

3-06 31 May 2006

INITIAL / DRAFT ASSESSMENT REPORT

APPLICATION A572

MAXIMUM RESIDUE LIMITS (OCTOBER, NOVEMBER, DECEMBER 2005)

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 12 July 2006 SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

Application 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 to concerning a Joint Food Standards System (the Treaty), excluded MRLs for agricultural and veterinary chemicals in food from the joint Australia New Zealand food standards setting system. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

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

There are no MRLs for antibiotic residues in this Application.

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

FSANZ decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act* 1991 (FSANZ Act), to omit to invite public submissions in relation to the Application prior to making a Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only. Submissions are now invited on this Report to assist FSANZ to make a Final Assessment.

Purpose

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

Preferred Approach

FSANZ recommends accepting Application A572 and the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits.

Reasons for Preferred Approach

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

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

- The 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 of the Therapeutic Goods Administration (OCS) has undertaken an appropriate toxicological assessment of the chemicals, and where applicable has established acceptable daily intakes (ADIs) and acute reference doses (ARfDs).
- FSANZ has undertaken a preliminary regulation impact assessment process 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 decided, pursuant to section 36 of the FSANZ Act, not to invite public submissions in relation to Application A572 prior to making an Initial / Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only.

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

Public comment on the Initial Assessment / Draft Assessment Report is sought from 31 May 2006 until 12 July 2006.

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

- any impacts (costs/benefits) of the proposed increases, deletions and changes to specific MRLs;
- any further public health and safety considerations with the proposed MRLs;

- likely costs and benefits on the importation of food if the proposed deletions to specific MRLs are advanced; and
- any other affected parties to this Application.

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

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INVITATION FOR PUBLIC SUBMISSIONS

Food Standards Australia New Zealand (FSANZ) invites public comment on this Initial / Draft Assessment Report based on regulation impact principles and the draft variations to the *Australia New Zealand Food Standards Code* (the Code) for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment of this application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

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

Food Standards Australia New Zealand PO Box 7186 Canberra BC ACT 2610 AUSTRALIA Tel (02) 6271 2222 www.foodstandards.gov.au Food Standards Australia New Zealand PO Box 10559 The Terrace WELLINGTON 6036 NEW ZEALAND Tel (04) 473 9942 www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 12 July 2006.

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

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

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

INTRODUCTION

Applications were received from Australian Pesticides and Veterinary Medicines Authority (APVMA) on 14 October, 4 November and 14 December 2005 seeking variations to the Code in Standard 1.4.2 – Maximum Residue Limits. The proposed variations to the Standard would align Maximum Residue Limits (MRLs) in the Code for non-antibiotic agricultural and veterinary chemicals with the MRLs in the APVMA MRL Standard.

1. Background

1.1 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 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.

1.2 Temporary MRLs requested for Bupivacaine, Cetrimide and Lignocaine

Temporary MRLs have been requested at the limit of quantification (LOQ) for Bupivacaine, Cetrimide and Lignocaine. Office of Chemical Safety (OCS) (part of the Therapeutic Goods Administration) has not established acceptable daily intakes (ADIs) or set acute reference doses (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 there are no health and safety concerns with the proposed MRLs.

1.3 Antibiotic MRLs

There are no MRLs for antibiotic¹ residues in this Application.

1.4 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.

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

1.5 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 its MRL Standard accordingly. Consequently there are discrepancies between the potential residues associated with the use of the relevant agricultural and/or veterinary chemicals and the MRLs in the Code under Standard 1 4 2

1.6 The use of agricultural and veterinary chemicals

In Australia, APVMA is responsible for assessing and registering agricultural and veterinary chemical products, and regulating them up to the point of sale. Following the sale of such products, the use of the chemicals is regulated by State and Territory 'control of use' legislation.

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

When a chemical product is registered for use or a permit for use granted, APVMA includes MRLs in its 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.

2. The Issue / Problem

2.1 Maximum Residue Limit Applications

After registering agricultural or veterinary chemical products, based on scientific evaluations, APVMA makes Applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews information provided by APVMA and validates whether the dietary exposure is within appropriate safety limits. If satisfied that the residues are within safety limits and subject to adequate resolution of any issues raised during public consultation, FSANZ will agree to incorporate the proposed MRLs into Standard 1.4.2.

FSANZ notifies the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) when variations to the Code are adopted. 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.

Including MRLs in the Code has the effect of allowing legally treated produce to be legally sold, provided that the residues in the treated produce do not exceed the MRL. 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.

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.

2.2 Maximum Residue Limits

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.

2.3 Australia and New Zealand Joint Food Standards-setting System

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

2.4 Trans Tasman Mutual Recognition Arrangement

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

- Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand.
- Food produced or imported into New Zealand that complies with the *New Zealand* (*Maximum Residue Limits of Agricultural Compounds*) Food Standards, 2005 (No. 2) can be legally sold in Australia.

2.5 Limit of Quantification

Some of the proposed MRLs in this Application are at the LOQ and are indicated by an * in the 'Summary of Requested MRLs for each Chemical...' (Attachment 2).

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. The inclusion of the MRLs at the LOQ means 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.

2.6 MRLs for Permits

Some of the proposed MRLs in this Application are temporary and are indicated by a 'T' in the 'Summary of Requested MRLs for each Chemical...' (Attachment 2). 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.

3. Objectives

In assessing this Application FSANZ aims to ensure that the proposed MRLs do not present a risk to public health and safety 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 FSANZ's section 10 objectives of food regulatory measures.

4. Key Assessment Questions

FSANZ's primary role 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.

RISK ASSESSMENT

5. Dietary Exposure

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code*, 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 for a chemical in food (i.e. the acceptable daily intake (ADI) and/or the acute reference dose (ARfD)); and
- calculating the dietary exposure to a chemical from relevant foods, using food consumption data from nutrition studies and comparing this to the acceptable reference health standard

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 Determination of the acceptable 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 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 recently 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 1995 National Nutrition Survey (NNS). The Australian Bureau of Statistics with the then Australian Government Department of Health and Aged Care undertook the NNS survey 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 a realistic 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 refined data including food consumption data for specific 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 total diet studies may also be used, such as the 19th and 20th Australian Total Diet Surveys (ATDS).

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.

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. If specific data on the residues are not available then a cautious approach is taken and the MRL is used.

The residues that are likely to occur in all foods are then multiplied by the mean daily consumption of these foods derived from individual dietary records from the latest 1995 National Nutrition Survey (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. These calculations for each food are 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 this 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 and this result is compared to the ARfD. NESTIs are calculated from ARfDs set by OCS and JMPR, the consumption data from the 1995 National Nutrition Survey 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 no risk to public health and safety when estimated exposures are below these reference health standards.

RISK MANAGEMENT

7. Options

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

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

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

Under this option, only those variations that were reductions and omissions would be approved for inclusion into the Code. The proposed increases and inclusions of new MRLs would not be approved.

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

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

Option 2 has been arranged into two sub-options because the impacts of each sub-option are different. Splitting the option into two sub-options also allows a more detailed impact analysis. However, FSANZ cannot legally separate these two sub-options and may only approve or reject the draft variations to Standard 1.4.2 - Maximum Residue Limits.

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 Application, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make a Final Assessment of this Application will include information from public submissions.

8.1 Affected Parties

The parties affected by proposed MRL amendments include:

- consumers, including domestic and overseas customers;
- 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 – status quo – no change to existing MRLs in the Code

8.2.1.1 Benefits

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

8.2.1.2 Costs

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

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

for growers and producers of domestic and export food commodities, adopting this option would result in costs resulting from not being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Primary producers do not produce food or use chemical products to comply with MRLs. They use chemical products to control pests and diseases in accordance with the prescribed label conditions, and expect that the resulting residues will be acceptable and that legally treated food can be legally sold. If legal use of chemical products results in the production of food that cannot be legally sold under food legislation then primary producers will incur substantial losses. Major losses for primary producers would in turn impact negatively upon rural and regional communities;

- for importers, adopting this option would not result in any discernable costs; and
- for Australian Government, State and Territory agencies, adopting this option would create discrepancies between agricultural and food legislation thereby creating uncertainty, inefficiency and confusion in the enforcement of regulations.
- 8.2.2 Option 2(a) vary the Code in Schedule 1 of Standard 1.4.2 to omit or decrease existing MRLs as proposed

8.2.2.1 Benefits

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

8.2.2.2 Costs

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

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

- for growers and producers of domestic and export food commodities, adopting this option is unlikely to result in any costs, as reductions in MRLs are adopted where this is practically achievable, with little or no impact on production costs;
- for importers, adopting this option may result in costs, as foods may not be permitted to be imported if these foods contain residues consistent with MRLs proposed for deletion or reduction. Any MRL deletions or reductions have the potential to restrict the 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 are addressed in section 11.1.1 and data on imported foods are addressed in section 11.1.2; and

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

- for Australian Government, State and Territory agencies, adopting this option would not result in any discernable costs, although there would need to be an awareness of changes in the standards for residues in food.
- 8.2.3 Option 2(b) vary the Code to include in Schedule 1 of Standard 1.4.2 the proposed changes to insert new, or change from temporary to permanent, or increase some existing MRLs

8.2.3.1 Benefits

• for consumers the major benefit would be potential flow on benefits resulting from the price and availability of food if growers can legally sell food containing residues consistent with increased MRLs or MRL additions;

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

- for growers and producers of domestic and export food commodities, the benefits of this option would result from being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Other benefits include the consistency between agricultural and food legislation thereby minimising compliance costs to primary producers;
- adopting this option would benefit importers in that that food containing residues consistent with increased MRLs or MRL additions 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 a viable but 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's preferred approach is to adopt Options 2(a) <u>and</u> 2(b) – to vary the Code in Schedule 1 of Standard 1.4.2 to include new MRLs or increase some existing MRLs and to delete or decrease some existing MRLs and to change the status of some MRLs from temporary to permanent.

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

FSANZ made its decision under section 36 because it was satisfied that Application A572 raised issues of minor significance or complexity only.

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

10. Consultation

Public comment on the Initial / Draft Assessment Report is sought from 31 May 2006 until 12 July 2006.

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

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

10.1 World Trade Organization

As a member of the 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 in Schedule 1 of Standard 1.4.2 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 that are addressed in the international Codex standard. MRLs in the Application also relate to chemicals used in the production of heavily traded agricultural commodities that may indirectly have a significant effect on trade of derivative food products between WTO members.

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

10.1.1 Codex Alimentarius Commission MRLs

Codex standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table lists the 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
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

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

10.1.2 Imported Foods

Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because different products may be used. This means that residues in imported foods may still be safe for human consumption, but 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 has compiled the following table of foods that have MRLs proposed for deletion and/or reduction.

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

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

CONCLUSION

10. Conclusion and Preferred Option

FSANZ has undertaken an assessment and recommends accepting Application A572 and the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits.

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

11. 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. The 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 considerable scope exists to review MRLs on a continual basis.

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

ATTACHMENTS

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

Draft Variations to the Australia New Zealand Food Standards Code

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-
	TRICHLOROISOPHALONITRILE 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 METABO	LITE (5-
amino-1-[2,6-dichloro-4-	
(TRIFLUOROMETHYL)PHENYL]-4-	
[(TRIFLUOROMETHYL) SULPHENYL]-1H-PYR	AZOLE-
3-CARBONITRILE),	FO (
THE SULPHONYL METABOLITE (5-AMINO-1	
DICHLORO-4-(TRIFLUOROMETHYL)PHENY	
[(TRIFLUOROMETHYL)SULPHONYL]-1H-PYR	
3-CARBONITRILE), AND THE TRIFLUOROME	
METABOLITE (5-AMINO-4-TRIFLUOROMETF [2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHEN	
PYRAZOLE-3-CARBONITRILE)	1LJ-111-
BERRIES AND OTHER SMALL FRUITS	T*0.01
[EXCEPT WINE GRAPES]	1 0.01
IMIDACLOPRID	
SUM OF IMIDACLOPRID AND METABOLIT	ΓES
CONTAINING THE 6-CHLOROPYRIDINYLMETH	HYLENE
MOIETY, EXPRESSED AS IMIDACLOPRI	D
Brassica leafy vegetables	5
CHERVIL	T5
JAPANESE GREENS	5
LETTUCE, HEAD	T5
LETTUCE, LEAF	T5
RUCOLA (ROCKET)	T5
Merry priving	
NIETALDEHYDE	
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 C	
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 O EXPRESSED AS METHOMYL SEE ALSO THIODICARB	
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 O EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD	
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL	
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL	OXIME'),
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB-	
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL	OXIME'),
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB-	OXIME'),
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUBTROPICAL FRUITS — INEDIBLE PEEL	*0.01
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD 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 OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUBTROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN I	*0.01
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN IN ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT]	*0.01 T0.5
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS – INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN INTERPRETATION OF SPINOSYN A AND SPINOSYN INTERPRETATION OF SPINOSY	*0.01 T0.5
METALDEHYDE TURMERIC ROOT METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN INTOPICAL 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 OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN I ASSORTED TROPICAL AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT] BANANA EGG PLANT KIWIFRUIT	*0.01 *0.01 T0.5
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN INTERPRETATION OF SPINOSYN AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT] BANANA EGG PLANT KIWIFRUIT MELONS [EXCEPT WATERMELON]	*0.01 *0.01 T0.5 0.2 0.2 0.3 T0.2
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL O	*0.01 *0.01 T0.5 0.2 0.2 0.3 T0.2 0.2
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OF EXPRESSED AS METHOMYL OF SEE ALSO THIODICARB CABBAGES, HEAD PACLOBUTRAZOL PACLOBUTRAZOL PACLOBUTRAZOL ASSORTED TROPICAL AND SUB- TROPICAL FRUITS — INEDIBLE PEEL SPINOSAD SUM OF SPINOSYN A AND SPINOSYN INTERPRETATION OF SPINOSYN AND SUB TROPICAL FRUITS — INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT] BANANA EGG PLANT KIWIFRUIT MELONS [EXCEPT WATERMELON]	*0.01 *0.01 T0.5 0.2 0.2 0.3 T0.2

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 B	1B AND
(z)-8,9 AVERMECTIN B1A, AND (z)-8,9 AVER	RMECTIN
B1B	
LETTUCE, HEAD	T0.05
2211002,11212	10.00
Buprofezin	
BUPROFEZIN	
DRIED GRAPES (CURRANTS,	1
RAISINS AND SULTANAS)	1
RAISINS AND SULTANAS)	
CHLORFENAPYR	
CHLORFENAPYR	77.1
SHALLOT	T1
SPRING ONION	T1
CHLOROTHALONIL	
COMMODITIES OF PLANT ORIGIN: CHLOROTH	
COMMODITIES OF ANIMAL ORIGIN: SUM	OF
CHLOROTHALONIL AND 4-HYDROXY-2, :	5, 6-
TRICHLOROISOPHALONITRILE METABOL	ITE,
EXPRESSED AS CHLOROTHALONIL	
EDIBLE OFFAL (MAMMALIAN)	Т3
MEAT (MAMMALIAN) (IN THE FAT)	T2
MILKS	T0.05
CHLORPYRIFOS	
CHLORY TRIFOS CHLORPYRIFOS	
BLUEBERRIES STATES	T1.0
DECEDERALES	11.0
CHLORTHAL-DIMETHYL	
CHLORTHAL-DIMETHYL	
	T1
LETTUCE, HEAD	
LETTUCE, LEAF	T1
VEGETABLES [EXCEPT LETTUCE]	5
Chanonana	
CYPRODINIL	
CYPRODINIL	- T-A
PEAS	T2
D	
ENDOSULFAN	
SUM OF A- AND B- ENDOSULFAN AND ENDOS	SULFAN
SULPHATE	
BERRIES AND OTHER SMALL FRUITS	T2
[EXCEPT STRAWBERRY]	
Strawberry	T0.5

FLUAZIFOP-BUTYL
FLUAZIFOP-BUTYL EGG PLANT T0.1
LOGILANI 10.1
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) 1
METHOMYL
SUM OF METHOMYL AND METHYL
HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'),
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	0.01
[EXCEPT AVOCADO]	
AVOCADO	T0.1
11100.120	10.1
Propachlor	
Propachlor	
LETTUCE, HEAD	*0.02
LETTUCE, LEAF	*0.02
PROPICONAZOLE	
PROPICONAZOLE	
SWEET CORN (CORN-ON-THE-COB)	*0.02
SETHOXYDIM	
SUM OF SETHOXYDIM AND METABOLIT	FS
CONTAINING THE 5-(2-	LU
ETHYLTHIOPROPYL)CYCLOHEXENE-3-ONE	AND 5-
(2-ETHYLTHIOPROPYL)-	THILD 5
5-HYDROXYCYCLOHEXENE-3-ONE MOIETIE	S AND
THEIR SULFOXIDES AND SULFONES, EXPRES	
SETHOXYDIM	
CHARD (SILVER BEET)	T*0.1
EGG PLANT	T*0.1
PEPPERS	T0.7
SPINOSAD	
SUM OF SPINOSYN A AND SPINOSYN I	
ASSORTED TROPICAL AND SUB	0.3
TROPICAL FRUITS – INEDIBLE PEEL	
COFFEE BEANS	*0.01
FRUITING VEGETABLES, OTHER	0.2
THAN CUCURBITS [EXCEPT SWEET	
CORN (CORN-ON-THE-COB)]	
THIODICARR	
THIODICARB SUM OF THIODICARB, METHOMYL AN	D
METHOMYLOXIME, EXPRESSED AS THIODI	
SEE ALSO METHOMYL	CARD
BRASSICA (COLE OR CABBAGE)	2
VEGETABLES, HEAD CABBAGES,	2
FLOWERHEAD BRASSICAS	
220 HEIGHERE BIGGOTORIO	
L	

[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
ТОМАТО	0.05

AZOXYSTROBIN					
AZOXYSTROBIN	0.6-				
Ротато	0.05				
Buprofezin					
BUPROFEZIN BUPROFEZIN					
GRAPES	0.3				
GRALES	0.5				
FIPRONIL					
SUM OF FIPRONIL, THE SULPHENYL METABOLIT	E (5-				
AMINO-1-[2,6-DICHLORO-4-					
(TRIFLUOROMETHYL)PHENYL]-4-					
[(TRIFLUOROMETHYL)SULPHENYL]-1H-PYRAZ	OLE-				
3-CARBONITRILE),	_				
THE SULPHONYL METABOLITE (5-AMINO-1-[2					
DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-					
[(TRIFLUOROMETHYL)SULPHONYL]-1H-PYRAZO					
3-CARBONITRILE), AND THE TRIFLUOROMETH METABOLITE (5-AMINO-4-TRIFLUOROMETHYL					
[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL					
PYRAZOLE-3-CARBONITRILE)	-111-				
,	*0.01				
WINE GRALES	0.01				
FORCHLORFENURON					
FORCHLORFENURON					
GRAPES	*0.01				
GLUFOSINATE AND GLUFOSINATE-AMMONI	UM				
SUM OF GLUFOSINATE-AMMONIUM, N-ACET					
GLUFOSINATE AND 3-[HYDROXY(METHYL)-					
PHOSPHINOYL] PROPIONIC ACID, EXPRESSED	AS				
GLUFOSINATE (FREE ACID)					
OLIVES	*0.1				
METALDEHYDE					
METALDEHTDE					
HERBS	1				
TIEROS					
METHOMYL					
SUM OF METHOMYL AND METHYL					
HYDROXYTHIOACETIMIDATE ('METHOMYL OXIN	мЕ'),				
EXPRESSED AS METHOMYL					
SEE ALSO THIODICARB					
FRUITING VEGETABLES, CUCURBITS	0.1				
D					
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.

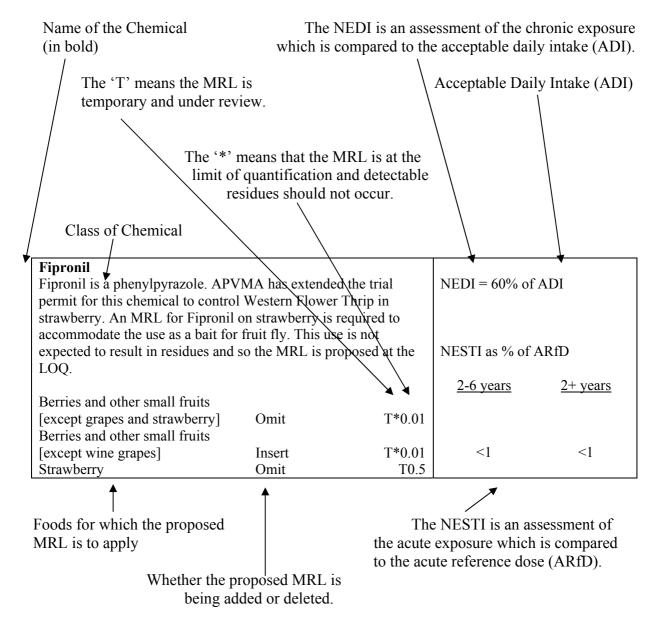
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

NEDI - National Estimated Dietary Intake - The NEDI represents a realistic estimate of chronic dietary exposure and is the preferred calculation. It may incorporate more refined food consumption data including that for specific 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 refined 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 National Nutrition Survey (NNS) and the MRL when the supervised trials median residue (STMR) is not available to calculate the NESTIs.

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

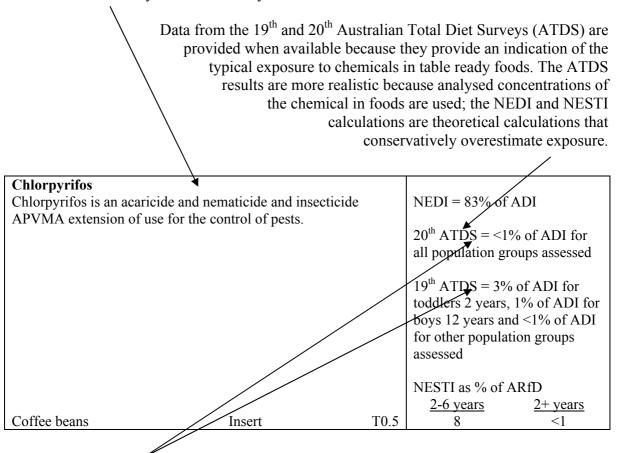
The following are examples of entries and the proposed MRLs listed are not part of this Application.



More information on the NEDI and the ADI is in the glossary. 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.

More information on the NESTI and the ARfD is in the glossary. 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.

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.

Glossary:

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.	FSC	Australia New Zealand Food Standards Code
6.	JMPR	Joint FAO/WHO Meeting on Pesticide Residues
7.	LOQ	Limit of Analytical Quantification
8.	NEDI	National Estimated Daily Intake
9.	NESTI	National Estimated Short Term Intake
10.	NNS	National Nutrition Survey of Australia 1995
11.	T	Temporary MRL
12.	WHP	Withholding Period

SUMMARY OF REQUESTED MRLS FOR APPLICATION A572 MAXIMUM RESIDUE LIMITS – OCTOBER NOVEMBER DECEMBER 2005

Abamectin is an insecticide and acaricide with contact and stomach action. APVMA has issued a permit for its use on lettuce, strawberry and tomato. Lettuce, head Insert T0.05 Strawberry Omit 0.02 Substitute 0.1 Tomato Omit 0.01 Substitute 0.05 Substitut	Requested MRLs			Dietary Expos	ure Estimates
Lettuce, head Insert T0.05 Strawberry Omit 0.02 Substitute 0.1 Tomato Omit 0.01 Substitute 0.01 Substitute 0.05 Azoxystrobin Azoxystrobin is a strobilurin fungicide. It has translaminar and systemic properties. Potato Omit *0.01 Substitute 0.05 Bupivacaine 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 Sheep meat (in the fat) Insert T*0.02 Sheep meat (in the fat) Insert T*0.02 Buprofezin Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae. Dried grapes (currants, raisins and sultanas) Insert 1 Grapes Omit T*0.01	stomach action. APVMA has issue				
Lettuce, head Insert T0.05 Strawberry Omit 0.02 Strawberry Omit 0.02 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. Potato Omit *0.01 Substitute 0.05 22 9 Potato Omit *0.01 Substitute 0.05	ictuce, shawberry and tomato.				
Strawberry Omit 0.02 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. Potato Omit *0.01 Substitute 0.05 Bupivacaine 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 Sheep meat (in the fat) Insert T*0.02 Buprofezin Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae. Dried grapes (currants, raisins and sultanas) Insert 1 Grapes Omit T*0.01	Lettuce head	Incert	T0.05	T	
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Azoxystrobin Azoxystrobin is a strobilurin fungicide. It has translaminar and systemic properties. Potato Omit *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 for at least a year; negligible residues are expected. Therefore no dietary exposure estimates have been calculated. Promporary 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 Sheep meat (in the fat) Insert T*0.02 Buprofezin Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae. Dried grapes (currants, raisins and sultamas) Insert 1 Grapes Omit T*0.01	Suawberry			22	6
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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 Sheep meat (in the fat) Insert T*0.02 Buprofezin Buprofezin Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae. Dried grapes (currants, raisins and sultanas) Insert 1 Grapes Omit T*0.01	Potato				
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Sheep meat (in the fat) Buprofezin Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae. Dried grapes (currants, raisins and sultanas) Insert Omit T*0.02 NEDI = 14% of ADI T*0.01	is used topically to prevent pain in production following mulesing. A production for at least a year; negl Temporary MRLs have been requactive constituent. Under the permestablished. Although this relative necessary, it has been included to of safety to overcome any concern of ADIs for the active constituents. New Chemical Residue definition: Bupivacaine	for wool ept in wool re expected. for each P has been not considered ute guarantee in the absence	Refer to details column and sec	in opposite	
Buprofezin Buprofezin Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae. Dried grapes (currants, raisins and sultanas) Insert Grapes Omit NEDI = 14% of ADI NEDI = 14% of ADI NEDI = 14% of ADI	* *				
Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae. NEDI = 14% of ADI NEDI = 14% of ADI NEDI = 14% of ADI T*0.01	• • • • • • • • • • • • • • • • • • • •	insert	1*0.02		
sultanas) Insert 1 Grapes Omit T*0.01	Buprofezin is an insecticide. It inh larvae.	NEDI = 14% of	fADI		
Grapes Omit T*0.01	'		1		
1			T*0.01		
	Grapes	Omit Substitute	1*0.01 0.3		

Carlantana			
Carbofuran	4.4	. ,	D: 4
This is a minor technical amendm	Dietary exposure assessment		
of the commodity name for sweet	corn kernels.		not required
Commodity name:			
Omit Sweet corn			
Substitute Sweet corn (kernels)			
Cetrimide			
Cetrimide is an antiseptic. It is an	active ingredient	in the product	ADI not established
Tri-Sulven. Bupivacaine and Light			ARfD not established
ingredients. APVMA has issued a			THEID Hot established
is used topically to prevent pain in			Therefore no dietery expenses
			Therefore no dietary exposure
production following mulesing. A			estimates have been calculated.
production for at least a year; neg			D C . 1 . 11
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		in the absence	
of ADIs for the active constituents	S.		
New Chemical			
Residue definition: Cetrimide			
Sheep, edible offal of	Insert	T*1.0	
Sheep meat (in the fat)	Insert	T*1.0	
Chlorfenapyr	1115011	1 1.0	
Chlorfenapyr is an insecticide. AF	OVMA has issued	a permit for	NEDI = 3% of ADI
its use on shallots and spring onio		a permit for	370 017151
ns use on shanots and spring one	115.		
Shallot	Insert	T1	
Spring onion	Insert	T1	
Chlorothalonil			
Chlorothalonil is a fungicide used	to control ascock	nyta blight and	NEDI = 78% of ADI
chocolate spot in pulses. APVMA	has issued a peri	mit for its use	
on stock feed pulses. Grazing or f			20^{th} and 19^{th} ATDS = <1% of
milk for human consumption on to			ADI for all population groups
Residues may occur in milk as a r	assessed		
Residue definition:			
Omit: Chlorothalonil			
Substitute: Commodities of plan			
Commodities of animal origin:			
4-hydroxy-2,5,6-trichloroisoph			
expressed as Chlorothalonil			
<u> </u>			
Edible offal (mammalian)	Insert	Т3	
Meat (mammalian) (in the fat)	Insert	T2	
Milks	Insert	T0.05	

Chlorpyrifos Chlorpyrifos is an acaricide and nematicide and insecticide. 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
Dhashamias	Incont	т1 о	2-6 years 2+ years 12
Blueberries Chlorthal-dimethyl	Insert	T1.0	21 12
Chlorthal-dimethyl is a pre emcissued a permit for its use to co This chemical is registered for crops.	ontrol stinging nettle i	n lettuce.	NEDI = 45% of ADI
Lettuce, head	Insert	T1	
Lettuce, leaf	Insert	T1	
Vegetables	Omit	5	
Vegetables [except lettuce]	Insert	5	
Cyprodinil Cyprodinil is a systemic fungic mycelial growth both inside the APVMA has issued a permit for and grey mould on snow, sugar	NEDI = 12% of ADI		
Peas	Insert	T2	
Diflufenican Diflufenican is a herbicide used blocks carotenoid biosynthesis mg/kg is in place for pulses, a strequired.	NEDI = <1% of ADI		
Lupin	Omit	0.05	

Endosulfan Endosulfan is a non-systemic insestomach action used to control we has issued a permit for its use on sexclude strawberries from berries 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	Review 6) 6 of ADI for oups assessed of ADI for 34 years, boys		
			infants 9 months; for adult males 2 girls 12 years	
Berries and other small fruits	Omit	T2	NESTI as % of A 2-6 years	ARfD 2+ years
Berries and other small fruits	Ollit	12		
[except strawberry]	Insert	T2		
Strawberry	Insert	T0.5	14	4
Fipronil				
Fipronil is a selective insecticide u	ised in various crop	s. The	NEDI = 76% of A	ADI
proposed use is for a directed spra				
vines. Residues data from Australi	an field trials indicate	ate residues	NESTI as % of A	ARfD
will be below the LOQ.				
		57.10.04	<u>2-6 years</u>	2+ years
Berries and other small fruits [except wine grapes]	Omit	T*0.01		
Wine grapes	Omit	T*0.01		
	Substitute	*0.01	0	6
Fluazifop-butyl	1.1.1		NEDI (OO) C	l DI
Fluazifop-butyl (Fluazifop) is a he			NEDI = 69% of A	ADI
weeds in broad leaf crops. APVM use on eggplant. The use pattern is				
pattern for tomatoes and capsicum		proved use		
Egg plant	Insert	T0.1		
Fludioxonil		10.1		
Fludioxonil is a non-systemic fung	gicide. APVMA has	s issued a	NEDI = 2% of A	DI
permit for its use to control sclero	•			
snow, sugar snap and garden peas.	• •			
· · · · · · · · · · · · · · · · · · ·				
Peas	Insert	T2		
Forchlorfenuron				
Forchlorfenuron is a cytokinin pla	NEDI = <0.1% o	f ADI		
used to increase berry size in table	• 1		DIAMOND	-11:
and international trials indicate res	sidues will be below	the LOQ.	DIAMOND mod estimated chronic	
			exposure of <0.1	•
			the general popul	
			<0.2% of ADI fo	
Grapes	Omit	T*0.01	percentile (high o	
*	Substitute	*0.01		,
	Substitute	'0.01		

Glufosinate and Glufosinate		1	NEDI 70/ C	. DI
Glufosinate-ammonium is a no			NEDI = 7% of A	ADI
to control broadleaf and grass				
international trials conducted a	0 1 1			
pattern found no residues on h		-		
APVMA has issued a permit f				
on saffron crops no later than		ering. The		
recommended MRL is at the L	ιOQ.			
Minor amendment to residue d	lefinition:			
Omit: Sum of Glufosinate-ami	nonium, N-acetyl glu	fosinate and		
3-[hydroxy(methyl)-phosphine	ol] propionic acid, exp	ressed as		
Glufosinate (free acid)				
Substitute: Sum of Glufosinate	e-ammonium, N-acety	l glufosinate		
and 3-[hydroxy(methyl)-phosp	phinoyl] propionic aci	d, expressed		
as glufosinate (free acid)				
Olives	Omit	T0.1		
	Substitute	*0.1		
Saffron	Insert	T*0.05		
Glyphosate				
Glyphosate is a non-selective of	contact herbicide. AP	VMA has	NEDI = 6% of A	ADI
issued a permit for its on saffro				
prior to flowering. The recom				
Saffron	Insert	T*0.05		
Imidacloprid				
Imidacloprid is a systemic inse			NEDI = 9% of A	ADI
nicotinic receptors in the CNS				
has issued permits for its use to				
foliar application and applicati				
lettuce aphid in lettuce, chicor				
Following application at transp	planting, residues are	expected to		
be non detectable in lettuce, chicory, endive and radicchio.			NESTI as % of	
			<u>2-6 years</u>	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		

т 1 1			
Indoxacarb		a.f	Distant sum saums sassagement
These are minor technical amendments		icy of	Dietary exposure assessment
use of commodity names for eggpla	ini and pome muits.		not required
Commodity name:			
Omit Eggplant			
Substitute Egg plant			
Omit Pome fruit			
Substitute Pome fruits			
Iprodione			
Iprodione is a fungicide. APVMA	nas issued a permit for i	ts use	NEDI = 43% of ADI
to control sclerotinia rot in adzuki b		to abc	13/0011121
to control selectoring for in adams of	, carro.		20^{th} ATDS = 1% of ADI for
			adult males 25 – 34 years and
			toddlers 2 years and <1% of
			ADI for other population groups
			assessed
			19^{th} ATDS = 1% of ADI for
Adzuki bean (dry)	Insert	T0.1	toddlers 2 years and <1% of
			ADI for other population groups
			assessed
Isoxaben			
Isoxaben is a selective pre-emergen			NEDI = <1% of ADI
absorbed by roots with translocation	n to stems and leaves. I	t	
disrupts root and stem development	in germinating seeds.		
Extensive residue trials found no de	etectable residues follow	ving	
the proposed use pattern. Recomme	ended MRLs are at the l	LOQ.	
New Chemical			
Residue definition: Isoxaben			
Assorted tropical and sub-tropical	T 4	* 0.01	
fruits – edible peel	Insert	*0.01	
Assorted tropical and sub-tropical	T	* 0.01	
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	

			7	
Kresoxim-methyl				
This is a minor technical amendment to ensure consistency of			Dietary exposure assessment not required	
use of the commodity name for p	use of the commodity name for pome fruits.			
Commodity name				
Commodity name: Omit Pome fruit				
Substitute Pome fruits				
Lignocaine	T/ : 1:		ADI 4 4 11: 1 1	
Lignocaine is a local anaesthetic.			ADI not established	
product Tri-Sulven. Bupivacaine			ARfD not established	
ingredients. APVMA has issued a is used topically to prevent pain i			Therefore no distant expenses	
production following mulesing. A			Therefore no dietary exposure estimates have been calculated.	
production for at least a year; neg			estimates have been calculated.	
Temporary MRLs have been requ			Refer to details in opposite	
active constituent. Under the perr			column and section 1.2 of this	
established. Although this relative			report.	
necessary, it has been included to			report.	
of safety to overcome any concer				
of ADIs for the active constituent		ausence		
of ADIS for the active constituent	.5.			
New Chemical				
Residue definition: Lignocaine				
Residue definition. Eighteume				
Sheep, edible offal of	Insert	T*0.02		
Sheep meat (in the fat)	Insert	T*0.02		
Metaldehyde				
Metaldehyde is a molluscicide. It	irreversibly destroys		NEDI = 2% of ADI	
mucocytes. It is used in pellet for		l slugs in		
agricultural crops and pastures. D				
parts is considered unlikely. It de				
water.				
Cereal grains	Insert	1		
Herbs	Omit	T1		
	Substitute	1		
Oilseed	Insert	1		
Pulses	Insert	1		
Spices	Insert	1		
Teas (Tea and Herb teas)	Insert	1		
Turmeric root	Omit	T1		

Methomyl Methomyl is a systemic insecticid and stomach action. APVMA has tomato, capsicum, eggplant, cucus western flower thrips. No changes or fruiting vegetables other than control of the story of t	Methomyl + T NEDI = 89% (NESTI as % o	of ADI			
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Cabbages, head	Brassica (cole or cabbage) vegetables, Head cabbages, Insert 2 Flowerhead brassicas Omit 1				ears 6 2 5 7
Fruiting vegetables, cucurbits	Substitute	0.1	8 h	iead	3
			Cuc	umber	
Metolachlor is a pre-emergent her APVMA has issued a permit for i crops. No residues above the LOC	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.				
Rhubarb	Insert	*0.05			
Novaluron This is a minor technical amendm use of the commodity name for po		sistency of	Dietary exposurequired	are assessm	ent not
Omit Pome fruit					
Substitute Pome fruits Paclobutrazol					
Paclobutrazol Paclobutrazol is a plant growth re compact plants and enhanced flow has received a permit application thinning and increased fruit size.	NEDI = 12% c	of ADI			
Assorted tropical and sub-tropical fruits – inedible peel Assorted tropical and sub-tropical					
fruits – inedible peel [except avocado] Avocado	Insert Insert	*0.01 T0.1			

Parathion-methyl			
This is a minor technical amendment to ensure consistency of			Dietary exposure assessment not
use of the commodity name for s	sweet corn (corn-or	n-the-cob).	required
Commodity name:			
Omit Fruiting vegetables other t	han cucurbits [exce	pt sweet	
corn		•	
Substitute Fruiting vegetables, o	ther than cucurbits	[except sweet	
corn (corn-on-the-cob)]			
Omit Sweet corn			
Substitute Sweet corn (corn-on-t	the-cob)		
Procymidone	1.11.		NEDI 2007 CADI
Procymidone is a fungicide. It is used to control fungal infections		synthesis. It is	NEDI = 28% of ADI
			20^{th} and 19^{th} ATDS = <1% of
			ADI for all population groups
			assessed
			NESTI as % of ARfD
			2-6 years 2+ years
Lentil (dry)	Omit	T0.5	<u>= - ,</u>
	Substitute	0.5	5 1
Propachlor Propachlor is a selective herbicide shoots with secondary translocate APVMA has issued a permit for seedlings to control grass and brown Residues data indicate no detect proposed use pattern.	NEDI = 6% of ADI		
Lettuce, head	Insert	*0.02	
Lettuce, leaf	Insert	*0.02	
Propamocarb	1110414	0.02	
			Complete chemical deletion –
			dietary exposure assessment not
Rice	Omit	*0.1	required.
Propiconazole			
Propiconazole is a systemic foliar fungicide with both protective			NEDI = 4% of ADI
and curative action. APVMA ha			
sweet corn to control northern corn leaf blight. Results following			∡ <u>1</u> . I
	orn leaf blight. Rest	ults following	20^{th} ATDS = $<1\%$ of ADI for all
trials at the maximum proposed	orn leaf blight. Resu use pattern with a 2	ults following 28 day WHP	20 th ATDS = <1% of ADI for all population groups assessed
	orn leaf blight. Resu use pattern with a 2	ults following 28 day WHP	

		1	
Sethoxydim Sethoxydim is a selective systemic and roots. APVMA has issued perr silver beet, peppers and eggplant. It the spinach MRL. Following trials application rate, no residues above recorded in eggplant.	NEDI = 28% of ADI		
Minor amendment to residue defin	ition:		
Omit: Sum of Sethoxydim and met ethylthiopropyl)cyclohexene-3-one 3-one moieties and their sulfoxides Sethoxydim	and 5-hydroxy	cyclohexene-	
Substitute: Sum of Sethoxydim and (2-ethylthiopropyl)cyclohexene-3-one moie sulfones, expressed as Sethoxydim	one and 5-(2-eth ties and their su	hylthiopropyl)-	
Chard (silver beet)	Insert	T*0.1	
Egg plant	Insert	T*0.1	
Peppers Peppers	Insert	T0.7	
Spinosad	msert	10.7	
Spinosad is an insecticide used to divegetable and agricultural crops. It APVMA has issued a minor use per Minor technical amendment to the Omit Spinosad Substitute Spinosad	NEDI = 33% of ADI		
Assorted tropical and sub-tropical			
fruits – inedible peel	Insert	0.3	
Assorted tropical and sub-tropical			
fruits – inedible peel [except			
banana and kiwifruit]	Omit	T0.5	
Banana	Omit	0.2	
Celery	Omit	T*0.25	
	Substitute	2.0	
Citrus fruits	Omit	T0.1	
	Substitute	0.3	
Coffee beans	Insert	*0.01	
Egg plant	Omit Omit	0.2 T0.2	
Fruiting vegetables, cucurbits			
Fruiting vegetables, other than			
cucurbits [except sweet corn			
(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. See also Methomyl.			Methomyl + Thiodicarb		
		NEDI = 89% of ADI			
			NIEGTI 0/ -CADED		
			NESTI as % of ARfD		
			(See also Methomyl)		
			<u>2-6 years</u> <u>2+ years</u>		
Brassica leafy vegetables	Omit	1			
Brassica (cole or cabbage)			17	Broccoli	6
vegetables, Head cabbages,	Insert	2	2	Brussels	2
Flowerhead brassicas			9	sprouts	7
			13	Cabbages,	5
				head	
				Cauliflowe	r