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Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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FINAL ASSESSMENT REPORT

APPLICATION A586

MAXIMUM RESIDUE LIMITS (JULY, AUGUST, SEPTEMBER 2006)

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

Executive Summary

Application A586 seeks to amend Maximum Residue Limits (MRLs) for agricultural and veterinary chemicals in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* (the Code). It is a routine Application from the Australian Pesticides and Veterinary Medicines Authority (APVMA), to update the Code in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

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

The Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food has been provided to FSANZ. In consultation with stakeholders, FSANZ will explore alternative options for regulating chemical residues in food. FSANZ considers the current regulatory approach is consistent with the Ministerial Policy Guideline, therefore MRL applications will continue to be progressed according to current practice. Submitters may provide specific data to support retaining MRLs; this will be considered by FSANZ in accordance with the statutory requirements of the FSANZ Act.

There are no MRLs for antibiotic residues in this Application.

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

FSANZ made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO). WTO Member Republic of the Philippines submitted comments. The comments are addressed in section 10.3.

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

Purpose

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

Decision

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

Reasons for Decision

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

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

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

- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

- APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in this Application.

- Office of Chemical Safety (OCS) part of the Therapeutic Goods Administration (TGA) has undertaken an appropriate toxicological assessment of each chemical and has established an acceptable daily intake (ADI) and where applicable an acute reference dose (ARfD).

- FSANZ has undertaken a regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and will benefit producers and consumers.

- The proposed draft variations would remove discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.

- The proposed changes are consistent with the FSANZ Act section 10 objectives.

Consultation

FSANZ has now completed the assessment of Application A586 and held a single round of public consultation under section 36 of the FSANZ Act. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

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

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INTRODUCTION

Applications were received from the APVMA on 7 July, 1 August and 8 September 2006 seeking to vary the Code. The proposed variations to Standard 1.4.2 – Maximum Residue Limits would align MRLs in the Code for non-antibiotic agricultural and veterinary chemicals with MRLs in the APVMA MRL Standard.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits.

FSANZ will not agree to adopt MRLs into the Code where dietary exposure to residues of a chemical presents a risk to public health and safety. In assessing this risk, FSANZ reviews dietary exposure assessments in accordance with internationally accepted practices and procedures.

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

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

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

MRLs are also used as standards for international trade in food. In addition, MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.

Some of the proposed MRLs in this Application are at the limit of quantification (LOQ) and are indicated by an * in front of the MRL. The LOQ is the lowest concentration of an agricultural or veterinary chemical residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. MRLs at the LOQ mean that no detectable residues of the relevant chemical should occur. FSANZ incorporates MRLs at the LOQ in the Code to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

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

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

- trial permits for research.

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

1. Background

1.1 Current Standard

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

1.2 Use of Agricultural and Veterinary Chemicals

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

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

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

1.3 Maximum Residue Limit Applications

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

FSANZ notifies the Ministerial Council when variations to the Code are approved. If the Ministerial Council does not request a review of the draft variations to Standard 1.4.2, the MRLs are automatically adopted by reference into the food laws of the Australian States and Territories.

Appropriate toxicology, residue, animal transfer, processing and metabolism studies were provided to APVMA in accordance with *The Manual of Requirements and Guidelines - MORAG - for Agricultural and Veterinary Chemicals 1 July 2005* to support the MRLs in the commodities as outlined in this Application.

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

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

The Ministerial Council has endorsed a Policy Guideline for the Regulation of Residues of Agricultural and Veterinary Chemicals in Food, which has now been provided to FSANZ. In consultation with stakeholders, FSANZ will explore alternative options for regulating chemical residues in food. To ensure appropriate consultation, this process will take some time to complete.

Some submitters have raised concerns about MRL deletions in recent applications, suggesting they are inconsistent with the Policy Guideline. FSANZ considers the current regulatory approach for setting MRLs in the Code is consistent with the Policy Guideline, therefore MRL applications will continue to be progressed according to current practice. Submissions including data demonstrating a requirement for certain MRLs to be retained may be made under the current process for considering variations to the Code. FSANZ will consider retaining MRLs proposed for deletion where these MRLs are necessary to continue to allow the sale of safe food; and where the MRLs are supported by adequate data or information demonstrating that the residues associated with these MRLs do not raise any public health or safety concerns (further information on data requirements may be obtained from FSANZ). MRL deletions are discussed in section 10.5 of this report.

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

Amendments under consideration in Application A586:

- adding a temporary MRL at the LOQ for new chemical florasulam;
- adding MRLs including some at the LOQ for new chemical tetraconazole;
- deleting the chemical and all associated entries for dinocap;
- adding a MRL at the LOQ for propiconazole;
- adding MRLs for certain foods for chlorothalonil, metalaxyl and pinoxaden;
- adding temporary MRLs including some at the LOQ for certain foods for amitrole, bifenazate, boscalid, clopyralid, difenoconazole, fenbutatin oxide and fenoxycarb;
- changing an existing temporary MRL to a MRL for cloquintocet-mexyl;
- increasing MRLs including changing some temporary MRLs to MRLs for certain foods for imidacloprid and pinoxaden;
- decreasing and changing temporary MRLs to MRLs for certain foods for chlorothalonil and pinoxaden; and

- varying the residue definition for pinoxaden.

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.

1.6 Antibiotic MRLs

There are no MRLs for antibiotic[1] residues in this Application.

1.7 Australia and New Zealand Joint Food Standards

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

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

- Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand.

- Food produced or imported into New Zealand that complies with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards, 2007 can be legally sold in Australia.

2. The Issue / Problem

Including MRLs in the Code has the effect of allowing legally treated produce to be sold legally where any residues do not exceed MRLs. Changes to Australian MRLs reflect the changing patterns of agricultural and veterinary chemicals available to farmers. These changes include the development of new products or crop uses, granting or expiry of temporary permissions and the withdrawal of older products following review.

3. Objectives

In assessing this Application FSANZ aims to ensure that the proposed MRLs do not present public health and safety concerns and that the sale of legally treated food is permitted. 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 microorganism.

- 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 reviews dietary exposure assessments in accordance with internationally accepted practices and procedures.

The three steps undertaken in conducting a dietary exposure assessment are:

- determination of the residues of a chemical in a treated food;
- determination of the acceptable reference health standard/s for a chemical in food (i.e. the ADI and/or the ARfD); and

- calculating the dietary exposure to a chemical from relevant foods, using food consumption data from national nutrition surveys and comparing this to the acceptable reference health standard.

RISK ASSESSMENT

5. Safety Assessment

5.1 Determination of the Residues of a Chemical in a Treated Food

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

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

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

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

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).

FSANZ is currently planning the next ATDS (now the Australian Total Diet Study). The study will analyse the levels of various agricultural and veterinary chemicals in food and estimate the potential dietary exposure of population groups in Australia to those chemicals.

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

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

The estimated dietary exposure is then divided by the average Australian's bodyweight to provide the amount of chemical consumed per day per kg of human bodyweight. This is compared to the ADI. It is therefore the overall dietary exposure to a chemical that is compared to the ADI - not the MRL.

FSANZ considers that the chronic dietary exposure to the residues of a chemical is acceptable where the best estimate of exposure does not exceed the ADI.

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

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

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

5.3.2 Acute Dietary Exposure Assessment

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

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

6. Risk Assessment Summary

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

For this Application, APVMA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005*, to support the use of chemicals on commodities as outlined in this Application.

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

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

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

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

RISK MANAGEMENT

7. Options

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

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

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

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

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

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

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

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

8. Impact Analysis

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

8.1 Affected Parties

The parties affected by proposed MRL amendments include:

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

8.2 Benefit Cost Analysis

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

8.2.1.1 Benefits

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

8.2.1.2 Costs

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

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

- for importers, this option would not result in any discernable costs; and

- for Australian Government, State and Territory agencies, this option would allow discrepancies between agricultural and food legislation thereby creating uncertainty, inefficiency and confusion in the enforcement of regulations.

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

8.2.2.1 Benefits

- for consumers the major benefit would be maintaining existing confidence in the food supply in relation to residues of agricultural and veterinary chemicals;

- for growers and producers of domestic and export food commodities, this option would not result in any discernable benefits;

- for importers, this option would not result in any discernable benefits; and

- for Australian Government, State and Territory agencies, this option would foster community confidence that regulatory authorities are maintaining standards to minimise residues in the food supply.

8.2.2.2 Costs

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

- for growers and producers of domestic and export food commodities, this option is unlikely to result in any costs, as changes in use patterns are made as required, proper use resulting in compliance with proposed MRLs already;

- for importers, 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. FSANZ is considering alternative regulatory options to address this issue. This is discussed in section 1.4 of this report. Codex MRLs and data on imported foods are addressed in section 10; and

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

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

8.2.3.1 Benefits

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

- for growers and producers of domestic and export food commodities, the benefits of this option would result from being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Other benefits include the consistency between agricultural and food legislation thereby minimising compliance costs to primary producers;

- this option benefits importers in that food containing residues consistent with increased or new MRLs could be legally imported; and

- removing discrepancies between agricultural and food legislation thereby creating certainty and allowing efficient enforcement of regulations benefits Australian Government, State and Territory agencies.

8.2.3.2 Costs

- for consumers there are no discernable costs;

- for growers and producers of domestic and export food commodities, this option would not result in any discernable costs;

- for importers, this option would not result in any discernable costs; and

- for Australian Government, State and Territory agencies, 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 A586, there are no options other than a variation to Standard 1.4.2.

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

- There are no public health and safety concerns associated with the proposed MRL amendments (this benefit also applies to option 1).

- The changes would minimise potential costs to primary producers and rural and regional communities in terms of legally being able to sell legally treated food.

- The changes would minimise residues consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases.

- The changes would remove discrepancies between agricultural and food legislation and assist enforcement.

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

Option 1 is an undesirable option.

- Potential substantial costs to primary producers may result. Additional costs may impact negatively on their viability and in turn the viability of the rural and regional communities that depend upon the sale of agricultural produce.

- Consequent discrepancies between agricultural and food legislation could have negative impacts on compliance costs for primary producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

COMMUNICATION

9. Communication and Consultation Strategy

Applications by the APVMA to amend maximum residue limits in the Code do not normally generate public interest. FSANZ adopts a basic communication strategy, with a focus on alerting the community that a change to the Code is being contemplated.

FSANZ publishes the details of the Application and subsequent assessment reports on its website, notifies the community of the period of public consultation through newspaper advertisements, and issues media releases drawing attention to proposed Code amendments. Once the Code has been amended, FSANZ incorporates the changes in the website version of the Code and, through its email and telephone advice service, responds to industry enquiries.

Should the media show an interest in any of the chemicals being assessed, FSANZ or the APVMA can provide background information and other advice, as required.

FSANZ decided, pursuant to section 36 of the FSANZ Act, to omit inviting public submissions in relation to Application A586 prior to making a Draft Assessment. However, FSANZ invited written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and had regard to submissions received.

10. Consultation

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

Submissions were received from Food Technology Association of Victoria Inc. (FTAV), Queensland Health Environmental Health Unit, NSW Food Authority, Department of Human Services Victoria (DHS), and Australian Food and Grocery Council (AFGC).

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

10.1 Summarised Submission from the NSW Food Authority

The NSW Food Authority supports option 2(a) and 2(b) to vary the Code as proposed. The NSW Food Authority suggested that FSANZ investigate the impact of proposed MRL deletions on trade of imported foods and stated that it would not be an appropriate use of State and Territory resources to pursue a violation of Standard 1.4.2 due to such deletions.

10.1.1 FSANZ Evaluation

Foods containing agricultural and veterinary chemical residues where there is no MRL are illegal for sale. MRL deletions have the potential to restrict the importation of foods as foods with no longer permitted residues could not be legally imported or sold in Australia. FSANZ advertises any proposed changes to MRLs through public consultation and lists all amendments on the FSANZ website to assist industry sectors and other interested parties in identifying any impacts following deletions or reductions of specific MRLs. No submissions were received from specific industry sectors addressing likely impacts on trade or importation for the relevant food commodities if the proposed deletions or reductions are progressed.

At Initial / Draft Assessment, FSANZ requested comment as to any possible ramifications of the proposed MRLs differing from international MRLs. No comments were received from any industry sectors. Following the WTO Notification, member countries raised no specific trade impact issues in regard to the proposed deletions or reductions. Therefore it is unlikely that there will be impacts on imported foods.

10.2 Summarised Submission from the Australian Food and Grocery Council

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

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

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

AFGC notes that progressing the proposed reductions and deletions of MRLs for chemicals that are used internationally may potentially impact on importation of certain commodities.

10.2.1 FSANZ Evaluation

No submissions were received identifying any specific trade or importation issues in regard to the relevant food commodities where MRL deletions or reductions are proposed. Submissions including data demonstrating a requirement for certain MRLs to be retained may be made under the current process for considering variations to the Code. FSANZ will consider retaining MRLs proposed for deletion where these MRLs are necessary to continue to allow the sale of safe food; and where the MRLs are supported by adequate data or information demonstrating that the residues associated with these MRLs do not present public health or safety concerns.

The Ministerial Council has endorsed a Policy Guideline on the regulation of residues of agricultural and veterinary chemicals in food, which has now been provided to FSANZ. In consultation with stakeholders, FSANZ will explore alternative options for regulating chemical residues in food. Issues associated with the current 'zero tolerance' approach including consideration of a default low level will be addressed as part of this process.

10.3 World Trade Organization

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

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

Application A586 includes requests to vary MRLs in the Code that are addressed in the international Codex standard. MRLs in the Application also relate to chemicals used in the production of heavily traded agricultural commodities this may indirectly have a significant effect on trade of derivative food products between WTO members.

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

WTO member the Republic of the Philippines notes that proposed MRL variations for bifenazate, dinocap, fenbutatin oxide and imidacloprid do not conform with the Codex international standard. The comments state that as stipulated in the WTO SPS Agreement, Australia must illustrate scientific evidence to support the proposed MRL variations. It is noted that the deletion of dinocap MRLs has the potential to be trade restrictive because exported foods may contain residues consistent with the MRLs proposed for deletion and Codex established standards, however no data identifying specific impacts on trade in any commodities was provided.

Currently, MRLs are set according to Australian Good Agricultural Practice (GAP) or Good Veterinary Practice (GVP). Each MRL is based on trial data submitted to APVMA and is set at a level that is known to be safe for people while still allowing the chemical to work effectively that is, no higher than is necessary for the effective control of pests and diseases. MRLs are set to reflect the legal use of a chemical. APVMA deletes MRLs to reflect current chemical use patterns and GAP.

To protect public health and safety, FSANZ assesses the dietary exposure to residues of agricultural and veterinary chemicals and ensures that dietary exposure does not exceed the acceptable health reference standards. To ensure that these assessments remain current and are based upon the best available science, residue limits are removed from the Code where residues of the specific chemical are no longer considered likely to occur in the specific food. FSANZ does not consider it appropriate to retain MRLs in the Code for specific food/chemical combinations where these residues are unlikely to occur in food due to a change in use pattern. This approach ensures that the assessment of dietary exposure is as accurate as possible for the chemical concerned. This approach also ensures openness and transparency in relation to the residues that could reasonably occur in food.

As a member of the WTO Australia is obliged to notify member nations where proposed mandatory regulatory measures are inconsistent with international standards. FSANZ advises other countries where there are Codex MRLs relevant to any food/chemical combination for which a MRL variation is proposed and specifically identifies them in consultation documents. This is done with a view to consider impacts identified by member nations exporting relevant food/s to Australia.

10.4 Codex Alimentarius Commission MRLs

Codex Alimentarius Commission (Codex) standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table lists the variations to MRLs in Application A586 that are addressed in the international Codex standard.

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Bifenazate		
Dried grapes	T2	Interim MRL 2
Grapes [except wine grapes]	T1	Interim MRL 1
Dinocap		
Fruiting vegetables, cucurbits	Omit 0.1	0.05
Grapes	Omit 0.1	0.5
Pome fruits	Omit 0.1	Apple 0.2
Stone fruits	Omit 0.1	Peach 0.1
Strawberry	Omit 0.1	Strawberry except glasshouse grown strawberry 0.5
Fenbutatin oxide		
Dried grapes	T10	Raisins 20
Grapes [except wine grapes]	T3	Grapes 5
Imidacloprid		
Leafy vegetables [except lettuce, leaf]	T5	Lettuce, head 2

10.5 Imported Foods

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

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

To assist in identifying possible impacts where imported foods may be affected, FSANZ compiled the following table of foods that have MRLs proposed for deletion and/or reduction and sought comment on any impacts of these reductions or deletions at Initial / Draft Assessment. The NSW Food Authority and AFGC made submissions on these impacts; these are discussed in section 10.1 and 10.2 above.

Chemical Food
Chlorothalonil
Fennel, bulb
Fennel, leaf
Dinocap
Fruiting vegetables, cucurbits
Grapes
Pome fruits
Stone fruits
Strawberry

Chemical Food
Pinoxaden
Edible offal (mammalian)
Eggs
Meat (mammalian)
Milks
Poultry, edible offal of
Poultry meat

CONCLUSION

11. Conclusion and Decision

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

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

Decision

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

11.1 Reasons for Decision

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

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- Dietary exposure assessments indicate that setting the maximum residue limits as proposed does not present any public health and safety concerns.
- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.
- APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005*, to support the use of chemicals on commodities as outlined in this Application.
- OCS has undertaken an appropriate toxicological assessment of each chemical and has established an ADI and where applicable an ARfD.

- FSANZ has undertaken a regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and will benefit producers and consumers.

- The proposed draft variations would remove discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.

- The proposed changes are consistent with the FSANZ Act section 10 objectives.

12. Implementation and Review

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

- State and Territory residue monitoring programs;

- Australian Government programs such as the National Residue Survey; and

- dietary exposure studies such as the Australian Total Diet Study.

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

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

ATTACHMENTS

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

Attachment 1

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 –*

Dinocap

[1.2] *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
PINOXADEN	SUM OF FREE AND CONJUGATED M4 METABOLITE, 8-(2,6-DIETHYL-4-HYDROXYMETHYLPHENYL)-TETRAHYDRO-PYRAZOLO [1,2-D][1,4,5] OXADIAZEPINE-7,9-DIONE, EXPRESSED AS PINOXADEN

[1.3] *inserting in* Schedule 1–

FLORASULAM FLORASULAM	
CEREAL GRAINS	T*0.01
TETRACONAZOLE TETRACONAZOLE	
EDIBLE OFFAL (MAMMALIAN)	0.2
GRAPES	0.5
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MILKS	*0.01

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

CHLOROTHALONIL *COMMODITIES OF PLANT ORIGIN*: CHLOROTHALONIL *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CHLOROTHALONIL AND 4-HYDROXY-2, 5, 6-TRICHLOROISOPHTHALONITRILE METABOLITE, EXPRESSED AS CHLOROTHALONIL	
HERBS	T7
FENBUTATIN OXIDE BIS[TRIS(2-METHYL-2-PHENYLPROPYL)TIN]-OXIDE	
BERRIES AND OTHER SMALL FRUITS	1

IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID	
LEAFY VEGETABLES	T5

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

AMITROLE AMITROLE	
BLUEBERRIES	T*0.01
BIFENAZATE SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOXYLIC ACID, 2-(4-METHOXY-[1,1'-BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
DRIED GRAPES	T2
GRAPES [EXCEPT WINE GRAPES]	T1
BOSCALID *COMMODITIES OF PLANT ORIGIN*: BOSCALID *COMMODITIES OF ANIMAL ORIGIN*: SUM OF BOSCALID, 2-CHLORO-N-(4'-CHLORO-5-HYDROXYBIPHENYL-2-YL) NICOTINAMIDE AND GLUCURONIDE CONJUGATE OF 2-CHLORO-N-(4'-CHLORO-5-HYDROXYBIPHENYL-2-YL) NICOTINAMIDE, EXPRESSED AS BOSCALID EQUIVALENTS	
BULB VEGETABLES [EXCEPT ONION, BULB]	T3
CARROT	T1
CHLOROTHALONIL *COMMODITIES OF PLANT ORIGIN*: CHLOROTHALONIL *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CHLOROTHALONIL AND 4-HYDROXY-2, 5, 6-TRICHLOROISOPHTHALONITRILE METABOLITE, EXPRESSED AS CHLOROTHALONIL	
FENNEL, LEAF	5
FENNEL, SEED	5
HERBS [EXCEPT FENNEL, LEAF]	T7
CLOPYRALID CLOPYRALID	
CAULIFLOWER	T0.2
DIFENOCONAZOLE DIFENOCONAZOLE	
PARSLEY	T15
FENBUTATIN OXIDE BIS[TRIS(2-METHYL-2-PHENYLPROPYL)TIN]-OXIDE	
BERRIES AND OTHER SMALL FRUITS [EXCEPT TABLE GRAPES]	1
DRIED GRAPES	T10

GRAPES [EXCEPT WINE GRAPES]	T3
FENOXYCARB FENOXYCARB	
OLIVE OIL, VIRGIN	T3
OLIVES	T1
IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID	
LEAFY VEGETABLES [EXCEPT LETTUCE, LEAF]	T5
LETTUCE, LEAF	T20
METALAXYL METALAXYL	
PARSLEY	0.3
PINOXADEN SUM OF FREE AND CONJUGATED M4 METABOLITE, 8-(2,6-DIETHYL-4-HYDROXYMETHYLPHENYL)-TETRAHYDRO-PYRAZOLO [1,2-D][1,4,5] OXADIAZEPINE-7,9-DIONE, EXPRESSED AS PINOXADEN	
WHEAT BRAN, UNPROCESSED	0.5
PROPICONAZOLE PROPICONAZOLE	
BEETROOT	*0.02

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

CHLOROTHALONIL *COMMODITIES OF PLANT ORIGIN*: CHLOROTHALONIL *COMMODITIES OF ANIMAL ORIGIN*: SUM OF CHLOROTHALONIL AND 4-HYDROXY-2, 5, 6-TRICHLOROISOPHTHALONITRILE METABOLITE, EXPRESSED AS CHLOROTHALONIL	
FENNEL, BULB	5
CLOQUINTOCET-MEXYL SUM OF CLOQUINTOCET MEXYL AND 5-CHLORO-8-QUINOLINOXYACETIC ACID, EXPRESSED AS CLOQUINTOCET MEXYL	
BARLEY	*0.1
PINOXADEN SUM OF FREE AND CONJUGATED M4 METABOLITE, 8-(2,6-DIETHYL-4-HYDROXYMETHYLPHENYL)-TETRAHYDRO-PYRAZOLO [1,2-D][1,4,5] OXADIAZEPINE-7,9-DIONE, EXPRESSED AS PINOXADEN	
BARLEY	0.1
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02

MEAT (MAMMALIAN)	*0.02
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
WHEAT	0.1

Attachment 2

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

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

NOTES ON TERMS USED IN THE TABLE

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

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

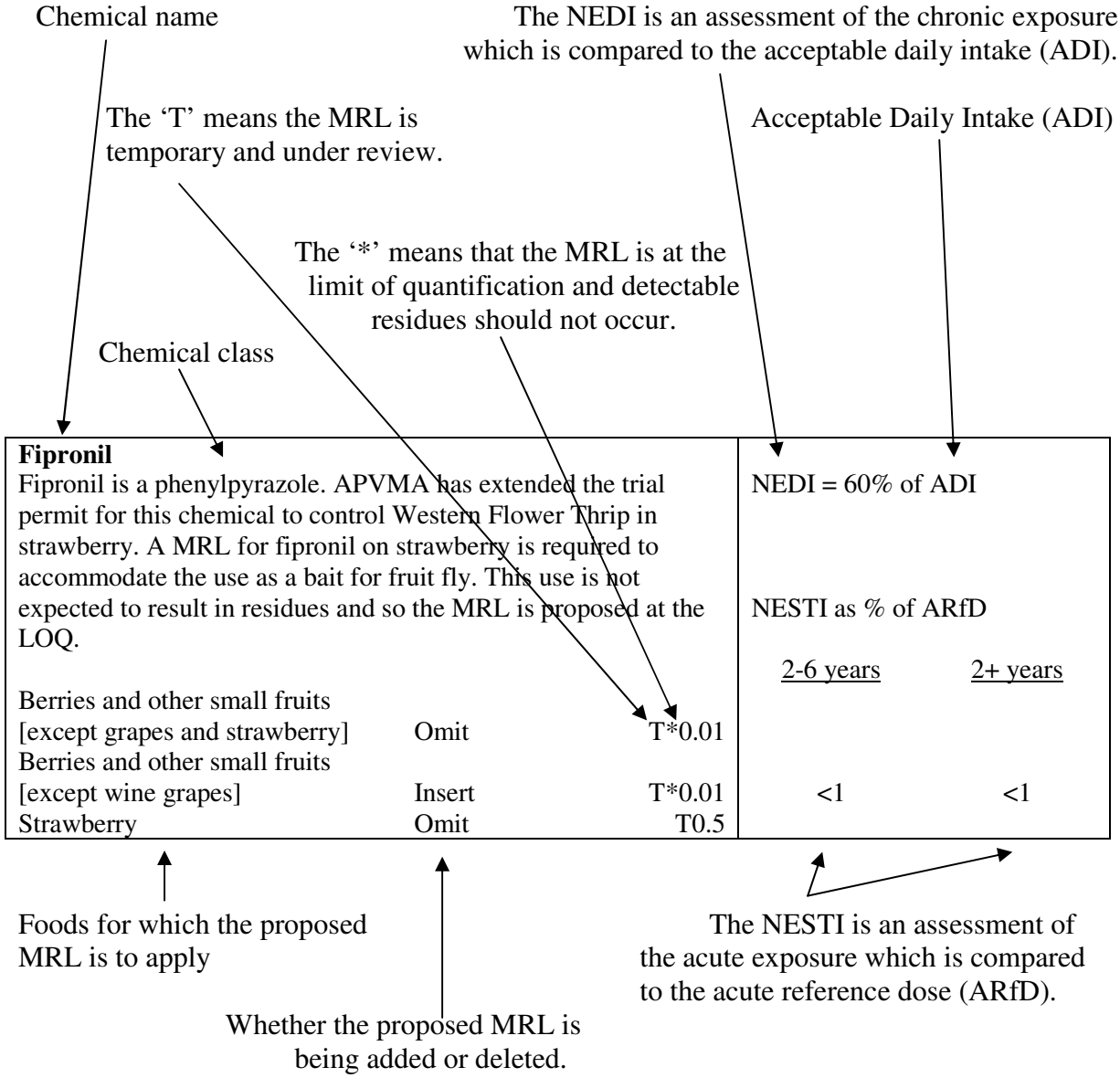
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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

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

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

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



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

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

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

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

Chlorpyrifos Chlorpyrifos is an acaricide, nematicide and insecticide APVMA has approved an extension of use for the control of pests in coffee crops.	
	NEDI = 83% of ADI 20th ATDS = <1% of ADI for all population groups assessed 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 NESTI as % of ARfD

Coffee beans	Insert	T0.5	2-6 years	2+ years
			8	<1

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

Acronyms:

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

SUMMARY OF REQUESTED MRLS FOR APPLICATION A586
MAXIMUM RESIDUE LIMITS – JULY AUGUST SEPTEMBER 2006

Requested MRLs			**Dietary Exposure Estimates**
Amitrole Amitrole is a non-selective systemic herbicide. APVMA has issued a permit for its use to control weeds among blueberries. Detectable residues are not expected to occur. The recommended temporary MRL is at the LOQ.			NEDI = 81% of ADI
Blueberries	Insert	T*0.01	
Bifenazate Bifenazate is a selective miticide registered to control phytophagous mites in pome and stone fruits. It has little impact on bees or other beneficial insects. APVMA has issued a permit for its use to control mites in grapes.			NEDI = 7% of ADI NESTI as % of ARfD 2-6 years / 2+ years
Dried grapes	Insert	T2	<1 / <1
Grapes [except wine grapes]	Insert	T1	4 / 2
Boscalid Boscalid is a fungicide. It inhibits spore germination, germ tube elongation, mycelial growth and sporulation by inhibition of succinate ubiquinone reductase (complex II) in the mitochondrial electron transport chain. APVMA has issued a permit for its use to control Sclerotinia rot in carrots and alliums.			NEDI = 7% of ADI NESTI as % of ARfD 2-6 years / 2+ years
Bulb vegetables [except onion, bulb]	Insert	T3	1 Fennel, bulb <1 <1 Garlic <1 1 Leek <1 <1 Shallot <1 <1 Spring onion <1
Carrot	Insert	T1	<1 / <1
Chlorothalonil Chlorothalonil is a non-systemic foliar fungicide with protective action. APVMA has issued a permit for its use to control downy mildew (*Peronospora destructor*) and purple blotch (*Alternaria porri*) on fennel. Residues data from two Australian field trials support lowering and confirming the current temporary fennel MRLs.			NEDI = 88% of ADI 19th ATDS = <1% of ADI for all population groups assessed 20th ATDS = <1% of ADI for all population groups assessed
Fennel, bulb	Omit	T10	
	Substitute	5	
Fennel, leaf	Insert	5	
Fennel, seed	Insert	5	
Herbs	Omit	T7	
Herbs [except fennel, leaf]	Insert	T7	
Clopyralid Clopyralid is a post-emergent selective herbicide. APVMA has issued a permit for its use to control capeweed and clover weeds in cauliflower.			NEDI = 1% of ADI
Cauliflower	Insert	T0.2	

Requested MRLs			Dietary Exposure Estimates
Cloquintocet-mexyl Cloquintocet-mexyl is a crop safener. It accelerates the detoxification process of some herbicides in cereals. Cloquintocet-mexyl and pinoxaden are active ingredients in the product 'Axial Herbicide'. The product is to be used to control post-emergent grass weeds in wheat and barley crops. Residues data from Australian and European trials support the current LOQ MRL for wheat and confirmation of the current temporary MRL for barley. The recommended MRL for barley grain is at the LOQ. Processing studies indicate that MRLs are not required for processed commodities.			NEDI = 4% of ADI
Barley	Omit	T*0.1 *0.1	
Difenoconazole Difenoconazole is a systemic azole fungicide with preventative and curative action. It is absorbed by the leaves with acropetal and strong translaminar translocation. APVMA has issued a permit for its use to control various fungal diseases in parsley.			NEDI = 13% of ADI
Parsley	Insert	T15	
Dinocap Dinocap is a contact fungicide with protective and curative action. It has been used to control powdery mildews on various crops. APVMA confirms that there are no registered products containing dinocap or current permits for use of this chemical and accordingly MRLs are not required. The whole entry for this chemical is to be omitted.			Complete chemical deletion - dietary exposure assessment not required.
Fruiting vegetables, cucurbits	Omit	0.1	
Grapes	Omit	0.1	
Pome fruits	Omit	0.1	
Stone fruits	Omit	0.1	
Strawberry	Omit	0.1	
Fenbutatin oxide Fenbutatin oxide is an insecticide with contact and stomach action. APVMA has issued a permit for its use to control mites on table grapes.			NEDI = 90% of ADI
Berries and other small fruits	Omit	1	
Berries and other small fruits [except table grapes]	Insert	1	
Dried grapes	Insert	T10	
Grapes [except wine grapes]	Insert	T3	

Requested MRLs			Dietary Exposure Estimates
Fenoxycarb Fenoxycarb is an insecticide. It is a non –neurotoxic insect growth regulator with contact and stomach action. It exhibits strong juvenile hormone activity, inhibiting metamorphosis to the adult stage and interfering with early instar larvae moulting. APVMA has issued a permit for its use to control black olive scale (*Saissetia oleae*) on olives. Olive oil, virgin Olives	 Insert Insert	 T3 T1	NEDI = 5% of ADI 19th ATDS = <1% of ADI for all population groups assessed 20th ATDS = <1% of ADI for all population groups assessed
Florasulam Florasulam is a post-emergent herbicide. It is an acetolactate synthase inhibitor. It inhibits synthesis of branched chain amino acids (leucine, isoleucine and valine). APVMA has issued a permit for its use to control broadleaf weeds in cereal crops. Florasulam is an active ingredient in the product 'Torpedo Herbicide'. Residues data indicate that florasulam residues are unlikely to occur in grain or animal feeds. The recommended MRL is at the LOQ. New chemical Insert residue definition: Florasulam Cereal grains	 Insert	 T*0.01	NEDI = <1% of ADI DIAMOND modelling estimated chronic dietary exposure as <1% of ADI
Imidacloprid Imidacloprid is a systemic herbicide. It binds to postsynaptic nicotinic receptors in the central nervous system acting as an antagonist. APVMA has issued an emergency permit for its use as a seedling drench prior to transplanting to control lettuce aphid in leafy lettuce varieties. The use is recommended for quarantine purposes and transport of seedlings across state borders. Leafy vegetables Leafy vegetables [except lettuce, leaf] Lettuce, leaf	 Omit Insert Insert	 T5 T5 T20	NEDI = 14% of ADI NESTI as % of ARfD 2-6 years / 2+ years 11 / 8 58 / 26
Metalaxyl Metalaxyl is a systemic fungicide with protective and curative action. APVMA has issued a permit for its use to control pythium and phytophthora root rots in parsley. Parsley	 Insert	 0.3	NEDI = 6% of ADI 20th ATDS = <1% of ADI for all population groups assessed

Requested MRLs			Dietary Exposure Estimates		
Pinoxaden Pinoxaden is a selective herbicide. It inhibits lipid synthesis or CoA carboxylase. Pinoxaden and cloquintocet-mexyl are active ingredients in the product 'Axial Herbicide'. The product is to be used to control post-emergent grass weeds in wheat and barley crops. The recommended MRLs for animal commodities are at the LOQ. Amendment to residue definition Omit: Sum of 8-(2,6-diethyl-4-methylphenyl)-tetrahydro-pyrazolo [1,2-d][1,4,5] oxadiazepine-7,9-dione and 8-(2,6-diethyl-4-hydroxymethylphenyl)-tetrahydro-pyrazolo [1,2-d][1,4,5] oxadiazepine-7,9-dione, expressed as Pinoxaden Substitute: Sum of free and conjugated M4 metabolite, 8-(2,6-diethyl-4-hydroxymethylphenyl)-tetrahydro-pyrazolo [1,2-d][1,4,5]oxa-diazepine-7,9-dione, expressed as pinoxaden			NEDI = <1% of ADI DIAMOND modelling estimated chronic dietary exposure as <1% of ADI for the general population and <2% of ADI for 95th percentile (high consumers). NESTI as % of ARfD		
			2-6 years		2+ years
Barley	Omit	T*0.02			
	Substitute	0.1	<1	Cereal grains	<1
			<1	Cereal grain fractions	<1
			<1	Early milling products (except wheat bran)	<1
Edible offal (mammalian)	Omit	T*0.05			
	Substitute	*0.02	<1		<1
Eggs	Omit	T*0.05			
	Substitute	*0.02	<1		<1
Meat (mammalian)	Omit	T*0.05			
	Substitute	*0.02	<1		<1
Milks	Omit	T*0.02			
	Substitute	*0.01	<1		<1
Poultry, edible offal of	Omit	T*0.05			
	Substitute	*0.02	<1		<1
Poultry meat	Omit	T*0.05			
	Substitute	*0.02	<1		<1
Wheat	Omit	T*0.02			
	Substitute	0.1			
Wheat bran, unprocessed	Insert	0.5	<1		<1
Propiconazole Propiconazole is a systemic foliar fungicide with protective and curative action. It inhibits ergosterol biosynthesis. APVMA has issued a permit for its use to control leaf spot (*Cercospora* spp.) in beetroot. Australian and international residues data support establishing a permanent MRL at the LOQ. Beetroot	Insert	*0.02	NEDI = 4% of ADI 20th ATDS = <1% of ADI for all population groups assessed		

Requested MRLs			**Dietary Exposure Estimates**		
Tetraconazole Tetraconazole is a broad spectrum systemic fungicide with protective curative and eradicant properties. It is a sterol C^{14} – demethylase inhibitor. It is used to control powdery mildew on grape vines. Residues data indicate that the recommended MRL for grapes will cover residues in dried grapes and that residues are unlikely to concentrate in wine and therefore a separate MRL is not required. MRLs are recommended for animal commodities to cover potential residues arising from feeding grape pomace to livestock. The recommended MRLs for meat and milks are at the LOQ. New chemical Insert residue definition: Tetraconazole			NEDI = 3% of ADI DIAMOND modelling estimated chronic dietary exposure as 3% of ADI NESTI as % of ARfD		
			2-6 years		2+ years
Edible offal (mammalian)	Insert	0.2	<1		<1
Grapes	Insert	0.5	2		<1
Meat (mammalian) (in the fat)	Insert	*0.01	<1		<1
Milks	Insert	*0.01	<1		<1
			<1	Wine	<1

Attachment 3

SUMMARY OF SUBMISSIONS AND WTO COMMENTS RECEIVED

Submitter	Comments
Food Technology Association of Victoria Inc.	Supported this Application.
Queensland Health Environmental Health Unit	Supported this Application.
NSW Food Authority	Supported this Application. NSW Food Authority suggests FSANZ investigate the impact of proposed MRL deletions on trade of imported foods. The submission states that to pursue a violation of the Standard due to such deletions would be an inappropriate use of State and Territory resources.
Department of Human Services Victoria	Supported this Application.
Australian Food and Grocery Council	Supported option 2(b) to include new or increase some existing MRLs, however rejects option 2(a) as there is no default low level MRL permitted for imported fruits and vegetables. AFGC expressed concern that where MRLs at or below 0.1 mg/kg for which there are no public health or safety concerns are deleted, this may create a barrier to international trade that provides no public health benefit. AFGC notes that progressing MRL deletions and reductions for chemicals used internationally may impact imports.
WTO Member	**Comments**
The Republic of the Philippines	Notes that some proposed MRL variations are not consistent with Codex MRLs. States that in accordance with the WTO SPS Agreement, Australia must illustrate scientific evidence to support the proposed MRL variations. Notes that MRL deletions have the potential to be trade restrictive as foods exported from the Philippines may contain residues consistent with the MRLs proposed for deletion and Codex MRLs.