

EXPLANATORY STATEMENT

APPLICATION A582

MAXIMUM RESIDUE LIMITS (APRIL, MAY, JUNE 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 A582 seeks to amend Maximum Residue Limits (MRLs) for agricultural and veterinary chemicals in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* (the Code). It is a routine Application from the Australian Pesticides and Veterinary Medicines Authority (APVMA), to update the Code in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits. Dietary exposure assessments indicate that in relation to current health reference standards, setting the MRLs as proposed does not present any public health and safety concerns.

There are no MRLs for antibiotic residues in this Application.

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

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

FSANZ decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), 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 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.
- APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series 1997*, to support the use of chemicals on commodities as outlined in this Application.
- Office of Chemical Safety (OCS) part of the Therapeutic Goods Administration (TGA) has undertaken an appropriate toxicological assessment of each chemical and has established an acceptable daily intake (ADI) and where applicable an acute reference dose (ARfD).
- FSANZ has undertaken a regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and will benefit producers and consumers.
- The proposed draft variations would remove discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.
- The proposed changes are consistent with the FSANZ Act section 10 objectives.

Consultation

FSANZ has now completed the assessment of Application A582 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 is 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 Australian Pesticides and Veterinary Medicines Authority (APVMA) on 4 April, 3 May and 13 June 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 detection that could lead to a lowering of this limit.

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

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

- trial permits for research.

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

1. Background

1.1 Current Standard

The APVMA has approved the use of the agricultural and veterinary chemical products associated with the MRLs in this Application, and made amendments to 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, 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, APVMA independently evaluates its safety and performance, making sure that the health and safety of people, animals and the environment are protected.

When a chemical product is registered for use or a permit for use granted, APVMA includes MRLs in the APVMA MRL Standard. These MRLs are then adopted into control of use legislation in some jurisdictions and assist States and Territories in regulating the use of agricultural and veterinary chemicals.

1.3 Maximum Residue Limit Applications

After registering agricultural or veterinary chemical products based on scientific evaluations, APVMA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews information provided by APVMA and validates whether 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 APVMA in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series 1997* to support the MRLs in the commodities as outlined in this Application.

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

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

Amendments under consideration in Application A582:

- adding MRLs including some at the LOQ for new chemical aminopyralid;
- deleting the chemical and all associated entries for 2-(thiocyanomethylthio)benzothiazole;
- deleting MRLs for certain foods for ethephon;
- adding MRLs at the LOQ for certain foods for imazamox and pyraclostrobin;
- adding MRLs for certain foods for azoxystrobin and chlorothalonil;
- adding temporary MRLs including some at the LOQ for certain foods for imidacloprid, iprodione, metalaxyl, metolachlor and metribuzin;
- removing the temporary status of existing MRLs for certain foods for epoxiconazole and phosphine;
- increasing MRLs including changing the status of some existing MRLs to temporary for certain foods for buprofezin, and iprodione;
- decreasing MRLs including reducing some to the LOQ for certain foods for epoxiconazole and fluroxypyr; and
- updating the residue definition for clothianidin.

Requested MRLs, dietary exposure estimates and other proposed variations are outlined in Attachment 2.

In considering the issues associated with MRLs it should be noted that MRLs and variations to MRLs in the Code do not permit or prohibit the use of agricultural and veterinary chemicals. Other Australian Government, State and Territory legislation regulates use and control of agricultural and veterinary chemicals.

1.5 Request to Remove Temporary Status of Phosphine MRL for Sugarcane

This Application includes a request to remove the temporary status of the phosphine MRL for sugarcane, that is to change the MRL from T*0.01 mg/kg to *0.01 mg/kg.

The phosphine MRL for sugarcane would remain at the LOQ. Phosphine is a rodenticide. It is registered for use as a mouse and rat poison in agricultural situations, specifically in sugarcane. Data on residues in sugarcane and in the soil following treatment were evaluated.

Residues were not detected in sugarcane following application at ten times the expected treatment rate. Under the proposed use pattern, detectable residues are not expected in food commodities. OCS has not established an ADI or set an ARfD for this chemical, therefore no estimates of the national daily or acute dietary exposure (NEDI and NESTI) have been conducted. These terms are explained in the risk assessment section of this report. The TGA supported registration of zinc phosphide on the basis that MRLs would be established at or about the LOQ. FSANZ considers that the proposed change does not present health and safety concerns.

1.6 Antibiotic MRLs

There are no MRLs for antibiotic¹ residues in this Application.

1.7 Australia and New Zealand Joint Food Standards

The Treaty excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

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

- Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand.
- Food produced or imported into New Zealand that complies with the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards, 2006* 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. APVMA has already established MRLs under its legislation, and now seeks to have the amendments included in the Code through this Application to vary Standard 1.4.2.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives set out in section 10 of the FSANZ Act:

- the protection of public health and safety;

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

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

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

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

The proposed draft variations to Standard 1.4.2 are consistent with the FSANZ Act section 10 objectives of food regulatory measures.

4. Key Assessment Questions

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

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

In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from potentially treated foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will 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

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

The MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. However, incorporating the MRL into food legislation means that the residues of a chemical are minimised (i.e. must not exceed the MRL), irrespective of whether the dietary exposure assessment indicates that higher residues would not represent a risk to public health and safety.

5.2 Determining the Acceptable Reference Health Standard for a Chemical in Food

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

Both APVMA and FSANZ use these reference health standards in dietary exposure assessments.

The ADI is the daily intake of an agricultural or veterinary chemical, which, during the consumer's entire lifetime, appears to be without appreciable risk to the health of the consumer. This is on the basis of all the known facts at the time of the evaluation of the chemical. It is expressed in milligrams of the chemical per kilogram of body weight.

The ARfD of a chemical is the estimate of the amount of a substance in food, expressed on a body weight basis that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer, on the basis of all the known facts at the time of evaluation.

5.3 Calculating Dietary Exposure

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

APVMA and FSANZ have agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by APVMA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest National Nutrition Survey (NNS). The Australian Bureau of Statistics with the then Australian Government Department of Health and Aged Care undertook the latest NNS over a 13-month period (1995 to early 1996). The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns was reported.

5.3.1 Chronic Dietary Exposure Assessment

The National Estimated Daily Intake (NEDI) represents an estimate of chronic dietary exposure. Chemical residue data, as opposed to the MRL, are the preferred concentration data to use if they are available, as they provide a more realistic estimate of dietary exposure. The NEDI calculation may incorporate more specific data including food consumption data for particular sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions and the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials rather than the MRL to represent pesticide residue levels. Monitoring and surveillance data or data from total diet studies may also be used, such as the 19th and 20th Australian Total Diet Surveys (ATDS).

In conducting chronic dietary exposure assessments, APVMA and FSANZ consider the residues that could result from the permitted uses of a chemical product on foods. Where data are not available on the specific residues in a treated food then a cautious approach is taken and the MRL is used. The use of the MRL in dietary exposure estimates may result in considerable overestimates of exposure because it assumes that the entire national crop is treated with a pesticide and that the entire national crop contains residues equivalent to the MRL. In reality, only a portion of a specific crop is treated with a pesticide; most treated crops contain residues well below the MRL at harvest; and residues are usually reduced during storage, preparation, commercial processing and cooking. It is also unlikely that every food for which a MRL is proposed will have been treated with the same pesticide over the lifetime of consumers.

The residues that are likely to occur in all foods are multiplied by the mean daily consumption of these foods derived from individual dietary records from the latest NNS. These calculations provide information on the level of a chemical that is consumed for each food and take into account the consumption of processed foods e.g. apple pie and bread. The estimated exposure for each food is added together to provide the total dietary exposure to a chemical from all foods with MRLs.

The estimated dietary exposure is then divided by the average Australian's bodyweight to provide the amount of chemical consumed per day per kg of human bodyweight. This is compared to the ADI. It is therefore the overall dietary exposure to a chemical that is compared to the ADI - not the MRL. FSANZ considers that the chronic dietary exposure to the residues of a chemical is acceptable where the best estimate of exposure does not exceed the ADI.

Further, where these calculations use the MRL they are considered to be overestimates of dietary exposure because they assume that:

- the chemical will be used on all crops for which there is a registered use;
- treatment occurs at the maximum application rate;
- the maximum number of permitted treatments have been applied;
- the minimum withholding period has been applied; and
- this will result in residues at the maximum residue limit.

In 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. The residues of a chemical in a specific food are multiplied by the 97.5 percentile food consumption of that food, a variability factor is applied, the exposure divided by a mean body weight for the population group being assessed and this result is compared to the ARfD. NESTIs are calculated from ARfDs set by OCS and JMPR, the consumption data from the 1995 NNS and the MRL when the data on the actual residues in foods are not available. FSANZ considers that the acute dietary exposure to the residues of a chemical is acceptable where the best estimate of acute dietary exposure does not exceed the ARfD.

6. Risk Assessment Summary

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

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

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

In the case that an Australian ADI or ARfD has not been established, a JMPR ADI or ARfD may be used for risk assessment purposes if appropriate.

FSANZ has reviewed the dietary exposure assessments submitted by APVMA as part of its Application and concluded that the residues associated with the MRLs do not present any public health and safety concerns. This is determined by comparing estimates of dietary exposure to the chemical (calculated using food consumption data and MRLs or residue data), with the ADI and in some cases with the ARfD. In addition, the MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. However, incorporating the MRL into food legislation means that the residues of a chemical are minimised (i.e. must not exceed the MRL), irrespective of whether the dietary exposure assessment indicates that higher residues would not represent an unacceptable risk to public health and safety.

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

The additional safety factors inherent in calculation of the ADI and ARfD mean that there is negligible risk to public health and safety when estimated exposures are below these reference health standards.

RISK MANAGEMENT

7. Options

7.1 Option 1 – no change to existing MRLs in the Code

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

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

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

7.2 Option 2(a) – vary the Code in Schedule 1 of Standard 1.4.2 - Maximum Residue Limits to omit, decrease or change from permanent to temporary existing MRLs as proposed

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

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

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

8. Impact Analysis

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

8.1 Affected Parties

The parties affected by proposed MRL amendments include:

- domestic and international consumers;
- growers and producers of domestic and export food commodities;
- importers of agricultural produce and foods; and
- Australian Government, State and Territory agencies involved in monitoring and regulating the use of agricultural and veterinary chemicals in food and the potential resulting residues.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – no change to existing MRLs in the Code

8.2.1.1 Benefits

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

8.2.1.2 Costs

- for consumers there are unlikely to be any discernable costs as unavailability of some foods from certain growers is likely to be seen as typical seasonal fluctuation in the food supply;
- for growers and producers of domestic and export food commodities, adopting this option would result in costs from not being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Primary producers do not produce food or use chemical products to comply with MRLs. They use chemical products to control pests and diseases in accordance with the prescribed label conditions, and expect that the resulting residues will be acceptable and that legally treated food can be legally sold. If legal use of chemical products results in the production of food that cannot be legally sold under food legislation then primary producers will incur substantial losses. Major losses for primary producers would in turn impact negatively upon rural and regional communities;
- for importers, adopting this option would not result in any discernable costs; and
- for Australian Government, State and Territory agencies, adopting this option would create discrepancies between agricultural and food legislation thereby creating uncertainty, inefficiency and confusion in the enforcement of regulations.

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

8.2.2.1 Benefits

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

8.2.2.2 Costs

- for consumers there are unlikely to be any discernable costs as the unavailability of some foods from certain importers is likely to be seen as typical seasonal fluctuation in the food supply;
- for growers and producers of domestic and export food commodities, adopting this option is unlikely to result in any costs, as reductions in MRLs are adopted where this is practically achievable, with little or no impact on production costs;

- for importers, adopting this option may result in costs, as foods may not be permitted to be imported if these foods contain residues consistent with MRLs proposed for deletion or reduction. Any MRL deletions or reductions have the potential to restrict importation of foods and could potentially result in higher food costs and a reduced product range available to consumers, as foods that exceed the new, lower MRLs could not be legally imported or sold to consumers. To assist in identifying any restrictions and possible trade impacts, Codex MRLs and data on imported foods are addressed in the World Trade Organization section of this report; and
- for Australian Government, State and Territory agencies, adopting this option would not result in any discernable costs, although there would need to be an awareness of changes in the standards for residues in food.

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

8.2.3.1 Benefits

- for consumers there 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.

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 A582, there are no options other than a variation to Standard 1.4.2.

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

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

Adopting option 2(a) may result in compliance costs for importers and industry where there are decreases or deletions of MRLs.

Option 1 is an undesirable option.

- Potential substantial costs to primary producers may result. Additional costs may impact negatively on their viability and in turn the viability of the rural and regional communities that depend upon the sale of agricultural produce.
- Consequent discrepancies between agricultural and food legislation could have negative impacts on compliance costs for primary producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

COMMUNICATION

9. Communication and Consultation Strategy

FSANZ decided, pursuant to section 36 of the FSANZ Act to omit inviting public submissions in relation to Application A582 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 costs/benefit impacts on the importation of food if the proposed deletions to specific MRLs are advanced; and any other affected parties to this Application.

Submissions were received from Food Technology Association of Victoria Inc. (FTAV), the Country Women's Association of New South Wales Social Issues Committee (CWA), Department of Health SA, Queensland Health Environmental Health Unit, Australian Food and Grocery Council (AFGC), and Department of Human Services Victoria (DHS).

Submissions from FTAV, Department of Health SA, Queensland Health Environmental Health Unit and DHS support the Application. These bodies support approving options 2(a) and 2(b) – to vary the Code in Schedule 1 of Standard 1.4.2 - Maximum Residue Limits as proposed.

10.1 Summarised Submission from the Country Women's Association of New South Wales Social Issues Committee

The CWA expressed concern about increasing MRLs of pesticides in foods in relation to effects of accumulated ingestion over time. The CWA notes background reading indicates that there does not appear to have been harm done. The CWA states that a closer check on limits is imperative.

The CWA commented in relation to endosulfan use in the cotton industry that even if the MRL for meat was increased slightly, consumption would still result in exposures comfortably within the acceptable daily intake.

10.1.1 FSANZ Evaluation

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ ensures that residues associated with proposed MRLs do not present a risk to public health and safety. OCS has undertaken a toxicological assessment of the chemicals for APVMA and has established an ADI and where appropriate an ARfD for each chemical. FSANZ accepts these assessments and reviews dietary exposure assessments in accordance with internationally accepted practices and procedures. The dietary exposure assessment takes into account the residues that may occur in all foods, not just the foods specified, for each chemical in the Application. FSANZ will not agree to adopt MRLs into the Code where dietary exposure to chemical residues could pose a health risk. FSANZ has reviewed the information provided by APVMA and has validated that the estimated dietary exposures for the proposed MRLs in this Application are within safety limits set by the TGA.

MRLs are not direct public health limits. MRLs are set at levels well below those that would cause an adverse health effect. MRLs protect public health and safety by ensuring that residues of agricultural chemical inputs are no higher than is necessary for effective control of pests, weeds and plant and animal diseases. A MRL indicates the highest legally permitted level of a chemical residue in a food. It does not indicate the amount of a chemical that is always present.

Across national agricultural production only a portion of a specific commodity is treated with a pesticide; most treated commodities contain residues well below the MRL before appearing on the market; and residues are usually reduced during storage, washing, preparation, commercial processing and cooking.

To date programs that monitor dietary exposure to residues present in food undertaken by FSANZ and other bodies have not found residues that are likely to cause harm. Surveys of fresh foods such as the Australian Government Department of Agriculture, Fisheries and Forestry National Residues Survey, State Departments of Agriculture/Primary Industries monitoring programs and surveys by major supermarket chains indicate that the vast majority of foods do not contain residues. Each ATDS of pesticide residues in foods has found many foods with no residues detected, no residues of many chemicals and where residues have been detected, the levels have been extremely low. Programs monitoring residues in food and health, agricultural and environmental issues associated with chemical product use are ongoing.

APVMA has not requested any changes to endosulfan MRLs in Application A582. No changes to endosulfan MRLs are to be made through this Application.

10.2 Summarised Submission from Australian Food and Grocery Council

AFGC supports option 2(b) and does not support option 2(a) to delete and decrease some existing MRLs until there has been adequate consultation with industry to ensure that imported produce will not be adversely affected.

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 APVMA rather than FSANZ and that APVMA considers chemical safety and toxicology and the necessary withholding periods before consumption.

AFGC notes that United Kingdom legislation and European Union legislation currently permit certain residues at the level of detection. AFGC expressed concern that where MRLs at or below 0.1 mg/kg for which there are no public health and safety concerns are deleted, this may create a barrier to international trade that provides no public health benefit. Differences with international standards in permissions for residues at low levels are not taken into account.

AFGC notes that adopting the proposed reductions and deletions of MRLs for chemicals that are in world-wide use may result in increased costs or reduced availability and consumer choice as foods may not be able to be imported from current sources if these foods contain residues consistent with MRLs proposed for deletion or reduction. AFGC rejects option 2(a) on the grounds that it will result in a technical barrier to trade and damage Australian industry.

10.2.1 FSANZ Evaluation

MRL deletions have the potential to restrict the importation of foods and could potentially result in a reduced product range available to consumers, as foods 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. However, no submissions were received from specific industry sectors that addressed the likely effects on trade or importation for the relevant food commodities if the proposed deletions take place.

At Initial / Draft Assessment, FSANZ requested comment as to any possible ramifications of the proposed MRLs differing from international MRLs. No comments were received from any industry sectors. Following the WTO Notification, member countries raised no issues in regard to the proposed deletions.

10.3 Summarised Submission from Department of Human Services Victoria

DHS supports option 2(a) and 2(b) to vary the Code as proposed. DHS raised concern that where MRLs are omitted from the Code, this means a default position of 'zero tolerance' for residues that pose no threat to health and safety. This has implications for enforcement.

10.3.1 FSANZ Evaluation

Foods containing low levels of agricultural and veterinary chemical residues with no MRL are illegal for sale. Where there is a negligible risk to public health and safety, mandatory enforcement action has resource implications for industry and enforcement agencies that are not commensurate with the risk involved.

Draft Ministerial Policy Guidelines on the regulation of low level residues from agricultural and veterinary chemicals in food were developed following public consultation. The Ministerial Council has now approved the Ministerial Policy Guidelines, which have been provided to FSANZ. The Policy Guidelines will form the parameters within which FSANZ will consider the development of alternative approaches to address the issues associated with the current 'zero tolerance' regulatory framework. Public consultation will be an important part of this process.

10.4 Summarised Submission from Food Technology Association of Victoria Inc.

FTAV supports option 2(a) and 2(b) to vary the Code as proposed. FTAV queried whether the proposed $T^*0.05$ mg/kg level of iprodione in broccoli is correct in relation to the 25 mg/kg level permitted in the EEC.

10.4.1 FSANZ Evaluation

The proposed MRL for iprodione in broccoli is $T^*0.05$ mg/kg. It is expected that the registered use pattern for dipping broccoli, cabbage and cauliflower seedlings prior to transplant will not result in residues in mature plants. The MRL has been established at the limit of analytical quantification. The Codex MRL for iprodione in broccoli is 25 mg/kg. There are no other Codex MRLs for iprodione in brassicas. MRLs are set according to Australian Good Agricultural Practice (GAP) (or Good Veterinary Practice (GVP)). Each MRL is based on trial data submitted to APVMA and is set at a level that is known to be safe for people while still allowing the chemical to work effectively that is, no higher than is necessary for the effective control of pests and diseases.

Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because permissions for products differ. MRLs are set to reflect the legal use of a chemical.

10.5 Summarised Submission from Queensland Health Environmental Health Unit

Queensland Health Environmental Health Unit supports option 2(a) and 2(b) to vary the Code as proposed. The submission notes that the chemical description for chlorothalonil as shown on page 20 of the Initial / Draft Assessment Report is not as it appears in the chlorothalonil entry in Schedule 1 of Standard 1.4.2.

10.5.1 FSANZ Evaluation

The residue definition for chlorothalonil was amended through Application A572. By legal drafting convention, the amended residue definition was included in the draft variations to the Code for this subsequent Application. This practice serves to minimise the potential for error on gazettal where there have been several applications to vary the Code at different stages of the assessment process under consideration at a time. Future instances will be noted in the summary table of requested MRLs.

10.6 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 A582 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.

10.7 Codex Alimentarius Commission MRLs

Codex Alimentarius Commission (Codex) standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table lists the variations to MRLs in Application A582 that are addressed in the international Codex standard.

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Buprofezin Tomato	T2	1
Ethephon Wheat	Omit T1	1
Imidacloprid Assorted tropical and sub-tropical fruits – inedible peel [except banana] Mango	T1	0.2
Iprodione Beans [except broad bean and soya bean] Broccoli Common bean (pods and/or immature seeds)	T1 T*0.05	25 2

10.8 Imported Foods

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

Deletions or reductions of MRLs may affect imported foods that may comply with existing MRLs even though these existing MRLs are no longer required for domestically produced food. This is because imported foods may contain residues consistent with the MRLs proposed for deletion or reduction.

To assist in identifying possible impacts where imported foods may be affected, FSANZ 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. AFGC made a submission on these impacts; this is discussed in section 10.2 above.

Chemical Food
Epoiconazole Barley Milks Poultry, edible offal of Poultry meat (in the fat) Wheat Wheat bran, unprocessed Wheat germ
Ethephon Triticale Wheat
Fluroxypyr Edible offal (mammalian)
2-(thiocyanomethylthio)benzothiazole Cotton seed

CONCLUSION

11. Conclusion and Preferred Option

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

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.
- APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series 1997*, to support the use of chemicals on commodities as outlined in this Application.
- OCS has undertaken an appropriate toxicological assessment of each chemical and has established an ADI and where applicable an ARfD.
- FSANZ has undertaken a regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and will benefit producers and consumers.
- The proposed draft variations would remove discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.
- The proposed changes are consistent with the FSANZ Act section 10 objectives.

12. Implementation and Review

The use of chemical products and MRLs are under constant review as part of the APVMA Existing Chemical Review Program. In addition, regulatory agencies continue to monitor health, agricultural and environmental issues associated with chemical product use. Residues in food are also monitored through:

- State and Territory residue monitoring programs;
- Australian Government programs such as the National Residue Survey; and
- dietary exposure studies such as the Australian Total Diet Study.

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

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

ATTACHMENTS

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

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 –*

2-(thiocyanomethylthio) benzothiazole

[1.2] *inserting in Schedule 1 –*

AMINOPYRALID	
<i>COMMODITIES OF PLANT ORIGIN: SUM OF AMINOPYRALID AND CONJUGATES, EXPRESSED AS AMINOPYRALID</i>	
<i>COMMODITIES OF ANIMAL ORIGIN: AMINOPYRALID</i>	
CEREAL GRAINS	0.1
EDIBLE OFFAL (MAMMALIAN) [EXCEPT KIDNEY]	0.02
EGGS	*0.01
KIDNEY (MAMMALIAN)	0.3
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
WHEAT BRAN, UNPROCESSED	0.3

[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
CLOTHIANIDIN	<i>COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN COMMODITIES OF ANIMAL ORIGIN: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN</i>

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

ETHEPHON	
ETHEPHON	
TRITICALE	T1
WHEAT	T1

FLUROXYPYR FLUROXYPYR	
EDIBLE OFFAL (MAMMALIAN)	2
MEAT (MAMMALIAN)	0.1

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

AZOXYSTROBIN AZOXYSTROBIN	
CARROT	0.2
CHLOROTHALONIL COMMODITIES OF PLANT ORIGIN: CHLOROTHALONIL COMMODITIES OF ANIMAL ORIGIN: SUM OF CHLOROTHALONIL AND 4-HYDROXY-2, 5, 6- TRICHLOROISOPHTHALONITRILE METABOLITE, EXPRESSED AS CHLOROTHALONIL	
PAPAYA (PAWPAW)	7
FLUROXYPYR FLUROXYPYR	
EDIBLE OFFAL (MAMMALIAN) [EXCEPT KIDNEY]	0.1
KIDNEY (MAMMALIAN)	1
MEAT (MAMMALIAN) (IN THE FAT)	0.1
IMAZAMOX IMAZAMOX	
RAPE SEED	*0.05
IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID	
ASSORTED TROPICAL AND SUB- TROPICAL FRUITS – INEDIBLE PEEL [EXCEPT BANANA]	T1
IPRODIONE IPRODIONE	
BEETROOT	T0.1
BROCCOLI	T*0.05
CABBAGES, HEAD	T*0.05
CAULIFLOWER	T*0.05
METALAXYL METALAXYL	
PAPAYA (PAWPAW)	T*0.05
METOLACHLOR METOLACHLOR	
CELERIAC	T*0.2

METRIBUZIN METRIBUZIN	
PEAS [EXCEPT PEAS, SHELLED]	T*0.05
ROOT AND TUBER VEGETABLES [EXCEPT POTATO]	T*0.05
PYRACLOSTROBIN COMMODITIES OF PLANT ORIGIN: PYRACLOSTROBIN COMMODITIES OF ANIMAL ORIGIN: SUM OF PYRACLOSTROBIN AND METABOLITES HYDROLYSED TO 1-(4-CHLORO-PHENYL)-1H-PYRAZOL-3-OL, EXPRESSED AS PYRACLOSTROBIN	
POTATO	*0.02

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

BUPROFEZIN BUPROFEZIN	
EGG PLANT	T2
TOMATO	T2
EPOXICONAZOLE EPOXICONAZOLE	
BARLEY	0.05
EDIBLE OFFAL (MAMMALIAN)	0.05
EGGS	*0.01
MILKS	*0.005
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT (IN THE FAT)	*0.01
WHEAT	0.05
WHEAT BRAN, UNPROCESSED	0.3
WHEAT GERM	0.2
IPRODIONE IPRODIONE	
BEANS [EXCEPT BROAD BEAN AND SOYA BEAN]	T1
PHOSPHINE ALL PHOSPHIDES, EXPRESSED AS HYDROGEN PHOSPHIDE (PHOSPHINE)	
SUGAR CANE	*0.01

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

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

NOTES ON TERMS USED IN THE TABLE

ADI – Acceptable Daily Intake - The ADI is the daily intake of an agricultural or veterinary chemical, which, during the consumer's entire lifetime, appears to be without appreciable risk to the health of the consumer. This is based on all the known facts at the time of the evaluation of the chemical. The ADI is expressed in milligrams of the chemical per kilogram of body weight.

ARfD – Acute Reference Dose - The ARfD is the estimate of the amount of a substance in food, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer, on the basis of all the known facts at the time of evaluation.

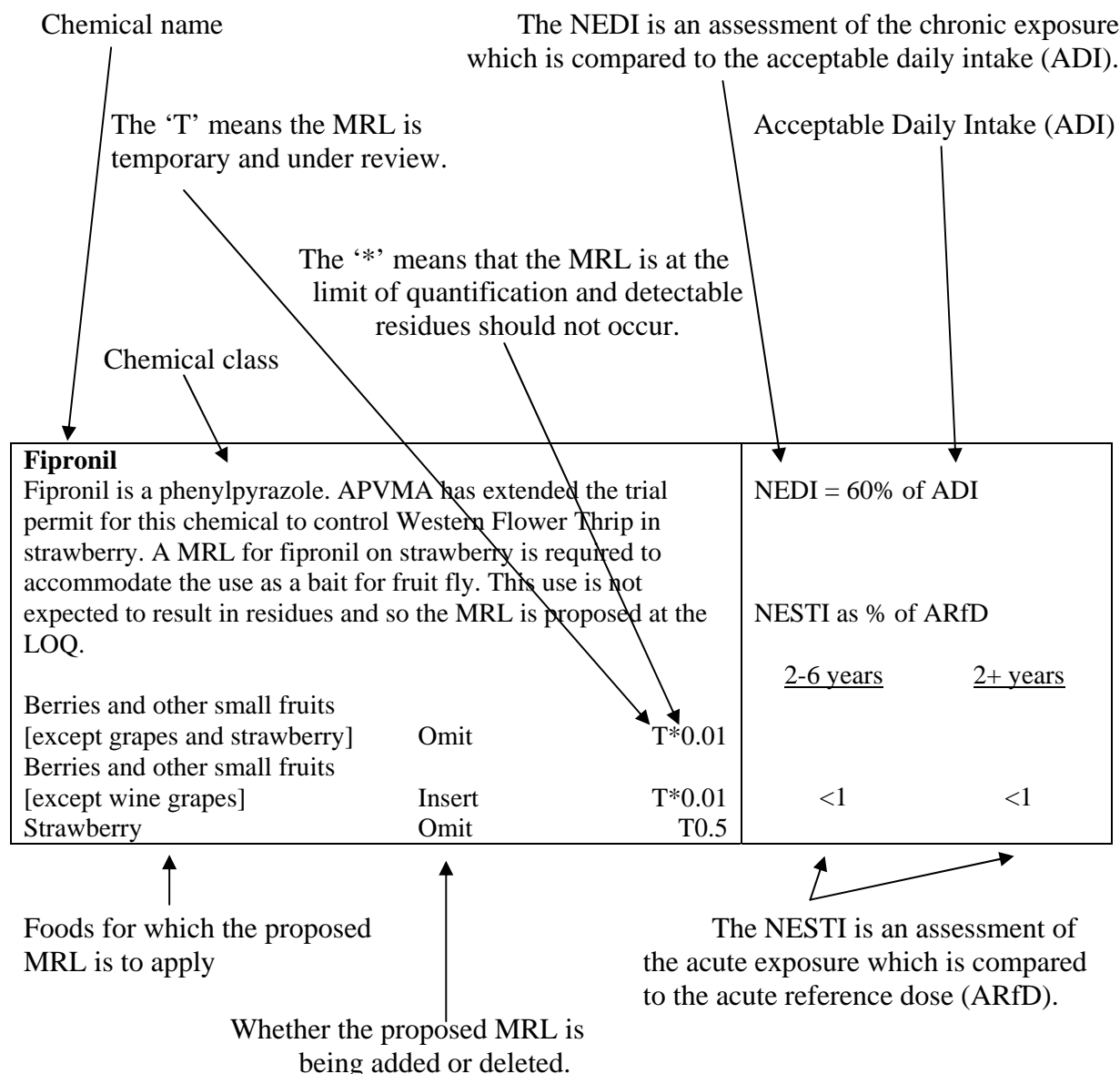
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

NEDI - National Estimated Dietary Intake - The NEDI represents a realistic estimate of chronic dietary exposure and is the preferred calculation. It may incorporate more specific food consumption data including that for particular sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions; the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials other than the MRL to represent pesticide residue levels. In most cases the NEDI is still an overestimation because more specific residue data are often not available and in these cases the MRL is used.

NESTI - National Estimated Short Term Intake - The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated based on consumption of raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis. FSANZ has used ARfDs set by the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 NNS and the MRL when the supervised trials median residue (STMR) is not available to calculate the NESTIs.

The NESTI calculation incorporates the large portion (97.5 percentile) food consumption data and can take into account such factors as the highest residue on a composite sample of an edible portion; the STMR, representing typical residue in an edible portion resulting from the maximum permitted pesticide use pattern; processing factors which affect changes from the raw commodity to the consumed food and the variability factor.

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



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

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

Data from the 19th and 20th Australian Total Diet Surveys (ATDS) are provided when available because they provide an indication of the typical exposure to chemicals in table ready foods. The ATDS results are more realistic because analysed concentrations of the chemical in foods are used; the NEDI and NESTI calculations are theoretical calculations that conservatively overestimate exposure.

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

Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and typically result because of the different range of foods in the individual studies.

Acronyms:

1. **ADI** Acceptable Daily Intake
2. **APVMA** Australian Pesticides and Veterinary Medicines Authority
3. **ARfD** Acute Reference Dose
4. **ATDS** Australian Total Diet Survey
5. **the Code** *Australia New Zealand Food Standards Code*
6. **FSANZ** Food Standards Australia New Zealand
7. **JMPR** Joint FAO/WHO Meeting on Pesticide Residues
8. **LOQ** Limit of Analytical Quantification
9. **MRL** Maximum Residue Limit
10. **NEDI** National Estimated Daily Intake
11. **NESTI** National Estimated Short Term Intake
12. **NNS** National Nutrition Survey of Australia 1995
13. **OCS** Office of Chemical Safety
14. **T** Temporary MRL
15. **TGA** Therapeutic Goods Administration
16. **WHP** Withholding Period

**SUMMARY OF REQUESTED MRLS FOR APPLICATION A582
MAXIMUM RESIDUE LIMITS – APRIL, MAY, JUNE 2006**

Requested MRLs	Dietary Exposure Estimates																																																									
<p>Aminopyralid Aminopyralid is a systemic herbicide; it induces auxin-type responses. It is used to control weeds in winter cereals and sorghum; and woody weeds in pasture. Animal metabolism data show that it is largely eliminated unchanged and there are no significant residues found in animal tissues, eggs and milk. The recommended MRLs for these commodities are at the LOQ. Aminopyralid and fluroxypyr are active ingredients in the product 'Hotshot Herbicide'.</p> <p>New chemical</p> <p>Insert residue definition:</p> <p><i>Commodities of plant origin:</i> Sum of Aminopyralid and conjugates, expressed as Aminopyralid <i>Commodities of animal origin:</i> Aminopyralid</p> <table border="0" data-bbox="177 958 983 1261"> <tr> <td>Cereal grains</td> <td>Insert</td> <td>0.1</td> </tr> <tr> <td>Edible offal (mammalian) [except kidney]</td> <td>Insert</td> <td>0.02</td> </tr> <tr> <td>Eggs</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Kidney (mammalian)</td> <td>Insert</td> <td>0.3</td> </tr> <tr> <td>Meat (mammalian)</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Milks</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Poultry, edible offal of</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Poultry meat</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Wheat bran, unprocessed</td> <td>Insert</td> <td>0.3</td> </tr> </table>	Cereal grains	Insert	0.1	Edible offal (mammalian) [except kidney]	Insert	0.02	Eggs	Insert	*0.01	Kidney (mammalian)	Insert	0.3	Meat (mammalian)	Insert	*0.01	Milks	Insert	*0.01	Poultry, edible offal of	Insert	*0.01	Poultry meat	Insert	*0.01	Wheat bran, unprocessed	Insert	0.3	<p>NEDI = <1% of ADI</p> <p>DIAMOND modelling estimated chronic dietary exposure of <1% ADI</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="983 927 1388 1261"> <thead> <tr> <th></th> <th><u>2-6 years</u></th> <th><u>2+ years</u></th> </tr> </thead> <tbody> <tr> <td>Cereal grains</td> <td><1</td> <td><1</td> </tr> <tr> <td>Edible offal (mammalian) [except kidney]</td> <td><1</td> <td><1</td> </tr> <tr> <td>Eggs</td> <td><1</td> <td><1</td> </tr> <tr> <td>Kidney (mammalian)</td> <td><1</td> <td><1</td> </tr> <tr> <td>Meat (mammalian)</td> <td><1</td> <td><1</td> </tr> <tr> <td>Milks</td> <td><1</td> <td><1</td> </tr> <tr> <td>Poultry, edible offal of</td> <td><1</td> <td><1</td> </tr> <tr> <td>Poultry meat</td> <td><1</td> <td><1</td> </tr> <tr> <td>Wheat bran, unprocessed</td> <td><1</td> <td><1</td> </tr> </tbody> </table>		<u>2-6 years</u>	<u>2+ years</u>	Cereal grains	<1	<1	Edible offal (mammalian) [except kidney]	<1	<1	Eggs	<1	<1	Kidney (mammalian)	<1	<1	Meat (mammalian)	<1	<1	Milks	<1	<1	Poultry, edible offal of	<1	<1	Poultry meat	<1	<1	Wheat bran, unprocessed	<1	<1
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<p>Azoxystrobin Azoxystrobin is a fungicide. It inhibits mitochondrial respiration in fungi. APVMA has issued a permit for its use to control leaf spot, black rot and Sclerotinia rot in carrots.</p> <table border="0" data-bbox="177 1431 983 1464"> <tr> <td>Carrot</td> <td>Insert</td> <td>0.2</td> </tr> </table>	Carrot	Insert	0.2	<p>NEDI = 2% of ADI</p>																																																						
Carrot	Insert	0.2																																																								
<p>Buprofezin Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae. APVMA has issued a permit for its use to control silverleaf whitefly on tomato and eggplant.</p> <table border="0" data-bbox="177 1641 983 1771"> <tr> <td rowspan="2">Egg plant</td> <td>Omit</td> <td>T1</td> </tr> <tr> <td>Substitute</td> <td>T2</td> </tr> <tr> <td rowspan="2">Tomato</td> <td>Omit</td> <td>1</td> </tr> <tr> <td>Substitute</td> <td>T2</td> </tr> </table>	Egg plant	Omit	T1	Substitute	T2	Tomato	Omit	1	Substitute	T2	<p>NEDI = 22% of ADI</p>																																															
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Tomato	Omit	1																																																								
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<p>Chlorothalonil Chlorothalonil is a non-systemic foliar fungicide with protective action. APVMA has issued a permit for its use to control black spot and brown spot on papaya. Adverse weather conditions following cyclone Larry have encouraged development of black spot and brown spot fungal diseases. Following application under the proposed use pattern, residues data from international trials support the recommended permanent MRL.</p> <p>Note: An amendment to the residue definition for chlorothalonil was included in the Application A572 draft variations to the Code</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>	
Papaya (pawpaw)	Insert	7		
<p>Clothianidin Amendment to residue definition</p> <p>Omit: Clothianidin</p> <p>Substitute: <i>Commodities of plant origin</i>: Clothianidin <i>Commodities of animal origin</i>: Sum of Clothianidin, 2-chlorothiazol-5-ylmethylguanidine, 2-chlorothiazol-5-ylmethylurea, and the pyruvate derivative of N-(2-chlorothiazol-5-ylmethyl)-N'-methylguanidine expressed as Clothianidin</p>			<p>Dietary exposure assessment not required.</p>	
<p>Epoxiconazole Epoxiconazole is a triazole fungicide. It inhibits C-14 demethylase in sterol biosynthesis. It is used to control rust diseases in barley and wheat.</p>			<p>NEDI = 1% of ADI</p> <p>NESTI as % of ARfD</p> <p><u>2-6 years</u> <u>2+ years</u></p>	
Barley	Omit	T0.5		
	Substitute	0.05	<1	<1
Edible offal (mammalian)	Omit	T0.05		
	Substitute	0.05	<1	<1
Eggs	Omit	T*0.01		
	Substitute	*0.01	<1	<1
Milks	Omit	T0.01		
	Substitute	*0.005	<1	<1
Poultry, edible offal of	Omit	T0.02		
	Substitute	*0.01	<1	<1
Poultry meat (in the fat)	Omit	T0.05		
	Substitute	*0.01	<1	<1
Wheat	Omit	T0.5		
	Substitute	0.05	<1	<1
Wheat bran, unprocessed	Omit	T3		
	Substitute	0.3	<1	<1
Wheat germ	Omit	T2		
	Substitute	0.2	<1	<1

<p>Ethephon Ethephon is a weak to moderate cholinesterase inhibitor. It is a growth regulator used for thinning, loosening or ripening in various crops. APVMA confirms that there are no uses of ethephon on wheat or triticale and accordingly no MRLs are required for these commodities.</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 40%;">Triticale</td> <td style="width: 30%;">Omit</td> <td style="width: 30%;">T1</td> </tr> <tr> <td>Wheat</td> <td>Omit</td> <td>T1</td> </tr> </table>	Triticale	Omit	T1	Wheat	Omit	T1	Dietary exposure assessment not required.									
Triticale	Omit	T1														
Wheat	Omit	T1														
<p>Fluroxypyr Fluroxypyr is a systemic herbicide; it induces auxin-type responses. It is used to control weeds in winter cereals and sorghum; and woody weeds in pasture. Fluroxypyr and aminopyralid are active ingredients in the product ‘Hotshot Herbicide’.</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 40%;">Edible offal (mammalian)</td> <td style="width: 30%;">Omit</td> <td style="width: 30%;">2</td> </tr> <tr> <td>Edible offal (mammalian) [except kidney]</td> <td>Insert</td> <td>0.1</td> </tr> <tr> <td>Kidney (mammalian)</td> <td>Insert</td> <td>1</td> </tr> <tr> <td>Meat (mammalian)</td> <td>Omit</td> <td>0.1</td> </tr> <tr> <td>Meat (mammalian) (in the fat)</td> <td>Insert</td> <td>0.1</td> </tr> </table>	Edible offal (mammalian)	Omit	2	Edible offal (mammalian) [except kidney]	Insert	0.1	Kidney (mammalian)	Insert	1	Meat (mammalian)	Omit	0.1	Meat (mammalian) (in the fat)	Insert	0.1	NEDI = <1% of ADI
Edible offal (mammalian)	Omit	2														
Edible offal (mammalian) [except kidney]	Insert	0.1														
Kidney (mammalian)	Insert	1														
Meat (mammalian)	Omit	0.1														
Meat (mammalian) (in the fat)	Insert	0.1														
<p>Imazamox Imazamox is an imidazolinone herbicide. It is an acetolactate synthase (ALS) (also known as acetohydroxyacid synthase (AHAS)) inhibitor It is used for the early post emergent control of annual grass and broadleaf weeds in imidazolinone resistant canola. Data from Australian and international trials indicate that under the proposed use pattern, residues will not be detectable in harvested canola seed. The recommended MRL is at the LOQ.</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 40%;">Rape seed</td> <td style="width: 30%;">Insert</td> <td style="width: 30%;">*0.05</td> </tr> </table>	Rape seed	Insert	*0.05	NEDI = <1% of ADI												
Rape seed	Insert	*0.05														
<p>Imidacloprid Imidacloprid is a systemic insecticide that binds to postsynaptic nicotinic receptors in the CNS acting as an antagonist. APVMA has issued a permit for its use to control citrus mealy bug (<i>Planococcus citri</i>) and red banded thrips (<i>Selenothrips rubrinctus</i>) on exotic tropical fruits – casimiroa, durian, mabolo, mammey, mangosteen, rambutan, rollinia and soursop.</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 40%;">Assorted tropical and sub-tropical fruits – inedible peel [except banana]</td> <td style="width: 30%;">Insert</td> <td style="width: 30%;">T1</td> </tr> </table>	Assorted tropical and sub-tropical fruits – inedible peel [except banana]	Insert	T1	<p>NEDI = 10% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;"><u>2-6 years</u></td> <td style="width: 50%; text-align: center;"><u>2+ years</u></td> </tr> <tr> <td style="width: 50%;">Up to 5 for all tropical fruits assessed</td> <td style="width: 50%;">Up to 1 for all tropical fruits assessed</td> </tr> </table>	<u>2-6 years</u>	<u>2+ years</u>	Up to 5 for all tropical fruits assessed	Up to 1 for all tropical fruits assessed								
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<p>Iprodione Iprodione is a contact fungicide. It has protective and curative action. It inhibits spore germination and mycelial growth. APVMA has issued permits for its use to control Sclerotinia rot in beans; for foliar application on beetroot to control Alternaria leaf spot, Sclerotinia rot and grey mould; and as a fungicide for broccoli, cabbage and cauliflower seedlings prior to transplanting. The recommended MRLs for broccoli, cabbage and cauliflower are at the LOQ; quantifiable residues are not expected in mature plants.</p> <table border="0" data-bbox="177 562 986 763"> <tr> <td>Beans [except broad bean and soya bean]</td> <td>Omit</td> <td>0.2</td> </tr> <tr> <td></td> <td>Substitute</td> <td>T1</td> </tr> <tr> <td>Beetroot</td> <td>Insert</td> <td>T0.1</td> </tr> <tr> <td>Broccoli</td> <td>Insert</td> <td>T*0.05</td> </tr> <tr> <td>Cabbages, head</td> <td>Insert</td> <td>T*0.05</td> </tr> <tr> <td>Cauliflower</td> <td>Insert</td> <td>T*0.05</td> </tr> </table>	Beans [except broad bean and soya bean]	Omit	0.2		Substitute	T1	Beetroot	Insert	T0.1	Broccoli	Insert	T*0.05	Cabbages, head	Insert	T*0.05	Cauliflower	Insert	T*0.05	<p>NEDI = 43% of ADI</p> <p>19th ATDS = 1% of ADI for toddlers 2 years and <1% of ADI for other population groups assessed</p> <p>20th ATDS = 1% of ADI for adult males 25 – 34 years and toddlers 2 years and <1% of ADI for other population groups assessed</p>
Beans [except broad bean and soya bean]	Omit	0.2																	
	Substitute	T1																	
Beetroot	Insert	T0.1																	
Broccoli	Insert	T*0.05																	
Cabbages, head	Insert	T*0.05																	
Cauliflower	Insert	T*0.05																	
<p>Metalaxyl Metalaxyl is a protective and curative fungicide. APVMA has issued a permit for its use to control phytophthora root rot and pythium root diseases on pawpaw in the wake of cyclone Larry. Residues data indicate that residues are not expected following the proposed use pattern. The recommended MRL is at the LOQ.</p> <table border="0" data-bbox="177 999 986 1032"> <tr> <td>Papaya (pawpaw)</td> <td>Insert</td> <td>T*0.05</td> </tr> </table>	Papaya (pawpaw)	Insert	T*0.05	<p>NEDI = 6% of ADI</p> <p>20th ATDS = <1% of ADI for all population groups assessed</p>															
Papaya (pawpaw)	Insert	T*0.05																	
<p>Metolachlor Metolachlor is a herbicide. It is a biosynthesis inhibitor; it is absorbed by emerging roots and shoots. APVMA has issued a permit for its use to control annual grasses and broadleaf weeds in celeriac. It is to be used directly after transplanting celeriac seedlings Residues data indicate that residues are not expected above the LOQ following the proposed use pattern. The recommended MRL is at the LOQ.</p> <table border="0" data-bbox="177 1339 986 1373"> <tr> <td>Celeriac</td> <td>Insert</td> <td>T*0.2</td> </tr> </table>	Celeriac	Insert	T*0.2	<p>NEDI = <1% of ADI</p>															
Celeriac	Insert	T*0.2																	
<p>Metribuzin Metribuzin is a selective systemic herbicide. It inhibits photosynthesis. APVMA has issued a permit for its use to control various grass and broad leaf weeds in sugar snap peas, snow peas and Asian root vegetables. Residues data indicate that detectable residues are not expected following the proposed use pattern. The recommended MRLs are at the LOQ.</p> <table border="0" data-bbox="177 1641 986 1706"> <tr> <td>Peas [except peas, shelled]</td> <td>Insert</td> <td>T*0.05</td> </tr> <tr> <td>Root and tuber vegetables [except potato]</td> <td>Insert</td> <td>T*0.05</td> </tr> </table>	Peas [except peas, shelled]	Insert	T*0.05	Root and tuber vegetables [except potato]	Insert	T*0.05	<p>NEDI = 4% of ADI</p>												
Peas [except peas, shelled]	Insert	T*0.05																	
Root and tuber vegetables [except potato]	Insert	T*0.05																	

<p>Phosphine Phosphine is a rodenticide. Zinc phosphide reacts with acidic digestive fluids liberating phosphine gas which interferes with cell respiration. It is registered for use as a mouse and rat poison in agricultural situations, specifically in sugarcane. Residues data for sugarcane and the soil following treatment were evaluated. Residues in sugarcane were not detected following application at 10 x the expected treatment rate. Under the proposed use pattern residues above the LOQ are not expected in food commodities. The TGA supported registration of zinc phosphide on the basis that MRLs would be established at or about the LOQ. The recommended MRL is at the LOQ.</p>	<p>ADI not established ARfD not established</p> <p>Therefore no dietary exposure estimates have been calculated.</p> <p>Residues of phosphine are not anticipated in treated produce. Use of zinc phosphide under the proposed use pattern is not expected to increase dietary exposure to phosphine.</p>						
<table border="0"> <tr> <td data-bbox="177 696 715 1003">Sugar cane</td> <td data-bbox="715 696 884 1003">Omit</td> <td data-bbox="884 696 986 1003">T*0.01</td> </tr> <tr> <td></td> <td data-bbox="715 696 884 1003">Substitute</td> <td data-bbox="884 696 986 1003">*0.01</td> </tr> </table>	Sugar cane	Omit	T*0.01		Substitute	*0.01	
Sugar cane	Omit	T*0.01					
	Substitute	*0.01					
<p>Pyraclostrobin Pyraclostrobin is a fungicide. It is used to control early and late blight in potatoes. Residues data from Australian and international trials indicate no detectable residues following application under the proposed use pattern. Also, when the chemical was applied at 6.7 x the proposed rate no detectable residues were found. The recommended MRL is at the LOQ.</p>	<p>NEDI = <1% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0"> <tr> <td data-bbox="986 1003 1203 1240"><u>2-6 years</u></td> <td data-bbox="1203 1003 1394 1240"><u>2+ years</u></td> </tr> <tr> <td data-bbox="986 1003 1203 1240">1</td> <td data-bbox="1203 1003 1394 1240"><1</td> </tr> </table>	<u>2-6 years</u>	<u>2+ years</u>	1	<1		
<u>2-6 years</u>	<u>2+ years</u>						
1	<1						
<table border="0"> <tr> <td data-bbox="177 1240 715 1270">Potato</td> <td data-bbox="715 1240 884 1270">Insert</td> <td data-bbox="884 1240 986 1270">*0.02</td> </tr> </table>	Potato	Insert	*0.02				
Potato	Insert	*0.02					
<p>2-(thiocyanomethylthio)benzothiazole 2-(thiocyanomethylthio)benzothiazole is a thiazole fungicide. The permit for its use as a pre-planting fungicidal treatment on cotton seed has expired. APVMA confirms that there are no registered uses for this chemical. Accordingly no MRLs are required and the whole entry for this chemical is to be omitted.</p>	<p>Complete chemical deletion – dietary exposure assessment not required.</p>						
<table border="0"> <tr> <td data-bbox="177 1270 715 1957">Cotton seed</td> <td data-bbox="715 1270 884 1957">Omit</td> <td data-bbox="884 1270 986 1957">T*0.01</td> </tr> </table>	Cotton seed	Omit	T*0.01				
Cotton seed	Omit	T*0.01					

SUMMARY OF SUBMISSIONS RECEIVED

Submitter	Comments raised
Food Technology Association of Victoria Inc.	Supported this Application.
Country Women's Association of New South Wales Social Issues Committee	The CWA expressed concern about increasing MRLs of pesticides in foods in relation to effects of accumulated ingestion over time. The CWA notes background reading indicates that there does not appear to have been harm done. The CWA states that a closer check on limits is imperative.
Department of Health SA	Supported this Application.
Queensland Health Environmental Health Unit	Supported this Application.
Australian Food and Grocery Council	Supported option 2(b) to include new or increase some existing MRLs, however rejects option 2(a) on the grounds that it would result in a technical barrier to trade and damage Australian industry. AFGC expressed concern that where MRLs at or below 0.1 mg/kg for which there are no public health or safety concerns are deleted, this may create a barrier to international trade that provides no public health benefit.
Department of Human Services Victoria	Supported this Application.