10 October 2001
05/02

DRAFT ASSESSMENT REPORT
(FULL ASSESSMENT - SECTION 15 OF THE ANZFA ACT)

APPLICATION A422

MAXIMUM RESIDUE LIMITS - ANTIBIOTICS

EXECUTIVE SUMMARY

- This Application seeks to amend Maximum Residue Limits (MRL) for antibiotics in the *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 Volume 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 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*.

- In its initial assessment ANZFA, in error, stated that the deletion of the MRLs for benzyl G penicillin and procaine penicillin would not result in MRLs that were more restrictive than Codex. As stated in a submission, Benzyl G penicillin and procaine penicillin form part of the Procaine benzylpenicillin group for which there are Codex MRLs. To allow additional public consultation on these MRLs ANZFA is seeking a second round of submissions under section 17(3)(a) of the Act.

- The current Application (**A422**) 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 antibiotics in veterinary use in Australia.

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

- ANZFA is satisfied from the dietary modelling performed that the changes to the *Food Standards Code* for the chemicals in this Application will not cause the ADI to be exceeded.

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

- ANZFA at initial assessment made a Sanitary and Phytosanitary notification to the World Trade Organization (and it is not necessary to make another).

1. ISSUES

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has registered chemical products for the uses associated with the MRLs in application A422 and is now seeking to amend the MRLs in the *Food Standards Code* to:

- include limit of quantification MRLs for a new antibiotic, avilamycin for poultry meat and poultry offal;

- delete MRLs for the antibiotics, benzyl G penicillin, and procaine penicillin for poultry meat, poultry offal and eggs;

- delete MRLs for the antibiotic, erythromycin for eggs; and

- include a temporary MRL for the antibiotic, oxytetracycline for honey.

2. BACKGROUND

In Australia, the NRA is responsible for registering agricultural and veterinary chemical products. Before registering such a product, they must be satisfied that the use of the product will not result in residues that would be an undue hazard to the safety of people, including people using anything containing its residues.

The Maximum Residue Limit (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 result from the registered conditions of use. The concentration is expressed in milligrams per kilogram (mg/kg) of the food. MRLs are indicators of 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. However, MRLs are not established for specific commodities if the residues resulting from the use of the chemical product could represent an unacceptable risk to public health and safety.

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 Maximum Residue Limits will 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 Volumes 1 & 2 .

2.1 Food Standards Setting in Australia and New Zealand

2.1.1 Treaty between the Commonwealth of 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. Australia and New Zealand separately develop MRLs for agricultural and veterinary chemicals in food.

2.1.2 Trans Tasman Mutual Recognition Arrangement

Following the implementation of the Trans Tasman Mutual Recognition Arrangement on 1 May 1998:

- Food produced in Australia that complies with the MRLs in the *Food Standards Code* can be legally sold in New Zealand; and

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

2.2 Anomalies between the NRA MRL Standard and the MRL Standard in the *Food Standards Code*

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has informed the Australia New Zealand Food Authority (ANZFA) of anomalies between the NRA MRL Standard and the *Food Standards Code* for the antibiotics benzyl G penicillin, erythromycin, and procaine penicillin. This application includes proposed amendments to correct these anomalies.

3. DIETARY EXPOSURE ASSESSMENT

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code Act 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 one that was considered in this application was the National Estimated Daily Intake (NEDI).

3.1 Toxicology of agricultural and veterinary chemicals

The Chemicals and Non-prescription Medicines Branch of the Therapeutic Goods Administration (TGA) assess the toxicology of agricultural and veterinary chemicals and establish the acceptable daily intake (ADI) for a chemical. Both the NRA and ANZFA use these health standards in dietary exposure assessments.

Neither the NRA nor ANZFA will establish or recommend MRLs where the toxicology aspects have not been addressed to the TGA's satisfaction.

3.2 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 does not exceed the ADI.

3.3 National Estimated Daily Intake

The NEDI may represent a more realistic estimate of dietary exposure than other methods if the data are available and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions and the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials rather than the MRL to represent pesticide residue levels. When adequate information is available, monitoring and surveillance data or total diet studies may also be used such as the Australian Total Diet Survey (ATDS).

3.4 Food Consumption Data

The NRA and ANZFA have recently agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the NRA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest 1995 National Nutrition Survey (NNS). The Australian Bureau of Statistics with the Commonwealth Department of Health and Aged Care undertook the NNS survey over a 12-month period (1995-early 1996). The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns were reported.

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.

4. EVALUATION OF ISSUES RAISED IN RESPONSE TO THE INITIAL ASSESSMENT REPORT

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

- quantity of poultry egg and egg products imported into Australia;
- the deletion of MRLs which have Codex MRLs in place;
- the potential for the development of antibiotic resistance;
- the use of and approval of antibiotics and growth promotants in agriculture;
- the recommendations from the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR);
- toxicity of antibiotics;
- penicillin as allergens;

Each of these is examined in turn below.

4.1 Importation of foods

The submission from the Food Technology Association – Victoria questioned the data on the quantity of poultry egg and egg products imported into Australia. ANZFA uses the data from the Australian Bureau of Statistics to compile information on the quantity of imported commodities. This information was included to allow importers to see if reductions or deletions of MRLs will affect imports.

The submission from Nestlé provided comments on potential difficulties pertaining to the export of milk powder to Malaysia and the importation of chilli sauce from Malaysia. Neither of these commodities is relevant to the commodities in this application and therefore there is no scope to address the concerns of Nestlé. However ANZFA will liase with Nestlé to determine whether these concerns can be addressed by other measures.

4.2 Deletion of antibiotic MRLs

Submissions from Food Technology Association – Victoria, Informed Systems Ltd, The National Council of Women of Australia (NCWA) and Queensland Health supported the deletion of antibiotic MRLs in this application.

In its initial assessment ANZFA, in error, stated that the deletion of the MRLs for benzyl G penicillin and procaine penicillin would not result in MRLs that were more restrictive than Codex. As stated in the submission from Nestlé, Benzyl G penicillin and procaine penicillin form part of the Procaine benzylpenicillin group for which there are Codex MRLs. To allow additional public consultation on these MRLs, ANZFA is inviting a second round of submissions under section 17(3)(a) of the Act.

No submissions were received at initial assessment opposing the deletion of the MRLs for benzyl G penicillin and procaine penicillin.

4.3 Potential resistance development and JETACAR recommendations

The NCWA had concerns about the potential for an increase in antibiotic resistance. The report of the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) has acknowledged that the use and over use of antibiotics in human medicine is well recognised and is the major factor contributing to the development of antibiotic resistance. The two media articles attached to the submission from the NCWA referred to the problems associated with the overuse of antibiotics in human medicine.

JETACAR also made a series of recommendations relating to the use of antibiotics in agriculture. The Commonwealth Government responded to the JETACAR report in October 2000 and has since established the Commonwealth Interdepartmental JETACAR Implementation Group to coordinate and implement the Government's response. ANZFA considers that this process is the means by which the issue of antibiotic use in agriculture can best be considered.

ANZFA will not recommend MRLs where advised that the associated residues in food could lead to the development of antibiotic resistance in human pathogens. In this regard, ANZFA has routinely sought the advice of the National Health and Medical Research Council Expert Advisory Group on Antimicrobial Resistance (EAGAR), or its predecessor the Working Party on Antibiotics (WPA), in order to ensure that the potential issue of the development of antibiotic resistance as a result of the consumption of antibiotic residues has been fully addressed.

The WPA believes that the proposed MRLs for avilamycin and oxytetracycline, as proposed in this application, do not appear to pose a resistance risk. ANZFA did not seek the advice from the WPA for the deletion of MRLs in this application.

4.4 The use of and approval for antibiotics in agriculture

The submission from Queensland Health stated that 'European countries are withdrawing antibiotics from use in animal feeds' and also commented on the requirements of field trials, the efficacy and labelling of formulations, and the appropriateness of withholding periods. The NRA approves the use of agricultural and veterinary chemicals, assesses labels and trial data and determines permit conditions. As the NRA is in a better position to answer these concerns, ANZFA has forwarded a copy of the Queensland Health submission to the NRA for them to reply to Queensland Health.

4.5 Potential toxicity of antibiotics

The submission from Informed Systems had concerns about the potential toxicity of tetracyclines and unforeseen effects of antibiotics. The Chemicals and Non-prescription Medicines Branch of the Therapeutic Goods Administration assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and, where relevant, the acute reference dose for a chemical. Both the NRA and ANZFA use these health standards in dietary exposure assessments. On the basis of the dietary exposure assessments, the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

The proposed MRL for oxytetracycline in honey is temporary to allow research and field trials into the treatment of European Foul Brood in bees and is indicated by a 'T' in the Summary of the Requested MRLs for A442 (Attachment 1). The NRA has stated that the trial is due to be completed on 31 December 2001.

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.

The proposed MRLs for avilamycin in poultry meat and poultry offal is to allow a new active ingredient in poultry feed premix to increase weight gain and improve feed efficiency by modifying gut microflora populations in poultry. The proposed MRLs will be at the limit of quantification (LOQ) and are indicated by an '*'.

The LOQ is the lowest concentration of a pesticide residue contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. The inclusion of the avilamycin MRLs at the LOQ means that current restrictions on the MRL standard still apply ie. no detectable residues are permitted.

4.6 Penicillins as allergens

Informed Systems supported the deletion of the MRLs for benzyl G penicillin and procaine penicillin and had general concerns about the allergenicity of penicillins. The NRA has assessed the allergenicity of antibiotic residues in food commodities. Evidence for a residue of antibiotics in foods causing allergic reactions is sparse and appears to be a very rare occurrence. The very rare occurrences of allergenicity appear to be associated with allergic reactions to the β-lactam antibiotics. Within this application, the MRLs for penicillins fall within the β-lactam antibiotic group. However, as ANZFA proposes to delete these MRLs, ANZFA considers that they do not represent an unacceptable risk to public health and safety.

5. REGULATORY IMPACT ANALYSIS

5.1 Objective

To ensure that the current standards permit the legal sale of food that has been legally treated.

5.2 There are two 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*.

5.3 Affected parties

The identified parties affected by this application are consumers, egg and poultry producers, apiculturists, food manufacturers who use eggs, poultry products and honey and importers of primary produce and foods into Australia.

5.4 Costs and benefits

5.4.1 Costs of making the changes sought by the NRA

- 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 an administrative burden with complying and enforcing the proposed MRLs;

- Importers will no longer be able to rely on existing MRLs;

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

5.4.2 Benefits of making the changes sought by the NRA

- Egg, poultry producers and apiculturists 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;

- It will benefit all stakeholders by maintaining public health and safety; and

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

5.4.3 Costs of not of making the changes sought by the NRA

- Producers will not be able to legally sell legally treated produce treated with chemicals intended to increase productivity by improving feed efficiency and weight gain;

- 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;

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

- As there are no unacceptable risks to public health and safety, consumers are not at risk if this application is not accepted

5.4.4 Benefits of not of making the changes sought by the NRA

- Importers may potentially benefit by filling a possible domestic production shortfall by local producers resulting from potential reduction in domestic agricultural productivity;

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

5.5 Conclusion and recommended option

The proposed deletion of the MRLs of erythromycin, benzyl G penicillin and procaine penicillin is consistent with the current registered uses of the chemical products and has public support.

The dietary exposure calculations indicate that the ADIs for avilamycin and oxytetracycline will not be exceeded. The NRA has already registered these antibiotics for which new MRLs are proposed 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 appropriate use of antibiotics in agriculture and veterinary treatment.

Option 1, to make the changes sought by the NRA and to vary the *Food Standards Code* is preferred.

6. ANZFA SECTION 10 OBJECTIVES

Section 10 (1), paragraphs (a) to (c) of the *Australia New Zealand Food Authority Act 1991* (ANZFA Act) sets out ANZFA's objectives in developing food regulatory matters and variations to food regulatory matters. Each of these matters is discussed below.

(a) The protection of public health and safety

The Chemicals and Non-prescription Medicines Branch of the TGA establishes the ADI for the antibiotics. The NRA and ANZFA carry out estimations of dietary exposure to antibiotics and compare them to the ADI. On the basis of dietary exposure assessments, the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

(b) The provision of adequate information relating to food to enable consumers to make informed choices

This is not relevant for this application.

(c) Prevention of misleading or deceptive conduct

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.

(a) The need for standards to be based on risk analysis using the best available scientific evidence

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

(b) The promotion of consistency between domestic and international food standards
The MRLs in this application reflect the registered domestic use of antibiotics in agriculture and veterinary treatment. These proposed variations represent some move away from consistency between Codex and domestic standards; this is because agricultural conditions vary from one geographic location to another; precise alignment of international and national MRLs may never be practical or even desirable.

(c) The desirability of an efficient and internationally competitive food industry
The requested MRLs are necessary to allow the legal sale of legally treated food. Varying the *Food Standards Code* to include the proposed MRLs would promote trade and commerce.

(d) The promotion of fair trading in food
As the MRLs in the *Food Standards Code* apply to all food produced or imported for sale or in Australia, the inclusion of the MRLs would benefit all producers equally.

7. CONCLUSION

The dietary exposure calculations indicate that the ADI for each chemical will not be exceeded. The proposed deletion of the MRLs of erythromycin, benzyl G penicillin and procaine penicillin is consistent with current registered uses of chemical products. The NRA has already registered the antibiotics in this application and rejection of the MRL for oxytetracycline 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 appropriate use of antibiotics.

Option 1, to make the changes sought by the NRA and to vary the *Food Standards Code* is preferred.

8. WORLD TRADE ORGANIZATION NOTIFICATION

At initial assessment ANZFA considered that this did constitute potential a Sanitary/Phytosanitary matter and therefore raised a World Trade Organisation (WTO) notification at initial assessment. No submissions were received from WTO members and it is proposed to not make another notification.

9. 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 Codex MRL.

In its initial assessment ANZFA, in error, stated that the deletion of the MRLs for benzyl G penicillin and procaine penicillin would not result in MRLs that were more restrictive than Codex. As stated in a submission, Benzyl G penicillin and procaine penicillin form part of the Procaine benzylpenicillin group for which there are Codex MRLs. To allow additional public consultation on these MRLs ANZFA is seeking a second round of submissions under section 17(3)(a) of the Act.

Chemical Food	**Proposed MRL mg/kg**	**Codex MRL mg/kg**
Benzyl G Penicillin Poultry, edible offal of Poultry meat	Deletions of existing MRLs therefore no detectable residues are permitted in these commodities.	**Procaine benzylpenicillin only** 0.05 (chicken kidney and liver) 0.05 (chicken muscle)
Procaine Penicillin Poultry, edible offal of Poultry meat	Deletions of existing MRLs therefore no detectable residues are permitted in these commodities.	**Procaine benzylpenicillin only** 0.05 (chicken kidney and liver). 0.05(chicken muscle)

ANZFA recognises that changes to MRLs have implications for the importation of food, particularly where MRLs are deleted and therefore no detectable residue is permitted. ANZFA requests comments on the significance of the changes to MRLs for imported foods.

10. IMPORTED FOODS

Australia has imported the following quantity of foods for 1999 and 2000.

Food	**1999**	**2000**
Honey	10,000 tonnes	18,000 tonnes
Poultry Eggs	67,000 tonnes	35,000 tonnes
Poultry meat	14,000 tonnes	14,000 tonnes

ANZFA recognises that changes to MRLs have implications for the importation of food, particularly where MRLs are deleted and therefore no detectable residue is permitted. ANZFA requests comments on the significance of the changes to MRLs for imported foods.

11. 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*.

12. INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a draft 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 draft 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 A422** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra BC 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: **21 November 2001**.

13. ATTACHMENTS

1. Summary of proposed MRLs for A422
2. Draft Variations to Volume 1 and Volume 2 of the *Food Standards Code*.
3. Statement of Reasons.
4. Summary of Public Submissions Received at Initial Assessment

ATTACHMENT 1

SUMMARY OF PROPOSED MRLS FOR A422

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 freed with an acceptable degree of certainty by a regulatory method of analysis.

NEDI - National Estimated Dietary Intake - The NEDI represents a more realistic estimate of dietary exposure and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions; the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials other than the MRL to represent pesticide residue levels. In most cases the NEDI is still an overestimation because the above data is often not available and in these cases the MRL is used.

Glossary:

1. **ADI** Acceptable Daily Intake.
2. **LOQ** Limit of Analytical Quantification.
3. **NEDI** National Estimated Daily Intake.
4. ***** MRL set at or about the limit of quantification.
5. **T** Temporary MRL

CHEMICAL Food	**MRL** (gm/kg)	**INFORMATION**
A1. Deletions and reductions		
Benzyl G Penicillin Eggs Poultry, edible offal of Poultry meat	 Delete 0.018 Delete 0.06 Delete 0.06	 As these are deletions no NEDI has been calculated
Erythromycin Eggs	 Delete 0.3	 As this is a deletion no NEDI has been calculated
Procaine Penicillin Eggs Poultry, edible offal of Poultry meat	 Delete 0.03 Delete 0.1 Delete 0.1	 As these are deletions no NEDI has been calculated

A5. Antibiotics used for therapeutic use but with human analogue		
Oxytetracycline Honey	Add T0.3	Temporary MRL to facilitate additional research and field trials to support the current registered use for the control of European Foul Brood in honey bees. NEDI = 38.3% of the ADI
A6. Growth Promotants with no human analogue.		
Avilamycin Poultry meat Poultry, Edible offal of	Add *0.05 Add *0.05	NRA has advised that this is a new active ingredient in poultry feed premix to improve feed efficiency by modifying gut microflora populations. Detectable levels are below LOQ. NEDI = 0.003% of ADI.

ATTACHMENT 2

DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

A422 - MAXIMUM RESIDUE LIMITS

To commence: On gazettal

[1] ***Standard A14*** *is varied b y-*

[1.1] *inserting in columns 1 and 2 respectively of Schedule 1 the chemical (shown in bold type) below and its associated food and maximum residue limit for that food as listed below –*

Chemical Food	MRL
Avilamycin	
Poultry meat	0.05
Poultry, edible offal of	0.05

Explanatory Note: These are new MRLs for the chemical, avilamycin and foods

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

Chemical Food	MRL
Oxytetracycline	
Honey	0.3

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

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

Chemical Food	MRL
Benzyl G Penicillin	
Eggs	0.018
Poultry, Edible offal of	0.06
Poultry meat	0.06
Erythromycin	
Eggs	0.3
Procaine Penicillin	
Eggs	0.03
Poultry, Edible offal of	0.106
Poultry meat	0.1

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

[2] ***Standard 1.4.2*** *is varied by -*

[2.1] *inserting (consistent with the alphabetical order of the other entries) the following entry in respect of avilamycin. -*

AVILAMYCIN INHIBITORY SUBSTANCE, IDENTIFIED AS AVILAMYCIN	
POULTRY MEAT	*0.05
POULTRY, EDIBLE OFFAL OF	*0.05

Explanatory Note: These are new MRLs for the chemical avilamycin and foods

[2.2] *inserting in relation to the chemical (shown in bold type) below the food and maximum residue limit of that food as listed below. -*

OXYTETRACYCLINE INHIBITORY SUBSTANCE, IDENTIFIED AS OXYTETRACYCLINE	
HONEY	T0.3

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

[2.3] *omitting from Schedule 1, in relation to each chemical (shown in bold type) below, the food and the maximum residue limit for that food as listed below -*

BENZYL G PENICILLIN INHIBITORY SUBSTANCE, IDENTIFIED AS BENZYL G PENICILLIN	
EGGS	0.018
POULTRY, EDIBLE OFFAL OF	0.06
POULTRY MEAT	0.06
ERYTHROMYCIN ERYTHROMYCIN	
EGGS	0.3
PROCAINE PENICILLIN INHIBITORY SUBSTANCE, IDENTIFIED AS PROCAINE PENICILLIN	
EGGS	0.03
POULTRY, EDIBLE OFFAL OF	0.1
POULTRY MEAT	0.1

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

ATTACHMENT 3

STATEMENT OF REASONS

APPLICATION A422

FOR RECOMMENDING A VARIATION TO STANDARD A14 - MAXIMUM RESIDUE LIMITS - ANTIBIOTICS.

On 24 November 2000, the Australia New Zealand Food Standards Council (ANZFSC) adopted the *Australia New Zealand Food Standards Code (known as* Volume 2 of the *Food Standards Code*). Subsequently all applications to amend Maximum Residue Limits (MRL) applies equally to Volume 1 and Volume 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 Volume 1 and Volume 2.

The Australia New Zealand Food Authority (ANZFA) has before it Application **A422** (received 6 September 2000), from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) to amend the current Maximum Residue Limits (MRLs) in the *Food Standards Code*.

ANZFA has completed a draft assessment (Full Assessment - s.15 of the ANZFA Act) of the Application, and prepared draft variations to Standard A14 in Volume 1 and Standard 1.4.2 in Volume 2 of the *Food Standards Code*.

ANZFA recommends progressing the application for the following reasons:

- The current Application (**A422**) 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 antibiotics in veterinary use in Australia.

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

- ANZFA is satisfied from the dietary modelling performed that the changes to the *Food Standards Code* for the chemicals in this Application will not cause the ADI to be exceeded.

- None of ANZFA's Section 10 objectives of food regulatory measures are compromised by the proposed changes. The requested variation to the *Food Standards Code* should commence on gazettal.

- ANZFA has made a Sanitary and Phytosanitary notification to the World Trade Organization and it is not necessary to make another.

- The Working Party on Antibiotics (WPA) believes that the proposed MRLs for avilamycin and oxytetracycline, as proposed in this application, do not appear to pose a resistance risk. ANZFA did not seek the advice from the WPA for the deletion of MRLs in this application.

SUMMARY OF PROPOSED MRLS FOR A422

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 freed with an acceptable degree of certainty by a regulatory method of analysis.

NEDI - National Estimated Dietary Intake - The NEDI represents a more realistic estimate of dietary exposure and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions; the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials other than the MRL to represent pesticide residue levels. In most cases the NEDI is still an overestimation because the above data is often not available and in these cases the MRL is used.

Glossary:

ADI	Acceptable Daily Intake.
LOQ	Limit of Analytical Quantification.
NEDI	National Estimated Daily Intake.
*****	MRL set at or about the limit of quantification.
T	Temporary MRL

CHEMICAL Food	**MRL** (gm/kg)	**INFORMATION**
A1. Deletions and reductions		
Benzyl G Penicillin Eggs Poultry, edible offal of Poultry meat	 Delete 0.018 Delete 0.06 Delete 0.06	 As these are deletions no NEDI has been calculated
Erythromycin Eggs	 Delete 0.3	 As this is a deletion no NEDI has been calculated
Procaine Penicillin Eggs Poultry, edible offal of Poultry meat	 Delete 0.03 Delete 0.1 Delete 0.1	 As these are deletions no NEDI has been calculated

A5. Antibiotics used for therapeutic use but with human analogue		
Oxytetracycline Honey	Add T0.3	Temporary MRL to facilitate additional research and field trials to support the current registered use for the control of European Foul Brood in honey bees. NEDI = 38.3% of the ADI

A6. Growth Promotants with no human analogue.		
Avilamycin Poultry meat Poultry, Edible offal of	Add *0.05 Add *0.05	NRA has advised that this is a new active ingredient in poultry feed premix to improve feed efficiency by modifying gut microflora populations. Detectable levels are below LOQ. NEDI = 0.003% of ADI.

REGULATORY IMPACT

ANZFA has undertaken a regulatory 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.

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 Codex MRL.

In its initial assessment ANZFA, in error, stated that the deletion of the MRLs for benzyl G penicillin and procaine penicillin would not result in MRLs that were more restrictive than Codex. As stated in a submission, Benzyl G penicillin and procaine penicillin form part of the Procaine benzylpenicillin group for which there are Codex MRLs. To allow additional public consultation on these MRLs ANZFA is seeking a second round of submissions under section 17(3)(a) of the Act.

Chemical Food	**Proposed MRL mg/kg**	**Codex MRL mg/kg**
Benzyl G Penicillin Poultry, edible offal of Poultry meat	Deletions of exiting MRLs therefore no detectable residues are permitted in these commodities.	**Procaine benzylpenicillin only** 0.05 (chicken kidney and liver) 0.05 (chicken muscle)
Procaine Penicillin Poultry, edible offal of Poultry meat	Deletions of exiting MRLs therefore no detectable residues are permitted in these commodities.	**Procaine benzylpenicillin only** 0.05 chicken kidney and liver. 0.05 chicken muscle

ANZFA recognises that changes to MRLs have implications for the importation of food, particularly where MRLs are deleted and therefore no detectable residue is permitted. ANZFA requests comments on the significance of the changes to the deletion of these MRLs for imported foods.

IMPORTED FOODS

Australia has imported the following quantity of foods for 1999 and 2000.

Food	1999	2000
Honey	10, 000 tonnes	18,000 tonnes
Poultry Eggs	67,000 tonnes	35,000 tonnes
Poultry meat	14,000 tonnes	14,000 tonnes

ANZFA recognises that changes to MRLs have implications for the importation of food, particularly where MRLs are deleted and therefore no detectable residue is permitted. ANZFA requests comments on the significance of the changes to MRLs in this application for imported foods.

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, and it is the registered conditions of use that protect human, animal and plant health and the environment.

This application contains MRLs which relate to antibiotics used in the production of heavily traded agricultural commodities which may indirectly have a significant effect on trade of derivative food products between WTO members.

ANZFA has made a Sanitary and Phytosanitary (SPS) notification in accordance with the WTO SPS agreement as the primary objective of the measure is to support regulating the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment. No WTO Member has made a submission and ANZFA will not be making another notification.

ATTACHMENT 4

SUMMARY OF PUBLIC SUBMISSIONS RECEIVED AT INITIAL ASSESSMENT

Submitter	Comments raised
Food Technology Association - Victoria	Supports the application. Questioned the quantity of poultry eggs imported into Australia.
Informed Systems Ltd	Supports the deletions of MRLs in the application. Did not support the inclusion of oxytetracycline in human foods. Considered that tetracyclines have a significant human toxicity. Did not support the inclusion of avilamycin as a they considered that unforeseen effects including allergies may eventuate.
National Council of Women of Australia	Did not support the application. However, does support the deletions of MRLs in the application. Is wary of supporting any increase in MRL levels or adding MRLs for new chemicals.
Nestlé	Had concerns about ANZFA not using Codex MRL standards.
Queensland Health	Supports the deletions of MRLs in the application. Had concerns about the approval process for antibiotics in agriculture