

12/03
8 October 2003

INITIAL / DRAFT ASSESSMENT REPORT

APPLICATION A497

MAXIMUM RESIDUE LIMITS

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:

20 November 2003

(See 'Invitation for Public Submissions' for details)

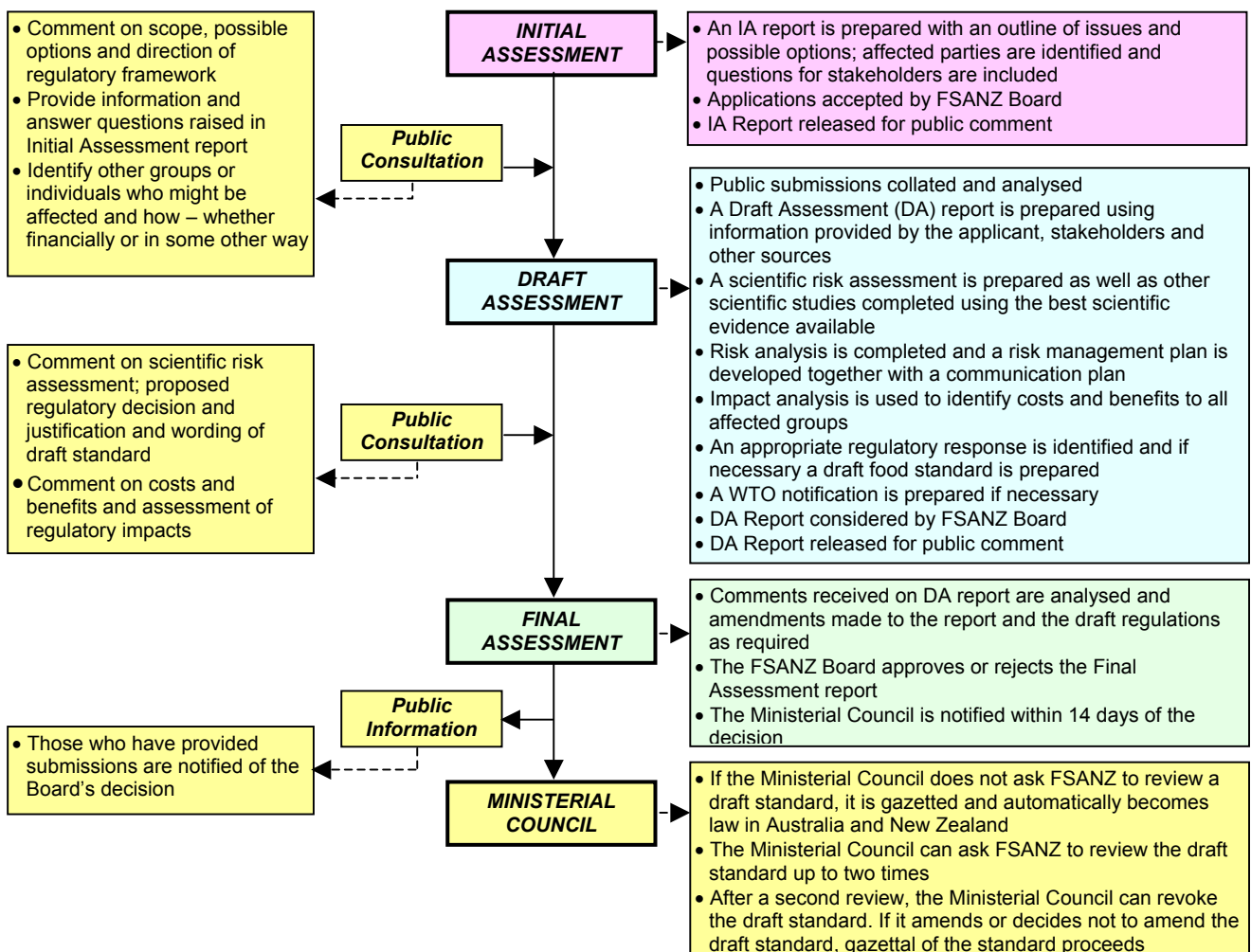
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

FSANZ has prepared an Initial / Draft Assessment Report of Application A497; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this 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 should be received by FSANZ **by 20 November 2003**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

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 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. 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.

CONTENTS

| | |
|--|-----------|
| EXECUTIVE SUMMARY AND STATEMENT OF REASONS..... | 6 |
| STATEMENT OF REASONS | 6 |
| 1. INTRODUCTION..... | 7 |
| 1.1 SUMMARY OF PROPOSED MRLS | 7 |
| 1.2 ANTIBIOTIC MRLS | 7 |
| 1.3 BROMOCHLOROMETHANE | 8 |
| 1.4 DIAZINON..... | 8 |
| 2. REGULATORY PROBLEM..... | 9 |
| 2.1 CURRENT REGULATIONS | 9 |
| 3. OBJECTIVE..... | 9 |
| 4. BACKGROUND..... | 10 |
| 4.1 THE USE OF AGRICULTURAL AND VETERINARY CHEMICALS | 10 |
| 4.2 MAXIMUM RESIDUE LIMIT APPLICATIONS..... | 10 |
| 4.3 MAXIMUM RESIDUE LIMITS | 11 |
| 4.4 FOOD STANDARDS-SETTING IN AUSTRALIA AND NEW ZEALAND | 11 |
| 4.5 TRANS TASMAN MUTUAL RECOGNITION ARRANGEMENT..... | 11 |
| 4.6 LIMIT OF QUANTIFICATION | 12 |
| 4.7 MRLS FOR PERMITS | 12 |
| 5. OPTIONS..... | 12 |
| 5.1 OPTION 1 – STATUS QUO – NO CHANGE TO THE EXISTING MRLS IN THE CODE. | 12 |
| 5.2 OPTION 2(A) – ADOPT THE CHANGE TO MRLS TO DELETE OR DECREASE SOME EXISTING MRLS. | 12 |
| 5.3 OPTION 2(B) – ADOPT THE CHANGES TO MRLS TO INCLUDE OR INCREASE SOME EXISTING MRLS. | 12 |
| 6. AFFECTED PARTIES | 13 |
| 7. IMPACT ANALYSIS | 13 |
| 7.1 OPTION 1 – STATUS QUO – NO CHANGE TO THE EXISTING MRLS IN THE CODE. | 13 |
| 7.2 OPTION 2(A) – ADOPT THE CHANGES TO MRLS TO DELETE AND DECREASE SOME EXISTING MRLS. | 14 |
| 7.3 OPTION 2(B) – ADOPT THE CHANGES TO MRLS TO INCLUDE AND INCREASE SOME EXISTING MRLS. | 15 |
| 8. CONSULTATION | 16 |
| 9. CONCLUSION..... | 16 |
| 10. IMPLEMENTATION AND REVIEW | 17 |
| 11. CONSIDERATION OF ISSUES UNDER SECTION 13 OF THE <i>FOOD STANDARDS AUSTRALIA NEW ZEALAND ACT 1991</i>..... | 17 |
| 11.1 PARAGRAPH 13(2)(A)..... | 17 |
| 11.2 PARAGRAPH 13(2)(B)..... | 17 |
| 11.3 PARAGRAPH 13(2)(C)..... | 17 |
| 11.4 PARAGRAPH 13(2)(D)..... | 18 |
| 11.5 PARAGRAPH 13(2)(E)..... | 18 |

| | |
|---|-----------|
| 12. CONSIDERATION OF ISSUES UNDER SECTION 15(3) OF THE <i>FOOD STANDARDS AUSTRALIA NEW ZEALAND ACT 1991</i>..... | 19 |
| 12.1 PARAGRAPH 15(3)(A)..... | 20 |
| 12.2 PARAGRAPH 15(3)(B)..... | 20 |
| 12.3 PARAGRAPH 15(3)(C)..... | 21 |
| 12.4 PARAGRAPH 15(3)(D)..... | 21 |
| 12.5 PARAGRAPH 15(3)(E)..... | 21 |
| 13. RECOMMENDATION | 21 |
| ATTACHMENT 1 - DRAFT VARIATIONS TO <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> | 23 |
| ATTACHMENT 2 - A SUMMARY OF THE REQUESTED MRLS FOR EACH CHEMICAL AND AN OUTLINE OF THE INFORMATION SUPPORTING THE REQUESTED CHANGES TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>. | 28 |
| ATTACHMENT 3 - BACKGROUND TO DIETARY EXPOSURE ASSESSMENTS .. | 37 |
| ATTACHMENT 4 - GLOSSARY OF ACRONYMS | 40 |

Executive Summary and Statement of Reasons

This Application (A497) 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 Australian Pesticide and Veterinary Medicines Authority (APVMA, formerly the National Registration Authority for Agricultural and Veterinary Chemicals), to update the Code in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

The *Agreement between the 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, where appropriate, 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 Commonwealth Department of Health and Ageing has undertaken an appropriate toxicological assessment of the chemical products and has established relevant acceptable daily intakes (ADI), as appropriate 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 APVMA on 10 April, 16 May, 13 June and 2 July 2003 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:

- changes to the residue definition for the carbamate, pirimicarb as proposed to correct a typographical error.
- the addition of new chemicals of tepraloxym and trinexapac-ethyl and their MRLs for certain foods
- the deletion of MRLs for certain foods for the chemicals chlorpyrifos, diafenthiuron, dithiocarbamates, ethofumesate, glyphosate, imidacloprid, linuron, oxyfluorfen, permethrin, procymidone and terbutryn;
- the addition of MRLs for certain foods for the chemicals cyhalothrin, dithiocarbamates, ethofumesate, glyphosate, imidacloprid, linuron, oxyfluorfen, permethrin, procymidone, pyrimethanil and terbutryn;
- the changing of MRLs for certain foods for the chemicals diafenthiuron, glyphosate, ioxynil, mesosulfuron-methyl, permethrin, procymidone, tebuconazole, tebufenozide and terbutryn; and
- the addition of temporary MRLs for certain foods for the chemicals bromochloromethane, chlorpyrifos, chlorthal-dimethyl, diazinon, dimethomorph, dithiocarbamates, halofuginone, imidacloprid, indoxacarb, linuron, methomyl, metolachlor, permethrin, procymidone, tebuconazole and tebufenozide.

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 Bromochloromethane

The APVMA has sought to include MRLs for bromochloromethane in the Code. The APVMA have issued a permit to the Commonwealth Scientific and Industrial Research Organisation (CSIRO) to allow the use of this chemical to study the potential decrease in the production of methane by cattle. This study involves only 26 cattle that will be eventually slaughtered for human consumption.

Taking into account the small number of animals involved, the OCS has advised that an ADI is not necessary for bromochloromethane and as a result a chronic dietary exposure assessment has not been estimated. The OCS has recommended that the proposed MRLs be established at the limit of quantification (LOQ) and has also advised that there is a large margin of safety for consumption of residues in food when the chemical is used according to good veterinary practice. While the OCS has not established an ADI for this chemical, the CSIRO has been advised to collect data so that the issue of an ADI can be addressed.

1.3.1 Conclusion

Given the limited number of the animals to be treated and the support of the OCS for the MRLs, it is considered that the residues of bromochloromethane associated with these proposed MRLs, for a limited permit only, would not represent an unacceptable risk to public health and safety.

1.4 Diazinon

The National Estimated Dietary Intake (NEDI) for, diazinon is at 95% of ADI (see Section 1.4 of the Initial/Draft Assessment Report). Although this estimation is approaching the ADI, which is the acceptable level of safe intake of residues, the NEDI is likely to be a large overestimation since it assumes that:

- all crops with a diazinon MRL will be treated with this chemical;
- treatment occurs at the maximum application rate;
- the maximum number of permitted treatments have been applied; and
- the minimum withholding period has been applied.

1.4.1 Diazinon and the Australian Total Diet Survey

Diazinon residues were not detected in any food in the 20th Australian Total Diet Survey (2000) (ATDS).

1.4.2 APVMA review of diazinon

The APVMA's Existing Chemical Review Program is reviewing diazinon and is seeking additional residue data for the use of this chemical. The APVMA recognises that this may take some time and it has stated that:

In the interim, where a commitment to generate residue data is obtained and where overseas data suggests safety standards can be met, it is proposed that uses continue at least until the data has been supplied and assessed.

The APVMA would then determine whether or not the registered uses of diazinon should continue and if so, under what conditions.

1.4.3 Conclusion

On the basis of the conservative exposure assessment, the results of the 20th ATDS and that the uses of this chemical are under review, FSANZ considers that the diazinon residues associated with the proposed MRL would not represent an unacceptable risk to public health and safety.

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 the APVMA 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 APVMA 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 APVMA 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 APVMA 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 APVMA has already established MRLs under the APVMA'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 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, the APVMA 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 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, the 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 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 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 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, APVMA includes MRLs in its APVMA MRL Standard when it registers a chemical product for use or grant a permit for use. APVMA 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 APVMA 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.

4.6 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 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 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. However, FSANZ cannot legally separate these two sub-options and may only accept or reject the 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
- 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 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 are addressed in section 11.5.3 and data on imported foods are 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 *Food Standards Australia New Zealand Act 1991*, 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, 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.

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 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;
- 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 *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 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. The following table sets out the proposed MRLs to be deleted, in the NRA application, which are more restrictive than the relevant Codex MRL. FSANZ requests comment as to any possible ramifications for imports of the reductions of the MRL for glyphosate for soya bean in this Application.

| Chemical Food | Proposed MRL mg/kg | Codex MRL mg/kg |
|--------------------------------------|-----------------------------------|--------------------------------|
| Glyphosate Soya bean (dry) | 10 | 20 |

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, 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 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 |
|-----------------|------------------------|------------------------|
| Beans | 20705 | 28017 |
| Potato | 18920 | 21933 |
| Soya bean (dry) | 189929 | 56131 |

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

The OCS (formerly the Chemicals and Non-prescription Medicines Branch of the TGA) establish the ADI and where applicable the acute reference dose (ARfD) 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, the OCS and the 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 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, 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. The 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.

- 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 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 doses.
- 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 Australia New Zealand Food Standards Code

To commence: On gazettal

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

[1.1] *omitting from Schedule 1 under the entry for the following chemical the chemical residue definition and substituting:*

| |
|---|
| PIRIMICARB |
| SUM OF PIRIMICARB, DEMETHYL-PIRIMICARB AND N-FORMYL-(METHYLAMINO) ANALOGUE (DEMETHYLFORMAMIDIO-PIRIMICARB), EXPRESSED AS PIRIMICARB |

[1.2] *inserting in Schedule 1-*

| | |
|---|--------|
| BROMOCHLOROMETHANE | |
| BROMOCHLOROMETHANE | |
| CATTLE, EDIBLE OFFAL | T*0.02 |
| CATTLE FAT | T*0.02 |
| CATTLE MEAT | T*0.02 |
| TEPRALOXIDIM | |
| SUM OF TEPRALOXIDIM AND METABOLITES CONVERTED TO 3-(TETRAHYDRO-PYRAN-4-YL) GLUTARIC AND 3-HYDROXY-3-(TETRAHYDRO-PYRAN-4-YL)-GLUTARTIC ACID, EXPRESSED AS TEPRALOXIDIM | |
| EDIBLE OFFAL (MAMMALIAN) | *0.1 |
| EGGS | *0.1 |
| MEAT (MAMMALIAN) | *0.1 |
| MILKS | *0.02 |
| POULTRY, EDIBLE OFFAL | *0.1 |
| POULTRY MEAT | *0.1 |
| PULSES | *0.1 |
| RAPE SEED | *0.1 |
| TRINEXAPAC-ETHYL | |
| 4-(CYCLOPROPL- α -HYDROXY-METHYLENE)-3,5-DIOXO-CYCLOHEXANECARBOXYLIC ACID | |
| SUGAR CANE | T*0.05 |

[1.3] *omitting from Schedule 1 the foods and associated MRL's for each of the following chemicals*

| | |
|---------------------|-------|
| CHLORPYRIFOS | |
| CHLORPYRIFOS | |
| OILSEED | T0.01 |

| | |
|--|-------|
| DIAFENTHIURON DIAFENTHIURON | |
| SOYA BEAN (DRY) | T0.1 |
| DITHIOCARBAMATES DITHIOCARBAMATES | |
| BULB VEGETABLES | 4 |
| ETHOFUMESATE ETHOFUMESATE | |
| GARLIC | *0.1 |
| ONION, BULB | *0.1 |
| GLYPHOSATE GLYPHOSATE | |
| BROAD BEAN (DRY) | 2 |
| CHICK-PEA (DRY) | T5 |
| FIELD PEA (DRY) | 5 |
| PULSES [EXCEPT AS ADZUKI BEANS; BROAD BEANS (DRY); CHICKPEAS; COWPEAS; FIELD PEA (DRY) AND SOYA BEAN] | *0.1 |
| IMIDACLOPRID IMIDACLOPRID | |
| MIZUNA | T5 |
| LINURON LINURON | |
| VEGETABLES | *0.05 |
| OXYFLUORFEN OXYFLUORFEN | |
| GARLIC | *0.05 |
| ONION, BULB | *0.05 |
| PERMETHRIN PERMETHRIN | |
| MILKS (IN THE FAT) | 0.05 |
| PROCYMIDONE PROCYMIDONE | |
| MEAT OF CATTLE, PIGS AND SHEEP (IN THE FAT) | *0.01 |
| TERBUTRYN TERBUTRYN | |
| BEANS [EXCEPT BROAD BEAN AND SOYA BEAN] | *0.1 |
| MEAT (MAMMALIAN) (IN THE FAT) | 0.1 |
| MILKS (IN THE FAT) | 0.1 |
| POTATO | *0.1 |
| POULTRY MEAT (IN THE FAT) | 0.1 |

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

| | |
|---|--------|
| CHLORPYRIFOS CHLORPYRIFOS | |
| OILSEED [EXCEPT PEANUT] | T0.01 |
| PEANUT | T*0.01 |
| PISTACHIO NUTS | T*0.05 |
| CHLORTHAL-DIMETHYL CHLORTHAL-DIMETHYL | |
| PARSLEY | T2 |
| CYHALOTHRIN CYHALOTHRIN | |
| RADISH | *0.01 |
| DIAZINON DIAZINON | |
| SHALLOT | T0.5 |
| SPRING ONION | T0.5 |
| DIMETHOMORPH DIMETHOMORPH | |
| SPRING ONION | T0.5 |
| DITHIOCARBAMATES DITHIOCARBAMATES | |
| BULB VEGETABLES [EXCEPT SPRING ONIONS] | 4 |
| SPRING ONIONS | T10 |
| ETHOFUMESATE ETHOFUMESATE | |
| BULB VEGETABLES | *0.1 |
| GLYPHOSATE GLYPHOSATE | |
| PULSES [EXCEPT ADZUKI BEAN (DRY); COWPEA (DRY); MUNG BEAN (DRY); SOYA BEAN (DRY)] | 5 |
| HALOFUGINONE HALOFUGINONE | |
| CATTLE KIDNEY | T*0.01 |
| CATTLE LIVER | T*0.01 |
| CATTLE MEAT | T*0.01 |
| IMIDACLOPRID IMIDACLOPRID | |
| BRASSICA LEAFY VEGETABLES | 5 |
| COMMON BEAN (PODS AND/OR IMMATURE SEEDS) | T1 |
| JAPANESE GREENS | 5 |
| INDOXACARB INDOXACARB | |
| ADZUKI BEAN (DRY) | T0.2 |

| | |
|-------------------------------------|--------|
| LINURON LINURON | |
| LEEK | T0.2 |
| VEGETABLES [EXCEPT LEEK] | *0.05 |
| METHOMYL METHOMYL | |
| BEETROOT | T1 |
| METOLACHLOR METOLACHLOR | |
| CHARD (SILVER BEET) | T*0.01 |
| SPINACH | T*0.01 |
| OXYFLUORFEN OXYFLUORFEN | |
| BULB VEGETABLES | *0.05 |
| PERMETHRIN PERMETHRIN | |
| MILKS | 0.05 |
| PEAS | 1 |
| RHUBARB | T5 |
| PROCYMIDONE PROCYMIDONE | |
| LENTIL (DRY) | T0.5 |
| MEAT (MAMMALIAN) (IN THE FAT) | 0.2 |
| PYRIMETHANIL PYRIMETHANIL | |
| EDIBLE OFFAL (MAMMALIAN) | *0.05 |
| MEAT (MAMMALIAN) | *0.05 |
| MILKS | *0.01 |
| TEBUCONAZOLE TEBUCONAZOLE | |
| LETTUCE, HEAD | T0.02 |
| LETTUCE, LEAF | T0.02 |
| TEBUFENOZIDE TEBUFENOZIDE | |
| PISTACHIO NUT | T0.05 |
| TERBUTRYN TERBUTRYN | |
| MEAT (MAMMALIAN) | 0.1 |
| MILKS | 0.1 |
| POULTRY MEAT | 0.1 |

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

| | |
|---|-------|
| DIAFENTHIURON DIAFENTHIURON | |
| COTTON SEED | 0.2 |
| GLYPHOSATE GLYPHOSATE | |
| ADZUKI BEAN (DRY) | 10 |
| COWPEA (DRY) | 10 |
| MUNG BEANS (DRY) | 10 |
| SOYA BEAN (DRY) | 10 |
| IOXYNIL IOXINYL | |
| LEEK | T1 |
| MESOSULFURON-METHYL MESOSULFURON-METHYL | |
| 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 |
| WHEAT | *0.02 |
| PERMETHRIN PERMETHRIN | |
| MEAT (MAMMALIAN) (IN THE FAT) | 0.3 |
| PROCYMIDONE PROCYMIDONE | |
| EDIBLE OFFAL (MAMMALIAN) | 0.05 |
| MILKS | 0.02 |
| POULTRY MEAT (IN THE FAT) | 0.1 |
| TEBUCONAZOLE TEBUCONAZOLE | |
| SUGAR CANE | 0.1 |
| TEBUFENOZIDE TEBUFENOZIDE | |
| LITCHI | 2 |
| LONGAN | 2 |
| TERBUTRYN TERBUTRYN | |
| EDIBLE OFFAL (MAMMALIAN) | 3 |

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.

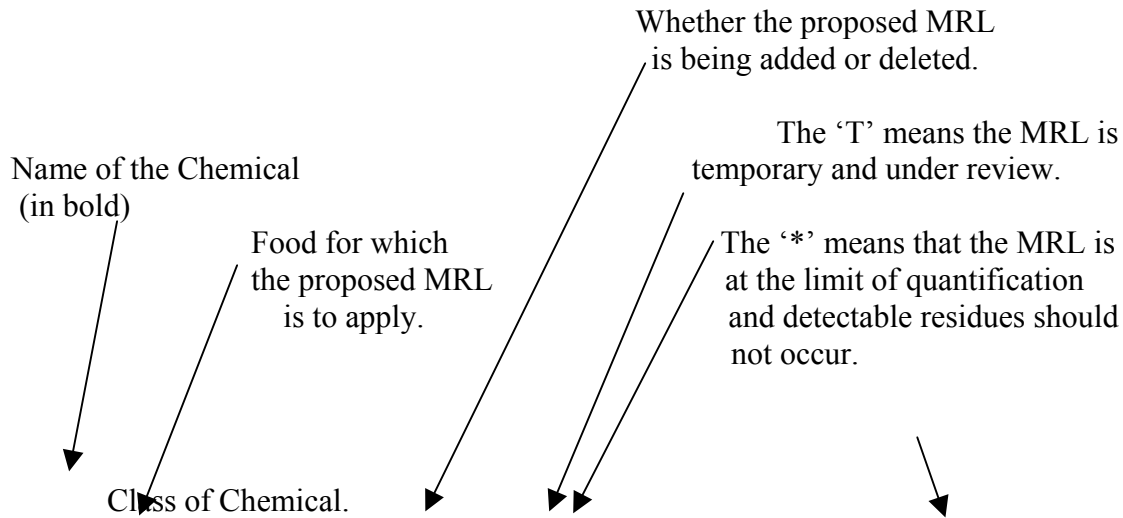
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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 OCS 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.



| | | | |
|---|--------|--------|---|
| Fipronil | | | |
| Berries and other small fruits [except grapes and strawberry] | Delete | T*0.01 | 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. NESTI = <1% of ARfD for berries NEDI = 60% of ADI |
| Berries and other small fruits [except wine grapes] | Add | T*0.01 | |
| Strawberry | Delete | T0.5 | |

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 | APVMA extension of use for the control of pests. The 18 th 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 19 th 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 A486

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. **ECRP** Existing Chemical Review Program
6. **LOQ** Limit of Analytical Quantification.
7. **NEDI** National Estimated Daily Intake.
8. **NESTI** National Estimated Short Term Intake.
9. **NNS** National Nutrition Survey of Australia 1995
10. **LOQ** MRL set at or about the limit of quantification.
11. **T** Temporary MRL.

| Chemical Food | MRL (mg/kg) | | Information |
|---|------------------------------------|------------------------------------|---|
| Bromochloromethane Cattle, edible offal Cattle fat Cattle meat | Add Add Add | T*0.02 T*0.02 T*0.02 | This chemical is an antimethanogen. The APVMA has issued a permit for this chemical to be used to decrease the production of methane by cattle. The OCS has advised that an ADI is not necessary for bromochloromethane and as a result a chronic dietary exposure assessment has not been estimated. The OCS has recommended that the proposed MRLs be established at the limit of quantification (LOQ) and has also advised that there is a large margin of safety for consumption of residues in food when the chemical is used according to good veterinary practice. On this basis and due to low levels of residues and the lack of oral activity of bromochloromethane, a numerical ADI is not considered necessary. While the OCS has not established an ADI for bromochloromethane, the CSIRO has been advised to collect data so that the issue of an ADI can be addressed. |
| Chlorpyrifos Oilseed Oilseed [except peanut] Peanut Pistachio nuts | Delete Add Add Add | T0.01 T0.01 T*0.01 T*0.05 | This chemical is an organophosphorus. The APVMA has issued a permit for this chemical to be used to control silver-leaf whitefly on peanut crops and insects on pistachio nuts. Peanut and Oilseed NESTI = <1 % of ARfD for 2 to 6 y.o. and for the whole population. Pistachio nut NESTI = <1% of ARfD for 2 to 6 y.o. and <1 % for the whole population. NEDI = 83% of ADI. |
| Chlorthal-dimethyl Parsley | Add | T2 | This chemical is a benzoic acid herbicide. The APVMA has issued a permit for this chemical to be used to control various broadleaf weeds and grasses in parsley crops. NEDI = 39% of ADI. |
| Cyhalothrin Radish | Add | *0.01 | This chemical is a synthetic pyrethroid insecticide; it is used is to control diamond back moth and loopers on radish. NEDI = 27% of ADI. |
| Diafenthiuron Cotton seed Soya bean (dry) | Delete Substitute Delete | 0.1 0.2 T0.1 | This chemical is a thiourea insecticide; it used to control mites on cotton crops. NEDI = 7% of ADI |

| | | | |
|--|-------------------------|----------------------|---|
| Diazinon Shallot Spring onion | Add Add | T0.5 T0.5 | This chemical is an organophosphorus. The APVMA has issued a permit for this chemical to be used to control thrips and onion seedling maggot on spring onions. In the 20 th (2000) ATDS the concentrations of residues of diazinon in surveyed foods were less than the LOQ and no pesticide residues were detected in onions. Bulb vegetables NESTI = 34% of ARfD for 2 to 6 y.o. Spring onion NESTI = 9% of ARfD for 2 + y.o. NEDI = 95% of ADI. |
| Dimethomorph Spring onion | Add | T0.5 | This chemical is a cinnamic acid fungicide. The APVMA has issued a permit for its use to control fungus on spring onions. NEDI = 3% of ADI. |
| Dithiocarbamates Bulb vegetables Bulb vegetables [except spring onions] Springs onions | Delete Add Add | 4 4 T10 | Dithiocarbamates are fungicides. The APVMA has issued a permit to for this chemical to be used to control fungus on spring onions. In the 19 th (1998) ATDS the estimated dietary exposure to thiram (the dithiocarbamate with the lowest ADI) was at 63% of the ADI two year olds and 20% of the ADI for adult males. On the basis of results from the 1998 ATDS and that mancozeb has higher ADIs than thiram, FSANZ considers that the residues associated with the MRL would not represent an unacceptable risk to public health and safety. NEDI = 72% of ADI. |
| Ethofumesate Bulb vegetables Garlic Onion, bulb | Add Delete Delete | *0.1 *0.1 *0.1 | This chemical is a benzofuron herbicide; it used to control annual grasses and broadleaf weeds on bulb vegetables. NEDI = <1% of ADI |

| | | | |
|---|-----------------------------|----------------------------|---|
| Glyphosate Adzuki bean (dry) | Delete Substitute | T10 10 | This chemical is a glycine derivative; it used to control weeds on pulse crops. NEDI = 4% of ADI |
| Broad bean (dry) | Delete | 2 | |
| Chick-pea (dry) | Delete | T5 | |
| Cowpea (dry) | Delete Substitute | T10 10 | |
| Field pea (dry) | Delete | 5 | |
| Mung beans (dry) | Delete Substitute | T10 10 | |
| Pulses [except as adzuki beans, broad beans (dry), chickpeas, cowpeas, field pea (dry) and soya bean] | Delete | *0.1 | |
| Pulses [except adzuki bean (dry), cowpea (dry), mung bean (dry) soya bean (dry)] | Add | 5 | |
| Soya bean (dry) | Delete Substitute | 20 10 | |
| Halofuginone Cattle kidney Cattle liver Cattle meat | Add Add Add | T*0.01 T*0.01 T*0.01 | |
| Imidacloprid Brassica leafy vegetables Common bean (pods and/or immature seeds) Japanese greens Mizuna | Add Add Add Delete | 5 T1 5 T5 | This chemical is a neonicotinoid insecticide: it is used to control thrips and aphids on brassica leafy vegetable crops. The APVMA has issued a permit for this chemical to be used to control insects on bean crops. NEDI = 7% of ADI |
| Indoxacarb Adzuki bean (dry) | Add | T0.2 | This chemical is an oxdiazine insecticide; it used to control insects on adzuki beans. NEDI = 82% of ADI |
| Ioxynil Leek | Delete Substitute | T*0.02 T1 | This chemical is a hydroxybenzotrile herbicide. The APVMA has extended the permit for this chemical to be used to control annual broadleaf weeds on leek crops. NEDI = 1% of ADI |
| Linuron Leek Vegetables Vegetables [except leek] | Add Delete Add | T0.2 *0.05 *0.05 | This chemical is a urea herbicide. The APVMA has issued a permit for this chemical to be used to control annual grass and broad leaf weeds on leek crops NEDI = 9% of ADI |

| | | | |
|--|---|---|--|
| Mesosulfuron-methyl Edible offal (mammalian) | Delete Substitute | T*0.01 *0.01 | This chemical is a sulfonylurea herbicide. It is used to control weeds in wheat crops. Based on the results of the available metabolism studies and the maximum estimated dietary exposure for livestock the predicted residues of this chemical in all tissues, milks and eggs are <0.01mg/kg. Therefore, it is appropriate to establish MRLs at the LOQ for animal commodities. This chemical was previously considered in Application A468. |
| Eggs | Delete Substitute | T*0.01 *0.01 | |
| Meat (mammalian) | Delete Substitute | T*0.01 *0.01 | |
| Milks | Delete Substitute | T*0.01 *0.01 | |
| Poultry, edible offal of | Delete Substitute | T*0.01 *0.01 | |
| Poultry meat | Delete Substitute | T*0.01* 0.01 | |
| Wheat | Delete Substitute | T*0.01 *0.02 | |
| Methomyl Beetroot | Add | T1 | This chemical is an oxime carbamate insecticide. The APVMA has issued a permit for its use to control insects and acarids on beetroot crops. In the 19 th (1998) ATDS the concentrations of residues of methomyl in surveyed foods were less than the LOQ. NEDI = 83% of ADI. |
| Metolachlor Chard (silver beet) Spinach | Add Add | T*0.01 T*0.01 | This chemical is a chloroacetamide herbicide. The APVMA has issued a permit for its use to control weeds in spinach and chard crops. NEDI = <1% of ADI. |
| Oxyfluorfen Bulb vegetables Garlic Onion, bulb | Add Delete Delete | *0.05 *0.05 *0.05 | This chemical is a diphenyl ether herbicide; it used to control broad leaf weeds and grasses in bulb vegetable crops. NEDI = 2% of ADI |
| Permethrin Meat (mammalian) (in the fat) Milks Milks (in the fat) Peas Rhubarb | Delete Substitute Add Delete Add Add | 0.1 0.3 0.05 0.05 1 T5 | This chemical is a synthetic pyrethroid insecticide; it is used to control insects on pea crops The APVMA has issued a permit for its use to control insects on rhubarb crops. NEDI = 24% of ADI. |

| | | | |
|--|--|--|---|
| Pirimicarb | | | This chemical is a carbamate insecticide. Due to a typographical error the residue definition is being changed from: Sum of pirimicarb, dimethyl-pirimicarb and N-formyl-(methylamino) analogue and dimethylformamido-pirimicarb, expressed as pirimicarb to: Sum of pirimicarb, demethyl-pirimicarb and N-formyl-(methylamino) analogue (demethylformamido-pirimicarb), expressed as pirimicarb |
| Procymidone Edible offal (mammalian) Lentil (dry) Meat of cattle, pigs and sheep (in the fat) Meat (mammalian) (in the fat) Milks Poultry meat (in the fat) | Delete Substitute Add Delete Add Delete Substitute Delete Substitute | *0.01 0.05 T0.5 *0.01 0.2 *0.01 0.02 *0.01 0.1 | This chemical is a dicarboximide fungicide. The APVMA has issued a permit for this chemical to be used to control the fungus <i>Sclerotinia</i> sp on lentil crops. Current animal MRLs were not adequate to cover residues in animal tissues from currently approved feed sources. Therefore, higher animal MRLs have been proposed for some commodities. NEDI = 24% of ADI |
| Pyrimethanil Edible offal (mammalian) Meat (mammalian) Milks | Add Add Add | *0.05 *0.05 *0.01 | This chemical is an anilino-pyrimidine fungicide; it is used to control fungus on grapes. The APVMA has issued a permit to allow the feeding of treated grape pomace to livestock. Therefore, it is appropriate to establish MRLs for meat, edible offal and milks at the LOQ. NEDI = 3% of ADI. |
| Tebuconazole Sugar cane Lettuce, Head Lettuce, Leaf | Delete Substitute Add Add | T0.1 0.1 T0.02 T0.02 | This chemical is a triazole fungicide; it is used to control fungus on sugar cane. The APVMA have issued a permit to control fungi on lettuce crops. NEDI = 15% of ADI. |
| Tebufenozide Litchi Longan Pistachio nut | Delete Substitute Delete Substitute Add | T2 2 T2 2 T0.05 | This chemical is a diacylhydrazine insecticide; it is used to control insects on litchi and longans. The APVMA has issued a permit for this chemical to be used to control insects on pistachio nuts. NEDI = 22% of ADI. |

| | | | |
|--|----------------------|------------|---|
| Tepraloxym | | | |
| Edible offal (mammalian) | Add | *0.1 | This chemical is a cyclohexanedione oxime herbicide. It is used to control grass weeds on pulse and rape crops. NEDI = <1% of ADI. NESTI = <1% of ARfD for 2 to 6 y.o. and <1% for the whole population for all commodities. |
| Eggs | Add | *0.1 | |
| Meat (mammalian) | Add | *0.1 | |
| Milks | Add | *0.02 | |
| Poultry, edible offal | Add | *0.1 | |
| Poultry meat | Add | *0.1 | |
| Pulses | Add | *0.1 | |
| Rape seed | Add | *0.1 | |
| Terbutryn | | | |
| Beans, except broad bean and soya bean | Delete | *0.1 | This chemical is a triazine herbicide. It is used to control grasses and broadleaf weeds in cereal crops. The proposed amendments of animal commodity MRLs reflect the latest available metabolism animal transfer study data. NEDI = 2% of ADI. |
| Edible offal (mammalian) | Delete Substitute | *0.05 3 | |
| Meat (mammalian) | Add | 0.1 | |
| Meat (mammalian) (in the fat) | Delete | 0.1 | |
| Milks | | | |
| Milks (in the fat) | Add | 0.1 | |
| Potato | Delete | 0.1 | |
| Poultry meat | Delete | *0.1 | |
| Poultry meat (in the fat) | Add Delete | 0.1 0.1 | |
| Trinexapac-ethyl | | | |
| Sugar cane | Add | T*0.05 | This chemical is a plant growth regulator. The APVMA has issued a permit for this chemical to be used as a growth regulator on sugar cane. NEDI = <1% of ADI |

Background to Dietary Exposure Assessments

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code, 1994 (Ag Vet Code Act)* requires 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 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 Commonwealth Department of Health and Aged Care undertook the NNS survey over a 12-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 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.

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 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.

Glossary Of Acronyms

| | |
|---------|---|
| ADI | Acceptable Daily Intake |
| ANZFSC | <i>Australia New Zealand Food Standards Code</i> |
| ANZFRMC | Australia and New Zealand Food Regulation Ministerial Council |
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| AQIS | Australian Quarantine and Inspection Service |
| ARfD | Acute Reference Dose |
| ATDS | Australian Total Diet Survey |
| Codex | Codex Alimentarius Commission |
| DHA | Department of Health and Ageing |
| 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 |
| OCS | Office of Chemical Safety of the Therapeutic Goods Administration |
| 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 |