

7-05

5 October 2005

INITIAL/DRAFT ASSESSMENT REPORT

APPLICATION A559 – MAXIMUM RESIDUE LIMITS (APRIL, MAY, JUNE 2005)

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 16 November 2005

SUBMISSIONS RECEIVED AFTER THIS DEADLINE

WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

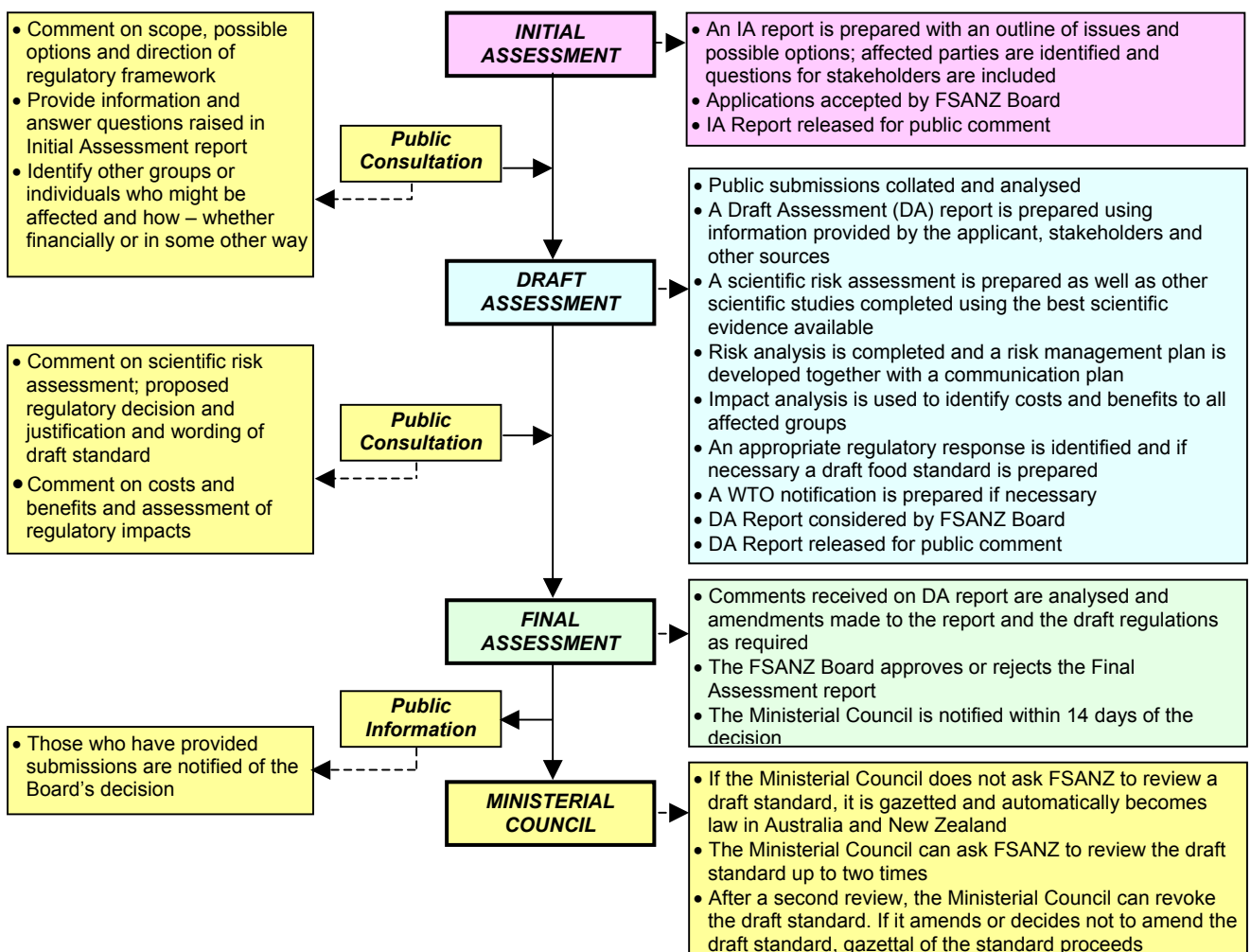
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 for Application A559 and prepared draft variations 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) 16 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 (A559) 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 Pesticide and Veterinary Medicines Authority (APVMA), to update the Code in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

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

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

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 public health and safety risk.
- 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 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 chemicals 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 7 April, 12 May and 16 June 2005 seeking variations to Standard 1.4.2 of the Code. The proposed variations to the Standard would align MRLs in the Code for agricultural and veterinary chemicals with the MRLs in the APVMA MRL Standard.

1.1 Summary of proposed changes to Standard 1.4.2

The MRL amendments under consideration in this Application are:

- the changing of the name tylosin to tylosin A;
- the addition of the MRLs for the new chemicals clothianidin, flumiclorac pentyl and forchlorfenuron;
- the deletion of all entries for the chemicals alloxydim, alloxydim sodium, diclobutrazol, diofenolan, diphenamid, methazole and promecarb;
- the deletion of MRLs for certain foods for the chemicals benfluralin, cyproconazole, difenoconazole, dimethomorph, dithiocarbamates, ethephon, ethoprophos, fenoxycarb, metalaxyl, procymidone and propachlor;
- the addition of MRLs for certain foods for the chemicals meloxicam, propachlor and sethoxydim;
- the changing of MRLs for certain foods for the chemicals azoxystrobin, cypermethrin, dithiocarbamates, dodine, fludioxonil, fluvalinate, halosulfuron-methyl, imazapic, procymidone, trichlorfon, trifloxystrobin; and
- the addition of temporary MRLs for certain foods for the chemicals azoxystrobin, boscalid, bupirimate, cyhalothrin, cypermethrin, dimethomorph, ethephon, iprodione, phenmedipham, procymidone and tolylfluanid.

In considering the issues associated with MRLs it should be noted that MRLs and variations to MRLs in Standard 1.4.2 of 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 The APVMA review of procymidone

The Australian Pesticides and Veterinary Medicines Authority (APVMA) announced the commencement of the review of procymidone in December 2004. An assessment of the chemical had 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, the APVMA considered that the acute reference dose (ARfD)¹ could be exceeded for some commodities. At this time 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;
- strawberry: all uses; and
- 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 nine days i.e. nil for faba 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 the 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 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). The 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.

¹ Confirmed by FSANZ

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

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 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, West Australia and South Australia indicate a very high compliance rate with the 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.

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

- deleted the uses for specific commodities (green beans, at a late and post-harvest stage on stone fruit and table grapes). MRLs are now temporary in these commodities until the APVMA completes its review;
- deleted the use and the subsequent MRL of procymidone in lettuce, strawberries 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 (Faba 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. The 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. 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 represent an unacceptable risk to the health and safety of women of child-bearing age.

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

1.3 Antibiotic MRLs

There are no MRLs for antibiotic⁴ 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 assess whether the residues associated with the proposed MRLs represent any public health and safety risk and to ensure that the food containing the residues can be legally sold. 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.

⁴ 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 in 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/or 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. However, FSANZ cannot legally separate these two sub-options and may only accept or reject this Application.

6. Impact Analysis

6.1 Affected Parties

The parties affected by proposed MRL amendments include:

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

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.

6.2.1.2 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;

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 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, 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 Standard 1.4.2 of 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 Standard 1.4.2 of 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 Agreement on the Application of SPS Measures because the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment.

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
Dithiocarbamates		
Almonds	T3	0.1
Potato	T1	0.2
Strawberry	T3	5
Dodine		
Stone fruits	*0.05	2 (cherries) 2 (nectarine) 5 (peach)
Ethephon		
Walnuts	T0.05	0.5
Ethoprophos		
Grapes	T*0.01	0.02
Iprodione		
Onion Bulb	T0.2	0.2
Metalaxyl		
Cereal grains	T*0.05	0.05
Procymidone		
Adzuki Bean (Dry)	T2	5
Peppers, Sweet	T10	1
Beans, except broad beans and soya bean	T2	5
Wine grapes	2	5
Lettuce, head	T0.2	0.2
Onion, bulb	T10	
Stone fruits		10 (cherries) 2 (Peach) 2 (plum)
Strawberry	5	10
Tomato	2	5
Trichlorfon		
Peppers	0.2	0.2 (capsicum and chillies)

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 Australia because of different pests or diseases or because of different climatic conditions. This means that residues in imported food may be different from those in domestically produced food although still be safe for human consumption.

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
Alloxydim Beetroot Bulb vegetables [alliums] Carrot Fruiting vegetables, Cucurbits Poppy seed Potato Strawberry Tomato
Alloxydim Sodium This is a consequential amendment arising from the proposed deletion Alloxydim (see above).
Benfluralin Edible offal (mammalian) Meat [mammalian] Milks
Cyproconazole Banana Grapes
Diclobutrazol Wheat
Difenoconazole Cereal grains

Chemical
Food
Diofenolan Avocado Citrus fruits Macadamia nuts Mango Papaya Pome fruits Stone fruits
Diphenamid Tomato
Ethephon Barley Triticale Wheat
Ethoprophos Grapes
Fenoxycarb Grapes Stone fruits
Metalaxyl Cereal grains
Methazole Onion, Bulb
Procymidone Carrot Strawberry Tomato Lettuce, Head Lettuce, Leaf
Promecarb Beans, except broad and soya bean Broad bean (green pods and immature seeds) Citrus fruits Fruiting vegetables, Cucurbits Grapes Onion, Bulb Stone fruits

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 public health and safety risk.
- 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.

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

To commence: On gazettal

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

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

Alloxydim
 Alloxydim Sodium
 Diclobutrazol
 Diofenolan
 Diphenamid
 Methazole
 Promecarb

[1.2] *inserting in Schedule 1 –*

CLOTHIANIDIN	
<i>COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN</i>	
<i>COMMODITIES OF ANIMAL ORIGIN: SUM OF</i>	
<i>CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-</i>	
<i>YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-</i>	
<i>YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE</i>	
<i>OF N²-(2-CHLOROTHIAZOL-5-YLMETHYL)-N²-</i>	
<i>METHYLGUANIDINE, EXPRESSED AS CLOTHIANIDIN</i>	
COTTON SEED	T*0.02
EDIBLE OFFAL (MAMMALIAN)	T*0.02
MEAT (MAMMALIAN) (IN THE FAT)	T*0.02
MILKS	T*0.01
FLUMICLORAC PENTYL	
FLUMICLORAC PENTYL	
COTTON SEED	T0.1
EDIBLE OFFAL (MAMMALIAN)	T*0.01
EGGS	T*0.01
MEAT (MAMMALIAN)	T*0.01
MILKS	T*0.01
POULTRY, EDIBLE OFFAL OF	T*0.01
POULTRY MEAT	T*0.01
FORCHLORFENURON	
FORCHLORFENURON	
GRAPES	T*0.01

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

COLUMN 1	COLUMN 2
TYLOSIN TYLOSIN	TYLOSIN TYLOSIN A

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

BENFLURALIN BENFLURALIN	
EDIBLE OFFAL (MAMMALIAN)	T*0.01
MEAT (MAMMALIAN)	T*0.01
MILKS	T*0.01
CYPROCONAZOLE CYPROCONAZOLE, SUM OF ISOMERS	
BANANA	T0.5
GRAPES	T0.5
DIFENOCONAZOLE DIFENOCONAZOLE	
CEREAL GRAINS	T*0.01
DIMETHOMORPH SUM OF E AND Z ISOMERS OF DIMETHOMORPH	
CHARD (SILVER BEET)	T2
LETTUCE, LEAF	T2
ETHEPHON ETHEPHON	
BARLEY	T1
TRITICALE	T1
WHEAT	T1

ETHOPROPHOS ETHOPROPHOS	
GRAPES	T*0.01
FENOXYCARB FENOXYCARB	
GRAPES	T2
STONE FRUITS	T0.5
METALAXYL METALAXYL	
CEREAL GRAINS	T*0.05
PROCYMIDONE PROCYMIDONE	
CARROT	T1
GRAPES	2
LETTUCE, HEAD	2
LETTUCE, LEAF	2
STRAWBERRY	5
TOMATO	2
PROPACHLOR PROPACHLOR	
CEREAL GRAINS	*0.05

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

AZOXYSTROBIN AZOXYSTROBIN	
OLIVES	T2
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	
ONION, BULB	T1.0
BUPIRIMATE BUPIRIMATE	
PEPPERS	T1

CYHALOTHRIN CYHALOTHRIN, SUM OF ISOMERS	
CUCUMBER	T0.05
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
CORIANDER (LEAVES, STEM, ROOTS)	T1
CORIANDER, SEED	T1
PARSLEY	T1
DIMETHOMORPH SUM OF E AND Z ISOMERS OF DIMETHOMORPH	
LEAFY VEGETABLES	T2
ETHEPHON ETHEPHON	
WALNUTS	T0.5

IPRODIONE IPRODIONE	
ONION, BULB	T0.2
MELOXICAM MELOXICAM	
PIG KIDNEY	*0.01
PIG LIVER	*0.01
PIG MEAT	0.02
PIG FAT/SKIN	0.1
PHENMEDIPHAM PHENMEDIPHAM	
LETTUCE, HEAD	T0.2
LETTUCE, LEAF	T0.2
PROCYMIDONE PROCYMIDONE	
PEPPERS, SWEET	T2
ROOT AND TUBER VEGETABLES (EXCEPT POTATO)	T1
WINE GRAPES	T2
PROPACHLOR PROPACHLOR	
CEREAL GRAINS [EXCEPT SORGHUM]	0.05

EDIBLE OFFAL (MAMMALIAN)	0.1
EGGS	*0.02
MEAT (MAMMALIAN) (IN THE FAT)	*0.02
MILKS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT (IN THE FAT)	*0.02
SORGHUM	0.2
SWEET CORN (CORN-ON-THE-COB)	0.05
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	
BARLEY	*0.1
TOLYLFLUANID TOLYLFLUANID	
DRIED GRAPES	T0.2
GRAPES	T*0.05

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

AZOXYSTROBIN AZOXYSTROBIN	
COTTON SEED	0.01
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
LINOLA OIL, EDIBLE	0.1
LINOLA SEED	0.1
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
ALMONDS	3
BEETROOT	1
CITRUS FRUITS	0.2
POME FRUITS	3
POTATO	1
STRAWBERRY	3
DODINE DODINE	
STONE FRUITS	*0.05

FLUDIOXONIL COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL COMMODITIES OF PLANT ORIGIN: FLUDIOXONIL	
COTTON SEED	*0.05
RAPE SEED	*0.01
FLUVALINATE FLUVALINATE, SUM OF ISOMERS	
COTTON SEED	0.1
HALOSULFURON-METHYL HALOSULFURON-METHYL	
EDIBLE OFFAL (MAMMALIAN)	0.2
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
IMAZAPIC SUM OF IMAZAPIC AND ITS HYDROXYMETHYL DERIVATIVE	
EGGS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01

PROCYMIDONE	
PROCYMIDONE	
ADZUKI BEAN (DRY)	T0.2
BEANS [EXCEPT BROAD BEAN AND SOYA BEAN]	T10
EDIBLE OFFAL (MAMMALIAN)	T0.05
EGGS	T*0.01
GARLIC	T5
LUPIN (DRY)	T*0.01
MEAT (MAMMALIAN) (IN THE FAT)	T0.2
MILKS	T0.02
ONION, BULB	T0.2
POME FRUITS	T1
POTATO	T0.1
POULTRY, EDIBLE OFFAL OF	T*0.01
POULTRY MEAT (IN THE FAT)	T0.1
SNOW PEAS	T5

STONE FRUITS	T10
TRICHLORFON	
TRICHLORFON	
MILKS	*0.05
PEPPERS, SWEET	0.2
TRIFLOXYSTROBIN	
SUM OF TRIFLOXYSTROBIN AND ITS ACID METABOLITE ((E,E)-METHOXYIMINO-[2-[1-(3-TRIFLUOROMETHYLPHENYL)-ETHYLIDENEAMINOXYMETHYL]PHENYL] ACETIC ACID), EXPRESSED AS TRIFLOXYSTROBIN EQUIVALENTS	
STRAWBERRY	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.

<p>Fipronil Berries and other small fruits [except grapes and strawberry]</p> <p>Berries and other small fruits [except wine grapes]</p> <p>Strawberry</p>	<p>Delete</p> <p>Add</p> <p>Delete</p>	<p>T*0.01</p> <p>T*0.01</p> <p>T0.5</p>	<p>This chemical is a phenylpyrazole. The 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.</p> <p>NESTI = <1% of ARfD for berries</p> <p>NEDI = 60% of ADI</p>
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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.

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.

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

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

Name of the Chemical (in bold)

Food for which the proposed MRL is to apply.

Whether the proposed MRL is being added or deleted.

The 'T' means the MRL is temporary and under review.

The '*' means that the MRL is at the limit of quantification and detectable residues should not occur.

Class of Chemical

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 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 A559
(APRIL, MAY, JUNE MRL AMENDMENTS)**

Alloxydim Beetroot Bulb vegetables [alliums] Carrot Fruiting vegetables, Cucurbits Poppy seed Potato Strawberry Tomato	Omit Omit Omit Omit Omit Omit Omit Omit	T0.1 T0.1 T0.2 T*0.1 T0.3 T0.1 T0.1 T0.2	
Alloxydim sodium			Consequential amendment
Azoxystrobin Cotton seed Olives	Omit Substitute Insert	T*0.01 *0.01 T2	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.
Benfluralin Edible offal (mammalian) Meat [mammalian] Milks	Omit Omit Omit	T*0.01 T*0.01 T*0.01	
Boscalid Onion, Bulb	Insert	T1.0	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. The NEDI for boscalid is equivalent to 5.3% of the ADI NESTI 2 years (+) <1% of ARfD; NESTI 2-6 years <1% of ARfD
Bupirimate VO 0051 Peppers	Insert	T1	Disruption of sporulation in the target pest. The NEDIs for bupirimate is less than 3% of the ADI

<p>Clothianidin Cotton seed Edible offal (mammalian) Meat (mammalian) [in the fat] Milks</p>	<p>Insert Insert Insert Insert</p>	<p>T*0.02 T*0.02 T*0.02 T*0.01</p>	<p>ADD: Clothianidin {T} Commodities of plant origin: Clothianidin {T} Commodities of animal origin: Sum of clothianidin, 2-chlorothiazol-5-ylmethylguanidine, 2-chlorothiazol-5-ylmethylurea, and the pyruvate derivative of N'-(2-chlorothiazol-5-ylmethyl)-N'-methylguanidine, expressed as clothianidin</p> <p>NEDI <1% of ADI</p> <p><i>NESTI 2 years (+):</i></p> <p>Meat (mammalian in the fat) <1% ARfD Edible offal (mammalian) <1% ARfD Milks <1% ARfD Oil seed <1% ARfD</p> <p><i>NESTI 2-6 years</i></p> <p>Meat (mammalian in the fat) <1% ARfD Edible offal (mammalian) <1% ARfD Milks <1% ARfD Oil seed <1% ARfD</p>
<p>Cyhalothrin Cucumber</p>	<p>Insert</p>	<p>T0.05</p>	<p>Lambda-cyhalothrin reaction product comprising equal quantities of (S)-α-cyano-3-phenoxybenzyl(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropanecarboxylate.</p> <p>NEDIs for cyhalothrin and lambda-cyhalothrin 4% and 77% of their respective ADIs.</p>

Cypermethrin Coriander (leaves, stem, roots) Coriander, seed Parsley	Insert Insert Insert	T1 T1 T1	<p>The APVMA has received a minor use permit application for alpha-cypermethrin treatment to control insect pests on parsley and coriander. The Applicant has provided residue data from two trials conducted on parsley. When alpha-cypermethrin is used according to the proposed use-pattern, residues of cypermethrin were 0.5 mg/kg (n=2). These data are satisfactory to support temporary MRLs of T1 mg/kg for parsley and coriander.</p> <p>The NEDI of alpha-cypermethrin is equivalent to <9% of the ADI. It is concluded that the chronic dietary exposure is small and the risk is acceptable.</p>
Cypermethrin Linola seed Linola seed Linola oil, edible Linola oil, edible	Omit Substitute Omit Substitute	T0.1 0.1 T0.1 0.1	<p>Used to control a wide range of chewing and sucking insect pests in horticulture and fruit production. Pyrethroid, non-systemic insecticide with contact and stomach action.</p> <p>The NEDI of alpha-cypermethrin is equivalent to <9% of the ADI</p>
Cyproconazole Banana Grapes	Omit Omit	T0.5 T0.5	
Diclobutrazol Wheat	Omit	T0.05	
Difenoconazole Cereal grains	Omit	T*0.01	<p>This chemical is a triazole fungicide used as a seed dressing on wheat and barley prior to sowing. NEDI = 11% of the ADI.</p>
Dimethomorph Chard [silverbeet] Lettuce, Leaf Leafy vegetables (except head lettuce)	Omit Omit Substitute	T2 T2 T2	<p>Dimethomorph is a local systematic fungicide with good protectant antispore activity.</p> <p>NEDI: The NEDI of dimethomorph is equivalent to <4% of the ADI.</p>
Diofenolan Avocado Citrus fruits Macadamia nuts Mango Papaya Pome fruits Stone fruits	Omit Omit Omit Omit Omit Omit Omit	T0.5 T0.5 T0.5 T0.5 T0.5 T0.5 T0.5	
Diphenamid Tomato	Omit	T*0.1	

Dithiocarbamates			
Almonds	Omit	T3	Dithiocarbamates are fungicides used to control fungal diseases on crops. Mancozeb is the main dithiocarbamate fungicide used in agriculture. Separate dietary exposure calculations are not performed for other individual dithiocarbamates (metiram, propineb, thiram, zineb and ziram) as the APVMA had advised FSANZ that they have limited use patterns and hence dietary exposure from these other chemicals would be limited. NEDI for mancozeb = 90% of ADI. No recent ATDS have analysed dithiocarbamates. However, in the 19 th (1998) ATDS the estimated dietary exposure to thiram (which has the lowest ADI of all dithiocarbamate chemicals) was at 63% of the ADI for two year olds and 20% of the ADI for adult males
	Substitute	3	
Beetroot	Omit	T1	
	Substitute	1	
Citrus fruits	Omit	T0.2	
	Substitute	0.2	
Pome fruits	Omit	T3	
	Substitute	3	
Potato	Omit	T1	Dithiocarbamates are fungicides used to control fungal diseases on crops. Mancozeb is the main dithiocarbamate fungicide used in agriculture. Separate dietary exposure calculations are not performed for other individual dithiocarbamates (metiram, propineb, thiram, zineb and ziram) as the APVMA had advised FSANZ that they have limited use patterns and hence dietary exposure from these other chemicals would be limited. NEDI for mancozeb = 90% of ADI. No recent ATDS have analysed dithiocarbamates. However, in the 19 th (1998) ATDS the estimated dietary exposure to thiram (which has the lowest ADI of all dithiocarbamate chemicals) was at 63% of the ADI for two year olds and 20% of the ADI for adult males
	Substitute	1	
Strawberry	Omit	T3	
	Substitute	3	
Dodine			
Stone fruits	Omit	5	For the prevention and control of leaf curl (<i>Taphrina deformans</i>) and blossom blight (<i>Monilinia fructicola</i>) in stone fruits The NEDI for dodine is equivalent to 5.8% of the ADI
	Substitute	*0.05	
Ethephon			
Walnuts	Insert	T0.5	Promote nut-fall in walnuts - Decomposes to ethylene in plant tissues The NEDI for ethephon is equivalent to 79% of the ADI. NESTI 2 years (+) <1% of ARfD; NESTI 2-6 years <1% of ARfD
Ethephon			
Barley	Omit	T1	
Triticale	Omit	T1	
Wheat	Omit	T1	
Ethoprophos			
Grapes	Omit	T*0.01	
Fenoxycarb			
Grapes	Omit	T2	
Stone fruits	Omit	T0.5	
Fludioxonil			
Cotton seed	Omit	T*0.05	
Cotton seed	Substitute	*0.05	
Fludioxonil			
Rape seed [canola seed]	Omit	T*0.01	The NEDI is equivalent to 1 % of the ADI.
Rape seed [canola seed]	Substitute	*0.01	

Flumiclorac pentyl Cotton seed Edible offal (Mammalian) Eggs Meat (Mammalian) Milks Poultry, Edible offal of Poultry meat	Insert Insert Insert Insert Insert Insert	T0.1 T*0.01 T*0.01 T*0.01 T*0.01 T*0.01 T*0.01	THIS IS A NEW CHEMICAL Flumiclorac pentyl is a N-phenylamide herbicide Defoliation and boll opening of cotton Inhibition of the porphyrin biosynthesis. The NEDI for flumiclorac pentyl is equivalent to 0.04% of the ADI
Fluvalinate Cotton seed	Omit Substitute	T0.1 0.1	The NEDI is equivalent to 13% of the ADI.
Forchlorfenuron Grapes	Insert	T*0.01	THIS IS A NEW CHEMICAL {T} Forchlorfenuron This chemical is a phenylurea type cytokinin plant growth regulator. Forchlorfenuron acts as a cytokinin plant growth regulator, that stimulates cell division, leading to increases in fruit size. The NEDI for forchlorfenuron is <0.1 % of the ADI
Halosulfuron-methyl Edible offal (Mammalian) Meat [mammalian] Milks	Omit Substitute Omit Substitute Omit Substitute	T0.2 0.2 T*0.01 *0.01 T*0.01 *0.01	
Imazapic (formerly known as Imazameth) Eggs Poultry, Edible offal of Poultry meat	Omit Substitute Omit Substitute Omit Substitute	T*0.01 *0.01 T*0.01 *0.01 T*0.01 *0.01	The NEDI is equivalent to 0.1 % of the ADI.
Iprodione Onion, Bulb	Insert	T0.2	Fungicide for the control of Neck rot (<i>Botrytis allii</i>) in onions Inhibition of spore germination and mycelium growth The NEDI for iprodione is equivalent to 43% of the ADI

Meloxicam Pig kidney Pig liver Pig meat Pig fat/skin	Insert Insert Insert Insert	*0.01 *0.01 0.02 0.1	Meloxicam is to be used in pigs to: (i) reduce the symptoms of lameness and inflammation associated with non-infectious locomotor disorders; and (ii) reduce clinical signs of inflammation, oppose the effects of endotoxins, and hasten recovery in cases of puerperal septicaemia and toxæmia (mastitis-metritis-agalactia syndrome), when used in combination with appropriate antibiotic therapy. The NEDI for meloxicam is calculated to be 68.5 % of the ADI. NESTI 2 years (+): Pig fat/skin <1% ARfD Pig meat <1.8 % ARfD Pig kidney <0% ARfD Pig liver <0.1% ARfD NESTI 2-6 years Pig fat/skin <0.41% ARfD Pig meat <3.5 % ARfD Pig offal 0% ARfD
Metalaxyl Cereal grains	Omit	T*0.05	This chemical is a phenylamide fungicide used as a seed dressing on barley and wheat seeds prior to sowing. NEDI = 8% of ADI
Methazole Onion, Bulb	Omit	T*0.1	
Phenmedipham Lettuce, Head Lettuce, Leaf	Insert Insert	T0.2 T0.2	Herbicide for control of broadleaf weeds in lettuce (minor use permit) Selective systemic herbicide, absorbed through leaves, with translocation primarily in the apoplast. Photosynthetic electron transport inhibitor. The NEDI for phenmedipham is equivalent to 1% of the ADI.
Procymidone Carrot Peppers Root and tuber vegetables (except potato)	Omit Insert Insert	T1 T2 T1	Fungicide - Inhibition of triglyceride synthesis in the target pest. The NEDI for procymidone including contributions from MRLs established as a result of the proposed use pattern is equivalent to 43% of the ADI

Procymidone			
Adzuki beans (dry)	Omit	0.2	As part of the new label instructions for procymidone (APVMA Gazette, December 2004), the following permanent MRLs have been changed to temporary MRLs.
	Substitute	T0.2	
Beans, except broad beans and soya bean	Omit	10	NESTI 2 years (+) 28 % of ARfD for Peppers sweet; <3% for peppers chilli.
	Substitute	T10	
Edible offal (mammalian)	Omit	0.05	NESTI 2-6 years 63% of ARfD for Peppers sweet; 19% of ARfD for peppers chilli.
	Substitute	T0.05	
Eggs	Omit	*0.01	<i>NESTI 2 years (+):</i>
	Substitute	T*0.01	
Garlic	Omit	5	Radish 14% ARfD Swede 24% ARfD Turnip, garden 8% ARfD Beetroot 13% ARfD Parsnip 14% ARfD
	Substitute	T5	
Grapes	Omit	2	NESTI 2-6 years
Wine Grapes	Insert	T2	
Lettuce, Head	Omit	2	Radish 22% ARfD Swede 30% ARfD Turnip, garden 14% ARfD Beetroot 34% ARfD Parsnip 12% ARfD
Lettuce, Leaf	Omit	2	
Lupin (dry)	Omit	*0.01	The NEDI for procymidone including contributions from MRLs established as a result of the proposed use pattern is equivalent to 43% of the ADI
	Substitute	T*0.01	
Meat (mammalian)[in the fat]	Omit	0.2	
	Substitute	T0.2	
Milks	Omit	0.02	
	Substitute	T0.02	
Onion, Bulb	Omit	0.2	
	Substitute	T0.2	
Pome fruits	Omit	1	
	Substitute	T1	
Potato	Omit	0.1	
	Substitute	T0.1	
Poultry, Edible offal of	Omit	*0.01	
	Substitute	T*0.01	
Poultry meat [in the fat]	Omit	0.1	
	Substitute	T0.1	
Snow-peas	Omit	5	
	Substitute	T5	
Stone fruits	Omit	10	
	Substitute	T10	
Strawberry	Omit	5	
Tomato	Omit	2	
Promecarb			
Beans, except broad and soya bean	Omit	T0.5	
Broad bean (green pods and immature seeds)	Omit	T0.5	
Citrus fruits	Omit	T1	
Fruiting vegetables, Cucurbits	Omit	T0.5	
Grapes	Omit	T0.2	
Onion, Bulb	Omit	T0.5	
Stone fruits	Omit	T0.5	

Propachlor Cereal grains Cereal grains (except sorghum) Sweet corn (corn-on-the-cob) Edible offal (mammalian) Eggs Meat (mammalian)[in the fat] Milks Poultry, Edible offal of Poultry meat [in the fat] Sorghum	Omit Substitute Insert Insert Insert Insert Insert Insert Insert	*0.05 0.05 0.05 0.1 *0.02 *0.02 *0.02 *0.02 *0.02 0.2	This chemical is a chloroacetamide herbicide used to control weeds in radish, swede and turnip crops. NEDI = 7% of ADI.
Sethoxydim Barley	Insert	*0.1	Control of grasses in broad-leaved crops. Selective systemic herbicide, absorbed predominantly by the foliage, and, to a lesser extent, by the roots. The NEDI is equivalent to 27.9% of the ADI.
Tolyfluanid Dried grapes Grapes	Insert Insert	T0.2 T*0.05	tolyfluanid N-dichlorofluoromethylthio-N',N'-dimethyl-N-p-tolylsulfamide polyvalent sulfamide fungicide Fungicide on grapes Inactivation of essential enzymes by reaction with -SH bonds The NEDI for tolyfluanid, including contributions from MRLs established as a result of the proposed use pattern, is equivalent to 0.3 % of the ADI
Trichlorfon Milks Peppers	Omit Substitute Omit Substitute	0.05 *0.05 T0.5 0.2	This chemical is an organophosphate insecticide used to control Haemonchus spp. on goats. NEDI = 84% of ADI.
Trifloxystrobin Strawberry	Omit Substitute	T2 2	Trifloxystrobin (E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneaminoxymethyl]phenyl}acetic acid methyl ester Strobilurin Fungicide on strawberries for control of powdery mildew and downy mildew Inhibition of mitochondrial respiration by blocking electron transfer The NEDI for trifloxystrobin is less than 3% of the ADI.
Tylosin	Omit Substitute		Tylosin Tylosin A

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 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 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.