

9-04

15 December 2004

INITIAL/DRAFT/ ASSESSMENT REPORT

APPLICATION A541

MAXIMUM RESIDUE LIMITS (June, July, August 2004)

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 9 February 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

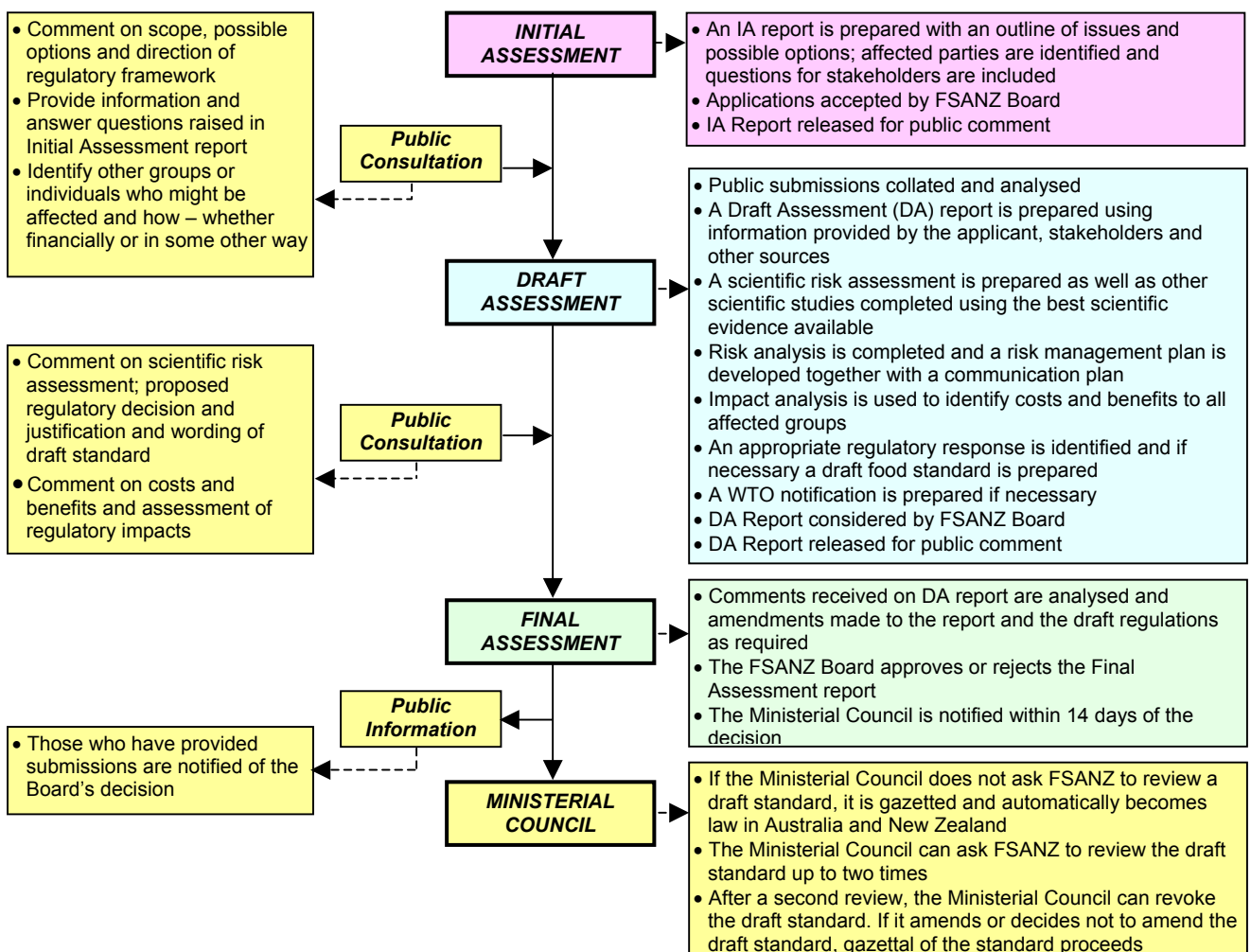
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 A541; 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) 9 February 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 and Statement of Reasons

This Application (A541) seeks to amend Maximum Residue Limits (MRLs) for non-antibiotic agricultural and veterinary chemicals in 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 Commonwealth of Australia and the Government of New Zealand to establish a system for the development of joint food standards* (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.

Statement of Reasons

FSANZ recommends progressing this Application 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 APVMA has already registered the chemical products associated with the MRLs in this Application and the rejection of the MRLs would result in legally treated food not being able to be legally sold. Therefore, the requested changes will benefit all 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 amendment to the Code is necessary, cost-effective and of benefit to both producers and consumers.
- None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed changes.

1. Introduction

Applications were received from the APVMA on 3 June, 21 July and 10 August 2004 seeking amendments to Standard 1.4.2 of the Code. The proposed amendments 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 boscalid, ethoxysulfuron, etoxazole, pinoxaden and pyraclostrobin;
- the deletion of all entries for the chemical cloquintocet acid;
- the deletion of MRLs for certain foods for the chemicals carbendazim, deltamethrin, emamectin, iprodione, linuron and metolachlor;
- the addition of MRLs for certain foods for the chemicals bifenthrin, carbendazim, chlorhexidine, deltamethrin, emamectin, procymidone and tebuconazole;
- the changing of MRLs for certain foods for the chemicals cloquintocet-mexyl, deltamethrin, emamectin, fludioxonil, guazatine, linuron, metolachlor, pendimethalin and spinosad;
- the changing of the residue definitions for cloquintocet-mexyl and fludioxonil; and
- the addition of temporary MRLs for certain foods for the chemicals chlorothalonil, chlorpyrifos, clofentezine, cloquintocet-mexyl, dithiocarbamates, imidacloprid, linuron, metolachlor, metsulfuron-methyl, oryzalin, pyrimethanil, ractopamine, spiroxamine and thiodicarb.

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 Antibiotic MRLs

There are no MRLs for antibiotic 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 the Code. This has led to the possibility that legally treated food may not comply with the Code.

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 APVMA's legislation, and now seeks by way of this Application to include the amendments to the Code.

4. Background

4.1 The use of agricultural and veterinary chemicals

In Australia, 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 will then agree to adopt the proposed MRLs into Standard 1.4.2 of the Code.

FSANZ then notifies the Ministerial Council of the adoption of the variation to the Code. If the Ministerial Council accepts the changes made by FSANZ, the MRLs are automatically adopted by reference under the food laws of the Australian States and Territories.

The inclusion of the MRLs in 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 agree to adopt MRLs into the 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.

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

4.4 Food Standards-setting in Australia and New Zealand

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

4.5 Trans Tasman Mutual Recognition Arrangement

Following 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 the Code to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

4.7 MRLs for Permits

Some of the proposed MRLs in this Application are temporary and are indicated by a ‘T’ in 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. Options

5.1 Option 1 – status quo – no change to the existing MRLs in the Code

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

5.2 Option 2(a) – adopt the change to MRLs to omit or decrease some existing MRLs

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

5.3 Option 2(b) – adopt the changes to MRLs to insert new or increase some existing MRLs

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

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

6. 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.

7. Impact Analysis

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

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

7.1.1 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.

7.1.2 *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.

7.2 Option 2(a) – adopt the changes to MRLs to delete and decrease some existing MRLs

7.2.1 *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.

7.2.2 *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 11.5.3 and data on imported foods are addressed in section 11.5.4; 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.

7.3 Option 2(b) – adopt the changes to MRLs to include new and increase some existing MRLs

7.3.1 *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.

7.3.2 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.

8. 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. However, FSANZ now invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to any submissions received. FSANZ was satisfied that omitting to invite public submissions prior to making a Draft Assessment was warranted as the Application of minor significance or complexity. Furthermore, FSANZ considered that omitting to invite public submissions prior to making a Draft Assessment would not significantly adversely affect the interests of any person or body.

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 of FSANZ under section 36 of the FSANZ Act not to do something.

In addition to the public consultation that is undertaken for all applications and proposals, and as the preferred option has some potential impacts for importers of food and associated industries, comment on the impacts of the proposed MRLs will be sought from them.

8.1 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 SPS agreement because the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment.

9. Conclusion

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 adopt Options 2(a) and 2(b) – to adopt the change to MRLs in the Code to include new or increase some existing MRLs and to delete or decrease some existing MRLs. FSANZ prefers this approach because:

- the residues associated with the MRL amendments would not result in an unacceptable risk to public health and safety (this benefit also applies to Option 1);
- the changes would minimise the potential costs to primary producers and rural and regional communities in terms of legally being able to sell legally treated food;
- the changes would minimise residues consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases; and
- the changes would remove discrepancies between agricultural and food legislation and assist enforcement.

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

10. Implementation and Review

The use of chemical products and MRLs are under constant 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 proposed MRL amendments should come into effect upon gazettal and continue to be monitored by the same means as other residues in food.

11. Consideration of Issues under section 13 of the *Food Standards Australia New Zealand Act 1991*

Subsection 13(1) of the FSANZ Act requires FSANZ to make an initial assessment of an application. In making that initial assessment, subsection 13(2) requires FSANZ to have regard to a number of matters set out in paragraphs 13(2)(a) to (e). Each of these matters is discussed below.

11.1 Paragraph 13(2)(a)

This Application relates to a matter that may warrant a variation to a food regulatory measure.

11.2 Paragraph 13(2)(b)

This Application is not so similar to a previous application that it ought not be accepted.

11.3 Paragraph 13(2)(c)

This Application does not suggest that the proposed amendment would present any further costs that would outweigh the direct and indirect benefits to the community, government or industry.

11.4 Paragraph 13(2)(d)

The nature of this Application is such that only an amendment to a standard (i.e. a food regulatory measure) can achieve what it is that the Applicant seeks. No other measures appear to be available, or as cost-effective.

11.5 Paragraph 13(2)(e)

Other relevant matters for consideration by FSANZ are as follows.

11.5.1 *Consideration of issues under Regulation 12 of the Food Standards Australia New Zealand Regulations 1994 which prescribes matters for the purpose of paragraph 13(2) (e) of the FSANZ Act.*

11.5.1.1 Regulation 12(a)

This is not relevant to this Application.

11.5.1.2 Regulation 12(b)

This is not relevant to this Application.

11.5.2 *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
Deltamethrin Goat meat (in the fat) Milks Sheep meat (in the fat)	0.2 0.05 0.2	0.5 Meat (in the fat) 0.02 Milks (in the fat) 0.5 Meat (in the fat)
Imidacloprid Grapes	T0.1	1
Spinosad Stone fruits	1	0.2
Tebuconazole Dried grapes Grapes	2 2	3 2
Thiodicarb Peppers, sweet	T5	1

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

11.5.3 *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.

Food
Edible offal (mammalian)
Eggs
Fruiting vegetables, other than cucurbits
Herbs
Kaffir lime leaves
Lemon balm
Lemon grass
Lemon verbena
Meat (mammalian)
Milks
Poultry, edible offal of
Poultry meat
Turmeric, root
Wheat

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

12. Consideration of Issues under section 15(3) of the *Food Standards Australia New Zealand Act 1991*

Subsection 15(1) of the FSANZ Act requires FSANZ to make a Draft Assessment of an application accepted under section 13A of the FSANZ Act. In making that Draft Assessment, subsection 15(3) requires FSANZ to have regard to a number of matters set out in paragraphs 15(3)(b) to (e). Each of these matters is discussed below.

12.1 Paragraph 15(3)(a)

This is not relevant to this Application.

12.2 Paragraph 15(3)(b)

Section 10(1), paragraphs (a) to (c) of the FSANZ Act sets out the objectives of food regulatory measures and variations to food regulatory matters. Each of these measures is discussed below.

12.2.1 Paragraph 10(1)(a) the protection of public health and safety

OCS establish the ADIs and where applicable the ARfDs for agricultural and veterinary chemicals. The APVMA and FSANZ carry out estimates of dietary exposure to agricultural and veterinary chemicals and compare them to the OCS standards. Based on dietary exposure assessments, the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

12.2.2 Paragraph 10(1)(b) the provision of adequate information relating to food to enable consumers to make informed choices

This is not relevant for this Application.

12.2.3 Paragraph 10(1)(c) the prevention of misleading or deceptive information

This is not relevant for this Application.

In addition to these objectives, subsection 10(2) requires FSANZ to have regard to a number of matters set out in paragraphs 10(2)(a) to (e). Each of these matters is discussed below.

12.2.4 Paragraph 10(2)(a) the need for standards to be based on risk analysis using the best available scientific evidence

FSANZ considers proposed MRLs in accordance with the best available scientific evidence. The procedures adopted by FSANZ, OCS and APVMA are based on a comprehensive examination of up to date detailed scientific information. That includes a rigorous toxicological assessment and dietary exposure assessments undertaken in accordance with international protocols.

12.2.5 Paragraph 10(2)(b) the promotion of consistency between domestic and international food standards

This is addressed in section 11.5.

12.2.6 Paragraph 10(2)(c) the desirability of an efficient and internationally competitive food industry

The inclusion of the requested MRLs would assist in permitting the legal sale of legally treated food. Varying the Code to include the proposed MRLs would promote trade and commerce and allow food industries to continue to be efficient and competitive.

12.2.7 Paragraph 10(2)(d) the promotion of fair trading in food

As the MRLs in the Code apply to all food whether produced domestically or imported, the inclusion of the MRLs would benefit all producers equally.

12.2.8 Paragraph 10(2)(e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to FSANZ

To date the Ministerial Council has not made a written notification to FSANZ of any policy guidelines that are relevant to this Application.

12.3 Paragraph 15(3)(c)

FSANZ has undertaken a preliminary regulation impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the Code did not produce costs to bodies or persons that outweighed the benefits to the public.

12.4 Paragraph 15(3)(d)

The nature of this Application is such that only an amendment to a standard (i.e. a food regulatory measure) can achieve what it is that the Applicant seeks. No other measures appear to be available, or as cost-effective.

12.5 Paragraph 15(3)(e)

This is addressed in section 11.5.

13. Recommendation

FSANZ recommends progressing this Application for the following reasons:

- The dietary exposure assessments indicate, where appropriate, that the residues associated with the MRLs do not represent an unacceptable risk to public health and safety. APVMA has already registered the chemical products in this Application and the rejection of the MRLs would result in legally treated food not being able to be legally sold. Therefore, the requested changes will benefit all stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.
- APVMA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.
- OCS has undertaken an appropriate toxicological assessment of the chemical products and has established relevant ADIs and where applicable ARfD.
- FSANZ has undertaken a preliminary regulation impact assessment process. That process concluded that the amendment to the Code is necessary, cost effective and of benefit to both producers and consumers.
- None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed changes.

Attachments

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

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 –*

Cloquintocet acid

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

COLUMN 1	COLUMN 2
CLOQUINTOCET-MEXYL	SUM OF CLOQUINTOCET MEXYL AND 5-CHLORO-8-QUINOLINOXYACETIC ACID, EXPRESSED AS CLOQUINTOCET MEXYL
FLUDIOXONIL	COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL COMMODITIES OF PLANT ORIGIN: FLUDIOXONIL

[1.3] *inserting in Schedule 1–*

BOSCALID	
<i>COMMODITIES OF PLANT ORIGIN: BOSCALID</i>	
<i>COMMODITIES OF ANIMAL ORIGIN: SUM OF BOSCALID, 2-CHLORO-N-(4'-CHLORO-5-HYDROXYBIPHENYL-2-YL) NICOTINAMIDE AND GLUCURONIDE CONJUGATE OF 2-CHLORO-N-(4'-CHLORO-5-HYDROXYBIPHENYL-2-YL) NICOTINAMIDE, EXPRESSED AS BOSCALID EQUIVALENTS</i>	
DRIED GRAPES	15
EDIBLE OFFAL (MAMMALIAN)	0.05
GRAPES	4
MEAT (MAMMALIAN) (IN THE FAT)	0.1
MILKS	*0.02
ETHOXSULFURON	
<i>COMMODITIES OF PLANT ORIGIN: ETHOXSULFURON</i>	
<i>COMMODITIES OF ANIMAL ORIGIN: 2-AMINO-4, 6-DIMETHOXPYRIMIDINE, EXPRESSED AS ETHOXSULFURON</i>	
EDIBLE OFFAL (MAMMALIAN)	T*0.05
MEAT (MAMMALIAN)	T*0.05
MILKS	T*0.01
SUGAR CANE	T*0.01

ETOXAZOLE ETOXAZOLE	
COTTON SEED	T0.2
EDIBLE OFFAL (MAMMALIAN)	T*0.01
EGGS	T*0.01
MEAT (MAMMALIAN) (IN THE FAT)	T*0.01
MILKS	T*0.01
POULTRY, EDIBLE OFFAL OF	T*0.01
POULTRY MEAT (IN THE FAT)	T*0.01
PINOXADEN SUM OF 8-(2,6-DIETHYL-4-METHYLPHENYL)- TETRAHYDRO-PYRAZOLO [1,2-D][1,4,5] OXADIAZEPINE-7,9-DIONE AND 8-(2,6-DIETHYL-4- HYDROXYMETHYLPHENYL)-TETRAHYDRO- PYRAZOLO [1,2-D][1,4,5] OXADIAZEPINE-7,9-DIONE, EXPRESSED AS PINOXADEN	
BARLEY	T*0.02
EDIBLE OFFAL (MAMMALIAN)	T*0.05
EGGS	T*0.05
MEAT (MAMMALIAN)	T*0.05
MILKS	T*0.02
POULTRY, EDIBLE OFFAL OF	T*0.05
POULTRY MEAT	T*0.05
WHEAT	T*0.02
PYRACLOSTROBIN <i>COMMODITIES OF PLANT ORIGIN:</i> PYRACLOSTROBIN <i>COMMODITIES OF ANIMAL ORIGIN:</i> SUM OF PYRACLOSTROBIN AND METABOLITES HYDROLYSED TO 1-(4-CHLORO-PHENYL)-1H-PYRAZOL-3-OL, EXPRESSED AS PYRACLOSTROBIN	
BANANA	*0.02
DRIED GRAPES	5
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.05
GRAPES	2
MEAT (MAMMALIAN) (IN THE FAT)	*0.05
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT (IN THE FAT)	*0.05

[1.4] *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	
FRUITING VEGETABLES, CUCURBITS	2
DELTAMETHRIN DELTAMETHRIN	
CATTLE MILK (IN THE FAT)	0.5
GOAT MILK (IN THE FAT)	0.2
SHEEP MILK (IN THE FAT)	0.2

EMAMECTIN EMAMECTIN B1A, PLUS ITS 8,9-Z ISOMER AND EMAMECTIN B1B, PLUS ITS 8,9-Z ISOMER	
FRUITING VEGETABLES, OTHER THAN CUCURBITS	T*0.01
IPRODIONE IPRODIONE	
HERBS	T5
TURMERIC ROOT	T5
LINURON SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
HERBS	T*0.05
METOLACHLOR METOLACHLOR	
CORIANDER (LEAVES, STEM, ROOTS)	T0.05

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

BIFENTHRIN BIFENTHRIN	
SWEET POTATO	*0.05
CARBENDAZIM SUM OF CARBENDAZIM AND 2- AMINOBENZIMIDAZOLE, EXPRESSED AS CARBENDAZIM	
FRUITING VEGETABLES, CUCURBITS [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	2
MELONS [EXCEPT WATERMELON]	4
CHLORHEXIDINE CHLORHEXIDINE	
SHEEP, EDIBLE OFFAL OF	*0.5
SHEEP FAT	*0.5
SHEEP MEAT	*0.5
CHLOROTHALONIL CHLOROTHALONIL	
FENNEL, BULB	T10
GALANGAL, GREATER	T7
GALANGAL, LESSER	T7
CHLORPYRIFOS CHLORPYRIFOS	
PARSLEY	T0.05

CLOFENTEZINE CLOFENTEZINE	
ALMONDS	T0.5
EDIBLE OFFAL (MAMMALIAN)	T*0.05
MEAT (MAMMALIAN)	T*0.05
MILKS	T*0.05
CLOQUINTOCET-MEXYL SUM OF CLOQUINTOCET MEXYL AND 5-CHLORO-8- QUINOLINOXYACETIC ACID, EXPRESSED AS CLOQUINTOCET MEXYL	
BARLEY	T*0.1
DELTA METHRIN DELTA METHRIN	
MILKS	0.05
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
CUSTARD APPLE	T5
EMAMECTIN EMAMECTIN B1A, PLUS ITS 8,9-Z ISOMER AND EMAMECTIN B1B, PLUS ITS 8,9-Z ISOMER	
PEPPERS, SWEET	0.01
TOMATO	0.01
IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6- CHLOROPYRIDINYMETHYLENEMOIEITY, EXPRESSED AS IMIDACLOPRID	
GRAPES	T0.1
LINURON SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
HERBS [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	T0.5
KAFFIR LIME LEAVES	T0.5
LEMON BALM	T0.5
LEMON GRASS	T0.5
LEMON VERBENA	T0.5
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
METOLACHLOR METOLACHLOR	
CORIANDER (LEAVES, STEM)	T*0.05
CORIANDER, ROOTS	T0.5
METSULFURON-METHYL METSULFURON-METHYL	
LINSEED	T*0.02

ORYZALIN ORYZALIN	
GARLIC	T*0.05
PROCYMIDONE PROCYMIDONE	
ADZUKI BEAN (DRY)	0.2
PYRIMETHANIL PYRIMETHANIL	
BANANA	T0.2
RACTOPAMINE {T}RACTOPAMINE	
CATTLE FAT	T*0.02
CATTLE KIDNEY	T0.1
CATTLE MEAT	T*0.02
SPIROXAMINE COMMODITIES OF PLANT ORIGIN: SPIROXAMINE COMMODITIES OF ANIMAL ORIGIN: SPIROXAMINE CARBOXYLIC ACID, EXPRESSED AS SPIROXAMINE	
BANANA	T5
TEBUCONAZOLE TEBUCONAZOLE	
DRIED GRAPES	5
GRAPES	2
THIODICARB SUM OF THIODICARB, METHOMYL AND METHOMYL OXIME, EXPRESSED AS THIODICARB <i>SEE ALSO</i> METHOMYL	
PEPPERS, SWEET	T5

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

CLOQUINTOCET-MEXYL SUM OF CLOQUINTOCET MEXYL AND 5-CHLORO-8- QUINOLINOXYACETIC ACID, EXPRESSED AS CLOQUINTOCET MEXYL	
EDIBLE OFFAL (MAMMALIAN)	*0.1
EGGS	*0.1
MEAT (MAMMALIAN)	*0.1
MILKS	*0.1
POULTRY, EDIBLE OFFAL OF	*0.1
POULTRY MEAT	*0.1
WHEAT	*0.1
DELTAMETHRIN DELTAMETHRIN	
GOAT MEAT (IN THE FAT)	0.2
SHEEP MEAT (IN THE FAT)	0.2

EMAMECTIN	
EMAMECTIN B1A, PLUS ITS 8,9-Z ISOMER AND EMAMECTIN B1B, PLUS ITS 8,9-Z ISOMER	
LETTUCE, HEAD	0.2
LETTUCE, LEAF	0.2
FLUDIOXONIL	
<i>COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL</i>	
<i>COMMODITIES OF PLANT ORIGIN: FLUDIOXONIL</i>	
MAIZE	*0.02
SWEET CORN (CORN-ON-THE-COB)	*0.02
GUAZATINE	
GUAZATINE	
MELONS [EXCEPT WATERMELON]	10
LINURON	
SUM OF LINURON PLUS 3,4-DICHLOROANILINE, EXPRESSED AS LINURON	
EDIBLE OFFAL (MAMMALIAN)	1
EGGS	*0.05
METOLACHLOR	
METOLACHLOR	
BERGAMOT	T*0.05
BURNET, SALAD	T*0.05
CHERVIL	T*0.05
CORIANDER, SEED	T*0.05
DILL, SEED	T*0.05
FENNEL, SEED	T*0.05
GALANGAL, GREATER	T0.5
HERBS	T*0.05
KAFFIR LIME LEAVES	T*0.05
LEMON GRASS	T*0.05
LEMON VERBENA (DRY LEAVES)	T*0.05
MIZUNA	T*0.05
ROSE AND DIANTHUS (EDIBLE FLOWERS)	T*0.05
RUCOLA (ROCKET)	T*0.05
TURMERIC, ROOT	T0.5
PENDIMETHALIN	
PENDIMETHALIN	
TOMATO	*0.05
SPINOSAD	
SUM OF SPINOSYN A AND SPINOSYN D	
STONE FRUITS	1

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 A541

Bifenthrin Sweet potato	Insert	*0.05	This chemical is a synthetic pyrethroid insecticide used to control insects on sweet potato. The 20 th ATDS (2000) dietary exposure estimate for bifenthrin, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 83% of the ADI.
Boscalid Dried grapes Edible offal (mammalian) Grapes Meat (mammalian)(in the fat) Milks	Insert Insert Insert Insert Insert	15 0.05 4 0.1 *0.02	This as new chemical. It is a carboxamide fungicide used control fungal diseases in grapes. NESTI for 2 to 6 y.o. for grapes [excluding wine] = 2 % of ARfD. All other NESTIs for this age group = <1% of the ARfD. NESTI for the whole population 2 years and above for all commodities = <1% of the ARFD. NEDI = 2% of the ADI.
Carbendazim Fruiting vegetables, cucurbits Fruiting vegetables, cucurbits [except as otherwise listed under this chemical] Melons [except watermelon]	Omit Insert Insert	2 2 4	This chemical is a benzimidazole fungicide used to control various rots on a wide range of fruits. In the 19 th (1998) ATDS the estimated dietary exposure to carbendazim was <1% of the ADI for whole population. NEDI = 84% of ADI.
Clofentezine Almonds Edible offal (mammalian) Meat (mammalian) Milks	Insert Insert Insert Insert	T0.5 T*0.05 T*0.05 T*0.05	This chemical is an acaricide. APVMA have issued a permit for this chemical to be used to control 'two spotted/brown mites' in almonds. The anticipated exposure to livestock from their consumption of almond hulls is considered negligible. Therefore, the proposed MRLs for animal commodities are at the LOQ. NEDI = 4% of the ADI.
Chlorhexidine Sheep, edible offal of Sheep fat Sheep meat	Insert Insert Insert	*0.5 *0.5 *0.5	This chemical is a cationic bis-biguanide antiseptic and disinfectant used to control and prevent blow fly strike in sheep. NEDI = <1% of ADI
Chlorothalonil Fennel, bulb Galangal, Greater Galangal, Lesser	Insert Insert Insert	T10 T7 T7	This chemical is a chloronitrile used to control a range of fungal diseases. NEDI = 77% of ADI

<p>Deltamethrin</p> <p>Cattle milk (in the fat)</p> <p>Goat meat (in the fat)</p> <p>Goat milk (in the fat)</p> <p>Milks</p> <p>Sheep meat (in the fat)</p> <p>Sheep milk (in the fat)</p>	<p>Omit 0.5</p> <p>Omit 0.1</p> <p>Substitute 0.2</p> <p>Omit 0.2</p> <p>Insert 0.05</p> <p>Omit 0.1</p> <p>Substitute 0.2</p> <p>Omit 0.2</p>	<p>This chemical is a synthetic pyrethroid insecticide used to control insects on grains. Deltamethrin has been reviewed as part of the APVMA's Stockfeed Guideline Project with the resultant proposed MRLS for animal commodities. In the 20th (2000) ATDS the concentrations of residues of deltamethrin in surveyed foods were less than the LOQ.</p> <p>Goat meat (in the fat) NESTI = 2% of ARfD for 2 to 6 y.o. and <1% of the ARfD for the whole population 2 years and above.</p> <p>Sheep meat (in the fat) NESTI = 2 % of ARfD for 2 to 6 y.o. and <1% of the ARfD for the whole population 2 years and above.</p> <p>Milks NESTI = 8 % of ARfD for 2 to 6 y.o. and 3% of the ARfD for the whole population 2 years and above.</p> <p>NEDI = 59% of the ADI.</p>
<p>Dithiocarbamates (Mancozeb)</p> <p>Custard apple</p>	<p>Insert T5</p>	<p>Dithiocarbamates are fungicides used to control fungal diseases on crops. In the 19th (1998) ATDS the estimated dietary exposure to thiram (the dithiocarbamate with the lowest ADI) was at 63% of the ADI for 2 year olds and 20% of the ADI for adult males. On the basis of results from the 1998 ATDS and that mancozeb has a higher ADI than thiram, FSANZ considers that the residues associated with the proposed MRL would not represent an unacceptable risk to public health and safety. APVMA has issued a permit for mancozeb to be used to control fungal diseases on custard apple. NEDI for mancozeb = 84% of ADI</p>
<p>Emamectin</p> <p>Fruiting vegetables, other than cucurbits</p> <p>Lettuce, head</p> <p>Lettuce, leaf</p> <p>Peppers, sweet</p> <p>Tomato</p>	<p>Omit T*0.01</p> <p>Omit T0.2</p> <p>Substitute 0.2</p> <p>Omit T0.2</p> <p>Substitute 0.2</p> <p>Insert 0.01</p> <p>Insert 0.01</p>	<p>This chemical is an avermectin insecticide used to control insects on vegetable crops.</p> <p>NEDI = 3% of the ADI.</p>

Ethoxysulfuron Edible offal (mammalian) Meat (mammalian) Milks Sugar cane	Insert T*0.05 Insert T*0.05 Insert T*0.01 Insert T*0.01	This as new chemical. It is a sulphonyl urea herbicide. APVMA have issued a permit for this chemical to be used to various weeds in sugar cane. The anticipated exposure to livestock from their consumption of the top of the mature cane is considered negligible. Therefore, the proposed MRLs for animal commodities are at the LOQ. NESTI = <1% of the ARfD for all relevant commodities for 2-6 year olds and for the population 2 years and above. NEDI = <1% of the ADI.
Etoxazole Cotton seed Edible offal (mammalian) Eggs Meat (mammalian) (in the fat) Milks Poultry, edible offal of Poultry meat (in the fat)	Insert T0.2 Insert T*0.01 Insert T*0.01 Insert T*0.01 Insert T*0.01 Insert T*0.01 Insert T*0.01	This as new chemical. It is an insecticide. APVMA have issued a permit for this chemical to be used to control insects on cotton. The anticipated exposure to livestock from their consumption of cotton seed is considered negligible. Therefore, the proposed MRLs for animal commodities are at the LOQ. NESTI = <1% of the ARfD for all relevant commodities for 2-6 year old and for the population 2 years and above. NEDI = <1% of the ADI.
Fludioxonil Maize Sweet corn (corn-on-the-cob)	Omit T*0.02 Substitute *0.02 Omit T*0.02 Substitute *0.02	This chemical is a phenylpyrrole fungicide used control fungal diseases in maize and sweet corn. NEDI = 2% of ADI.
Guazatine Melons [except watermelon]	Omit 5 Substitute 10	This chemical is a guanidine fungicide used to control various rots on a wide range of fruits. NEDI = 79% of the ADI.
Imidacloprid Grapes	Insert T0.1	This chemical is a neonicotinoid insecticide. APVMA has issued a permit for this chemical to be used to control long tailed mealy bug and citrus mealy bug on grape crops. NESTI = <1% of the ARfD for 2-6 year olds and for the population 2 years and above. NEDI = 7% of ADI

<p>Iprodione Herbs Turmeric, root</p>	<p>Omit T5 Omit T5</p>	<p>This chemical is a dicarboximide used to control fungal diseases on culinary herb crops. In the 19th (1998) and 20th (2000) ATDSs the estimated dietary exposure to iprodione was at 1% of the ADI for the whole population. NEDI = 60% of ADI.</p>
<p>Linuron Edible offal (mammalian) Eggs Herbs Herbs [except as otherwise listed under this chemical] Kaffir lime leaves Lemon balm Lemon grass Lemon verbena Poultry, edible offal of Poultry meat</p>	<p>Omit *0.05 Substitute 1 Omit 0.05 Substitute *0.05 Omit T*0.05 Insert T0.5 Insert T0.5 Insert T0.5 Insert T0.5 Insert T0.5 Insert *0.05 Insert *0.05</p>	<p>This chemical is a urea. APVMA has reviewed a permit renewal for this chemical to be used to control weeds in culinary herb crops. NEDI = 9% of ADI.</p>
<p>Metolachlor Bergamot Burnet, salad Chervil Coriander (leaves, stem, roots) Coriander (leaves, stem) Coriander, seed Coriander, roots Dill, seed Fennel, seed Galangal, Greater Herbs</p>	<p>Omit T0.05 Substitute T*0.05 Omit T0.05 Substitute T*0.05 Omit T0.05 Substitute T*0.05 Omit T0.05 Insert T*0.05 Omit T0.05 Substitute T*0.05 Insert T0.5 Omit T0.05 Substitute T*0.05 Omit T0.05 Substitute T*0.05 Omit T0.1 Substitute T0.5 Omit T0.05 Substitute T*0.05</p>	<p>This chemical is a chloroacetamide herbicide. APVMA have reviewed the permit renewal for the use of this chemical to control weeds in culinary herbs.</p>

Kaffir lime leaves	Omit Substitute	T0.05 T*0.05	
Lemon grass	Omit Substitute	T0.05 T*0.05	
Lemon verbena (dry leaves)	Omit Substitute	T0.05 T*0.05	
Metolachlor (cont)			
Mizuna	Omit Substitute	T0.05 T*0.05	
Rose and dianthus (edible flowers)	Omit Substitute	T0.05 T*0.05	
Rucola (rocket)	Omit Substitute	T0.05 T*0.05	
Turmeric, root	Omit Substitute	T0.1 T0.5	NEDI = <1% of ADI
Metsulfuron-methyl Linseed	Insert	T*0.02	This chemical is a sulfonylurea. APVMA has issued a permit for metsulfuron-methyl to be used to control broad leaf weeds in linseed crops. NEDI = 11% of ADI
Oryzalin Garlic	Insert	T*0.05	This chemical is a dinitroaniline. APVMA has issued a permit for oryzalin to be used to control weeds garlic crops. NEDI = <1% of the ADI
Pendimethalin Tomato	Omit Substitute	T*0.05 *0.05	This chemical is a dinitroaniline. The APVMA has issued a permit for the use of pendimethalin as an herbicide to control annual grasses and broadleaf weeds in tomato crops. NEDI = <1% of ADI
Pinoxaden Barley Edible offal (mammalian) Eggs Meat (mammalian) Milks Poultry, edible offal of Poultry meat Wheat	Insert Insert Insert Insert Insert Insert Insert Insert	T*0.02 T*0.05 T*0.05 T*0.05 T*0.02 T*0.05 T*0.05 T*0.02	This as new chemical. It is a herbicide. APVMA has issued a permit for pinoxaden to be used to control weeds in cereal grain crops. NESTI for 2-6 year old and 2 years and above = <1% for all commodities. NEDI = 4% of ADI

<p>Procymidone Adzuki beans (dry)</p>	<p>Insert 0.2</p>	<p>This chemical is a dicarboximide fungicide used control fungal diseases in adzuki beans (dry). In the 20th (2000) ATDS the concentrations of residues of procymidone in surveyed foods were estimate at being less than 1% of the ADI for the whole population. NEDI = 24% of ADI.</p>
<p>Pyraclostrobin Banana Dried grapes Edible offal (mammalian) Eggs Grapes Meat (mammalian)(in the fat) Milks Poultry, edible offal of Poultry meat (in the fat)</p>	<p>Insert *0.02 Insert 5 Insert *0.05 Insert *0.05 Insert 2 Insert *0.05 Insert *0.01 Insert *0.05 Insert *0.05</p>	<p>This as new chemical. It is a strobilurin fungicide used to control fungal diseases on grape and banana crops. Banana NESTI for 2-6 year old = <1% of ARfD Banana NESTI for 2 years and above = 2% of ARfD Dried grapes NESTI for 2-6 year old = 14% of ARfD Dried grapes NESTI for 2 years and above = 4% of ARfD Edible offal mammalian NESTI for 2-6 year old and 2 years and above = <1% of ARfD. Eggs NESTI for 2-6 year old and 2 years and above = <1% of ARfD. Grapes NESTI for 2-6 year olds = <34% of ARfD. Grapes NESTI for 2 years and above = 14% of ARfD Meat (mammalian) NESTI for 2-6 year old = 2% of ARfD. Meat (mammalian) NESTI for 2 years and above = <1% of ARfD Milks NESTI for 2-6 year old = 2% of ARfD. Milks NESTI for 2 years and above = <1% of ARfD. Poultry, edible offal of NESTI for 2-6 year old and 2 years and above = <1% of ARfD. Poultry meat NESTI for 2-6 year old = 2% of ARfD. Poultry meat NESTI for 2 years and above = <1% of ARfD. NEDI = <1% of ADI</p>
<p>Pyrimethanil Banana</p>	<p>Insert T0.2</p>	<p>This chemical is an anilinopyrimidine. APVMA has issued a permit to allow the use of pyrimethanil to control fungal diseases on bananas. In the 20th (2000) ATDS the concentrations of residues of pyrimethanil in surveyed foods were estimate at being less than 1% of the ADI for the whole population. NEDI = 3% of ADI.</p>

<p>Ractopamine Cattle fat Cattle kidney Cattle meat</p>	<p>Insert T*0.02 Insert T0.1 Insert T*0.02</p>	<p>This chemical is a Phenethanolamine. APVMA has issued a permit to allow the use of ractopamine to increase weight gain, improve feed efficiency and increased carcass leanness in beef cattle. Cattle fat NESTI for 2-6 year olds and 2 years and above = <1% of ARfD. Cattle meat NESTI for 2-6 year olds = 25% of ARfD and for 2 years and above = 14% of ARfD. Cattle kidney NESTI for 2-6 year old = 34% of the ARfD. Cattle kidney NESTI for 2 years and above = 54% of ARfD. NEDI = 4% of ADI.</p>
<p>Spinosad Stone fruits</p>	<p>Omit 0.7 Substitute 1</p>	<p>This chemical is a spinosyn; it is used to control arthropods in various crops. NEDI = 32% of the ADI.</p>
<p>Spiroxamine Banana</p>	<p>Insert T5</p>	<p>This chemical is a morpholine: spiroketamine. APVMA has issued a permit to allow the use of spiroxamine to control fungal diseases on bananas. NESTI = 58% of the ARfD for 2-6 year olds and 16% of the ARfD for the population 2 years and above. NEDI = 13% of ADI.</p>
<p>Tebuconazole Dried grapes Grapes</p>	<p>Insert 5 Insert 2</p>	<p>This chemical is a triazole used is to control powdery mildew on grape. In the 20th (2000) ATDS the concentrations of residues of tebuconazole in surveyed foods were less than the LOQ. NEDI = 17% of ADI.</p>
<p>Thiodicarb Peppers, sweet</p>	<p>Insert T5</p>	<p>This chemical is an oxime carbamate. APVMA has issued a permit to allow the use of spiroxamine to control insects on capsicum. NEDI = 10% of ADI.</p>

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 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.