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

09/03
21 May 2003

INITIAL / DRAFT ASSESSMENT REPORT (s.36)

APPLICATION A477

MAXIMUM RESIDUE LIMITS

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter: **2 July 2003** (See "Invitation for Public Submissions" for details)

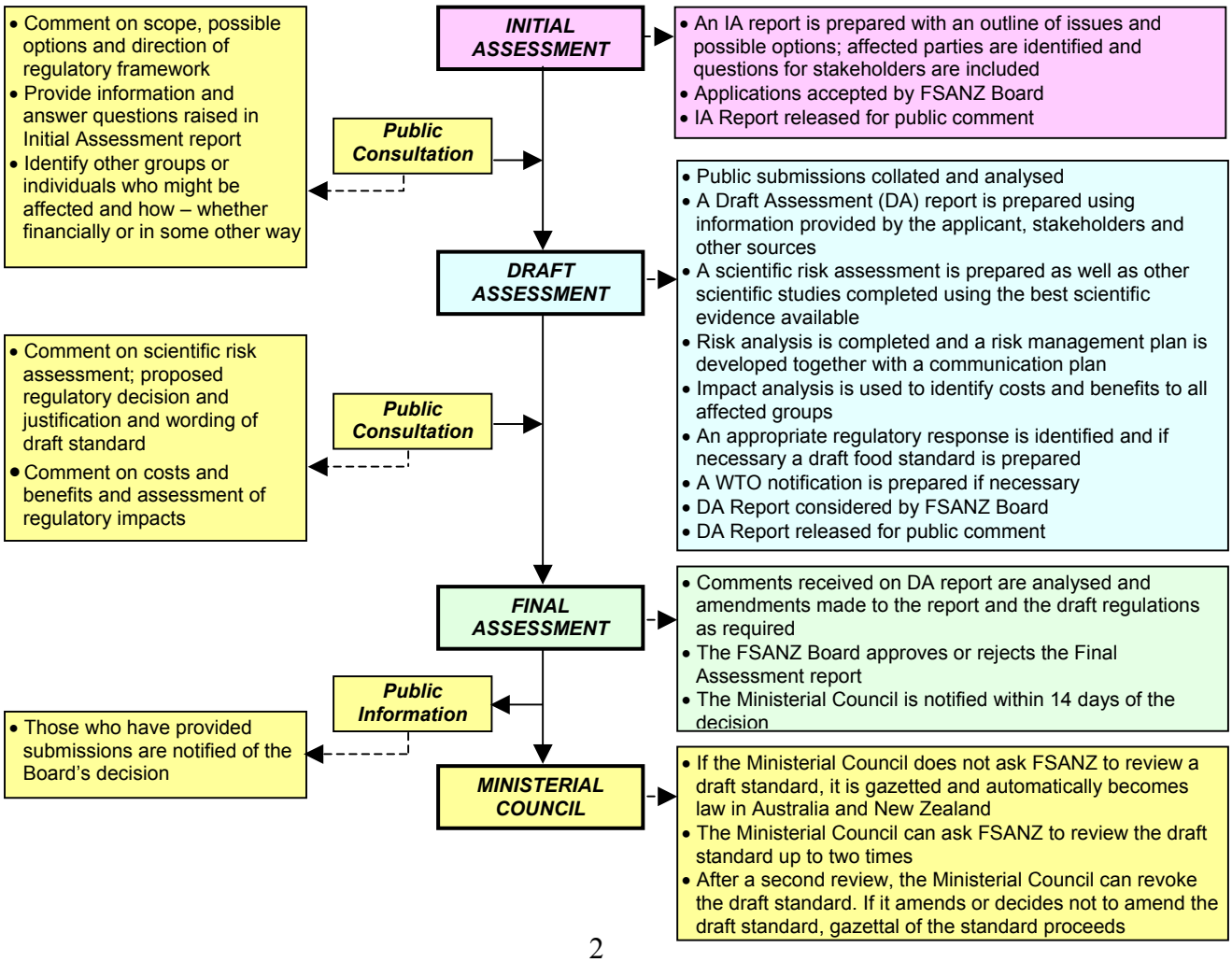
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Commonwealth; 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 Commonwealth, 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 Commonwealth, 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* 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

The Authority has prepared an Initial/Draft Assessment Report of Application A477; and prepared a draft variation to Standard 1.4.2 of the *Australia New Zealand Food Standards Code.*

The Authority invites public comment on this Initial/Draft Assessment Report based on regulation impact principles and the draft variation of the *Food Standards Code* for the purpose of preparing an amendment to the *Australia New Zealand Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Final Assessment for this Application. Submissions should, where possible, address the objectives of the Authority as set out in Section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Australia New Zealand Food Standards 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 the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority 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 should be received by the Authority **by 2 July 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent 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 Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

Further Information
Further information on this and other matters should be addressed to the Standards Liaison Officer at the Food Standards Australia New Zealand at one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
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CONTENTS

EXECUTIVE SUMMARY AND STATEMENT OF REASONS

Executive Summary

This Application (A477) seeks to amend Maximum Residue Limits (MRLs) for non-antibiotic agricultural and veterinary chemicals in the *Australia New Zealand Food Standards Code* (the Code). It is a routine application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) (now known as the Australian Pesticides and Veterinary Medicines Authority), to update the Code in order to reflect 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 NRA has already registered and restricted the use of 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 NRA 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 Therapeutic Goods Administration (TGA) of the Commonwealth 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, the 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 then NRA on 3 October, 7 November and 10 December 2002 seeking amendment to Standard 1.4.2 of the Code. As of 5 March 2003, the NRA is to be known as the Australian Pesticides and Veterinary Medicines Authority (APVMA). However, since this application was received prior to 5 March 2003, this document refers to the NRA throughout. The proposed amendments to the Standard would align MRLs in the Code for non-antibiotic agricultural and veterinary chemicals with the MRLs in the NRA MRL Standard.

1.1 Summary of proposed MRLs

The MRL amendments under consideration in this Application are:

- the deletion of MRLs for certain foods for the chemicals carbaryl, chlorfenapyr, cyfluthrin, cyhalothrin and pyrazophos;
- the addition of MRLs for certain foods for the new chemicals ractopamine, 2-(thiocyanomethylthio)benzothiazole (TCMTB) and tolfenamic acid;
- the addition of MRLs for certain foods for the chemicals, chlorfenapyr, cyhalothrin, flutriafol, indoxacarb, meloxicam, methoxyfenozide, mevinphos, pymetrozine, pyrazophos, thiacloprid and trifloxystrobin sodium;
- the changing of MRLs for certain foods for the chemicals azoxystrobin, carbendazim, chlorothalonil, cyhalothrin, dithiocarbamate, emamectin, ethephon, imidacloprid, indoxacarb, methoxyfenozide, mevinphos, pymetrozine, pyriproxyfen, thiacloprid and trifloxystrobin sodium; and
- the addition of temporary MRLs for certain foods for the chemicals azoxystrobin, bentazone, benzyladenine, chlorothalonil, dichlorvos, iprodione, pendimethalin, pirimicarb, propiconazole, pymetrozine, pyrazophos and pyridaben.

In considering the issues associated with MRLs it should be noted that MRLs and amendments to MRLs 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 Commonwealth, State and Territory legislation.

1.2 Antibiotic MRLs

There are no MRLs for antibiotic residues in this Application.

1.3 Stop clocks for Bromochloromethane and 2-(thiocyanomethylthio) benzothiazole

Pursuant to section 34 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), requested that the NRA confirm in writing the advice of the TGA, that ADIs for these chemicals are unnecessary at this time because the proposed temporary MRLs for bromochloromethane and TCMTB are at the limit of quantification (LOQ) and residues should not occur.

1.3.1 Bromochloromethane

On 26 February 2003, the NRA informed FSANZ that the trials using bromochloromethane had been completed and that the proposed MRLs for this chemical were not longer required. Therefore, the NRA requested that the proposed MRLs for this chemical be withdrawn from the Application.

1.3.2 2-(thiocyanomethylthio)benzothiazole

On 26 February 2003 the NRA forwarded a copy of the TGA advice on 2-(thiocyanomethylthio) benzothiazole (TCMTB). The TGA had established a temporary ADI of 0.01 mg/kg bw/day for the purposes for the trial of this chemical. Using this temporary ADI, the chronic estimated dietary exposure (see Attachment 2) indicates that the residues associated with the proposed MRL do not represent an unacceptable risk to public health and safety.

1.4 Mancozeb

1.4.1 Group Headings for MRLs

Results from an Australian residue trial indicate that it is appropriate to reduce the Japanese persimmon Maximum Residue limit (MRL) from 5 mg/kg to 3 mg/kg. This proposed change would reduce estimated dietary exposure to the residues of mancozeb. In addition, the worst case contribution of Japanese persimmon to the dietary exposure is only 0.02% of the acceptable daily intake (ADI).

1.4.2 The NEDI for Mancozeb

The National Estimated Dietary Intake (NEDI) for the dithiocarbamate, mancozeb is at 96% of the ADI. Although this estimation is approaching the ADI, which is the acceptable level of safe intake of residues, it is likely to be a large overestimation. The estimation assumes that all commodities for which there is a mancozeb MRL have been treated with this chemical at the maximum application rate, minimum pre-harvest interval and maximum permitted number of treatments. In addition, the ADI for mancozeb incorporates inherent safety factors, which gives an additional margin of confidence.

1.4.3 Dithiocarbamates and the Australian Total Diet Survey

Dietary exposure to the dithiocarbamate group of agricultural chemicals was estimated in the 19th Australian Total Diet Survey (1998). The estimate was calculated using the compound with the lowest ADI in the dithiocarbamate group. On the basis of this conservative assumption the maximum dietary exposure was estimated to be 63% of the ADI for two year olds and 20% of the ADI for adult males.

1.4.4 Conclusion

On the basis of the conservative exposure assessment, that the proposed MRL is a reduction, the minimal consumption of persimmons and the results of the 19th ATDS, FSANZ considers that the mancozeb residues associated with the MRL reduction would not represent an unacceptable risk to public health and safety.

1.5 Mevinphos

The National Estimated Short Term Intake for mevinphos for children 2 to 6 years old in broccoli ranges from 74% up to 98% of the acute reference dose (ARfD). The upper figure is approaching the ARfD, however, the estimate is still does not exceed the ARfD even though a number of conservative assumptions have been included in the acute dietary exposure assessment. These conservative assumptions arise from three factors.

Firstly, the consumption figure used is that of a very high consumption, namely, the 97.5th percentile of eaters' consumption per day for the food. These consumption data are taken from the National Nutrition Survey 1995, which is the most recent, independent and comprehensive data available for broccoli. Secondly, where available, the estimation uses the highest residue of the edible portion found from the supervised trial data. In practice residues found in treated food are usually well below the highest residue. Finally, the calculation incorporates a variability factor that takes account of the possible inter-unit variability; it is generally accepted that this factor is an overestimate of the actual variability that is likely to occur. In addition, the ARfD for mevinphos incorporates inherent safety factors, which gives an additional margin of confidence.

1.5.1 Conclusion

Given these conservative assumptions and as the estimated acute dietary exposure for mevinphos for broccoli does not exceed the ARfD, FSANZ considers that the mevinphos residues associated with broccoli do not represent an unacceptable risk to public health and safety.

2. Regulatory Problem

2.1 Current Regulations

The NRA has approved the use of the agricultural and veterinary chemical products associated with the MRLs in this Application, and made consequent amendments to the NRA MRL Standard. The approval of the use of these products now means that there is a discrepancy between the residues associated with the use and the MRLs in the Code. In turn, this means that:

- where the NRA has increased MRLs, food cannot be legally sold under food legislation if it contains residues in excess of the existing MRLs in the Code;

- where the NRA has included MRLs for new chemicals or for additional foods that are not included in the Code, the particular food cannot be legally sold under food legislation if it contains any detectable residues of the particular chemical; and

- where the NRA has decreased or deleted MRLs, food may be legally sold under food legislation if it contains residues that are inconsistent with the current registered uses of chemical products.

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. The NRA has already established MRLs under the NRA's legislation, and now seeks, by way of this Application to include the amendments in the Code.

4. Background

4.1 The use of agricultural and veterinary chemicals

In Australia, the NRA 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, the NRA must be satisfied that the use of the product will not result in residues that would be an undue risk to the safety of people, including people using anything containing its residues.

When a chemical product is registered for use or a permit for use granted, the NRA includes MRLs in its NRA 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, the NRA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews the information provided by the NRA and validates whether the dietary exposure is within agreed 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 Australia and New Zealand Food Regulation Ministerial Council, which is made up of Commonwealth, State and Territory and New Zealand Health Ministers, of the adoption of the variation to the Code. If the 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 the NRA 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 Manager 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 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 of control pests and diseases.

As stated above, the NRA includes MRLs in its NRA MRL Standard when they register a chemical product for use or grant a permit for use. The NRA then notifies FSANZ of these MRLs so that FSANZ may consider them for inclusion into the Code.
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, the MRLs in the NRA MRL Standard are used in some jurisdictions to assist in regulating the use of agricultural and veterinary chemical products under State and Territory 'control-of-use' legislation. Whereas the 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 (TTMRA) 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.

4.7 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 *Food Standards 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.

4.8 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 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 chemical use can be found on the website of the NRA at http://www.nra.gov.au or by contacting the NRA 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 delete or decrease some existing MRLs.

Under this option, only those variations that were reductions and deletions 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 include or increase some existing MRLs.

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

Option 2 has been arranged into two sub-options because the impacts of each sub-option are different. Splitting the option into two sub-options also allows a more detailed impact analysis.

6. 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
- Commonwealth, 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 Food Standards 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 Commonwealth, 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 Commonwealth, 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 Commonwealth, 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 have been addressed in section 11.5.3 and data on imported foods have been addressed in section 11.5.4. FSANZ invites comments from importers on the impacts of the deletions or reduction of MRLs; and

- for Commonwealth, 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 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 as to whether this benefit is likely to be discernable;

- 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 Commonwealth, 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 Commonwealth, 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 Proposal 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 Proposal raises matters of a mechanical nature that are of minor significance or complexity. Furthermore, the Authority 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 the Authority 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.

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 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. Industry is invited to submit specific details of these costs.

10. Implementation and Review

The use of chemical products and MRLs are under constant review as part of the NRA'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;
- Commonwealth 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 FSANZ Act

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 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.

Regulation 12(a)

This is not relevant for this Application.

Regulation 12(b)

This is not relevant for this Application.

11.5.2 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.

In administrative terms and consistent with international practice, MRLs assist in regulating the use of agricultural and veterinary chemical products. MRLs indicate whether agricultural and veterinary chemical products have been used in accordance with the registered conditions of use.

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. MRLs are also used as standards for the international trade in food.

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.

11.5.3 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. There are no MRLs proposed to be deleted in the NRA application which are more restrictive than the relevant Codex MRL.

11.5.4 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, 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 that states the imported quantity of relevant foods for the years 2000 and 2001. These data are for foods for which deletions or reductions of MRLs are proposed. FSANZ requests comment as to any possible ramifications for imports of the deletion or reductions of the MRLs in this Application.

Food	**2000 Tonnes**	**2001 Tonnes**
Cotton seed oil	220	705
Herbs	155	477
Onion	8573	14473
Fresh peaches (incl. Nectarines)	773	299
Turmeric	226	284
Vegetables	420045	230807

12. Consideration of Issues under section 15(3) of the FSANZ Act

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 for 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

The Office of Chemical Safety (formerly the Chemicals and Non-prescription Medicines Branch) of the TGA establish the ADI and where applicable the ARfD for agricultural and veterinary chemicals. The NRA and FSANZ carry out estimates of dietary exposure to agricultural and veterinary chemicals and compare them to the TGA 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, the TGA and the NRA 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 the Authority

To date the Ministerial Council has not made a written notification to the Authority 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. That process concluded that the amendment to the Code did not produce costs to bodies or persons that outweigh 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 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 that the residues associated with the MRLs do not represent an unacceptable risk to public health and safety. The NRA has already registered and restricted the use of 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 NRA 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 Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Ageing has undertaken an appropriate toxicological assessment of the chemical products and has established relevant ADI and where applicable the ARfDs.

- FSANZ has undertaken a preliminary regulation impact assessment process. That process concluded that the amendment to the *Food Standards 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.

Attachment 1

DRAFT VARIATIONS TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: On gazettal

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

[1.1] *inserting in* Schedule 1–

RACTOPAMINE {T}RACTOPAMINE	
PIG FAT	T0.02
PIG, KIDNEY	T0.1
PIG, LIVER	T0.05
PIG MEAT	T0.02
2-(THIOCYANOMETHYLTHIO) BENZOTHIAZOLE 2-(THIOCYANOMETHYLTHIO)BENZOTHIAZOLE	
COTTON SEED	T*0.01
TOLFENAMIC ACID TOLFENAMIC ACID	
CATTLE, KIDNEY	*0.01
CATTLE, LIVER	*0.01
CATTLE MEAT	0.05
CATTLE MILK	0.05
PIG, KIDNEY	*0.01
PIG, LIVER	0.1
PIG MEAT	*0.01

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

CARBARYL CARBARYL	
CHERVIL	T10
GALANGAL, RHIZOMES	T5
HERBS	T10
RUCOLA (ROCKET)	T10
TURMERIC, ROOT	T5
CHLORFENAPYR CHLORFENAPYR	
PEAR	0.5
CYFLUTHRIN CYFLUTHRIN, SUM OF ISOMERS	
ONION, BULB	0.02

CYHALOTHRIN	
CYHALOTHRIN, SUM OF ISOMERS	
ALL OTHER FOODS	*0.01
CATTLE MEAT (IN THE FAT)	0.5
GOAT MEAT (IN THE FAT)	0.1
PIG MEAT (IN THE FAT)	0.1
SHEEP MEAT (IN THE FAT)	0.1
PYRAZOPHOS	
PYRAZOPHOS	
FRUITING VEGETABLES, CUCURBITS	0.2

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

AZOXYSTROBIN	
AZOXYSTROBIN	
MANGO	T0.5
BENTAZONE	
BENTAZONE	
EDIBLE OFFAL (MAMMALIAN)	T*0.05
EGGS	T*0.05
MEAT (MAMMALIAN)	T*0.05
MILKS	T*0.05
POULTRY EDIBLE OFFAL OF	T*0.05
POULTRY MEAT	T*0.05
RICE	T*0.03
BENZYLADENINE	
BENZYLADENINE	
PEAR	T0.2
CHLORFENAPYR	
CHLORFENAPYR	
POME FRUIT	0.5
CHLOROTHALONIL	
CHLOROTHALONIL	
RICE	T*0.1
CYHALOTHRIN	
CYHALOTHRIN, SUM OF ISOMERS	
MEAT (MAMMALIAN) (IN THE FAT)	0.5
DICHLORVOS	
DICHLORVOS	
RAPE SEED	T0.1
FLUTRIAFOL	
FLUTRIAFOL	
GARDEN PEA (YOUNG PODS)	*0.01
INDOXACARB	
INDOXACARB	
EGGS	*0.01
EGGPLANT	0.5
MUNG BEAN (DRY)	0.2

PEPPERS (CAPSICUM)	0.5
POULTRY (EDIBLE OFFAL OF)	*0.01
POULTRY MEAT (IN THE FAT)	*0.01
SOYA BEAN (DRY)	0.2
SOYA BEAN OIL, REFINED	0.2
STONE FRUITS [EXCEPT CHERRIES]	2
IPRODIONE IPRODIONE	
PISTACHIO NUT	T*0.05
MELOXICAM MELOXICAM	
CATTLE MILK	0.005
METHOXYFENOZIDE METHOXYFENOZIDE	
EDIBLE OFFAL (MAMMALIAN)	*0.01
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MILKS	*0.01
MEVINPHOS MEVINPHOS	
MILKS	*0.05
PENDIMETHALIN PENDIMETHALIN	
TOMATO	T*0.05
PIRIMICARB SUM OF PIRIMICARB, DIMETHYL-PIRIMICARB AND N-FORMYL-(METHYLAMINO) ANALOGUE AND DIMETHYLFORMAMIDO-PIRIMICARB, EXPRESSED AS PIRIMICARB	
TREE NUTS	T*0.05
PROPICONAZOLE PROPICONAZOLE	
TREE NUTS	T0.2
PYMETROZINE PYMETROZINE	
ALMONDS	T*0.02
EGGS	*0.01
PISTACHIO NUT	T*0.02
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
PYRAZOPHOS PYRAZOPHOS	
CUCUMBER	T2
FRUITING VEGETABLES CUCURBITS [EXCEPT CUCUMBER]	0.2
PYRIDABEN PYRIDABEN	
TREE NUTS	T*0.05

THIACLOPRID THIACLOPRID	
EDIBLE OFFAL (MAMMALIAN)	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.01
TRIFLOXYSULFURON SODIUM TRIFLOXYSULFURON	
COTTON SEED OIL, EDIBLE	*0.01
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01

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

AZOXYSTROBIN AZOXYSTROBIN	
EDIBLE OFFAL (MAMMALIAN)	*0.01
CARBENDAZIM SUM OF CARBENDAZIM AND 2-AMINOBENZIMIDAZOLE, EXPRESSED AS CARBENDAZIM	
CUSTARD APPLE	1
CHLOROTHALONIL CHLOROTHALONIL	
PERSIMMON, JAPANESE	T5
CYHALOTHRIN CYHALOTHRIN, SUM OF ISOMERS	
SORGHUM	0.5
DITHIOCARBAMATE TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
PERSIMMON, JAPANESE	3
EMAMECTIN EMAMECTIN B1A, PLUS ITS 8,9-Z ISOMER AND EMAMECTIN B1B, PLUS ITS 8,9-Z ISOMER	
EDIBLE OFFAL (MAMMALIAN)	0.01
GRAPES	*0.002
ETHEPHON ETHEPHON	
NECTARINE	0.01

IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYMETHYLENEMOIETY, EXPRESSED AS IMIDACLOPRID	
CELERY	0.3
INDOXACARB INDOXACARB	
CHICK-PEA (DRY)	0.2
METHOXYFENOZIDE METHOXYFENOZIDE	
COTTON SEED	3
TOMATO	3
MEVINPHOS MEVINPHOS	
BRASSICA (COLE OR CABBAGE) VEGETABLES	0.3
EDIBLE OFFAL (MAMMALIAN)	*0.05
MEAT (MAMMALIAN)	*0.05
PYMETROZINE PYMETROZINE	
COTTON SEED	*0.02
COTTON SEED OIL, EDIBLE	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
PYRIPROXYFEN PYRIPROXYFEN	
COTTON SEED	T*0.01
THIACLOPRID THIACLOPRID	
POME FRUITS	1
TRIFLOXYSULFURON SODIUM TRIFLOXYSULFURON	
COTTON SEED	*0.01
COTTON SEED OIL, CRUDE	*0.01

ATTACHMENT 2

A SUMMARY OF THE REQUESTED MRLS FOR EACH CHEMICAL AND AN OUTLINE OF THE INFORMATION SUPPORTING THE REQUESTED CHANGES TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*.

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

NOTES ON TERMS USED IN THE TABLE

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

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

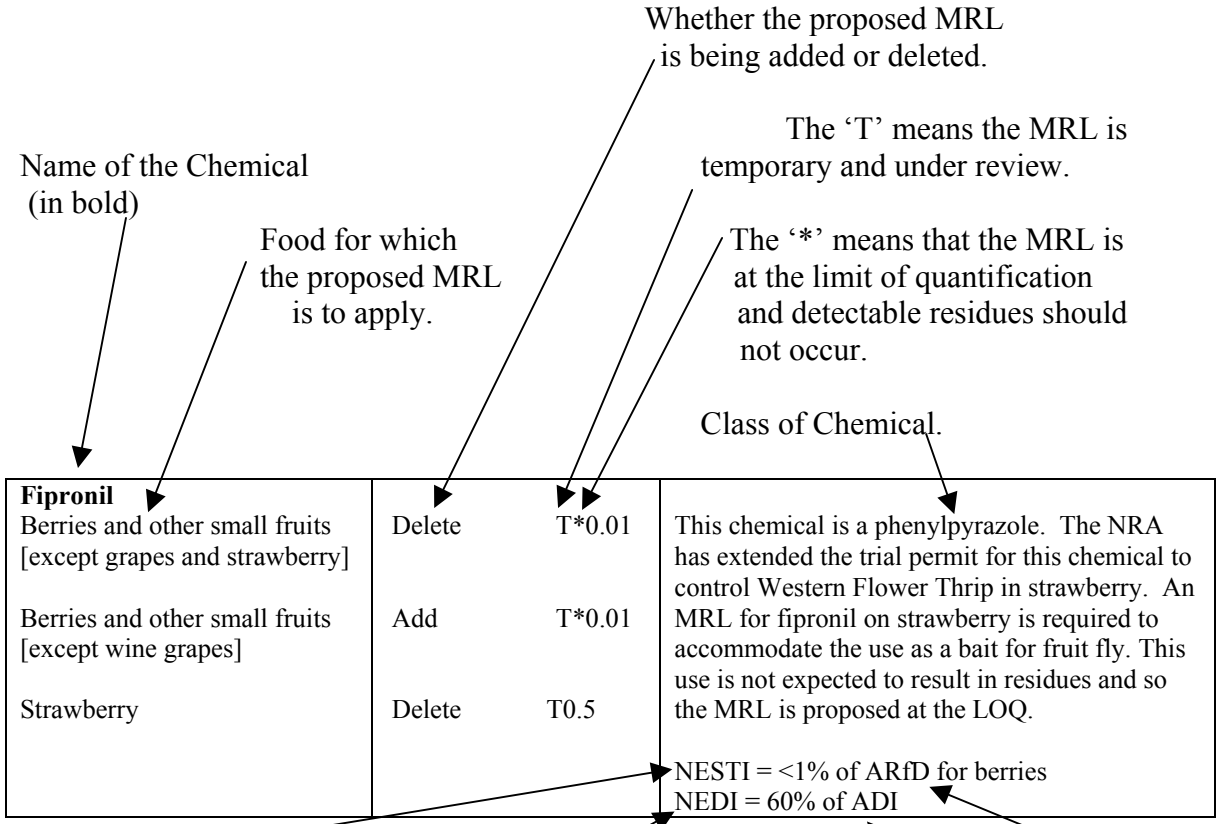
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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 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.



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

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

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

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

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

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

Chlorpyrifos Coffee beans	Add	T0.5	NRA extension of use for the control of pests. The 18th ATDS (1996) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to 0.53% of ADI for adult males and up to 1.42% for 2 year olds. 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. NEDI = 83% of ADI

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

SUMMARY OF THE REQUESTED MRLS FOR APPLICATION A477

Glossary;

1. **ADI** Acceptable Daily Intake.
2. **ARfD** Acute Reference Dose.
3. **ATDS** Australian Total Diet Survey.
4. **ECRP** Existing Chemical Review Program
5. **LOQ** Limit of Analytical Quantification.
6. **NEDI** National Estimated Daily Intake.
7. **NESTI** National Estimated Short Term Intake.
8. **NNS** National Nutrition Survey of Australia 1995
9. ***** MRL set at or about the limit of quantification.
10. **T** Temporary MRL.

Chemical Food	MRL (mg/kg)		Information
Azoxystrobin			
Edible offal (mammalian)	Delete Substitute	0.01 *0.01	This chemical is a strobilurin analogue; it is used as a fungicide on fruits and vegetable crops. The proposed MRLs are in relation to the NRA's development of Animal Residue Data Sheets. No changes to the actual uses of the chemical are in involved.
Mango	Add	T0.5	The NRA has issued a permit for the use of this chemical to control stem end rot and anthracnose on mangoes. NEDI = <1% of ADI.
Bentazone			
Edible offal (mammalian)	Add	T*0.05	This chemical is a benzothiadiazinone. The NRA has issued a permit for the use of this chemical to control weeds in rice crops.
Eggs	Add	T*0.05	
Meat (mammalian)	Add	T*0.05	
Milks	Add	T*0.05	
Poultry, edible offal of	Add	T*0.05	
Poultry meat	Add	T*0.05	
Rice	Add	T*0.03	NEDI = <1% of ADI.
Benzyladenine			
Pear	Add	T0.2	This chemical is a cytokinin. The NRA has issued a permit for the use of this chemical as a plant growth regulator. NEDI = 1% of ADI
Carbaryl			
Chervil	Delete	T10	This chemical is a carbamate; it is used as an insecticide on fruits, herbs and vegetable crops. The temporary use permit for carbaryl on herbs and related commodities has expired
Galangal, rhizomes	Delete	T5	
Herbs	Delete	T10	
Kaffir lime leaves	Delete	T10	
Lemon grass	Delete	T10	
Lemon verbena	Delete	T10	
Mizuna	Delete	T10	
Rucola (rocket)	Delete	T10	
Turmeric, root	Delete	T5	
Carbendazim			
Custard apple	Delete Substitute	T1 1	This chemical is a benzimidazole fungicide; it is used to inhibit the growth of mycelia on custard apple. In the 19th (1998) ATDS the estimated dietary exposure to carbendazim was <1% of the ADI for whole population. NEDI = 83% of ADI.

Chlorfenapyr			
Pear	Delete	0.5	This chemical is a pyrazole analogue; it is used to control two spotted mite on pome trees. NEDI = 7% of ADI.
Pome fruit	Add	0.5	
Chlorothalonil			
Persimmon, Japanese	Delete	T10	This chemical is a chloronitrile. The NRA has issued a permit for the use of this chemical to control fungus on persimmon crops and molluscicide in rice. In the 20th (2000) ATDS the estimated dietary exposure to **c**hlorothalonil was <1% of the ADI for whole population. NEDI = 77% of ADI.
	Substitute	T5	
Rice	Add	T*0.1	
Cyfluthrin			
Onion, bulb	Delete	0.02	This chemical is a synthetic pyrethroid; it is used as an insecticide on fruits and vegetable crops. There is no current use pattern for this chemical on bulb onions.
Cyhalothrin			
All other foods	Delete	*0.01	This chemical is a synthetic pyrethroid; it is used as an insecticide on fruits and vegetable crops. The proposed MRLs are in relation to the NRA's development of Animal Residue Data Sheets. In the 20th (2000) ATDS the residues of cyhalothrin were all below the LOQ. In the 19th (1998) ATDS the estimated dietary exposure to cyhalothrin was <1% of the ADI. NEDI = 24% of ADI.
Cattle meat (in the fat)	Delete	0.5	
Goat meat (in the fat)	Delete	0.1	
Meat (mammalian) (in the fat)	Add	0.5	
Pig meat (in the fat)	Delete	0.1	
Sheep meat (in the fat)	Delete	0.1	
Sorghum	Delete	0.2	
	Substitute	0.5	
Dichlorvos			
Rape seed	Add	T0.1	This chemical is an organophosphorous insecticide. The NRA has issued a permit for the use of this chemical to control insect infestations in stored rape seed. In the 20th (2000) ATDS the residues of dichlorvos were all below the LOQ. NEDI = 79% of ADI. NESTI = 3% of ARfD (for the whole population).

Dithiocarbamate Persimmon, Japanese	Delete Substitute	5 3	These MRLs relate to the dithiocarbamate class of compounds. It is used to control fungus on persimmon crops. This proposed MRL is associated with the use of the dithiocarbamate, mancozeb. In the 19th (1998) ATDS the estimated dietary exposure to thiram (the dithiocarbamate with the lowest ADI) was at 63% of the ADI two year olds and 20% of the ADI for adult males. This estimated exposure would be lower for mancozeb. On the basis of the conservative exposure assessment and the minimal consumption of persimmons, FSANZ considers that the residues associated with the MRL would not represent an unacceptable risk to public health and safety. NEDI = 96% of ADI.
Emamectin Edible offal (mammalian)	Delete Substitute	*0.002 0.01	This chemical is an avermectin analogue; it is used as an insecticide on fruits and vegetable crops. The proposed MRLs for edible offal are in relation to the NRA's development of Animal Residue Data Sheets.
Grapes	Delete Substitute	T*0.002 *0.002	NEDI = 3% of ADI.
Ethephon Nectarine	Delete Substitute	T0.5 0.01	This chemical is an ethylene generator: it is used as a plant growth regulator. As this chemical degrades it releases ethylene, a plant growth regulator. Ethylene is responsible for regulating a large number of plant functions. These include fruit ripening, leaf and fruit epinasty and abscission and induce flowering. NEDI = 63% of ADI.
Flutriafol Garden pea (young pods)	Add	*0.01	This chemical is a triazole; it is used as a fungicide on grain and vegetable crops. NEDI = 7% of ADI.
Imidacloprid Celery	Delete Substitute	*0.05 0.3	This chemical is a neonicotinoid: it is used to control thrips and aphids on celery crops. NEDI = 6% of ADI

Indoxacarb			
Chick-pea (dry)	Delete Substitute	T0.2 0.2	This chemical is an oxadiazine: it is used as an insecticide in cotton crops, vegetables and fruit trees.
Eggs	Add	*0.01	
Eggplant	Add	0.5	
Mung bean (dry)	Add	0.2	
Peppers (Capsicum)	Add	0.5	
Poultry, edible offal of	Add	*0.01	
Poultry meat (in the fat)	Add	*0.01	
Soya bean (dry)	Add	0.2	
Soya bean oil, refined	Add	0.2	
Stone fruits [except cherries]	Add	2	NEDI = 68% of ADI.
Iprodione			
Pistachio nut	Add	T*0.05	This chemical is a dicarboximide. The NRA has issued a permit for the use of this chemical as a fungicide on pistachio nuts. In the 20th (2000) ATDS the estimated dietary exposure to iprodione was 1% of the ADI for the whole population. In the 19th (1998) ATDS the estimated dietary exposure to iprodione was <1% of the ADI for adult males and was 1% of the ADI for children of 2 years of age. On the basis of the level of consumption of pistachio nuts, the results from the 1998 and 2000 ATDS and that this is a permit, FSANZ considers that the residues associated with the proposed MRL would not represent an unacceptable risk to public health and safety. NEDI = 60% of ADI.
Meloxicam			
Cattle milk	Add	0.005	This chemical is a non-steroidal anti-inflammatory drug; it is used for the treatment of acute respiratory infection, diarrhoea and acute mastitis in calves, young cows and lactating cows. NEDI = 58% of ADI

Methoxyfenozide			
Cotton seed	Delete Substitute	T*0.05 3	This chemical is a diacylhydrazine; it is used as an insecticide on cotton and tomato crops.
Edible offal (mammalian)	Add	*0.01	
Meat (mammalian) (in the fat)	Add	*0.01	
Milks	Add	*0.01	
Tomato	Delete Substitute	T2 3	NEDI = <1% of ADI.
Mevinphos			
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	Delete Substitute	T0.25 0.3	This chemical is an organophosphorous insecticide; it is used to control diamond back moth on brassica crops.
Edible offal (mammalian)	Delete Substitute	T*0.05 *0.05	The NRA considers that brassica vegetables are not a significant animal feed commodity and they concluded that the establishment of an MRL for this chemical in meat, offal and milk at the LOQ would not result in an unacceptable risk to public health and safety. In the 20th (2000) ATDS the residues of mevinphos were all below the LOQ. In the 19th (1998) ATDS the estimated dietary exposure to mevinphos was <1% of the ADI. NEDI = 32% of ADI. NESTI for whole population for Broccoli raw = 27% of ARfD. NESTI for whole population for Brussels sprouts = 7% of ARfD. NESTI for whole population for Cabbage, raw = 39% of ARfD. NESTI for whole population for Cauliflower, raw = 29% of ARfD. NESTI for children 2 - 6 years old for Broccoli = ranged from 74 to 98% of ARfD according to whether the commodity was cooked or raw. NESTI for children 2 - 6 years old. For Brussels sprouts = 13% of ARfD. NESTI for children 2 - 6 years old for Cabbage, raw = 49% of ARfD. NESTI for children 2 - 6 years old for Cauliflower = 58% of ARfD.
Meat (mammalian)	Delete Substitute	T*0.05 *0.05	
Milks	Add	*0.05	

Pendimethalin			
Tomato	Add	T*0.05	This chemical is a dinitroaniline. The NRA has issued a permit for the use of this chemical as an herbicide to control weeds in tomato crops. NEDI = <1% of ADI
Pirimicarb			
Tree nuts	Add	T*0.05	This chemical is a carbamate. The NRA has issued a permit for the use of this chemical as an insecticide to control green peach aphid on tree nuts. In the 19th (1998) and 20th (2000) ATDSs the estimated dietary exposure to pirimicarb was <1% of the ADI for the whole population. NEDI = 81% of ADI.
Propiconazole			
Tree nuts	Add	T0.2	This chemical is a triazole. The NRA has issued a permit for the use of this chemical to control of blossom blight (*Monilinia* spp) and Anthracnose (*Colletotrichum acutatum*) on almonds (*Prunus amygdalus*). In the 20th (1998) ATDS the estimated dietary exposure to propiconazole was <1% of the ADI for whole population. NEDI = 5% of ADI
Pymetrozine			
Almonds	Add	T*0.02	This chemical is a pyridine. The NRA has issued a permit for the use of this chemical as an insecticide to control insects on tree nuts. The NRA has reviewed the residue trial data for pymetrozine for cotton and has proposed that the MRL for cotton seed be reduced. Animal transfer data indicate that is appropriate to establish animal commodity MRLs at the LOQ.
Cotton seed	Delete	T0.1	
	Substitute	*0.02	
Cotton seed oil, edible	Delete	T*0.02	
	Substitute	*0.02	
Edible offal (mammalian)	Delete	T*0.01	
	Substitute	*0.01	
Eggs	Add	*0.01	
Meat (mammalian)	Delete	T*0.01	
	Substitute	*0.01	
Milks	Delete	T*0.01	
	Substitute	*0.01	
Pistachio nut	Add	T*0.02	
Poultry, edible offal of	Add	*0.01	
Poultry meat	Add	*0.01	NEDI = 5% of ADI.

Pyrazophos Cucumber Fruiting vegetables, cucurbits Fruiting vegetables, Cucurbits [except cucumber]	 Add Delete Add	 T2 0.2 0.2	This chemical is a phosphorothiolate. The NRA has issued a permit for the use of this insecticide to control western flower thrips in cucumber crops. NEDI = 3% of ADI.
Pyridaben Tree nuts	 Add	 T*0.05	This chemical is a pyridazinone. The NRA has issued a permit for the use of this insecticide to control two-spotted mite and brown almond mite on tree nuts. NEDI = 15% of ADI.
Pyriproxyfen Cotton seed	 Delete Substitute	 T0.1 T*0.01	This chemical is a juvenile hormone mimic. The NRA has reviewed the submitted residue data for pyriproxyfen in cotton and has proposed that the MRL for cotton seed be reduced to the LOQ. NEDI = <1% of ADI.
Ractopamine Pig fat Pig, kidney Pig, liver Pig meat	 Add Add Add Add	 T0.02 T0.1 T0.05 T0.02	This chemical is a phenethanolamine (β-agonist) The NRA has issued a permit for the use of this chemical to increase the rate of weight gain in pigs. NEDI = <1% of ADI NESTI for pig fat = <1% of ARfD for 2-6 years old and the whole population. NESTI for pig meat = 5 % of ARfD for 2-6 years old and 2% for the whole population. NESTI for pig offal = 11 % of ARfD for 2-6 years old and 39% for the whole population.
2-(thiocyanomethylthio) benzothiazole Cotton seed	 Add	 T*0.01	This chemical is a thiazole. The NRA has issued a trial permit for the use of this chemical as pre-planting fungicidal treatment for cotton seed. NEDI = <1% of ADI.

Thiacloprid			
Edible offal (mammalian)	Add	*0.02	This chemical is a neonicotinoid; it is used as an insecticide on pome and stone fruits. NEDI = 8% of ADI. NESTI for apple = 65% of ARfD for 2-6 years old and 20% for the whole population. NESTI for pear = 65% of ARfD for 2-6 years old and 20% for the whole population. NESTI for meat and offal = <1 % of ARfD for 2-6 years old and the whole population. NESTI for pig fat = <1% of ARfD for 2-6 years old and the whole population. NESTI for pig meat = 5 % of ARfD for 2-6 years old and 2% for the whole population. NESTI for milks = 1 % of ARfD for 2-6 years old and 3% for the whole population.
Meat (mammalian)	Add	*0.02	
Milks	Add	*0.01	
Pome fruits	Delete	T1	
	Substitute	1	
Tolfenamic acid			
Cattle, kidney	Add	*0.01	This chemical is a non-steroidal anti-inflammatory drug; it is used to relieve inflammation and pain. NEDI = 10% of ADI NESTI for cattle meat = 10 % of ARfD for 2-6 years old and 6% for 7 y.o. and above. NESTI for cattle kidney and liver = 0% of ARfD for the whole population. NESTI for cattle milk = 15 % of ARfD for 2-6 years old and 6% for 7 y.o. and above. NESTI for pig meat = 2 % of ARfD for 2-6 years old and 1% for 7 y.o. and above. NESTI for pig kidney and pig liver = 0% of ARfD for the whole population.
Cattle, liver	Add	*0.01	
Cattle meat	Add	0.05	
Cattle milk	Add	0.05	
Pig, kidney	Add	*0.01	
Pig, liver	Add	0.1	
Pig meat	Add	*0.01	

Trifloxysulfuron sodium			
Cotton seed	Delete	T*0.01	This chemical is a sulfonylurea; it is used as a herbicide to control broadleaf weeds and nutgrass on cotton crops.
	Substitute	*0.01	
Cotton seed oil, crude	Delete	T*0.01	
	Substitute	*0.01	
Cotton seed oil, edible	Add	*0.01	
Edible offal (mammalian)	Add	*0.01	
Eggs	Add	*0.01	
Meat (mammalian)	Add	*0.01	
Milks	Add	*0.01	NEDI = <1% of ADI.
Poultry, edible offal of	Add	*0.01	NESTIs for all commodities = <1% of
Poultry meat	Add	*0.01	ARfD.

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 NRA 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 ADI and/or the ARfD); and
- calculating the dietary exposure to a chemical from all foods and comparing this to the acceptable health standard.

Determination of the residues of a chemical in a treated food

The NRA assesses a range of data when considering the proposed use of a chemical product on a food. These data enable the NRA to determine what the likely residues of a chemical will be on a treated food. These data also enable the NRA to determine what the maximum residues will be on a treated food if the chemical product is used as proposed and from this, the NRA 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 Chemicals and Non-prescription Medicines Branch 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 NRA 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 NRA and FSANZ undertake chronic dietary exposure assessments for all agricultural and veterinary chemicals and undertake acute dietary exposure assessments where either the TGA or Joint FAO/WHO Meeting on Pesticide Residues has established an ARfD.

The NRA and FSANZ have recently agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the NRA 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 Commonwealth Department of Health and Aged Care undertook the NNS survey over a 12-month period (1995 to early 1996) by The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns were reported.

Chronic Dietary Exposure Assessment

The National Estimated Daily Intake (NEDI) represents a realistic estimate of chronic dietary exposure <u>if the data are available</u> and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions and the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials rather than the MRL to represent pesticide residue levels. When adequate information is available, monitoring and surveillance data or total diet studies may also be used such as the Australian Total Diet Survey (ATDS).

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

In conducting chronic dietary exposure assessments, the NRA 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.

These calculations are overestimates of dietary exposure because they usually assume that all of a particular food will contain the proposed chemical. 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 TGA 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.

Attachment 4

Glossary Of Acronyms

ADI	Acceptable Daily Intake
ANZFRMC	Australia and New Zealand Food Regulation Ministerial Council
AQIS	Australian Quarantine and Inspection Service
ARfD	Acute Reference Dose
ATDS	Australian Total Diet Survey
Codex	Codex Alimentarius Commission
DHA	Health and Ageing, Department of
ECRP	Existing Chemical Review Program
FSANZ	Food Standards Australia New Zealand
LOQ	Limit of Quantification
MRL	Maximum Residue Limit
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short Term Intake
NNS	National Nutrition Survey of Australia 1995
NRA	National Registration Authority for Veterinary and Agricultural Chemicals
RIS	Regulation Impact Statement
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
TGA	Therapeutic Goods Administration
TTMRA	Trans-Tasman Mutual Recognition Arrangement
WHO	World Health Organization
WTO	World Trade Organization