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8 August 2007

FINAL ASSESSMENT REPORT

APPLICATION A591

MAXIMUM RESIDUE LIMITS (OCTOBER, NOVEMBER, DECEMBER 2006)

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.

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 reference health standards, setting the MRLs as proposed does not present any public health and safety concerns.

The Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food 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 *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

There are no MRLs for antibiotic residues in this Application.

The draft variations to Standard 1.4.2 at Final Assessment differ from those proposed at Initial / Draft Assessment for etoxazole and quinoxifen in grapes. FSANZ has recommended an MRL of 0.5 mg/kg for etoxazole and an MRL of 0.6 mg/kg for quinoxifen in grapes. These MRLs are marginally higher than those requested by the APVMA for these chemicals. The dietary exposure assessment concluded that this raises no health or safety concerns. Incorporating these MRLs in the Code would facilitate trade in grapes and promote consistency between domestic and international standards and potentially benefit industry and consumers through greater choice and access to table grapes. FSANZ's consideration of incorporating these MRLs in the Code is discussed in section 10.2 of this report.

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

FSANZ made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO). No submissions were received from WTO members.

FSANZ decided, pursuant to section 36 of the 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. FSANZ considered submissions on the Initial / Draft Assessment Report to assist in making a Final Assessment.

Purpose

The purpose of this Application is to update the Code with current MRLs for agricultural and veterinary chemicals in use in Australia. This will permit the sale of treated foods and protect public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

Decision

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

Reasons for Decision

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

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- Dietary exposure assessments indicate that setting the 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 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 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 draft variations for etoxazole and quinoxyfen in grapes are marginally higher than those requested by the APVMA and are appropriate because incorporating them in the Code would facilitate trade in grapes and promote consistency between domestic and international standards. In addition, these MRLs would potentially benefit industry and consumers through greater choice and access to table grapes.
- The proposed changes are consistent with the FSANZ Act section 18 objectives.

Consultation

FSANZ has now completed the assessment of Application A591 and held a single round of public consultation under section 36 of the FSANZ Act. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

If the Ministerial Council does not request FSANZ review the draft amendments to the Code, an amendment to the Code will be published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

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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 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 analysis that could lead to a lowering of this limit.

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

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

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

1. Background

1.1 Current Standard

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

1.2 Use of Agricultural and Veterinary Chemicals

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

When a chemical product is registered for use or a permit for use granted, the 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, the APVMA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews information provided by the APVMA and validates whether 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 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 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 upon 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 on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food, which has now been provided to FSANZ (Attachment 3). The purpose of this Ministerial Policy Guideline is to form a framework within which FSANZ is to consider alternative approaches to address the issues surrounding the regulation of residues of agricultural and veterinary chemicals in food. The specific policy principles outlined in the Policy Guideline apply only to alternative approaches that FSANZ might consider for addressing these issues. In consultation with stakeholders, FSANZ will explore alternative options for regulating chemical residues in food. To ensure appropriate consultation, this process will take some time to complete.

1.5 Scope for Retaining MRLs Proposed for Deletion or Reduction

Some submitters have raised concerns about MRL deletions and reductions in recent applications, suggesting they may be inconsistent with the Policy Guideline. FSANZ considers that the current approach for varying MRLs in the Code is consistent with the Policy Guideline and that the current process for progressing MRL variations is appropriate. However, FSANZ is committed to ensuring that the implications of MRL deletions and reductions are considered. To facilitate this FSANZ identifies MRLs proposed for deletion or reduction and Codex Alimentarius Commission (Codex) MRLs in assessment reports and routinely requests comment on any possible ramifications for imported foods. Comment is also invited on impacts of any proposed MRL variations which may differ from Codex MRLs.

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. Proposed MRL deletions and reductions are outlined in section 10.6 of this report.

1.6 Summary of Proposed Variations to Standard 1.4.2

Amendments under consideration in Application A591:

- adding a temporary MRL 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 an MRL at the LOQ for azoxystrobin and MCPA¹;

¹ (4-chloro-2-methylphenoxy)acetic acid

- 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 an 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 an MRL at the LOQ for thiamethoxam and trifloxysulfuron sodium.

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.

1.7 Antibiotic MRLs

There are no MRLs for antibiotic² residues in this Application.

1.8 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.

² An antibiotic is a chemical inhibitor of the growth of organisms produced by a microorganism.

- 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 the development of new products or crop uses, granting or expiry of temporary permissions and the withdrawal of older products following review.

3. Objectives

In assessing this Application FSANZ aims to ensure that 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 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 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 proposed draft variations to Standard 1.4.2 are consistent with the FSANZ Act section 18 objectives of food regulatory measures.

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 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

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 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, 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 entire national crop is treated with a particular 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 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. 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 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.

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 97.5 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. 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 appropriate 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 an appropriate 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 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 an 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 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 food products; and
- Australian Government, State and Territory agencies involved in monitoring and regulating the use of agricultural and veterinary chemicals in food and the potential resulting residues.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – no change to 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, 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, 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;
- 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, 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;
- 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
- 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 existing MRLs or change temporary MRLs to 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;
- 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.

Adopting options 2(a) and 2(b) does not impose any additional/discernable costs to industry. This is reflected in the Business Cost Calculator Report (Attachment 5), in accordance with the Office of Best Practice Regulation guidelines.

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 to include new MRLs, increase, delete, decrease or change the status of some existing TMRLs to MRLs, subject to minor variations from those MRLs proposed at Initial / Draft Assessment. FSANZ has recommended an MRL of 0.5 mg/kg for etoxazole in grapes (higher than the 0.3 mg/kg MRL requested by the APVMA) and an MRL of 0.6 mg/kg for quinoxifen in grapes (higher than the 0.5 mg/kg MRL requested by the APVMA). These variations do not compromise public health and safety and are proposed to facilitate importation of grapes (See Section 10.2 for details).

Options 2(a) and 2(b) and the variations for etoxazole and quinoxifen MRLs for grapes are recommended.

- 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 AND CONSULTATION STRATEGY

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 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.

FSANZ decided, pursuant to section 36 of the FSANZ Act, to omit inviting public submissions in relation to Application A591 prior to making a Draft Assessment. However, FSANZ invited written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and had regard to submissions received.

10. Consultation

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

Submissions were received from the Food Technology Association of Victoria Inc. (FTAV), the Queensland Government and the Australian Food and Grocery Council (AFGC). Other correspondence in relation to the Application was received from the California Table Grapes Commission and the NSW Food Authority.

Submissions from FTAV and the Queensland Government support approving options 2(a) and 2(b) to vary the Code in Schedule 1 of Standard 1.4.2 as proposed at Initial / Draft Assessment.

10.1 Summarised Submission from the Australian Food and Grocery Council

AFGC supports option 2(b) and does not support option 2(a) to delete and decrease some existing MRLs while there is no default or threshold level permitted for low levels of residues on imported fruits and vegetables.

AFGC notes that the dietary exposure assessments indicate that the residues associated the proposed MRLs do not represent an unacceptable public health and safety risk. AFGC supports the harmonisation of MRLs permitted under agricultural legislation with those prescribed in the Code. AFGC notes that the agricultural and veterinary justification for chemical use is a matter for the APVMA rather than FSANZ and that the APVMA considers chemical safety and toxicology and the necessary withholding periods before consumption.

AFGC notes that where there is a corresponding MRL in the Codex standard, the MRLs proposed in A591 are at the same level or higher than the Codex MRLs and are therefore not considered to pose restrictions on trade.

AFGC notes that progressing proposed deletions of MRLs may create an unnecessary barrier to international trade in some circumstances for no public health benefit.

10.1.1 FSANZ Evaluation

MRL reductions and deletions have the potential to restrict the importation of foods and could potentially result in a reduced product range available to consumers, as foods that do not comply with the Code could not be legally imported or sold to consumers. FSANZ publicly advertises any proposed changes to MRLs as part of the round of public consultation and lists all amendments on the FSANZ website to assist industry sectors in identifying any impacts following deletions or reductions of specific MRLs.

The AFGC submission did not identify any specific trade or importation issues in regard to relevant food commodities for which MRL deletions or reductions are proposed. Submissions including data demonstrating a requirement for certain MRLs to be retained or varied may be made under the current process for considering amendments to the Code. FSANZ would consider retaining MRLs proposed for deletion or incorporating MRLs at levels other than those consulted on at Initial / Draft Assessment where this is necessary to continue to allow the sale of safe food; and where the MRLs are supported by adequate data or information demonstrating that the residues associated with these MRLs do not present public health or safety concerns. The correspondence from the California Table Grape Commission provided such information and this has been considered and assessed below.

10.2 Other Correspondence – California Table Grape Commission

The California Table Grapes Commission (the Commission) commented that Australia is an increasingly important market for table grapes, noting that since the market opened in 2001, Australia has become one of the industry's largest export markets. The Commission stated that it recognised Australia's right to establish nationally appropriate standards and requested alternative MRLs for etoxazole and quinoxifen to avoid potential impediments to trade in table grapes.

The Commission requested that FSANZ consider an MRL of 0.5 mg/kg for etoxazole for grapes instead of the MRL of 0.3 mg/kg proposed at Initial / Draft Assessment. This was on the basis that an MRL of 0.5 mg/kg would be consistent with the current US tolerance (MRL) for etoxazole for grapes and eliminate the potential for trade disruption due to a difference in MRLs between Australian and US standards.

The Commission expressed concern about the proposed reduction of the quinoxifen MRL for grapes from 2 mg/kg to 0.5 mg/kg noting that in October 2006 JMPR recommended an MRL of 2 mg/kg to the Codex Committee on Pesticide Residues. The Commission requested that FSANZ consider maintaining the current quinoxifen MRL for grapes of 2 mg/kg or alternatively harmonise with the current US tolerance of 0.6 mg/kg on the basis that this would minimise potential trade disruption.

10.2.1 FSANZ Evaluation

The California Table Grapes Commission identified a trade issue in relation to the etoxazole MRL of 0.3 mg/kg and the quinoxifen MRL of 0.5 mg/kg for grapes proposed at Initial / Draft Assessment.

The following table lists the etoxazole and quinoxifen MRLs for grapes under consideration in Application A591 and includes the corresponding US tolerances. No Codex MRLs have been established for etoxazole or quinoxifen in grapes. FSANZ notes that JMPR has recommended an MRL of 2 mg/kg for quinoxifen in grapes to Codex but that at the time of writing this report Codex had not yet agreed to this MRL.

Chemical Commodity	APVMA MRL mg/kg	US Tolerance mg/kg	Commission requested MRL mg/kg	FSANZ recommended MRL at Final Assessment mg/kg
Etoxazole Grapes	0.3	0.5	0.5	0.5
Quinoxifen Grapes	0.5	0.6	0.6 or 2	0.6

FSANZ must consider proposed variations to the Code in accordance with the FSANZ Act, including the objectives of food regulatory measures set out in section 18 of the Act. This consideration included a consideration of the dietary exposure to residues associated with the Commission's proposed MRLs, as well as the views of the APVMA and the impacts of including MRLs in the Code that were different from those requested by the APVMA.

10.2.1.1 Dietary exposure

The baseline estimated mean dietary exposure (NEDI) to etoxazole from all foods based on current MRLs is 1% of the ADI. Based on either the APVMA MRL of 0.3 mg/kg or the MRL proposed by the Commission of 0.5 mg/kg for grapes, the estimated mean dietary exposure (NEDI) to etoxazole from all foods is approximately 2% of the ADI.

The estimated acute exposure to grapes (NESTI) based on the APVMA etoxazole MRL of 0.3 mg/kg for the population aged 2 years and above is less than 1% of the ARfD, and for children aged 2-6 years is less than 1% of the ARfD. The estimated acute dietary exposure based on the Commission's proposed MRL of 0.5 mg/kg for the population aged 2 years and above is also less than 1% of the ARfD, and for children aged 2-6 years the exposure is also less than 1% of the ARfD.

The baseline estimated mean dietary exposure (NEDI) to quinoxifen from all foods based on the current MRLs is less than 1% of the ADI for the population aged 2 years and above. Based on the Commission's proposed MRL of 0.6 mg/kg for grapes, the estimated mean dietary exposure to quinoxifen from all foods is still less than 1% of the ADI.

As an ARfD has not been established for quinoxifen a NESTI calculation has not been conducted.

FSANZ considers that there are no health or safety concerns associated with incorporating MRLs for grapes of 0.5 mg/kg for etoxazole or 0.6 mg/kg for quinoxifen in the Code. This is on the basis that the dietary exposure to the residues associated with these MRLs does not exceed the acceptable reference health standards.

10.2.1.2 Views of the APVMA on the MRLs requested by the Commission

FSANZ liaised with the APVMA in considering the MRLs requested by the Commission. The APVMA advised that it has confidence in the US and Codex MRL setting arrangements including dietary intake evaluations and agreed that there are no food safety issues associated with the MRLs requested by the Commission. The APVMA noted that the Australian and US MRLs reflect different GAPs (Good Agricultural Practice). Different countries arrive at different MRLs because of different use patterns and differences in methods for determining MRLs. The APVMA noted that it considers the ALARA (As Low As Reasonably Possible) Principle in establishing MRLs to lower the burden of chemicals in the environment. The APVMA agreed that an MRL of 0.5 mg/kg for etoxazole in grapes was appropriate but opposed any variation to the MRL for quinoxifen in grapes, without FSANZ seeking prior agreement from the sponsor company and the Australian Wine Industry.

In considering alternative MRLs to those requested by the APVMA, FSANZ has noted that the MRLs proposed by the Commission would accommodate residues associated with the APVMA MRLs. On this basis there should be no implications for domestic producers or the sponsor company if the MRLs proposed by the Commission are included. In any case, grape producers in Australia would need to comply with conditions of use approved in Australia and the lower APVMA MRLs would therefore be adequate for these producers. FSANZ also noted that the MRLs proposed by the Commission are not substantially different in magnitude from those requested by the APVMA and would have limited relevance to the Australian Wine Industry and wine produced in Australia.

On this basis, FSANZ notes the respective supporting and opposing views of the APVMA on the MRLs for etoxazole and quinoxifen, and does not consider that the further consultation suggested by the APVMA in relation to the quinoxifen MRL for grapes is necessary.

10.2.1.3 Impacts of including MRLs in the Code different from the APVMA MRL Standard

Including the MRLs requested by the APVMA in the Code may unnecessarily restrict trade as grapes could not be legally sold or imported if residues of etoxazole or quinoxifen exceeded the APVMA MRLs. According to the Commission, table grapes from California are imported into Australia and could potentially and legitimately contain residues higher than those requested by the APVMA. The US tolerance for etoxazole in grapes is 0.5 mg/kg and an etoxazole MRL of 0.3 mg/kg for grapes in the Code could restrict the importation of table grapes from California. The US tolerance for quinoxifen in grapes is 0.6 mg/kg and reducing the current quinoxifen MRL from 2 mg/kg to 0.5 mg/kg could also restrict the importation of grapes from California. On this basis, FSANZ considers that incorporating the Commission's proposed MRLs in the Code would facilitate trade in grapes and promote consistency between domestic and international standards (including US standards). In addition, incorporating the MRLs proposed by the Commission would potentially benefit industry and consumers through greater choice and access to table grapes.

10.2.1.4 Summary

On the basis of the points above, FSANZ recommends that an MRL of 0.5 mg/kg for etoxazole and an MRL of 0.6 mg/kg for quinoxifen for grapes be incorporated into the Code.

10.3 Other Correspondence – NSW Food Authority

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

The NSW Food Authority (the Authority) suggested that FSANZ assess the impact of proposed MRL withdrawals on trade of imported foods. The Authority stated that it would not like to deploy its resources in the recall of long shelf life foods affected by the MRL withdrawals proposed in this Application.

10.3.1 FSANZ Evaluation

Foods containing agricultural or veterinary chemical residues must comply with the requirements in Standard 1.4.2 of the Code. MRL reductions and deletions have the potential to restrict the importation of foods as foods containing non-permitted residues could not be legally imported or sold in Australia. It can be difficult to determine the likely impacts of MRL reductions and deletions and FSANZ relies on public consultation to determine those foods which may be implicated by reductions and deletions. FSANZ advertises and publicly consults on proposed changes to MRLs and lists all amendments on the FSANZ website to assist industry sectors and other interested parties in identifying any impacts following deletions or reductions of specific MRLs. FSANZ also includes details of Codex MRLs in all Applications and for this Application, as identified in the AFGC submission, FSANZ has noted that there are no proposed MRLs that are lower than existing Codex MRLs.

At Initial / Draft Assessment, FSANZ requested comment as to any possible ramifications of the proposed MRLs including differences from international MRLs. Comments were received from the California Table Grape Commission; these are discussed above. Following WTO Notification, member nations raised no specific trade impact issues in regard to the proposed deletions or reductions. On this basis, and taking into account the consideration of the MRLs for grapes, it is unlikely that there will be impacts on trade of imported foods as a result of variations to the Code through this Application. However, if subsequent impacts are identified then it is possible to make an Application to FSANZ to amend the MRLs in the Code and this Application would be considered in accordance with the FSANZ Act.

10.4 World Trade Organization

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

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

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

FSANZ made a Sanitary and Phytosanitary (SPS) notification to the WTO for this Application in accordance with the WTO Agreement on the Application of SPS Measures as the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment. No WTO member made a submission on this Application.

10.5 Codex Alimentarius Commission MRLs

Codex standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table lists MRLs proposed in Application A591 where there is a corresponding MRL in the international Codex standard.

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

10.6 Imported Foods

Internationally, countries set MRLs under their own regulations and according to GAP or GVP (Good Veterinary Practice). Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because product use patterns differ. This means that residues in imported foods may be different from those in domestically produced foods.

Deletions or reductions of MRLs may 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 compiled the following table of foods that have MRLs proposed for deletion and/or reduction and sought comment on any impacts of these reductions or deletions at Initial / Draft Assessment. The California Table Grapes Commission commented on these impacts, this is discussed in section 10.2 above.

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

CONCLUSION

11. Conclusion and Decision

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

The draft variations to Standard 1.4.2 at Final Assessment differ from those proposed at Initial / Draft Assessment for etoxazole and quinoxifen. FSANZ has recommended an MRL of 0.5 mg/kg for etoxazole and an MRL of 0.6 mg/kg for quinoxifen for grapes. The results of the dietary exposure assessment showed that this raises no health or safety concerns. Incorporating the MRLs as proposed at Initial / Draft Assessment may restrict trade. FSANZ's consideration of incorporating these MRLs in the Code is discussed in section 10.2 of this report.

The recommendation 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 at Initial / Draft Assessment but subject to a minor variation for the MRLs for etoxazole and quinoxifen for grapes.

Decision

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

11.1 Reasons for Decision

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

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- Dietary exposure assessments indicate that setting the maximum residue limits as proposed does not present any public health and safety concerns.
- 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 an appropriate toxicological assessment of each chemical and has established an ADI and where applicable an ARfD.

- FSANZ has undertaken a 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 draft variations for etoxazole and quinoxifen in grapes are marginally higher than those requested by the APVMA and are appropriate because incorporating them in the Code would facilitate trade in grapes and promote consistency between domestic and international standards. In addition, these MRLs would potentially benefit industry and consumers through greater choice and access to table grapes.
- 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 Australian Total Diet Study.

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

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

ATTACHMENTS

1. Draft Variations to the *Australia New Zealand Food Standards Code*
2. A Summary of Requested MRLs for each Chemical and an Outline of Information Supporting the Requested Variations to the *Australia New Zealand Food Standards Code*
3. Ministerial Policy Guidelines
4. Summary of Submissions and Comments Received
5. Business Cost Calculator Report

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	<i>COMMODITIES OF PLANT ORIGIN:</i> THIABENDAZOLE <i>COMMODITIES OF ANIMAL ORIGIN:</i> 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	T0.5

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 <i>SEE ALSO THIODICARB</i>	
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	
<i>COMMODITIES OF PLANT ORIGIN:</i> THIABENDAZOLE	
<i>COMMODITIES OF ANIMAL ORIGIN:</i> 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	0.6
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	
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

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.

Chemical name

The NEDI is an assessment of the chronic exposure which is compared to the acceptable daily intake (ADI).

The 'T' means the MRL is temporary and under review.

Acceptable Daily Intake (ADI)

The '*' means that the MRL is at the limit of quantification and detectable residues should not occur.

Chemical class

<p>Fipronil</p> <p>Fipronil is a phenylpyrazole. The APVMA has extended the trial permit for this chemical to control Western Flower Thrip in strawberry. An MRL for fipronil on strawberry is required to accommodate the use as a bait for fruit fly. This use is not expected to result in residues and so the MRL is proposed at the LOQ.</p>			<p>NEDI = 60% of ADI</p>	
			<p>NESTI as % of ARfD</p>	
			<p><u>2-6 years</u></p>	<p><u>2+ years</u></p>
Berries and other small fruits [except grapes and strawberry]	Omit	T*0.01	<1	<1
Berries and other small fruits [except wine grapes]	Insert	T*0.01	<1	<1
Strawberry	Omit	T0.5		

Foods for which the proposed MRL is to apply

Whether the proposed MRL is being added or deleted.

The NESTI is an assessment of the acute exposure which is compared to the acute reference dose (ARfD).

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, nematicide and insecticide. The APVMA has approved an extension of use for the control of pests in coffee crops.</p> <p>Coffee beans</p> <p style="text-align: center;">Insert</p> <p style="text-align: right;">T0.5</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 style="width: 100%; border: none;"> <tr> <td style="text-align: center; border-bottom: 1px solid black;">2-6 years</td> <td style="text-align: center; border-bottom: 1px solid black;">2+ years</td> </tr> <tr> <td style="text-align: center;">8</td> <td style="text-align: center;"><1</td> </tr> </table>	2-6 years	2+ years	8	<1
2-6 years	2+ years				
8	<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 | <i>Australia New Zealand Food Standards Code</i> |
| 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**

Requested MRLs	Dietary Exposure Estimates																																																												
<p>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.</p> <p>New chemical</p> <p>Insert residue definition:</p> <p>Azimsulfuron</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Edible offal (mammalian)</td> <td style="width: 15%;">Insert</td> <td style="width: 15%;">*0.02</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>Eggs</td> <td>Insert</td> <td>*0.02</td> <td><1</td> <td><1</td> <td><1</td> </tr> <tr> <td>Meat (mammalian)</td> <td>Insert</td> <td>*0.02</td> <td><1</td> <td><1</td> <td><1</td> </tr> <tr> <td>Milks</td> <td>Insert</td> <td>*0.02</td> <td><1</td> <td><1</td> <td><1</td> </tr> <tr> <td>Poultry, edible offal of</td> <td>Insert</td> <td>*0.02</td> <td><1</td> <td><1</td> <td><1</td> </tr> <tr> <td>Poultry meat</td> <td>Insert</td> <td>*0.02</td> <td><1</td> <td><1</td> <td><1</td> </tr> <tr> <td>Rice</td> <td>Insert</td> <td>*0.02</td> <td><1</td> <td>Rice, raw plain</td> <td><1</td> </tr> <tr> <td></td> <td></td> <td></td> <td><1</td> <td>Rice, polished</td> <td><1</td> </tr> </table>	Edible offal (mammalian)	Insert	*0.02				Eggs	Insert	*0.02	<1	<1	<1	Meat (mammalian)	Insert	*0.02	<1	<1	<1	Milks	Insert	*0.02	<1	<1	<1	Poultry, edible offal of	Insert	*0.02	<1	<1	<1	Poultry meat	Insert	*0.02	<1	<1	<1	Rice	Insert	*0.02	<1	Rice, raw plain	<1				<1	Rice, polished	<1	<p>NEDI = <1% of ADI</p> <p>DIAMOND modelling estimated chronic dietary exposure as <1% of ADI</p> <p>NESTI as % of ARfD</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;"></th> <th style="width: 15%;"></th> <th style="width: 15%;"></th> <th style="width: 10%; text-align: center;"><u>2-6 years</u></th> <th style="width: 10%; text-align: center;"><u>2+ years</u></th> <th style="width: 10%;"></th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td><1</td> <td><1</td> <td><1</td> </tr> </tbody> </table>				<u>2-6 years</u>	<u>2+ years</u>					<1	<1	<1
Edible offal (mammalian)	Insert	*0.02																																																											
Eggs	Insert	*0.02	<1	<1	<1																																																								
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			<u>2-6 years</u>	<u>2+ years</u>																																																									
			<1	<1	<1																																																								
<p>Azoxystrobin Azoxystrobin is a fungicide used to control certain fungal diseases in peanuts by inhibiting mitochondrial respiration in fungi. The 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.</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Broccoli</td> <td style="width: 15%;">Insert</td> <td style="width: 15%;">T0.5</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>Brussels sprouts</td> <td>Insert</td> <td>T0.5</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Cauliflower</td> <td>Insert</td> <td>T0.5</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Eggs</td> <td>Insert</td> <td>*0.01</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Peanut</td> <td>Omit</td> <td>T0.2</td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>0.05</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Peanut oil, crude</td> <td>Omit</td> <td>T0.3</td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>0.1</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Poultry, edible offal of</td> <td>Insert</td> <td>*0.01</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Poultry meat</td> <td>Insert</td> <td>*0.01</td> <td></td> <td></td> <td></td> </tr> </table>	Broccoli	Insert	T0.5				Brussels sprouts	Insert	T0.5				Cauliflower	Insert	T0.5				Eggs	Insert	*0.01				Peanut	Omit	T0.2					Substitute	0.05				Peanut oil, crude	Omit	T0.3					Substitute	0.1				Poultry, edible offal of	Insert	*0.01				Poultry meat	Insert	*0.01				<p>NEDI = 3% of ADI</p>
Broccoli	Insert	T0.5																																																											
Brussels sprouts	Insert	T0.5																																																											
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Poultry, edible offal of	Insert	*0.01																																																											
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<p>Bifenthrin Bifenthrin is a synthetic pyrethroid insecticide with contact and stomach action. The APVMA has issued a permit for its use to control cluster caterpillar on taro. The recommended temporary MRL for taro is at the LOQ.</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Taro</td> <td style="width: 15%;">Insert</td> <td style="width: 15%;">T*0.05</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> </table>	Taro	Insert	T*0.05				<p>NEDI = 72% of ADI</p> <p>20th ATDS = <1% of ADI for all population groups assessed</p>																																																						
Taro	Insert	T*0.05																																																											

Requested MRLs	Dietary Exposure Estimates
<p>Chlorothalonil Chlorothalonil is a fungicide. The 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.</p> <p>Asparagus Insert T*0.1</p>	<p>NEDI = 76% of ADI</p> <p>19th ATDS = <1% of ADI for all population groups assessed</p> <p>20th ATDS = <1% of ADI for all population groups assessed</p>
<p>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. The 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.</p> <p>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</p>	<p>Complete chemical deletion – dietary exposure assessment not required.</p>
<p>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. The 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.</p> <p>Leek Insert T0.5 Shallot Insert T0.5 Spring onion Insert T0.5</p>	<p>NEDI = 9% of ADI</p> <p>19th ATDS = <1% of ADI for all population groups assessed</p>
<p>Difenoconazole Difenoconazole is a triazole fungicide. The 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.</p> <p>Beetroot Insert T0.2</p>	<p>NEDI = 13% of ADI</p>

Requested MRLs	Dietary Exposure Estimates																																	
<p>Ethephon Ethephon is a growth regulator used for thinning, loosening or ripening in various crops. It is a weak to moderate cholinesterase inhibitor. The 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.</p> <table border="0" data-bbox="177 521 983 723"> <tr> <td>Barley</td> <td>Omit</td> <td>T1</td> </tr> <tr> <td></td> <td>Substitute</td> <td>1</td> </tr> <tr> <td>Mango</td> <td>Insert</td> <td>T10</td> </tr> <tr> <td>Olives</td> <td>Insert</td> <td>T5</td> </tr> <tr> <td>Wheat</td> <td>Insert</td> <td>T1</td> </tr> </table>	Barley	Omit	T1		Substitute	1	Mango	Insert	T10	Olives	Insert	T5	Wheat	Insert	T1	<p>NEDI = 88% of ADI</p>																		
Barley	Omit	T1																																
	Substitute	1																																
Mango	Insert	T10																																
Olives	Insert	T5																																
Wheat	Insert	T1																																
<p>Etoxazole Etoxazole is an insecticide. It inhibits the insect moulting process by disrupting the cell wall. The APVMA has issued a permit for its use to control mites on grape, pear and stone fruit crops. An MRL of 0.3 mg/kg for grapes in line with the permit was considered at Initial / Draft Assessment. An MRL of 0.5 mg/kg is recommended to address a potential trade impact. This is discussed in section 10.2 of this report.</p> <table border="0" data-bbox="177 1025 983 1261"> <tr> <td>Grapes</td> <td>Insert</td> <td>T0.5</td> </tr> <tr> <td>Pear</td> <td>Insert</td> <td>T0.2</td> </tr> <tr> <td>Stone fruits</td> <td>Insert</td> <td>T0.5</td> </tr> </table>	Grapes	Insert	T0.5	Pear	Insert	T0.2	Stone fruits	Insert	T0.5	<p>NEDI = 2% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="983 992 1390 1261"> <thead> <tr> <th></th> <th><u>2-6 years</u></th> <th><u>2+ years</u></th> </tr> </thead> <tbody> <tr> <td><1</td> <td></td> <td><1</td> </tr> <tr> <td><1</td> <td></td> <td><1</td> </tr> <tr> <td><1</td> <td>Apricot</td> <td><1</td> </tr> <tr> <td><1</td> <td>Cherries</td> <td><1</td> </tr> <tr> <td><1</td> <td>Nectarine</td> <td><1</td> </tr> <tr> <td><1</td> <td>Peach</td> <td><1</td> </tr> <tr> <td><1</td> <td>Plums</td> <td><1</td> </tr> </tbody> </table>		<u>2-6 years</u>	<u>2+ years</u>	<1		<1	<1		<1	<1	Apricot	<1	<1	Cherries	<1	<1	Nectarine	<1	<1	Peach	<1	<1	Plums	<1
Grapes	Insert	T0.5																																
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<1	Plums	<1																																
<p>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.</p> <table border="0" data-bbox="177 1462 983 1529"> <tr> <td>Cotton seed</td> <td>Omit</td> <td>T5</td> </tr> <tr> <td></td> <td>Substitute</td> <td>3</td> </tr> </table>	Cotton seed	Omit	T5		Substitute	3	<p>NEDI = 7% of ADI</p>																											
Cotton seed	Omit	T5																																
	Substitute	3																																
<p>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.</p> <table border="0" data-bbox="177 1765 983 1830"> <tr> <td>Cotton seed</td> <td>Omit</td> <td>10</td> </tr> <tr> <td></td> <td>Substitute</td> <td>15</td> </tr> </table>	Cotton seed	Omit	10		Substitute	15	<p>NEDI = 6 % of ADI</p>																											
Cotton seed	Omit	10																																
	Substitute	15																																

Requested MRLs	Dietary Exposure Estimates																																																
<p>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 nicotinic acetylcholine receptors.</p> <table border="0" data-bbox="177 521 983 656"> <tr> <td>Banana</td> <td>Omit</td> <td>T0.1</td> </tr> <tr> <td></td> <td>Substitute</td> <td>0.5</td> </tr> <tr> <td>Citrus fruits</td> <td>Omit</td> <td>T2</td> </tr> <tr> <td></td> <td>Substitute</td> <td>2</td> </tr> </table>	Banana	Omit	T0.1		Substitute	0.5	Citrus fruits	Omit	T2		Substitute	2	<p>NEDI = 15% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="983 488 1390 656"> <tr> <td></td> <td><u>2-6 years</u></td> <td><u>2+ years</u></td> </tr> <tr> <td></td> <td>3</td> <td><1</td> </tr> <tr> <td></td> <td>22</td> <td>8</td> </tr> </table>		<u>2-6 years</u>	<u>2+ years</u>		3	<1		22	8																											
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<p>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. The 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.</p> <table border="0" data-bbox="177 925 983 1328"> <tr> <td>Dried grapes</td> <td>Insert</td> <td>2</td> </tr> <tr> <td>Grapes</td> <td>Insert</td> <td>0.5</td> </tr> <tr> <td>Leafy vegetables [except lettuce, head]</td> <td>Insert</td> <td>5</td> </tr> <tr> <td>Linseed</td> <td>Insert</td> <td>T0.5</td> </tr> <tr> <td>Safflower seed</td> <td>Insert</td> <td>T0.5</td> </tr> <tr> <td>Strawberry</td> <td>Insert</td> <td>T1</td> </tr> <tr> <td>Wine grapes</td> <td>Omit</td> <td>1</td> </tr> </table>	Dried grapes	Insert	2	Grapes	Insert	0.5	Leafy vegetables [except lettuce, head]	Insert	5	Linseed	Insert	T0.5	Safflower seed	Insert	T0.5	Strawberry	Insert	T1	Wine grapes	Omit	1	<p>NEDI = 9% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="983 891 1390 1328"> <tr> <td></td> <td><u>2-6 years</u></td> <td><u>2+ years</u></td> </tr> <tr> <td></td> <td>5</td> <td>1</td> </tr> <tr> <td></td> <td>2</td> <td>Grapes- excluding wine</td> </tr> <tr> <td></td> <td><1</td> <td>Grapes-wine only</td> </tr> <tr> <td></td> <td><1</td> <td>7</td> </tr> <tr> <td></td> <td><1</td> <td>7</td> </tr> <tr> <td></td> <td><1</td> <td><1</td> </tr> <tr> <td></td> <td><1</td> <td><1</td> </tr> <tr> <td></td> <td>9</td> <td>2</td> </tr> </table>		<u>2-6 years</u>	<u>2+ years</u>		5	1		2	Grapes- excluding wine		<1	Grapes-wine only		<1	7		<1	7		<1	<1		<1	<1		9	2
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<p>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. The APVMA has issued a permit for its use in rhubarb. The recommended MRL for rhubarb is at the LOQ.</p> <table border="0" data-bbox="177 1597 983 1630"> <tr> <td>Rhubarb</td> <td>Insert</td> <td>*0.02</td> </tr> </table>	Rhubarb	Insert	*0.02	<p>NEDI = 7% of ADI</p>																																													
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<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 cluster caterpillar on taro.</p> <table border="0" data-bbox="177 1865 983 1998"> <tr> <td>Taro</td> <td>Insert</td> <td>T1</td> </tr> </table>	Taro	Insert	T1	<p>NEDI = 90% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="983 1832 1390 1998"> <tr> <td></td> <td><u>2-6 years</u></td> <td><u>2+ years</u></td> </tr> <tr> <td></td> <td>52</td> <td>Taro</td> </tr> <tr> <td></td> <td>8</td> <td>Radish</td> </tr> <tr> <td></td> <td>24</td> <td>Swede</td> </tr> <tr> <td></td> <td>24</td> <td>Turnip</td> </tr> <tr> <td></td> <td></td> <td>52</td> </tr> <tr> <td></td> <td></td> <td>8</td> </tr> <tr> <td></td> <td></td> <td>30</td> </tr> <tr> <td></td> <td></td> <td>14</td> </tr> </table>		<u>2-6 years</u>	<u>2+ years</u>		52	Taro		8	Radish		24	Swede		24	Turnip			52			8			30			14																		
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Requested MRLs	Dietary Exposure Estimates											
<p>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. The APVMA has issued a permit for its use on mangoes to enhance flowering and fruiting.</p> <p>Assorted tropical and sub-tropical fruits - inedible peel [except avocado] Omit *0.01</p> <p>Assorted tropical and sub-tropical fruits - inedible peel [except avocado and mango] Insert *0.01</p> <p>Mango Insert T1</p>	<p>NEDI = 13% of ADI</p>											
<p>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. The 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.</p> <p>Beans [except green beans] Omit T10</p> <p>Broad bean (dry) Insert T10</p> <p>Broad bean (green pods and immature seeds) Insert T10</p> <p>Common bean (dry) Insert T10</p> <p>Common bean (pods and/or immature seeds) Insert T3</p>	<p>NEDI = 25% of ADI</p> <p>19th ATDS = <1% of ADI for all population groups assessed</p> <p>20th ATDS = <1% of ADI for all population groups assessed</p> <p>NESTI as % of ARfD</p> <table border="0" style="width: 100%;"> <tr> <td style="text-align: center;"><u>2-6 years</u></td> <td style="text-align: center;"><u>2+ years</u></td> </tr> <tr> <td style="text-align: center;">51</td> <td style="text-align: center;">21</td> </tr> </table>		<u>2-6 years</u>	<u>2+ years</u>	51	21						
<u>2-6 years</u>	<u>2+ years</u>											
51	21											
<p>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.</p> <p>New chemical</p> <p>Insert residue definition:</p> <p>Sum of the free and conjugated forms of prohexadione expressed as prohexadione</p> <p>Apple Insert *0.02</p> <p>Edible offal (mammalian) Insert *0.05</p> <p>Meat (mammalian) Insert *0.05</p> <p>Milks Insert *0.01</p>	<p>NEDI = <1% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0" style="width: 100%;"> <tr> <td style="text-align: center;"><u>2-6 years</u></td> <td style="text-align: center;"><u>2+ years</u></td> </tr> <tr> <td style="text-align: center;"><1</td> <td style="text-align: center;"><1</td> </tr> <tr> <td style="text-align: center;"><1</td> <td style="text-align: center;"><1</td> </tr> <tr> <td style="text-align: center;"><1</td> <td style="text-align: center;"><1</td> </tr> <tr> <td style="text-align: center;"><1</td> <td style="text-align: center;"><1</td> </tr> </table>		<u>2-6 years</u>	<u>2+ years</u>	<1	<1	<1	<1	<1	<1	<1	<1
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Australia and New Zealand Food Regulation Ministerial Council

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

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

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

The purpose of this Ministerial Policy Guideline is to form a framework within which FSANZ is to consider alternative approaches to address the issues surrounding the current zero tolerance approach to the regulation of residues of agricultural and veterinary chemicals in food.

HIGH ORDER POLICY PRINCIPLES

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

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

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

SPECIFIC POLICY PRINCIPLES

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

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

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

Summary of Submissions and Comments Received

Submitter	Comments
Food Technology Association of Victoria Inc.	Supported this Application
Queensland Government	Supported this Application
Australian Food and Grocery Council	<p>AFGC supports option 2(b) and does not support option 2(a) to delete and decrease some existing MRLs while there is no default or threshold level permitted for low levels of residues on imported fruits and vegetables. AFGC notes that where there is a corresponding MRL in the Codex standard, the MRLs proposed in A591 are at the same level or higher than the Codex MRLs and are therefore not considered to pose restrictions on trade. AFGC notes that progressing proposed reductions and deletions of MRLs for chemicals for which residues are at the LOQ are permitted internationally may create an unnecessary barrier to international trade that is of no public health benefit. Differences with international standards in permissions for residues at low levels are not taken into account.</p>
Other correspondence	Comments
California Table Grapes Commission	<p>The Commission commented that Australia is one of the industry's largest export markets. The Commission recognizes Australia's right to establish nationally appropriate standards. The Commission requested alternative MRLs consistent with US tolerances of 0.5 mg/kg for etoxazole and 0.6 mg/kg (or 2 mg/kg consistent with a JMPR recommendation to Codex) for quinoxifen to avoid potential impediments to trade.</p>
NSW Food Authority	<p>Supported this Application and suggested that FSANZ assess the impact of proposed MRL withdrawals on trade of imported foods. The Authority stated that it would not like to deploy its resources in the recall of long shelf life foods affected by the proposed MRL withdrawals.</p>

Business Cost Calculator Report

Application A591 – Maximum Residue Limits October, November, December 2006

Problem:	Including Maximum Residue Limits (MRLs) in the Food Standards Code has the effect of allowing legally treated produce to be sold legally. Development of new products, crop uses and withdrawal of older products leads to variations in MRLs.
Objective:	Update the Code with current MRLs to reflect the changing patterns of agricultural and veterinary chemicals available to farmers.

Policy Options

Option Name	Quickscan Result
Status Quo	TRUE
Amend the Code to omit or decrease MRLs as proposed	TRUE
Amend the Code to insert new, increase or change existing temporary MRLs to MRLs as proposed	FALSE

Compliance Cost Summary

Option Name:	Status Quo		
Businesses Affected:		N/A	
	Type	Cost per Business	Total Cost of Regulation
	N/A	N/A	N/A

Option Name:	Amend the Code to omit or decrease MRLs as proposed		
Businesses Affected:		N/A	
	Type	Cost per Business	Total Cost of Regulation
	N/A	N/A	N/A

Option Name:	Amend the Code to insert new, increase or change existing temporary MRLs to MRLs as proposed		
Businesses Affected:		N/A	
	Type	Cost per Business	Total Cost of Regulation
	N/A	N/A	N/A

Caution should be used comparing options and interpreting results over time. The Business Cost Calculator does not estimate the future values of ongoing costs. Refer to the User Guidelines for further information. This report contains summaries of compliance costs only. An assessment on the compliance cost in itself does not provide an answer to which policy option is the most effective or efficient one. Rather, it provides information which needs to be considered alongside other relevant factors and issues when deciding between alternative policy options.