10/02
26 June 2002

INITIAL / DRAFT ASSESSMENT REPORT (PRELIMINARY/FULL ASSESSMENT - SS.13/15)

APPLICATION A461

MAXIMUM RESIDUE LIMITS

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
7 August 2002
(See "Invitation for Public Submissions" for details)

THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY

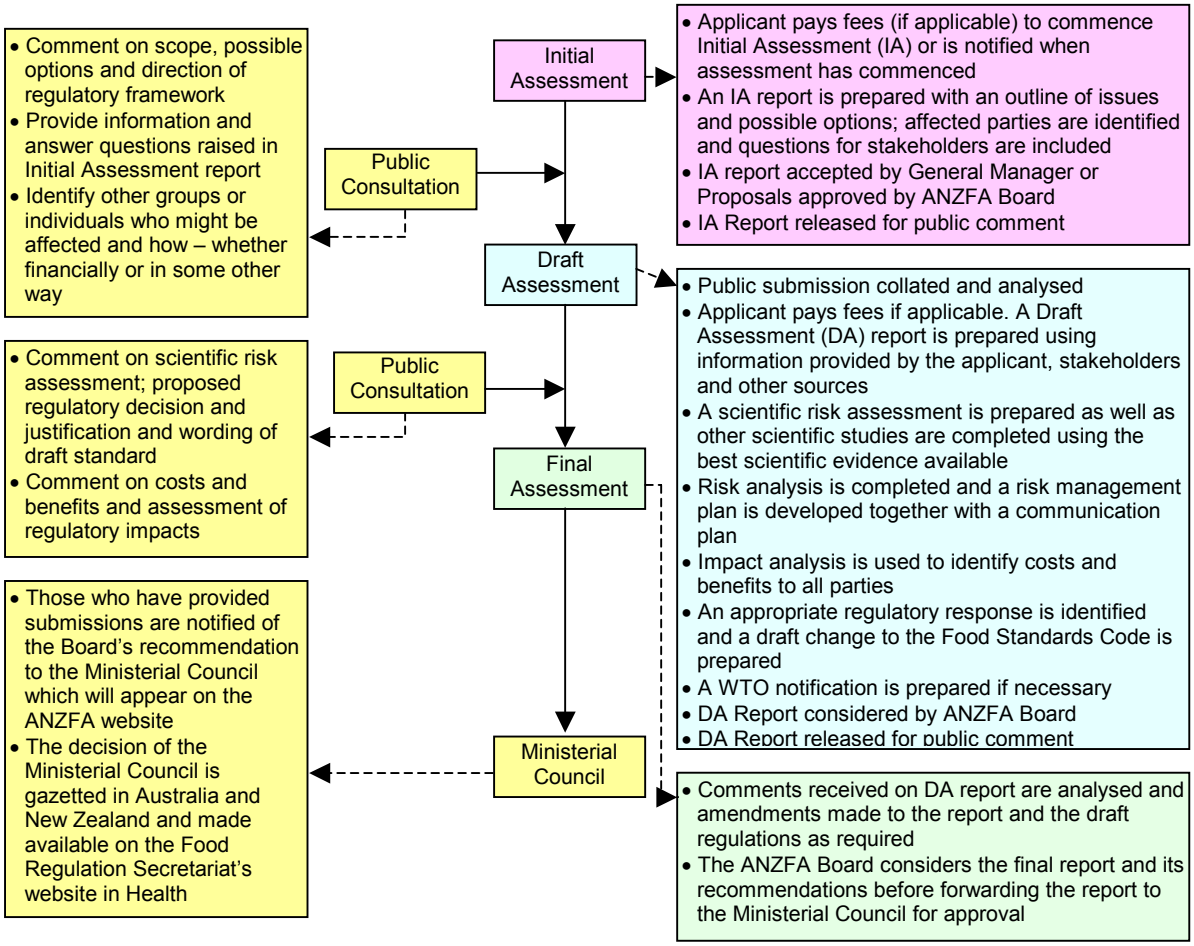
The Australia New Zealand Food Authority's (ANZFA) is a partnership between the Commonwealth Government, Australian State and Territory governments and the New Zealand Government. ANZFA is a bi-national, statutory body whose role, in association with others, is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply.

ANZFA seeks to achieve this goal by developing, varying and reviewing standards for food available for sale in Australia and New Zealand and through a range of other functions including national food surveillance and recall systems, conducting research, assessing policies about imported food and developing codes of practice with industry.

In developing and reviewing food standards for both Australia and New Zealand, ANZFA makes recommendations to change the food standards to the Australia New Zealand Food Standards Council, Ministerial Council made up of Commonwealth, State and Territory and New Zealand Health Ministers. If the Council approves the recommendations made by ANZFA, the food standards are automatically adopted as regulations into the food laws of the Australian States and Territories and New Zealand.

STEPS IN DEVELOPING AND REVIEWING FOOD STANDARDS

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Australia New Zealand Food Authority Act 1991* (ANZFA 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 made an Initial/Draft Assessment on Proposal P261 (referred to as the 'Preliminary Assessment'/ 'Full Assessment' in section 22 of the ANZFA Act), which includes [the identification and discussion of the key issues] or [a Draft Assessment; and draft variation to Volumes 1 and 2 of the *Food Standards Code*]. The Authority will conduct a [Draft Assessment (referred to as the 'Full Assessment' in section 24 of the ANZFA Act) following which a further round of public consultation will be undertaken.] or [Final Assessment (referred to as 'Inquiry' in section 17 of the ANZFA Act).]

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment/Final assessment for this application/proposal. Submissions should, where possible, address the objectives of the Authority as set out in Section 10 of the ANZFA 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 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. The ANZFA 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:

Australia New Zealand Food Authority

PO Box 7186	PO Box 10559
Canberra Mail Centre ACT 2610	The Terrace WELLINGTON 6036
AUSTRALIA	NEW ZEALAND
Tel (02) 6271 2222	Tel (04) 473 9942

Submissions should be received by the Authority by 7 August 2002. 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 submission form on the ANZFA website. Electronic submissions should also include the full contact details of the person making the submission in the main body of the submission so that contact details are not separated.

Further questions in relation to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by Email on slo@anzfa.gov.au. General enquiries and requests for information should be directed to the Information Officer at the above addresses or info@anzfa.gov.au.

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EXECUTIVE SUMMARY AND STATEMENT OF REASONS

Executive Summary

- This Application (A461) seeks to amend Maximum Residue Limits (MRLs) for non-antibiotic agricultural and veterinary chemicals in the *Food Standards Code*. It is a routine application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the *Food Standards Code* in order to reflect current registration status of agricultural and veterinary chemicals in use in Australia.

- On 24 November 2000, the Australia New Zealand Food Standards Council adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). On 24 May 2002, the Ministerial Council agreed to vary the *Food Standards Code* to amend Standard A14 (Volume 1) by deleting schedules 1, 2 and 3 of that Standard and referring the schedules in Standard A14 to the MRL schedules of Standard 1.4.2. This created a single set of schedules for MRLs. Subsequently all applications to amend MRLs will now be incorporated into schedules 1,2 and 3 of Standard 1.4.2 of the *Food Standards Code*. Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

- 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 Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aged Care has undertaken an appropriate toxicological assessment of the agricultural and veterinary chemicals and has established relevant acceptable daily intakes (ADI).

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

- None of the Australia New Zealand Food Authority's (ANZFA's) section 10 objectives of food regulatory measures are compromised by the proposed changes.

- There are no MRLs for antibiotic residues in this Application.

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

Statement Of Reasons

ANZFA recommends progressing the 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 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 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 Aged Care 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.

- None of the Australia New Zealand Food Authority's (ANZFA) section 10 objectives of food regulatory measures are compromised by the proposed changes.

- ANZFA 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 *Food Standards Code* is necessary, cost effective and of benefit to both producers and consumers.

A Summary of the Requested MRLs

Please see Attachment 2 of the Final Assessment Report.

World Trade Organization (WTO) 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 *Food Standards 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 *Food Standards 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.

Draft Variations to the *Food Standards Code*

Please see Attachment 1 of the Final Assessment Report.

1. Introduction

Applications were received from the NRA on 13 February, 5 March, 9 April and 7 May 2002 seeking amendment to Standard 1.4.2 of the *Food Standards Code*. The proposed amendments to the Standard would align MRLs for non-antibiotic agricultural and veterinary chemicals, in the *Food Standards Code* with the MRLs in the NRA MRL Standard.

1.1 Summary of proposed MRLs

The MRL amendments under consideration in this Application are:

- remove the chemical febantel and all associated foods;
- delete MRLs for certain foods for the chemicals, butafenacil, procymidone, profenofos and pymetrozine;
- add MRLs for certain foods for the new chemicals ethametsulfuron methyl, flutolanil, pyriproxyfen, spiroxamine and thiacloprid;
- add MRLs for certain foods for the chemicals butafenacil, pirimiphos-methyl, profenofos, pymetrozine and tebufenozide;
- change MRLs for certain foods for 2,4-D, bifenthrin, butafenacil, ethylene dichloride, fipronil, imazapic, procymidone, tebufenozide and trifluralin; and
- add temporary MRLs for certain foods for abamectin, benalaxyl, bifenthrin, buprofezin, chlorpyrifos, doramectin, fenoxaprop-ethyl, fluazifop-butyl, fludioxonil, fluquinconazole, procymidone, propiconazole, spinosad, triadimenol and trifluralin.

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 MRL for Dithiocarbamates in Vetch

The NRA made an Application for a proposed temporary MRL for mancozeb in Vetch at T0.5 mg/kg in February 2002.

The term ‘vetch’, describes many plant species belonging to the genus *Vicia*. This genus is very large and includes Faba beans and Narbon beans, in general the term Vetch describes a large group of prostrate or trailing species that have been used for fodder or grain for stock feed.

Vetch has no history of use in Australia as a human food and is usually used as a farm animal food item. Vetch has a known potential for adverse effects in humans in that it contains a toxin call cyanoalanine. Vetch cannot be considered a traditional food and ANZFA cannot accept an MRL for a commodity that is not used as a food for humans in Australia.

The NRA MRL Standard has listed Vetch in Table 1 as the Codex commodity classification AL 1029. The AL prefix is usually associated with Table 4 - MRLs for Pesticides in Animal Feed Commodities.

Although Vetch is listed in Schedule 4 of the Standard 1.4.2 – Maximum Residue Limits of the *Food Standards Code*, the listing is anomalous and that clause 1(2) of the *Food Standards Code* provides that:

> *Commodity names specified in Schedule 4 apply only for the purposes of this Standard and Standard 1.4.1.*

Because the *Food Standards Code* only applies to food for human consumption, it follows that an MRL for vetch can only be included in Standard 1.4.2 – Maximum Residue Limits of the *Food Standards Code* if vetch is a food used for human consumption. The listing of vetch will be removed when these provisions are reviewed.

Given the above, the NRA has agreed to withdraw the proposed MRL for mancozeb in Vetch.

1.4 Proposed MRLs for Bitertanol

The NRA made an application for proposed MRLs for bitertanol in a variety of foods in April 2002.

ANZFA has noticed discrepancies between the NRA application and the NRA gazettal to amend the NRA MRL Standard for the proposed MRLs for eggs and strawberry for this chemical. After discussions between ANZFA and the NRA, the NRA has withdrawn the application for the proposed MRLs will make a new application in June 2002.

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 mean that there is a discrepancy between the residues associated with the use and the MRLs in the *Food Standards Code* meaning 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 *Food Standards Code*;

- where the NRA has included MRLs for new chemicals or for additional foods that are not included in the *Food Standards 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 *Food Standards 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 ANZFA to include MRLs in the *Food Standards Code*. ANZFA 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 following consultation, ANZFA makes recommendations to the Ministerial Council to adopt a draft variation to the *Food Standards Code* and include the MRLs in the *Food Standards Code*. The inclusion of the MRLs in the *Food Standards 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.

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. MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective 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 ANZFA of these MRLs so that ANZFA may consider them for inclusion into the *Food Standards Code*.

In relation to MRLs, ANZFA's role is to ensure that the potential residues in food do not represent an unacceptable risk to public health and safety. ANZFA will not recommend 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, ANZFA 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 *Food Standards 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 *Food Standards 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 *Food Standards Code*

On 24 November 2000, the Australia New Zealand Food Standards Council adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). On 24 May 2002, the Ministerial Council agreed to vary the *Food Standards Code* to amend Standard A14 (Volume 1) by deleting schedules 1, 2 and 3 of that Standard and referring the schedules in Standard A14 to the MRL schedules of Standard 1.4.2. This created a single set of schedules for MRLs. Subsequently all applications to amend MRLs will now be incorporated into schedules 1,2 and 3 of Standard 1.4.2 of the *Food Standards Code*. Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

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. ANZFA 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.

ANZFA does not issue permits or grant permission for the temporary use of agricultural and veterinary chemicals. Further information on MRLs for permits 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.

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 ANZFA on +61 2 6271 2222.

5. Regulatory Options

5.1 Option 1 – status quo – no change to the existing MRLs in the *Food Standards Code.*

Under this option, the status quo would be maintained and the *Food Standards Code* would not change and a recommendation would not be made to include any changes in the existing MRLs.

5.2 Option 2(a) – recommend changes to MRLs to delete or decrease some existing MRLs.

Under this option, variations that were reductions and deletions would be recommended to be included and increases in MRLs and inclusions of new MRLs would not be recommended.

5.3 Option 2(b) – recommend changes to MRLs to include new MRLs or increase some existing MRLs.

Under this option, those variations that were increases and additions of MRLs would be recommended for inclusion and decreases and deletions would not be recommended.

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 and is considered more conducive to public consultation.

6. Impact Analysis

The parties affected by this application are consumers, government, producers and food manufacturers of primary produce and foods imported into Australia.

6.1 Costs and benefits

6.1.1 Costs of accepting the application

- There will be a cost of disposal, replacement and dissemination of information about proscribed agricultural and veterinary chemicals;

- Initially, enforcement agencies, food manufacturers may have costs associated with compliance and enforcement of MRLs following the proposed amendments;

- Some consumers may consider that any residues of agricultural and veterinary chemicals in food are not in the public interest and may regard the presence of any chemical residues in foods as a cost.

6.1.2 Benefits of accepting the application

- Food producers will be legally able to sell produce legally treated with chemicals intended to improve stock and yields as well as controlling diseases and pests;

- It will ensure consistency between the health and agricultural regulations; and

- Consumers may receive the potential benefits of improved crop and stock production through cheaper or better quality produce.

6.1.3 Costs of not accepting the application

- Producers will not be able to legally sell legally treated produce treated with chemicals intended to increase productivity and/or control disease and pests. This will have costs for primary producers with consequent potential impacts on regional Australia;

- There may be increased production costs for manufacturers and ultimately increased costs to consumers if commodities which have been legally treated to improve productivity and/or control pests and disease cannot be legally sold; and

- the discrepancies between the *Food Standards Code* and the NRA MRL Standard would become greater leading to confusion for producers, consumers and government agencies.

6.1.4 Benefits of not accepting the application

- Products complying with the existing MRLs could continue to be legally sold.

7. Consideration of Issues under section 13 of the *Australia New Zealand Food Authority Act 1991*

Subsection 13(1) of the *Australia New Zealand Food Authority Act 1991* (ANZFA Act) requires ANZFA to make a preliminary assessment of an application. In making that preliminary assessment, subsection 13(2) requires ANZFA to have regard to a number of matters set out in paragraphs 13(2)(a) to (e). Each of these matters is discussed below.

7.1 Paragraph 13(2)(a)

This Application relates to a matter that may warrant a variation to a food regulatory measure, because the application seeks an amendment of a standard. Under the ANZFA Act, a standard, by definition, is a food regulatory measure.

7.2 Paragraph 13(2)(b)

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

7.3 Paragraph 13(2)(c)

The Application does not suggest that the proposed amendment would present any further costs to the community, Government or industry. ANZFA has reviewed the Application and has not identified any adverse health effects that would result from the variations being made.

7.4 Paragraph 13(2)(d)

The nature of the Application is such that only an amendment to a standard (i.e. a food regulatory measure) can bring about what the applicant is seeking. No other measures appear to be available.

7.5 Paragraph 13(2)(e)

Other relevant matters for consideration by ANZFA are as follows.

7.5.1 Consideration of issues under Regulation 12 of the Australia New Zealand Food Authority Regulations 1994 which prescribes matters for the purpose of paragraph 13(2) (e) of the ANZFA Act.

7.5.1.1 Regulation 12(a)

Because it is a simple variation of a food regulatory matter requiring only the updating of a standard set out in the *Food Standards Code* this matter will be in category 2.

7.5.1.2 Regulation 12(b)

ANZFA considers that this Application will not confer an exclusive capturable commercial benefit on the applicant.

7.5.2 World Trade Organization Notification

As a member of the World Trade Organization (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.

The MRLs prescribed in the *Food Standards 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 *Food Standards 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 assist in ensuring that residues are no higher than is necessary for effective control of pests and diseases. MRLs are also used as standards for the international trade in food.

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. Therefore, this application will be notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO SPS agreement, in order to enable other member countries to comment on standards, which may have a significant impact on them.

7.5.3 Codex MRLs

The standards of the Codex Alimentarius Commission are used as the relevant international standards or basis as to whether a new or changed standard requires a WTO notification. There are no proposed MRLs in this application, which have a relevant Codex MRL.

7.5.4 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 while still being safe for human consumption, may be different from that 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.

To assist in identifying possible impacts where imported food may be affected, ANZFA has compiled the following table that states the imported quantity of relevant foods for the years 1999 and 2000. These data are for foods for which reductions and deletions of MRLs are proposed. ANZFA requests comment as to any possible ramifications for imports of the changes of the MRLs in this Application.

Food	**1999 Tonnes**	**2000 Tonnes**
Apple	332	162
Cattle, edible offal of	1462	1847
Cattle meat	1376	1107
Cereal grains	71834	74466
Eggs	672	353
Goat meat	0	5
Meat (mammalian)	25992	40012
Milk fats	23527	22689
Milks	22033	19345
Peanut	6389	7716
Pome fruits	1652	1843
Poultry, edible offal of	142	143
Poultry meat	142	143
Pulses	172147	191741
Sheep meat	335	459
Strawberry	5165	5889
Sweet corn (kernels)	13745	12907

8. Consideration of Issues under section 15 of the *Australia New Zealand Food Authority Act 1991*

Subsection 15(1) of the ANZFA Act requires ANZFA to make a Draft Assessment (Full Assessment - s.15) of an application. In making that Draft Assessment (Full Assessment - s.15), subsection 15(3) requires ANZFA to have regard to a number of matters set out in paragraphs 15(3)(a) to (e). Each of these matters is discussed below.

8.1 Paragraph 15(3)(a)

As this application raises issues of minor significance and complexity only, ANZFA has not invited written submissions for the purposes of making the Initial / Draft Assessment. However, ANZFA will invite written submissions for the purpose of the Inquiry under s. 17(3)(c) of the ANZFA Act and will have regard to any submissions received.

8.2 Paragraph 15(3)(b)

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

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

The Chemicals and Non-prescription Medicines Branch of the TGA establish the ADI and where applicable the acute reference dose (ARfD) for the agricultural and veterinary chemicals. The NRA and ANZFA carry out estimations 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.

8.2.2 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.

8.2.3 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 ANZFA to have regard to a number of matters set out in paragraphs 10(2)(a) to (d). Each of these matters is discussed below.

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

The procedures used by ANZFA, the TGA and the NRA rely on the comprehensive examination of detailed scientific information, including a rigorous toxicological assessment and the dietary exposure assessments are undertaken in accordance with international protocols.

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

This is addressed in section 7.5.

8.2.6 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 *Food Standards Code* to include the proposed MRLs would promote trade and commerce and allow food industries to continue to be efficient and competitive.

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

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

8.3 Paragraph 15(3)(c)

ANZFA 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 *Food Standards Code* is necessary, cost effective and of benefit to both producers and consumers.

8.4 Paragraph 15(3)(d)

The nature of the Application is such that only an amendment to a standard (i.e. a food regulatory measure) can bring about what the applicant is seeking. No other measures appear to be available.

8.5 Paragraph 15(3)(e)

This is addressed in section 7.5.

8. Consultation

ANZFA has decided, pursuant to section 36 of the *Australia New Zealand Food Authority Act 1991*, to omit to invite public submissions in relation to the Application prior to making a Draft Assessment. However, ANZFA now invites written submissions for the purpose of the Inquiry under s.17 (3)(c) of the ANZFA Act and will have regard to any submissions received. ANZFA was satisfied that omitting to invite public submissions prior to making a draft assessment was warranted as the Application 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. Subject to the *Administrative Appeals Tribunal Act 1975*, application may be made to the Administrative Appeals Tribunal, for review of the decision (under section 36) by a person whose interests are affected by the decision.

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. Recommendation

ANZFA recommends progressing the 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 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 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 Aged Care 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.

- None of the Australia New Zealand Food Authority's (ANZFA) section 10 objectives of food regulatory measures are compromised by the proposed changes.

- ANZFA 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 *Food Standards Code* is necessary, cost effective and of benefit to both producers and consumers.

10. Implementation and review

The use of chemical products and MRLs are subject to 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.

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.

ATTACHMENTS

1. Draft Variations to the *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 *Food Standards Code*.
3. Statement of Reasons
4. Background to Dietary Exposure Assessments.
5. Glossary Of Acronyms.

ATTACHMENT 1

DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

To commence: On gazettal

[1] ***Standard 1.4.2 of*** *Volume 2 of the Food Standards Code is varied by -*

[1.1] *inserting in columns 1 and 2 respectively of* Schedule 1 *each chemical (shown in bold type) and its associated food and maximum residue limit for that food -*

ETHAMETSULFURON METHYL ETHAMETSULFURON METHYL	
EDIBLE OFFAL (MAMMALIAN)	T*0.02
EGGS	T*0.02
LUPIN (DRY)	T*0.02
MEAT (MAMMALIAN)	T*0.02
MILKS	T*0.02
POULTRY, EDIBLE OFFAL OF	T*0.02
POULTRY MEAT	T*0.02
FLUTOLANIL COMMODITIES OF PLANT ORIGIN: FLUTOLANIL COMMODITIES OF ANIMAL ORIGIN: FLUTOLANIL AND METABOLITES HYDROLYSED TO 2-TRIFLUOROMETHYL-BENZOIC ACID AND EXPRESSED AS FLUTOLANIL	
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.05
MEAT (MAMMALIAN) (IN THE FAT)	*0.05
MILKS	*0.05
POTATO	0.05
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT (IN THE FAT)	*0.05
PYRIPROXYFEN PYRIPROXYFEN	
BEANS [EXCEPT BROAD BEAN AND SOYA BEAN]	T0.2
COTTON SEED	T0.1
COTTON SEED OIL, CRUDE	T*0.02
COTTON SEED OIL, EDIBLE	T*0.02
EDIBLE OFFAL (MAMMALIAN)	T*0.02
FRUITING VEGETABLES, CUCURBITS	T0.2
FRUITING VEGETABLES, OTHER THAN CUCURBITS	T0.2
MEAT (MAMMALIAN) (IN THE FAT)	T*0.02
MILKS	T*0.02
SPIROXAMINE COMMODITIES OF PLANT ORIGIN: SPIROXAMINE COMMODITIES OF ANIMAL ORIGIN: SPIROXAMINE CARBOXYLIC ACID, EXPRESSED AS SPIROXAMINE	
DRIED GRAPES	3
EDIBLE OFFAL (MAMMALIAN)	0.5
GRAPES	2

MAMMALIAN FATS [EXCEPT MILK FATS]	0.05
MEAT (MAMMALIAN)	0.05
MILKS	0.05
THIACLOPRID THIACLOPRID	
POME FRUITS	T1
STONE FRUITS	T2

Explanatory Note: These are new chemicals not previously listed.

[1.2] *omitting from columns 1 and 2 respectively of* Schedule 1, *in relation to each chemical (shown in bold type), the food and the maximum residue limit for that food –*

BUTAFENACIL BUTAFENACIL	
CEREAL GRAINS [EXCEPT MAIZE; SORGHUM; MILLET; AND RICE]	T*0.02
PROCYMIDONE PROCYMIDONE	
BROCCOLI	T5
PROFENOFOS PROFENOFOS	
SWEET CORN (KERNELS)	*0.02
PYMETROZINE **PYMETROZINE**	
APRICOT	*0.05
NECTARINE	*0.05
PEACH	*0.05
PLUMS (INCLUDING PRUNES)	*0.05

Explanatory Note: Permission for a residue of the specified chemical in these foods is being repealed.

[1.3] *inserting in columns 1 and 2 respectively of* Schedule 1, *in relation to each chemical (shown in bold type), the food and the maximum residue limit for that food –*

ABAMECTIN SUM OF AVERMECTIN B 1A, AVERMECTIN B 1B AND D-8,9 ISOMER OF AVERMECTIN B 1A	
SOYA BEAN (DRY)	T*0.002
BENALAXYL BENALAXYL	
SHALLOT	T0.5
BIFENTHRIN BIFENTHRIN	
KAFFIR LIME LEAVES	T10
LEMON BALM	T10

LEMON GRASS	T10
LEMON VERBENA	T10
MIZUNA	T10
BUPROFEZIN BUPROFEZIN	
COTTON SEED	T1
COTTON SEED OIL, CRUDE	T0.3
BUTAFENACIL BUTAFENACIL	
CEREAL GRAINS [EXCEPT RICE]	*0.02
CHLORPYRIFOS CHLORPYRIFOS	
PERSIMMON, JAPANESE	T*0.05
DORAMECTIN DORAMECTIN	
CATTLE MILK	T0.06
FENOXAPROP-ETHYL SUM OF FENOXAPROP-ETHYL (ALL ISOMERS) AND 2-(4-(6-CHLORO-2-BENZOXAZOLYLOXY)PHENOXY)-PROPANOATE AND 6-CHLORO-2,3-DIHYDROBENZOXAZOL-2-ONE, EXPRESSED AS FENOXAPROP-ETHYL	
RICE	T*0.02
FLUAZIFOP-BUTYL FLUAZIFOP-BUTYL	
PARSNIP	T0.1
FLUDIOXONIL FLUDIOXONIL	
RAPE SEED	T*0.01
FLUQUINCONAZOLE FLUQUINCONAZOLE	
RAPE SEED	T*0.01
PIRIMIPHOS-METHYL PIRIMIPHOS-METHYL	
PEANUT	5
PEANUT OIL, EDIBLE	15
PROCYMIDONE PROCYMIDONE	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	T5
INDIAN MUSTARD	T2
MUSTARD GREENS	T2
PROFENOFOS PROFENOFOS	
CATTLE MILK	*0.01
EDIBLE OFFAL (MAMMALIAN)	*0.05

EGGS	*0.02
MEAT (MAMMALIAN)	*0.05
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
PROPICONAZOLE PROPICONAZOLE	
BLUEBERRIES	T2
PYMETROZINE PYMETROZINE	
STONE FRUITS	*0.05
SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
CELERY	T*0.25
TEBUFENOZIDE TEBUFENOZIDE	
EDIBLE OFFAL (MAMMALIAN)	*0.02
MEAT (MAMMALIAN) (IN THE FAT)	*0.02
MILKS	*0.01
TRIADIMENOL TRIADIMENOL *SEE ALSO* TRIADIMEFON	
PEPPERS	T0.5
TRIFLURALIN TRIFLURALIN	
PARSNIPS	T0.5

Explanatory Note: These are new MRLs for existing chemicals, but for foods that are not currently listed.

[1.4] *omitting from column 2 of* Schedule 1, *the maximum residue limit in relation to each chemical (shown in bold type), substituting the maximum residue limit for that food* -

2,4-D 2,4-D	
CEREAL GRAINS	0.2
BIFENTHRIN BIFENTHRIN	
GALANGAL, RHIZOMES	T10
HERBS	T10
RUCOLA (ROCKET)	T10
TURMERIC, ROOT	T10
BUTAFENACIL BUTAFENACIL	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.02

POULTRY MEAT	*0.01
ETHYLENE DICHLORIDE (EDC) 1,2-DICHLOROETHANE	
CEREAL GRAINS	*0.1
FIPRONIL SUM OF FIPRONIL, THE SULPHENYL METABOLITE (5-AMINO-1-[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-4-[(TRIFLUOROMETHYL) SULPHENYL]-1H-PYRAZOLE-3-CARBONITRILE), THE SULPHONYL METABOLITE (5-AMINO-1-[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-4-[(TRIFLUOROMETHYL)SULPHONYL]-1H-PYRAZOLE-3-CARBONITRILE), AND THE TRIFLUOROMETHYL METABOLITE (5-AMINO-4-TRIFLUOROMETHYL-1-[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-1H-PYRAZOLE-3-CARBONITRILE)	
SUNFLOWER SEEDS	*0.01
IMAZAPIC SUM OF IMAZAPIC AND ITS HYDROXYMETHYL DERIVATIVE	
PEANUT	*0.1
PROCYMIDONE PROCYMIDONE	
RAPE SEED RAPE SEED OIL, CRUDE	T1 T3
TEBUFENOZIDE TEBUFENOZIDE	
LITCHI LONGAN POME FRUITS	T2 T2 1
TRIFLURALIN TRIFLURALIN	
VEGETABLES [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	0.05

Explanatory note: These are changes in the level of the MRL for existing chemicals in an existing food.

[1.5] *omitting from* Schedule 1, *the following chemical (shown in bold type),residue definition and all associated foods and maximum residue limit entries -*

FEBANTEL FEBANTEL

Explanatory Note: Permission for the chemical is being repealed.

ATTACHMENT 2

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

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

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.

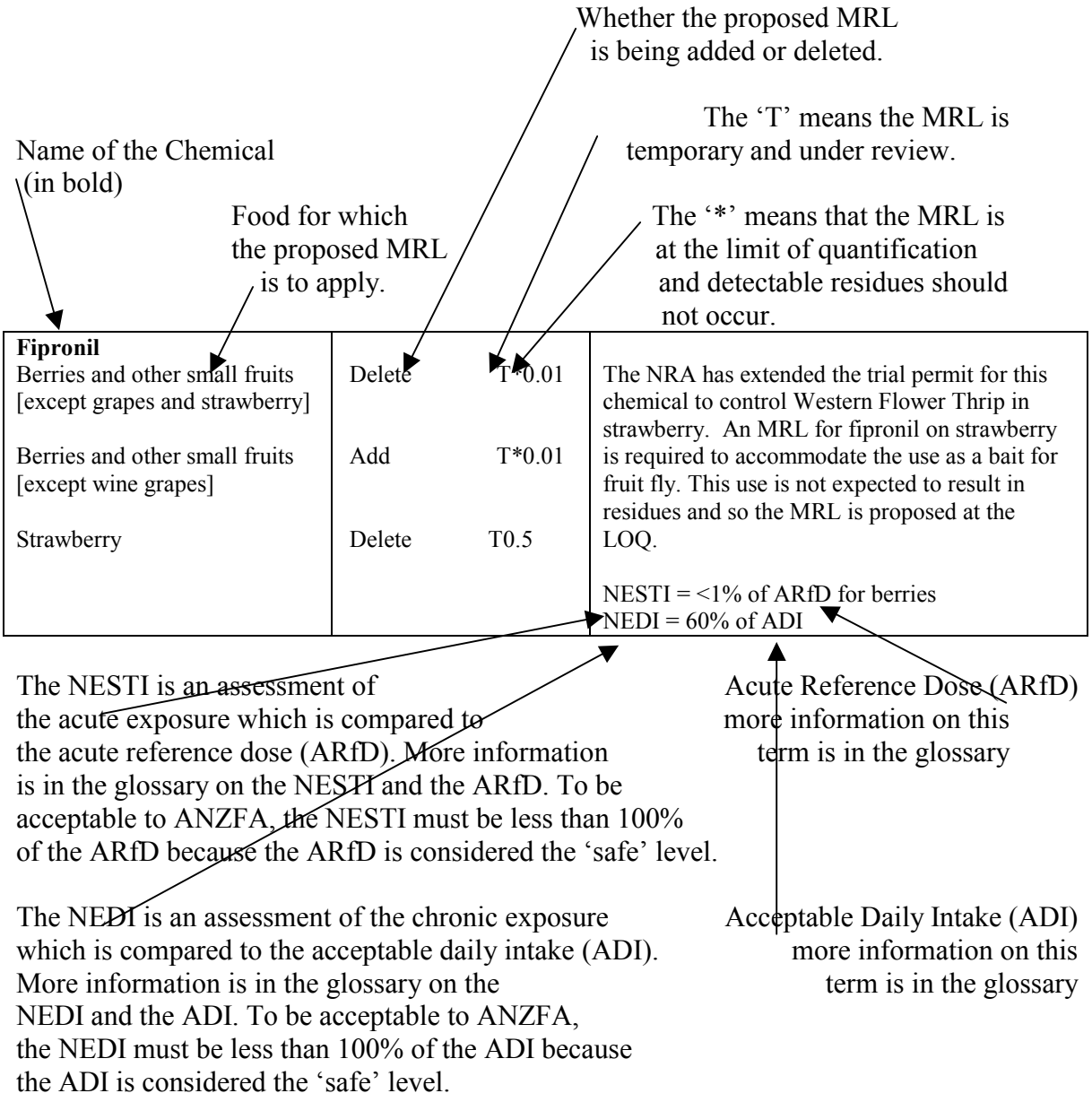
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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. ANZFA 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.



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 A461

Glossary;

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

Chemical Food	MRL (mg/kg)	Information
Abamectin		
Soya bean (dry)	Add T*0.002	The NRA has issued a permit for a trial of this chemical to control insects on soya bean crops. NEDI = 48% of ADI
2,4-D		
Cereal grains	Delete T2 Substitute 0.2	This chemical is used to control weeds in cereal crops. NEDI = 52% of ADI
Benalaxyl		
Shallot	Add T0.5	The NRA has issued a permit for this chemical to be used to control fungal diseases in shallots. NEDI = 3% of ADI
Bifenthrin		
Galangal, rhizomes	Delete T0.5 Substitute T10	This chemical is used to control insects on herb crops. The Queensland Department of Primary Industry have provided residue monitoring data indicating that the original temporary MRLs recommended for herbs may be exceeded when bifenthrin is used according to the minor use permit. To avoid unnecessary violations the temporary MRLs will be increased in the interim period while the industry generates additional residue data. The contribution of herbs to the dietary intake of bifenthrin is negligible. The temporary MRLs may be revised downwards once new data are available. Raising the MRLs for herbs has made negligible difference to the NEDI (<1% increase). As it is recognised that the NEDI calculation is a conservative indicator of dietary exposure, ANZFA concludes that there is no unacceptable risk to public health and safety NEDI = 89% of ADI
Herbs	Delete T0.5 Substitute T10	
Kaffir lime leaves	Delete T0.5 Substitute T10	
Lemon balm	Delete T0.5 Substitute T10	
Lemon grass	Delete T0.5 Substitute T10	
Lemon verbena	Delete T0.5 Substitute T10	
Mizuna	Delete T0.5 Substitute T10	
Rucola (rocket)	Delete T0.5 Substitute T10	
Turmeric, root	Delete T0.5 Substitute T10	
Buprofezin		
Cottonseed Cotton seed oil, crude	Add T1 Add T0.3	The NRA has issued a permit for this chemical to be used to control insects on cotton plants. NEDI = 2% of ADI.

Butafenacil			
Cereal grains [except maize, sorghum, millet and rice]	Delete	T*0.02	This chemical is used to control broad leaf weeds and some grass weeds in cereal crops.
Cereal grains [except rice]	Add	*0.02	
Edible offal (mammalian)	Delete	T*0.02	
	Substitute	*0.02	
Eggs	Delete	T*0.01	
	Substitute	*0.01	
Meat (Mammalian)	Delete	T*0.01	
	Substitute	*0.01	
Milks	Delete	T*0.01	
	Substitute	*0.01	
Poultry, Edible offal of	Delete	T*0.02	
	Substitute	*0.02	
			NEDI = 5% of ADI
Poultry meat	Delete	T*0.01	
	Substitute	*0.01	
Chlorpyrifos			
Persimmon, Japanese	Add	T*0.05	The NRA has issued permit for this chemical to be used to control ant nests under persimmon trees. NEDI = 83% of ADI NESTI = 1% of ARfD for the whole population and 2% of ARfD for children
Doramectin			
Cattle milk	Add	T0.06	The NRA has issued a permit for this chemical to be used to control parasites on and in dairy cattle and then to conduct a milk residue study. When the proposed MRL was included in the NEDI , the estimated chronic dietary intake of this chemical was 138% of the ADI, with 133% of this total being associated with the consumption of cattle milk. The potential dietary risks associated with the use of this chemical in dairy cattle have been reduced by applying the following conditions to the permit approval:

Doramectin (cont)		• A maximum of 50 diary cattle are to be used in the residue trials associated with this permit i.e. 25 animals in the treatment group and 2 treatment groups (injection/pour on) = 50 animals; and • The milk from the treated animals must be co-mingled with milk from an equal (or higher) number of untreated animals at the dairy (in the farm vat). Restricting the dairy cattle being exposed to this chemical largely mitigates the potential risk to human health. The requirement to co-mingle milk from treated animals with milk from untreated animals effectively reduces the maximum level of this chemical in milk to half the proposed MRL (0.03 mg/kg), thereby reducing the NEDI calculation to 68% of the ADI. Subsequent dilution (in the milk tanker) and processing of the milk (separation and pasteurisation) are likely to reduce the level of any residues of this chemical even further. Therefore, the dietary exposure assessment indicates that the residues associated with this chemical does not represent an unacceptable risk to public health and safety. Expected NEDI = 68% of ADI.

Ethametsulfuron methyl			
Edible offal (Mammalian)	Add	T*0.02	This chemical is used control weeds in lupin. NEDI = <1% of ADI
Eggs	Add	T*0.02	
Lupin (dry)	Add	T*0.02	
Meat (Mammalian)	Add	T*0.02	
Milks	Add	T*0.02	
Poultry, Edible offal of	Add	T*0.02	
Poultry meat	Add	T*0.02	
Ethylene dichloride			
Cereal grains	Delete	50	This chemical is used as a fumigant insecticide in the treatment of rice milling equipment. No ADI has been set for this chemical. However, ANZFA considers dietary exposure does not represent an unacceptable risk to public health and safety, as the rice grains are not treated directly with this chemical and the proposed MRL has been set at the LOQ. Therefore, detectable residues are not expected in rice or its processed fractions following the treatment of the rice milling equipment with this chemical.
	Substitute	*0.1	
Febantel			
Cattle, Edible offal of	Delete	0.5	This chemical is a pro-drug, metabolising to oxfendazole. It is no longer registered for use in food producing animals, so MRLs for this chemical are no longer required. As this a deletion of the chemical no NEDI is required.
Cattle meat	Delete	0.1	
Goat, Edible offal of	Delete	0.5	
Goat meat	Delete	0.1	
Milk fats	Delete	4	
Milks	Delete	0.5	
Sheep, Edible offal of	Delete	0.5	
Sheep meat	Delete	0.1	
Fenoxaprop-ethyl			
Rice	Add	T*0.02	The NRA has issued a permit for this chemical to be used to control weeds in rice crops. NEDI = 10% of ADI.
Fipronil			
Sunflower seed	Delete	T*0.01	This chemical is used to control insects on sunflower seed. There is an ARfD for this chemical. However, an acute dietary exposure was not carried out as no detectable residues are expected in seed grown from treated seed. NEDI = 27% of ADI.
	Substitute	*0.01	

Fluazifop-butyl Parsnip	Add	T0.1	The NRA has issued a permit for this chemical to be used to control grass weeds in parsnip crops. NEDI = 69% of ADI.
Fludioxonil Rape seed	Add	T*0.01	The NRA has issued a permit for this chemical to be used to control fungal diseases on rape seed. NEDI = 2% of ADI
Fluquinconazole Rape seed	Add	T*0.01	The NRA has issued a permit for a field trial for the use of this chemical to control blackleg in rape seed crops. NEDI = 22% of ADI
Flutolanil Edible offal (Mammalian) Eggs Meat (Mammalian) (in the fat) Milks Potato Poultry meat (in the fat) Poultry, Edible offal of	 Add Add Add Add Add Add Add	 *0.05 *0.05 *0.05 *0.05 0.05 *0.05 *0.05	This chemical is used to control fungal diseases in potato. NEDI = 3% of ADI
Imazapic Peanut	Delete Substitute	T*0.1 *0.1	This chemical is used to control weeds in peanut crops. NEDI = <1% of ADI.
Pirimiphos-methyl Peanut Peanut oil, edible	Add Add	5 15	This chemical is used to control insect on peanuts. NEDI = 46% of ADI.
Procymidone Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Broccoli Indian mustard Mustard greens Rape seed Rape seed oil, crude	Add Delete Add Add Delete Substitute Delete Substitute	T5 T5 T2 T2 1 T1 3 T3	This chemical is used to control fungal diseases in various plants. NEDI = 22% of ADI

Profenofos			
Cattle milk	Add	*0.01	This chemical is used to control insects on cotton crops. Available residues data for cotton and animal feed items have been reviewed as part of the NRA's Stockfeed Guideline project. Entries are deleted for commodities for which there are no registered or approved uses. Animal commodity MRLs are reviewed based anticipated dietary exposure of livestock to profenofos residues and available animal transfer studies. No changes to current use patterns are proposed. NEDI = 34% of ADI
Edible offal (Mammalian)	Add	*0.05	
Eggs	Add	*0.02	
Meat (Mammalian)	Add	*0.05	
Poultry meat	Add	*0.05	
Poultry, Edible offal of	Add	*0.05	
Sweet corn (kernels)	Delete	*0.02	
Propiconazole			
Blueberries	Add	T2	The NRA has issued a permit for this chemical to be used control fungi on blueberries. NEDI = 5% of ADI.
Pymetrozine			
Apricot	Delete	*0.05	This chemical is used to control insects on stone fruits.
Nectarine	Delete	*0.05	
Peach	Delete	*0.05	
Plums (including prunes)	Delete	*0.05	
Stone fruits	Add	*0.05	NEDI = 5% of ADI.
Pyriproxyfen			
Beans [except broad bean and soya bean]	Add	T0.2	The NRA have issued an emergency permit for this chemical to be used to control white fly on cotton crops and have issued a permit for this chemical to be used to control silver leaf whitefly on various vegetable crops.
Cotton seed	Add	T0.1	
Cotton seed oil, crude	Add	T*0.02	
Cotton seed oil, edible	Add	T*0.02	
Edible offal (Mammalian)	Add	T*0.02	
Fruiting vegetables, cucurbits	Add	T0.2	
Fruiting vegetables, other than cucurbits	Add	T0.2	
Meat (Mammalian) (in the fat)	Add	T*0.02	
Milks	Add	T*0.02	NEDI = <1% of ADI.
Spinosad			
Celery	Add	T*0.25	The NRA has issued a permit for this chemical to be used to control insects on celery. NEDI = 11% of ADI

Spiroxamine			
Dried grapes	Add	3	This chemical is used to control powdery mildew on grapes. The MRLs for animal products are included as grape pomace is fed to livestock. The highest NESTI calculated was for grapes in infants (2 - 6 years) and is equivalent to 17 % of the ARfD. The NESTI for grapes consumed by adults (7 years and above) is equivalent to 7% of the ARfD. NESTIs for all other commodities were ≤2% of the ARfD. NEDI = 4% of ADI
Edible offal (Mammalian)	Add	0.5	
Grapes	Add	2	
Mammalian fats [except milk fats]	Add	0.05	
Meat (Mammalian)	Add	0.05	
Milks	Add	0.05	
Tebufenozide			
Edible offal (Mammalian)	Add	*0.02	This chemical is used to control Lightbrown apple moths in apples and pears and codling moth on apples. The NRA has issued a permit for this chemical to control insects on litchi and longans. Animal commodity MRLS are recommended as a result of the use of apple and pear pomace as animal feed commodities. NEDI = 11% of ADI.
Litchi	Delete	T1	
	Substitute	T2	
Longan	Delete	T1	
	Substitute	T2	
Meat (Mammalian) (in the fat)	Add	*0.02	
Milks	Add	*0.01	
Pome fruit	Delete	T2	
	Substitute	1	
Thiacloprid			
Pome fruits	Add	T1	The NRA has issued a permit for this chemical to control codling moth and oriental fruit moth on stone and pome fruits. The NESTI was calculated using raw fruit consumption figures, and was, as a maximum, 26 % of the ARfD for the whole population and 80 % of the ARfD for children. NEDI = 18% of ADI.
Stone fruits	Add	T2	
Triadimenol			
Peppers	Add	T0.5	The NRA has issued a permit for this chemical to be used to control powdery mildew on capsicum. NEDI =2% of ADI

Trifluralin			
Parsnip	Add	T0.5	The NRA has issued a permit for this chemical to be used to control winter grasses in parsnip crops.
Vegetables [except carrot; fennel bulb; and galangal, greater]	Delete	0.05	
Vegetables [except carrot; fennel bulb; galangal, greater; and parsnip]	Add	0.05	NEDI =7% of ADI

ATTACHMENT 3

BACKGROUND TO DIETARY EXPOSURE ASSESSMENTS

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code, 1994* (*Ag Vet Code Act*) requires the 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.

ANZFA'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, ANZFA considers the dietary exposure to chemical residues from all foods in the diet by comparing the dietary exposure with the relevant health standard. ANZFA will not recommend 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, ANZFA 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); an
- 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 ANZFA 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 ANZFA 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 have established an ARfD.

The NRA and ANZFA 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 ANZFA 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. ANZFA 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. ANZFA 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
ANZFA	Australia New Zealand Food Authority
AQIS	Australian Quarantine and Inspection Service
ARfD	Acute Reference Dose
Codex	Codex Alimentarius Commission
DHA	Health and Ageing, Department of
FSC	*Food Standards Code*
LOQ	Limit of Quantification
MRL	Maximum Residue Limit
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short Term Intake
NNS	National Nutrition Survey
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