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FINAL ASSESSMENT REPORT

APPLICATION A568

MAXIMUM RESIDUE LIMITS
(JULY, AUGUST, SEPTEMBER 2005)

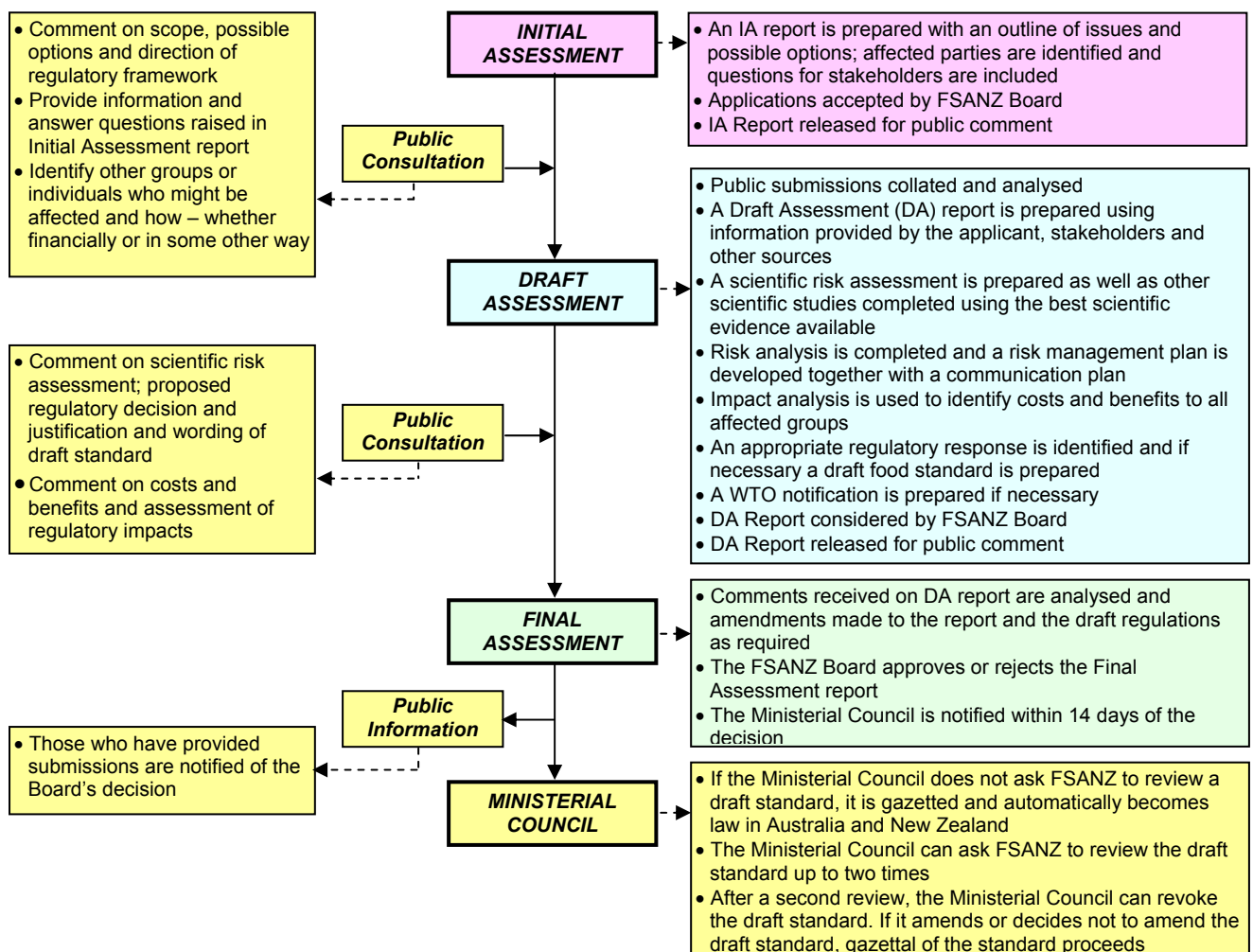
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



Final Assessment Stage (s.36)

FSANZ has now completed the assessment of Application A568 and held a single round of public consultation under section 36 of the FSANZ Act. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

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

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au. Other general enquiries and requests for information may also be directed to the Information Officer.

CONTENTS

EXECUTIVE SUMMARY	6
Statement of Reasons	6
1. INTRODUCTION.....	8
1.1 Summary of proposed MRLs	8
1.2 APVMA review of procymidone.....	8
1.3 Antibiotic MRLs	10
1.4 Deletion of dwarf banana MRLs.....	10
1.5 Request to vary tolylfluanid MRL to exclude grapes	11
2. REGULATORY PROBLEM.....	11
2.1 Current Regulations	11
3. OBJECTIVE	11
4. BACKGROUND	12
4.1 The use of agricultural and veterinary chemicals	12
4.2 Maximum Residue Limit Applications.....	12
4.3 Maximum Residue Limits.....	12
4.4 Food Standard-setting in Australia and New Zealand	13
4.5 Trans Tasman Mutual Recognition Arrangement.....	13
4.6 Limit of Quantification	13
4.7 MRLs for Permits	14
5. EVALUATION OF ISSUES RAISED IN PUBLIC SUBMISSIONS.....	14
5.1 Submission from Australian Food and Grocery Council.....	14
5.2 Submission from Ms Jacqui Simcock.....	15
5.3 Other correspondence – Queensland Health.....	16
6. OPTIONS.....	16
6.1 Option 1 – <i>status quo</i> – no change to existing MRLs in the Code.	16
6.2 Option 2(a) – vary MRLs to omit or decrease some existing MRLs.....	16
6.3 Option 2(b) – vary MRLs to insert new or increase some existing MRLs.....	16
7. AFFECTED PARTIES.....	16
8. IMPACT ANALYSIS	17
8.1 Option 1 – <i>status quo</i> – no change to existing MRLs in the Code.	17
8.2 Option 2(a) – vary MRLs to omit or decrease some existing MRLs.....	18
8.3 Option 2(b) – vary MRLs to insert new or increase some existing MRLs.....	18
9. CONSULTATION	19
9.1 World Trade Organization Notification.....	19
10. CONCLUSION	21
11. IMPLEMENTATION AND REVIEW	22
12. RECOMMENDATION	22

**ATTACHMENT 1 - DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND
FOOD STANDARDS CODE.....24**

**ATTACHMENT 2 - A SUMMARY OF THE REQUESTED MRLS FOR EACH
CHEMICAL AND AN OUTLINE OF THE INFORMATION SUPPORTING THE
REQUESTED CHANGES TO THE AUSTRALIA NEW ZEALAND FOOD
STANDARDS CODE29**

ATTACHMENT 3 - BACKGROUND TO DIETARY EXPOSURE ASSESSMENTS38

ATTACHMENT 4 - SUMMARY OF SUBMISSIONS RECEIVED.....41

Executive Summary

This Application (A568) seeks to amend Maximum Residue Limits (MRLs) for agricultural and veterinary chemicals in Standard 1.4.2 – Maximum Residue Limits of the Code. It is a routine Application from the Australian Pesticides and Veterinary Medicines Authority (APVMA), to update the *Australia New Zealand Food Standards Code* (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 joint Australia New Zealand food standards setting system. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

The dietary exposure assessments indicate that setting the residues as proposed does not present any public health and safety concerns.

There are no MRLs for antibiotic residues in this Application.

FSANZ made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO). No submissions were received from WTO Members.

FSANZ Decision

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

Statement of Reasons

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.
- The dietary exposure assessments indicate that setting the residues as proposed does not present any public health and safety concerns.
- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.
- APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.

- Office of Chemical Safety of the Therapeutic Goods Administration (OCS) has undertaken an appropriate toxicological assessment of the chemicals and has established relevant acceptable daily intakes (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 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.
- None of FSANZ's section 10 objectives are compromised by the proposed changes.

1. Introduction

Applications were received from APVMA on 20 July, 5 August and 12 September 2005 seeking variations to the Code in Standard 1.4.2. The proposed variations to the Standard would align MRLs in the Code for non-antibiotic agricultural and veterinary chemicals with the MRLs in the APVMA MRL Standard.

1.1 Summary of proposed MRLs

Amendments under consideration in Application A568:

- deleting MRLs for certain foods for Acephate, Dithiocarbamates, Methamidophos, Metolachlor, Oxamyl, Procymidone, Pyridaben, Tebuconazole and Terbufos;
- adding MRLs for certain foods for cyhalofop-butyl and Uniconazole-p;
- changing MRLs for certain foods for Abamectin, Cypermethrin, Doramectin, Fluquinconazole, Iprodione, Pyrimethanil and TRIADIMENOL; and
- adding temporary MRLs for certain foods for Azoxystrobin, Boscalid, Chlorpyrifos, Cypermethrin, Fluazifop-butyl, Glufosinate-ammonium, Iprodione, metolachlor, Prometryn, Sethoxydim, Thiamethoxam, Triadimenol and Trifloxystrobin.

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

1.2 APVMA review of procymidone

APVMA announced the commencement of the review of Procymidone in December 2004. An assessment of the chemical identified public health and safety concerns associated with its use, in relation to persons working with this chemical; specifically (for women of child bearing age) following acute occupational exposure to Procymidone (e.g. during spraying, dipping, packing).

On the basis of an assessment of available residue data, APVMA considered that the acute reference dose (ARfD)¹ could be exceeded for some commodities. The registrations and label approvals for all procymidone products were suspended and new instructions for use issued.

It was determined that the use of Procymidone was inappropriate for the following commodities:

- beans: all uses i.e. uses for control of Sclerotinia rot and Sclerotinia post-harvest rot
- grapes: to control for grey mould for table grapes and grapes to be used for dried fruit production
- lettuce: all uses
- stone fruit: to control brown rot and post-harvest use for control of brown rot and transit rot

¹ Confirmed by FSANZ

- strawberry: all uses
- tomato: all uses.

In addition, a 9-day re-entry interval was established by OCS to ensure protection of workers. For a number of previous uses, the label withholding periods (WHP) were shorter than 9 days i.e. nil for fava beans and navy beans, 5 days for grapes, 7 days for potatoes. Withholding periods currently shorter than 9 days were amended to 9 days to coincide with the 9 day re-entry interval.

Therefore, the use on green beans, at a late and post-harvest stage on stone fruit and table grapes is no longer allowed according to APVMA's suspension notice. Uses such as on wine grapes² and on stone fruit at the flowering stage (early stage) and dry beans only are still permitted on the label (http://www.apvma.gov.au/chemrev/procymidone_poster.pdf). The use of Procymidone on lettuce, strawberries, table grapes and tomatoes is no longer permitted and the MRLs have been deleted. The MRLs for beans, wine grapes and stone fruits remain as temporary (T) until the APVMA assesses new data as part of the review of Procymidone (http://www.apvma.gov.au/chemrev/procymidone_scope.pdf). APVMA has also withdrawn permits issued for the use of procymidone on brassicas and cucurbits.

1.2.1 Dietary exposure assessments

Due to specific occupational health and safety concerns for women of child-bearing age, FSANZ undertook a National Estimated Short Term Intake (NESTI) and a National Estimated Dietary Intake (NEDI) calculation to ascertain whether any public health and safety concerns existed from residues of procymidone for this target group (females aged 16 to 44 years).

1.2.2 NESTI

Previous calculations of the NESTI for Procymidone in December 2004 indicated that there may be a potential for the ARfD to be exceeded for women of childbearing age. In the worst case NESTI, the ARfD was exceeded for beans, cucurbits, lettuce, nectarine and peach. In a modified NESTI calculation the ARfD was exceeded for cucurbits, nectarine and peach.

These preliminary calculations were done in the absence of up to date residue data, and only provide a guide as to the likely risk.

On the basis of the NESTI conducted by FSANZ, there appeared to be a small risk for consumers of nectarines, peaches and cucurbits. However, when a balanced diet containing a range of healthy foods is consumed (including a broad range of fruit and vegetables) FSANZ concluded that the risk to public health and safety from residues of Procymidone on those foods was low.

In addition, recent reports of surveys of residues in foods carried out in Victoria, Western Australia and South Australia indicate a very high compliance rate with Procymidone MRLs in the Code, with only two breaches of Standard 1.4.2 detected on samples of lettuce and broccoli for Procymidone. Although the actual levels were not stated in the reports, this data suggests that there are limited Procymidone residues in foods.

² This does not include use on table grapes or grapes used for production of dried fruit

In summary, APVMA has recently undertaken the following actions in relation to procymidone:

- deleted the uses for specific commodities (green beans and wine grapes and at a late and post-harvest stage on stone fruit). MRLs are now temporary in these commodities until APVMA completes its review;
- deleted the use and the subsequent MRL of Procymidone in lettuce, strawberry, table grapes and tomatoes;
- withdrawn the permits for brassicas and cucurbits. The associated MRLs have been requested to be deleted in the September 2005 APVMA notifications;
- revised use patterns for the remaining commodities and increased the WHP to 9 days for stone fruit, wine grapes and dry beans (Fava and Navy).

Therefore, residues from the current remaining existing uses are now not expected to exceed the ARfD for any commodity with residues of Procymidone. Consequently there are no expected public health and safety concerns. APVMA and FSANZ will be in a position to perform a revised NESTI once additional residue data is available following the review of Procymidone.

1.2.3 NEDI

The current National Estimated Dietary Intake (NEDI) of residues of Procymidone (based on the MRL) in food for women of childbearing age is 40% of the acceptable daily intake (ADI). Further, in the 18th, 19th and 20th Australian Total Diet Surveys (ATDS) the estimated dietary exposure to Procymidone was less than 1% of the ADI for adult females 25-34 years of age³. On the basis of results from the NEDI and the results from the ATDSs, FSANZ considers that chronic dietary exposure to the potential residues associated with MRLs for Procymidone would not present a risk to the health and safety of women of child-bearing age.

1.3 Antibiotic MRLs

There are no MRLs for antibiotic⁴ residues in this Application.

1.4 Deletion of dwarf banana MRLs

MRLs for Acephate, Dithiocarbamates, Methamidophos, Oxamyl, Pyridaben, Tebuconazole and Terbufos in dwarf bananas are requested for deletion as MRLs for these chemicals in dwarf bananas are covered by existing MRLs for bananas in the Code. The commodity name 'Banana' includes dwarf bananas. For each chemical, the MRL for banana is the same as the dwarf banana MRL requested for deletion. Effectively, MRLs for dwarf bananas will remain the same.

³ Data was not available for the age groups 35 to 46 years

⁴ An antibiotic is a chemical inhibitor of the growth of organisms produced by a micro-organism.

1.5 Request to vary Tolyfluanid MRL to exclude grapes

APVMA requested a variation in the Tolyfluanid MRL for grapes in this Application, namely that the commodity name ‘Berries and other small fruits [except strawberry]’ be substituted with ‘Berries and other small fruits [except grapes and strawberry]’. This change was effected in Application A556.

2. Regulatory Problem

2.1 Current Regulations

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 chemical and the MRLs in the Code.

3. Objective

This Application 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.

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

- the protection of public health and safety; and
- 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;
- any written policy guidelines formulated by the Ministerial Council.

None of FSANZ’s section 10 objectives of food regulatory measures are compromised by the proposed draft variations to Standard 1.4.2.

4. Background

4.1 The use of agricultural and veterinary chemicals

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

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

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

4.2 Maximum Residue Limit Applications

After registering agricultural or veterinary chemical products, based on scientific evaluations, APVMA makes Applications to FSANZ to adopt the MRLs into the Code in Standard 1.4.2. 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 the Code in Standard 1.4.2.

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

Including MRLs in the Code has the effect of allowing legally treated produce to be sold legally, provided that the residues in the 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.

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.

4.3 Maximum Residue Limits

The MRL is the highest concentration of a chemical residue that is legally permitted or accepted in a food. The MRL does 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.

4.4 Food Standard-setting in Australia and New Zealand

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

4.5 Trans Tasman Mutual Recognition Arrangement

Following commencement of the Trans Tasman Mutual Recognition Arrangement between Australia and New Zealand on 1 May 1998:

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

4.6 Limit of Quantification

Some of the proposed MRLs in this Application are at the limit of quantification (LOQ), this is 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. The inclusion of the MRLs at the LOQ means that no detectable residues of the relevant chemical should occur. FSANZ incorporates MRLs at the LOQ in the Code to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

4.7 MRLs for Permits

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;
- 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.

5. EVALUATION OF ISSUES RAISED IN PUBLIC SUBMISSIONS

Submissions were received from Food Technology Association of Victoria Inc. (FTAV), Australian Food and Grocery Council (AFGC), Jacqui Simcock, Department of Health South Australia, and Department of Human Services Victoria (DHS).

The submissions from FTAV, Department of Health South Australia and DHS support the Application. FTAV, Department of Health South Australia and DHS support option 2(a) to vary Standard 1.4.2 to decrease or delete some existing MRLs and option 2(b) to vary Standard 1.4.2 to include new and increase some existing MRLs.

5.1 Submission from Australian Food and Grocery Council

AFGC supports option 2(b) and does not support option 2(a) to vary Standard 1.4.2 to delete and decrease some existing MRLs until there has been adequate consultation with industry to ensure that produce imports will not be adversely affected.

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

AFGC notes that Procymidone may be permitted in exporting countries and therefore does not support deleting Procymidone MRLs.

5.1.1 Evaluation

MRL deletions have the potential to restrict the importation of foods and could potentially result in a reduced product range available to consumers, as foods could not be legally imported or sold to consumers. FSANZ publicly advertises any proposed changes to MRLs as part of the round of public consultation and lists all amendments on the FSANZ website to assist industry sectors in identifying any impacts following deletions or reductions of specific MRLs.

However, no submissions were received from specific industry sectors that addressed the likely effects on trade or importation for the relevant food commodities if the proposed deletions take place.

At Initial / Draft Assessment, FSANZ requested comment as to any possible ramifications of the proposed MRLs differing from international MRLs. No comments were received from any industry sectors or WTO members.

Following the APVMA review of Procymidone and new label instructions (APVMA Gazette December 2004), there have been consequent changes to MRLs. Use of Procymidone on lettuce, strawberry, table grape and tomato crops is no longer permitted; the MRLs are to be omitted from the Code. Permanent MRLs for other uses have been changed to temporary MRLs. For further detail refer section 1.2 and Attachment 2 of this report. Refer also Application A559.

5.2 Submission from Ms Jacqui Simcock

Ms Simcock supports option 2(a) and does not support option 2(b) to vary Standard 1.4.2 to include new and increase some existing MRLs.

Ms Simcock expressed concern that FSANZ should prioritise the health of New Zealanders over convenience and commercial gain to agriculture. Ms Simcock is concerned about future population health impacts of chemicals in fresh foods and stated that the number of permitted chemicals should be reduced and MRLs must be kept low.

5.2.1 Evaluation

FSANZ's role is to protect the health and safety of people in New Zealand and Australia through the maintenance of a safe food supply. FSANZ ensures that residues associated with proposed MRLs do not present a risk to public health and safety. In assessing this risk, FSANZ conducts dietary exposure assessments in accordance with internationally accepted practices and procedures. FSANZ will not agree to adopt MRLs into the Code where dietary exposure to chemical residues could pose a health risk. FSANZ has reviewed the information provided by APVMA and has validated that the estimated dietary exposures for the proposed MRLs in this Application are within safety limits.

MRLs are not direct public health limits. MRLs are set at levels well below those that would cause an adverse health effect. MRLs protect public health and safety by ensuring that residues of both conventional and organic agricultural chemical inputs are no higher than is necessary for effective control of pests, weeds and plant and animal diseases. An MRL indicates the highest legally permitted residue of a chemical in a food; it does not indicate the amount of a chemical that is always present. To date none of the programs that monitor dietary exposure to residues present in food undertaken by the New Zealand Food Safety Authority (NZFSA), FSANZ and other parties have found residues that are likely to cause harm.

FSANZ does not regulate nor enforce the use of agricultural and veterinary chemicals in New Zealand nor in Australia. FSANZ does not have any statutory role in questioning the merits or enforcement of agricultural or veterinary chemical use.

In New Zealand, maximum residue limits are regulated under the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2005 (No. 2)*. Agricultural Compounds and Veterinary Medicines (ACME), a business group of NZFSA, is the responsible body. ACME Group assesses residues of agricultural and veterinary chemicals using internationally accepted best practice methodologies. In Australia, APVMA is responsible for registering, granting permits for use and regulating the sale of agricultural and veterinary chemical products. Following sale, use of chemicals is regulated by State and Territory 'control of use' legislation. Note that foods produced or imported into Australia that comply with the Code can be sold in New Zealand and foods produced in New Zealand that comply with New Zealand MRL regulations can be sold in Australia.

5.3 Other correspondence – Queensland Health

Queensland Health supports options 2(a) and 2(b). Queensland Health also pointed out two inconsistencies in the Initial / Draft Assessment Report.

The MRL entry for Cypermethrin in radish in Attachment 1 under 1.4 has been corrected from *0.05 to T*0.05. The commodity name for salad burnet, namely Burnet, Salad now appears in the correct form under Azoxystrobin in Attachment 2.

6. Options

6.1 Option 1 – *status quo* – no change to existing MRLs in the Code.

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

6.2 Option 2(a) – vary MRLs to omit or decrease some existing MRLs.

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

6.3 Option 2(b) – vary MRLs to insert new or increase some existing MRLs.

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

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

7. 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. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying 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 Option 1 – *status quo* – no change to existing MRLs in the Code.

8.1.1 Benefits

- For consumers the major benefit would be the maintenance of the 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.
- For Australian Government, State and Territory agencies, adopting this option would not result in any discernable benefits.

8.1.2 Costs

- For consumers there are unlikely to be any discernable costs as the unavailability of some food from certain growers is likely to be seen as typical seasonal fluctuations in the food supply.
- For growers and producers of domestic and export food commodities, adopting this option would result in costs resulting from not being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Primary producers do not produce food or use chemical products to comply with MRLs. They use chemical products to control pests and diseases in accordance with the prescribed label conditions, and expect that the resulting residues will be acceptable and that the legally treated food can be legally sold. If the 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.

- 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 Option 2(a) – vary MRLs to omit or decrease some existing MRLs.

8.2.1 Benefits

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

8.2.2 Costs

- For consumers there are unlikely to be any discernable costs as the unavailability of some food from certain importers is likely to be seen as typical seasonal fluctuation in the food supply.
- For growers and producers of domestic and export food commodities, adopting this option is unlikely to result in any costs, as reductions in MRLs are adopted where this is practically achievable, with little or no impact on production costs.
- For importers, adopting this option may result in costs, as foods may not be permitted to be imported if these foods contain residues consistent with the MRLs proposed for deletion or reduction. Any MRL deletions or reductions have the potential to restrict the importation of foods and could potentially result in higher food costs and a reduced product range available to consumers, as foods that exceed the new, lower MRLs could not be legally imported or sold to consumers.
- 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.

8.3 Option 2(b) – vary MRLs to insert new or increase some existing MRLs.

8.3.1 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.

- 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.
- For importers, adopting this option would result in the benefit that food could be legally imported if it contained residues consistent with increased MRLs or MRL additions.
- 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.

8.3.2 *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.
- 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.

9. Consultation

9.1 World Trade Organization Notification

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.

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

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

9.1.1 Codex MRLs

The standards of the Codex Alimentarius Commission 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 this Application that are addressed in the international Codex standard.

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Cypermethrin Leafy vegetables [except lettuce, head] Lettuce, head	T5 Existing MRL 2	2 mg/kg for Lettuce, head
Dithiocarbamates Banana, dwarf Banana	2 mg/kg under Banana in the Code	2 mg/kg for Banana
Procymidone Fruiting vegetables, cucurbits	T2	2 mg/kg for Cucumber
Tebuconazole Banana, dwarf Banana	0.2 mg/kg under Banana in the Code	0.05 mg/kg for Banana
Terbufos Banana, dwarf Banana	0.05 mg/kg under Banana in the Code	0.05 mg/kg for Banana
Triadimenol Cereal grains [except sorghum] Peppers, Sweet	*0.01 T1	0.2 for Oats 0.2 for Rye 0.2 for Wheat 0.1 for Peppers, Sweet

The deletions for dwarf bananas are requested in order to avoid duplication in the Code, as dwarf bananas are already covered by existing MRLs for bananas in the Code. FSANZ notes that the existing MRLs for bananas are equivalent to the Codex MRL or higher as in the case of the chemical Tebuconazole.

FSANZ requested comment on any possible ramifications of the proposed MRLs differing from Codex MRLs. No comments were received on this issue.

9.1.2 Imported Foods

Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because permissions for products differ. This means that residues in imported food may still be safe for human consumption, but may be different from those in domestically produced food.

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

To assist in identifying possible impacts where imported food may be affected, FSANZ compiled the following table of foods that have MRLs that are proposed for deletion and/or reduction and sought comment on any impacts of these reductions or deletions at Initial / Draft Assessment. AFGC made a submission on these impacts; this is discussed in section 5.1 above.

Chemical
Food
Acephate Banana, dwarf*
Dithiocarbamates Banana, dwarf*
Doramectin Cattle milk
Methamidophos Banana, dwarf*
Metolachlor Chard (silver beet) Spinach
Oxamyl Banana, dwarf*
Procymidone [†] Beans [except broad bean, and soya bean] Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Broad bean (green pods and immature seeds) Fruiting vegetables, cucurbits Indian mustard Mustard greens
Pyridaben Banana, dwarf*
Tebuconazole Banana, dwarf*
Terbufos Banana, dwarf*

* Effectively, MRLs for dwarf bananas remain the same. MRLs for dwarf bananas are covered by existing MRLs for bananas. Therefore, FSANZ foresees no impacts on imported foods.

[†] An MRL of T10 has been requested for beans except green beans.

10. Conclusion

Option 1 is a viable but undesirable option.

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

FSANZ's preferred approach is to adopt Options 2(a) and 2(b) – to vary MRLs in the Code to insert new or increase some existing MRLs and to omit or decrease some existing MRLs.

- There are no public health and safety concerns associated with the proposed MRL variations (this benefit also applies to Option 1).
- The changes would minimise the 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.

11. Implementation and Review

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

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

These monitoring programs and the continual review of the use of agricultural and veterinary chemicals mean that considerable scope exists to review MRLs on a continual basis.

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

12. Recommendation

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

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- The dietary exposure assessments indicate that setting the residues as proposed does not present any public health and safety concerns.
- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.
- APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.
- Office of Chemical Safety of the Therapeutic Goods Administration (OCS) has undertaken an appropriate toxicological assessment of the chemicals and has established relevant acceptable daily intakes (ADI) and where applicable, an acute reference dose (ARfD).
- FSANZ has undertaken a regulation impact assessment and concluded that the amendment to the Code is 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.
- None of FSANZ's section 10 objectives are compromised by the proposed changes.

Attachments

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

Draft Variations to the *Australia New Zealand Food Standards Code*

To commence: On gazettal

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

[1.1] *omitting from Schedule 1, under the entries for the following chemicals, the food appearing in Column 1 of the Table to this sub-item, substituting the food appearing in Column 2 –*

CHEMICAL	COLUMN 1	COLUMN 2
PROCYMIDONE	BEANS [EXCEPT BROAD BEAN AND SOYA BEAN]	BEANS [EXCEPT GREEN BEANS]
TRIADIMENOL	CEREAL GRAINS	CEREAL GRAINS [EXCEPT SORGHUM]

[1.2] *inserting in Schedule 1 –*

CYHALOFOP-BUTYL SUM OF CYHALOFOP-BUTYL, CYHALOFOP AND METABOLITES EXPRESSED AS CYHALOFOP-BUTYL	
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.05
MEAT (MAMMALIAN) (IN THE FAT)	*0.05
MILKS	*0.05
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
RICE	*0.01

[1.3] *inserting for the chemicals appearing in Column 1 of the Table to this sub-item, the chemical residue definitions appearing in Column 2 –*

COLUMN 1	COLUMN 2
UNICONAZOLE-P	SUM OF UNICONAZOLE-P AND ITS Z-ISOMER EXPRESSED AS UNICONAZOLE-P

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

ACEPHATE ACEPHATE (NOTE: THE METABOLITE METHAMIDOPHOS HAS SEPARATE MRLS)	
BANANA, DWARF	1
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
LEAFY VEGETABLES (EXCEPT LETTUCE HEAD AND LETTUCE LEAF)	T2
LETTUCE, LEAF	2

DITHIOCARBAMATES	
TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
BANANA, DWARF	2
METHAMIDOPHOS	
METHAMIDOPHOS <i>SEE ALSO ACEPHATE</i>	
BANANA, DWARF	0.2
METOLACHLOR	
METOLACHLOR	
CHARD (SILVER BEET)	T*0.01
SPINACH	T*0.01
OXAMYL	
SUM OF OXAMYL AND 2-HYDROXYIMINO-N,N-DIMETHYL-2-(METHYLTHIO)-ACETAMIDE, EXPRESSED AS OXAMYL	
BANANA, DWARF	0.2
PROCYMIDONE	
PROCYMIDONE	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	T5
BROAD BEAN (GREEN PODS AND IMMATURE SEEDS)	10
FRUITING VEGETABLES, CUCURBITS	T2
INDIAN MUSTARD	T2
MUSTARD GREENS	T2
PYRIDABEN	
PYRIDABEN	
BANANA, DWARF	0.5
TEBUCONAZOLE	
TEBUCONAZOLE	
BANANA, DWARF	0.2
TERBUFOS	
SUM OF TERBUFOS, ITS OXYGEN ANALOGUE AND THEIR SULFOXIDES AND SULFONES, EXPRESSED AS TERBUFOS	
BANANA, DWARF	0.05

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

AZOXYSTROBIN	
AZOXYSTROBIN	
BERGAMOT	T10
BURNET, SALAD	T10
CHERVIL	T10
CORIANDER (LEAVES, STEM,	T10

ROOTS)	
CORIANDER, SEED	T10
DILL, SEED	T10
FENNEL, SEED	T10
FENNEL, BULB	T0.1
GALANGAL, GREATER	T0.1
HERBS [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	T10
KAFFIR LIME LEAVES	T10
LEMON GRASS	T10
LEMON VERBENA (DRY LEAVES)	T10
MIZUNA	T10
PEAS	T3
ROSE AND DIANTHUS (EDIBLE FLOWERS)	T10
RUCOLA (ROCKET)	T10
TURMERIC, ROOT	T0.1
BOSCALID	
<i>COMMODITIES OF PLANT ORIGIN: BOSCALID</i>	
<i>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</i>	
PEAS	T5
CHLORPYRIFOS	
CHLORPYRIFOS	
SWEDE	T0.3
CYPERMETHRIN	
CYPERMETHRIN, SUM OF ISOMERS	
LEAFY VEGETABLES [EXCEPT LETTUCE HEAD]	T5
RADISH	T*0.05
FLUAZIFOP-BUTYL	
FLUAZIFOP-BUTYL	
SWEET POTATO	T0.1
GLUFOSINATE AND GLUFOSINATE-AMMONIUM	
SUM OF GLUFOSINATE-AMMONIUM, N-ACETYL GLUFOSINATE AND 3-[HYDROXY(METHYL)-PHOSPHINOL] PROPIONIC ACID, EXPRESSED AS GLUFOSINATE (FREE ACID)	
COTTON SEED	T5
IPRODIONE	
IPRODIONE	
CHARD (SILVER BEET)	T5
SPINACH	T5
METOLACHLOR	
METOLACHLOR	
BRASSICA LEAFY VEGETABLES	T*0.01

PROMETRYN PROMETRYN	
CORIANDER (LEAVES, STEM, ROOTS)	T1
CORIANDER, SEED	T1
SETHOXYDIM SUM OF SETHOXYDIM AND METABOLITES CONTAINING THE 5-(2-ETHYLTHIOPROPYL)CYCLOHEXENE-3-ONE AND 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES AND THEIR SULFOXIDES AND SULFONES, EXPRESSED AS SETHOXYDIM	
RHUBARB	T0.1
THIAMETHOXAM <i>COMMODITIES OF PLANT ORIGIN:</i> THIAMETHOXAM <i>COMMODITIES OF ANIMAL ORIGIN:</i> SUM OF THIAMETHOXAM AND N-(2-CHLORO- THIAZOL-5-YLMETHYL)-N'-METHYL-N'-NITRO- GUANIDINE, EXPRESSED AS THIAMETHOXAM	
TREE NUTS	T0.02
TRIADIMENOL TRIADIMENOL <i>SEE ALSO TRIADIMEFON</i>	
PARSNIP	T0.2
RADISH	T0.2
SORGHUM	0.5
SWEDE	T0.2
TURNIP, GARDEN	T0.2
TRIFLOXYSTROBIN SUM OF TRIFLOXYSTROBIN AND ITS ACID METABOLITE ((E,E)-METHOXYIMINO-[2-[1-(3- TRIFLUOROMETHYLPHENYL)- ETHYLIDENEAMINOXYMETHYL]PHENYL] ACETIC ACID), EXPRESSED AS TRIFLOXYSTROBIN EQUIVALENTS	
MACADAMIA NUTS	T*0.05
UNICONAZOLE-P SUM OF UNICONAZOLE-P AND ITS Z-ISOMER EXPRESSED AS UNICONAZOLE-P	
POPPY SEED	*0.01

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

ABAMECTIN SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
SOYA BEAN (DRY)	*0.002

DORAMECTIN DORAMECTIN	
CATTLE MILK	0.05
FLUQUINCONAZOLE FLUQUINCONAZOLE	
POME FRUITS	0.3
IPRODIONE IPRODIONE	
BRUSSELS SPROUTS	T1
PYRIMETHANIL PYRIMETHANIL	
POME FRUITS	0.05
TRIADIMENOL TRIADIMENOL <i>SEE ALSO TRIADIMEFON</i>	
PEPPERS, SWEET	T1

A Summary of the Requested MRLs for Each Chemical and an Outline of the Information Supporting the Requested Changes 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 more realistic estimate of dietary exposure and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions; the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials other than the MRL to represent pesticide residue levels. In most cases the NEDI is still an overestimation because the above data is often not available and in these cases the MRL is used.

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

The NESTI calculation incorporates the large portion (97.5 percentile) food consumption data and can take into account such factors as the highest residue on a composite sample of an edible portion; 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			
Berries and other small fruits [except grapes and strawberry]	Delete	T*0.01	This chemical is a phenylpyrazole. APVMA has extended the trial permit for this chemical to control Western Flower Thrip in strawberry. An 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.
Berries and other small fruits [except wine grapes]	Add	T*0.01	
Strawberry	Delete	T0.5	
			NESTI = <1% of ARfD for berries NEDI = 60% of ADI

The NESTI is an assessment of the acute exposure which is compared to the acute reference dose (ARfD). More information is in the glossary on the NESTI and the ARfD. To be acceptable to FSANZ, the NESTI must be less than 100% of the ARfD because the ARfD is considered the 'safe' level.

Acute Reference Dose (ARfD)
more information on this term is in the glossary

The NEDI is an assessment of the chronic exposure which is compared to the acceptable daily intake (ADI). More information is in the glossary on the NEDI and the ADI. To be acceptable to FSANZ, the NEDI must be less than 100% of the ADI because the ADI is considered the 'safe' level.

Acceptable Daily Intake (ADI)
more information on this term is in the glossary

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 Australian Total Diet Survey (ATDS) is provided when available because it provides an indication of the typical exposure to chemicals in table ready foods. The ATDS results are more realistic because the NEDI and NESTI calculations are theoretical calculations that conservatively overestimate exposure.

<p>Chlorpyrifos Coffee beans</p>	<p>Add T0.5</p>	<p>APVMA extension of use for the control of pests. The 19th ATDS (1998) dietary exposure estimate for Chlorpyrifos, as a percentage of the ADI is equivalent to 0.51% of ADI for adult males and up to 2.55% of ADI for 2 year olds. The 20th ATDS (2000) dietary exposure estimate for Chlorpyrifos, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 83% of ADI</p>
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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 surveys.

Glossary:

- 1. **ADI** Acceptable Daily Intake
- 2. **APVMA** Australian Pesticides and Veterinary Medicines Authority
- 3. **ARfD** Acute Reference Dose
- 4. **ATDS** Australian Total Diet Study
- 5. **FSC** *Australia New Zealand Food Standards Code*
- 6. **JMPR** Joint FAO/WHO Meeting on Pesticide Residues
- 7. **LOQ** Limit of Analytical Quantification
- 8. **NEDI** National Estimated Daily Intake
- 9. **NESTI** National Estimated Short Term Intake
- 10. **NNS** National Nutrition Survey of Australia 1995
- 11. **T** Temporary MRL
- 12. **WHP** Withholding Period

Boscalid Peas	Insert	T5	<p>Boscalid is a fungicide; it inhibits spore germination, germ tube elongation, mycelial growth and sporulation. APVMA has received a permit application for its use to control sclerotinia rot and chocolate spot in peas.</p> <p>NESTI 2-6 years <1% ARfD NESTI 2 years + <1% ARfD NEDI = 7% of ADI</p>																										
Chlorpyrifos Swede	Insert	T0.3	<p>Chlorpyrifos is an acaricide, nematocide and insecticide; it inhibits acetylcholine esterase. APVMA has issued a minor use permit for its use to control wireworm in swede crops.</p> <p>20th ATDS estimated dietary exposure as <1% of ADI for all population groups surveyed.</p> <p>NESTI 2-6 years 7% ARfD NESTI 2 years + 6% ARfD NEDI = 88% of ADI</p>																										
Cyhalofop-butyl Edible offal (mammalian)	Insert	*0.05	<p>This is a new chemical. Residue definition: Sum of cyhalofop-butyl, cyhalofop and metabolites expressed as cyhalofop-butyl</p> <p>Cyhalofop-butyl is a post emergent herbicide used to control barnyard grasses and silver top grasses in rice crops. Its activity is mediated via the inhibition of acetyl coenzyme-A carboxylase, a pivotal enzyme in plant fatty acid synthesis.</p> <p>DIAMOND modelling estimated the chronic dietary exposure as 35% of the ADI.</p> <table border="1"> <thead> <tr> <th rowspan="2">NESTI</th> <th colspan="2">% of ARfD</th> </tr> <tr> <th>2-6 yrs</th> <th>2+ yrs</th> </tr> </thead> <tbody> <tr> <td>Edible offal (mammalian)</td> <td><1</td> <td><1</td> </tr> <tr> <td>Eggs</td> <td><1</td> <td><1</td> </tr> <tr> <td>Meat (mammalian) (in the fat)</td> <td>2</td> <td>1</td> </tr> <tr> <td>Milks</td> <td>13</td> <td>5</td> </tr> <tr> <td>Poultry, edible offal of</td> <td><1</td> <td><1</td> </tr> <tr> <td>Poultry meat</td> <td>2</td> <td>1</td> </tr> <tr> <td>Rice</td> <td><1</td> <td><1</td> </tr> </tbody> </table> <p>NEDI = 29% of ADI</p>	NESTI	% of ARfD		2-6 yrs	2+ yrs	Edible offal (mammalian)	<1	<1	Eggs	<1	<1	Meat (mammalian) (in the fat)	2	1	Milks	13	5	Poultry, edible offal of	<1	<1	Poultry meat	2	1	Rice	<1	<1
NESTI	% of ARfD																												
	2-6 yrs	2+ yrs																											
Edible offal (mammalian)	<1	<1																											
Eggs	<1	<1																											
Meat (mammalian) (in the fat)	2	1																											
Milks	13	5																											
Poultry, edible offal of	<1	<1																											
Poultry meat	2	1																											
Rice	<1	<1																											
Eggs	Insert	*0.05																											
Meat (mammalian) (in the fat)	Insert	*0.05																											
Milks	Insert	*0.05																											
Poultry, edible offal of	Insert	*0.05																											
Poultry meat	Insert	*0.05																											
Rice	Insert	*0.01																											

Cypermethrin Leafy vegetables (except lettuce head and lettuce leaf)	Omit	T2	Cypermethrin is a non-systemic pyrethroid insecticide with contact and stomach action. APVMA has issued a permit for its use to control insect pests in leafy vegetable and radish crops. 19 th ATDS estimated dietary exposure as <1% of ADI for all population groups assessed. NEDI = 9% of ADI
Lettuce, leaf	Omit	2	
Leafy vegetables [except lettuce head]	Substitute	T5	
Radish	Insert	T*0.05	
Dithiocarbamates Banana, dwarf	Omit	2.0	Dietary exposure assessment not required.
Doramectin Cattle milk	Omit Substitute	T0.06 0.05	Doramectin is used in the treatment and control of internal and external parasites. Variation of the MRL is due to extension of use of the registered product, <i>Dectomax Pour-On Endectocide</i> , to lactating dairy cattle. NESTI 2-6 years 14% ARfD NESTI 2 years + 5% ARfD NEDI = 48% of ADI
Fluazifop-butyl Sweet potato	Insert	T0.1	Fluazifop-butyl is a herbicide; it inhibits acetyl-coA carboxylase. APVMA has received a permit application for its use to control grass weeds in sweet potato crops. NEDI = 69% of ADI
Fluquinconazole Pome fruits	Omit Substitute	*0.05 0.3	Fluquinconazole is a fungicide which inhibits ergosterol biosynthesis. NEDI = 13% of ADI
Glufosinate-ammonium Cotton seed	Insert	T5	Glufosinate-ammonium is a non-selective contact herbicide. It inhibits glutamine synthesis, leading to accumulation of ammonium ions and inhibition of photosynthesis. APVMA has received a permit application for its use to control weeds in cotton. NEDI = 7% of ADI

Iprodione Brussels sprouts	Omit	T*0.05	Iprodione is a contact fungicide with protective and curative action; it inhibits germination of spores and growth of fungal mycelium. APVMA has received a permit application for its use in chard and spinach. APVMA has issued a minor use permit for Brussels sprouts. 20 th ATDS estimated dietary exposure as 1% for adult males 25 - 34 years and toddlers 2 years and <1% of ADI for other population groups surveyed. NEDI = 43% of ADI
Chard (silver beet)	Substitute	T1	
Spinach	Insert	T5	
Methamidophos <i>see also</i> Acephate Banana, dwarf	Omit	0.2	Dietary exposure assessment not required.
Metolachlor Chard (silver beet)	Omit	T*0.01	Metolachlor is a selective herbicide; it is absorbed predominantly by the hypocotyls and shoots. It inhibits cell division; this inhibits germination. APVMA has received a permit application for its use in brassica leafy vegetables. NEDI = <1% of ADI
Spinach	Omit	T*0.01	
Brassica leafy vegetables	Insert	T*0.01	
Oxamyl Banana, dwarf	Omit	0.2	Dietary exposure assessment not required.
Procymidone Beans [except broad bean and soya bean]	Omit	T10	Procymidone is a fungicide; it inhibits triglyceride synthesis in target pests. Dietary exposure assessment not required. The variations relating to beans are part of an administrative tidy up following changes gazetted in the June 2005 APVMA Gazette. The other requested variations are a result of cancelled permits. The review of procymidone is ongoing. Refer to Application A559 for other variations to procymidone MRLs following gazettal of new label instructions in December 2004.
Beans [except green beans]	Substitute	T10	
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	Omit	T5	
Broad bean (green pods and immature seeds)	Omit	10	
Fruiting vegetables, cucurbits	Omit	T2	
Indian mustard	Omit	T2	
Mustard greens	Omit	T2	
	Omit		

Prometryn Coriander (leaves, stem, roots)	Insert	T1	Prometryn is a triazine herbicide; it inhibits photosynthesis. APVMA has received a permit application for its use to control weeds in coriander. NEDI = 4% of ADI
Coriander, seed	Insert	T1	
Pyridaben Banana, dwarf	Omit	0.5	Dietary exposure assessment not required.
Pyrimethanil Pome fruits	Omit Substitute	*0.05 0.05	Pyrimethanil is a fungicide; it inhibits secretion of enzymes necessary for fungal infection. Please note that this is a substitution and there is no change in dietary exposure. The LOQ for the analytical method used is 0.01 mg/kg.
Sethoxydim Rhubarb	Insert	T0.1	Sethoxydim is a systemic herbicide used to control selected grass weeds. APVMA has received a permit application for its use to control grass weeds among rhubarb. NEDI = 28% of ADI
Tebuconazole Banana, dwarf	Omit	0.2	Dietary exposure assessment not required.
Terbufos Banana, dwarf	Omit	0.05	Dietary exposure assessment not required.
Thiamethoxam Tree nuts	Insert	T0.02	Thiamethoxam is an insecticide; it has contact, stomach and systemic activity. The APVMA has received an application for an off-label, minor-use permit for its use on macadamia trees. NEDI = 3% of ADI
Tolyfluanid Berries and other small fruits [except strawberry]	Omit	T15	Please note that this change was effected in Application A556.
Berries and other small fruits [except grapes and strawberry]	Substitute	T15	

Triadimenol Cereal grains	Omit	*0.01	Triadimenol is a systemic fungicide with protective, curative and eradication action. It is absorbed by roots and leaves, with ready translocation in young growing tissues, but less ready translocation in older, woody tissues. It inhibits gibberellin and ergosterol biosynthesis and hence the rate of cell division. APVMA has received permits for its use to control powdery mildew (<i>Leveillula taurica</i>) on capsicums (<i>Capsicum annuum</i> var. <i>annuum</i>); ergot on sorghum; and on certain root crops. NEDI = 2% of ADI
Cereal grains [except sorghum]	Substitute	*0.01	
Parsnip	Insert	T0.2	
Peppers, Sweet	Omit	T0.5	
Radish	Substitute	T1	
Sorghum	Insert	T0.2	
Swede	Insert	0.5	
Turnip, garden	Insert	T0.2	
Trifloxystrobin Macadamia nuts	Insert	T*0.05	Trifloxystrobin is a broad-spectrum fungicide with preventative and specific curative action used to control powdery mildew, leaf spot and rust. It inhibits mitochondrial respiration by blocking electron transfer at the Q0 centre of cytochrome bc1. APVMA has received a permit application for its use on macadamias. NEDI = 3% of ADI
Uniconazole-p Poppy seed	Insert	*0.01	Uniconazole-p is used to reduce flower straw length; it regulates azole based plant growth inhibiting gibberellin biosynthesis. APVMA has received a permit application for its use in poppies. Following trials on poppies, at above the maximum proposed use rate with a 84 day WHP, no residues were found above the LOQ of 0.01 mg/kg. Residue definition: Sum of Uniconazole-p and its Z-isomer expressed as Uniconazole-p NEDI = <1% of ADI

BACKGROUND TO DIETARY EXPOSURE ASSESSMENTS

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

FSANZ's primary role in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential residues in treated food do not present public health and safety concerns. In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from all foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will not approve MRLs for inclusion in the *Food Standards 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 health standard for a chemical in food (i.e. the acceptable daily intake (ADI) and/or the acute reference dose (ARfD))
- calculating the dietary exposure to a chemical from all foods, using food consumption data from nutrition surveys and comparing this to the acceptable health standard.

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.

Determination of the acceptable health standard for a chemical in food

The Office of Chemical Safety (OCS) of the Therapeutic Goods Administration assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where applicable, the ARfD for a chemical.

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

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

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

Calculating the 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 FAO/WHO Meeting on Pesticide Residues has established an ARfD.

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

Chronic Dietary Exposure Assessment

The National Estimated Daily Intake (NEDI) represents a realistic estimate of chronic dietary exposure if the chemical residue data are available and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions 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. When adequate information is available, monitoring and surveillance data or total diet studies may also be used such as the Australian Total Diet Survey (ATDS).

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

In conducting chronic dietary exposure assessments, APVMA and FSANZ consider the residues that could result from the use of a chemical product on all foods. If specific data on the residues are not available then a cautious approach is taken and the MRL is used.

The residues that are likely to occur in all foods are then multiplied by the daily consumption of these foods derived from individual dietary records from the latest 1995 National Nutrition Survey (NNS). These calculations provide information on the level of a chemical that is consumed for each food and take into account the consumption of processed foods e.g. apple pie and bread. These calculations for each food are added together to provide the total dietary exposure to a chemical from all foods.

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

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

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

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

Acute Dietary Exposure Assessment

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

The NESTI is calculated in a similar way to the chronic dietary exposure. The residues of a chemical in a specific food are multiplied by the 97.5 percentile food consumption of that food, a variability factor is applied and this result is compared to the ARfD. NESTIs are calculated from ARfDs set by OCS and the Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey and the MRL when the data on the actual residues in foods are not available. FSANZ considers that the acute dietary exposure to the residues of a chemical is acceptable where the acute dietary exposure does not exceed the ARfD.

SUMMARY OF SUBMISSIONS RECEIVED

Submitter	Comments raised
Food Technology Association of Victoria	Supported this Application.
Australian Food and Grocery Council	Supported option 2(b) to include new or increase some existing MRLs, however raised the possibility that negative impacts may result if option 2(a) to decrease or delete some existing MRLs is adopted. 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.
Jacqui Simcock	Supported option 2(a) and not option 2(b) to vary Standard 1.4.2 to include new and increase some existing MRLs. Ms Simcock expressed concern that FSANZ should prioritise the health of New Zealanders over convenience and commercial gain to agriculture. Ms Simcock is concerned about future population health impacts of chemicals in fresh foods and stated that the number of permitted chemicals should be reduced and that MRLs must be kept low.
Department of Health South Australia	Supported this Application.
Department of Human Services Victoria	Supported this Application.