

7-06 4 October 2006

FINAL ASSESSMENT REPORT

APPLICATION A572

MAXIMUM RESIDUE LIMITS (OCTOBER, NOVEMBER, DECEMBER 2005)

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 A572 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.

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

Dietary exposure assessments indicate that setting the maximum residue limits as proposed does not present any public health and safety concerns.

There are no MRLs for antibiotic residues in this Application.

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 the chemicals and has established acceptable daily intakes (ADI) and where applicable acute reference doses (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 any 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 A572 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 Ministerial Council.

If the Ministerial Council does not request FSANZ to 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 Australian Pesticides and Veterinary Medicines Authority (APVMA) on 14 October, 4 November and 14 December 2005 seeking to vary the Code. The proposed variations to Standard 1.4.2 - Maximum Residue Limits would align Maximum Residue Limits (MRLs) in the Code for non-antibiotic agricultural and veterinary chemicals with the MRLs in the APVMA MRL Standard.

The MRL is the highest concentration of a chemical residue that is legally permitted or accepted in a food. The MRL does <u>not</u> 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. In relation to MRLs, FSANZ's role is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits.

FSANZ will <u>not</u> 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 conducts dietary exposure assessments in accordance with internationally accepted practices and procedures.

In summary, MRLs in the Code apply in relation to the <u>sale</u> of food under State and Territory food legislation and the <u>inspection</u> of imported foods by the Australian Quarantine and Inspection Service.

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 6272 5158.

1. Background

1.1 Current Standard

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.

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 Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) when variations to the Code are approved. If the Ministerial Council does not request a review of the draft variations to Standard 1.4.2, the MRLs are automatically adopted by reference into the food laws of the Australian States and Territories.

Appropriate toxicology, residue, animal transfer, processing and metabolism studies were provided to APVMA in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997* to support the MRLs in the commodities as outlined in this Application. Full evaluation 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 A572:

- changing the residue definitions for chlorothalonil, glufosinate and glufosinate ammonium, and sethoxydim;
- adding temporary MRLs at the limit of quantification for new chemicals bupivacaine, cetrimide and lignocaine;
- adding MRLs at the limit of quantification for new chemical isoxaben;
- deleting MRLs for certain foods for fipronil, spinosad and thiodicarb;
- deleting the chemical and all associated entries for propamocarb;
- adding MRLs for certain foods for buprofezin, metaldehyde, methomyl, metolachlor, propachlor, propiconazole, spinosad, and thiodicarb;
- adding temporary MRLs for certain foods for abamectin, chlorfenapyr, chlorothalonil, chlorpyrifos, chlorthal-dimethyl, cyprodinil, endosulfan, fluazifop-butyl, fludioxonil, glufosinate and glufosinate –ammonium, glyphosate, imidacloprid, iprodione, metolachlor and sethoxydim;
- removing the temporary status of existing MRLs for certain foods for fipronil, forchlorfenuron, glufosinate and glufosinate –ammonium, metaldehyde, methomyl, procymidone and spinosad;
- increasing MRLs for certain foods for abamectin, azoxystrobin, buprofezin, methomyl, paclobutrazol and spinosad;
- decreasing MRLs for certain foods for endosulfan and methomyl;
- making administrative changes among MRLs that do not result in variations to MRLs for certain foods for diflufenican, imidacloprid and spinosad; and
- amending anomalies among commodity names for eggplant, pome fruits and corn.

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 Temporary MRLs Requested for Bupivacaine, Cetrimide and Lignocaine

Temporary MRLs have been requested at the LOQ for bupivacaine, cetrimide and lignocaine. OCS has not established ADIs or set ARfDs for these chemicals, therefore no estimates of the national daily or acute dietary exposures (NEDIs and NESTIs) have been conducted. These terms are explained in the risk assessment section of this report. Bupivacaine and lignocaine are local anaesthetics. Cetrimide is an antiseptic. These chemicals are active ingredients in the product Tri-Sulven. APVMA has issued a permit for its use. The product is used topically to prevent pain in lambs intended for wool production following mulesing. Animals will be kept in wool production for at least a year; negligible residues are expected. Residues are unlikely to occur in foods. Under the permit, a 90 day withholding period (WHP) has been established. Although this relatively long meat WHP is not considered necessary, it has been included to provide an absolute guarantee of safety to overcome any concerns that may arise in the absence of ADIs for the active constituents. FSANZ considers that the proposed MRLs do not present health and safety concerns.

1.6 Antibiotic MRLs

There are no MRLs for antibiotic¹ residues in this Application.

1.7 Minor Technical Amendments

The commodity name for eggplant is 'Egg plant'. The entry under indoxacarb in Schedule 1 of Standard 1.4.2 is to be changed to 'Egg plant' to make it consistent with other entries. Similarly, the commodity name for pome fruits is 'Pome fruits'; the entries under indoxacarb, kresoxim-methyl and novaluron are to be changed to 'Pome fruits' consistent with other entries. Anomalies among sweet corn commodity names are to be corrected; accordingly, the sweet corn commodity name under carbofuran is to be changed to 'Sweet corn (kernels)' and the commodity name under parathion-methyl is to be changed to 'Sweet corn (corn-on-the-cob)' in line with the APVMA MRL Standard. The chemical name 'spinosad' is to be changed to 'Spinosad' consistent with other chemical name headings in Schedule 1. These are minor technical amendments to ensure consistency of use of commodity names and format of chemical names.

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.

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

• Food produced or imported into New Zealand that complies with the *New Zealand* (*Maximum Residue Limits of Agricultural Compounds*) Food Standards, 2005 (No. 2) 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, provided that any residues in treated produce do not exceed MRLs. Changes to Australian MRLs reflect the changing patterns of agricultural and veterinary chemicals available to farmers. These changes include both the development of new products and crop uses, and the withdrawal of older products following review.

3. Objectives

In assessing this Application FSANZ aims to ensure that the proposed MRLs do not present public health and safety concerns and that the sale of legally treated food is permitted. APVMA has already established MRLs under its legislation, and now seeks to have the amendments included in the Code through this Application to vary Standard 1.4.2.

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

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

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

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

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

4. Key Assessment Questions

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

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

In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from potentially treated foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will <u>not</u> approve MRLs for inclusion in the Code where the dietary exposure to the residues of a chemical could represent a risk to public health and safety. In assessing this risk, FSANZ conducts 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 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

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 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. These calculations provide information on the level of a chemical that is consumed for each food and take into account the consumption of processed foods e.g. apple pie and bread. The estimated exposure for each food is added together to provide the total dietary exposure to a chemical from all foods with MRLs.

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

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

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

In agricultural and animal husbandry this is not the case, but for the purposes of undertaking a risk assessment, it is important to be conservative in the absence of reliable data to refine the dietary exposure estimates further.

5.3.2 Acute Dietary Exposure Assessment

The National Estimated Short Term Intake (NESTI) is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated for raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis.

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

6. Risk Assessment Summary

APVMA assesses a range of data when considering the proposed use of a chemical product on a food. These data enable APVMA to determine what the likely residues of a chemical will be on a treated food. These data also enable APVMA to determine what the maximum residues will be on a treated food if the chemical product is used as proposed and from this, APVMA determines an 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 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 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. The information needed to make a final assessment of proposed changes includes information from public submissions.

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 A572, there are no options other than a variation to Standard 1.4.2.

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.

FSANZ recommends approving options 2(a) <u>and</u> 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.

COMMUNICATION

9. Communication and Consultation Strategy

FSANZ decided, pursuant to section 36 of the FSANZ Act to omit to invite public submissions in relation to Application A572 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 gave due 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), Australian Food and Grocery Council (AFGC), Dr Alison Bleaney OBE, Queensland Department of Health, and Department of Human Services Victoria (DHS).

Submissions from FTAV, Queensland Department of Health 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 to include new MRLs, increase, delete, decrease or change the temporary or permanent status of some existing MRLs.

10.1 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.

10.1.1 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.

10.2 Summarised Submission from Dr Alison Bleaney OBE

Dr Bleaney notes that commonly used pesticides can cause ill health, and many diseases including cancers, cardiovascular disease, obesity, allergies, fertility problems, immune system disturbances, neurodegenerative diseases, and some mental illnesses. Children, the developing foetus, the aged and the sick are particularly vulnerable. People should have a right to buy and consume non toxic foods. People have a choice when they are informed and understand the consequences of their actions. At present food packaging does not contain information about pesticide contamination. Organic foods are more expensive than nonorganic produce. This discriminates against lower socio-economic groups. The average shopper has no idea which goods are produced using pesticides and what the potential effects may be. Pesticides in food add to the over 4000 toxic chemicals already in a person's body and the combined effects are unknown. The ATDS does not reflect the total daily pesticide dose that an individual is exposed to from all sources. There is no testing for pesticides in food produced in Tasmania.

Dr Bleaney states that allowing pesticide residues, or any introduced substances such as growth factors that can cause genetic changes, cannot be condoned and that labelling should reflect potential presence of pesticides. Considering current research and medical findings, it can no longer be considered a safe or ethical practice to sell food not labelled indicating maximum possible pesticide residues.

10.2.1 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, part of the TGA, has undertaken a toxicological assessment of the chemicals for APVMA and has established an acceptable daily intake (ADI) and where appropriate an acute reference dose (ARfD) for each chemical. FSANZ accepts these assessments and conducts dietary exposure assessments in accordance with internationally accepted practices and procedures. 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 at harvest; and residues are usually reduced during storage, preparation, commercial processing, washing and cooking.

FSANZ does not consider that introducing labelling of foods with maximum potential levels of pesticide residues is appropriate. Use of MRLs in this manner would be misleading as it may give the impression that each pesticide registered for use on a given commodity is applied in the production of foods derived from it and that the entire national production of each food may contain residues equivalent to the MRL.

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. Tasmania is included in ATDS sampling.

FSANZ does not have any statutory role in questioning the merits or enforcement of agricultural or veterinary chemical use. APVMA is responsible for assessing and registering agricultural and veterinary chemical products.

Before registering a product and determining usage patterns, withholding periods and other label instructions, APVMA independently evaluates its safety and performance, making sure that the health and safety of people, animals and the environment are protected. Decisions are based on scientific evaluations of Australian and international data including field trial studies. APVMA has a program of reviewing currently registered chemicals in the light of new data. State and territory governments regulate the use of agricultural and veterinary chemicals after sale.

10.3 Other Correspondence – NSW Food Authority

NSW Food Authority supports options 2(a) and 2(b).

NSW Food Authority supports updating the Code to reflect the current registration status of agricultural and veterinary chemicals in use in Australia and to protect public health and safety by minimising residues in foods.

10.4 Other Correspondence – Australian Food and Grocery Council

AFGC expressed concern that spinosad MRL permissions for brassicas were to be removed.

APVMA has not requested any changes to spinosad MRLs for brassicas in Application A572. No changes to spinosad MRLs for brassicas are to be made through this application. The MRL for assorted tropical and sub-tropical fruits with inedible peel except banana and kiwifruit is to be reduced. (The banana MRL is to be increased and the kiwifruit MRL will remain the same.) No spinosad permissions are to be removed and no other reductions are proposed in A572. The proposed changes are outlined in Attachment 2.

10.5 World Trade Organization

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

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

Application A572 includes requests to vary MRLs in the Code that are addressed in the international Codex standard. MRLs in the Application also relate to chemicals used in the production of heavily traded agricultural commodities that may indirectly have a significant effect on trade of derivative food products between WTO members.

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

10.6 Codex Alimentarius Commission MRLs

Codex 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 A572 that are addressed in the international Codex standard.

Chemical	Proposed MRL	Codex MRL
Food	mg/kg	mg/kg
Abamectin		
Lettuce, head	T0.05	
Lettuce, leaf		0.05
Strawberry	0.1	0.02
Tomato	0.05	0.02
Imidacloprid		
Bananas	T0.1	0.05
Leafy vegetables	T5	
Lettuce, head		2
Iprodione		
Adzuki bean	T0.1	
Beans (dry)		0.1
Methomyl		
Brassica (cole or cabbage)		
vegetables, Head cabbages,		
Flowerhead brassicas	2	
Cabbages, head	Omit 1	5 2
Cauliflower		2
Spinosad		
Assorted tropical and sub-tropical		
fruits-inedible peel	0.3	
Celery	2	2
Citrus fruits	0.3	0.3
Fruiting vegetables, cucurbits	0.2	0.2
Kiwifruit*	Omit 0.3	0.05
Thiodicarb		see Methomyl [†]
Brassica leafy vegetables	Omit 1	
Brassica (cole or cabbage)		
vegetables, Head cabbages,		
Flowerhead brassicas	2	
Cabbages, Head		5
Cauliflower		2

^{*} Kiwifruit is included under assorted tropical and sub-tropical fruits-inedible peel

10.7 Imported Foods

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.

[†] Codex Committee on Pesticide Residues has combined the listings for thiodicarb and methomyl under methomyl.

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 10.1 above.

Chemical
Food
Chlorthal-dimethyl
Lettuce, head
Lettuce, leaf
Endosulfan
Strawberry
Fipronil
Berries and other small fruits [except wine-
grapes]
Methomyl
Fruiting vegetables, cucurbits
Propamocarb
Rice
Spinosad
Assorted tropical and sub-tropical fruits-
inedible peel [except banana and kiwifruit]
Thiodicarb
Brassica leafy vegetables

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 include new MRLs, increase, delete, decrease or change the temporary or permanent status of some existing MRLs in Schedule 1 of Standard 1.4.2 – Maximum Residue Limits.

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, the commodity name for the chemicals appearing in Column 1 of the Table to this sub- item, substituting the commodity name in Column 2 –

COLUMN 1	COLUMN 2
CARBOFURAN	SWEET CORN (KERNELS)
INDOXACARB	EGG PLANT
	POME FRUITS
KRESOXIM-METHYL	POME FRUITS
Novaluron	POME FRUITS
PARATHION-METHYL	FRUITING VEGETABLES, OTHER
	THAN CUCURBITS [EXCEPT
	SWEET CORN (CORN-ON-THE-
	COB)]
	SWEET CORN (CORN-ON-THE-
	COB)

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

Propamocarb

[1.3] omitting from Schedule 1 the chemical residue definitions for the chemicals appearing in Column 1 of the Table to this sub-item, substituting the chemical residue definition appearing in Column 2 –

COLUMN 1	Column 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
GLUFOSINATE AND GLUFOSINATE-AMMONIUM	SUM OF GLUFOSINATE-AMMONIUM, N-
	ACETYL GLUFOSINATE AND 3-
	[HYDROXY(METHYL)-PHOSPHINOYL]
	PROPIONIC ACID, EXPRESSED AS
	GLUFOSINATE (FREE ACID)
SETHOXYDIM	SUM OF SETHOXYDIM AND METABOLITES
	CONTAINING THE 5-(2-
	ETHYLTHIOPROPYL)CYCLOHEXENE-3-ONE
	AND 5-(2-ETHYLTHIOPROPYL)-
	5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES
	AND THEIR SULFOXIDES AND SULFONES,
	EXPRESSED AS SETHOXYDIM

[1.4] inserting in Schedule 1–

BUPIVACAINE	
BUPIVACAINE	_
SHEEP, EDIBLE OFFAL OF	T*0.02
SHEEP MEAT (IN THE FAT)	T*0.02
CETRIMIDE	
Cetrimide	
SHEEP, EDIBLE OFFAL OF	T*1.0
SHEEP MEAT (IN THE FAT)	T*1.0
Tooy in the	
ISOXABEN	
ISOXABEN	10.01
ASSORTED TROPICAL AND SUB-	*0.01
TROPICAL FRUITS - EDIBLE PEEL	
ASSORTED TROPICAL AND SUB-	*0.01
TROPICAL FRUITS - INEDIBLE PEEL	
CITRUS FRUITS	*0.01
GRAPES	*0.01
POME FRUITS	*0.01
STONE FRUITS	*0.01
TREE NUTS	*0.01
LIGNOCAINE	
LIGNOCAINE	
SHEEP, EDIBLE OFFAL OF	T*0.02
SHEEP MEAT (IN THE FAT)	T*0.02

$[1.5] \quad \textit{omitting from Schedule 1 the foods and associated MRLs for each of the following chemicals} -$

CHLORTHAL-DIMETHYL	
CHLORTHAL-DIMETHYL	
VEGETABLES	5
DIFLUFENICAN	
DIFLUFENICAN	
LUPIN	0.05
Endosulfan	
SUM OF A- AND B- ENDOSULFAN AND ENDOSU	JLFAN
SULPHATE	
BERRIES AND OTHER SMALL FRUITS	T2

FIPRONIL	
SUM OF FIPRONIL, THE SULPHENYL METABOLITE (5-	
AMINO-1-[2,6-DICHLORO-4-	
(TRIFLUOROMETHYL)PHENYL]-4-	
[(TRIFLUOROMETHYL) SULPHENYL]-1H-PYRA	AZOLE-
3-CARBONITRILE),	
THE SULPHONYL METABOLITE (5-AMINO-1-	
DICHLORO-4-(TRIFLUOROMETHYL)PHENYI	
[(TRIFLUOROMETHYL)SULPHONYL]-1H-PYRA	
3-CARBONITRILE), AND THE TRIFLUOROME	
METABOLITE (5-AMINO-4-TRIFLUOROMETH [2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENY	
PYRAZOLE-3-CARBONITRILE)	1LJ-111-
BERRIES AND OTHER SMALL FRUITS	T*0.01
[EXCEPT WINE GRAPES]	1 0.01
[EACELL WINE ORALES]	
IMIDACLOPRID	
SUM OF IMIDACLOPRID AND METABOLIT	ES
CONTAINING THE 6-CHLOROPYRIDINYLMETH	
MOIETY, EXPRESSED AS IMIDACLOPRIE)
BRASSICA LEAFY VEGETABLES	5
CHERVIL	T5
JAPANESE GREENS	5
LETTUCE, HEAD	T5
LETTUCE, LEAF	T5
RUCOLA (ROCKET)	T5
METALDEHYDE	
METALDEHYDE	
	T1
METALDEHYDE TURMERIC ROOT	T1
METALDEHYDE TURMERIC ROOT METHOMYL	T1
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL	
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE (*METHOMYL OZ.)	
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL O' EXPRESSED AS METHOMYL	
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE (*METHOMYL OZ.)	
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB	XIME'),
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB	XIME'),
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD	XIME'),
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL	XIME'),
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE (*METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL	XIME'),
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUBTROPICAL FRUITS — INEDIBLE PEEL	XIME'),
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUBTROPICAL FRUITS — INEDIBLE PEEL SPINOSAD	*0.01
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUBTROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	*0.01
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL O' EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB	*0.01
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL O' EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL	*0.01
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE (*METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND	*0.01
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE (*METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUBTROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUBTROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT]	*0.01
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL O' EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT] BANANA	*0.01 T0.5
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL O' EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT] BANANA EGG PLANT	*0.01 T0.5
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL O' EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT] BANANA EGG PLANT KIWIFRUIT	*0.01 T0.5
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL O' EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT] BANANA EGG PLANT KIWIFRUIT MELONS [EXCEPT WATERMELON]	*0.01 T0.5 0.2 0.2 0.3 T0.2
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL O' EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT] BANANA EGG PLANT KIWIFRUIT	*0.01 T0.5

THIODICARB SUM OF THIODICARB, METHOMYL AND METHOMYLOXIME, EXPRESSED AS THIODICARB SEE ALSO METHOMYL BRASSICA LEAFY VEGETABLES 1

 $[1.6] \quad \textit{inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals} \, - \,$

ABAMECTIN	
SUM OF AVERMECTIN B1A, AVERMECTIN B1B A	
(z)-8,9 AVERMECTIN B1A, AND (z)-8,9 AVERME	CTIN
B1B	
LETTUCE, HEAD T	0.05
_	
Buprofezin	
Buprofezin	
DRIED GRAPES (CURRANTS,	1
RAISINS AND SULTANAS)	
CHLORFENAPYR	_
Chlorfenapyr	
SHALLOT	T1
SPRING ONION	T1
-	
CHLOROTHALONIL	
COMMODITIES OF PLANT ORIGIN: CHLOROTHALO	NIL
COMMODITIES OF ANIMAL ORIGIN: SUM OF	
CHLOROTHALONIL AND 4-HYDROXY-2, 5, 6-	
TRICHLOROISOPHALONITRILE METABOLITE,	
EXPRESSED AS CHLOROTHALONIL	TD2
EDIBLE OFFAL (MAMMALIAN)	T3
MEAT (MAMMALIAN) (IN THE FAT)	T2
MILKS T	0.05
CHLORPYRIFOS	
CHLORPYRIFOS	
	T1.0
CHLORTHAL-DIMETHYL	
CHLORTHAL-DIMETHYL	
LETTUCE, HEAD	T1
LETTUCE, LEAF	T1
VEGETABLES [EXCEPT AS	5
OTHERWISE LISTED UNDER THIS	
CHEMICAL]	
Cyprodinil	
Cyprodinil	
PEAS	T2

Endosulfan
SUM OF A- AND B- ENDOSULFAN AND ENDOSULFAN
SULPHATE
BERRIES AND OTHER SMALL FRUITS T2
[EXCEPT STRAWBERRY]
STRAWBERRY T0.5
FLUAZIFOP-BUTYL
FLUAZIFOP-BUTYL
EGG PLANT T0.1
FLUDIOXONIL
COMMODITIES OF ANIMAL ORIGIN: SUM OF
FLUDIOXONIL AND OXIDISABLE METABOLITES,
EXPRESSED AS FLUDIOXONIL
COMMODITIES OF PLANT ORIGIN: FLUDIOXONIL
PEAS T2
GLUFOSINATE AND GLUFOSINATE-AMMONIUM
SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL
GLUFOSINATE AND 3-[HYDROXY(METHYL)-
PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS
GLUFOSINATE (FREE ACID)
SAFFRON T*0.05
GLYPHOSATE
SUM OF GLYPHOSATE AND
AMINOMETHYLPHOSPHONIC ACID (AMPA)
METABOLITE, EXPRESSED AS GLYPHOSATE
SAFFRON T*0.05
IMIDACLOPRID
SUM OF IMIDACLOPRID AND METABOLITES
CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE
MOIETY, EXPRESSED AS IMIDACLOPRID
BANANA T0.1
LEAFY VEGETABLES T5
IPRODIONE
IPRODIONE
ADZUKI BEAN (DRY) T0.1
METALDEHYDE METALDEHYDE
CEREAL GRAINS 1
OILSEED 1
Pulses 1
SPICES 1
TEAS (TEA AND HERB TEAS)

METHOMYL	
SUM OF METHOMYL AND METHYL	
HYDROXYTHIOACETIMIDATE ('METHOMYL OX	IME'),
EXPRESSED AS METHOMYL	
SEE ALSO THIODICARB	
BRASSICA (COLE OR CABBAGE)	2
VEGETABLES, HEAD CABBAGES,	
FLOWERHEAD BRASSICAS	
METOLACHLOR	
METOLACHLOR	
Rhubarb	*0.05
PACLOBUTRAZOL	
PACLOBUTRAZOL	
ASSORTED TROPICAL AND SUB-	*0.01
TROPICAL FRUITS – INEDIBLE PEEL	
[EXCEPT AVOCADO]	
AVOCADO	T0.1
_	
PROPACHLOR	
PROPACHLOR	
LETTUCE, HEAD	*0.02
LETTUCE, LEAF	*0.02
PROPICONAZOLE	
PROPICONAZOLE	dt 0. 0.2
SWEET CORN (CORN-ON-THE-COB)	*0.02
SETHOXYDIM	
SUM OF SETHOXYDIM SUM OF SETHOXYDIM AND METABOLITE	c
CONTAINING THE 5-(2-	3
ETHYLTHIOPROPYL)CYCLOHEXENE-3-ONE A	ND 5-
ETHILIHOFKOFILICICLOHEAENE-3-ONE A	IND J
(2-ETHYLTHIOPROPYL)-	AND
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES	
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS	
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM	SED AS
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET)	T*0.1
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET) EGG PLANT	T*0.1 T*0.1
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET)	T*0.1
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET) EGG PLANT PEPPERS	T*0.1 T*0.1
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET) EGG PLANT PEPPERS SPINOSAD	T*0.1 T*0.1
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET) EGG PLANT PEPPERS	T*0.1 T*0.1
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET) EGG PLANT PEPPERS SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	T*0.1 T*0.1 T*0.1
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET) EGG PLANT PEPPERS SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB	T*0.1 T*0.1 T*0.1
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET) EGG PLANT PEPPERS SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB TROPICAL FRUITS – INEDIBLE PEEL	T*0.1 T*0.1 T0.7
(2-ETHYLTHIOPROPYL)- 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES THEIR SULFOXIDES AND SULFONES, EXPRESS SETHOXYDIM CHARD (SILVER BEET) EGG PLANT PEPPERS SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL COFFEE BEANS	T*0.1 T*0.1 T0.7

THIODICARB SUM OF THIODICARB, METHOMYL AND METHOMYLOXIME, EXPRESSED AS THIODICARB SEE ALSO METHOMYL BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS

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

ABAMECTIN	
SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND	
(Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN	
в1в	
STRAWBERRY 0.1	
TOMATO 0.05	
AZOXYSTROBIN	
AZOXYSTROBIN	
POTATO 0.05	
BUPROFEZIN	
Buprofezin	
GRAPES 0.3	
FIPRONIL	
SUM OF FIPRONIL, THE SULPHENYL METABOLITE (5-	
AMINO-1-[2,6-DICHLORO-4-	
(TRIFLUOROMETHYL)PHENYL]-4-	
[(TRIFLUOROMETHYL) SULPHENYL]-1H-PYRAZOLE-	
3-CARBONITRILE),	
THE SULPHONYL METABOLITE (5-AMINO-1-[2,6-	
DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-4-	
[(TRIFLUOROMETHYL)SULPHONYL]-1H-PYRAZOLE-	
3-CARBONITRILE), AND THE TRIFLUOROMETHYL	
METABOLITE (5-AMINO-4-TRIFLUOROMETHYL-1-	
[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-1H-	
PYRAZOLE-3-CARBONITRILE)	
WINE GRAPES *0.01	
FORCHLORFENURON	
FORCHLORFENURON	
GRAPES *0.01	
GLUFOSINATE AND GLUFOSINATE-AMMONIUM	
SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL	
GLUFOSINATE AND 3-[HYDROXY(METHYL)-	
PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS	
GLUFOSINATE (FREE ACID)	
OLIVES *0.1	
METALDEHYDE	
METALDEHYDE	
HERBS 1	

METHOMYL	
SUM OF METHOMYL AND METHYL	
HYDROXYTHIOACETIMIDATE ('METHOMYL OXII	ΜΕ'),
EXPRESSED AS METHOMYL	
SEE ALSO THIODICARB	
FRUITING VEGETABLES, CUCURBITS	0.1
PROCYMIDONE	
Procymidone	
LENTIL (DRY)	0.5
, ,	
SPINOSAD	
SUM OF SPINOSYN A AND SPINOSYN D	
CELERY	2.0
CITRUS FRUITS	0.3
FRUITING VEGETABLES, CUCURBITS	0.2

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

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

NOTES ON TERMS USED IN THE TABLE

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

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

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

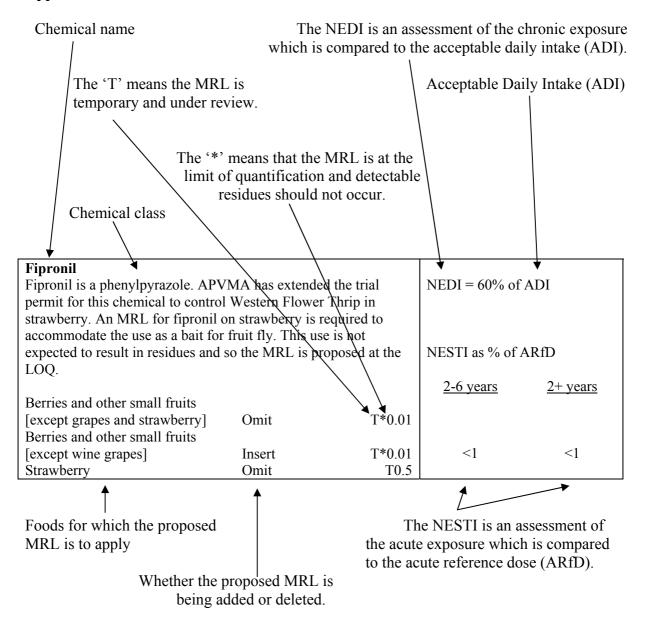
NEDI - National Estimated Dietary Intake - The NEDI represents a realistic estimate of chronic dietary exposure and is the preferred calculation. It may incorporate more specific food consumption data including that for particular sub-groups of the population. The NEDI calculation may take into account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

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

The NESTI calculation incorporates the large portion (97.5 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.

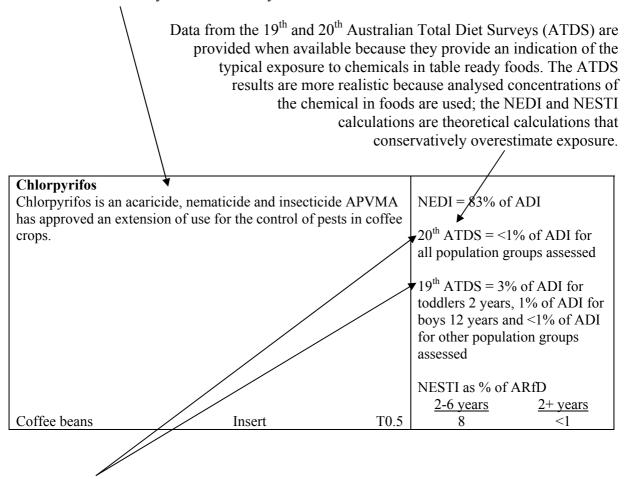
30

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.



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 A572 MAXIMUM RESIDUE LIMITS – OCTOBER NOVEMBER DECEMBER 2005

Requested MRLs			Dietary Exposi	ure Estimates
Abamectin Abamectin is an insecticide and acaricide with contact and stomach action. APVMA has issued a permit for its use on			NEDI = 64% of	î ADI
lettuce, strawberry and tomato	-	use on	NESTI as % of 2-6 years	
Lettuce, head	Insert	T0.05	9	<u>2+ years</u> 5
Strawberry	Omit	0.02		
3	Substitute	0.1	22	6
Tomato	Omit	0.01		
	Substitute	0.05	22	9
Azoxystrobin Azoxystrobin is a strobilurin fungicide. It has translaminar and systemic properties.			NEDI = 2% of A	ADI
Potato	Omit Substitute	*0.01 0.05		
Bupivacaine Bupivacaine is a local anaesthetic. It is an active ingredient in the product Tri-Sulven. Cetrimide and lignocaine are also active ingredients. APVMA has issued a permit for its use. The product is used topically to prevent pain in lambs intended for wool production following mulesing. Animals will be kept in wool production for at least a year; negligible residues are expected. Temporary MRLs have been requested at the LOQ for each active constituent. Under the permit, a 90 day WHP has been established. Although this relatively long WHP is not considered necessary, it has been included to provide an absolute guarantee of safety to overcome any concerns that may arise in the absence of ADIs for the active constituents. New Chemical Residue definition: Bupivacaine Sheep, edible offal of Insert T*0.02			ADI not establic ARfD not establic ARfD not establic ARfD not establic are stimates have be stimated and second and second and second are port.	etary exposure been calculated.
Sheep meat (in the fat) Buprofezin	Insert	T*0.02		
Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae.			NEDI = 14% of	^c ADI
Dried grapes (currants, raising sultanas)	Insert	1		
Grapes	Omit	T*0.01		
1	Substitute	0.3		

Carbofuran			
This is a minor technical amendm		sistency of use	Dietary exposure assessment
of the commodity name for sweet corn kernels.			not required
Common literana na			
Commodity name:			
Omit: Sweet corn			
Omit. Sweet com			
Substitute: Sweet corn (kernels)			
Cetrimide			
Cetrimide is an antiseptic. It is an	active ingredient	in the product	ADI not established
Tri-Sulven. Bupivacaine and ligne	•		ARfD not established
ingredients. APVMA has issued a			
is used topically to prevent pain in			Therefore no dietary exposure
production following mulesing. A			estimates have been calculated.
production for at least a year; neg			
Temporary MRLs have been requ			Refer to details in opposite
active constituent. Under the perm	•		column and section 1.2 of this
established. Although this relative			report.
necessary, it has been included to			
of safety to overcome any concern			
of ADIs for the active constituent	S.		
New Chemical			
Residue definition: Cetrimide			
Chaon adible offel of	Insert	T*1.0	
Sheep, edible offal of	Insert	T*1.0	
Sheep meat (in the fat) Chlorfenapyr	HISCIT	1.1.0	
1 V	NEDI = 3% of ADI		
Chlorfenapyr is an insecticide. APVMA has issued a permit for its use on shallots and spring onions.			NLDI – 370 01 ADI
no use on sharrots and spring one			
Shallot	Insert	T1	
Spring onion	Insert	T1	
Chlorothalonil			
Chlorothalonil is a fungicide used			NEDI = 78% of ADI
chocolate spot in pulses. APVMA			th th
on stock feed pulses. Grazing or f			20^{th} and 19^{th} ATDS = <1% of
milk for human consumption on t			ADI for all population groups
Residues may occur in milk as a r	result of feeding li	ivestock grain.	assessed
Residue definition:			
Residue defilition.			
Omit: Chlorothalonil			
Substitute: Commodities of plan	_		
Commodities of animal origin:	Commodities of animal origin: Sum of chlorothalonil and		
4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite			
expressed as chlorothalonil			
	T .	TF.0	
Edible offal (mammalian) Most (mammalian) (in the fat)	Insert	T3	
Meat (mammalian) (in the fat)	Insert	T2	
Milks	Insert	T0.05	

APVMA has issued a permit for its use on soil in blueberry crops. Residues are likely to be considerably lower than those arising from foliar applications.			NEDI = 88% 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
Blueberries	Insert	T1.0	2-6 years 2+ years 21 12
Chlorthal-dimethyl Chlorthal-dimethyl is a pre emerge issued a permit for its use to control This chemical is registered for sim crops. Lettuce, head Lettuce, leaf Vegetables Vegetables [except as otherwise]	ent herbicide. APV	MA has n lettuce.	NEDI = 45% of ADI
listed under this chemical] Cyprodinil Cyprodinil is a systemic fungicide that inhibits penetration and mycelial growth both inside the plant and on leaf surfaces. APVMA has issued a permit for its use to control sclerotinia rot and grey mould on snow, sugar snap and garden peas.			NEDI = 12% of ADI
Peas Insert T2 Diflufenican Diflufenican is a herbicide used to control broadleaf weeds; it blocks carotenoid biosynthesis. Given that an MRL of 0.05 mg/kg is in place for pulses, a separate MRL for lupins is not required.			NEDI = <1% of ADI
Lupin	Omit	0.05	

stomach action used to control western flower thrips. APVMA has issued a permit for its use on strawberry crops. The change to exclude strawberries from berries and other small fruits is a consequential amendment.			NEDI = 27% of A Endosulfan Final Report June 2005 20 th ATDS = <1% all population gro 19 th ATDS = 1% adult females 25- 12 years, toddlers infants 9 months; for adult males 23 girls 12 years	Review 6) 6 of ADI for pups assessed of ADI for 34 years, boys 5 2 years and <1% of ADI
			NESTI as % of A	RfD
			2-6 years	2+ years
Berries and other small fruits	Omit	T2		
Berries and other small fruits	Insert	Т2		
[except strawberry] Strawberry	Insert	T0.5	14	4
Fipronil	msert	10.5	11	'
Fipronil is a selective insecticide u	sed in various crops	. The	NEDI = 76% of A	ADI
proposed use is for a directed spra				
vines. Residues data from Australi	an field trials indica	te residues	NESTI as % of A	RfD
will be below the LOQ.				
			<u>2-6 years</u>	2+ years
Berries and other small fruits	Omit	T*0.01		
[except wine grapes]	Omit	T*0.01		
Wine grapes	Substitute	*0.01	0	6
Fluazifop-butyl	Substitute	0.01	U	0
Fluazifop-butyl (Fluazifop) is a he	rbicide used to cont	rol grass	NEDI = 69% of A	ADI
weeds in broad leaf crops. APVM		_	0,70011	101
use on eggplant. The use pattern is				
pattern for tomatoes and capsicum				
Egg plant	Incont	TO 1		
Egg plant Fludioxonil	Insert	T0.1		
Fludioxonil is a non-systemic fung	vicide APVMA has	issued a	NEDI = 2% of A	DI
permit for its use to control sclerot	-		11ED1 2700171	Di
snow, sugar snap and garden peas.				
, 5 , 1 8				
Peas	Insert	T2		
Forchlorfenuron		.	NEDI = <0.1% o	CADI
	Forchlorfenuron is a cytokinin plant growth regulator. It is to be			t ADI
used to increase berry size in table and international trials indicate res	• 1		DIAMOND mod	ellina
and international trials indicate les	ordinacs will be below	uic LOQ.	estimated chronic	
			exposure of <0.19	•
			mean consumers	
			incan consumers	01
			forchlorfenuron a	and <0.2% of
Grapes	Omit Substitute	T*0.01 *0.01		and <0.2% of percentile (high

Glufosinate and Glufosinate-ammonium Glufosinate-ammonium is a non-selective contact herbicide used to control broadleaf and grass weeds. Australian and international trials conducted according to the proposed use pattern found no residues on harvested olives above the LOQ. APVMA has issued a permit for use of Glufosinate ammonium on saffron crops no later than 6 weeks prior to flowering. The recommended MRL is at the LOQ. Minor amendment to residue definition: Omit: Sum of Glufosinate-ammonium, N-acetyl glufosinate and 3-[hydroxy(methyl)-phosphinol] propionic acid, expressed as			NEDI = 7% of A	ADI
Glufosinate (free acid)				
Substitute: Sum of glufosinate-ar and 3-[hydroxy(methyl)-phosphi as glufosinate (free acid)				
Olives	Omit	T0.1		
Olives	Substitute	*0.1		
Saffron	Insert	T*0.05		
Glyphosate				
Glyphosate is a non-selective con	ntact herbicide. AP	VMA has	NEDI = 6% of A	\DI
issued a permit for its use on saffron crops no later than 6 weeks				
prior to flowering. The recommended MRL is at the LOQ.				
	_			
Saffron	Insert	T*0.05		
Imidacloprid			NEDI ON CA	DI
Imidacloprid is a systemic insect			NEDI = 9% of A	ADI
nicotinic receptors in the CNS ac				
has issued permits for its use to c foliar application and application				
lettuce aphid in lettuce, chicory,				
Following application at transpla				
be non detectable in lettuce, chic			NESTI as % of A	ARfD
oe non detectable in lettace, eme	ory, onarvo ana rad	ileemo.	2-6 years	2+ years
Banana	Insert	T0.1	<1	<1
Brassica leafy vegetables	Omit	5		
Chervil	Omit	T5		
Japanese greens	Omit	5		
Leafy vegetables	Insert	T5	11	8
Lettuce, head	Omit	T5		
Lettuce, leaf	Omit	T5		
Rucola (rocket)	Omit	T5		

Indoxacarb			
These are minor technical amendm use of commodity names for eggpla		ncy of	Dietary exposure assessment not required
Commodity name:			
Omit: Eggplant			
Substitute: Egg plant			
Omit: Pome fruit			
Substitute: Pome fruits			
Iprodione Iprodione is a fungicide. APVMA l		its use	NEDI = 43% of ADI
to control sclerotinia rot in adzuki b	peans.		$20^{\text{th}} \text{ ATDS} = 1\% \text{ of ADI for}$
			adult males 25 – 34 years and toddlers 2 years and <1% of ADI for other population groups assessed
Adzuki bean (dry)	Insert	T0.1	19 th ATDS = 1% of ADI for toddlers 2 years and <1% of ADI for other population groups assessed
Isoxaben			
Isoxaben is a selective pre-emergent herbicide principally absorbed by roots with translocation to stems and leaves. It disrupts root and stem development in germinating seeds. Extensive residue trials found no detectable residues following the proposed use pattern. Recommended MRLs are at the LOQ.			NEDI = <1% of ADI
New Chemical			
Residue definition: Isoxaben			
Assorted tropical and sub-tropical			
fruits – edible peel	Insert	*0.01	
Assorted tropical and sub-tropical			
fruits – inedible peel	Insert	*0.01	
Citrus fruits	Insert	*0.01	
Grapes	Insert	*0.01	
Pome fruits	Insert	*0.01	
Stone fruits	Insert	*0.01	
Tree nuts	Insert	*0.01	
Kresoxim-methyl This is a minor technical amendment to ensure consistency of use of the commodity name for pome fruits.		Dietary exposure assessment not required	
Commodity name:			
Omit: Pome fruit			
Substitute: Pome fruits			

-			
Lignocaine Lignocaine is a local anaesthetic product Tri-Sulven. Bupivacaine ingredients. APVMA has issued is used topically to prevent pain production following mulesing. production for at least a year; ne Temporary MRLs have been requestive constituent. Under the perestablished. Although this relative necessary, it has been included to of safety to overcome any conce of ADIs for the active constituent.	ADI not established ARfD not established Therefore no dietary exposure estimates have been calculated. Refer to details in opposite column and section 1.2 of this report.		
New Chemical Residue definition: Lignocaine			
Sheep, edible offal of	Insert	T*0.02	
Sheep meat (in the fat)	Insert	T*0.02	
Metaldehyde	1115011	1 0.02	
Metaldehyde is a molluscicide. It irreversibly destroys mucocytes. It is used in pellet form to control snails and slugs in agricultural crops and pastures. Direct contact with edible crop parts is considered unlikely. It degrades quickly on contact with water.			NEDI = 2% of ADI
Cereal grains	Insert	1	
Herbs	Omit	T1	
	Substitute	1	
Oilseed	Insert	1	
Pulses	Insert	1	
Spices Toos (Too and Harb toos)	Insert Insert	1 1	
Teas (Tea and Herb teas) Turmeric root	Omit	T1	
Methomyl	Omit	11	
Methomyl is a systemic insectical and stomach action. APVMA has tomato, capsicum, eggplant, cuc western flower thrips. No change	Methomyl + Thiodicarb NEDI = 89% of ADI		
or fruiting vegetables other than	cucurbits are recom	mended.	NESTI as % of ARfD
Brassica (cole or cabbage) vegetables, Head cabbages,			2-6 years 2+ years 17 Broccoli 6 2 Brussels sprouts 2
Flowerhead brassicas	Insert	2	13 Cauliflower 5
Cabbages, head	Omit	1	9 Cabbages, head 7
Fruiting vegetables, cucurbits	Omit Substitute	T0.2 0.1	8 Cucumber 3
Metolachlor			
Metolachlor is a pre-emergent herbicide. It inhibits germination. APVMA has issued a permit for its use on celery and rhubarb crops. No residues above the LOQ were detected in rhubarb following pre-planting treatment of soil at the proposed rate.			NEDI = <1% of ADI
Rhubarb	Insert	*0.05	

NT 1			
Novaluron This is a minor technical amandma	mt to ongure con	aistonay of	Dietary exposure assessment not
	This is a minor technical amendment to ensure consistency of		
use of the commodity name for pome fruits.			required
Commodity name:			
Omit: Pome fruit			
Substitutes Dame Smits			
Substitute: Pome fruits Paclobutrazol			
Paclobutrazol is a plant growth reg	ulator that produ	ices more	NEDI = 12% of ADI
compact plants and enhanced flower			NLDI — 1270 01 ADI
has received a permit application for			
thinning and increased fruit size.	115 abe on avo	200 101	
<i>S</i>			
Assorted tropical and sub-tropical			
fruits – inedible peel	Omit	*0.01	
Assorted tropical and sub-tropical			
fruits – inedible peel [except			
avocado]	Insert	*0.01	
Avocado	_		
	Insert	T0.1	
Parathion-methyl			D: .
This is a minor technical amendme			Dietary exposure assessment not
use of the commodity name for swe	eet corn (corn-o	n-tne-cob).	required
Commodity name:			
Commodity name.			
Omit: Fruiting vegetables other tha	n cucurbits [exc	ept sweet	
corn]	L	1	
_			
Substitute: Fruiting vegetables, oth	er than cucurbit	s [except	
sweet corn (corn-on-the-cob)]			
Omit: Sweet corn			
Substitute: Sweet corn (corn-on-the	a cob)		
Procymidone			
Procymidone is a fungicide. It inhib	hits triolyceride	synthesis It is	NEDI = 28% of ADI
used to control fungal infections in		symmesis. It is	112D1 20/0 01 AD1
and the control ranger intections in			20^{th} and 19^{th} ATDS = <1% of
			ADI for all population groups
			assessed
			NESTI as % of ARfD
			<u>2-6 years</u> <u>2+ years</u>
Lentil (dry)	Omit	T0.5	
	Substitute	0.5	5 1

Propachlor Propachlor is a selective herbicide; it is absorbed by seedling shoots with secondary translocation throughout the plant. APVMA has issued a permit for its use post transplanting of seedlings to control grass and broad leaf weeds in lettuce crops. Residues data indicate no detectable residues following the			NEDI = 6% of ADI
proposed use pattern.			
Lettuce, head	Insert	*0.02	
Lettuce, leaf	Insert	*0.02	
Propamocarb Rice	Omit	*0.1	Complete chemical deletion – dietary exposure assessment not required.
	Ollit	0.1	required.
Propiconazole Propiconazole is a systemic foliar fungicide with both protective and curative action. APVMA has issued a permit for its use on sweet corn to control northern corn leaf blight. Results following trials at the maximum proposed use pattern with a 28 day WHP found no detectable residues above the LOQ of 0.02 mg/kg.			NEDI = 4% of ADI 20^{th} ATDS = $<1\%$ of ADI for all population groups assessed
Sweet corn (corn-on-the-cob) Insert	*0.02	
Sethoxydim Sethoxydim is a selective systemic herbicide absorbed by foliage and roots. APVMA has issued permits for its use on spinach, silver beet, peppers and eggplant. No amendment is necessary to the spinach MRL. Following trials at the maximum proposed application rate, no residues above the LOQ of 0.1 mg/kg were recorded in eggplant.			NEDI = 28% of ADI
Minor amendment to residue definition:			
Omit: Sum of Sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as Sethoxydim			
Substitute: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim			
Chard (silver beet) Egg plant Peppers	Insert Insert Insert	T*0.1 T*0.1 T0.7	

Spinosad Spinosad is an insecticide used to covegetable and agricultural crops. It APVMA has issued a minor use pe	NEDI = 33% of ADI		
Minor technical amendment to the	chemical name:		
Omit: spinosad			
Substitute: Spinosad			
Assorted tropical and sub-tropical fruits – inedible peel Assorted tropical and sub-tropical fruits – inedible peel forcent	Insert	0.3	
fruits – inedible peel [except	Omit	T0 5	
banana and kiwifruit] Banana	Omit	T0.5	
	Omit	0.2	
Celery	Omit	T*0.25	
Giv. C. iv	Substitute	2.0	
Citrus fruits	Omit	T0.1	
C CC 1	Substitute	0.3	
Coffee beans	Insert	*0.01	
Egg plant	Omit	0.2	
Fruiting vegetables, cucurbits	Omit	T0.2	
	Substitute	0.2	
Fruiting vegetables, other than			
cucurbits [except sweet corn	T	0.2	
(corn-on-the-cob)]	Insert	0.2	
Kiwifruit	Omit	0.3	
Melons [except watermelon]	Omit	T0.2	
Peppers, Sweet	Omit	0.2	
Tomato	Omit	0.2	
Thiodicarb Thiodicarb is a systemic insecticide	e. See also Methomyl.		Methomyl + Thiodicarb NEDI = 89% of ADI
	0. %		NESTI as % of ARfD (See also Methomyl) 2-6 years 2+ years
Brassica leafy vegetables Brassica (cole or cabbage)	Omit	1	17 Broccoli 6
vegetables, Head cabbages, Flowerhead brassicas	Insert	2	2 Brussels sprouts 2 9 Cabbages, head 7 13 Cauliflower 5

Attachment 3

SUMMARY OF SUBMISSIONS RECEIVED

Submitter	Comments raised
Food Technology Association of Victoria Inc.	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.
Dr Alison Bleaney OBE	Dr Bleaney notes that pesticides can cause
	many diseases. People should have a right to
	buy and consume non toxic foods. Dr Bleaney
	states that allowing pesticide residues, or any
	introduced substances such as growth factors
	that can cause genetic changes, cannot be
	condoned and that labelling should reflect
	potential presence of pesticides. Considering
	current research and medical findings, it can
	no longer be considered a safe or ethical
	practice to sell food not labelled indicating
	maximum possible pesticide residues.
Queensland Department of Health	Supported this Application.
Department of Human Services Victoria	Supported this Application.