

5-06
9 August 2006

INITIAL / DRAFT ASSESSMENT REPORT

APPLICATION A582

MAXIMUM RESIDUE LIMITS (APRIL, MAY, JUNE 2006)

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 20 September 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 A582 seeks to amend Maximum Residue Limits (MRLs) for agricultural and veterinary chemicals in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* (the Code). It is a routine Application from the Australian Pesticides and Veterinary Medicines Authority (APVMA), to update the Code in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty), excluded 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) 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 A582 and the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits.

Reasons for Preferred Approach

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

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

- Dietary exposure assessments indicate that setting the 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.
- The Office of Chemical Safety (OCS) part of the Therapeutic Goods Administration (TGA) 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 A582 prior to making an Initial / Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only.

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

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

- any impacts (costs/benefits) of the proposed increases, deletions and changes to specific MRLs;
- any further public health and safety considerations associated with the proposed MRLs;
- likely costs and benefits impacting the importation of food if the proposed deletions to specific MRLs are advanced; and

- any other affected parties to this Application.

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

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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) 20 September 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 Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

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

INTRODUCTION

Applications were received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 4 April, 3 May and 13 June 2006 seeking variations to Standard 1.4.2 - Maximum Residue Limits of the Code. 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.

The MRL is the highest concentration of a chemical residue that is legally permitted or accepted in a food. The MRL does not indicate the amount of chemical that is always present in a treated food but it does indicate the highest residue that could possibly result from the registered conditions of use. The concentration is expressed in milligrams of the chemical per kilogram (mg/kg) of the food.

MRLs assist in indicating whether an agricultural or veterinary chemical product has been used according to its registered use and if the MRL is exceeded then this indicates a likely misuse of the chemical product.

MRLs are also used as standards for international trade in food. In addition, MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases. 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 not agree to adopt MRLs into the Code where dietary exposure to residues of a chemical presents a risk to public health and safety. In assessing this risk, FSANZ conducts dietary exposure assessments in accordance with internationally accepted practices and procedures.

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

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 its MRL Standard accordingly. Consequently there are discrepancies between the potential residues associated with the use of the relevant agricultural and/or veterinary chemicals and the MRLs in Standard 1.4.2 of the Code.

1.2 Use of Agricultural and Veterinary Chemicals

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

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

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

1.3 Maximum Residue Limit Applications

After registering agricultural or veterinary chemical products, based on scientific evaluations, APVMA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews information provided by APVMA and validates whether the dietary exposure is within appropriate safety limits. If satisfied that the residues are within safety limits and subject to adequate resolution of any issues raised during public consultation, FSANZ will agree to incorporate the proposed MRLs into 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 A582:

- adding MRLs including some at the LOQ for new chemical Aminopyralid;
- deleting the chemical and all associated entries for 2-(thiocyanomethylthio)benzothiazole;
- deleting MRLs for certain foods for Ethephon;
- adding MRLs at the LOQ for certain foods for Imazamox and Pyraclostrobin;
- adding MRLs for certain foods for Azoxystrobin and Chlorothalonil;
- adding temporary MRLs including some at the LOQ for certain foods for Imidacloprid, Iprodione, Metalaxyl, Metolachlor and Metribuzin;
- removing the temporary status of existing MRLs for certain foods for Epoxiconazole and Phosphine;
- increasing MRLs including changing the status of some existing MRLs to temporary for certain foods for Buprofezin, and Iprodione;
- decreasing MRLs including reducing some to the LOQ for certain foods for Epoxiconazole and Fluroxypyr; and
- updating the residue definition for clothianidin.

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

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

1.5 Request to Remove Temporary Status of Phosphine MRL for Sugarcane

This Application includes a request to remove the temporary status of the Phosphine MRL for sugarcane, that is to change the MRL from T*0.01 to *0.01. The Phosphine MRL for sugarcane would remain at the LOQ. Phosphine is a rodenticide. It is registered for use as a mouse and rat poison in agricultural situations, specifically in sugarcane. Data on residues in sugarcane and in the soil following treatment were evaluated. Residues were not detected in sugarcane following application at ten times the expected treatment rate.

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

1.6 Antibiotic MRLs

There are no MRLs for antibiotic¹ residues in this Application.

1.7 Australia and New Zealand Joint Food Standards

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

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

- Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand.
- Food produced or imported into New Zealand that complies with the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards, 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 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:

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

- 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 not approve MRLs for inclusion in the Code where the dietary exposure to the residues of a chemical could represent a risk to public health and safety. In assessing this risk, FSANZ 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 no 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.

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.

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 for 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 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;

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

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

8.2.2 Option 2(a) – vary the Code in Schedule 1 of Standard 1.4.2 to omit, 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;

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

- for growers and producers of domestic and export food commodities, adopting this option is unlikely to result in any costs, as reductions in MRLs are adopted where this is practically achievable, with little or no impact on production costs;

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

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

- for Australian Government, State and Territory agencies, adopting this option would not result in any discernable costs, although there would need to be an awareness of changes in the standards for residues in food.

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

8.2.3.1 Benefits

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

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

- for growers and producers of domestic and export food commodities, the benefits of this option would result from being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Other benefits include the consistency between agricultural and food legislation thereby minimising compliance costs to primary producers;
- adopting this option would benefit importers in that food containing residues consistent with increased or new MRLs could be legally imported; and
- for Australian Government, State and Territory agencies, the benefits of this option would include the removal of discrepancies between agricultural and food legislation thereby creating certainty and allowing efficient enforcement of regulations.

8.2.3.2 Costs

- for consumers there are no discernable costs;
- for growers and producers of domestic and export food commodities, adopting this option would not result in any discernable costs;
- for importers, adopting this option would not result in any discernable costs; and

- for Australian Government, State and Territory agencies, adopting this option would not result in any discernable costs, although there may be minimal impacts associated with slight changes to residue monitoring programs.

8.3 Comparison of Options

In assessing applications, FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community, including consumers, food industries and governments in Australia.

For Application A582, 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 adopting options 2(a) and 2(b) – to vary the Code in Schedule 1 of Standard 1.4.2 to include new MRLs, increase, delete, decrease or change the 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 A582 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 A582 raised issues of minor significance or complexity only.

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

10. Consultation

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

Application A582 includes requests to vary MRLs in the Code that are addressed in the international Codex standard. MRLs in the Application also relate to chemicals used in the production of heavily traded agricultural commodities that may indirectly have a significant effect on trade of derivative food products between WTO members.

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

10.2 Codex Alimentarius Commission MRLs

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

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

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

10.3 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.

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

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

CONCLUSION

11. Conclusion and Preferred Option

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

The preferred approach is to adopt options 2(a) and 2(b) to 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*

Draft Variations to the Australia New Zealand Food Standards Code

To commence: on gazettal

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

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

2-(thiocyanomethylthio) benzothiazole

[1.2] *inserting in* Schedule 1 –

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

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

COLUMN 1	COLUMN 2
CLOTHIANIDIN	<i>COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN COMMODITIES OF ANIMAL ORIGIN: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN</i>

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

ETHEPHON	
ETHEPHON	
TRITICALE	T1
WHEAT	T1

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

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

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

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

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

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

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

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

NOTES ON TERMS USED IN THE TABLE

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

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

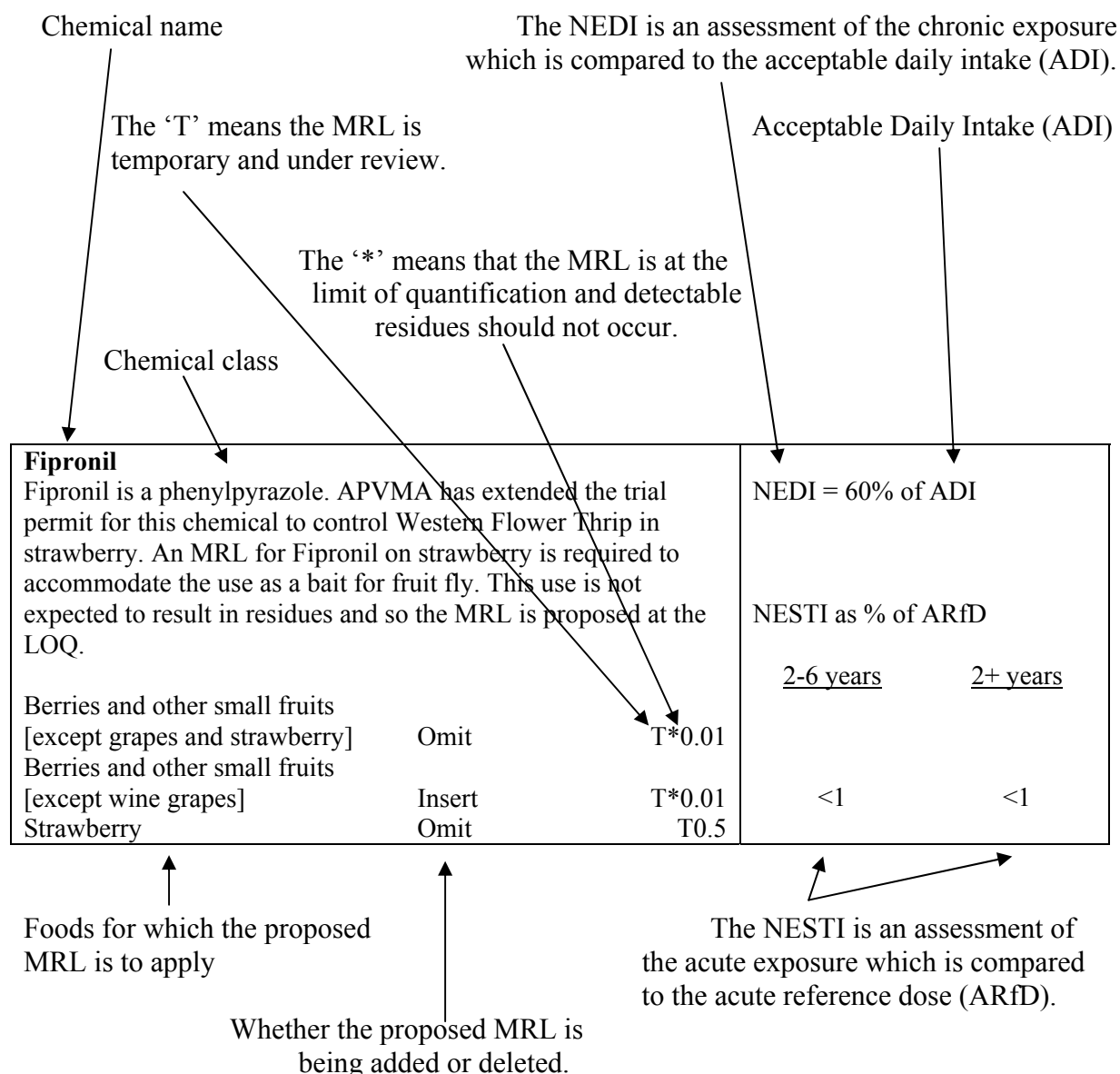
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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

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

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

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



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

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

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

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

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

Acronyms:

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

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

Requested MRLs	Dietary Exposure Estimates																																																																																																			
<p>Aminopyralid Aminopyralid is a systemic herbicide; it induces auxin-type responses. It is used to control weeds in winter cereals and sorghum; and woody weeds in pasture. Animal metabolism data show that it is largely eliminated unchanged and there are no significant residues found in animal tissues, eggs and milk. The recommended MRLs for these commodities are at the LOQ. Aminopyralid and Fluroxypyr are active ingredients in the product 'Hotshot Herbicide'.</p> <p>New chemical</p> <p>Insert residue definition:</p> <p><i>Commodities of plant origin:</i> Sum of Aminopyralid and conjugates, expressed as Aminopyralid <i>Commodities of animal origin:</i> Aminopyralid</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%;">Cereal grains</td> <td style="width: 15%;">Insert</td> <td style="width: 10%;">0.1</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 15%;"></td> </tr> <tr> <td>Edible offal (mammalian) [except kidney]</td> <td>Insert</td> <td>0.02</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Eggs</td> <td>Insert</td> <td>*0.01</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Kidney (mammalian)</td> <td>Insert</td> <td>0.3</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Meat (mammalian)</td> <td>Insert</td> <td>*0.01</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Milks</td> <td>Insert</td> <td>*0.01</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Poultry, edible offal of</td> <td>Insert</td> <td>*0.01</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Poultry meat</td> <td>Insert</td> <td>*0.01</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Wheat bran, unprocessed</td> <td>Insert</td> <td>0.3</td> <td></td> <td></td> <td></td> </tr> </table>	Cereal grains	Insert	0.1				Edible offal (mammalian) [except kidney]	Insert	0.02				Eggs	Insert	*0.01				Kidney (mammalian)	Insert	0.3				Meat (mammalian)	Insert	*0.01				Milks	Insert	*0.01				Poultry, edible offal of	Insert	*0.01				Poultry meat	Insert	*0.01				Wheat bran, unprocessed	Insert	0.3				<p>NEDI = <1% of ADI</p> <p>DIAMOND modelling estimated chronic dietary exposure of <1% ADI</p> <p>NESTI as % of ARfD</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;"></th> <th style="width: 10%;"></th> <th style="width: 10%; text-align: center;"><u>2-6 years</u></th> <th style="width: 10%;"></th> <th style="width: 10%; text-align: center;"><u>2+ years</u></th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td style="text-align: center;"><1</td> <td></td> <td style="text-align: center;"><1</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;"><1</td> <td></td> <td style="text-align: center;"><1</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;"><1</td> <td></td> <td style="text-align: center;"><1</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;"><1</td> <td></td> <td style="text-align: center;"><1</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;"><1</td> <td></td> <td style="text-align: center;"><1</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;"><1</td> <td></td> <td style="text-align: center;"><1</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;"><1</td> <td></td> <td style="text-align: center;"><1</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;"><1</td> <td></td> <td style="text-align: center;"><1</td> </tr> </tbody> </table>			<u>2-6 years</u>		<u>2+ years</u>			<1		<1			<1		<1			<1		<1			<1		<1			<1		<1			<1		<1			<1		<1			<1		<1
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<p>Azoxystrobin Azoxystrobin is a fungicide. It inhibits mitochondrial respiration in fungi. APVMA has issued a permit for its use to control leaf spot, black rot and Sclerotinia rot in carrots.</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%;">Carrot</td> <td style="width: 15%;">Insert</td> <td style="width: 10%;">0.2</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 15%;"></td> </tr> </table>	Carrot	Insert	0.2				<p>NEDI = 2% of ADI</p>																																																																																													
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<p>Buprofezin Buprofezin is an insecticide. It inhibits moulting of nymphs and larvae. APVMA has issued a permit for its use to control silverleaf whitefly on tomato and eggplant.</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%;">Egg plant</td> <td style="width: 15%;">Omit</td> <td style="width: 10%;">T1</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 15%;"></td> </tr> <tr> <td></td> <td>Substitute</td> <td>T2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Tomato</td> <td>Omit</td> <td>1</td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>T2</td> <td></td> <td></td> <td></td> </tr> </table>	Egg plant	Omit	T1					Substitute	T2				Tomato	Omit	1					Substitute	T2				<p>NEDI = 22% of ADI</p>																																																																											
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Requested MRLs			Dietary Exposure Estimates																																																																													
<p>Chlorothalonil Chlorothalonil is a non-systemic foliar fungicide with protective action. APVMA has issued a permit for its use to control black spot and brown spot on papaya. Adverse weather conditions following cyclone Larry have encouraged development of black spot and brown spot fungal diseases. Following application under the proposed use pattern, residues data from international trials support the recommended permanent MRL.</p>			<p>NEDI = 76% of ADI</p> <p>19th ATDS = <1% of ADI for all population groups assessed</p> <p>20th ATDS = <1% of ADI for all population groups assessed</p>																																																																													
Papaya (pawpaw)	Insert	7																																																																														
<p>Clothianidin Amendment to residue definition</p> <p>Omit: Clothianidin</p> <p>Substitute: <i>Commodities of plant origin:</i> Clothianidin <i>Commodities of animal origin:</i> Sum of Clothianidin, 2-chlorothiazol-5-ylmethylguanidine, 2-chlorothiazol-5-ylmethylurea, and the pyruvate derivative of N-(2-chlorothiazol-5-ylmethyl)-N'-methylguanidine expressed as Clothianidin</p>			<p>Dietary exposure assessment not required.</p>																																																																													
<p>Epoxiconazole Epoxiconazole is a triazole fungicide. It inhibits C-14 demethylase in sterol biosynthesis. It is used to control rust diseases in barley and wheat.</p>			<p>NEDI = 1% of ADI</p> <p>NESTI as % of ARfD</p> <table border="1"> <thead> <tr> <th></th> <th></th> <th>2-6 years</th> <th>2+ years</th> </tr> </thead> <tbody> <tr> <td>Barley</td> <td>Omit</td> <td>T0.5</td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>0.05</td> <td><1</td> </tr> <tr> <td>Edible offal (mammalian)</td> <td>Omit</td> <td>T0.05</td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>0.05</td> <td><1</td> </tr> <tr> <td>Eggs</td> <td>Omit</td> <td>T*0.01</td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>*0.01</td> <td><1</td> </tr> <tr> <td>Milks</td> <td>Omit</td> <td>T0.01</td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>*0.005</td> <td><1</td> </tr> <tr> <td>Poultry, edible offal of</td> <td>Omit</td> <td>T0.02</td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>*0.01</td> <td><1</td> </tr> <tr> <td>Poultry meat (in the fat)</td> <td>Omit</td> <td>T0.05</td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>*0.01</td> <td><1</td> </tr> <tr> <td>Wheat</td> <td>Omit</td> <td>T0.5</td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>0.05</td> <td><1</td> </tr> <tr> <td>Wheat bran, unprocessed</td> <td>Omit</td> <td>T3</td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>0.3</td> <td><1</td> </tr> <tr> <td>Wheat germ</td> <td>Omit</td> <td>T2</td> <td></td> </tr> <tr> <td></td> <td>Substitute</td> <td>0.2</td> <td><1</td> </tr> </tbody> </table>				2-6 years	2+ years	Barley	Omit	T0.5			Substitute	0.05	<1	Edible offal (mammalian)	Omit	T0.05			Substitute	0.05	<1	Eggs	Omit	T*0.01			Substitute	*0.01	<1	Milks	Omit	T0.01			Substitute	*0.005	<1	Poultry, edible offal of	Omit	T0.02			Substitute	*0.01	<1	Poultry meat (in the fat)	Omit	T0.05			Substitute	*0.01	<1	Wheat	Omit	T0.5			Substitute	0.05	<1	Wheat bran, unprocessed	Omit	T3			Substitute	0.3	<1	Wheat germ	Omit	T2			Substitute	0.2	<1
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<p>Ethephon Ethephon is a weak to moderate cholinesterase inhibitor. It is a growth regulator used for thinning, loosening or ripening in various crops. APVMA confirms that there are no uses of Ethephon on wheat or triticale and accordingly no MRLs are required for these commodities.</p>			<p>Dietary exposure assessment not required.</p>																																																																													
Triticale	Omit	T1																																																																														
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Requested MRLs	Dietary Exposure Estimates																		
<p>Fluroxypyr Fluroxypyr is a systemic herbicide; it induces auxin-type responses. It is used to control weeds in winter cereals and sorghum; and woody weeds in pasture. Fluroxypyr and Aminopyralid are active ingredients in the product ‘Hotshot Herbicide’.</p> <table border="0" data-bbox="177 488 986 656"> <tr> <td>Edible offal (mammalian)</td> <td>Omit</td> <td>2</td> </tr> <tr> <td>Edible offal (mammalian) [except kidney]</td> <td>Insert</td> <td>0.1</td> </tr> <tr> <td>Kidney (mammalian)</td> <td>Insert</td> <td>1</td> </tr> <tr> <td>Meat (mammalian)</td> <td>Omit</td> <td>0.1</td> </tr> <tr> <td>Meat (mammalian) (in the fat)</td> <td>Insert</td> <td>0.1</td> </tr> </table>	Edible offal (mammalian)	Omit	2	Edible offal (mammalian) [except kidney]	Insert	0.1	Kidney (mammalian)	Insert	1	Meat (mammalian)	Omit	0.1	Meat (mammalian) (in the fat)	Insert	0.1	<p>NEDI = <1% of ADI</p>			
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<p>Imazamox Imazamox is an imidazolinone herbicide. It is an acetolactate synthase (ALS) (also known as acetohydroxyacid synthase (AHAS)) inhibitor It is used for the early post emergent control of annual grass and broadleaf weeds in imidazolinone resistant canola. Data from Australian and international trials indicate that under the proposed use pattern, residues will not be detectable in harvested canola seed. The recommended MRL is at the LOQ.</p> <table border="0" data-bbox="177 958 986 992"> <tr> <td>Rape seed</td> <td>Insert</td> <td>*0.05</td> </tr> </table>	Rape seed	Insert	*0.05	<p>NEDI = <1% of ADI</p>															
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<p>Imidacloprid Imidacloprid is a systemic insecticide that binds to postsynaptic nicotinic receptors in the CNS acting as an antagonist. APVMA has issued a permit for its use to control citrus mealy bug (<i>Planococcus citri</i>) and red banded thrips (<i>Selenothrips rubrinctus</i>) on exotic tropical fruits – casimiroa, durian, mabolo, mammey, mangosteen, rambutan, rollinia and soursop.</p> <table border="0" data-bbox="177 1261 986 1379"> <tr> <td>Assorted tropical and sub-tropical fruits – inedible peel [except as otherwise listed under this chemical]</td> <td>Insert</td> <td>T1</td> </tr> </table>	Assorted tropical and sub-tropical fruits – inedible peel [except as otherwise listed under this chemical]	Insert	T1	<p>NEDI = 10% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="986 1227 1388 1379"> <tr> <td><u>2-6 years</u></td> <td><u>2+ years</u></td> </tr> <tr> <td>Up to 5 for all tropical fruits assessed</td> <td>Up to 1 for all tropical fruits assessed</td> </tr> </table>	<u>2-6 years</u>	<u>2+ years</u>	Up to 5 for all tropical fruits assessed	Up to 1 for all tropical fruits assessed											
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<p>Iprodione Iprodione is a contact fungicide. It has protective and curative action. It inhibits spore germination and mycelial growth. APVMA has issued permits for its use to control Sclerotinia rot in beans; for foliar application on beetroot to control Alternaria leaf spot, Sclerotinia rot and grey mould; and as a fungicide for broccoli, cabbage and cauliflower seedlings prior to transplanting. The recommended MRLs for broccoli, cabbage and cauliflower are at the LOQ; quantifiable residues are not expected in mature plants.</p> <table border="0" data-bbox="177 1753 986 1948"> <tr> <td>Beans [except broad bean and soya bean]</td> <td>Omit</td> <td>0.2</td> </tr> <tr> <td></td> <td>Substitute</td> <td>T1</td> </tr> <tr> <td>Beetroot</td> <td>Insert</td> <td>T0.1</td> </tr> <tr> <td>Broccoli</td> <td>Insert</td> <td>T*0.05</td> </tr> <tr> <td>Cabbages, head</td> <td>Insert</td> <td>T*0.05</td> </tr> <tr> <td>Cauliflower</td> <td>Insert</td> <td>T*0.05</td> </tr> </table>	Beans [except broad bean and soya bean]	Omit	0.2		Substitute	T1	Beetroot	Insert	T0.1	Broccoli	Insert	T*0.05	Cabbages, head	Insert	T*0.05	Cauliflower	Insert	T*0.05	<p>NEDI = 43% of ADI</p> <p>19th ATDS = 1% of ADI for toddlers 2 years and <1% of ADI for other population groups assessed</p> <p>20th ATDS = 1% of ADI for adult males 25 – 34 years and toddlers 2 years and <1% of ADI for other population groups assessed</p>
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