ANZFA
Australia New Zealand Food Authority
TE MANA WHAKARITE KAI MŌ ĀHITEREIRIA ME AOTEAROA

10/02
26 June 2002

FINAL ASSESSMENT REPORT (INQUIRY - SECTION 17)

APPLICATION A455

MAXIMUM RESIDUE LIMITS

THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY

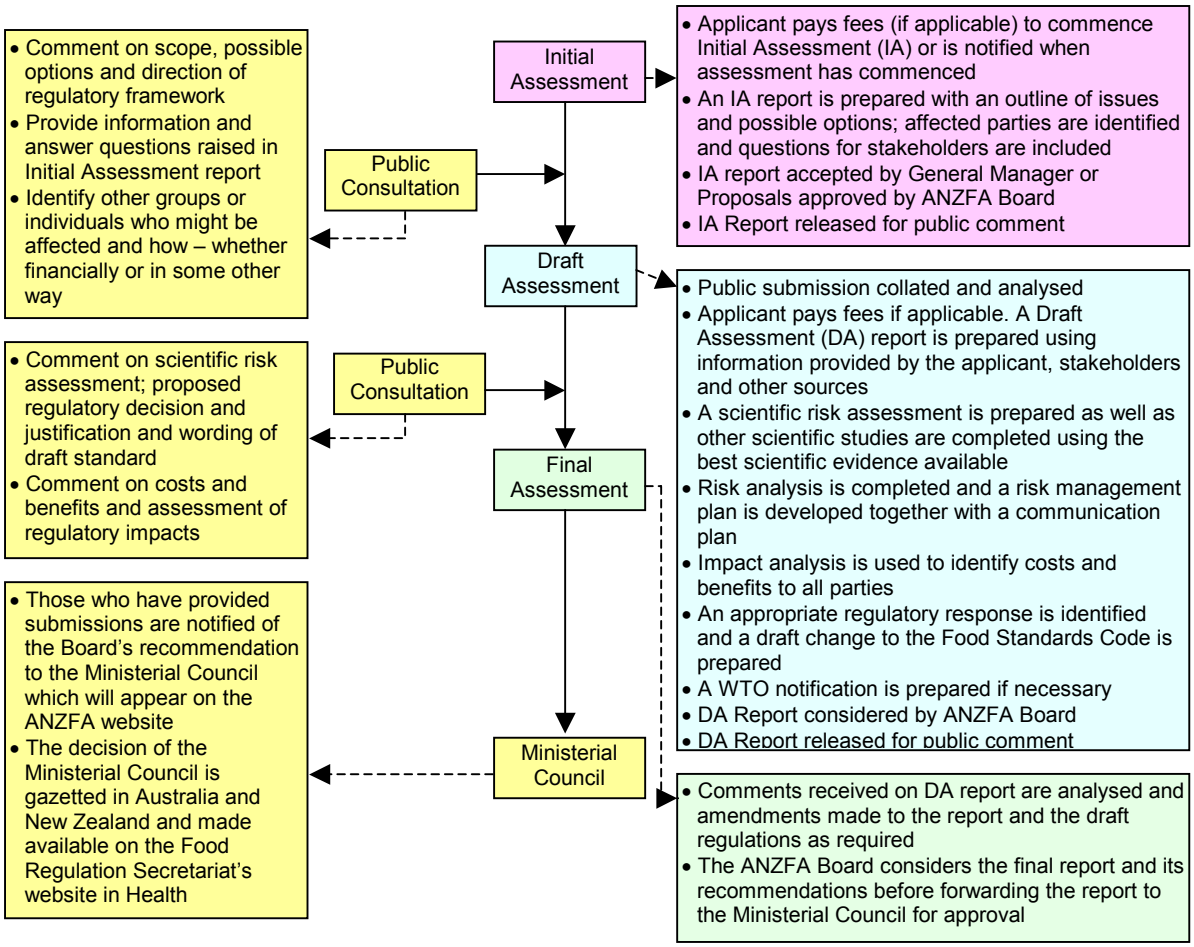
The Australia New Zealand Food Authority's (ANZFA) is a partnership between the Commonwealth Government, Australian State and Territory governments and the New Zealand Government. ANZFA is a bi-national, statutory body whose role, in association with others, is to protect the health and safety of people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



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EXECUTIVE SUMMARY

- This Application (A455) 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 has made a Sanitary and Phytosanitary notification to the World Trade Organization. No WTO member has made a submission.

1. Introduction

An Application was received from the NRA on 13 and 29 November 2001 and 10 January 2002, seeking amendment to Standard 1.4.2 of the *Food Standards Code*. The proposed amendments to the Standards 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

In summary, the proposed changes are:

- add MRLs for certain foods for the new chemicals, acetamiprid, dichlorprop, quinoxyfen and trifloxystrobin;
- add MRLs for certain foods for aminoethoxyvinylglycine, cadusafos, indoxacarb, metalaxyl, picolinafen and thiodicarb;
- change MRLs for certain foods for aminoethoxyvinylglycine, bifenthrin, myclobutanil, procymidone and spinosad; and
- add temporary MRLs for certain foods for azoxystrobin, butafenacil, dithiocarbamates, metalaxyl, procymidone, spinosad and tebufenozide.

1.2 Antibiotic MRLs

There are no MRLs for antibiotic residues in this Application.

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 <u>any</u> 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*.

3.1 Consideration of Issues under Section 10 of the *Australia New Zealand Food Authority Act 1991*

In developing or varying a food standard, ANZFA is required by its legislation to meet three primary objectives which are set out in Section 10 of the *Australia New Zealand Food Authority Act 1991*. These are:

3.1.1 The protection of public health and safety

The Chemicals and Non-prescription Medicines Branch of the TGA establish the ADI and where applicable the 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.

3.1.2 The provision of adequate information relating to food to enable consumers to make informed choices

This is not relevant for this Application.

3.1.3 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.

3.1.4 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.

3.1.5 The promotion of consistency between domestic and international food standards

This is addressed in section 7.

3.1.6 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.

3.1.7 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.

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. Evaluation of Issues Raised in Public Comment

Three submissions have been made in response to the preliminary assessment, they are:

- Dairy Food Safety Victoria, supported the proposed MRL for acetamiprid;
- Food Technology Association of Victoria, supported Option 1 to accept the requests made by the NRA and vary the *Food Standards Code*; and
- New Zealand Ministry of Health had no particular concerns about this Application.

6. Options and Impact Analysis

6.1 Options

Option 1: - to accept the requests made by the NRA and vary the *Food Standards Code*.
Option 2: - to reject the requests and make no changes to the *Food Standards Code*.

6.2 Affected parties

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

6.3 Costs and benefits

6.3.1 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.

6.3.2 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.

6.3.3 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.

6.3.4 Benefits of not accepting the application

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

6.4 Conclusion and recommended option

The inclusion of the proposed MRLs is consistent with the current registered uses of the chemical products. The dietary exposure assessments indicate that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. The NRA has already registered the chemical products and rejection of the MRLs would result in legally treated food not being able to be legally sold. Therefore, accepting the requested changes (Option 1) 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.

7. Consultation

7.1 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.

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.

This Application has been 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. No WTO member has made a submission.

7.2 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.

7.3 Imported Foods

As none of the proposed MRLs are reductions or deletions, the proposed MRLs cannot be considered to be trade restrictive.

8. Conclusion and Recommendation

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 chemicals in this application and 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.

9. 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.

Submissions

No submissions on this matter are sought as the Authority has completed its assessment and the matter is now with the Australia New Zealand Food Standards Council for consideration.

Further Information

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

Australia New Zealand Food Authority
PO Box 7186

Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2258
email: slo@anzfa.gov.au

Australia New Zealand Food Authority

PO Box 10559

The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
email: nz.reception@anzfa.gov.au

Assessment reports are available for viewing and downloading from the ANZFA website **www.anzfa.gov.au** . People without access to internet facilities may request paper copies of reports from the Information Officer.

ATTACHMENTS

1. The draft variation 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. Dietary Exposure Assessment.
4. Statement of Reasons
5. Summary of Submissions Received
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 -*

ACETAMIPRID *COMMODITIES OF PLANT ORIGIN*: ACETAMIPRID *COMMODITIES OF ANIMAL ORIGIN*: SUM OF ACETAMIPRID AND N-DIMETHYL ACETAMIPRID ((E)-N^1-[(6-CHLORO-3-PYRIDYL)METHYL]-N^2-CYANOACETAMIDINE), EXPRESSED AS ACETAMIPRID	
COTTON SEED	T0.05
CUCUMBER	T0.2
EDIBLE OFFAL (MAMMALIAN)	T*0.05
EGGS	T*0.01
MEAT (MAMMALIAN)	T*0.01
MILKS	T*0.01
POTATO	T*0.01
POULTRY, EDIBLE OFFAL OF	T*0.05
POULTRY MEAT	T*0.01
TOMATO	T0.1
DICHLORPROP DICHLORPROP	
CITRUS FRUITS	T0.1
PICOLINAFEN *COMMODITIES OF PLANT ORIGIN*: PICOLINAFEN *COMMODITIES OF ANIMAL ORIGIN*: SUM OF PICOLINAFEN AND 6-[3-TRIFLUOROMETHYL) PHENOXY]-2-PYRIDINE CARBOXYLIC ACID.	
FIELD PEA (DRY)	*0.02
QUINOXYFEN QUINOXYFEN	
DRIED GRAPES	T5
GRAPES	T2
TRIFLOXYSTROBIN SUM OF TRIFLOXYSTROBIN AND ITS ACID METABOLITE ((E,E)-METHOXYIMINO-[2-[1-(3-TRIFLUOROMETHYLPHENYL)-ETHYLIDENEAMINOOXYMETHYL]PHENYL] ACETIC ACID), EXPRESSED AS TRIFLOXYSTROBIN EQUIVALENTS	
DRIED GRAPES	2

Explanatory Note: These are new MRLs for the new chemicals and foods.

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

AMINOETHOXYVINYLGLYCINE AMINOETHOXYVINYLGLYCINE	
*STONE FRUITS	T0.2

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

* this entry was inserted as part of P261

[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 -*

AMINOETHOXYVINYLGLYCINE AMINOETHOXYVINYLGLYCINE	
NECTARINE	0.2
PEACH	0.2
STONE FRUITS [EXCEPT AS OTHERWISE LISTED]	T0.2
AZOXYSTROBIN AZOXYSTROBIN	
POPPY SEED	T*0.02
BUTAFENACIL BUTAFENACIL	
GRAPES	T*0.02
POME FRUITS	T*0.02
STONE FRUITS	T*0.02
CADUSAFOS CADUSAFOS	
CITRUS FRUITS	*0.01
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
PARSNIP	T1
INDOXACARB INDOXACARB	
LETTUCE, HEAD	3
TOMATO	0.2
WINE GRAPES	1
METALAXYL METALAXYL	
PODDED PEA (YOUNG PODS)	T1
POPPY SEED	*0.02

PROCYMIDONE PROCYMIDONE	
CARROT	T2
SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
POULTRY FAT/SKIN	T0.2
TEBUFENOZIDE TEBUFENOZIDE	
PERSIMMON, JAPANESE	T1
THIODICARB THIODICARB	
POTATO	0.1

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

[2.4] *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* -

AMINOETHOXYVINYLGLYCINE AMINOETHOXYVINYLGLYCINE	
APPLE	0.1
BIFENTHRIN BIFENTHRIN	
STONE FRUITS	T1
MYCLOBUTANIL MYCLOBUTANIL	
STRAWBERRY	2
PROCYMIDONE PROCYMIDONE	
SNOW PEAS	5
SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
EGGS	T0.05
POULTRY, EDIBLE OFFAL OF	T0.05

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

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.

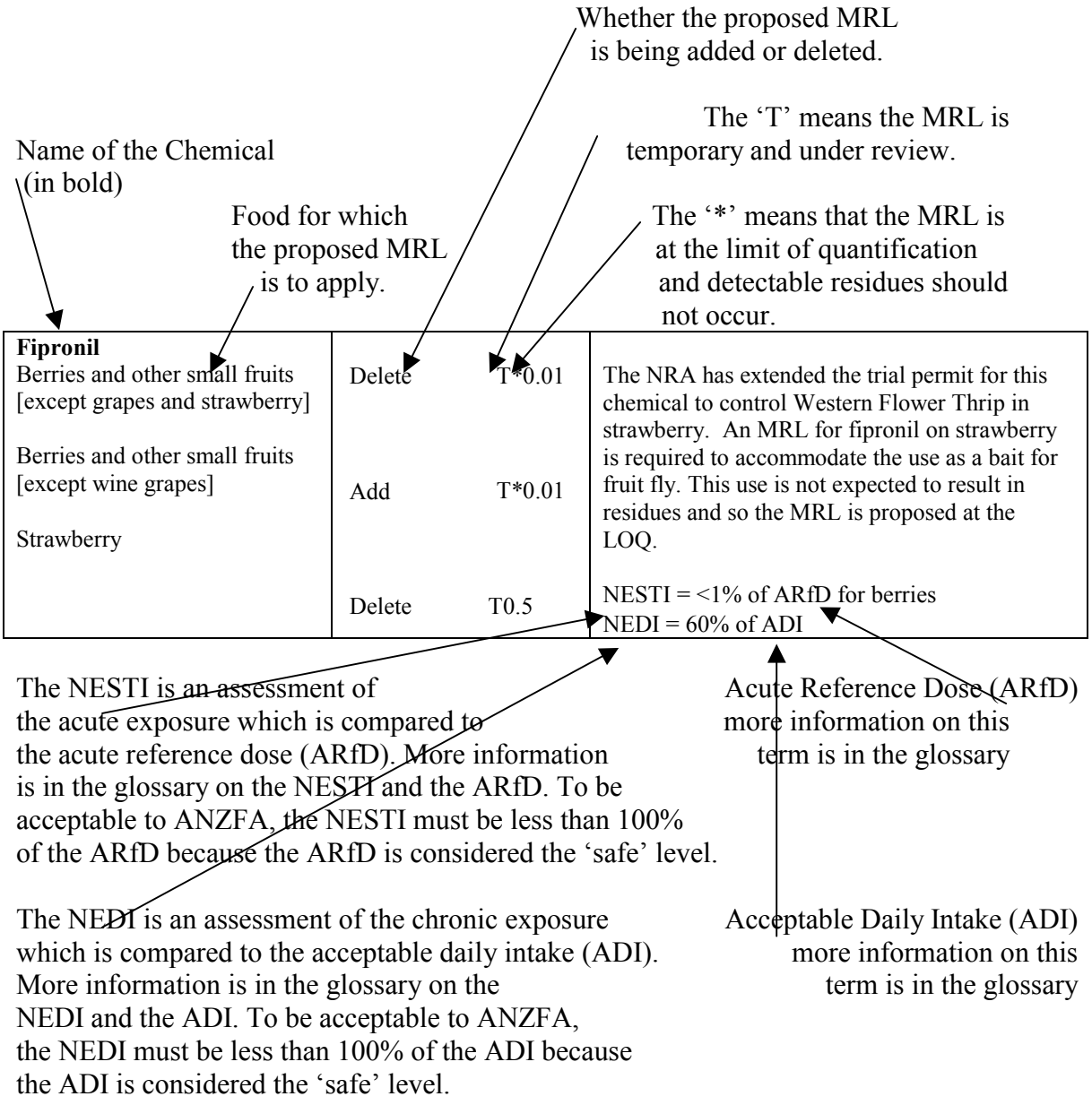
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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 acute reference dose (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 A455

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**
Acetamipirid			
Cotton seed	Add	T0.05	This chemical is used to control insects on vegetable crops.
Cucumber	Add	T0.2	
Edible offal (mammalian)	Add	T*0.05	
Eggs	Add	T*0.01	
Meat (mammalian)	Add	T*0.01	
Milks	Add	T*0.01	
Potato	Add	T*0.01	
Poultry, Edible offal of	Add	T*0.05	
Poultry meat	Add	T*0.01	
Tomato	Add	T0.1	NEDI = <1% of ADI NESTI = <1% of ARfD
Aminoethoxyvinylglycine			
Apple	Delete	T0.1	This chemical is used as a plant growth regulator for stone fruit to improve harvest management, fruit quality and storage potential.
	Substitute	0.1	
Nectarine	Add	0.2	
Peach	Add	0.2	
Stone fruits	Delete	T0.2	
Stone fruits [except nectarine and peach]	Add	T0.2	NEDI = 32% of ADI
Azoxystrobin			
Poppy seed	Add	T*0.02	The NRA has issued a trial permit to Tasmanian growers of poppies to use this chemical to prevent fungal growth on poppies. NEDI = <1% of ADI
Bifenthrin			
Stone fruits	Delete	T0.5	The NRA has issued a trial permit for this chemical to be used to control carpophilus beetle in stone fruit. NEDI = 89% of ADI (MRLs have been used to calculate the NEDI and the exposure would be much lower if typical residues were used)
	Substitute	T1	
Butafenacil			
Grapes	Add	T*0.02	This chemical is used to control weeds in dormant pome and stone fruit and grapevines. NEDI = 5% of ADI
Pome fruits	Add	T*0.02	
Stone fruits	Add	T*0.02	
Cadusafos			
Citrus fruits	Add	*0.01	This chemical is used to control insect pests in the soil around citrus trees. NEDI = <1% of ADI
Dichlorprop			
Citrus fruits	Add	T0.1	The NRA have issued a trial permit for this chemical to be used in field trials to control fruit drop in citrus fruit trees. NEDI = <1% of ADI

Dithiocarbamates Parsnip	Add	T1	The NRA have issued an off the label permit for mancozeb to be used to control a variety of fungal diseases in parsnips in Tasmania. In the 19th (1998) ATDS the estimated dietary exposure to thiram (the dithiocarbamate with the lowest ADI) was at 63% of the ADI. This MRL is for the use of the dithiocarbamate mancozeb, which has a higher ADI than thiram. Given the consumption of parsnips, the results from the 1998 ATDS, the fact that the trial permit is for the chemical mancozeb and on the basis of the ATDS and data from an Australian trial, the additional exposure to dithiocarbamate residues from parsnips would not result in an unacceptable risk to public health.
Indoxacarb Lettuce, Head Tomato Wine grapes	Delete Substitute Add Add	T3 3 0.2 1	This chemical is used to control insects on wine grapes, lettuce and tomatoes NEDI = 49% of ADI
Metalaxyl Podded pea (young pods) Poppy seed Vegetables [except fruiting vegetables, cucurbits and leafy vegetables] Vegetables [except fruiting vegetables, cucurbits; leafy vegetables and Podded pea (young pods)]	Add Add Delete Add	T1 *0.02 0.1 0.1	This chemical is used to control fungal diseases on vegetables and poppies NEDI = 4% of ADI
Myclobutanil Strawberry	Delete Substitute	T1 2	This chemical is used to control powdery mildew in strawberry. NEDI = 2% of ADI
Picolinafen Field pea (dry)	Add	*0.02	This chemical is used to control weeds in field pea crops. NEDI = 2% of ADI
Procymidone Carrot Snow peas	Add Delete Substitute	T2 T5 5	This chemical is used to control fungal diseases in carrots and snow peas. NEDI = 20% of ADI
Quinoxyfen Dried grapes Grapes	Add Add	T5 T2	This chemical is used to treat powdery mildew in grapes. NEDI = <1% of ADI
Spinosad Eggs Poultry, Edible offal of Poultry fats/skin	Delete Substitute Delete Substitute Add	*0.01 T0.05 *0.01 T0.05 T0.2	The NRA has issued a trial permit for this chemical to be used to control litter beetle and flies in poultry sheds. NEDI = 11% of ADI

Tebufenozide Persimmon, Japanese	Add	T1	This chemical is used to control insects on persimmons NEDI = 11% of ADI
Thiodicarb Potato	Add	0.1	This chemical is used to control Heliothis on potato crops. NEDI = 84% of ADI. MRLs have been used to calculate the NEDI; the exposure would be much lower if typical residues were used. In addition, this calculation uses the MRLs for both thiodicarb and methomyl because the metabolism of these compounds is similar. Methomyl has a lower ADI than thiodicarb and this lower ADI has been used in the combined NEDI. Where MRLs are established for both compounds the higher MRL has been used. NESTI = 3% of the ARfD
Trifloxystrobin Dried grapes	Add	2	This chemical is used to control powdery and downy mildew in table grapes. NEDI = 2% of ADI

ATTACHMENT 3

DIETARY EXPOSURE ASSESSMENT

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code, 1994* 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 responsibility is to ensure that the residues in food resulting from the use of agricultural and veterinary chemical products do not represent an unacceptable risk to public health and safety.

Comparing the dietary exposure with the relevant health standard assesses the potential public health implications. There are a number of methods for estimating dietary exposure based on the type of information that is available. In this application, ANZFA considered the National Estimated Daily Intake (NEDI) and the National Estimated Short Term Intake (NESTI).

National Estimated Daily Intake

The NEDI may represent a more realistic estimate of dietary exposure if the data are available and it 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).

The chronic dietary risk estimated by the NEDI calculation encompasses all registered/temporary uses of MRLs and dietary intake data from the 1995 National Nutrition Survey of Australia. The calculation has been made in accordance with the Guidelines for predicting dietary intake of pesticide residues (revised) (World Health Organization, 1997).

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.

ANZFA considers that the dietary exposure to the residues of a chemical is acceptable where the best estimate of dietary exposure does not exceed or is less than the ADI.

National Estimated Short Term Intake

The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an acute reference dose (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.

The NESTI calculation incorporates a large portion (97.5 percentile) of 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) that represents typical residues 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.

ANZFA has used the ARfD set by the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey (NNS) and the MRL when the STMR is not available to calculate the NESTIs. The 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. 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.

Food Consumption Data

The NRA and ANZFA have 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 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-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 was reported.
A computer program developed by ANZFA derives raw commodity consumption data used in the NRA dietary exposure assessments. The program accesses the 13,858 individual dietary records from the 1995 NNS, and applies recipes to all mixed foods consumed by each individual to enable the total amounts of raw commodity equivalents consumed per individual person to be calculated. Population statistics (mean consumption, all respondents) are then derived from these individual raw commodity totals for use in NRA dietary exposure assessments.

However, for all new chemicals, review chemicals and those where the initial dietary exposure assessment based on mean consumption data appears to approach or exceed the ADI, the ANZFA computer program is used to calculate the total dietary exposure to a given chemical for each individual in the survey. Population statistics such as mean chemical exposure are then derived, thus taking into account as much as possible, individual dietary patterns from a diverse and representative sample of the Australian population. This program also enables high consumers of a given chemical to be identified, as well as the major foods contributing to total dietary exposure for that chemical.

ATTACHMENT 4

STATEMENT OF REASONS

APPLICATION A455 – MAXIMUM RESIDUE LIMITS

FOR RECOMMENDING A VARIATION TO THE *FOOD STANDARDS CODE*

This Application (A455) 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.

There are no proposed MRLs for antibiotic residues in this application.

ANZFA has before it Application A455.

ANZFA has completed a Final Assessment (Inquiry s.17) of the Application, and prepared draft variations to Standard 1.4.2 in Volume 2 of the *Food Standards Code*.

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 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 not 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 has been 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. No WTO member has made a submission.

DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

Please see Attachment 1 of the Final Assessment Report.

ATTACHMENT 5

SUMMARY OF PUBLIC SUBMISSIONS

Submitter	Comments raised
Dairy Food Safety Victoria	Supported the proposed MRL for acetamiprid.
Food Technology Association	The Technical Sub-committee of the Association accepted this application without further comment.
New Zealand Ministry of Health	Had no particular concerns about this application.

ATTACHMENT 6

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*
FTA	Food Technology Association
JETACAR	Joint Expert Technical Advisory Committee on Antibiotic Resistance
LOQ	Limit of Quantification
MRL	Maximum Residue Limit
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short Term Intake
NH&MRC	National Health and Medical Research Council
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