8 August 2001
02/02

INITIAL ASSESSMENT REPORT

APPLICATION A442

MAXIMUM RESIDUE LIMITS

Applicant: National Registration Authority for Agricultural and Veterinary Chemicals.

Date received: 9 May and 12 June 2001.

1 BACKGROUND

An application has been received from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) seeking amendment to Standards A14 and 1.4.2 for the *Food Standards Code*. The proposed amendments to Schedule 1 of the Standards would align Maximum Residue Limits (MRL) for non-antibiotic agricultural chemicals in the *Food Standards Code,* with the MRLs in the *NRA MRL Standard*.

1.1 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 their *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.

1.2 Maximum Residue Limits 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 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 treated produce to be legally sold, provided that the residues in the treated produce are less than or equal to 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.

1.3 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 assist in ensuring that residues are no higher than is necessary for effective control of pests and disease.

As stated above, the NRA includes MRLs in their *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 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.

1.4 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.

1.5 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 in 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 in New Zealand, which complies with the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard, 1999* can be legally sold in Australia.

1.6 Food Standards Code

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

1.7 MRLs for Permits

Many of the proposed MRLs in this application are temporary and are indicated by a 'T' in the Summary of the Requested MRLs for A442 (Attachment 1). 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 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 following amendments to the *Food Standards Code*.

This application seeks to include:

- **new** MRLs at the limit of quantification for a new chemical, butafenacil;

- **extensions of use for the chemicals** abamectin, bupirimate, captan, cyfluthrin, cypermethrin, dichlofluanid, dithiocarbamates, fenarimol, imazapic, imazapyr, methabenzthiazuron, metalaxyl, prochloraz, procymidone, pyrimethanil and triadimenol; and

- **changes** to existing MRLs for the dithiocarbamates and isoxaflutole.

More specific details of the proposed MRL changes are provided in the Summary of Proposed MRLs for A442 (Attachment 1).

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 use of the chemicals on commodities as outlined in this application. It is also the responsibility of the NRA to assess the efficacy of the chemical under Australian agricultural conditions. Full evaluation reports for individual chemicals are available upon request from the relevant Project Manager at ANZFA on +61 2 6271 2222.

3 DIETARY EXPOSURE ASSESSMENT

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code, 1994* (*Ag Vet Code Act*) requires the NRA to be satisfied that there will not be any appreciable risk to the consumer, to the person handling, applying or administering the chemical, to the environment, to the target crop or animal or to trade in an agricultural commodity. ANZFA's 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.

There are a number of methods for estimating dietary exposure based on the type of information that is available. The three that were considered in this application were the National Theoretical Maximum Daily Intake (NTMDI), the National Estimated Daily Intake (NEDI) and the National Estimated Short Term Intake (NESTI).

3.1 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 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.

ANZFA considers that the dietary exposure to the residues of a chemical is acceptable where the best estimate of dietary exposure is less than the ADI.

3.2 National Theoretical Maximum Daily Intake

The NTMDI is a prediction of the long-term daily intake of a pesticide 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.

$\mathbf{NTMDI} = \sum \mathbf{MRL_1} \times \mathbf{F_1}$, where
$\mathbf{MRL_1}$ = Maximum Residue Limit for a given food commodity (mg/kg)
$\mathbf{F_1}$ = National consumption of that food commodity per person (kg/day)

The NTMDI is calculated in milligrams of residue per person and expressed as a percent of the ADI, adjusting for the average bodyweight of the population.

The NTMDI is an overestimate of the true pesticide residue intake because it assumes that the entire national crop is treated with a pesticide and that the entire national crop contains residues equivalent to the MRL.
In reality, only a portion of a specific crop is treated with a pesticide; most treated crops contain residues well below the MRL at harvest; and residues are usually reduced during storage, preparation, commercial processing and cooking. It is also unlikely that every food for which an MRL is proposed will have been treated with the same pesticide over the lifetime of consumers.

As the NTMDI is a gross overestimate of dietary exposure, it is commonly used as a screening calculation. If the NTMDI does not exceed the ADI, it is highly unlikely that the ADI would ever be exceeded, even for high intake consumers.

3.3 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).

3.4 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 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.

3.5 National Estimated Short Term Intake

The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated based on consumption of raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis.

The NESTI calculation incorporates the large portion (97.5^{th} 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 pesticide use pattern;
- processing factors which affect changes from the raw commodity to the consumed food; and
- the variability factor.

ANZFA has used acute reference doses (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 is less than the ARfD.

3.6 Antibiotic MRLs

There are no MRLs for antibiotic residues in this application.

4 REGULATORY IMPACT ASSESSMENT

This Regulatory Impact Statement (RIS) is preliminary only and based on information provided by the applicant. The RIS identifies the affected parties, any alternative regulatory options and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make an assessment of this application will include the information from public submissions. This preliminary RIS invites public comment on these areas.

4.1 Objective

To ensure that the residues of agricultural and veterinary chemicals do not represent an unacceptable risk to the public health and safety while permitting the legal sale of food that has been legally treated.

4.2 Possible Options (Including Alternatives)

4.2.1 Option 1

Vary the *Food Standards Code* in accordance with the NRA's Application A442. The effect of this option would be that legally treated food could be legally sold or imported if it contained residues consistent with the MRLs in this application.

4.2.2 Option 2

Maintain the status quo and not include the MRLs in accordance with the NRA's application. The effect of this option would be that food could not be legally sold or imported if it contained residues greater than those currently stipulated in the *Food Standards Code*.

4.3 Identification of Affected Parties

The parties affected by this application include:

- Growers and producers of domestic and export food commodities;
- Consumers, including domestic and overseas customers;
- Importers and exporters of agricultural produce and foods; and
- Commonwealth, State and Territory agencies involved in monitoring agricultural and veterinary chemicals in food.

4.4 Potential Regulatory Impacts

In considering the regulatory impact of the options listed below, it needs to be noted that the inclusion of MRLs in the *Food Standards Code* only permits the treated food to be legally sold if it contains chemical residues that do not exceed the MRL for the specified chemical(s).

The inclusion of an MRL does not on its own permit or prohibit a particular chemical product from being used. This is regulated by other legislation.

The inclusion of MRLs in the *Food Standards Code* allows food producers to trade food that has been legally treated with registered agricultural and veterinary products. The use of agricultural and veterinary products provides effective pest and disease control and this potentially leads to improved productivity for producers, better quality food for consumers and more competitive primary industries.

Any MRL deletions or reductions have the potential to restrict the importation of foods and could potentially result in higher food costs and a reduced product range available to consumers, as foods containing residues that exceed the newer, lower MRLs could not be legally sold to consumers. To identify any restrictions and possible trade impacts, Codex MRLs and data on imported foods have been considered in assessing the reductions and deletions within this application.

Option 1: To Include the Proposed MRLs in the *Food Standards Code*:

Will:

- not result in an unacceptable risk to public health and safety;
- permit greater flexibility for producers and importers of food, as food may be legally permitted to contain residues up to the MRL permitted for that food;
- result in a slight impact on government monitoring programs, as more comprehensive monitoring may be needed; and
- potentially permit more variety and more competitively priced food for consumers as food treated with legally registered products can be legally sold.

On the basis of the dietary exposure assessments and information supplied by the NRA, ANZFA considers that the benefits of option 1 outweigh the direct and indirect cost to the community, Government and industry.

Option 2: Do not include the proposed MRLs in the *Food Standards Code*:

Will result in:

- a discrepancy between agricultural and food legislation in that the agricultural legislation will permit the use of agricultural and veterinary products but the food legislation would prohibit the sale of such legally treated food;
- potentially less flexibility for producers and importers as treated food may not be able to be legally sold; and
- the possibility of reducing the range and quality of foods for consumers as the treated food could not then be legally sold.

5 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.

5.1 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.

5.2 Paragraph 13(2)(b)

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

5.3 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.

5.4 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.

5.5 Paragraph 13(2)(e)

Other relevant matters for consideration by ANZFA are as follows.

5.5.1 Consideration of issues under Regulation 12 of the Australia New Zealand Food Authority Regulations 1994

Regulation 12a

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

Regulation 12b

ANZFA considers that this application will <u>not</u> confer an exclusive capturable commercial benefit on the applicant.

5.5.2 World Trade Organization Notification

As a member of the World Trade Organization (WTO) Australia is obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any

existing or imminent international standards and the proposed measure may have a significant effect on trade.

The MRLs prescribed in the *Australia New Zealand 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 disease. MRLs are also used as standards for the international trade in food.

This application contains a variation to an MRL that is 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. A WTO notification for this application will therefore be made following the endorsement of the Preliminary Assessment.

This application will be notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO SPS agreement because the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment.

5.5.3 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 only MRL proposed in the NRA application, which is more restrictive than the Codex MRL.

Chemical Food	**Proposed MRL**	**Codex MRL**	**Comments**
Fenarimol Berries and other small fruits [except grapes]	T0.1	1	Codex MRL is for Strawberries only

ANZFA requests comment as to any possible ramifications of the proposed change of this MRL.

6 CONCLUSION

The above application A442 fulfils the requirements for preliminary assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.*

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

Following its full assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry, which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A442** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Fax (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the authority by: **11 September 2001**.

SUMMARY OF PROPOSED MRLS

APPLICATION A442

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 on the basis of all the known facts at the time of the evaluation of the chemical. An ADI is expressed in milligrams of the chemical per kilogram of body weight.

LOQ - Limit of Quantification – The LOQ is the lowest concentration of an agricultural or veterinary chemical 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 than the NTMDI (see below) 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. However, 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.

NTMDI - National Theoretical Maximum Dietary Intake - The NTMDI is a prediction of the long-term daily intake of a pesticide 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 pesticide residue intake because it assumes that the entire national crop is treated with a pesticide and that all the treated produce contains residues equivalent to the MRL.

Glossary

1. **ADI** Acceptable Daily Intake.
2. **ATDS** Australian Total Diet Survey
3. **LOQ** Limit of Analytical Quantification.
4. **NEDI** National Estimated Daily Intake.
5. **NTMDI** National Theoretical Maximum Daily Intake
6. ***** MRL set at or about the limit of analytical determination.
7. **T** Temporary MRL

B2. DRAFTING ERRORS AND TECHNICAL CLARIFICATIONS			
Chemical Food	**MRL** **(gm/kg)**		**Information**
Dithiocarbamates			
Beans (dry)	Delete	0.5	The dithiocarbamate, mancozeb is used to control fungi in pulse crops. The 19th ATDS (1998) dietary exposure estimate for dithiocarbamates, as a percentage of the ADI is equivalent to 20% of ADI for adult males and up to 63% of the ADI for 2 year olds.† Mancozeb has an ADI which is 10 times higher than that for thiram. Given that there is very little change in the level of consumption of pulses as distinct from the consumption of the individual pulses and using the results from the 19th ATDS, ANZFA considers that there is not an unacceptable risk to public health and safety with the residues of mancozeb in pulses.
Broad beans (dry)(Faba bean)		0.5	
Chick-pea (dry)		T0.5	
Lentil (dry)		T0.5	
Peas (dry)		T0.5	
Pulses	Add	0.5	
Fenarimol			
Currant, black	Delete	T0.1	A temporary use permit has been issued to extend the use of this chemical to control fungi in berries. NEDI = 6% of ADI
Berries and other small fruits [except grapes]	Add	T0.1	
B6. MRLs FOR EXISTING CHEMICALS ASSOCIATED WITH A DIETARY EXPOSURE LESS THAN 90% OF THE ADI OR LESS THAN 90% OF THE ARfD WHERE APPLICABLE			
Chemical Food	**MRL** **(gm/kg)**		**Information**
Abamectin			
Pig kidney	Add	0.01	The chemical is used for the treatment and control of internal and external parasites of pigs NEDI = 48% of ADI
Pig liver		0.02	
Pig meat (in the fat)		0.02	
Imazapic			
Wheat	Add	*0.05	The chemical is used to control weeds in wheat crops. NEDI = 1% of the ADI
Imazapyr			
Wheat	Add	*0.05	The chemical is used to control weeds in wheat crops. NEDI = 1% of the ADI

† This estimate is based on the ADI for thiram, the dithiocarbamate with the lowest ADI.

B8. MRLs FOR PERMITS ASSOCIATED WITH A DIETARY EXPOSURE LESS THAN 90% OF THE ADI OR LESS THAN 90% OF THE ARfD WHERE APPLICABLE			
Chemical Food	**MRL** **(gm/kg)**		**Information**
Bupirimate			
Melons [except Watermelon]	Delete	1	A temporary permit has been issued, to extend the use of this chemical to all cucurbits, to control powdery mildew. NEDI = 3% of the ADI
Fruiting vegetables, cucurbits	Add	T1	
Butafenacil			
Cereal grains [except maize, sorghum, millet and rice]	Add	T*0.02	A temporary permit has been issued for the use of this chemical to control various broadleaf weeds and some grass weeds in cereal crops.
Edible offal (mammalian)	Add	T*0.02	
Eggs	Add	T*0.01	
Meat (mammalian)	Add	T*0.01	
Milks	Add	T*0.01	
Poultry, edible offal of	Add	T*0.02	
Poultry meat	Add	T*0.01	NEDI = 4% of the ADI
Captan			
Berries and other small fruits [except grapes, strawberries and blueberries]	Add	T30	The chemical is used to control a wide range of fungal pathogens in berries. In the 19th ATDS (1998) captan residues were not detected in the surveyed foods. NEDI = 22% of ADI
Cyfluthrin			
Carambola	Add	T0.1	A temporary use permit has been issued for the foliar spray use of this chemical, to control fruit spotting bug. The 18th ATDS (1996) dietary exposure estimate for cyfluthrin, as a percentage of the ADI is equivalent to <0.01% of ADI for the whole population. The 19th ATDS (1998) dietary exposure estimate for cyfluthrin, as a percentage of the ADI is equivalent to <0.01% of ADI for adult males and up to 0.01% of ADI for 12 year olds. NEDI = 67% of the ADI

Cypermethrin Olives	Add	T*0.05	An off label permit has been issued for the control of insects as a bait spray in surrounding pastures and as drench to the butt of trees. The 18th ATDS (1996) dietary exposure estimate for cypermethrin, as a percentage of the ADI is equivalent to <0.01% of ADI for adult males and up to 0.01% of ADI for 2 year olds. The 19th ATDS (1998) dietary exposure estimate for cypermethrin, as a percentage of the ADI is equivalent to 0.01% of ADI for adult males and up to 0.02% of ADI for 2 year olds. NEDI = 7% of ADI
Dichlofluanid Berries and other small fruits [except grapes and strawberries]	Add	T50	A temporary use permit has been issued for this chemical to control fungi on berries. NEDI = 13% of ADI
Isoxaflutole Chick pea (dry)	Delete Substitute	*0.01 T*0.03	A temporary use permit has been issued for this chemical to control weeds in chick pea crops. NEDI = 3% of ADI
Metalaxyl Berries and other small fruits [except grapes]	Add	T0.5	A temporary use permit has been issued, for this chemical to control fungi in berries. NEDI = 4% of ADI
Methabenzthiazuron Leek	Add	T*0.05	An off label permit has been issued for the control of post emergent weeds in leek crops. NEDI = 6% of ADI
Prochloraz Pistachio nut	Add	T0.5	A temporary use permit has been issued for this chemical to control Anthracnose on pistachio nuts. NEDI = 31% of ADI

Procymidone Rape seed Rape seed oil, crude	 Add Add	 1 3	The chemical is used to control fungal infections in canola. The 18th ATDS (1996) dietary exposure estimate for procymidone, as a percentage of the ADI is equivalent to 0.14% of ADI for adult males and up to 0.2% of ADI for 2 year olds. The 19th ATDS (1998) dietary exposure estimate for procymidone, as a percentage of the ADI is equivalent to 0.12% of ADI for adult males and up to 0.3% of ADI for 2 year olds. NEDI = 19% of the ADI
Pyrimethanil Berries and other small fruits [except grapes and strawberries]	Add	T5	A temporary use permit has been issued, for this chemical to control fungi in berries. NEDI = 3% of ADI
Triadimenol Berries and other small fruits [except grapes and strawberries]	Add	T0.5	A temporary use permit has been issued, for this chemical to control fungi in berries. In this case the NEDI is an overestimation because the MRLs were used i.e. processing data and median residue data were not available to refine the estimate. In the 19th ATDS (1998) triadimenol residues were not detected in the surveyed foods. NEDI = 72% of ADI

B9 MRLS FOR PERMITS ASSOCIATED WITH A DIETARY EXPOSURE GREATER THEN 90% OF THE ADI OR GREATER THAN 90% OF THE ARFD WHERE APPLICABLE		
Chemical Food	**MRL** **(gm/kg)**	**Information**
Dithiocarbamates Berries and other small fruits [except strawberries]	Delete T5 Substitute T10	A temporary use permit has been issued for the dithiocarbamate, mancozeb, to control fungi in berries. The 19th ATDS (1998) dietary exposure estimate for dithiocarbamates as a percentage of the ADI is equivalent to 20% of ADI for adult males and up to 63% of ADI for 2 year olds.† Mancozeb has an ADI which is 10 times higher than that for thiram. Given the level of consumption of berries, that this is a temporary permit and using the results from the 19th ATDS, ANZFA considers that there is not an unacceptable risk to public health and safety with the residues of mancozeb in berries.
Dithiocarbamates Pistachio nut	Add T3	A temporary use permit has been issued to control Anthracnose in pistachio nuts. The 19th ATDS (1998) dietary exposure estimate for dithiocarbamates as a percentage of the ADI is equivalent to 20% of ADI for adult males and up to 63% of ADI for 2 year olds.† NRA estimates that the increase in dietary exposure for the consumption of mancozeb treated pistachio nuts is equivalent to less than 0.1% of the ADI. Mancozeb has an ADI which is10 times higher than that for thiram. Given the level of consumption of pistachio nuts, that this is a temporary permit, and using the results from the 19th ATDS, ANZFA considers that there is not an unacceptable risk to public health and safety with the residues of mancozeb in pistachio nuts.

† This estimate is based on the ADI for thiram, the dithiocarbamate with the lowest ADI.