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

1-07
21 March 2007

INITIAL / DRAFT ASSESSMENT REPORT

APPLICATION A591

MAXIMUM RESIDUE LIMITS (OCTOBER, NOVEMBER, DECEMBER 2006)

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 2 May 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 A591 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). It is a routine Application from the Australian Pesticides and Veterinary Medicines Authority (APVMA), to update the Code in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits. 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. In consultation with stakeholders, FSANZ will explore alternative options for regulating chemical residues in food. FSANZ considers the current regulatory approach is consistent with the Ministerial Policy Guideline, therefore, MRL applications will continue to be progressed according to current practice. Submitters may provide specific data to support retaining MRLs; this will be considered by FSANZ in accordance with the statutory requirements of the FSANZ Act.

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 A591 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.

- APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.

- Office of Chemical Safety (OCS) part of the Therapeutic Goods Administration (TGA) has undertaken an appropriate 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 10 objectives.

Consultation

FSANZ decided, pursuant to section 36 of the FSANZ Act, not to invite public submissions in relation to Application A591 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.

Section 63 of the FSANZ Act provides that, subject to the *Administrative Appeals Act 1975*, application may be made to the Administrative Appeals Tribunal for review of a decision made by FSANZ under section 36 of the FSANZ Act.

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;
- any further public health and safety considerations associated with the proposed MRLs;
- likely costs and benefits impacting the importation of food if the proposed deletions to specific MRLs are advanced; 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.

CONTENTS

INVITATION FOR PUBLIC SUBMISSIONS

Food Standards Australia New Zealand (FSANZ) invites public comment on this Initial / Draft Assessment Report based on regulation impact principles and the draft variations to the *Australia New Zealand Food Standards Code* (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 10 of the *Food Standards Australia New Zealand Act 1991* (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 commercial-in-confidence. Section 39 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) 2 May 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

Applications were received from the APVMA on 6 October, 14 November and 6 December 2006 seeking to vary the Code. The proposed variations to Standard 1.4.2 – Maximum Residue Limits would align MRLs in the Code for non-antibiotic agricultural and veterinary chemicals with the MRLs in the APVMA MRL Standard.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits.

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 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, 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, APVMA independently evaluates its safety and performance, making sure that the health and safety of people, animals and the environment are protected.

When a chemical product is registered for use or a permit for use granted, APVMA includes MRLs in the APVMA MRL Standard. These MRLs are then adopted into control of use legislation in some jurisdictions and 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, APVMA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews information provided by APVMA and validates whether the 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 APVMA in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997* 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 Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food

The Ministerial Council has endorsed a Policy Guideline for the Regulation of Residues of Agricultural and Veterinary Chemicals in Food, 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.

Some submitters have raised concerns about MRL deletions in recent applications, suggesting they are inconsistent with the Policy Guideline. However, FSANZ considers the current regulatory approach for setting MRLs in the Code is consistent with the Policy Guideline, therefore MRL applications will continue to be progressed according to current practice. Submissions including data demonstrating a requirement for certain MRLs to be retained may be made under the current process for considering variations to the Code. FSANZ will consider retaining MRLs proposed for deletion 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). MRL deletions are discussed in section 10.3 of this report.

1.5 Summary of Proposed Variations to Standard 1.4.2 - Maximum Residue Limits

Amendments under consideration in Application A591:

- adding temporary MRLs for certain foods at the LOQ for new chemical azimsulfuron;
- adding MRLs at the LOQ for new chemical prohexadione-calcium;
- deleting the chemical and all associated entries for coumaphos;
- adding MRLs at the LOQ for azoxystrobin and MCPA;
- adding MRLs for certain foods for indoxacarb and pymetrozine;
- adding temporary MRLs including some at the LOQ for certain foods for azoxystrobin, bifenthrin, chlorothalonil, cypermethrin, difenoconazole, ethephon, etoxazole, indoxacarb, methomyl, paclobutrazol, procymidone, propiconazole, tebuconazole and thiabendazole;
- changing an existing temporary MRL to a MRL for certain foods for ethephon, imidacloprid and uniconazole-p;
- increasing MRLs including changing some temporary MRLs to MRLs for certain foods for glyphosate, imidacloprid and paclobutrazol;

- decreasing and changing temporary MRLs to MRLs for certain foods for azoxystrobin and glufosinate and glufosinate-ammonium;

- decreasing existing MRLs for indoxacarb and quinoxyfen;

- deleting existing MRLs for tetrachlorvinphos; and

- changing an existing temporary MRL at the LOQ to a MRL at the LOQ for thiamethoxam and trifloxysulfuron sodium.

- making a minor technical amendment to the residue definition for thiabendazole to ensure consistency of format with other residue definitions.

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.

1.6 Antibiotic MRLs

There are no MRLs for antibiotic[1] residues in this Application.

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* can be legally sold in Australia.

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.

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

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. APVMA has already established MRLs under its legislation, and now seeks to have the amendments included in the Code through this Application to vary Standard 1.4.2.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives set out in section 10 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 proposed draft variations to Standard 1.4.2 are consistent with the FSANZ Act section 10 objectives of food regulatory measures.

4. Key Assessment Questions

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 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 <u>not</u> 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 in accordance with internationally accepted practices and procedures.

The three steps undertaken in conducting a dietary exposure assessment are:

- determination of the residues of a chemical in a treated food;
- determination of the acceptable reference health standard/s for a chemical in food (i.e. the ADI and/or the ARfD); 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.

RISK ASSESSMENT

5. Safety Assessment

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

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

OCS assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where applicable, the ARfD for a chemical.

Both 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

APVMA and FSANZ undertake chronic dietary exposure assessments for all agricultural and veterinary chemicals and undertake acute dietary exposure assessments where either OCS or Joint Food and Agriculture Organization / World Health Organization Meeting on Pesticide Residues (JMPR) has established an ARfD.

APVMA and FSANZ have agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by 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 next 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, 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 entire national crop is treated with a pesticide and that the entire national crop contains residues equivalent to the MRL. 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 a 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. 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. This 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.

Further, where these calculations use the MRL, they are considered to be overestimates of dietary exposure because they assume 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 has been applied; and
- this will result in residues at the maximum residue limit.

In agricultural 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.

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. The residues of a chemical in a specific food are multiplied by the 97.5^{th} percentile food consumption of that food, 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. NESTIs are calculated from ARfDs set by 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. 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

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

For this Application, APVMA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.

OCS has undertaken an appropriate toxicological assessment of the chemical products and has established relevant ADIs and where applicable, an ARfD. In the case that an Australian ADI or ARfD has not been established, a JMPR ADI or ARfD may be used for risk assessment purposes if appropriate.

FSANZ has reviewed the dietary exposure assessments submitted by APVMA as part of its 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.

In reality, only a portion of a specific commodity is treated with a pesticide; most treated commodities contain residues well below the MRL before they appear on the market; and residues are usually reduced during storage, washing, preparation, commercial processing and cooking. It is also unlikely that every food for which a MRL is proposed will have been treated with the same pesticide during production and eaten over the lifetime of consumers.

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 sub-options for the purpose of outlining the implications in the benefit cost analysis below.

Note: FSANZ may only approve or reject option 2 in full and cannot legally approve or reject one sub-option without the other.

7.2 Option 2(a) – vary the Code in Schedule 1 of Standard 1.4.2 – Maximum Residue Limits 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 to permanent MRLs would not be approved.

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

Under this option, only those variations that were additions, increases and changes from temporary to permanent 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, adopting this option would result in costs from not being able to legally sell food containing residues consistent with increased MRLs or MRL additions. 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 legally sold. If legal use of chemical products results in the production of food that cannot be legally 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, adopting this option would not result in any discernable costs; and

- for Australian Government, State and Territory agencies, adopting this option would create 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, 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 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, adopting this option is unlikely to result in any costs, as reductions in MRLs are adopted where this is practically achievable, with little or no impact on production costs;

- for importers, adopting 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 the World Trade Organization section 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, adopting 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 or change from temporary to permanent existing MRLs as proposed

8.2.3.1 Benefits

- for consumers the major benefit would be potential flow on benefits resulting from the price and availability of food 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;

- adopting this option would benefit importers in that food containing residues consistent with increased or new MRLs could be legally imported; and

- for Australian Government, State and Territory agencies, the benefits of this option would include the removal of discrepancies between agricultural and food legislation thereby creating certainty and allowing efficient enforcement of regulations.

8.2.3.2 Costs

- for consumers there are no discernable costs;

- for growers and producers of domestic and export food commodities, adopting this option would not result in any discernable costs;

- for importers, adopting this option would not result in any discernable costs; and

- for Australian Government, State and Territory agencies, adopting 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 A591, there are no options other than a variation to Standard 1.4.2.

FSANZ recommends approving options 2(a) and 2(b) – to vary the Code in Schedule 1 of Standard 1.4.2 – Maximum Residue Limits to include new MRLs, increase, delete, decrease or change the status of some existing MRLs.

- 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.

Adopting option 2(a) only 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.

COMMUNICATION

9. Communication

Applications by the APVMA to amend maximum residue limits 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 to 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 Strategy

FSANZ decided, pursuant to section 36 of the FSANZ Act to omit to invite public submissions in relation to Application A591 prior to making a Draft Assessment.

However, FSANZ now invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to any submissions received.

FSANZ made its decision under section 36 because it was satisfied that Application A591 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 increases, deletions and changes to specific MRLs;

- any further public health and safety considerations with the proposed MRLs;

- likely costs and benefits in relation to the importation of food if the proposed deletions to specific MRLs are advanced; and

- any other affected parties to this Application.

10.1 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 A591 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 the proposed variations to MRLs in Application A591 that are addressed in the international Codex standard.

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
Cypermethrin		
Leek	T0.5	0.5
Ethephon		
Barley	1	1
Wheat	T1	1
Glyphosate		
Cotton seed	15	10
Imidacloprid		
Banana	0.5	0.05
Citrus fruits	2	1
Procymidone		
Common bean (pods and/or immature seeds)	T3	1

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

10.3 Imported Foods

Internationally, countries set MRLs under their own regulations and 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 permissions for products differ. This means that residues in imported foods may be different from those in domestically produced foods.

Deletions or reductions of MRLs may affect 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.

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.

Chemical Food
Azoxystrobin Peanut Peanut oil, crude
Coumaphos Cattle, edible offal of Cattle meat (in the fat) Eggs Goat, edible offal of Goat meat (in the fat) Milks (in the fat) Pig, edible offal of Pig meat (in the fat) Poultry, edible offal of Poultry meat (in the fat) Sheep, edible offal of Sheep meat (in the fat)
Glufosinate and Glufosinate–ammonium Cotton seed
Indoxacarb Wine grapes
Quinoxyfen Dried grapes Grapes
Tetrachlorvinphos Leafy vegetables

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

CONCLUSION

11. Conclusion and Preferred Option

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 options 2(a) and 2(b) to vary MRLs in Schedule 1 of Standard 1.4.2 – Maximum Residue Limits as proposed.

Preferred Approach

FSANZ recommends accepting Application A591 and the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits.

11.1 Reasons for Preferred Approach

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

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

- Dietary exposure assessments indicate that setting the 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.

- APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.

- OCS has undertaken an appropriate 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 10 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 Australian Total Diet Study.

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

It is proposed that the MRL 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*

Attachment 1

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

To commence: on gazettal

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

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

Coumaphos

[1.2] *inserting in* Schedule 1 –

AZIMSULFURON AZIMSULFURON	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
RICE	*0.02
PROHEXADIONE-CALCIUM SUM OF THE FREE AND CONJUGATED FORMS OF PROHEXADIONE EXPRESSED AS PROHEXADIONE	
APPLE	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.05
MEAT (MAMMALIAN)	*0.05
MILKS	*0.01

[1.3] *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**
THIABENDAZOLE	*COMMODITIES OF PLANT ORIGIN*: THIABENDAZOLE *COMMODITIES OF ANIMAL ORIGIN*: SUM OF THIABENDAZOLE AND 5-HYDROXYTHIABENDAZOLE, EXPRESSED AS THIABENDAZOLE

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

INDOXACARB INDOXACARB	
WINE GRAPES	1

PACLOBUTRAZOL PACLOBUTRAZOL	
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – INEDIBLE PEEL [EXCEPT AVOCADO]	*0.01
PROCYMIDONE PROCYMIDONE	
BEANS [EXCEPT GREEN BEANS]	T10
TETRACHLORVINPHOS TETRACHLORVINPHOS	
LEAFY VEGETABLES	2

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

AZOXYSTROBIN AZOXYSTROBIN	
BROCCOLI	T0.5
BRUSSELS SPROUTS	T0.5
CAULIFLOWER	T0.5
EGGS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
BIFENTHRIN BIFENTHRIN	
TARO	T*0.05
CHLOROTHALONIL *COMMODITIES OF PLANT ORIGIN*: CHLOROTHALONIL *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CHLOROTHALONIL AND 4-HYDROXY-2, 5, 6-TRICHLOROISOPHTHALONITRILE METABOLITE, EXPRESSED AS CHLOROTHALONIL	
ASPARAGUS	T*0.1
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
LEEK	T0.5
SHALLOT	T0.5
SPRING ONION	T0.5
DIFENOCONAZOLE DIFENOCONAZOLE	
BEETROOT	T0.2
ETHEPHON ETHEPHON	
MANGO	T10
OLIVES	T5
WHEAT	T1
ETOXAZOLE ETOXAZOLE	
GRAPES	T0.3
PEAR	T0.2

STONE FRUITS	T0.5
INDOXACARB INDOXACARB	
DRIED GRAPES	2
GRAPES	0.5
LEAFY VEGETABLES [EXCEPT LETTUCE, HEAD]	5
LINSEED	T0.5
SAFFLOWER SEED	T0.5
STRAWBERRY	T1
MCPA MCPA	
RHUBARB	*0.02
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
TARO	T1
PACLOBUTRAZOL PACLOBUTRAZOL	
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – INEDIBLE PEEL [EXCEPT AVOCADO AND MANGO]	*0.01
MANGO	T1
PROCYMIDONE PROCYMIDONE	
BROAD BEAN (DRY)	T10
BROAD BEAN (GREEN PODS AND IMMATURE SEEDS)	T10
COMMON BEAN (DRY)	T10
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	T3
PROPICONAZOLE PROPICONAZOLE	
ASPARAGUS	T*0.1
PYMETROZINE PYMETROZINE	
PODDED PEA (YOUNG PODS) (SNOW AND SUGAR SNAP)	0.3
TEBUCONAZOLE TEBUCONAZOLE	
ASPARAGUS	T*0.02
THIABENDAZOLE *COMMODITIES OF PLANT ORIGIN*: THIABENDAZOLE *COMMODITIES OF ANIMAL ORIGIN*: SUM OF THIABENDAZOLE AND 5-HYDROXYTHIABENDAZOLE, EXPRESSED AS THIABENDAZOLE	
SWEET POTATO	T0.05

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

AZOXYSTROBIN AZOXYSTROBIN	
PEANUT	0.05
PEANUT OIL, CRUDE	0.1
ETHEPHON ETHEPHON	
BARLEY	1
GLUFOSINATE AND GLUFOSINATE-AMMONIUM SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL GLUFOSINATE AND 3-[HYDROXY(METHYL)-PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS GLUFOSINATE (FREE ACID)	
COTTON SEED	3
GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
COTTON SEED	15
IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID	
BANANA	0.5
CITRUS FRUITS	2
QUINOXYFEN QUINOXYFEN	
DRIED GRAPES	2
GRAPES	0.5
THIAMETHOXAM *COMMODITIES OF PLANT ORIGIN*: THIAMETHOXAM *COMMODITIES OF ANIMAL ORIGIN*: SUM OF THIAMETHOXAM AND N-(2-CHLORO-THIAZOL-5-YLMETHYL)-N'-METHYL-N'-NITRO-GUANIDINE, EXPRESSED AS THIAMETHOXAM	
SUNFLOWER SEED	*0.02
TRIFLOXYSULFURON SODIUM TRIFLOXYSULFURON	
SUGAR CANE	*0.01
UNICONAZOLE-P SUM OF UNICONAZOLE-P AND ITS Z-ISOMER EXPRESSED AS UNICONAZOLE-P	
AVOCADO	0.5

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.

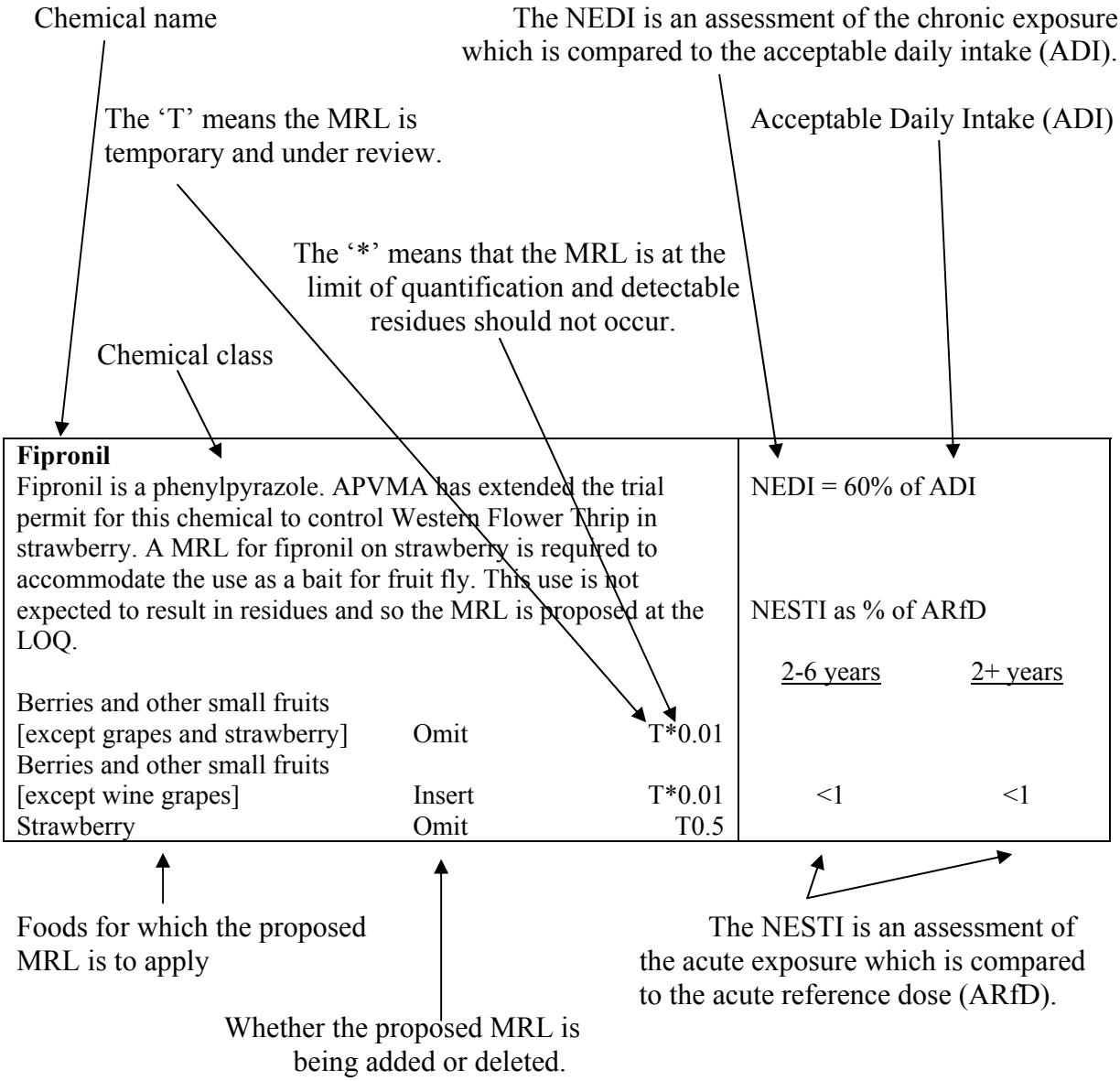
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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 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^{th} 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.

Chlorpyrifos Chlorpyrifos is an acaricide, nematicide and insecticide APVMA has approved an extension of use for the control of pests in coffee crops. Coffee beans Insert T0.5	NEDI = 83% of ADI 20th ATDS = <1% of ADI for all population groups assessed 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 NESTI as % of ARfD 2-6 years: 8 2+ years: <1

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**	Office of Chemical Safety
15.	**T or TMRL**	Temporary MRL
16.	**TGA**	Therapeutic Goods Administration
17.	**WHP**	Withholding Period

SUMMARY OF REQUESTED MRLS FOR APPLICATION A591
MAXIMUM RESIDUE LIMITS – OCTOBER NOVEMBER DECEMBER 2006

<table>
<tr><th>Requested MRLs</th><th>Dietary Exposure Estimates</th></tr>
<tr><td>

Azimsulfuron
Azimsulfuron is a new active constituent. It is a sulfonyl urea herbicide for the control of barnyard grass and aquatic weeds when applied to rice crops. It is an acetolactate synthase (ALS) inhibitor, and thus inhibits the biosynthesis of some essential amino acids, stopping cell division and plant growth in target weeds. The recommended MRLs are at the LOQ.

New chemical

Insert residue definition:

Azimsulfuron

<table>
<tr><td></td><td></td><td></td></tr>
<tr><td>Edible offal (mammalian)</td><td>Insert</td><td>*0.02</td></tr>
<tr><td>Eggs</td><td>Insert</td><td>*0.02</td></tr>
<tr><td>Meat (mammalian)</td><td>Insert</td><td>*0.02</td></tr>
<tr><td>Milks</td><td>Insert</td><td>*0.02</td></tr>
<tr><td>Poultry, edible offal of</td><td>Insert</td><td>*0.02</td></tr>
<tr><td>Poultry meat</td><td>Insert</td><td>*0.02</td></tr>
<tr><td>Rice</td><td>Insert</td><td>*0.02</td></tr>
</table>

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NEDI = <1% of ADI

DIAMOND modelling estimated chronic dietary exposure as <1% of ADI

NESTI as % of ARfD

<table>
<tr><th></th><th>2-6 years</th><th></th><th>2+ years</th></tr>
<tr><td>Edible offal (mammalian)</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Eggs</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Meat (mammalian)</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Milks</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Poultry, edible offal of</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Poultry meat</td><td><1</td><td></td><td><1</td></tr>
<tr><td>Rice</td><td><1</td><td>Rice, raw plain</td><td><1</td></tr>
<tr><td></td><td><1</td><td>Rice, polished</td><td><1</td></tr>
</table>

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<tr><td>

Azoxystrobin
Azoxystrobin is a fungicide used to control certain fungal diseases in peanuts by inhibiting mitochondrial respiration in fungi. APVMA has issued an emergency permit for its use to control white blister in cauliflower, broccoli and Brussels sprouts. Poultry may be exposed to azoxystrobin residues in peanut meal; anticipated exposure is very low. The recommended MRLs for eggs, poultry meat and edible poultry offal are at the LOQ.

<table>
<tr><td>Broccoli</td><td>Insert</td><td>T0.5</td></tr>
<tr><td>Brussels sprouts</td><td>Insert</td><td>T0.5</td></tr>
<tr><td>Cauliflower</td><td>Insert</td><td>T0.5</td></tr>
<tr><td>Eggs</td><td>Insert</td><td>*0.01</td></tr>
<tr><td>Peanut</td><td>Omit</td><td>T0.2</td></tr>
<tr><td></td><td>Substitute</td><td>0.05</td></tr>
<tr><td>Peanut oil, crude</td><td>Omit</td><td>T0.3</td></tr>
<tr><td></td><td>Substitute</td><td>0.1</td></tr>
<tr><td>Poultry, edible offal of</td><td>Insert</td><td>*0.01</td></tr>
<tr><td>Poultry meat</td><td>Insert</td><td>*0.01</td></tr>
</table>

</td><td>

NEDI = 2% of ADI

</td></tr>
<tr><td>

Bifenthrin
Bifenthrin is a synthetic pyrethroid insecticide with contact and stomach action. APVMA has issued a permit for its use to control cluster caterpillar on taro. The recommended temporary MRL for taro is at the LOQ.

</td><td>

NEDI = 72% of ADI

20th ATDS = <1% of ADI for all population groups assessed

</td></tr>
</table>

Taro	Insert	T*0.05	
Chlorothalonil Chlorothalonil is a fungicide. APVMA has issued a permit for its use to control purple spot disease and asparagus rust on asparagus ferns. It acts as a non-systemic foliar fungicide with protective action. The recommended temporary MRL for asparagus is at the LOQ.			NEDI = 76% of ADI 19th ATDS = <1% of ADI for all population groups assessed 20th ATDS = <1% of ADI for all population groups assessed
Asparagus	Insert	T*0.1	
Coumaphos Coumaphos is an organophosphate insecticide for the control of ectoparasites. Its action involves inhibition of cholinesterase enzymes, leading to continued stimulation of the insect's nervous system, resulting in tremors, uncoordinated movement, and ultimately death. APVMA confirms that there are no currently registered or permitted uses for coumaphos in food-producing animal species in Australia, and accordingly MRLs are not required. The whole entry for this chemical is to be omitted.			Complete chemical deletion – dietary exposure assessment not required.
Cattle, edible offal of	Omit	1	
Cattle meat (in the fat)	Omit	1	
Eggs	Omit	0.05	
Goat, edible offal of	Omit	0.5	
Goat meat (in the fat)	Omit	0.5	
Milks (in the fat)	Omit	0.1	
Pig, edible offal of	Omit	0.5	
Pig meat (in the fat)	Omit	0.5	
Poultry, edible offal of	Omit	1	
Poultry meat (in the fat)	Omit	1	
Sheep, edible offal of	Omit	0.5	
Sheep meat (in the fat)	Omit	0.5	
Cypermethrin Cypermethrin is a pyrethroid, non-systemic insecticide with contact and stomach action. It is used to control a wide range of chewing and sucking insect pests in horticulture and fruit production. APVMA has issued a permit for its use to control red legged earth mite on chicory and onion thrips on leeks, spring onions and shallots. The existing leafy vegetable MRL covers the proposed use on chicory.			NEDI = 9% of ADI 19th ATDS = <1% of ADI for all population groups assessed
Leek	Insert	T0.5	
Shallot	Insert	T0.5	
Spring onion	Insert	T0.5	
Difenoconazole Difenoconazole is a triazole fungicide. APVMA has issued a permit for its use to control leaf spot in beetroot. It is a systemic fungicide with preventative and curative action. It is absorbed by the leaves, with acropetal and strong translaminar translocation.			NEDI = 13% of ADI
Beetroot	Insert	T0.2	

Ethephon

Ethephon is a growth regulator used for thinning, loosening or ripening in various crops. It is a weak to moderate cholinesterase inhibitor. APVMA has issued permits for its use to promote pre-harvest ripening in mangoes, to loosen olives prior to harvest and also as an anti-lodging treatment for wheat. The data are sufficient to support a permanent MRL for barley.

NEDI = 88% of ADI

Barley	Omit	T1
	Substitute	1
Mango	Insert	T10
Olives	Insert	T5
Wheat	Insert	T1

Etoxazole

Etoxazole is an insecticide. It inhibits the insect moulting process by disrupting the cell wall. APVMA has issued a permit for its use to control mites on grape, pear and stone fruit crops.

NEDI = 1% of ADI

NESTI as % of ARfD

			2-6 years	2+ years
Grapes	Insert	T0.3	<1	<1
Pear	Insert	T0.2	<1	<1
Stone fruits	Insert	T0.5	<1	<1
			<1	<1
			<1	<1
			<1	<1
			<1	<1

		Apricot	
		Cherries	
		Nectarine	
		Peach	
		Plums	

Glufosinate and Glufosinate-ammonium

Glufosinate is a non-selective contact herbicide. It acts as a glutamine synthesis inhibitor, leading to accumulation of ammonium ions and inhibition of photosynthesis. Glufosinate is used to control grass and broad leaf weeds in crops.

NEDI = 7% of ADI

Cotton seed	Omit	T5
	Substitute	3

Glyphosate

Glyphosate is a herbicide. It is used to control annual and perennial grasses and broad-leaf weeds in many crops. It is a systemic herbicide absorbed by the foliage, with rapid translocation throughout the plant. It inactivates amino acid biosynthesis.

NEDI = 6 % of ADI

Cotton seed	Omit	10
	Substitute	15

Imidacloprid

Imidacloprid is a neonicotinoid insecticide. It is used to control citrus leafminer, black citrus aphid, red scale and pink wax scale, as well as banana rust thrips and banana weevil borer. It is a systemic insecticide with contact and stomach action that acts on the central nervous system of insects, causing blockage of post synaptic nicotinergic acetylcholine receptors.

NEDI = 14% of ADI

NESTI as % of ARfD

			2-6 years	2+ years
Banana	Omit	T0.1		
	Substitute	0.5	3	<1
Citrus fruits	Omit	T2		
	Substitute	2	22	8

Indoxacarb

Indoxacarb is an insecticide with contact and stomach action. It blocks sodium ion channels in nerve cells. It is used for broad spectrum control of Lepidoptera in cotton, vegetables and fruit. APVMA has issued permits for its use on linseed and safflower seed to control Helicoverpa spp. and on strawberries to control whitefringed and garden weevils.

NEDI = 9% of ADI

			NESTI as % of ARfD		
			2-6 years		2+ years
Dried grapes	Insert	2	5		1
Grapes	Insert	0.5	2	Grapes-excluding wine	<1
			<1	Grapes-wine only	7
Leafy vegetables [except lettuce, head]	Insert	5	<1		7
Linseed	Insert	T0.5	<1		<1
Safflower seed	Insert	T0.5	<1		<1
Strawberry	Insert	T1	9		2
Wine grapes	Omit	1			

MCPA

MCPA is a selective, systemic, hormone-type herbicide, absorbed by the leaves and roots with translocation, which inhibits growth. It is used for post emergence control of annual and perennial broad-leaf weeds in horticultural production and various crops. APVMA has issued a permit for its use in rhubarb. The recommended MRL for rhubarb is at the LOQ.

NEDI = 6% of ADI

Rhubarb	Insert	*0.02

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. APVMA has issued a permit for its use to control cluster caterpillar on taro.

NEDI = 90% of ADI

			NESTI as % of ARfD		
			2-6 years		2+ years
Taro	Insert	T1	52		52
			8	Radish	8
			24	Swede	30
			24	Turnip	14

Paclobutrazol

Paclobutrazol is a plant growth regulator. It inhibits gibberellin and sterol synthesis. It is used on fruit trees to produce more compact plants and improve fruit set. APVMA has issued a permit for its use on mangoes to enhance flowering and fruiting.

NEDI = 12% of ADI

Assorted tropical and sub-tropical fruits - inedible peel [except avocado]	Omit	*0.01
Assorted tropical and sub-tropical fruits - inedible peel [except avocado and mango]	Insert	*0.01
Mango	Insert	T1

Procymidone

Procymidone is a systemic fungicide with protective and curative properties. It inhibits triglyceride synthesis in target pests. It is used to control fungal infections on fruit, vines, vegetables and cereals. APVMA has issued a permit for its use to control Sclerotinia rot in beans. The existing procymidone MRL for Beans [except green beans] does not accurately cover the existing uses for broad beans and navy beans approved under the label. It is recommended that the MRL be replaced with the MRLs for Broad bean (dry), Broad bean (green pods and immature seeds) and Common bean (dry) of the same magnitude.

NEDI = 25% of ADI

19th ATDS = <1% of ADI for all population groups assessed

20th ATDS = <1% of ADI for all population groups assessed

			NESTI as % of ARfD	
			2-6 years	2+ years
Beans [except green beans]	Omit	T10		
Broad bean (dry)	Insert	T10		
Broad bean (green pods and immature seeds)	Insert	T10		
Common bean (dry)	Insert	T10		
Common bean (pods and/or immature seeds)	Insert	T3	51	21

Prohexadione-calcium

Prohexadione-calcium is a new active constituent. It is a plant growth regulator acting as a gibberellin synthesis inhibitor to reduce stem length. The recommended MRLs are at the LOQ.

NEDI = <1% of ADI

New chemical

Insert residue definition:

Sum of the free and conjugated forms of prohexadione expressed as prohexadione

			NESTI as % of ARfD	
			2-6 years	2+ years
Apple	Insert	*0.02	<1	<1
Edible offal (mammalian)	Insert	*0.05	<1	<1
Meat (mammalian)	Insert	*0.05	<1	<1
Milks	Insert	*0.01	<1	<1

Propiconazole

Propiconazole is a fungicide. It acts a non-systemic foliar fungicide with protective action. It is used to control fungal infections in cereals and fruit. APVMA has issued a permit for its use to control purple spot disease and asparagus rust on asparagus ferns. The recommended temporary MRL for asparagus is at the LOQ.

NEDI = 4% of ADI

20th ATDS = <1% of ADI for all population groups assessed

			NESTI as % of ARfD	
			2-6 years	2+ years
Asparagus	Insert	T*0.1	<1	<1

Pymetrozine

Pymetrozine is an azomethine insecticide. It is selective against Homoptera, causing them to stop feeding. It is used to control juvenile and adult stages of aphids and whitefly in vegetables, fruit and cotton. APVMA has issued a permit for its use to control aphids on snow peas and sugar snap peas.

NEDI = 20% of ADI

Podded pea (young pods) (snow and sugar snap)	Insert	0.3

Quinoxyfen Quinoxyfen is a fungicide used on grapevines as a protectant against powdery mildew. It inhibits appressorial development in fungi (appressoria are specialized cells that are important in plant penetration and pathogenesis). The proposed reductions are in line with data from stewardship trials indicating that the label did not reflect current GAP.			NEDI = <1% of ADI
Dried grapes	Omit	5	
	Substitute	2	
Grapes	Omit	2	
	Substitute	0.5	
Tebuconazole Tebuconazole is a fungicide. It acts a non-systemic foliar fungicide with protective action. It controls numerous pathogens in many crops. APVMA has issued a permit for its use to control purple spot disease and asparagus rust on asparagus ferns. The recommended temporary MRL for asparagus is at the LOQ.			NEDI = 17% of ADI
Asparagus	Insert	T*0.02	
Tetrachlorvinphos Tetrachlorvinphos is a non-systemic insecticide and acaricide with contact and stomach action. It is a cholinesterase inhibitor. It has been used to control white butterfly and cabbage moth on leafy vegetables. APVMA confirms that there are no registered products containing tetrachlorvinphos or current permits for its use on leafy vegetables, accordingly no MRLs are required for these commodities.			Dietary exposure assessment not required.
Leafy vegetables	Omit	2	
Thiabendazole Thiabendazole is a fungicide used to control fungal rot on potatoes. It forms a protective deposit on the treated surface of fruit and tubers and inhibits mitosis by binding to tubuline and thus severely impairs fungal growth and development. APVMA has issued a permit for its use to control field rot of seed roots caused by scurf and root rot on sweet potato. This is a minor technical amendment to the residue definition to ensure consistency of format with other entries. Omit: Thiabendazole or, in the case of animal products, sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole. Substitute: *Commodities of plant origin*: Thiabendazole *Commodities of animal origin*: Sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole.			NEDI = 13% of ADI NESTI as % of ARfD <u>2-6 years</u> <u>2+ years</u>
Sweet potato	Insert	T0.05	<1 <1

Thiamethoxam Thiamethoxam is an 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 as seed dressing for sunflower seeds to control various early season soil and sucking pests. The recommended MRL for sunflower seed is at the LOQ.			NEDI = 3% of ADI
Sunflower seed	Omit	T*0.02	
	Substitute	*0.02	
Trifloxysulfuron sodium Trifloxysulfuron sodium is a sulfonyl urea herbicide. As such it exhibits selective systemic properties. It is absorbed by the foliage and roots, with rapid translocation acropetally and basipetally. It inhibits acetolactase synthase (ALS), thereby inhibiting the biosynthesis of the essential branched chain amino acids, valine and isoleucine, stopping cell division and plant growth. It is used to control grass and broad-leaf weeds in sugarcane. The recommended MRL for sugarcane is at the LOQ.			NEDI = <1% of ADI NESTI as % of ARfD 2-6 years 2+ years
Sugar cane	Omit	T*0.01	
	Substitute	*0.01	<1 <1
Uniconazole-p Uniconazole-p is a growth regulator. It regulates azole based plant growth, inhibiting gibberellin biosynthesis. It is used on avocado flowers; exposure of fruit is incidental resulting from treatment applied to flowers for the crop in the following season.			NEDI = <1% of ADI
Avocado	Omit	T0.5	
	Substitute	0.5	