNS and the MRL when the supervised trials median residue (STMR) is not available to calculate the NESTIs.

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 residues 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.

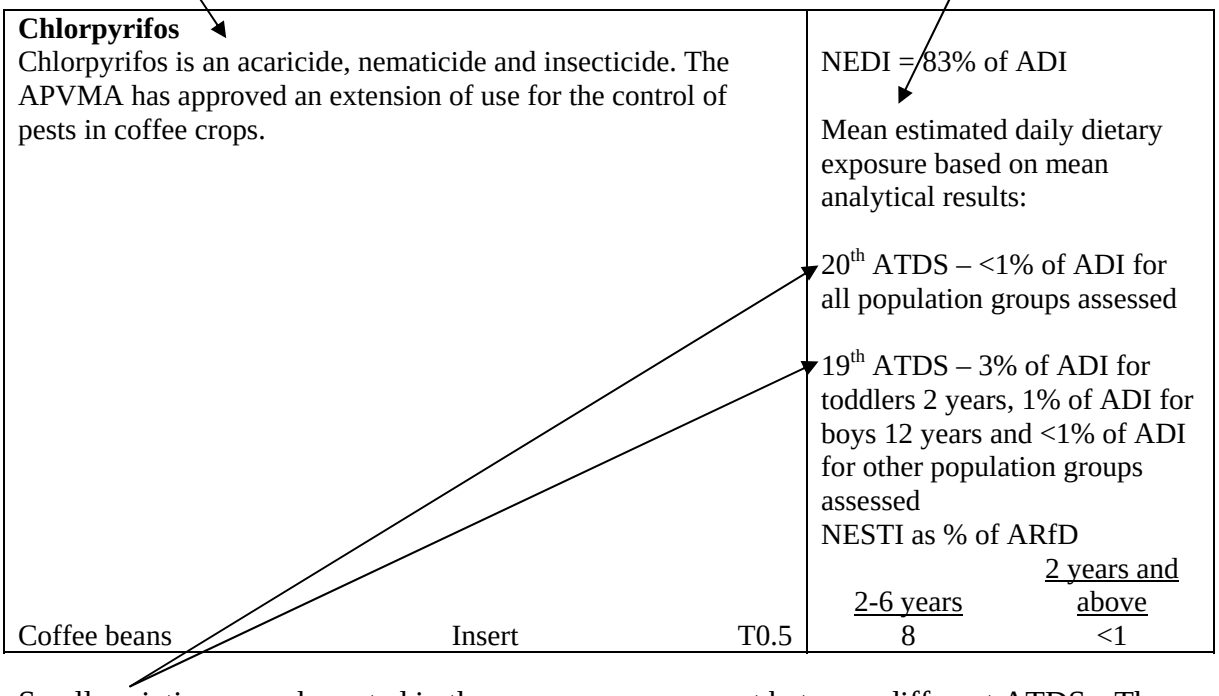
The following are examples of entries and the proposed MRLs listed are not part of this Application.



There is more information on the NEDI, NESTI, ADI and ARfD above and in the Risk Assessment section of this report. FSANZ considers that the chronic dietary exposure to the residues of a chemical is acceptable where the best estimate of this exposure does not exceed the ADI and that the acute dietary exposure to the residues of a chemical is acceptable where the best estimate of acute dietary exposure does not exceed the ARfD.

Information about the use of the chemical is provided so consumers can see the reason why the residues may occur in food.

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.

Acronyms:

1.	**ADI**	Acceptable Daily Intake
2.	**APVMA**	Australian Pesticides and Veterinary Medicines Authority
3.	**ARfD**	Acute Reference Dose
4.	**ATDS**	Australian Total Diet Survey (now the Australian Total Diet Study)
5.	**the Code**	*Australia New Zealand Food Standards Code*
6.	**DIAMOND**	Dietary Modelling of Nutritional Data computer program
7.	**FSANZ**	Food Standards Australia New Zealand
8.	**JECFA**	Joint FAO/WHO Expert Committee on Food Additives
9.	**JMPR**	Joint FAO/WHO Meeting on Pesticide Residues
10.	**LOQ**	Limit of Analytical Quantification
11.	**MRL**	Maximum Residue Limit
12.	**NEDI**	National Estimated Daily Intake
13.	**NESTI**	National Estimated Short Term Intake
14.	**NNS**	National Nutrition Survey of Australia 1995
15.	**OCS**	The Office of Chemical Safety
16.	**T or TMRL**	Temporary MRL
17.	**WHP**	Withholding Period

SUMMARY OF REQUESTED MRLS FOR APPLICATION A610
MAXIMUM RESIDUE LIMITS – JULY AND AUGUST 2007

<table>
<tr><th colspan="4">Requested MRLs</th><th colspan="3">Dietary Exposure Estimates</th></tr>
<tr><td colspan="4">Abamectin
Abamectin the active ingredient in a broad spectrum antiparasitic treatment for goats. Abamectin blocks signal transmission from interneurons to excitatory motoneurons. It stimulates release of gamma-aminobutyric acid causing paralysis i.e. it is a GABA agonist. The product is orally administered to goats to treat and control abamectin sensitive strains of adult and immature gastrointestinal worms and lungworms.</td><td colspan="3">NEDI = 68% of ADI

NESTI as % of ARfD</td></tr>
<tr><td></td><td></td><td></td><td>2-6 years</td><td></td><td>2 years and above</td></tr>
<tr><td>Goat fat</td><td>Insert</td><td>0.1</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Goat kidney</td><td>Insert</td><td>0.01</td><td><1</td><td>Goat, edible offal of</td><td>3</td></tr>
<tr><td>Goat liver</td><td>Insert</td><td>0.05</td><td></td><td></td><td></td></tr>
<tr><td>Goat milk</td><td>Insert</td><td>0.005</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Goat muscle</td><td>Insert</td><td>0.01</td><td>3</td><td></td><td>2</td></tr>
<tr><td colspan="4">Acibenzolar-S-methyl
Acibenzolar-S-methyl is a fungicide used as a seed treatment for cotton. It is a plant host defence inducer i.e. it activates the host plant’s natural defence mechanism. It has no intrinsic fungicidal activity. Following six Australian field trials, no quantifiable residues were found in cotton seed at harvest after application of the product at twice the proposed rate. Livestock dietary exposure will be negligible. The recommended MRLs are at the LOQ.

Amendment to residue definition

Omit: Sum of acibenzolar-S-methyl and Benzo[1,2,3]thiadiazole-7-carboxylic acid metabolite, expressed as acibenzolar-S-methyl

Substitute: Acibenzolar-S-methyl and all metabolites containing the benzo[1,2,3]thiadiazole-7-carboxyl moiety hydrolysed to benzo[1,2,3]thiadiazole-7-carboxylic acid, expressed as acibenzolar-S-methyl</td><td colspan="3">NEDI = 2% of ADI

NESTI as % of ARfD</td></tr>
<tr><td></td><td></td><td></td><td>2-6 years</td><td></td><td>2+ years and above</td></tr>
<tr><td>Cotton seed</td><td>Omit</td><td>T*0.02</td><td></td><td></td><td></td></tr>
<tr><td></td><td>Substitute</td><td>*0.02</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Edible offal (mammalian)</td><td>Insert</td><td>*0.02</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Eggs</td><td>Insert</td><td>*0.02</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Meat (mammalian)</td><td>Insert</td><td>*0.02</td><td>3</td><td></td><td>2</td></tr>
<tr><td>Milks</td><td>Insert</td><td>*0.005</td><td>4</td><td></td><td>2</td></tr>
<tr><td>Poultry, edible offal of</td><td>Insert</td><td>*0.02</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Poultry meat</td><td>Insert</td><td>*0.02</td><td>2</td><td></td><td>1</td></tr>
</table>

Requested MRLs			Dietary Exposure Estimates
Cloquintocet-mexyl Cloquintocet-mexyl is a herbicide safener used with the herbicide fenoxaprop-ethyl to control weeds in cereal crops. It accelerates the detoxification process of some herbicides in cereals. It regulates the expression of genes involved in herbicide metabolism. Residues are not expected in rye and triticale at harvest. The recommended MRLs are at the LOQ. Residues data demonstrate that levels of fenoxaprop-ethyl are within current MRLs for the required cereals.			NEDI = 3% of ADI
Rye	Insert	*0.1	
Triticale	Insert	*0.1	
Dimethomorph Dimethomorph is a fungicide. It inhibits the formation of the oomycete fungal cell wall. The APVMA has received new data to support an existing permit for use of dimethomorph to control downy mildew and purple blotch on spring onions and shallots.			NEDI = 4% of ADI 20th ATDS – not detected in any foods sampled
Shallot	Omit	T0.5	
	Substitute	0.5	
Spring onion	Omit	T0.5	
	Substitute	2	
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 greenhouse whitefly, onion thrips, plague thrips and green peach aphid.			NEDI = 15% of ADI
Burdock, greater	Insert	T0.05	
Ginger, Japanese	Insert	T5	
Ginger, root	Insert	T0.05	
Radish, Japanese	Insert	T0.05	
Taro	Insert	T0.05	
Yam bean	Insert	T0.05	
Yams	Insert	T0.05	

Requested MRLs			Dietary Exposure Estimates
Iprodione Iprodione is a contact fungicide with protective and curative action. It inhibits spore germination and fungal mycelium growth. The APVMA has issued a permit for its use to control Sclerotinia (*Sclerotinia sclerotiorum*), grey mould (*Botrytis cinerea*) and Alternaria leaf spot (*Alternaria brassicae*) in brassica leafy vegetables and a permit for its use to control black rot in carrots. Brassica leafy vegetables Carrot	Insert Insert	15 T0.5	NEDI = 44% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS – 1% of ADI for adult males 25 – 34 years and toddlers 2 years and <1% of ADI for other population groups assessed 19th ATDS – 1% of ADI for toddlers 2 years and <1% of ADI for other population groups assessed
Methabenzthiazuron Methabenzthiazuron is a selective herbicide. It is primarily absorbed through roots and to a lesser extent through leaves. It is used to control broad leaf and grass weeds in cereals and onions. The APVMA has issued permits for its use to control weeds in leeks, spring onions and shallots. Residues data support setting the leek MRL at the LOQ. Leek Shallot Spring onion	Omit Substitute Insert Insert	T0.2 T*0.05 T0.2 T0.2	NEDI = 6% of ADI
Milbemectin Milbemectin is an insecticide. It is a GABA agonist with contact and stomach action. It is used to control two-spotted mite on strawberries. New chemical Insert residue definition: Sum of milbemycin MA_3 and milbemycin MA_4 and their photoisomers, milbemycin (Z) 8,9-MA_3 and (Z) 8,9Z-MA_4 Strawberry	Insert	0.2	NEDI = <1% of ADI NESTI as % of ARfD 2-6 years: <1 2 years and above: <1

Requested MRLs			Dietary Exposure Estimates		
Prothioconazole Prothioconazole is a triazole fungicide. It inhibits steroid demethylation in the biosynthesis of ergosterol. The APVMA has issued a permit for its use to treat wheat and barley. Residues and feeding studies data support establishing MRLs at the LOQ for wheat and barley grain and animal commodities. New chemical Insert residue definition: *Commodities of plant origin:* Sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole *Commodities of animal origin:* Sum of prothioconazole, prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), prothioconazole-3-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-3-hydroxyphenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol) and prothioconazole-4-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-4-hydroxyphenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole			NEDI = 2% of ADI NESTI as % of ARfD		
			2-6 years		2+ years and above
Barley	Insert	T*0.05	<1		<1
				Barley, beer only	1
Edible offal (mammalian)	Insert	T*0.05	<1		<1
Eggs	Insert	T*0.01	<1		<1
Meat (mammalian) (in the fat)	Insert	T*0.01	<1		<1
Milks	Insert	T*0.01	3		<1
Poultry, edible offal of	Insert	T*0.05	<1		<1
Poultry meat (in the fat)	Insert	T*0.05	2		1
Wheat	Insert	T*0.05	<1	Wheat grain	<1
			2	Wheat grain milling fractions	<1
			1	Early milling products	<1

Requested MRLs			Dietary Exposure Estimates	
Pyraflufen-ethyl Pyraflufen-ethyl is a defoliant and post emergent herbicide. It inhibits the protoporphyrinogen-IX oxidase enzyme. It is readily absorbed into plant tissues, and rapid necrosis or desiccation of stems and leaves is induced in the presence of light. It is used to control broad leaf weeds in winter cereals and as a defoliant in cotton. The recommended MRLs are at the LOQ. New chemical Insert residue definition: Sum of pyraflufen-ethyl and its acid metabolite (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid)			NEDI = <1% of ADI NESTI as % of ARfD	
			2-6 years	2 years and above
Cereal grains	Insert	*0.02	<1	<1
Cotton seed	Insert	*0.05	<1	<1
Edible offal (mammalian)	Insert	*0.02	<1	<1
Eggs	Insert	*0.02	<1	<1
Meat (mammalian)	Insert	*0.02	<1	<1
Milks	Insert	*0.02	<1	<1
Poultry, edible offal of	Insert	*0.02	<1	<1
Poultry meat	Insert	*0.02	<1	<1
Trinexapac-ethyl Trinexapac-ethyl is a plant growth regulator. It reduces stem growth by disrupting internode elongation. It is used to increase seed set and yield and to prevent lodging and elongation. The requested milk and meat MRLs are at the LOQ. Edible offal (mammalian) Meat (mammalian) Milks Sugar cane	Insert Insert Insert Omit Substitute	0.05 *0.02 *0.005 T*0.05 0.1	NEDI = 2% of ADI	

Attachment 3

Summary of Submissions

Submitter	Comments
Queensland Government	Supported this Application providing the 'Goat muscle' entry issue is adequately addressed. The submission states that the proposed abamectin MRL entry for 'Goat muscle' should be replaced by a 'Goat meat' MRL. 'Goat muscle' is not a standard commodity name in the Code. Other MRLs are set on meat. The Codex MRL for abamectin applies to 'Goat meat'. Furthermore, sampling instructions in Standard 1.6.1 Microbiological Limits for Food refer to 'meat' and not 'muscle'.
NSW Food Authority	Supported this Application and suggested that FSANZ adequately investigate the impact of proposed MRL withdrawals on trade of imported foods. The Authority stated that it would not be an appropriate use of limited State and Territory resources to pursue a violation of Standard 1.4.2 due to such withdrawals.
Australian Food and Grocery Council	Supported this Application and notes that the AFGC is not aware of any issues arising from it that may adversely impact imported foods. The AFGC acknowledges that FSANZ would consider varying MRLs where evidence is presented that proposed changes would affect imported food. The AFGC notes that the dietary exposure assessments indicate that the residues associated with the proposed MRLs do not represent an unacceptable public health and safety risk and that there are no MRLs for antibiotic residues in this Application. The AFGC supports the harmonisation of MRLs permitted under agricultural legislation with those prescribed in the Code. The AFGC notes that the agricultural and veterinary justification for chemical use is a matter for the APVMA rather than FSANZ and that the APVMA considers chemical safety and toxicology and the necessary withholding periods before consumption.
Country Women's Association of New South Wales	Noted that in view of concerns regarding antibiotic resistance, the CWA would only support the Application on the grounds that rigorous independent scientific testing has already been carried out to prove there are no health or safety concerns.
Food Technology Association of Australia Inc.	Supported this Application.