



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

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3 October 2007

INITIAL / DRAFT ASSESSMENT REPORT

APPLICATION A599

MAXIMUM RESIDUE LIMITS (JANUARY, FEBRUARY, MARCH 2007)

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 14 November 2007
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

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) 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. 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 is exploring alternative options for regulating chemical residues in food.

There are no MRLs for antibiotic residues in this Application.

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

Food Standards Australia New Zealand (FSANZ) will make a Sanitary and Phytosanitary notification to the World Trade Organization (WTO).

FSANZ decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), to omit 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. Submissions are now invited on this Report to assist FSANZ make 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.

Preferred Approach:

FSANZ recommends accepting Application A599 and the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits.

Reasons for Preferred Approach

This Application has been assessed against the requirements for Initial and Draft Assessments in sections 13 and 15 respectively, of the FSANZ Act. FSANZ recommends accepting this Application and 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.
- 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), part of the Therapeutic Goods Administration (TGA), has undertaken a toxicological assessment of each chemical and has established an acceptable daily intake (ADI) and where applicable an acute reference dose (ARfD).
- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and will benefit producers and consumers.
- The proposed draft variations would remove discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.
- The proposed changes are consistent with the FSANZ Act section 18 objectives.

Consultation

FSANZ decided, pursuant to section 36 of the FSANZ Act, not to invite public submissions in relation to Application A599 prior to making an Initial / Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only.

FSANZ is seeking public comment on this Initial / Draft Assessment Report to assist in assessing the Application. Comments on, but not limited to, the following would be useful:

- any impacts (costs/benefits) of the proposed additions, deletions and changes to specific MRLs, in particular the likely costs and benefits impacting importation of food if the proposed deletions or reductions of specific MRLs are advanced;
- any further public health and safety considerations associated with the proposed MRLs; and
- any other affected parties to this Application.

Further details on making submissions are provided in the Invitation for Public Submissions section of this report.

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INVITATION FOR PUBLIC SUBMISSIONS

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

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

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

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

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

Submissions need to be received by FSANZ by 6pm (Canberra time) 14 November 2007

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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.

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.

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.

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 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 detection 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 its 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. When a chemical product is registered for use or a permit for use approved, the APVMA includes MRLs in the APVMA 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, based on scientific evaluations, the APVMA notifies FSANZ to incorporate the MRL variations in Standard 1.4.2 of the Code. 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 in 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 – Maximum Residue Limits

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 variation to the Code is at **Attachment 1** and 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 antibiotic¹ 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.

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

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

1.7 Australia and New Zealand Joint Food Standards

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 10.3 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 both the development of new products and crop uses, and the withdrawal of older products following review.

3. Objectives

In assessing this Application FSANZ aims to ensure that the proposed MRLs do 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 Food², 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 FSANZ Act section 18 objectives of food regulatory measures, including the Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food.

4. Assessment Approach

The primary role of FSANZ 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 the 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.

²

[http://www.health.gov.au/internet/wcms/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/\\$File/pol-g-line-reg-res.pdf](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/$File/pol-g-line-reg-res.pdf) accessed 17 August 2007.

At the risk characterisation step, the estimated dietary exposure to a chemical is compared to the acceptable 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 applicable, 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 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; 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 dietary exposure to a chemical from all foods with MRLs.

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

The NESTI is calculated in a similar way to the chronic dietary exposure. Generally, the residues of a chemical in a specific food are multiplied by the 97.5th percentile food consumption of that food based on consumers only, a variability factor is applied, 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 and JMPR, the 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 dietary exposure is compared to the ADI. It is therefore the overall dietary exposure to a chemical that is compared to the ADI - not the MRL. FSANZ considers that the chronic dietary exposure to the residues of a chemical is acceptable where the best estimate of exposure does not exceed the ADI.

FSANZ considers 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.

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 applicable, 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 existing MRLs in the Code

Under this option, the *status quo* would be maintained and there would be no changes to existing MRLs in the Code.

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 the Code in Schedule 1 of Standard 1.4.2 to omit or decrease existing MRLs as proposed

Under this option, only those variations that were deletions or reductions would be approved. The proposed increases, inclusions of new MRLs and changes from temporary MRLs to MRLs would not be approved.

7.3 Option 2(b) – vary the Code in Schedule 1 of Standard 1.4.2 to insert new, increase existing MRLs or change temporary MRLs to MRLs as proposed

Under this option, only those variations that were insertions, increases and changes from temporary MRLs to MRLs would be approved for inclusion in the Code. The proposed deletions and reductions would not be approved.

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 foods; 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 existing MRLs in the Code

8.2.1.1 Benefits

- For consumers the major benefit would be maintaining existing confidence in the food supply in relation to residues of agricultural and veterinary chemicals;
- for growers and producers of domestic and export food commodities, adopting this option would not result in any discernable benefits;
- for importers, adopting this option would not result in any discernable benefits; and
- for Australian Government, State and Territory agencies, adopting this option would not result in any discernable benefits.

8.2.1.2 Costs

- For consumers there are unlikely to be any discernable costs as unavailability of some foods from certain growers is likely to be seen as typical seasonal fluctuation in the food supply;

FSANZ invites comment on whether these costs are likely to be discernable by consumers.

- for growers and producers of domestic and export food commodities, this option would result in costs as food containing residues consistent with increased MRLs or MRL additions 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;
- for importers, this option would not result in any discernable costs; and

- for Australian Government, State and Territory agencies, this option would allow discrepancies between agricultural and food legislation thereby creating uncertainty, inefficiency and confusion in the enforcement of regulations.

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

8.2.2.1 Benefits

- For consumers the major benefit would be maintaining existing confidence in the food supply in relation to residues of agricultural and veterinary chemicals;
- for growers and producers of domestic and export food commodities, this option would not result in any discernable benefits;
- for importers, this option would not result in any discernable benefits; and
- for Australian Government, State and Territory agencies, adopting this option would foster community confidence that regulatory authorities are maintaining standards to minimise residues in the food supply.

8.2.2.2 Costs

- For consumers there are unlikely to be any discernable costs as the unavailability of some foods from certain importers is likely to be seen as typical seasonal fluctuation in the food supply;

FSANZ invites comment on whether these costs are likely to be discernable by consumers.

- for growers and producers of domestic and export food commodities, this option is unlikely to result in any costs, as changes in use patterns are made as required, proper use resulting in compliance with proposed MRLs already;
- for importers, this option may result in costs, as foods may not be permitted to be imported if these foods contain residues consistent with MRLs proposed for deletion or reduction. Any MRL deletions or reductions have the potential to restrict importation of foods and could potentially result in higher food costs and a reduced product range available to consumers, as foods that exceed the new, lower MRLs could not be legally imported or sold to consumers. To assist in identifying any restrictions and possible trade impacts, Codex MRLs and data on imported foods are addressed in section 10 of this report; and

FSANZ invites comment on whether these costs are likely to be discernable by importers of food commodities.

- for Australian Government, State and Territory agencies, this option would not result in any discernable costs, although there would need to be an awareness of changes in the standards for residues in food.

8.2.3 *Option 2(b) – vary the Code in Schedule 1 of Standard 1.4.2 to insert new, increase existing MRLs or change temporary MRLs to MRLs as proposed*

8.2.3.1 Benefits

- For consumers there would be potential flow on benefits resulting from the price and availability of foods if growers can legally sell food containing residues consistent with increased MRLs or MRL additions;

FSANZ invites comment on whether these benefits are likely to be discernable by consumers.

- for growers and producers of domestic and export food commodities, the benefits of this option would result from being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Other benefits include the consistency between agricultural and food legislation thereby minimising compliance costs to primary producers;
- this option would benefit importers in that food containing residues consistent with increased or new MRLs could be legally imported; and
- removing discrepancies between agricultural and food legislation thereby creating certainty and allowing efficient enforcement of regulations benefits Australian Government, State and Territory agencies.

8.2.3.2 Costs

- For consumers there are no discernable costs;
- for growers and producers of domestic and export food commodities, this option would not result in any discernable costs;
- for importers, this option would not result in any discernable costs; and
- for Australian Government, State and Territory agencies, this option would not result in any discernable costs, although there may be minimal impacts associated with slight changes to residue monitoring programs.

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 the Code in Schedule 1 of Standard 1.4.2 to include new MRLs, increase, delete, decrease or change the status of some existing MRLs for the following reasons:

- There are no public health and safety concerns associated with the proposed MRL amendments (this benefit also applies to option 1).
- The changes would minimise potential costs to primary producers and rural and regional communities in terms of legally being able to sell legally treated food.
- The changes would minimise residues consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases.
- The changes would remove discrepancies between agricultural and food legislation and assist enforcement.

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

The conclusion of the impact analysis is that 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, to omit inviting public submissions in relation to Application A599 prior to making a Draft Assessment. However, FSANZ invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to submissions received.

FSANZ made its decision under section 36 because it was satisfied that Application A599 raised issues of minor significance or complexity only.

Section 63 of the FSANZ Act provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for review of the decision to omit to invite public submissions prior to making a Draft Assessment, may be made to the Administrative Appeals Tribunal.

FSANZ is seeking public comment on this Initial / Draft Assessment Report to assist in assessing the Application. Comments on, but not limited to, the following would be useful:

- any impacts (costs/benefits) of the proposed additions, deletions and changes to specific MRLs, in particular the likely costs and benefits impacting importation of food if the proposed deletions or reductions of specific MRLs are advanced;
- any further public health and safety considerations associated with the proposed MRLs; and
- any other affected parties to this Application.

10.1 World Trade Organization

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

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

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

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

10.2 Codex Alimentarius Commission MRLs

Codex standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table lists MRLs proposed in Application A599 where there is a corresponding MRL in the international Codex standard.

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
Fruiting vegetables, cucurbits	1	Cucumber 0.5 Melons, except watermelon 0.5 Squash 0.5 Tomato 0.5
Fruiting vegetables, other than cucurbits	1	
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

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Oxamyl Peppers, Sweet	1	2

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

10.3 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 Vegetables 2
Broccoli	1	
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	

10.4 Imported Foods

Internationally, countries set MRLs according to good agricultural practice (GAP) or good veterinary practice (GVP). Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because product use patterns differ. This means that residues in imported foods may be 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 has compiled the following table of foods that have MRLs proposed for deletion and/or reduction. Refer to Attachment 2 for further detail.

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

Chemical
Food
Shallot
Stalk and stem vegetables
Stone fruits
Tea, green, black
Tree nuts
Fenvalerate
Peanut

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

CONCLUSION

11. Conclusion and Preferred Approach

This Application has been assessed against the requirements for Initial and Draft Assessments in sections 13 and 15 respectively, of the FSANZ Act. FSANZ recommends accepting this Application and the proposed draft variations to Standard 1.4.2. – Maximum Residue Limits.

The preferred approach is to adopt option 2 to vary MRLs in Schedule 1 of Standard 1.4.2 – Maximum Residue Limits as proposed.

Preferred Approach:

FSANZ recommends accepting Application A599 and the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits.

11.1 Reasons for Preferred Approach

FSANZ accepting this Application and 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.
- 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 applicable an ARfD.
- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and will benefit producers and consumers.
- The proposed draft variations would remove discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.
- The proposed changes are consistent with the FSANZ Act section 18 objectives.

12. Implementation and Review

The use of chemical products and MRLs are under constant review as part of the APVMA Existing 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 ATDS.

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

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

ATTACHMENTS

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

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 sunseting.

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
TEA, GREEN, BLACK	T30
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 <i>SEE ALSO THIODICARB</i>	
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	
<i>COMMODITIES OF PLANT ORIGIN:</i> THIAMETHOXAM <i>COMMODITIES OF ANIMAL ORIGIN:</i> 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

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.

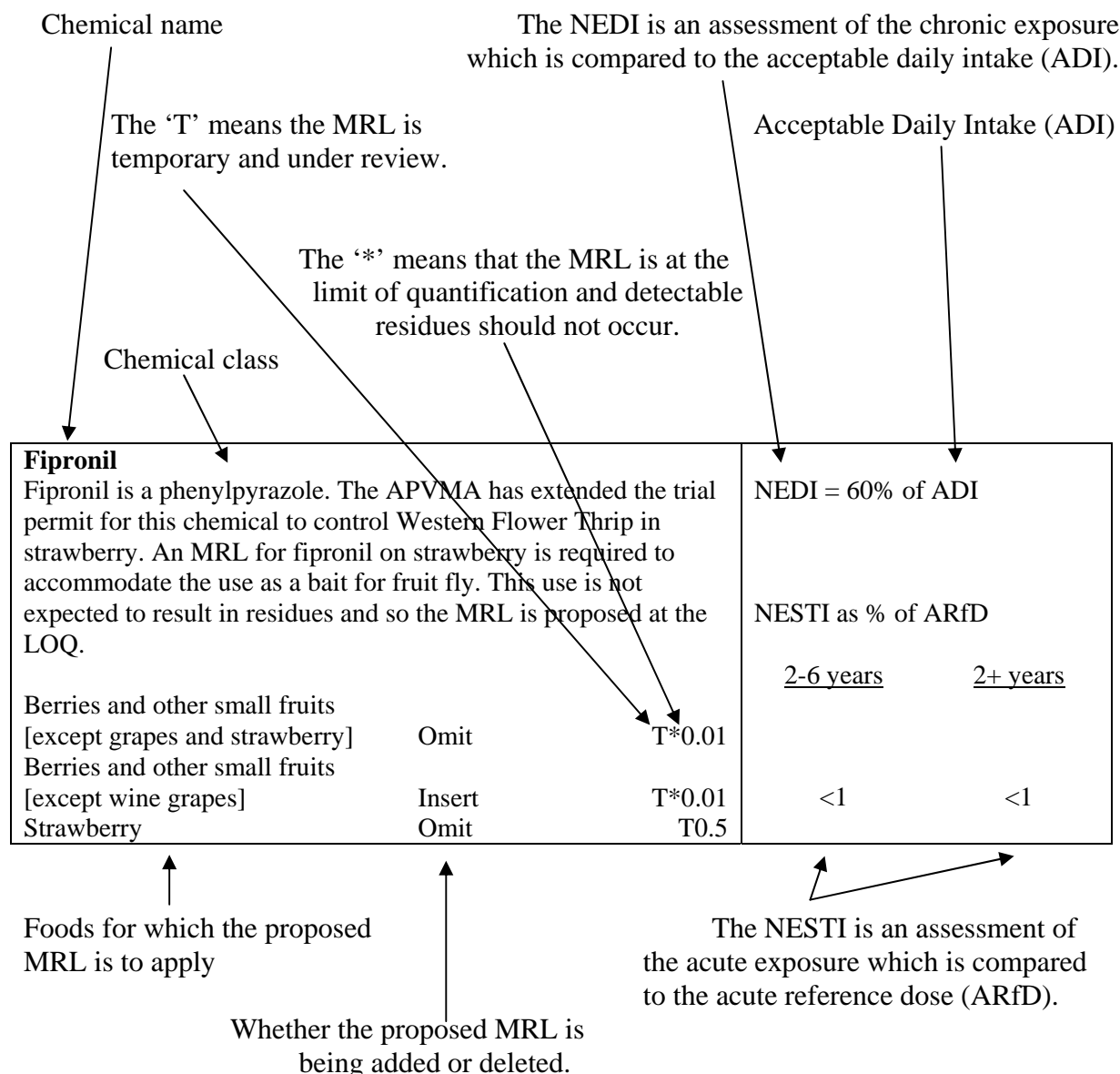
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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 TGA 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.

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 Australian Total Diet Surveys (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 are used; the NEDI and NESTI calculations are theoretical calculations that conservatively overestimate exposure.

<p>Chlorpyrifos Chlorpyrifos is an acaricide, nematocide and insecticide. The APVMA has approved an extension of use for the control of pests in coffee crops.</p>		<p>NEDI = 83% of ADI</p> <p>20th ATDS = <1% of ADI for all population groups assessed</p> <p>19th ATDS = 3% of ADI for toddlers 2 years, 1% of ADI for boys 12 years and <1% of ADI for other population groups assessed</p> <p>NESTI as % of ARfD</p> <table border="1"> <tr> <td><u>2-6 years</u></td> <td><u>2+ years</u></td> </tr> <tr> <td>8</td> <td><1</td> </tr> </table>	<u>2-6 years</u>	<u>2+ years</u>	8	<1
<u>2-6 years</u>	<u>2+ years</u>					
8	<1					
Coffee beans	Insert	T0.5				

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
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. **TGA** Therapeutic Goods Administration
17. **WHP** Withholding Period

Requested MRLs	Dietary Exposure Estimates					
<p>Endosulfan</p> <p>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</p>	<p>NEDI = 28% of ADI</p> <p>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</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="1027 891 1347 925"> <thead> <tr> <th></th> <th><u>2-6 years</u></th> <th><u>2+ years</u></th> </tr> </thead> </table>				<u>2-6 years</u>	<u>2+ years</u>
	<u>2-6 years</u>	<u>2+ years</u>				
Assorted tropical and sub-tropical fruits – edible peel	Omit	T2				
Assorted tropical and sub-tropical fruits – inedible peel	Omit	T2	17	Avocado	3	
	Substitute	2	57	Mango	20	
			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		
			<u>2-6 years</u>		<u>2+ years</u>
Cereal grains	Omit	T0.2			
	Substitute	0.1	1	Cereals	2
Citrus fruits	Omit	T2	22	Lemon	5
	Substitute	0.3	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)	
			27	(in the fat)	5
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			
	Substitute	0.05	3	Poultry meat	2
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	Omit	T30			
Tree nuts	Omit	T2			
	Substitute	0.05	<1	Macadamia nuts	<1

Requested MRLs	Dietary Exposure Estimates																																					
<p>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 (<i>Etiella behrii</i>) 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.</p> <table border="0" data-bbox="177 645 983 741"> <tr> <td>Oilseed</td> <td>Omit</td> <td>0.5</td> </tr> <tr> <td>Oilseed [except peanut]</td> <td>Insert</td> <td>0.5</td> </tr> <tr> <td>Peanut</td> <td>Insert</td> <td>T0.1</td> </tr> </table>	Oilseed	Omit	0.5	Oilseed [except peanut]	Insert	0.5	Peanut	Insert	T0.1	<p>NEDI = 87% of ADI</p> <p>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</p>																												
Oilseed	Omit	0.5																																				
Oilseed [except peanut]	Insert	0.5																																				
Peanut	Insert	T0.1																																				
<p>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 broadacre 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.</p> <table border="0" data-bbox="177 1151 983 1451"> <tr> <td>Broad bean (dry)</td> <td>Omit</td> <td>*0.1</td> </tr> <tr> <td>Chick-pea (dry)</td> <td>Omit</td> <td>*0.1</td> </tr> <tr> <td>Cotton seed</td> <td>Omit</td> <td>*0.1</td> </tr> <tr> <td>Field pea (dry)</td> <td>Omit</td> <td>*0.1</td> </tr> <tr> <td>Lentil (dry)</td> <td>Omit</td> <td>*0.1</td> </tr> <tr> <td>Lupin (dry)</td> <td>Omit</td> <td>*0.1</td> </tr> <tr> <td>Oilseed</td> <td>Insert</td> <td>*0.1</td> </tr> <tr> <td>Pulses</td> <td>Insert</td> <td>*0.1</td> </tr> <tr> <td>Rape seed</td> <td>Omit</td> <td>*0.1</td> </tr> </table>	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	Pulses	Insert	*0.1	Rape seed	Omit	*0.1	<p>NEDI = 9% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="983 1115 1390 1413"> <tr> <td></td> <td><u>2-6 years</u></td> <td><u>2+ years</u></td> </tr> <tr> <td></td> <td><1</td> <td><1</td> </tr> <tr> <td></td> <td>3</td> <td><1</td> </tr> </table>			<u>2-6 years</u>	<u>2+ years</u>		<1	<1		3	<1
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	<1	<1																																				
	3	<1																																				
<p>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.</p> <table border="0" data-bbox="177 1621 983 1653"> <tr> <td>Persimmon, Japanese</td> <td>Insert</td> <td>T1</td> </tr> </table>	Persimmon, Japanese	Insert	T1	<p>NEDI = 14% of ADI</p>																																		
Persimmon, Japanese	Insert	T1																																				
<p>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 (<i>Tiracola plagiata</i>) on macadamia nuts.</p> <table border="0" data-bbox="177 1989 983 2020"> <tr> <td>Macadamia nuts</td> <td>Insert</td> <td>T1</td> </tr> </table>	Macadamia nuts	Insert	T1	<p>NEDI = 84% of ADI</p> <p>Mean estimated daily dietary exposure based on mean analytical results: 19th ATDS – not detected</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="983 1957 1390 2020"> <tr> <td></td> <td><u>2-6 years</u></td> <td><u>2+ years</u></td> </tr> <tr> <td></td> <td>7</td> <td>6</td> </tr> </table>			<u>2-6 years</u>	<u>2+ years</u>		7	6																											
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Requested MRLs	Dietary Exposure Estimates
<p>Triclabendazole This is a minor technical amendment to amend the residue definition as advised by the APVMA.</p> <p>Omit: Triclabendazole</p> <p>Substitute: Sum of triclabendazole and metabolites oxidisable to keto-triclabendazole and expressed as keto-triclabendazole equivalents</p>	<p>Dietary exposure assessment not required.</p>