FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

7-05
5 October 2005

INITIAL / DRAFT ASSESSMENT REPORT

APPLICATION A556 – MAXIMUM RESIDUE LIMITS (JANUARY, FEBRUARY, MARCH 2005)

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 25 November 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

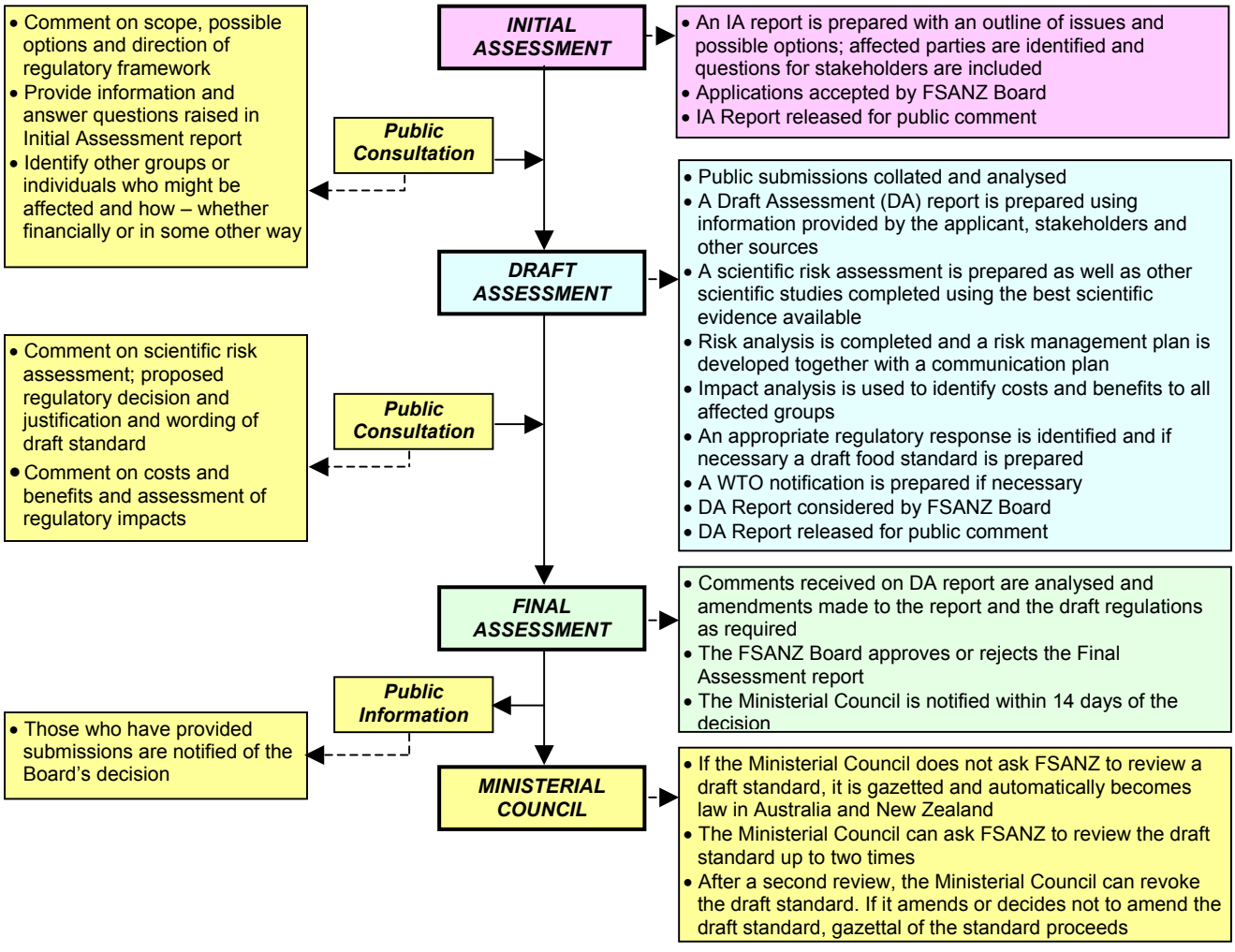
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial / Draft Assessment Report of Application A556 and prepared a draft variation to the Code.

FSANZ invites public comment on Initial / Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

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

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

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

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 25 November 2005.

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

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

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

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Executive Summary

This Application (A556) seeks to amend Maximum Residue Limits (MRLs) for non-antibiotic 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 to concerning a Joint Food Standards System* (the Treaty), excluded MRLs for agricultural and veterinary chemicals in food from the joint Australia New Zealand food standards setting system. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

The dietary exposure assessments indicate that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

There are no MRLs for antibiotic residues in this Application.

FSANZ will make a Sanitary and Phytosanitary notification to the World Trade Organization.

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

FSANZ Decision:

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

Statement of Reasons

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

- The dietary exposure assessments indicate that the residues associated with the MRLs do not represent an unacceptable risk to public health and safety.

- 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.

- The APVMA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.

- The Office of Chemical Safety of the Therapeutic Goods Administration (OCS) of the Australian Government Department of Health and Ageing has undertaken an appropriate toxicological assessment of the chemical products and has established relevant acceptable daily intakes (ADI) and where applicable, an acute reference dose (ARfD).

- FSANZ has undertaken a preliminary regulation impact assessment process. That process concluded that the proposed draft variations are necessary, cost-effective and of benefit to both 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 the APVMA on 24 January, 3 February and 8 March 2005 seeking variations to Standard 1.4.2 of the Code. 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

The MRL amendments under consideration in this Application are:

- the addition of the MRLs for the new chemicals methyl isothiocyanate, robenidine;
- the deletion of MRLs for certain foods for the chemical carbendazim, chlorpyrifos-methyl, diquat, dithiocarbamates, fluvalinate, linuron, metalaxyl and phosphorous acid;
- the addition of MRLs for certain foods for the chemicals abamectin, carbendazim, chlormequat, difenoconazole, diquat, dithiocarbamates, fluvalinate, imazalil, linuron, metalaxyl, methomyl, metribuzin, metsulfuron methyl, phosphorous acid, picolinafen, propachlor, pymetrozine, sethoxydim, and trichlorfon;
- the changing of MRLs for certain foods for the chemicals abamectin, chlormequat, dithiocarbamates, epoxiconazole, fluazifop-butyl, fluvalinate, glyphosate, linuron, metalaxyl, methomyl, norflurazon, pirimicarb, propachlor and sethoxydim; and
- the addition of temporary MRLs for certain foods for the chemicals abamectin, azoxystrobin, bifenthrin, boscalid, carbendazim, chlormequat, chlorpyrifos, dithiocarbamates, epoxiconazole, fipronil, glyphosate, maleic hydrazide, methomyl, methyl isothiocyanate, phosphorous acid, spinosad, tolclofos-methyl, toltrazuril, tolyfluanid, triclopyr.

In considering the issues associated with MRLs it should be noted that MRLs and amendments to MRLs in the Code do not permit or prohibit the use of agricultural and veterinary chemicals. The approvals for the use of agricultural and veterinary chemicals and the control of the use of agricultural and veterinary chemicals are regulated by other Australian Government, State and Territory legislation.

1.2 Use of the ARfD for Chlormequat

FSANZ requested that the APVMA provide estimated short term dietary intakes for the relevant commodities for which APVMA has proposed chlormequat MRLs and that APVMA seek written advice from the Office of Chemical Safety (OCS) on whether or not the use of the acute reference dose (ARfD) of 0.05 mg/kg body weight, established by the Joint Meeting on Pesticides Residues (JMPR) in 1999 was appropriate.

The advice provided by the OCA was that at this stage it would be more appropriate to use the current Australian ADI of 0.07 mg/kg body weight as the ARfD in order to calculate the NESTI for various population groups. The APVMA calculations provided by the APVMA satisfied FSANZ that there were no acute or chronic public health and safety concerns from residues of chlormequat in food.

1.3 Antibiotic MRLs

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

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 consequent amendments to its APVMA MRL Standard. The approval of the use of these products now means that there is a discrepancy between the potential residues associated with the use of the relevant agricultural and/or veterinary chemical and the MRLs in Standard 1.4.2. This has led to the possibility that legally treated food may not comply with Standard 1.4.2.

3. Objective

The objective of this Application is to ensure that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety and that the proposed MRLs permit the legal sale of food that has been legally treated. APVMA has already established MRLs under the APVMA's legislation, and now seeks by way of this Application to include the variations to Standard 1.4.2.

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

- 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.

None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed MRLs.

[1] An antibiotic is a chemical inhibitor of the growth of organisms produced by a microorganism.

4. Background

4.1 The use of agricultural and veterinary chemicals

In Australia, the APVMA is responsible for registering agricultural and veterinary chemical products, granting permits for use of chemical products and regulating the sale of agricultural and veterinary chemical products. Following the sale of these products, the use of the chemicals is then regulated by State and Territory 'control of use' legislation.

Before registering such a product, APVMA must be satisfied that the use of the product will not result in residues that would be an unacceptable risk to the safety of people, including occupational health and safety issues.

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 the agricultural or veterinary chemical products, based on their scientific evaluations, APVMA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews the information provided by the APVMA and validates whether the dietary exposure is within appropriate safety limits. If satisfied that the residues do not represent an unacceptable risk to public health and safety and subject to adequate resolution of any issues raised during public consultation, FSANZ approves the proposed MRLs.

FSANZ then notifies the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) of its decision. If the Ministerial Council does not request a review of the draft variations approved by FSANZ, the MRLs are gazetted and adopted by reference under the food laws of the Australian States and Territories.

The inclusion of the MRLs in Standard 1.4.2 of the Code has the effect of allowing legally treated produce to be legally sold, provided that the residues in the treated produce do not exceed the MRL. Changes to Australian MRLs reflect the changing patterns of agricultural and veterinary chemicals available to farmers. These changes include both the development of new products and crop uses, and the withdrawal of older products following review.

Appropriate toxicology, residue, animal transfer, processing and metabolism studies were provided to APVMA in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997* to support the MRLs in the commodities as outlined in this Application. Full evaluation reports for individual chemicals are available upon request from the relevant Project Coordinator at FSANZ on +61 2 6271 2222.

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 the 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 ensure that the potential residues in food do not represent an unacceptable risk to public health and safety.

FSANZ will not approve MRLs where the dietary exposure to the residues of a chemical could represent an unacceptable 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 Standard 1.4.2 of the Code apply in relation to food sold or prepared for sale in Australia and all imported food.

4.4 Food Standards System in Australia and New Zealand

The Treaty excluded MRLs for agricultural and veterinary chemicals in food from the joint food standards 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 the 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 of the Code can be legally sold in New Zealand; and

- food produced or imported into New Zealand, which complies with the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard, 1999* 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) and are indicated by an * in the 'Summary of the Requested MRLs for each Chemical…' (Attachment 2). The LOQ is the lowest concentration of an agricultural or veterinary chemical residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. The inclusion of the MRLs at the LOQ means that no detectable residues of the relevant chemical should occur.

FSANZ incorporates MRLs at the LOQ into Standard 1.4.2 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 the 'Summary of the Requested MRLs for each Chemical…' (Attachment 2). These MRLs may include uses associated with:

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

FSANZ does not issue permits or grant permission for the temporary use of agricultural and veterinary chemicals. Further information on permits for the use of agricultural and veterinary chemicals can be found on the APVMA website at www.apvma.gov.au or by contacting APVMA on +61 2 6272 5158.

5. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia.

There are no options other than a variation to Standard 1.4.2 for this Application. Therefore the regulatory options available for this Application are:

5.1 Option 1 – *status quo* – no change to Standard 1.4.2

Under this option, the *status quo* would be maintained and there would be no changes in the existing MRLs under Standard 1.4.2.

5.2 Option 2(a) – vary Standard 1.4.2 to delete and decrease some existing MRLs

Under this option, only those variations that were reductions and omissions would be approved for inclusion into Standard 1.4.2. The proposed increases and inclusions of new MRLs would not be approved.

5.3 Option 2(b) – vary Standard 1.4.2 to include new MRLs and increase some existing MRLs

Under this option, only those variations that were increases and insertions of MRLs would be approved for inclusion into Standard 1.4.2. 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.

6. Impact Analysis

6.1 Affected Parties

The parties affected by this Application include the following:

- 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 enforcing the use of agricultural and veterinary chemical residues in food.

6.2 Impact Analysis

The impact analysis considers the likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the Application, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make a Final Assessment of this Application will include information from public submissions.

6.2.1 Option 1 – status quo – no change to the existing MRLs in Standard 1.4.2

6.2.1.1 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, the adoption of this option would not result in any discernable benefits;
- for importers, the adoption of this option would not result in any discernable benefits; and
- for Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable benefits.

6.2.1. 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;

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

- for growers and producers of domestic and export food commodities, the adoption of this option would result in costs resulting from not being able to legally sell food containing residues consistent with new or decreased MRLs. Primary producers use chemical products to control pests and diseases in accordance with the prescribed label conditions. Accordingly they expect that any residues will be acceptable and the commodities as treated can be legally sold as food. 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, the adoption of this option would not result in any discernable costs; and

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

6.2.2 Option 2(a) – vary Standard 1.4.2 to delete and decrease some existing MRLs

6.2.2.1 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, the adoption of this option would not result in any discernable benefits;

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

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

6.2.2.2 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 fluctuations in the food supply;

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

- for growers and producers of domestic and export food commodities, the adoption of 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, the adoption of this option may result in costs, as foods may not be able to be imported if these foods contained 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. To identify any restrictions and possible trade impacts, Codex MRLs are addressed in section 8.1.1 and data on imported foods are addressed in section 8.1.2; and

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

- for Australian Government, State and Territory agencies, the adoption of 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.

6.2.3 Option 2(b) – vary Standard 1.4.2 to include new MRLs and increase some existing MRLs

6.2.3.1 Benefits

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

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

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

- for importers, the adoption of this option would result in the benefit that food could be legally imported if it contained residues consistent with increased MRLs or MRL additions; and

- for Australian Government, State and Territory agencies, the benefits of this option would include the removal of discrepancies between agricultural and food legislation thereby creating certainty and allowing efficient enforcement of regulations.

6.2.3.2 Costs

- for consumers there are no discernable costs;

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

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

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

Option 1 is a viable option but its adoption would result in:

- potential substantial costs to primary producers that may have a negative impact on their viability and in turn the viability of the rural and regional communities that depend upon the sale of the agricultural produce; and

- discrepancies between agricultural and food legislation which could have negative impacts on the compliance costs of 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 Standard 1.4.2 of the Code to include new MRLs or increase some existing MRLs and to delete or decrease some existing MRLs.

7. Consultation

FSANZ decided, pursuant to section 36 of the 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 now invites written submissions for the purpose of making a Final Assessment under s.17(3)(c) of the FSANZ Act.

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

7.1 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 their relevant MRL set out in the Code cannot legally be supplied in Australia.

This Application contains variations to MRLs which 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.

This Application will be notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Sanitary and Phyto Sanitary Agreement.

7.1.1 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 which are addressed in the international Codex standard.

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
Abamectin		
Cucumber	0.02	0.01
Squash, summer	0.02	0.01
Chlormequat		
Barley	T2	2
Eggs	0.1	0.1
Milks	0.5	0.5
Poultry, edible offal of	0.1	0.1
Poultry meat	*0.05	0.04
Diquat		
Vegetable oils, crude	1	0.05
Glyphosate		
Sorghum	10	20
Imazalil		
Melons, except watermelon	10	2
Methomyl		
Leafy vegetables, except chard	1	30

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

7.1.2 Imported Foods

Agricultural and veterinary chemicals are used differently in countries other than in Australia because of different pests or diseases or because different products may be used. 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 which may be complying with existing MRLs even though these existing MRLs are no longer required for domestically produced food. This is because imported food that 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 has compiled the following table of foods that have MRLs that are proposed for deletion and/or reduction.

Chemical Food
Carbendazim Broad beans (dry) Chick-pea (dry) Lentils (dry) Tree nuts
Chlorpyrifos-methyl Cotton seed oil, crude
Diquat Cotton seed Cotton seed oil, crude Lentils (dry) Lupin (dry) Poppy seed Rape seed Rape seed oil, crude Sesame seed Sesame seed oil, crude Soya bean (dry) Sunflower seed Sunflower seed oil, crude
Dithiocarbamates Broad beans (dry) Chick-pea (dry) Herbs [except parsley] Lentil (dry) Peas (dry)
Fluvalinate Stone fruits
Metalaxyl Herbs
Phosphorous Acid Apple Avocado Chervil Chestnuts Durian Cucurbits Grape leaves Grapes Pineapple Pistachio Raspberries Rucola (rocket) Strawberry Turmeric, root Walnuts

Chemical Food
Sethoxydim Peanut oil, crude

FSANZ requests comment as to any possible ramifications for imports of the deletion or reductions of the MRLs in this application.

8. The Decision

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

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

- The dietary exposure assessments indicate that the residues associated with the MRLs do not represent an unacceptable risk to public health and safety.

- 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.

- The APVMA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.

- The Office of Chemical Safety of the Therapeutic Goods Administration (OCS) of the Australian Government Department of Health and Ageing has undertaken an appropriate toxicological assessment of the chemical products and has established relevant acceptable daily intakes (ADI) and where applicable, an acute reference dose (ARfD).

- FSANZ has undertaken a preliminary regulation impact assessment process. That process concluded that the proposed draft variations are necessary, cost-effective and of benefit to both 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.

9. Implementation and Review

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

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

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.

At this time it is proposed that the draft MRL variations come into effect upon gazettal and continue to be monitored by the same means as other residues in food.

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.

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] *inserting in* Schedule 1 –

METHYL ISOTHIOCYANATE METHYL ISOTHIOCYANATE	
BARLEY	T0.1
RAPE SEED	T0.1
WHEAT	T0.1
ROBENIDINE ROBENIDINE	
POULTRY, EDIBLE OFFAL OF	*0.1
POULTRY MEAT	*0.1

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

CARBENDAZIM SUM OF CARBENDAZIM AND 2-AMINOBENZIMIDAZOLE, EXPRESSED AS CARBENDAZIM	
BROAD BEANS (DRY)	T0.5
CHICK-PEA (DRY)	T0.5
LENTILS (DRY)	T0.5
TREE NUTS	T0.1
CHLORPYRIFOS-METHYL CHLORPYRIFOS-METHYL	
COTTON SEED OIL, CRUDE	*0.01
DIQUAT DIQUAT CATION	
COTTON SEED	1
COTTON SEED OIL, CRUDE	0.1
LENTIL (DRY)	T0.5
LUPIN (DRY)	0.5
POPPY SEED	5
RAPE SEED	2
RAPE SEED OIL, CRUDE	0.1
SESAME SEED	5
SESAME SEED OIL, CRUDE	0.1
SOYA BEAN (DRY)	1
SUNFLOWER SEED	1
SUNFLOWER SEED OIL, CRUDE	1

DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
BROAD BEANS (DRY) (FAVA BEAN)	0.5
CHICK-PEA (DRY)	0.5
HERBS [EXCEPT PARSLEY]	T5
LENTIL (DRY)	0.5
PEAS (DRY)	T0.5
FLUVALINATE FLUVALINATE, SUM OF ISOMERS	
CHERRIES	T*0.05
NECTARINE	0.1
PEACH	T0.1
PLUMS (INCLUDING PRUNES)	T0.1
LINURON SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
VEGETABLES [EXCEPT LEEK]	*0.05
METALAXYL METALAXYL	
HERBS	T0.3
MEAT (MAMMALIAN) (IN THE FAT)	*0.05
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
LEAFY VEGETABLES	1
PHOSPHOROUS ACID PHOSPHOROUS ACID	
APPLE	50
AVOCADO	100
CHERVIL	T5
CHESTNUTS	T500
CUCURBITS	25
DURIAN	T100
GRAPE LEAVES	300
GRAPES	50
PEACH	100
PINEAPPLE	50
PISTACHIO NUT	T1000
RASPBERRIES	T50
RUCOLA (ROCKET)	T5
STRAWBERRY	T50
TURMERIC, ROOT	T5
WALNUTS	T50

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

ABAMECTIN SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
CUCUMBER	0.02
PEAS	T0.2
SQUASH, SUMMER	0.02
AZOXYSTROBIN AZOXYSTROBIN	
BEANS [EXCEPT BROAD AND SOYA BEAN]	T3
LETTUCE, HEAD	T3
LETTUCE, LEAF	T3
BIFENTHRIN BIFENTHRIN	
PEAS (PODS AND SUCCULENT, IMMATURE SEEDS)	T*0.01
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	
BEANS [EXCEPT BROAD BEAN AND SOYA BEAN]	T3
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	T2
BRASSICA LEAFY VEGETABLES	T10
LETTUCE, HEAD	T2
LETTUCE, LEAF	T2
STRAWBERRY	T5
CARBENDAZIM SUM OF CARBENDAZIM AND 2-AMINOBENZIMIDAZOLE, EXPRESSED AS CARBENDAZIM	
MACADAMIA NUTS	0.1
PISTACHIO NUT	T0.1
PULSES	0.5
CHLORMEQUAT CHLORMEQUAT CATION	
BARLEY	T2
EDIBLE OFFAL (MAMMALIAN)	0.5
EGGS	0.1
MEAT (MAMMALIAN)	0.2
POULTRY, EDIBLE OFFAL OF	0.1
POULTRY MEAT	*0.05

CHLORPYRIFOS CHLORPYRIFOS	
STAR APPLE	T*0.05
DIFENOCONAZOLE DIFENOCONAZOLE	
BARLEY	*0.01
WHEAT	*0.01
DIQUAT DIQUAT CATION	
OILSEED [EXCEPT LINSEED]	5
PULSES	1
VEGETABLE OILS, CRUDE	1
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
PULSES	0.5
RADISH	T1
SWEDE	T1
TURNIP, GARDEN	T1
EPOXICONAZOLE EPOXICONAZOLE	
BARLEY	T0.5
EGGS	T*0.01
POULTRY, EDIBLE OFFAL OF	T0.02
POULTRY MEAT (IN THE FAT)	T0.05
WHEAT	T0.5
WHEAT BRAN, UNPROCESSED	T3
WHEAT GERM	T2
FIPRONIL SUM OF FIPRONIL, THE SULPHENYL METABOLITE (5-AMINO-1-[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-4-[(TRIFLUOROMETHYL) SULPHENYL]-1H-PYRAZOLE-3-CARBONITRILE), THE SULPHONYL METABOLITE (5-AMINO-1-[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-4-[(TRIFLUOROMETHYL)SULPHONYL]-1H-PYRAZOLE-3-CARBONITRILE), AND THE TRIFLUOROMETHYL METABOLITE (5-AMINO-4-TRIFLUOROMETHYL-1-[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-1H-PYRAZOLE-3-CARBONITRILE)	
HONEY	T0.05
FLUVALINATE FLUVALINATE, SUM OF ISOMERS	
STONE FRUITS	0.05

GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
SORGHUM	T10
IMAZALIL IMAZALIL	
MELONS [EXCEPT WATERMELON]	10
LINURON SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
CELERY	*0.05
VEGETABLES [EXCEPT CELERY AND LEEK]	*0.05
MALEIC HYDRAZIDE SUM OF FREE AND CONJUGATED MALEIC HYDRAZIDE, EXPRESSED AS MALEIC HYDRAZIDE	
CARROT	T40
METALAXYL METALAXYL	
BARLEY	*0.01
EGGS	*0.05
MEAT (MAMMALIAN)	*0.05
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
WHEAT	*0.01
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
CHARD	T2
LEAFY VEGETABLES [EXCEPT CHARD]	1
METRIBUZIN METRIBUZIN	
SUGAR CANE	0.1
PHOSPHOROUS ACID PHOSPHOROUS ACID	
ASSORTED TROPICAL AND SUBTROPICAL FRUITS – INEDIBLE PEEL	T100
BERRIES AND OTHER SMALL FRUITS	T50
BULB VEGETABLES	T10
KAFFIR LIME LEAVES	T5
LEAFY VEGETABLES	T100
LEMON GRASS	T5
LEMON VERBENA	T5
PEAS, SHELLED	T100
POPPY SEED	1
ROOT AND TUBER VEGETABLES	T100
TREE NUTS	T1000
PICOLINAFEN *COMMODITIES OF PLANT ORIGIN*: PICOLINAFEN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF PICOLINAFEN AND 6-[3-TRIFLUOROMETHYL PHENOXY]-2-PYRIDINE CARBOXYLIC ACID	
EGGS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT (IN THE FAT)	*0.02
PROPACHLOR PROPACHLOR	
TURNIP	*0.02
PYMETROZINE PYMETROZINE	
BEETROOT	*0.02
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	
LINSEED	0.5
SPRING ONION	T0.5
SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
SAFFLOWER SEED	T*0.01
TOLCLOFOS-METHYL TOLCLOFOS-METHYL	
BEETROOT	T0.5
TOLTRAZURIL SUM OF TOLTRAZURIL, ITS SULFOXIDE AND SULFONE, EXPRESSED AS TOLTRAZURIL	
EGGS	T*0.05
TOLYLFLUANID TOLYLFLUANID	
BERRIES AND OTHER SMALL FRUITS [EXCEPT GRAPES AND STRAWBERRY]	T15
TRICHLORFON TRICHLORFON	
GOAT, EDIBLE OFFAL OF	0.1
GOAT MEAT	0.1
TRICLOPYR TRICLOPYR	
CITRUS FRUITS	T0.1

[1.4] *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	
EGG PLANT	0.02
CHLORMEQUAT CHLORMEQUAT CATION	
MILKS	0.5
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
COTTON SEED	10
CUSTARD APPLE	5
EPOXICONAZOLE EPOXICONAZOLE	
EDIBLE OFFAL (MAMMALIAN)	T0.05
MILKS	T0.01
FLUAZIFOP-BUTYL FLUAZIFOP-BUTYL	
GINGER, ROOT	0.05
FLUVALINATE FLUVALINATE, SUM OF ISOMERS	
TABLE GRAPES	0.05
GLYPHOSATE SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
CEREAL GRAINS [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	T*0.1
METALAXYL METALAXYL	
EDIBLE OFFAL (MAMMALIAN)	*0.05
MILKS	*0.01
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
CORIANDER (LEAVES, STEM, ROOTS)	T10
HERBS	T10
NORFLURAZON NORFLURAZON	
ASPARAGUS	0.05
PIRIMICARB SUM OF PIRIMICARB, DIMETHYL-PIRIMICARB AND N-FORMYL-(METHYLAMINO) ANALOGUE (DIMETHYLFORMAMIDIO-PIRIMICARB), EXPRESSED AS PIRIMICARB	
LEAFY VEGETABLES	T5
PROPACHLOR PROPACHLOR	
RADISH	*0.02
SWEDE	*0.02
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	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	0.5
LETTUCE, HEAD	0.2
LETTUCE, LEAF	0.2
PEANUT	3

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 Code*

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

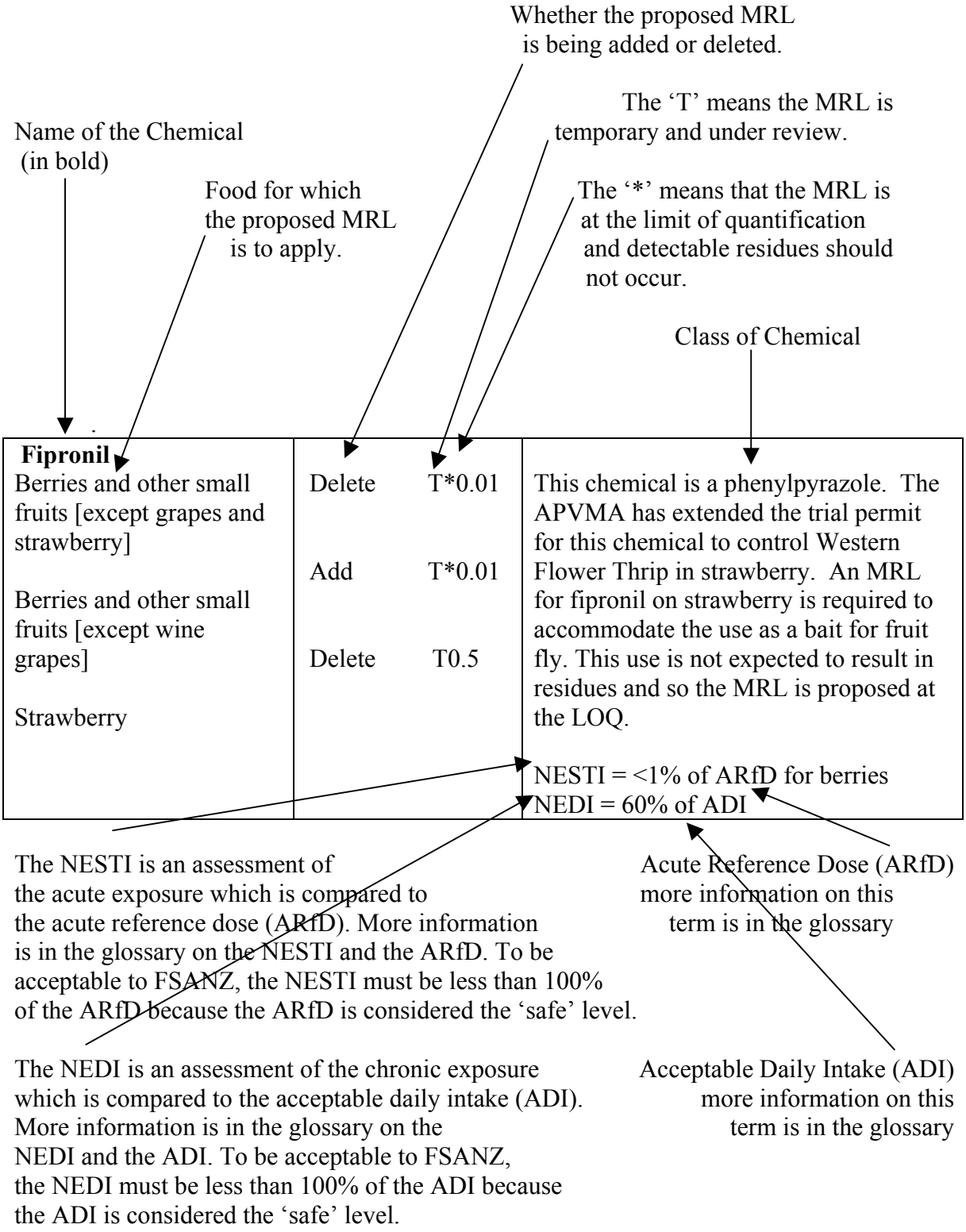
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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 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 supervised trials median residue (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.



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.

Chlorpyrifos Coffee beans	Add	T0.5	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

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 Survey.
5. **FSC** *Australia New Zealand Food Standards Code.*
6. **JMPR** Joint FAO/WHO Meeting on Pesticide Residues
7. **LOQ** Limit of Analytical Quantification.
8. **NEDI** National Estimated Daily Intake.
9. **NESTI** National Estimated Short Term Intake.
10. **NNS** National Nutrition Survey of Australia 1995
11. **LOQ** MRL set at or about the limit of quantification.
12. **JMPR** Joint FAO/WHO Meeting on Pesticide Residues
13. **T** Temporary MRL.
14. **WHP** With Holding Period

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

SUMMARY OF THE REQUESTED MRLS FOR APPLICATION A556

Abamectin			
Cucumber Egg plant	Insert Omit Substitute	0.02 T0.02 0.02	This chemical is an insecticide used to control two-spotted mite in cucumbers and squash.
Peas Squash, summer	Insert Insert	T0.2 0.02	APVMA has issued a permit for this chemical to be used to control two-spotted mite in snow peas and sugar snap peas. NESTI for peas for the whole population 2 years and above, and the 2 to 6 y.o. age group for peas = <1% of the ARFD. NESTI for Squash, summer for the whole population 2 years and above, and the 2 to 6 y.o. age group for peas = <1% of the ARFD. NESTI for cucumber for the whole population 2 years and above = <1% of the ARfD. NESTI for cucumber for the age group 2 to 6 y.o. age = 2% of the ARFD. NESTI for egg plant for the whole population 2 years and above = <1% of the ARfD. NESTI for egg plant for the age group 2 to 6 y.o. age = 2% of the ARFD. NEDI = 47% of the ADI.
Azoxystrobin			
Beans [except broad bean and soya bean] Lettuce, head Lettuce, leaf	Insert Insert Insert	T3 T3 T3	This chemical is a strobilin fungicide. The APVMA has issued a permit for this chemical to be used to control fungal diseases on lettuce and bean crops. NEDI = 2% of ADI.
Bifenthrin			
Peas (pods and succulent, immature seeds)	Insert	T*0.01	This chemical is a synthetic pyrethroid insecticide. The APVMA have issued a permit for this chemical to be used to control insects on pea crops. The 20th ATDS (2000) dietary exposure estimate for bifenthrin, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 72% of the ADI.

Boscalid			
Beans [except broad and soya bean]	Insert	T3	This chemical is a fungicide. APVMA have issued permits for this chemical to be used to control sclerotinia in beans and sclerotinia and botrytis rot on lettuce, brassica and strawberry crops. Beans [except broad and soya bean] NESTI for the whole population 2 years and above, and the 2 to 6 y.o. age group for and lettuce = <1% of the ARFD. Brassica (cole or cabbage) vegetables, Head cabbages, flowerhead brassicas NESTI = 2% of ARfD for 2 to 6 y.o. and <1% of the ARfD for the whole population. Brassica leafy vegetables NESTI = 5% of ARfD for 2 to 6 y.o. and 4 % of the ARfD for the whole population. Strawberry NESTI = 2% of ARfD for 2 to 6 y.o. and <1% of the ARfD for the whole population. NEDI = 5% of the ADI.
Brassica (cole or cabbage) vegetables, Head cabbages, flowerhead brassicas	Insert	T2	
	Insert	T10	
Brassica leafy vegetables	Insert	T2	
Lettuce, head	Insert	T2	
Lettuce, leaf	Insert	T5	
Strawberry			
Carbendazim			
Broad beans (dry)	Omit	T0.5	This chemical is a benzimidazole fungicide used to control fungal diseases on macadamia nuts and various pulse crops. In the 19th (1998) ATDS the estimated dietary exposure to carbendazim was <1% of the ADI for whole population. NEDI = 77% of ADI.
Chick-pea (dry)	Omit	T0.5	
Lentils (dry)	Omit	T0.5	
Macadamia nuts	Insert	0.1	
Pistachio nut	Insert	T0.1	
Pulses	Insert	0.5	
Tree nuts	Omit	T0.1	
Chlormequat			
Barley	Insert	T2	This chemical is a quaternary ammonium plant growth regulator. APVMA has issued a permit for the use of this chemical to regulate the growth of barley. Highest NESTI for 2 to 6 year olds=55% of ARfD (milk) and for 2+ years 23% for barley. NESTI whole population NEDI = 21% of ADI.
Edible offal (mammalian)	Insert	0.5	
Eggs	Insert	0.1	
Meat (mammalian)	Insert	0.2	
Milks	Omit	*0.1	
	Substitute	0.5	
Poultry, edible offal of	Insert	0.1	
Poultry meat	Insert	*0.05	

Chlorpyrifos Star apple	Insert	T*0.05	This chemical is an organophosphate insecticide. APVMA has issued a permit for this chemical to be used to control insects on Star apple crops. 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. NESTI for the whole population 2 years and above for star apple = <1% of the ARFD. NESTI for the 2 to 6 y.o. age group for Star apple = 2 % of ARfD. NEDI = 85% of the ADI
Chlorpyrifos-methyl Cotton seed oil, crude	Omit	*0.01	This chemical is an organophosphate insecticide. The proposed change to the MRL has come about from the APVMA's Stockfeed Guideline Project. In the 20th (2000) ATDS the estimated dietary exposure to chlorpyrifos-methyl was <2% of the ADI for infants, two year olds and 12 y.o. old boys and <1% of the ADI for the rest of the population. NEDI = 88% of the ADI.
Difenoconazole Barley Wheat	Insert Insert	*0.01 *0.01	This chemical is a triazole fungicide used as a seed dressing on wheat and barley prior to sowing. NEDI = 11% of the ADI.
Diquat Cotton seed Cotton seed oil, crude Lentils (dry) Lupin (dry) Oilseed [except linseed] Poppy seed Pulses Rape seed Rape seed oil, crude Sesame seed Sesame seed oil, crude Soya bean (dry) Sunflower seed Sunflower seed oil, crude Vegetable oils, crude	Omit Omit Omit Omit Insert Omit Insert Omit Omit Omit Omit Omit Omit Omit Insert	1 0.1 T0.5 0.5 5 5 1 2 0.1 5 0.1 1 1 1 1	This chemical is a biprodylium herbicide used as a preharvest desiccant. NESTI for the 2 to 6 y.o. age group: Oilseed [except linseed] = 15 % of ARfD. Pulses = 16 % of ARfD. Vegetable oils, crude = <1 % of ARfD. NESTI for the whole population 2 years and above: Oilseed [except linseed] = 8 % of ARfD. Pulses = 5 % of ARfD. Vegetable oils, crude = <1 % of ARfD. NEDI = 64% of the ADI

Dithiocarbamates (Mancozeb)			Dithiocarbamates are fungicides. The APVMA has issued a permit for this chemical to be used to control fungal diseases on radish, swede and turnip. In the 19th (1998) ATDS the estimated dietary exposure to thiram (the dithiocarbamate with the lowest ADI) was at 63% of the ADI two year olds and 20% of the ADI for adult males. On the basis of results from the 1998 ATDS and that mancozeb has higher ADIs than thiram. FSANZ considers that the residues associated with the proposed MRL would not represent an unacceptable risk to public health and safety. NEDI for mancozeb = 90% of ADI
Broad beans (dry) (Fava bean)	Omit	0.5	
Cotton seed	Omit	T10	
	Substitute	10	
Chick-pea (dry)	Omit	0.5	
Custard apple	Omit	T5	
	Substitute	5	
Herbs [except parsley]	Omit	5	
Lentil (dry)	Omit	0.5	
Peas (dry)	Omit	0.5	
Pulses	Insert	0.5	
Radish	Insert	T1	
Swede	Insert	T1	
Turnip, garden	Insert	T1	
Epoxiconazole			This chemical is a triazole fungicide. APVMA has issued a permit for this chemical to be used to control rust diseases in wheat and barley. The proposed meat, milk poultry commodity MRLs are based on animal feed studies. NESTI for the 2 to 6 y.o. age group and the whole population 2 years and above for Barley, Edible offal (mammalian), Eggs, Milks, Poultry meat (in the fat), Poultry, edible offal of, Wheat, Wheat bran, unprocessed and Wheat germ = <1% of ARfD. NEDI = 2% of ADI
Barley	Insert	T0.5	
Edible offal (mammalian)	Omit	*0.01	
	Substitute	T0.05	
Eggs	Insert	T*0.01	
Milks	Omit	*0.001	
	Substitute	T0.01	
Poultry, edible offal of	Insert	T0.02	
Poultry meat (in the fat)	Insert	T0.05	
Wheat	Insert	T0.5	
Wheat bran, unprocessed	Insert	T3	
Wheat germ	Insert	T2	
Fipronil			This chemical is a phenylpyrazole insecticide. APVMA has issued a permit for the use of fipronil-impregnated cardboard in bee hives and combs to control infestations of Small Hive Beetle. Honey NESTI = 4% of ARfD for 2 to 6 y.o. and 2% of the ARfD for the whole population. NEDI = 77% of the ADI.
Honey	Insert	T0.05	
Fluazifop-butyl			This chemical is a propionate herbicide used to control grass weeds on ginger crops. NEDI = 70% of ADI.
Ginger, root	Omit	T0.05	
	Substitute	0.05	

Fluvalinate			
Cherries	Omit	T*0.05	This chemical is a synthetic pyrethroid insecticide used to control insects on stone fruit and grapes. NEDI = 12% of the ADI.
Nectarine	Omit	0.1	
Peach	Omit	T0.1	
Plums (including prunes)	Omit	T0.1	
Stone fruits	Insert	0.05	
Table grapes	Omit	T0.05	
	Substitute	0.05	
Glyphosate			
Cereal grains [except as otherwise listed under this chemical]	Omit	*0.1	This chemical is glycine derivative herbicide. APVMA has issued a permit for this chemical to be used to control weeds on sorghum crops. NEDI = 6% of ADI.
	Substitute	T*0.1	
Sorghum	Insert	T10	
Imazalil			
Melons [except watermelon]	Insert	10	This chemical is an imidazole fungicide used to control fungal diseases on rock melon crops. In the 20th (2000) ATDS imazalil residues were not detected in any surveyed foods. NEDI = 56% of the ADI.
Linuron			
Celery	Insert	*0.05	This chemical is a urea herbicide used to control annual grasses and broad-leaved weeds in vegetable crops. APVMA proposes a separate MRL for celery for linuron. APVMA will eventually remove the group MRL for vegetables and replace it with separate entries for commodities for which there are approved uses of linuron. NEDI = 9% of the ADI.
Vegetables [except leek]	Omit	*0.05	
Vegetables [except celery and leek]	Insert	*0.05	
Maleic hydrazide			
Carrot	Insert	T40	This chemical is a pyridazine plant growth regulator. APVMA has issued a permit for the use of this chemical to regulate the growth of carrots. NEDI = 5% of the ADI.

Metalaxyl			
Barley	Insert	*0.01	This chemical is a phenylamide fungicide used as a seed dressing on barley and wheat seeds prior to sowing.
Edible offal (mammalian)	Omit	0.5	
	Substitute	*0.05	
Eggs	Insert	*0.05	
Herbs	Omit	T0.3	
Meat (mammalian)	Insert	*0.05	
Meat (mammalian) (in the fat)	Omit	*0.05	
Milks	Omit	T*0.05	
	Substitute	*0.01	
Poultry, edible offal of	Insert	*0.05	
Poultry meat	Insert	*0.05	
Wheat	Insert	*0.01	NEDI = 6% of ADI
Methomyl			
Chard	Insert	T2	This chemical is a carbamate insecticide used to control insects on leafy vegetable crops. APVMA has issued a permit for the use of this chemical to western flower thrips on herb crops. In the 19th (1998) ATDS methomyl residues were not detected in any surveyed foods. Herbs NESTI for the whole population 2 years and above = 23% of the ARfD and for the age group 2 to 6 y.o. age = 49% of the ARFD. Chard NESTI = 91% of ARfD for 2 to 6 y.o. and 54% of the ARfD for the whole population. Leafy vegetables NESTI = 45% of ARfD for 2 to 6 y.o. and 33% of the ARfD for the whole population. NEDI = 83% of the ADI.
Coriander (leaves, stem, roots)	Omit	T5	
	Substitute	T10	
Herbs	Omit	T5	
	Substitute	T10	
Leafy vegetables	Omit	1	
Leafy vegetables [except chard]	Insert	1	

Methyl isothiocyanate Barley Rape seed Wheat	 Insert Insert Insert	 T0.1 T0.1 T0.1	**THIS IS A NEW CHEMICAL.** Please Include The Residue Definition of: Methyl isothiocyanate. This is a new chemical fumigant APVMA has issued a permit for this chemical to be used fumigate cereal grains. Cereal grains NESTI = 21% of ARfD for 2 to 6 y.o. and 39% of the ARfD for the whole population. Cereal grain milling fractions NESTI = 89% of ARfD for 2 to 6 y.o. and 42% of the ARfD for the whole population. Early milling products NESTI = 49% of ARfD for 2 to 6 y.o. and 26% of the ARfD for the whole population. Rape seed NESTI = 55% of ARfD for 2 to 6 y.o. and 19% of the ARfD for the whole population. NEDI = 64% of the ADI.
Metribuzin Sugar cane	 Insert	 0.1	 This chemical is a triazinone herbicide used control weeds in sugar cane crops. NEDI = 4% of ADI.
Norflurazon Asparagus	 Omit Substitute	 T0.05 0.05	 This chemical is a pyridazinone herbicide used to control weeds in asparagus crops. NEDI = 4% of ADI.

Phosphorous Acid			
Apple	Omit	50	This chemical is a phosphonate fungicide used to control fungal diseases on fruit and vegetables.
Assorted tropical and subtropical fruits – inedible peel.	Insert	T100	
Avocado	Omit	100	
Berries and other small fruits	Insert	T50	
Bulb vegetables	Insert	T10	
Chervil	Omit	T5	
Chestnuts	Omit	T500	
Durian	Omit	T100	
Cucurbits	Omit	25	
Grape leaves	Omit	300	
Grapes	Omit	50	
Kaffir lime leaves	Insert	T5	
Leafy vegetables	Insert	T100	
Lemon grass	Insert	T5	
Lemon verbena	Insert	T5	
Peach	Omit	100	
Peas, shelled	Insert	T100	
Pineapple	Omit	50	
Pistachio	Omit	T1000	
Poppy seed	Insert	1	
Raspberries	Omit	T50	
Root and tuber vegetables	Insert	T100	
Rucola (rocket)	Omit	T5	
Strawberry	Omit	T50	
Tree nuts	Insert	T1000	
Turmeric, root	Omit	T5	
Walnuts	Omit	T50	NEDI = 6% of ADI.
Picolinafen			
Eggs	Insert	*0.01	This chemical is a pyridinecarboxamide herbicide used to control weeds in cereal grain, lupin and field pea crops. ADI = 2% of ADI.
Poultry, edible offal of	Insert	*0.02	
Poultry meat (in the fat)	Insert	*0.02	
Pirimicarb			
Leafy vegetables	Omit	T3	This chemical is a carbamate insecticide. APVMA has issued a permit for this chemical to be used to control aphids on leafy vegetable crops. NEDI = 82% of ADI.
	Substitute	T5	
Propachlor			
Radish	Omit	T*0.05	This chemical is a chloroacetamide herbicide used to control weeds in radish, swede and turnip crops. ADI = 5% of ADI.
	Substitute	*0.02	
Swede	Omit	T*0.05	
	Substitute	*0.02	
Turnip	Insert	*0.02	

Pymetrozine			
Beetroot	Insert	*0.02	This chemical is an azomethine insecticide used to control aphids on beetroot crops. NEDI = 8% of ADI.
Robenidine			**THIS IS A NEW CHEMICAL.**
Poultry, edible offal of	Insert	*0.1	Please Include The Residue Definition
Poultry meat	Insert	*0.1	of: Robenidine. This is a new chemical. It is a synthetic anticoccidial derivative of guanine used to control coccidiosis caused by *Eimeria* spp. NEDI = 2% of ADI.
Sethoxydim			
Brassica (cole or cabbage)	Omit	0.2	This chemical is a cyclohexanedione
vegetables, Head cabbages,	Substitute	0.5	oxime herbicide used to control weeds
Flowerhead brassicas			on various crops. The proposed
Lettuce, head	Omit	0.1	changes to the MRLs have come about
	Substitute	0.2	from the APVMA's Stockfeed
			Guideline Project.
Lettuce, leaf	Omit	0.1	
	Substitute	0.2	
Linseed	Insert	0.5	
Peanut	Omit	2	
	Substitute	3	NEDI = 28% of ADI.
Peanut oil, crude	Omit	2	
Spring onion	Insert	T0.5	
Spinosad			
Safflower seed	Insert	T*0.01	This chemical is a spinosyn insecticide. APVMA has issued a permit for this chemical to be used to control insects on safflower crops. NEDI = 32% of the ADI.
Tolclofos-methyl			
Beetroot	Insert	T0.5	This chemical is a nitrophenyl fungicide used as seed or soil treatment to control fungal diseases on beetroot crops. NEDI = <1% of ADI.
Toltrazuril			
Eggs	Insert	T*0.05	This chemical is a triazinetrione derivative coccidiostat. APVMA has issued a permit for this chemical to be used to control *Eimeria* spp. in replacement pullets. NEDI = 12% of the ADI.

Tolyfluanid Berries and other small fruits [except grapes and strawberry]	Insert	T15	This chemical is a sulfamide herbicide. APVMA has issued a permit for this chemical to be used to control grey moulds on ribus berry crops. NESTI for the 2 to 6 y.o. age group and the whole population 2 years and above for Berries and other small fruits [except, grapes, strawberry]= <1% of ARfD. NEDI = <1% of the ADI.
Trichlorfon Goat, edible offal of Goat meat	Insert Insert	0.1 0.1	This chemical is an organophosphate insecticide used to control *Haemonchus* spp. on goats. NEDI = 77% of ADI.
Triclopyr Citrus fruits	Insert	T0.1	This chemical is a 4-pyridine carboxylic acid herbicide. APVMA has issued a permit for this chemical to be used as a growth promotant for citrus fruit. NEDI = 8% of the ADI

Attachment 3

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 the 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 represent an unacceptable risk to public health and safety. 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 an unacceptable 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 the:

- 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 and/or the acute reference dose); and
- 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

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

Determination of the acceptable health standard for a chemical in food

The Office of Chemical Safety 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 the 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

The APVMA and FSANZ undertake chronic dietary exposure assessments for all agricultural and veterinary chemicals and undertake acute dietary exposure assessments where either the OCS or Joint FAO/WHO Meeting on Pesticide Residues has established an ARfD.

The APVMA and FSANZ have recently agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the 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 <u>if the chemical residue data are available</u> 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 the data is 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, the 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 is multiplied by 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 the 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.