09/02
8 May 2002

FINAL ASSESSMENT REPORT
[INQUIRY – S.17]

APPLICATION A450

MAXIMUM RESIDUE LIMITS

EXECUTIVE SUMMARY

- This Application (A450) seeks to amend Maximum Residue Limits (MRLs) for agricultural and veterinary chemicals in the *Food Standards Code*.

- This Application 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 chemicals in agricultural and veterinary use in Australia.

- On 24 November 2000, the Australia New Zealand Food Standards Council (ANZFSC) adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). Subsequently, all applications to amend MRLs will now be incorporated into Volumes 1 and 2 of the *Food Standards Code* (Standard A14 and Standard 1.4.2 respectively). 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. Australia and New Zealand separately and independently develop MRLs for agricultural and veterinary chemicals in food.

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

- 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 Agricultural and Veterinary Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this application.

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

- ANZFA is satisfied from the accompanying dietary modelling performed that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

- None of ANZFA's section 10 objectives are compromised by the proposed changes. The requested variations to the *Food Standards Code* should commence on gazettal.

- The Regulation Impact Assessment supports the requested MRLs. ANZFA considers that this application raises matters that constitute a potential Sanitary and Phytosanitary matter and raised a World Trade Organization (WTO) notification at Initial Assessment. No WTO Member has made a submission on this application.

1. ISSUES

The NRA has registered or varied the registration of non-antibiotic agricultural and veterinary chemicals for the uses associated with the MRLs in Application A450 and is now seeking to amend the MRLs in the *Food Standards Code* to:

- add new MRLs for the new chemicals iodosulfuron methyl and trifloxysulfuron sodium;

- add MRLs for certain foods for aldicarb, buprofezin, cyprodinil, dithiocarbamates and fenhexamid;

- change MRLs for certain foods for abamectin, aldicarb, bitertanol, buprofezin, cyanamide, dithiocarbamates, fenhexamid, fipronil, fluazinam, isoxaflutole, pyrimethanil, quizalofop-ethyl and spinosad;

- delete MRLs for certain foods for aldicarb, dithiocarbamates and fipronil; and

- add temporary MRLs for certain foods for chlorothalonil, chlorpyrifos, fenthion , fluazifop-butyl, glufosinate-ammonium, methidathion and pendimethalin .

ANZFA has provided specific details of the proposed MRL changes in the 'Summary of Proposed MRLs for A450' (Attachment 2).

1.1 Antibiotic MRLs

There are no MRLs for antibiotic residues in this Application.

2. BACKGROUND

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.

2.1 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 it registers 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 treated 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.

2.2 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 ANZFSC 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.

2.3 Food Standards-setting in Australia and New Zealand

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 food standards setting system. Australia and New Zealand separately and independently develop MRLs for agricultural and veterinary chemicals in food.

2.4 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 A14 or 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.

2.5 *Food Standards Code*

On 24 November 2000, the ANZFSC adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). Subsequently all applications to amend MRLs will now be incorporated into Volumes 1 and 2 of the *Food Standards Code* (Standard A14 and Standard 1.4.2 respectively). Consequently all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

2.6 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 A450 (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.

2.7 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 A450 (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.

3. OBJECTIVE

The objective of the proposed amendment in this application is to allow the legal sale under food legislation of legally treated produce. The NRA has already registered or varied the registration of specific chemical products under the NRA's legislation, and now seeks, by way of this Application to include the relevant MRLs in to the *Food Standards Code*.

4. 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.

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

4.1 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.

4.2 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).

4.3 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 and the NRA have used the ARfD 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 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.

4.4 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 National Nutrition Survey (NNS). The Australian Bureau of Statistics with the Commonwealth Department of Health and Age Care undertook the NNS survey over a 12-month period (1995-early 1996). The sample of 13,858 respondents aged two 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.

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.

5. EVALUATION OF ISSUES RAISED IN RESPONSE TO THE DRAFT ASSESSMENT REPORT

The submissions made in response to the draft assessment expressed concerns about:

- the timetable for comment; and
- the trade implications of reducing and deleting MRLs for importers of food.

Each of these is examined in turn below.

5.1 Timetable for comment

The submission from the National Council of Women of Australia expressed concerns about the timetable for comment on Application A450. ANZFA has statutory timeframes for progressing applications and these timeframes mean that ANZFA must limit the amount of time for which public comment can be accepted. This means that ANZFA normally allows four weeks for public comment on applications. However, ANZFA recognised that the public consultation for the MRLs associated with this Application was undertaken during the Christmas/New Year period and arranged for the public comment period to extend to six weeks.

In addition, ANZFA must progress MRL applications in a timely manner, particularly when it is recognised that the use of the chemical products has already been registered and as a result producers could potentially be producing food containing residues in excess of the existing MRLs.

In summary, the timeframe for comment is a compromise between allowing sufficient time for the community to comment on the MRLs, and ANZFA complying with statutory timeframes and progressing the MRLs in a timely manner to minimise disruption to producers.

5.2 Trade implications of reducing and deleting MRLs for importers of food

The submission from the Food Safety and Surveillance Section of the Commonwealth Department of Health and Ageing expressed concerns about the effect of the reductions and deletions of MRLs and the resultant possible trade implications for importers of food. However, no importer of foods or World Trade Organization member has made a submission or expressed concerns about any proposed MRLs in this Application including the deletions and reductions.

6. REGULATION IMPACT ASSESSMENT

6.1 Objective

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.

6.2 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*.

6.3 Affected parties

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

6.4 Costs and benefits

6.4.1 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 and importers may have costs associated with compliance and enforcement of MRLs following the proposed amendments;
- importers will no longer be able to rely on existing MRLs; and
- 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.

6.4.2 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.

6.4.3 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.

6.4.4 Benefits of not accepting the Application

- importers may potentially benefit by filling a possible domestic production shortfall if domestic agricultural productivity is reduced; and

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

6.5 Conclusion and recommended option

The inclusion of the proposed MRLs is consistent with the current registered uses of 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, 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. 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 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 us, and it is the registered conditions of use that protect human, animal and plant health, and the environment.

MRLs also ensure that the residues of chemicals are minimised consistent with the effective use of chemical products to control pests and diseases, and act as trading standards.

This Application contains variations to MRLs that are included 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.

ANZFA made a WTO notification at Initial/Draft Assessment. No WTO member has made a submission on this application.

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. The following table sets out the proposed MRLs in the NRA application which are more restrictive than the relevant Codex MRL.

Chemical Food	**Proposed MRL mg/kg**	**Codex MRL mg/kg**
Aldicarb Cereal grains	Deletions of existing MRLs for cereal grains and grapes (therefore no detectable residues are permitted in these commodities)	Barley 0.02 Maize 0.05 Wheat 0.02
Grapes	(As above)	Grapes 0.2
Sugar cane	*0.02	Sugar cane 0.1

No submissions were received on the effect of the proposed MRLs on the importation of the relevant foods.

7.5.4 Imported Foods

The following table lists the quantities of foods that have been imported to Australia in 1999 and 2000. These data are for foods for which reductions and deletions of MRLs are proposed.

Chemical Food	**1999**	**2000**
Aldicarb		
Cereal grains	7,447 tonnes	7,447 tonnes
Grape	1038 kg	N/A
(including wine)	14,705 kilolitres	13,025 kilolitres
Potato	1,102 tonnes	1,946 tonnes
Strawberry	516 tonnes	589 tonnes
Strawberry in liquid state	72,000 litres	26,000 litres
Bitertanol		
Strawberry	516 tonnes	589 tonnes
Strawberry in liquid state	720 litres	260 litres
Mancozeb (Dithiocarbamates)		
Papaya (Paw Paw)	1665 kg	1600 kg
Buprofezin		
Citrus fruits	3,947 tonnes	4,170 tonnes
Fipronil		
Strawberry	516 tonnes	589 tonnes
Strawberry in liquid state	720litres	260 litres
Pyrimethanil		
Tomato	4,091 tonnes	14,184 tonnes
Spinosad		
Pome fruits	169 tonnes	134 tonnes

No submissions were received on the effect of the proposed reductions and/or deletions of MRLs for imported foods.

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 has invited written submissions for the purpose of the Inquiry under s. 17(3)(c) of the ANZFA Act, and in section 5 of this document, has had 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 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 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. 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 7.5.3 above.

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 regulation impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs.

This 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.

9. CONCLUSION

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.

10. 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: anzfa.nz@anzfa.gov.au

Assessment reports are available for viewing and downloading from the ANZFA website www.anzfa.gov.au or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@anzfa.gov.au.

11. ATTACHMENTS

1. Draft Variation to the *Food Standards Code*.
2. Summary of MRLs
3. Statement of Reasons.
4. Summary of Public Submissions Received at Draft Assessment.

ATTACHMENT 1

DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

To commence: On gazettal

[1] ***Standard A14 of*** *Volume 1 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 -*

Chemical Food	MRL
Iodosulfuron methyl	
Edible offal (mammalian)	0.01
Eggs	0.01
Meat (mammalian) (in the fat)	0.01
Milks	0.01
Poultry, edible offal of	0.01
Poultry meat (in the fat)	0.01
Wheat	0.01
Trifloxysulfuron sodium	
Cotton seed	0.01
Cotton seed oil, crude	0.01
Sugar cane	0.01

Explanatory Note: These are new MRLs for the new chemicals, Iodosulfuron methyl and Trifloxysulfuron sodium and foods.

[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 -*

Chemical Food	MRL
Aldicarb	
Cereal grains	0.02
Grapes	0.05
Potato	0.2
Strawberry	0.2
Buprofezin	
Meat (mammalian)	0.05
Fipronil	
Berries and other small fruits [except grapes and strawberry]	0.01
Strawberry	0.5

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 the chemical (shown in bold type), the food and the maximum residue limit for that food -*

Chemical Food	MRL
Aldicarb	
Edible offal (mammalian)	0.01
Meat (mammalian)	0.01
Milks	0.01
Buprofezin	
Mango	0.2
Meat (mammalian) (in the fat)	0.05
Chlorothalonil	
Berries and other small fruits [except blackcurrant; grapes]	10
Chlorpyrifos	
Olives	0.05
Cyanamide	
Stone fruits	0.05
Cyprodinil	
Stone fruits	0.5
Fenhexamid	
Dried grapes	20
Edible offal (mammalian)	2
Grapes	10
Meat (mammalian) (in the fat)	0.05
Milks	0.01
Fenthion	
Olives	1
Olive oil, crude	3
Fipronil	
Berries and other small fruits [except wine grapes]	0.01
Fluazifop-butyl	
Olives	0.05
Fluazinam	
Pome fruits	0.05
Glufosinate and Glufosinate ammonium	
Olives	0.1
Methidathion	
Olives	1
Olive oil, crude	2
Pendimethalin	
Olives	0.05

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 -*

Chemical Food	MRL
Bitertanol	
Strawberry	0.05
Buprofezin	
Citrus fruits	2
Dithiocarbamates	
Papaya (Pawpaw)	5
Fenhexamid	
Strawberry	10
Pyrimethanil	
Potato	0.01
Tomato	1
Quizalofop-ethyl	
Pulses	0.2
Spinosad	
Grapes	0.5
Pome fruits	0.2

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

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

[2.1] *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 -*

IODOSULFURON METHYL IODOSULFURON METHYL	
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT (IN THE FAT)	*0.01
WHEAT	*0.01
TRIFLOXYSULFURON SODIUM TRIFLOXYSULFURON	
COTTON SEED	T*0.01
COTTON SEED OIL, CRUDE	T*0.01
SUGAR CANE	T*0.01

Explanatory Note: These are new MRLs for the new chemicals, Iodosulfuron methyl and Trifloxysulfuron sodium and foods.

[2.2] *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 -*

ALDICARB SUM OF ALDICARB, ITS SULFOXIDE AND ITS SULFONE, EXPRESSED AS ALDICARB	
CEREAL GRAINS	*0.02
GRAPES	0.05
POTATO	0.2
STRAWBERRY	0.2
BUPROFEZIN BUPROFEZIN	
MEAT (MAMMALIAN)	T*0.05
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)	
BERRIES AND OTHER SMALL FRUITS [EXCEPT GRAPES AND STRAWBERRY]	T*0.01
STRAWBERRY	T0.5

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

[2.3] *inserting in 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 -*

ALDICARB SUM OF ALDICARB, ITS SULFOXIDE AND ITS SULFONE, EXPRESSED AS ALDICARB	
EDIBLE OFFAL (MAMMALIAN)	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
BUPROFEZIN BUPROFEZIN	
MANGO	0.2
MEAT (MAMMALIAN) (IN THE FAT)	*0.05

CHLOROTHALONIL CHLOROTHALONIL	
BERRIES AND OTHER SMALL FRUITS [EXCEPT BLACKCURRANT AND GRAPES]	T10
CHLORPYRIFOS CHLORPYRIFOS	
OLIVES	T*0.05
CYANAMIDE CYANAMIDE	
STONE FRUITS	T*0.05
CYPRODINIL CYPRODINIL	
STONE FRUITS	T0.5
FENHEXAMID FENHEXAMID	
DRIED GRAPES	20
EDIBLE OFFAL (MAMMALIAN)	2
GRAPES	10
MEAT (MAMMALIAN) (IN THE FAT)	*0.05
MILKS	*0.01
FENTHION SUM OF FENTHION, ITS OXYGEN ANALOGUE, AND THEIR SULFOXIDES AND SULFONES, EXPRESSED AS FENTHION	
OLIVES	T1
OLIVE OIL, CRUDE	T3
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)	
BERRIES AND OTHER SMALL FRUITS [EXCEPT WINE GRAPES]	T*0.01
FLUAZIFOP-BUTYL FLUAZIFOP-BUTYL	
OLIVES	T0.05
FLUAZINAM FLUAZINAM	
POME FRUITS	T*0.05

GLUFOSINATE AND GLUFOSINATE-AMMONIUM SUM OF GLUFOSINATE-AMMONIUM AND 3-[HYDROXY(METHYL)-PHOSPHINOYL] PROPIONIC ACID, EXPRESSED AS GLUFOSINATE (FREE ACID)	
OLIVES	T0.1
METHIDATHION METHIDATHION	
OLIVES	T1
OLIVE OIL, CRUDE	T2
PENDIMETHALIN PENDIMETHALIN	
OLIVES	T*0.05

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

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 (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.

LOQ – Limit of Quantification – The LOQ is the lowest concentration of a chemical residue contaminant than can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulation method of analysis

NTMDI - National Theoretical Maximum Dietary Intake - The NTMDI is a prediction of the long-term daily intake of an agricultural or veterinary chemical and is calculated by multiplying the MRLs established and proposed for a chemical by the average daily consumption for each food commodity across the whole population and summing the products. While a useful screening tool, the NTMDI is an overestimate of the true chemical residue intake because it assumes that the entire national crop is treated with a chemical and that all the treated produce contains residues equivalent to the MRL.

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 chemical 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.

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;

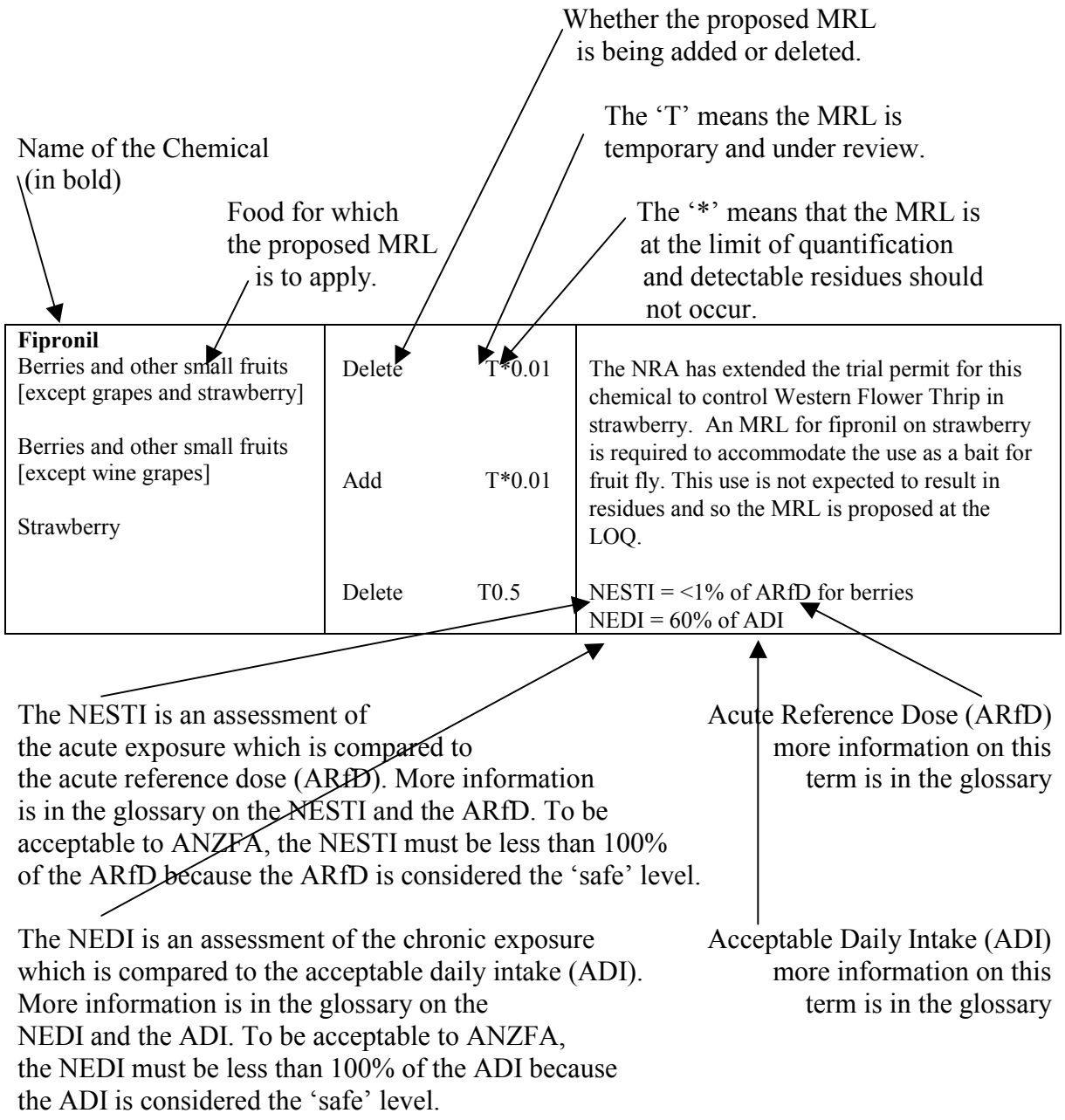
- the supervised trials median residue (STMR) that represents typical residues in an edible portion resulting from the maximum permitted agricultural or veterinary chemical use pattern;

- processing factors which affect changes from the raw commodity to the consumed food; and

- the variability factor.

ANZFA and the NRA have used the 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 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 is less than the ARfD.

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 REQESTED MRLS FOR APPLICATION A450

Glossary;

1. **ADI** Acceptable Daily Intake.
2. **ARfD** Acute Reference Dose
3. **ATDS** Australian Total Diet Survey
4. **LOQ** Limit of 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 Peppers	Delete T0.02 Substitute 0.02	This chemical is used to control the motile stages of mites, leaf miners, suckers and Colorado beetle. NEDI = 48% of ADI

Aldicarb Cereal grains Edible offal (mammalian) Grapes Meat (mammalian) Milks Potato Strawberry Sugar cane	Delete Add Delete Add Add Delete Delete Delete Substitute	*0.02 *0.01 0.05 *0.01 *0.01 0.2 0.2 0.02 *0.02	This chemical is used to control nematodes in crops, The NRA has registered uses for aldicarb on citrus (orange and mandarin), cotton and sugar cane. It is proposed that the MRLs for grapes, cereal grains, potato and strawberry will be deleted. This chemical is not used directly on animals in any situation. The animal commodity MRLs are proposed to address residues that may occur through animals consuming feed containing aldicarb residues. It should be noted that the animal commodity MRLs are proposed to be 'set at or about the LOQ'. Based on predicted animal dietary burdens and evaluation of animal feeding studies there is no reasonable expectation of residues of this chemical occurring in animal tissues or milk and consideration of acute dietary exposure is not required. The NRA has concluded that there is no reasonable expectation that aldicarb residues will occur in cane stalks or any edible commodity derived thereof and consideration of acute dietary exposure is not required. NEDI = 14% of ADI
Bitertanol Strawberry	Delete Substitute	T*0.1 *0.05	This chemical is used to control fungal pathogens in strawberries. In the 19th (1998) ATDS the estimated dietary exposure to bitertanol was less than 1% of the ADI for the whole population. Given the level of consumption of strawberries, the results from the 1998 ATDS and the fact that the proposed MRL has been set at the LOQ, the exposure to bitertanol from strawberries would not result in an unacceptable risk to public health and safety. NEDI = 22% of ADI
Buprofezin Citrus fruits Edible offal (mammalian) Mango Meat (mammalian) Meat (mammalian) (in the fat) Milks	Delete Substitute Delete Substitute Add Delete Add Delete Substitute	T3 2 T*0.05 *0.05 0.2 T*0.05 *0.05 T*0.01 *0.01	This chemical is used to control white fly in citrus, cotton and vegetables as well as scale insects and mealy bugs in citrus and mango. This chemical is not used directly on animals in any situation. The animal commodity MRLs are proposed to address residues that may occur through animals consuming feed containing buprofezin residues. It should be noted that these proposed MRLs would be set 'at or about the LOQ' as detectable residues are not expected. NEDI = 2% of ADI

Chlorothalonil Berries and other small fruits [except blackcurrant and grapes]	Add T10	The NRA has granted a permit to use the chemical to control fungal pathogens in berries. In the 19th (1998) ATDS the estimated dietary exposure to chlorothalonil was less than 1% of the ADI for the whole population. Given the level of consumption of berries, the results from the 1998 ATDS and the fact that this is a trial permit, the additional exposure to chlorothalonil from berries would not result in an unacceptable risk to public health and safety. NEDI = 95% of ADI
Chlorpyrifos Olives	Add T*0.05	The NRA has granted a permit to use this chemical to control insects on olive trees in non-bearing situations or as a butt treatment only. Measurable residues of chlorpyrifos are unlikely to occur in olive fruit or olive oil when the chemical is used in this manner. In the 19th (1998) ATDS the estimated dietary exposure to chlorpyrifos was less than 3% of the ADI for 2 year olds and less than 1% of the ADI for the adult population. Given the results from the 1998 ATDS and the fact that this is a trial permit where detectable residues are not expected, the additional exposure to chlorpyrifos from olives would not result in an unacceptable risk to public health and safety. NESTI = <1% of ARfD NEDI = 84% of ADI
Cyanamide Stone fruits	Add T*0.05	The NRA has granted a permit to use this chemical on low chill stone fruit to trigger flowering in areas where insufficient chilling results in reduced flowering. NEDI = 4% of ADI
Cyprodinil Stone fruits	Add T0.5	The NRA has granted a permit for a production trial to use this chemical to control Blossom Blight/Brown Rot in stone fruit NEDI = 24% of ADI
Mancozeb (Dithiocarbamates) Papaya (Pawpaw)	Delete T30 Substitute 5	This chemical is used to control fungal pathogens in fruit and vegetables. In the 19th (1998) ATDS the estimated dietary exposure to thiram (the dithiocarbamate with the lowest ADI) was at 63% of the ADI for 2 year olds and 20% of ADI for adult males. This MRL is for the use of the dithiocarbamate, mancozeb which has higher ADI than thiram. Given the results from the 1998 ATDS, the additional exposure to mancozeb would not result in an unacceptable risk to public health and safety. NEDI = 82% of ADI

Fenhexamid Dried grapes Edible offal (mammalian) Grapes Meat (mammalian) (in the fat) Milks Strawberry	Add Add Add Add Add Delete Substitute	20 2 10 *0.05 *0.01 T5 10	This chemical is used to control fungal pathogens. This chemical is not used directly on animals in any situation. The animal commodity MRLs are proposed to address residues that may occur through animals consuming feed containing fenhexamid residues. It should be noted that these proposed MRLs are proposed to be set at or about the LOQ and detectable residues are not expected. NEDI = 3% of ADI
Fenthion Olives Olive oil, crude	Add Add	T1 T3	The NRA has granted a permit to allow the use of this chemical to be used to control insect pests in olives. NESTI for Olives = 17% of ARfD NESTI for Olive oil = 33% of ARfD NEDI = 23% of ADI
Fipronil Berries and other small fruits [except grapes and strawberry] Berries and other small fruits [except wine grapes] Strawberry	Delete Add Delete	T*0.01 T*0.01 T0.5	The NRA has extended the trial permit for this chemical to control Western Flower Thrip in strawberry. An MRL for fipronil on strawberry is required to accommodate the use as a bait for fruit fly. This use is not expected to result in residues and so the MRL is proposed 'at or about the LOQ'. NESTI = <1% of ARfD for berries NEDI = 60% of ADI
Fluazifop-butyl Olives	Add	T0.05	The NRA has granted a permit for the use of this chemical in olive groves to control annual and perennial grass weeds. NEDI = 69% of ADI
Fluazinam Pome fruits	Add	T*0.05	The NRA has granted a permit for this chemical to be used to control fungal pathogens on pome fruit trees. NEDI = <1% 0f ADI
Glufosinate-ammonium Olives	Add	T0.1	The NRA has granted a permit for the use of this chemical in olive groves to control grass and broadleaf weeds. NEDI = 19% of ADI

Iodosulfuron methyl Edible offal (mammalian) Eggs Meat (mammalian) (in the fat) Milks Poultry, edible offal of Poultry meat (in the fat) Wheat	Add Add Add Add Add Add Add	*0.01 *0.01 *0.01 *0.01 *0.01 *0.01 *0.01	This chemical is used to control weeds in wheat. Finite residues were not detected in wheat grain. Residue data provided with the application indicate that residues greater than the LOQ are unlikely to occur in wheat grain. This chemical is not used directly on animals in any situation. The animal commodity MRLs are proposed to address residues that may occur through animals consuming feed containing iodosulfuron methyl residues. It should be noted that the animal commodity MRLs are proposed to be set 'at or about the LOQ' and detectable residues are not expected. NEDI = <1% of ADI
Isoxaflutole Chick pea (dry) Edible offal (mammalian) Meat (mammalian) Milks Sugar cane	Delete Substitute Delete Substitute Delete Substitute Delete Substitute Delete Substitute	T*0.03 *0.03 T*0.05 *0.05 T*0.05 *0.05 T*0.05 *0.05 T*0.01 *0.01	This chemical is used to control grasses and broadleaf weeds in sugar cane and chickpeas. This chemical is not used directly on animals in any situation. The animal commodity MRLs are proposed to address residues that may occur through animals consuming feed containing isoxaflutole residues. It should be noted that the animal commodity MRLs are proposed to be 'set at or about the LOQ' and detectable residues are not expected. NEDI = 3% of ADI
Methidathion Olives Olive oil, crude`	Add Add	T1 T2	The NRA has granted a permit for this chemical to be used to control scale insects in olives. NESTI for Olives = 12% of ARfD NESTI for Olive oil = 15% of ARfD NEDI = 31% of ADI
Pendimethalin Olives	Add	T*0.05	The NRA has granted a permit for this chemical to be used to control annual grasses and broadleaf weeds in olive groves. NEDI = <1% of ADI
Pyrimethanil Potato Tomato	Delete Substitute Delete Substitute	T*0.01 *0.01 T2 1	This chemical is to be used to control Target spot in potatoes and tomatoes. NEDI = 3% of ADI
Quizalofop-ethyl Pulses	Delete Substitute	0.1 0.2	This chemical is used to control various annual and perennial grasses in a variety of crops. NEDI = 19% of ADI

Spinosad Grapes Pome fruits	 Delete Substitute Delete Substitute	 T0.1 0.5 T0.1 0.2	 This chemical is used to control various insect pests on grapes and pome fruits. NEDI = 6% of ADI
Trifloxysulfuron sodium Cotton seed Cotton seed oil, crude Sugar cane	 Add Add Add	 T*0.01 T*0.01 T*0.01	 The NRA has granted a permit to use this chemical to control broad leaf weeds and nutgrass in cotton and sugar cane crops. NEDI = <1% of the ADI

ATTACHMENT 3

STATEMENT OF REASONS

APPLICATION A450 – MAXIMUM RESIDUE LIMITS

FOR RECOMMENDING A VARIATION TO THE *FOOD STANDARDS CODE*

On the 17 July 2001, ANZFA received an Application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) seeking to amend Standards A14 and 1.4.2 for the *Food Standards Code*. The proposed amendments would align the Maximum Residue Limits (MRLs) for agricultural and veterinary chemicals in the *Food Standards Code* with the MRLs in the *NRA MRL Standard*.

This Application (A450) is a routine Application from the NRA, to update the *Food Standards Code* to reflect the current registration status of agricultural and veterinary chemical use in Australia.

The *Agreement between the Commonwealth of Australia and the Government of New Zealand to Establish a System for the Development of Joint Food Standards*, 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.

ANZFA has completed a Draft Assessment (Full Assessment - s.15) of the Application, and prepared draft variations to Standard A14 of Volume 1 and Standard 1.4.2 of 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 Ageing has undertaken an appropriate toxicological assessment of the chemical products and has established relevant acceptable daily intakes (ADI) and where applicable the acute reference dose.

- None of ANZFA's 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.

SUMMARY OF PROPOSED MRLS FOR A450

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. Additionally, 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 contains variations to MRLs that are included in the relevant 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.

ANZFA, at Initial/Draft assessment, made 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 made a submission.

DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

Please see Attachment 1 of the Final Assessment Report.

ATTACHMENT 4

SUMMARY OF PUBLIC SUBMISSIONS RECEIVED AT DRAFT ASSESSMENT

Submitter	Comments raised
Commonwealth Department of Health and Ageing	The Department supported the application and had some concerns about the effect of adopting MRLs that are lower than Codex Alimentarius Commission MRLs.
Department of Agriculture Fisheries and Forestry - Australia	The Department supported the Application
Food Technology Association	The Technical Sub-committee of the Association accepted this Application without further comment
National Council of Women of Australia	The Council was unable to supply a submission due to their offices being closed.