EXPLANATORY STATEMENT

APPLICATION A599

MAXIMUM RESIDUE LIMITS
(JANUARY, FEBRUARY, MARCH 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 A599 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 health reference 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 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 draft variations to Standard 1.4.2 at Final Assessment differ from those proposed at Initial / Draft Assessment for endosulfan in tea. FSANZ has recommended that the MRL of T30 mg/kg for endosulfan in 'Tea, green, black' be retained in the Code. The APVMA requested MRL variations in the Code in accordance with the recommendations of the APVMA chemical review of the active constituent endosulfan. The APVMA advised that currently there are no products approved or permits issued for endosulfan use in tea cultivation in Australia, and as such, the MRL for tea has been deleted from the APVMA MRL Standard. The MRL is not required to allow for the sale of domestically produced tea. Submitters identified the need to retain the MRL to continue to allow for the importation and sale of legitimately treated tea. The dietary exposure assessment concluded that this raises no health or safety concerns. Retaining this MRL would facilitate trade in tea and promote consistency between domestic and international standards and potentially benefit industry and consumers through continued choice and access to tea. FSANZ's consideration of retaining this MRL is discussed in section 10.1 of this Report.

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.

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 recommends approving the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits.

Reasons for Decision

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

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

- Dietary exposure assessments indicate that setting the MRLs as proposed does not present any public health and safety concerns.

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

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

- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines - MORAG - for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in this 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 retention of the endosulfan MRL for tea is appropriate because it would facilitate trade in tea and promote consistency between domestic and international standards.

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

Consultation

FSANZ has now completed the assessment of Application A599 and held a single round of public consultation under section 36 of the FSANZ Act (as was in force prior to 1 July 2007). This Final Assessment Report and its recommendations have been approved by the FSANZ Board and 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.

CONTENTS

INTRODUCTION

Notifications were received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 30 January, 8 February and 26 March 2007 seeking to vary the *Australia New Zealand Food Standards Code* (the Code). Information required to complete the dietary exposure assessment was received from the APVMA on 21 September 2007. The proposed variations to Standard 1.4.2 – Maximum Residue Limits would 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 of the Code.

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 A599:

- adding temporary MRLs at the LOQ for new chemical prosulfocarb;
- adding MRLs at the LOQ for azoxystrobin, carfentrazone-ethyl and flumioxazin;
- adding MRLs for certain foods for abamectin and oxamyl;
- adding temporary MRLs for certain foods for bifenazate, fenvalerate, imidacloprid, methomyl, tebufenozide and thiamethoxam;
- changing temporary MRLs to MRLs for abamectin and endosulfan;
- deleting MRLs for certain foods for endosulfan;
- decreasing MRLs for certain foods including some to the LOQ for endosulfan; and
- decreasing and changing temporary MRLs to MRLs for certain foods for endosulfan.

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[1] residues in this Application.

1.6 Minor Technical Amendments

The commodity name 'Peppers, sweet' in the entry for bifenthrin in Schedule 1 of Standard 1.4.2 is to be changed to 'Peppers'. This is an administrative change to correct the commodity name. The APVMA has advised that bifenthrin is approved for use on peppers, that is, its use is approved on both capsicum and chilli peppers.

The residue definition for triclabendazole is to be amended as advised by the APVMA.

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

1.7 Australia and New Zealand Joint Food Standards

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

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

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

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

New Zealand MRLs are discussed further in section 10.7 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[2], 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.

The proposed draft variations to Standard 1.4.2 are consistent with the section 18 objectives of the FSANZ Act, 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.

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2 http://www.health.gov.au/internet/wcms/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/$File/pol-g-line-reg-res.pdf accessed 19 November 2007.

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

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

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

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

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 97.5^{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.

5.3.3 Risk Characterisation

The estimated mean dietary exposure is compared to the ADI. It is therefore the overall mean dietary exposure to a chemical that is compared to the ADI - not the MRL. FSANZ considers that the chronic and acute dietary exposure to the residues of a chemical is acceptable where the best estimates of mean and acute dietary exposure do not exceed the ADI or ARfD.

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 MRLs or 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 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, FSANZ consideration of retaining the endosulfan MRL for tea, 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 A599, 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, subject to a minor variation from those MRLs proposed at Initial / Draft Assessment. FSANZ has recommended retaining the MRL of T30 mg/kg for endosulfan in ‘Tea, green, black’ rather than omit it as recommended by the APVMA and consulted on at Initial / Draft Assessment. This variation does not compromise public health and safety and is proposed to facilitate importation of tea (See section 10.1 for details).

Options 2(a) and 2(b) and retaining the endosulfan MRL for ‘Tea, green, black’ are recommended.

- 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.

- The proposed retention of the endosulfan MRL for tea is appropriate because it would facilitate trade in tea and promote consistency between domestic and international standards.

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 advice service, responds to industry enquiries.

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

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 A599 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 its decision because it was satisfied that Application A599 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 Food and Agriculture Organisation (FAO) Inter-Governmental Group (IGG) on Tea Working Group on Pesticides, Unilever Australasia, Tetley Australia Pty Limited, the Australian Food and Grocery Council (AFGC) including comments from the AFGC Tea Industry Forum, and the Food Technology Association of Australia Inc. (FTAA).

Submissions from the Queensland Government and NSW Food Authority support 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 Summarised Submissions from the FAO Inter-Governmental Group on Tea Working Group on Pesticides, Unilever Australasia, Tetley Australia Pty Limited and the AFGC Tea Industry Forum

The FAO Inter-Governmental Group on Tea Working Group on Pesticides, Unilever Australasia, Tetley Australia Pty Limited and the AFGC Tea Industry Forum requested that FSANZ consider retaining the current MRL of 30 mg/kg for endosulfan in 'Tea, green, black'. This was on the basis that endosulfan residues resulting from the controlled use of endosulfan on tea in producer countries are consistent with the current MRL in the Code; consistency with international standards; the current requirements for the economic cultivation of tea and the impact that deleting the MRL would have on the tea industry.

The submitters support FSANZ's role to maintain the Code to reflect the current registration status of agricultural and veterinary chemicals in use in Australia and ensure consumer safety. The submitters note that the consultation process is appropriate to ensure any impact of the proposed changes to specific MRLs can be evaluated. This particularly allows for an understanding of the costs and benefits impacting importation of food if particular deletions are progressed.

The FAO IGG on Tea Global Plant Protection Initiative in Tea aims to ensure that tea is safe for consumers; facilitate the improvement of pest management systems within the tea trade; facilitate discussions with all stakeholders (including regulatory bodies, tea companies and tea associations) both in producer and consumer countries; and ensure that tea is traded in a compliant manner across international boundaries.

Unilever Australasia, Tetley Australia Pty Limited, Tata Tea Limited, the Food and Beverage Importers Association and the AFGC Tea Industry Forum have been active participants in this initiative.

Submitters raised concerns that the proposed deletion of the endosulfan MRL for tea would significantly impact on industry and consumers. Endosulfan is an important pest management tool for economic cultivation of tea internationally. It is used to treat a wide range of pests including leaf hopper, whitefly, caterpillars, Lepidoptera larvae, tea jassid, tea leaf weevil, tea mosquito bug and thrips. No effective alternative plant protection products have been found to replace endosulfan. Tea is an international commodity and it is important to ensure that there is consistency in standards on an international basis. The majority of tea in Australia is imported, with only a very small amount grown here. The major suppliers of tea to Australia are China and India. Other producer and importing countries have equivalent MRLs, these are summarised in the table below.

10.1.1 FSANZ Evaluation

Submitters identified a trade issue in relation to the deletion of the endosulfan MRL for 'Tea, green, black' of T30 mg/kg proposed at Initial / Draft Assessment.

FSANZ must consider proposed variations to the Code in accordance with the FSANZ Act, including the objectives of food regulatory measures set out in section 18 of the Act. This consideration included a consideration of the dietary exposure to residues associated with the proposed retention of the tea MRL; the legitimate use of the chemical on the commodity and the relevant MRLs internationally; as well as the views of the APVMA and the impacts of including an MRL in the Code where the APVMA has requested a deletion.

The following table lists the endosulfan MRL for tea under consideration at Final Assessment and includes corresponding international MRLs.

Chemical Commodity	**APVMA MRL mg/kg**	**Codex, EU, India, Indonesia and Japan MRL mg/kg**	**US Tolerance mg/kg**	**China MRL mg/kg**	**FSANZ recommended MRL at Final Assessment mg/kg**
Endosulfan Tea, green, black	- (T30 deleted January 2007)	30	24[†]	10	T30

[†] A tolerances of 24 parts per million (ppm) is established for the combined residues of the insecticide endosulfan, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide (alpha and beta isomers), and its metabolite endosulfan sulfate, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide, in or on dried tea (reflecting less than 0.1 ppm residues in beverage tea) resulting from application of the insecticide to growing tea.

FSANZ notes that JMPR recommended the withdrawal of the Codex MRL, and that as stated by submitters, it was decided at the 30th Session of the Codex Alimentarius Commission in July 2007 to retain the standard for four years under the Periodic Review Procedure.

10.1.1.1 Dietary exposure

The baseline estimated mean dietary exposure (NEDI) to endosulfan residues from all foods based on current MRLs is 28% of the ADI. Based on retaining the MRL for 'Tea, green, black' of T30 mg/kg, the estimated mean dietary exposure (NEDI) to endosulfan residues from all foods is approximately 53% of the ADI.

The estimated acute dietary exposure to endosulfan residues in tea (NESTI) based on retaining the MRL of T30 mg/kg for 'Tea, green, black' for the population aged 2 years and above is 45% of the ARfD, and for children aged 2-6 years is 55% of the ARfD.

FSANZ considers that there are no health or safety concerns associated with retaining the current endosulfan MRL of T30 mg/kg for 'Tea, green, black' in the Code. This is on the basis that the estimated dietary exposure to endosulfan residues from all foods, including residues in tea at 30 mg/kg, does not exceed the acceptable reference health standards.

10.1.1.2 Views of the APVMA on FSANZ retaining the endosulfan MRL for tea in the Code

FSANZ liaised with the APVMA in considering retaining the endosulfan MRL of T30 mg/kg for 'Tea, green, black' in the Code.

The APVMA requested MRL variations in the Code in accordance with the recommendations of the APVMA chemical review of the active constituent endosulfan. The APVMA advised that currently there are no products approved or permits issued for endosulfan use in tea cultivation in Australia, and as such the MRL for tea has been deleted from the APVMA MRL Standard. The APVMA agreed that there are no food safety issues associated with retaining the MRL.

In considering retaining an MRL that the APVMA requested FSANZ omit from the Code, FSANZ has noted that while the MRL is not required to allow the sale of domestically produced tea, it is required to allow for the continued importation and sale of legitimately treated tea. In any case, tea producers in Australia would need to comply with conditions of use currently approved in Australia. On this basis there should be no implications for domestic producers if the MRL is retained.

10.1.1.3 Impacts of retaining an MRL in the Code deleted from the APVMA MRL Standard

Deleting the MRL from the Code as requested by the APVMA could unnecessarily restrict trade as without an MRL, tea could not be legally sold or imported if residues of endosulfan were detected. Tea is imported into Australia and could potentially and legitimately contain endosulfan residues consistent with the current MRL. The Codex MRL for endosulfan in 'Tea, green, black' is 30 mg/kg and tea producing countries and other international jurisdictions have equivalent MRLs. On this basis, FSANZ considers that retaining the endosulfan MRL of T30 mg/kg for 'Tea, green, black' in the Code would facilitate trade in tea and promote consistency between domestic and international standards. In addition, retaining the MRL as proposed by submitters would potentially benefit industry and consumers through continued choice and access to tea.

10.1.1.4 Summary

FSANZ recommends retaining the endosulfan MRL of 30 mg/kg for 'Tea, green, black' in the Code. Submitters identified the need to retain the MRL to continue to allow for the importation and sale of legitimately treated tea. The dietary exposure assessment concluded that this raises no health or safety concerns. Retaining this MRL in the Code would facilitate trade in tea and promote consistency between domestic and international standards and benefit industry and consumers through continued choice and access to tea.

10.2 Summarised Submission from the Australian Food and Grocery Council

The AFGC supports option 2(b) and does not support option 2(a) to omit or decrease some existing MRLs as this will have a detrimental effect on the food industry and on consumers. The effect will be particularly significant with the deletion or reduction of endosulfan MRLs for a variety of foods and most particularly on the importation of tea.

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. 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. The APVMA does not give due regard to the effect of changing MRLs on imported foods. This is a responsibility of FSANZ under the section 18 objectives of the FSANZ Act. Until such time as there is default or threshold level equivalent to Codex permission for residues on imported fruits and vegetables, the Code fails to meet the requirements of the section 18 objectives and results in a barrier to trade.

The AFGC notes that the current Codex endosulfan MRL for tea is 30 mg/kg and that deleting this MRL will place the Code at variance with international standards and create an unnecessary barrier to trade that is of no public health benefit.

10.2.1 FSANZ Evaluation

FSANZ is committed to ensuring that the implications of MRL deletions and reductions are considered. 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 that do not comply with the Code could not be legally imported or sold to consumers. FSANZ publicly advertises any proposed changes to MRLs as part of the round of public consultation and lists all amendments on the FSANZ website to assist industry sectors in identifying any impacts following deletions or reductions of specific MRLs. This approach ensures openness and transparency in relation to the residues that could reasonably occur in food. The issues raised in relation to the proposed deletion of the endosulfan MRL for tea and the AFGC Tea Industry Forum comments are addressed above.

Other than in relation to the endosulfan MRL for tea, the AFGC submission did not identify any specific trade or importation issues in regard to relevant food commodities for which MRL deletions or reductions are proposed. 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. The submissions from the tea industry provided such information and this has been considered and assessed.

10.3 Summarised Submission from the Food Technology Association of Australia Inc.

The FTAA supports option 2(b) and does not support option 2(a) to omit or decrease some existing MRLs.

The FTAA notes that under Standard 1.4.2, if an MRL for an agricultural or veterinary chemical is not listed in Schedule 1, there must be no detectable residues of that agricultural or veterinary chemical in that food. Due to advances in analytical capability, extremely low levels of some residues are detectable. This means that in the absence of an MRL, even where residues are detected at low levels, the food may not be sold. The FTAA considers that this is trade restrictive. These extremely low detectable or inconsequential levels are often deemed harmless and are often not deliberately used in conjunction with the food, but may be present for another reason i.e. cross contamination during legitimate use on another crop; carry over in the case of a mixed food; or inadvertent addition through common use of spraying equipment.

The FTAA contends that because of this, residues of agricultural and veterinary chemicals should be regulated in the same way as contaminants and natural toxicants (Standard 1.4.1). That is, MRLs should be as low as reasonably achievable (the ALARA principle) and at levels consistent with public health and safety and which are reasonably achievable from sound production and natural resource management practices. The FTAA suggests that FSANZ consider modifying Standard 1.4.2 such that the regulatory approach to contaminants would also apply to residues of agricultural and veterinary chemicals.

10.3.1 FSANZ Evaluation

The FTAA has not raised issues or concerns in relation to any specific proposed MRL reductions or deletions in Application A599. The FTAA has however, proposed changing the overall approach for regulating residues of agricultural and veterinary chemicals in food and suggested that the approach used for contaminants and natural toxicants in Standard 1.4.1 should be used (i.e. no prohibition on presence of residues unless they exceed a specific maximum level in the Standard).

Varying the overall basis of Standard 1.4.2 as the FTAA suggests is beyond the scope of this Application. This is because the FTAA suggestion relates to the overall regulatory framework for residues of agricultural and veterinary chemicals in food, rather than the specific MRLs in this Application. In addition, the use of the approach in Standard 1.4.1 (contaminants) as proposed by the FTAA would represent a major departure from the overall approach used to regulate residues of agricultural and veterinary chemicals in food. FSANZ considers that this may have a significant impact on the capability of compliance agencies to monitor and control the use of agricultural and veterinary chemical products in Australia. For these reasons, FSANZ does not propose to amend Standard 1.4.2 as proposed by the FTAA.

Commensurate with international practice, FSANZ incorporates MRLs in the Code where the residues are associated with the approved use of chemical products on the relevant commodities and where estimated dietary exposure is below reference health standards. MRLs are not set on the basis of health standards, but according to good agricultural practice (GAP) irrespective of whether the dietary exposure assessment indicates that higher residues do not raise any public health concerns. The current approach for regulating residues in Standard 1.4.2 ensures that residues of chemicals in food are minimised consistent with their approved use to protect plants and animals from pests and diseases i.e. residues in food are both safe and legitimate.

The issues raised by the FTAA are currently being considered by FSANZ in the context of implementing the Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food. In consultation with stakeholders, FSANZ will explore alternative options for regulating chemical residues in food. FSANZ will include the FTAA in any public consultation on the implementation of the Policy Guideline.

10.4 Summarised Submission from the NSW Food Authority

The NSW Food Authority supports options 2(a) and 2(b) to vary the Code as proposed.

The NSW Food Authority suggested that FSANZ adequately investigate the impact of proposed MRL withdrawals, especially endosulfan, on trade of imported foods. The Authority stated that it would not be appropriate to expend limited State and Territory resources in pursuit of such violations of Standard 1.4.2.

10.4.1 FSANZ Evaluation

Foods containing agricultural or veterinary chemical residues must comply with the requirements in Standard 1.4.2 of the Code. MRL reductions and deletions have the potential to restrict the importation of foods as foods containing non-permitted residues could not be legally imported or sold in Australia. 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 advertises and publicly 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.

At Initial / Draft Assessment, FSANZ requested comment as to any possible ramifications of the proposed MRLs including differences from international MRLs. Comments were received on the proposed deletion of the endosulfan MRL for tea; these are discussed above. Following WTO Notification, member nations raised no specific trade impact issues in regard to the proposed deletions or reductions. On this basis, and taking into account the consideration of the endosulfan MRL for tea, 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.

10.5 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 A599 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.

10.6 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 A599 where there is a corresponding MRL in the international Codex standard.

Several submitters commented on the impacts of the proposed deletion of the endosulfan MRL for tea. On this basis, FSANZ has recommended retaining the MRL; this is discussed in section 10.1 of this Report. No submitters raised any issues in relation to other specific MRLs differing from Codex or other international standards.

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
Abamectin		
Lettuce, leaf	T0.2	0.05
Bifenazate		
Almonds	T0.1	Tree nuts 0.2
Endosulfan		
Assorted tropical and sub-tropical fruits – inedible peel	2	Pineapple 2
Berries and other small fruits	Omit T2	Grapes 1
Broccoli	1	0.5
Cabbages, head	1	except Cabbage, Savoy 1
Cauliflower	1	0.5
Cereal grains	0.1	Rice 0.1 Maize 0.1 Wheat 0.2
Citrus fruits	0.3	Oranges, Sweet, Sour 0.5
Cotton seed oil, crude	Omit T0.5	0.5

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
Fruiting vegetables, cucurbits	1	Cucumber 0.5 Melons, except watermelon 0.5 Squash 0.5
Fruiting vegetables, other than cucurbits	1	Tomato 0.5
Legume vegetables	Omit T2	Broad bean (green pods and immature seeds) 0.5 Common bean (pods and/or immature seeds) 0.5 Garden pea (young pods) 0.5
Milks	0.02	0.004
Oilseed	1	Cotton seed 1 Rape seed 0.5 Sunflower seed 1
Onion, Bulb	Omit T0.2	0.2
Pome fruits	1	1
Pulses	*0.1	Soya bean (dry) 1
Root and tuber vegetables	0.5	Carrot 0.2 Potato 0.2 Sugar beet 0.1 Sweet potato 0.2
Stalk and stem vegetables	1	Celery 2
Stone fruits	Omit T2	Cherries 1 Peach 1 Plums (including prunes) 1
Tea, green, black	Omit T30[†]	30
Fenvalerate Peanut	T0.1	Peanut, whole 0.1
Oxamyl Peppers, Sweet	1	2

[†] FSANZ recommends retaining this MRL

10.7 New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

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

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

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

The following table lists the proposed variations to MRLs in Application A599 and includes the corresponding MRL in the New Zealand MRL Standards.

Chemical Food	**Proposed MRL** **mg/kg**	**NZ MRL** **mg/kg**
Endosulfan		
Berries and other small fruits	Omit T2	Berries and other small fruits (except grapes) 2
Broccoli	1	Vegetables 2
Cabbages, head	1	
Cauliflower	1	
Fruiting vegetables, cucurbits	1	
Fruiting vegetables, other than cucurbits	1	
Legume vegetables	Omit T2	
Onion, Bulb	Omit 0.02	
Pulses	*0.1	
Root and tuber vegetables	0.5	
Shallot	Omit T2	
Stalk and stem vegetables	1	

10.8 Imported Foods

Internationally, countries set MRLs under their own regulations and according to GAP 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 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 where imported foods may be affected, FSANZ compiled the following table of foods that have MRLs proposed for deletion and/or reduction and sought comment on any impacts of these reductions or deletions at Initial / Draft Assessment.

Several submitters commented on the impacts of the proposed deletion of the endosulfan MRL for tea. No submitters raised any issues in relation to other specific MRLs proposed for deletion or reduction. 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
Azoxystrobin Almonds
Endosulfan Assorted tropical and sub-tropical fruits – edible peel Berries and other small fruits [except strawberry] Broccoli Cabbages, head Cauliflower Cereal grains Citrus fruits Cotton seed oil, crude Eggs Fruiting vegetables, cucurbits Fruiting vegetables, other than cucurbits Legume vegetables Milks Onion, bulb Pome fruits Poultry, edible offal of Poultry meat (in the fat) Pulses Root and tuber vegetables Shallot Stalk and stem vegetables **Endosulfan** continued Stone fruits Tea, green, black† Tree nuts
Fenvalerate Peanut

† FSANZ recommends retaining this MRL

CONCLUSION

11. Conclusion and Decision

This Application has been assessed against the requirements of the FSANZ Act. FSANZ recommends approving the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits.

The draft variations to Standard 1.4.2 at Final Assessment differ from those proposed at Initial / Draft Assessment for endosulfan. FSANZ has recommended retaining the endosulfan MRL of T30 mg/kg for 'Tea, green, black' rather than omit it as was requested by the APVMA and consulted on at Initial / Draft Assessment. The results of the dietary exposure assessment show that this raises no health or safety concerns. Deleting the MRL as proposed at Initial / Draft Assessment may restrict trade. FSANZ's consideration of retaining this MRL in the Code is discussed in section 10.1 of this Report.

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 but subject to a minor variation to retain the endosulfan MRL for 'Tea, green, black'.

Decision

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

11.1 Reasons for Decision

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

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

- Dietary exposure assessments indicate that setting the maximum residue limits 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 retention of the endosulfan MRL for tea is appropriate because it would facilitate trade in tea and promote consistency between domestic and international standards.

- 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
TRICLABENDAZOLE	SUM OF TRICLABENDAZOLE AND METABOLITES OXIDISABLE TO KETO-TRICLABENDAZOLE AND EXPRESSED AS KETO-TRICLABENDAZOLE EQUIVALENTS

[1.2] *inserting in* Schedule 1 –

PROSULFOCARB PROSULFOCARB	
BARLEY	T*0.01
WHEAT	T*0.01

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

AZOXYSTROBIN AZOXYSTROBIN	
TREE NUTS	T0.02
BIFENTHRIN BIFENTHRIN	
PEPPERS, SWEET	T0.5
CARFENTRAZONE-ETHYL CARFENTRAZONE-ETHYL	
OLIVES	*0.05
ENDOSULFAN SUM OF A- AND B- ENDOSULFAN AND ENDOSULFAN SULPHATE	
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – EDIBLE PEEL	T2
BERRIES AND OTHER SMALL FRUITS [EXCEPT STRAWBERRY]	T2
CABBAGE HEAD	T2
COTTON SEED OIL, CRUDE	T0.5
LEGUME VEGETABLES	T2

MILKS (IN THE FAT)	T0.5
ONION, BULB	T0.2
RICE	T0.1
SHALLOT	T2
STONE FRUITS	T2
FENVALERATE FENVALERATE, SUM OF ISOMERS	
OILSEED	0.5
FLUMIOXAZIN FLUMIOXAZIN	
BROAD BEAN (DRY)	*0.1
CHICK-PEA (DRY)	*0.1
COTTON SEED	*0.1
FIELD PEA (DRY)	*0.1
LENTIL (DRY)	*0.1
LUPIN (DRY)	*0.1
RAPE SEED	*0.1

[1.4] *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	
LETTUCE, LEAF	T0.2
AZOXYSTROBIN AZOXYSTROBIN	
ALMONDS	*0.01
TREE NUTS [EXCEPT ALMONDS]	T0.02
BIFENAZATE SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOXYLIC ACID, 2-(4-METHOXY-[1,1'-BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
ALMONDS	T0.1
BIFENTHRIN BIFENTHRIN	
PEPPERS	T0.5
CARFENTRAZONE-ETHYL CARFENTRAZONE-ETHYL	
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – EDIBLE PEEL	*0.05
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – INEDIBLE PEEL	*0.05
CITRUS FRUITS	*0.05
ENDOSULFAN SUM OF A- AND B- ENDOSULFAN AND ENDOSULFAN SULPHATE	
CABBAGES, HEAD	1

MILKS	0.02
FENVALERATE FENVALERATE, SUM OF ISOMERS	
OILSEED [EXCEPT PEANUT]	0.5
PEANUT	T0.1
FLUMIOXAZIN FLUMIOXAZIN	
OILSEED	*0.1
PULSES	*0.1
IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID	
PERSIMMON, JAPANESE	T1
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
MACADAMIA NUTS	T1
OXAMYL SUM OF OXAMYL AND 2-HYDROXYIMINO-N,N-DIMETHYL-2-(METHYLTHIO)-ACETAMIDE, EXPRESSED AS OXAMYL	
PEPPERS, SWEET	1
TEBUFENOZIDE TEBUFENOZIDE	
RAMBUTAN	T3
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	
MANGO	T0.1

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

ABAMECTIN SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
LETTUCE, HEAD	0.05

ENDOSULFAN SUM OF A- AND B- ENDOSULFAN AND ENDOSULFAN SULPHATE	
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – INEDIBLE PEEL	2
BROCCOLI	1
CAULIFLOWER	1
CEREAL GRAINS	0.1
CITRUS FRUITS	0.3
EDIBLE OFFAL (MAMMALIAN)	0.2
EGGS	0.02
FRUITING VEGETABLES, CUCURBITS	1
FRUITING VEGETABLES, OTHER THAN CUCURBITS	1
OILSEED	1
POME FRUITS	1
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT (IN THE FAT)	0.05
PULSES	*0.1
ROOT AND TUBER VEGETABLES	0.5
STALK AND STEM VEGETABLES	1
TREE NUTS	0.05

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.

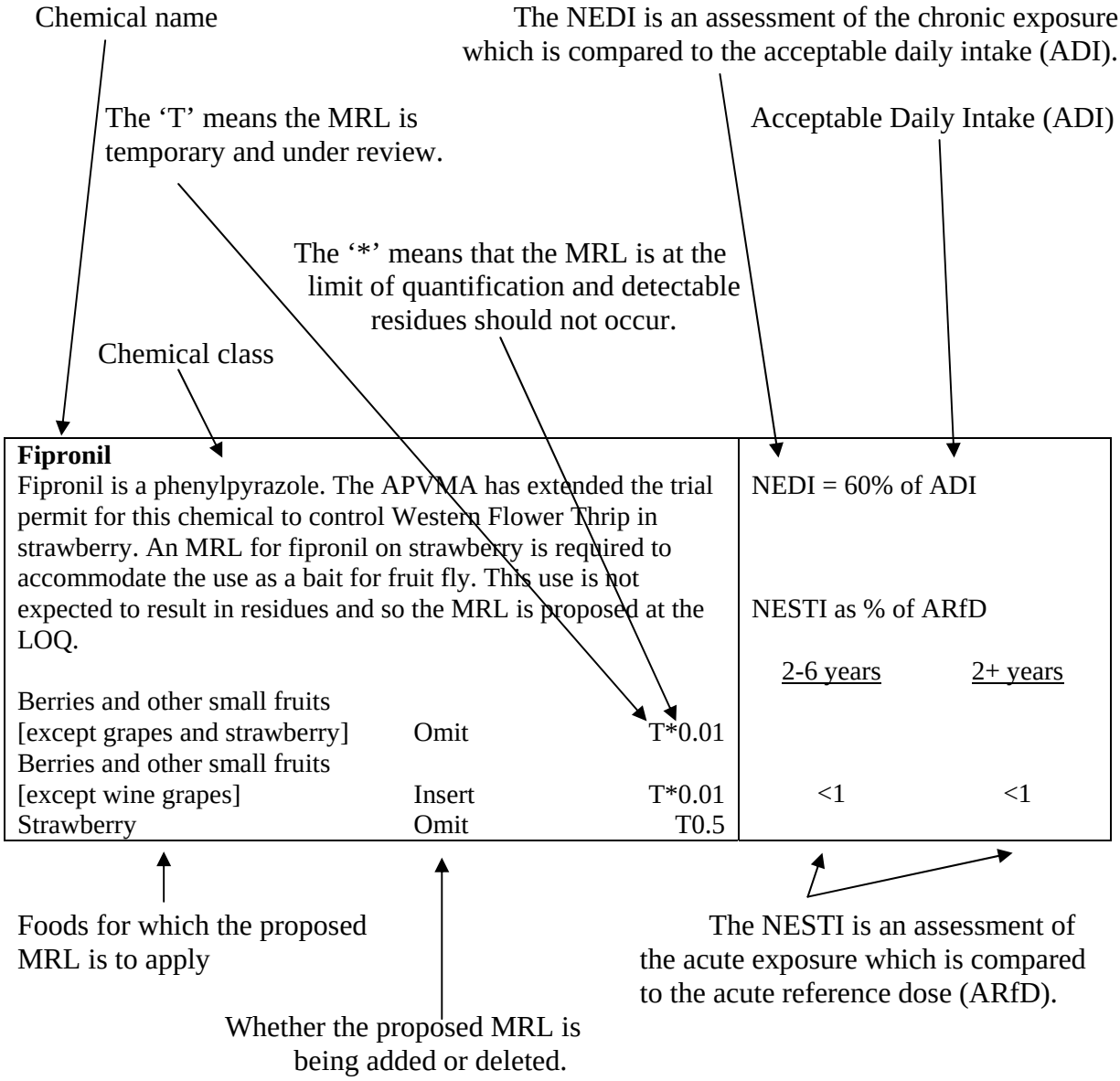
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

NEDI - National Estimated Dietary Intake - The NEDI represents a realistic estimate of chronic dietary exposure and is the preferred calculation. It may incorporate more specific food consumption data including that 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 other than the MRL 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 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.

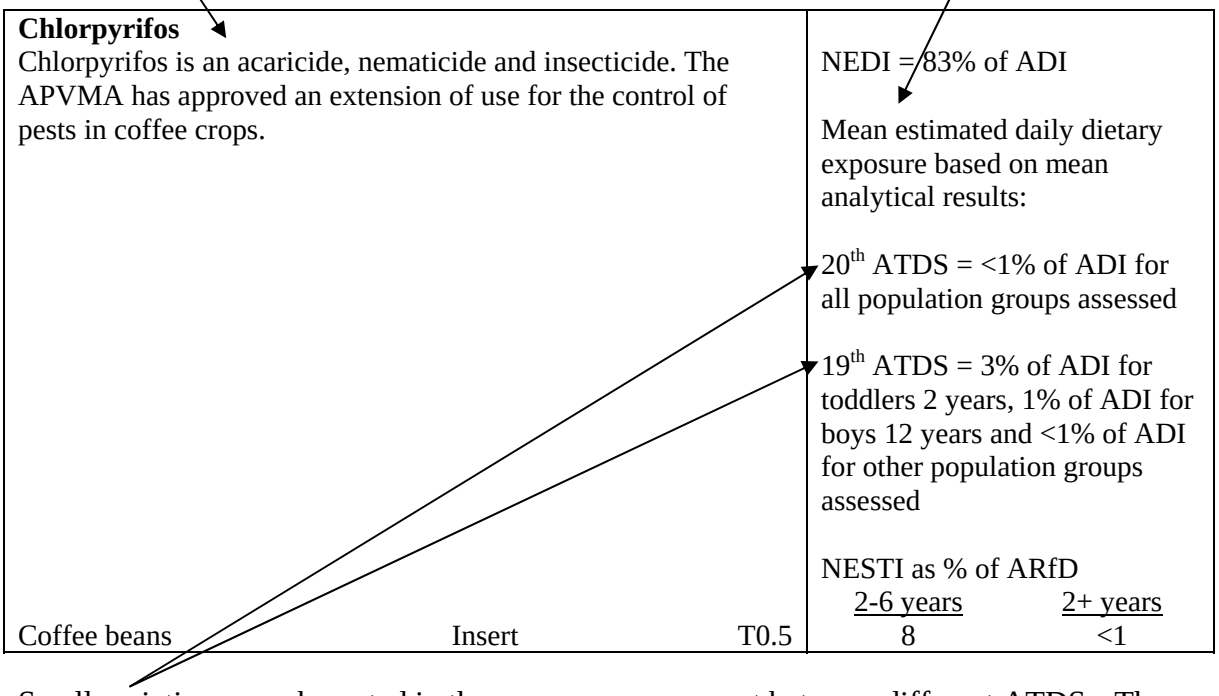
The following are examples of entries and the proposed MRLs listed are not part of this Application.



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
7.	**FSANZ**	Food Standards Australia New Zealand
8.	**JMPR**	Joint FAO/WHO Meeting on Pesticide Residues
9.	**LOQ**	Limit of Analytical Quantification
10.	**MRL**	Maximum Residue Limit
11.	**NEDI**	National Estimated Daily Intake
12.	**NESTI**	National Estimated Short Term Intake
13.	**NNS**	National Nutrition Survey of Australia 1995
14.	**OCS**	The Office of Chemical Safety
15.	**T or TMRL**	Temporary MRL
16.	**WHP**	Withholding Period

SUMMARY OF REQUESTED MRLS FOR APPLICATION A599
MAXIMUM RESIDUE LIMITS – JANUARY FEBRUARY MARCH 2007

Requested MRLs			**Dietary Exposure Estimates**	
Abamectin				
Abamectin is an insecticide and acaricide with contact and stomach action. It stimulates release of gamma-aminobutyric acid causing paralysis. The APVMA has issued a permit for its use to control two-spotted mite (*Tetranychus urticae*) on lettuce.			NEDI = 64% of ADI NESTI as % of ARfD	
			2-6 years	2+ years
Lettuce, head	Omit	T0.05	9	5
	Substitute	0.05		
Lettuce, leaf	Insert	T0.2	37	21
Azoxystrobin				
Azoxystrobin is a broad spectrum fungicide used to control four main groups of fungal disease caused by ascomycetes, basidiomycetes, deuteromycetes and oomycetes. It inhibits mitochondrial respiration in fungi. The APVMA has issued a permit for its use to control anthracnose (*Colletotrichum acutatum*) on almonds. The recommended MRL is at the LOQ.			NEDI = 2% of ADI	
Almonds	Insert	*0.01		
Tree nuts	Omit	T0.02		
Tree nuts [except almonds]	Insert	T0.02		
Bifenazate				
Bifenazate is a selective non-systemic miticide and acaricide registered to control the egg and motile stages of phytophagous mites in pome and stone fruits. It is absorbed primarily by contact. It has little impact on bees or other beneficial insects. The APVMA has issued a permit for its use to control mites in almonds.			NEDI = 7% of ADI NESTI as % of ARfD	
			2-6 years	2+ years
Almonds	Insert	T0.1	<1	<1
Bifenthrin				
This is a minor technical amendment to correct the commodity name as advised by the APVMA.			Dietary exposure assessment not required.	
Peppers, sweet	Omit	T0.5		
Peppers	Insert	T0.5		
Carfentrazone-ethyl				
Carfentrazone-ethyl is a triazolone herbicide. It inhibits protoporphyrinogen oxidase, leading to membrane disruption. The APVMA has approved extension of use of the chemical into fruit and nut orchards, as a desuckering agent on grapevines and for weed control in grass based pastures. The registered use pattern is expected to result in residues below the LOQ. Feeding studies indicate animal residues remain less than the LOQ following the use pattern.			NEDI = 2% of ADI	
Assorted tropical and sub-tropical fruits – edible peel	Insert	*0.05		
Assorted tropical and sub-tropical fruits – inedible peel	Insert	*0.05		
Citrus fruits	Insert	*0.05		
Olives	Omit	*0.05		

Requested MRLs			Dietary Exposure Estimates		
Endosulfan Endosulfan is a broad spectrum non-systemic insecticide and acaricide with contact and stomach action. It has been registered for use in Australia for over 35 years. It is widely used to control a large variety of insects and mites in horticultural and agricultural crops including oilseeds, cereal, fruit, vegetables and other crops. The APVMA notes that although alternative products are available for all use patterns, endosulfan has a number of advantages in that it has relatively low toxicity to many species of beneficial insects which prevent population explosions of damaging pests which would in turn require harsher pesticides to control and it provides a different chemistry useful in resistance management. The recommended MRL variations are a result of the APVMA review of endosulfan. The final review report and regulatory decision on the reconsideration of approval of the active constituent endosulfan, registrations of products containing endosulfan and their associated labels is available on the APVMA website at: http://www.apvma.gov.au/chemrev/endosulfan.shtml The APVMA requested that FSANZ omit the endosulfan MRL for tea from the Code. FSANZ consulted on deleting the MRL at Initial / Draft Assessment. Submitters identified the need for it to be retained. The APVMA advised that the MRL for tea was deleted from the APVMA MRL Standard as there was no current approved use pattern or permit issued for endosulfan in tea at the time the review was conducted and that the deletion was not due to any safety concern. FSANZ recommends retaining the MRL to continue to allow for the importation and sale of legitimately treated tea. The dietary exposure assessment concluded that this raises no health or safety concerns. Retaining this MRL in the Code would facilitate trade in tea and promote consistency between domestic and international standards. FSANZ's consideration of retaining the MRL is outlined in section 10.1 of this Report.			NEDI = 53% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS <1% of ADI for all population groups assessed 19th ATDS <1% of ADI for adult males 25 – 34 years and girls 12 years and 1% of ADI for other population groups assessed NESTI as % of ARfD		
			2-6 years		2+ years
Assorted tropical and sub-tropical fruits – edible peel	Omit	T2			
Assorted tropical and sub-tropical fruits – inedible peel	Omit	T2	17	Avocado	3
			57	Mango	20
	Substitute	2	80	Pawpaw	21
			36	Persimmon	15
			26	Litchi	13
			81	Custard apple	32
Berries and other small fruits [except strawberry]	Omit	T2			
Broccoli	Omit	T2			
	Substitute	1	38	Broccoli	11
Cabbage head	Omit	T2			
Cabbages, head	Insert	1	6	Cabbage	5
Cauliflower	Omit	T2			
	Substitute	1	10	Cauliflower	4

Requested MRLs			Dietary Exposure Estimates		
Endosulfan continued			NESTI as % of ARfD		
			2-6 years		2+ years
Cereal grains	Omit	T0.2			
	Substitute	0.1	1	Cereals	2
Citrus fruits	Omit	T2	57	Citrus fruits	18
	Substitute	0.3	22	Lemon	5
			14	Mandarin	4
			29	Orange	11
Cotton seed oil, crude	Omit	T0.5			
Edible offal (mammalian)	Omit	T0.2		Edible offal	
	Substitute	0.2	4	(mammalian)	14
				Meat (mammalian)	
			23	Fat	13
			4	Muscle	2
Eggs	Omit	T*0.05			
	Substitute	0.02	<1	Eggs	<1
Fruiting vegetables, cucurbits	Omit	T2	12	Cucumber	4
	Substitute	1	46	Melon	18
			7	Zucchini	3
Fruiting vegetables, other than cucurbits	Omit	T2	53	Capsicum	8
			7	Eggplant	5
	Substitute	1	11	Tomato	4
Legume vegetables	Omit	T2			
Milks (in the fat)	Omit	T0.5			
Milks	Insert	0.02	23	Milks	9
Oilseed	Omit	T1			
	Substitute	1	7	Oilseed	4
Onion, bulb	Omit	T0.2			
Pome fruits	Omit	T2	16	Apple	5
	Substitute	1	49	Pear	13
Poultry, edible offal of	Omit	0.2		Poultry, edible	
	Substitute	*0.01	<1	offal of	<1
Poultry meat (in the fat)	Omit	0.2		Poultry meat	
	Substitute	0.05	<1	Fat	<1
			3	Muscle	1
Pulses	Omit	T1			
	Substitute	*0.1	4	Pulses	1
Rice	Omit	T0.1			
Root and tuber vegetables	Omit	T2	30	Beetroot	4
	Substitute	0.5	9	Carrot	2
			3	Potato	1
			<1	Sweet potato	1
Shallot	Omit	T2			
Stalk and stem vegetables	Omit	T2	39	Celery	13
	Substitute	1	18	Rhubarb	18
Stone fruits	Omit	T2			
Tea, green, black	Retain	T30	55	Tea	45
Tree nuts	Omit	T2			
	Substitute	0.05	<1	Macadamia nuts	<1

Requested MRLs			Dietary Exposure Estimates	
Fenvalerate Fenvalerate is a non-systemic pyrethroid insecticide with contact and stomach action. It acts on the nervous system of the insect and disrupts the function of neurons by interaction with the sodium channel. The APVMA has issued a minor use permit for its use to control lucerne seed web moth *(Etiella behrii)* on peanuts. The current oilseed MRL would cover the proposed use, however a temporary MRL has been established to more accurately reflect the expected residues in peanuts.			NEDI = 87% of ADI Mean estimated daily dietary exposure based on mean analytical results: 20th ATDS – not detected in any foods sampled 19th ATDS <1% of ADI for all population groups assessed	
Oilseed	Omit	0.5		
Oilseed [except peanut]	Insert	0.5		
Peanut	Insert	T0.1		
Flumioxazin Flumioxazin is a diphenyl ether herbicide absorbed by foliage and germinating seedlings. It inhibits protoporphyrinogen oxidase. It is used to control many annual broadleaf weeds including bell vine, capeweed, marshmallow and sow thistle in broad acre situations. The data are sufficient to support label amendments to include maize, sorghum, mungbean, soya bean, and sunflowers. Given that the data could be used to support extrapolation to other commodities in each group, the recommended MRLs are for the crop groups. The recommended MRLs are at the LOQ.			NEDI = 9% of ADI NESTI as % of ARfD	
			2-6 years	2+ years
Broad bean (dry)	Omit	*0.1		
Chick-pea (dry)	Omit	*0.1		
Cotton seed	Omit	*0.1		
Field pea (dry)	Omit	*0.1		
Lentil (dry)	Omit	*0.1		
Lupin (dry)	Omit	*0.1		
Oilseed	Insert	*0.1	<1	<1
Pulses	Insert	*0.1	3	<1
Rape seed	Omit	*0.1		
Imidacloprid Imidacloprid is a systemic herbicide. It binds to postsynaptic nicotinic receptors in the central nervous system acting as an antagonist. The APVMA has issued a permit for its use to control mealy bug on persimmons.			NEDI = 14% of ADI	
Persimmon, Japanese	Insert	T1		
Methomyl Methomyl is a carbamate insecticide and acaricide with contact and stomach action. It is a cholinesterase inhibitor. Methomyl is used to control a wide range of insects and spider mites in fruit, vines, vegetables and field crops. The APVMA has issued a permit for its use to control banana fruit caterpillar or cacao armyworm *(Tiracola plagiata)* on macadamia nuts.			NEDI = 84% of ADI Mean estimated daily dietary exposure based on mean analytical results: 19th ATDS – not detected NESTI as % of ARfD	
			2-6 years	2+ years
Macadamia nuts	Insert	T1	7	6

Requested MRLs			Dietary Exposure Estimates
Oxamyl Oxamyl is a systemic oxime carbamate insecticide, acaricide and nematicide absorbed by foliage and roots. It is a cholinesterase inhibitor. It has contact action, translocation occurs within plants. It is used to control chewing and sucking insects, spider mites and nematodes in fruit, vegetables, cereals and other crops. It is to be used to control nematodes in capsicums. Peppers, Sweet	Insert	1	NEDI = 23% of ADI
Prosulfocarb Prosulfocarb is a S-benzyl thiocarbamate selective herbicide. It inhibits lipid synthesis in the meristematic region. The APVMA has issued an experimental trial permit for its use to control annual ryegrass and toad rush in wheat and barley crops. The recommended MRLs are at the LOQ and have been established for a limited period while the permit is current. New chemical Insert residue definition: Prosulfocarb Barley Wheat	Insert Insert	T*0.01 T*0.01	NEDI = <1% of ADI DIAMOND modelling estimated chronic dietary exposure as <1% of ADI NESTI as % of ARfD 2-6 years / 2+ years <1 Barley grain and beer <1 <1 Wheat bran, processed <1 <1 Wheat bran, unprocessed <1 <1 Wheat flour <1 <1 Wheat germ <1 <1 Wheat wholemeal <1
Tebufenozide Tebufenozide is an ecdysone agonist insecticide. It binds to the receptor site of the insect moulting hormone ecdysone. It lethally accelerates the moulting process. It is used to control lepidopteran larvae on fruits nuts and other crops. The APVMA has issued a permit for its use to control various insect pests on rambutans. Rambutan	Insert	T3	NEDI = 23% of ADI
Thiamethoxam Thiamethoxam is a neonicotinoid insecticide. 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. The APVMA has issued a minor use permit for its use to control mango seed weevil *(Sternochetus mangifrae)* in mangoes. Mango	Insert	T0.1	NEDI = 3% of ADI

Requested MRLs	Dietary Exposure Estimates
Triclabendazole This is a minor technical amendment to amend the residue definition as advised by the APVMA. Omit: Triclabendazole Substitute: Sum of triclabendazole and metabolites oxidisable to keto-triclabendazole and expressed as keto-triclabendazole equivalents	Dietary exposure assessment not required.

Attachment 3

SUMMARY OF SUBMISSIONS

Submitter	Comments
Queensland Government	Supported this Application
NSW Food Authority	Supported this Application and suggested that FSANZ adequately investigate the impact of proposed MRL withdrawals, especially endosulfan, on trade of imported foods. The Authority stated that it would not be appropriate to expend limited State and Territory resources in pursuit of such violations of Standard 1.4.2.
Food and Agriculture Organisation Inter-Governmental Group on Tea Working Group on Pesticides, Unilever Australasia, Tetley Australia Pty Limited and the AFGC Tea Industry Forum.	Requested that FSANZ consider retaining the current MRL for endosulfan in tea on the basis of the severe economic impact that deleting the MRL would have on the tea industry, the current requirements for the commercial cultivation of tea and consistency with international standards.
Australian Food and Grocery Council	Supported option 2(b) and not option 2(a) to omit or decrease some existing MRLs as this will have a detrimental effect on the food industry and on consumers. The effect will be particularly significant with the deletion or reduction of endosulfan MRLs for a variety of foods and most particularly on the importation of tea. The APVMA does not give due regard to the effect of changing MRLs on imported foods. This is a responsibility of FSANZ under the section 18 objectives of the FSANZ Act. Until such time as the there is default or threshold level equivalent to Codex permission for residues on imported fruits and vegetables, the Code fails to meet the requirements of the FSANZ Act and results in a barrier to trade.
Food Technology Association of Australia Inc.	Supports option 2(b) and not option 2(a) to omit or decrease some existing MRLs. Due to advances in analytical capability, extremely low levels of some residues are detectable. This means that in the absence of an MRL, even where residues are detected at low levels, the food may not be sold. This is trade restrictive. These extremely low detectable levels are often deemed harmless and are often not deliberately used in conjunction with the food but may be present for another reason. The FTAA suggests FSANZ vary Standard 1.4.2 to regulate residues of agricultural and veterinary chemicals as per contaminants and natural toxicants in Standard 1.4.1 i.e. no prohibition on the presence of residues unless they exceed a specific maximum level in the Standard.