12 December 2001
06/02

INITIAL/DRAFT ASSESSMENT

[PRELIMINARY ASSESSMENT - S.13 AND FULL ASSESSMENT - S.15] S.36

APPLICATION A440

MAXIMUM RESIDUE LIMITS - ANTIBIOTICS

DEADLINE FOR SUBMISSIONS to the Authority in relation to this matter: **23 JANUARY 2002** (See 'Invitation for Public Submissions' for details)

EXECUTIVE SUMMARY

- This Application (A440) seeks to amend Maximum Residue Limits (MRLs) for the antibiotics ampicillin and cloxacillin in cattle milk in the *Food Standards Code*. It is a routine application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the *Food Standards Code* in order to reflect current registration status of ampicillin and cloxacillin in 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 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*.

- The *Agreement between the Commonwealth of Australia and the Government of New Zealand to establish a system for the development of joint food standards* (the Treaty), excluded MRLs for agricultural and veterinary chemicals in food from the joint Australia New Zealand food standards setting system. Australia and New Zealand separately develop MRLs for agricultural and veterinary chemicals in food.

- The Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aged Care has undertaken a toxicological assessment of the antibiotic cloxacillin and has established an acceptable daily intake (ADI).

- This Application contains MRLs for antibiotics residues and the Expert Advisory Group on Antimicrobial Resistance (EAGAR) have recently agreed that the use of these antibiotics would not lead to the development of antibiotic resistance.

- The dietary exposure assessments indicate that the residues associated with the proposed MRL for ampicillin does not represent an unacceptable risk to public health and safety.

- The NRA's proposed increase in the MRL for cloxacillin in cattle milk is not supported, as ANZFA considers this increase is unnecessary and is not consistent with the achievable limit of quantification.

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

- ANZFA will make a make a Sanitary and Phytosanitary notification to the World Trade Organization at the Initial / Draft Assessment (Preliminary Assessment - s.13 / Full Assessment - s.15).

1. ISSUES

An application was received from the NRA on 19 April 2001 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 MRLs for ampicillin and cloxacillin in the *Food Standards Code* with the MRLs in the *NRA MRL Standard*.

The Application from the NRA seeks to change the MRL for the antibiotic cloxacillin in cattle milk to reflect the achievable limit of quantification (LOQ) and add a new MRL for the antibiotic, ampicillin in cattle milk. Both proposed MRLs are at the LOQ which means that no detectable residues of these antibiotics would be permitted in cattle milk. The NRA's proposed increase in the MRL for cloxacillin in cattle milk is not supported, as ANZFA considers that an increase is unnecessary and is not consistent with the achievable limit of quantification.

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 chemicals on commodities as outlined in this application. Full evaluation reports for individual chemicals are available upon request from the relevant Project Manager at ANZFA.

1.2 Stop clock

A 'stop clock' was placed on the Application from 6 August to 4 October 2001 while ANZFA sought additional information from the NRA about an acceptable daily intake for ampicillin in cattle milk.

2 BACKGROUND

2.1 The use of agricultural and veterinary chemicals

In Australia, the NRA is responsible for registering agricultural and veterinary chemical products, granting permits for use of chemical products and regulating the sale of agricultural and veterinary chemical products. Following the sale of these products, the use of the chemicals is then regulated by State and Territory 'control of use' legislation.

Before registering such a product, the NRA must be satisfied that the use of the product will not result in residues that would be an undue risk to the safety of people, including people using anything containing its residues. When a chemical product is registered for use or a permit for use granted, the NRA includes MRLs in its NRA MRL Standard. These MRLs are then adopted into control of use legislation in some jurisdictions and assist States and Territories in regulating the use of agricultural and veterinary chemicals.

2.2 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.

2.3 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 its NRA MRL Standard when they register a chemical product for use or grant a permit for use. The NRA then notifies ANZFA of these MRLs so that ANZFA may consider them for inclusion into the *Food Standards Code*.

In relation to MRLs, ANZFA's role is to ensure that the potential residues in 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.

2.4 Food Standards-setting in Australia and New Zealand

The Treaty excluded MRLs for agricultural and veterinary chemicals in food from the joint food standards setting system. Australia and New Zealand separately and independently develop MRLs for agricultural and veterinary chemicals in food.

2.5 Trans Tasman Mutual Recognition Arrangement

Following the commencement of the Trans Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand on 1 May 1998:

- food produced or imported into Australia, which complies with Standard 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.

2.6 *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 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*.

3. DIETARY EXPOSURE ASSESSMENT

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code, 1994* requires the NRA to be satisfied that there will not be any appreciable risk to the consumer, to the person handling, applying or administering the chemical, to the environment, to the target crop or animal or to trade in an agricultural commodity. ANZFA's responsibility is to ensure that the residues in food resulting from the use of agricultural and veterinary chemical products do not represent an unacceptable risk to public health and safety.

The potential public health impacts are assessed by considering the dietary exposure and comparing this to the relevant health standard. 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 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 is less than the ADI.

3.3 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.

3.4 National Estimated Daily Intake

The National Estimated Daily Intake (NEDI) may represent a more realistic estimate of dietary exposure 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).

3.5 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) by The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns were reported.

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. MRLS FOR ANTIBIOTICS

4.1 Antimicrobial resistance

The issue of potential antibiotic resistance development as a result of exposure to these antibiotic residues has been considered by the Working Party on Antibiotics (WPA), which did not raise any objections to these MRLs. However, the Expert Advisory Group on Antimicrobial Resistance (EAGAR) has superseded the WPA.

EAGAR is a National Health and Medical Research Council committee that consists of internationally recognised experts on human and veterinary medicine, public health, appropriate use of antibiotics and development of antibiotic resistance. The role of the Expert Advisory Group on Antimicrobial Resistance (EAGAR) is to provide expert advice to the Commonwealth through the Commonwealth Interdepartmental JETACAR Implementation Group, State and Territory Governments, and Commonwealth Statutory authorities, on measures to reduce the risks of antibiotic resistance.

As a result of a request from ANZFA, EAGAR has recently reviewed the advice of the WPA and advised ANZFA that the previous assessment of the WPA remains current and that they have no objection to the proposed MRLs in this application.

Both these antibiotics are members of the penicillin group of β-lactam antibiotics. These antibiotics have been widely used in human and veterinary medicine for several decades. A major use of these antibiotics in veterinary medicine is as an intramammary infusion to treat mastitis.

4.2 Penicillins as allergens

The NRA has assessed the allergenicity of antibiotic residues in food commodities. While evidence for residues of antibiotics in foods causing allergic reactions is sparse, there is some evidence for rare occurrences of allergic reactions to the β-lactam antibiotics. For this reason β-lactam antibiotics are only used as therapeutic treatments for individual animals and not as a mass medication. Furthermore cattle milk is a blended food which means that the undetectable residues in milk from treated animals will be blended with the milk from untreated animals thereby reducing any residues even further. Therefore the potential for allergic reactions to residues of β-lactam antibiotics is considered to be very low.

4.3 Ampicillin

The TGA has not established an ADI for ampicillin and as a result a dietary exposure assessment could not be conducted. However, ampicillin is only registered for use as a therapeutic intended for single animal use to treat mastitis when necessary. This use means that no detectable residues of ampicillin should occur in milk. On this basis, the MRL has been established at the limit of analytical quantification to:

- maintain the current prohibition on detectable residues in the Standard; and
- assist in the policing of any possible misuse, as detectable residues would only occur if the ampicillin formulations were misused.

4.4 Cloxacillin

The current MRL for cloxacillin in cattle milk is *0.01 mg/kg but the NRA has stated that analytical methods are unable to detect cloxacillin residues at this level. As a consequence the NRA has proposed that an MRL of *0.02 mg/kg be set to reflect the most up to date limit of quantification in milk.

ANZFA has noted that the United States of America (USA) has established an MRL for cloxacillin of 0.01 mg/kg in milk and that the European Union has established an MRL of 0.03 mg/kg for cloxacillin in milk. On this basis, ANZFA considers that the US MRL more accurately reflects the most up to date analytical methods and in the interests of minimising residues, ANZFA considers that the MRL for cloxacillin should remain unchanged.

5. REGULATORY IMPACT ANALYSIS

5.1 OBJECTIVE

To ensure that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety, and to ensure that the standards permit the legal sale of food that has been legally treated.

5.2 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*.
Option 3: - to accept the requests made by the NRA for ampicillin but not for cloxacillin.

5.3 Affected parties

The parties affected by this application are consumers, government, producers, food manufacturers and importers of primary produce and foods into Australia. In considering these proposed MRLs, it should be noted that they are both at the LOQ. This means that detectable residues of these antibiotics should not occur and the only benefit of including these proposed MRLs is to allow for the possibility that improved analytical methods may have a lower LOQ in the future.

5.4 Costs and benefits

5.4.1 Costs of accepting the NRA application (Option 1)

- initially enforcement agencies, food manufacturers and importers may have costs associated with compliance and enforcement of MRLs following the proposed amendments; 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, including undetectable residues, as a cost.

5.4.2 Benefits of accepting the NRA application (Option 1)

- 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, although in this case residues should not be detectable;

- 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.

5.4.3 Costs of not accepting the application (Option 2)

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

5.4.4 Benefits of not accepting the application (Option 2)

- Importers may potentially benefit by filling a possible domestic production shortfall if domestic agricultural productivity is reduced.

5.4.5 Costs of accepting the NRA application for ampicillin only (Option 3)

- initially enforcement agencies, food manufacturers and importers may have costs associated with compliance and enforcement of MRLs following the proposed amendment for ampicillin;

- 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, including undetectable residues, as a cost; 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.

5.4.6 Benefits of accepting the NRA application for ampicillin only (Option 3)

- 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, although in this case residues should not be detectable;

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

- residues of cloxacillin will be minimised.

5.5 Conclusion and recommended option

The inclusion of the NRA's proposed MRLs is consistent with the current registered uses of the chemical products. The dietary exposure assessments indicate that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. The NRA has already registered the chemical products and while rejection of the MRLs would not result in legally treated food not being able to be legally sold, it would create discrepancies between agricultural and health legislation. However, increasing the MRL for cloxacillin is unnecessary and potentially counter-productive to minimising residues.

Therefore including the proposed MRL for ampicillin only (Option 3) will benefit all stakeholders by maintaining public health and safety, minimising residues and permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

6. 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 an Initial Assessment of an application. In making that Initial 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.

6.1 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.

6.2 Paragraph 13(2)(b)

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

6.3 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.

6.4 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.

6.5 Paragraph 13(2)(e)

Other relevant matters for consideration by ANZFA are as follows.

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

6.5.1.1 Regulation 12a

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.

6.5.1.2 Regulation 12b

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

6.5.2 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 *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. Additionally, 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 variations to MRLs which are not addressed in the international Codex standard. MRLs in this application also relate to chemicals used in the production of heavily traded agricultural commodities which 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 Initial/Draft Assessment Report.

The application **will be** notified as a Sanitary and Phytosanitary (SPS) measure 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.

7. 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 of an application. In making that Draft Assessment, 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.

7.1 Paragraph 15(3)(a)

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

7.2 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 is discussed below.

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

The Chemicals and Non-prescription Medicines Branch of the TGA establish the ADI 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 their standards. 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.

7.2.2 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.

7.2.3 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.

7.2.3 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.

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

This is not relevant for this Application because there are no Codex MRLs for ampicillin and cloxacillin in cattle milk.

7.2.5 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 MRL for ampicillin would promote trade and commerce and allow food industries to continue to be efficient and competitive.

7.2.6 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.

7.3 Paragraph 15(3)(c)

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.

7.4 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.

7.5 Paragraph 15(3)(e)

This paragraph has been dealt with at the above section 6.5.

8. CONCLUSION

The inclusion of the proposed MRLs is consistent with the current registered uses of the chemical products. The dietary exposure assessments indicate that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. The NRA has already registered the chemical products and while rejection of the MRLs would not result in legally treated food not being able to be legally sold, it would create discrepancies between agricultural and health legislation. However, increasing the MRL for cloxacillin is unnecessary and potentially counter-productive to minimising residues. Therefore including the proposed MRL for ampicillin only will benefit all stakeholders by maintaining public health and safety, minimising residues and permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

9. PUBLIC SUBMISSIONS

The Authority has decided, pursuant to section 36 of the *Australia New Zealand Food Authority Act 1991*, to omit to invite public submissions in relation to the application prior to making a Draft Assessment. However, ANZFA now invites written submissions for the purpose of the Inquiry under s.17(3)(c) of the ANZFA Act and will have regard to any submissions received. The Authority was satisfied that omitting to invite public submissions prior to making a draft assessment was warranted as the application raises matters of a mechanical nature that are of minor significance or complexity. Furthermore, the Authority considered that omitting to invite public submissions prior to making a draft assessment, would not significantly adversely affect the interests of any person or body.

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
Fax (02) 6271 2278
email: slo@anzfa.gov.au

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
Fax (04) 473 9855
email: anzfa.nz@anzfa.gov.au

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

Submissions should be received by the Authority by: 23 JANUARY 2002

Submissions may also be sent electronically through the submission form on the ANZFA website www.anzfa.gov.au. Electronic submissions should also include the full contact details of the person making the submission on the main body of the submission so that the contact details are not separated.

11. ATTACHMENTS

1. A Summary of the Requested MRLs
2. Draft Variation to the *Food Standards Code*.
3. Statement of Reasons

ATTACHMENT 1

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

The Full Evaluation Reports are available upon request from the Project Manager at ANZFA.

NOTES ON TERMS USED IN THE TABLE

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.

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.

National Estimated Dietary Intake

The National Estimated Dietary Intake (NEDI) represents an estimate of dietary exposure. It may incorporate 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 as the above data is often not available and in these cases the MRL is used.

Glossary of Acronyms:

ADI Acceptable Daily Intake
LOQ Limit of Quantification.
NEDI National Estimated Dietary Intake.
* MRL is set at or about the limit of quantification, and therefore no detectable residues should be in the food.

A5. Antibiotics used for therapeutic use but with a human analogue		
CHEMICAL Food	**MRL** (mg/kg)	**INFORMATION**
Ampicillin Cattle milk	Add *0.01	The TGA has not established an ADI for ampicillin and as a result a dietary exposure assessment has not been conducted. However, ampicillin is only registered for use as a therapeutic intended for single animal use to treat mastitis when necessary. This use means that no detectable residues of ampicillin should occur in milk. On this basis, the MRL has been established at the LOQ to: • maintain the current prohibition on detectable residues in the Standard; and • assist in the policing of any possible misuse as detectable residues would only occur if the ampicillin formulations were misused.

ATTACHMENT 2

DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

A440 - MAXIMUM RESIDUE LIMITS

To commence: On gazettal

The *Food Standards Code* is varied by -

[1] *inserting in columns 1 and 2 respectively of Schedule 1 in Standard A14 in Volume 1, in relation to each chemical shown in bold type below, the food and the maximum residue limit for that food listed below -*

Chemical Food	**MRL**
Ampicillin Cattle milk	0.01

Explanatory Note: This is a new MRL for the antibiotic, ampicillin in cattle milk, which is not currently listed.

[2] *inserting in columns 1 and 2 respectively of Schedule 1 in Standard 1.4.2 in the Volume 2, in relation to each chemical shown in bold type below, the food and the maximum residue limit for that food listed below -*

AMPICILLIN INHIBITORY SUBSTANCE, IDENTIFIED AS AMPICILLIN	
CATTLE MILK	*0.01

Explanatory Note: This is a new MRL for the antibiotic, ampicillin in cattle milk which is not currently listed.

ATTACHMENT 3

STATEMENT OF REASONS

APPLICATION A440 – MAXIMUM RESIDUE LIMITS – ANTIBIOTICS

FOR RECOMMENDING A VARIATION TO STANDARDS A14 AND STANDARD 1.4.2 - MAXIMUM RESIDUE LIMITS - ANTIBIOTICS.

On 19 April 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 (MRL) for ampicillin and cloxacillin in the *Food Standards Code* with the MRLs in the *NRA MRL Standard*.

This Application (**A440**) is a routine application from the NRA, to update the *Food Standards Code* to reflect the current registration status of antibiotics in veterinary use in Australia. The Application seeks to change the MRL for the antibiotic cloxacillin in cattle milk to reflect current analytical methods and add a new MRL for the antibiotic, ampicillin in cattle milk.

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.

ANZFA has completed an Initial / Draft Assessment (Preliminary Assessment - s.13 / Full Assessment - s.15) of the Application, and has 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 MRL for ampicillin but that the MRL for cloxacillin in cattle milk should remain unchanged 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 antibiotics in this application and while rejection of the MRLs would not necessarily result in legally treated food not being able to be legally sold, it would create discrepancies between health and agricultural legislation. However, increasing the MRL for cloxacillin is unnecessary and potentially counter-productive to minimising residues. Therefore including the proposed MRL for ampicillin only will benefit all stakeholders by maintaining public health and safety, minimising residues and permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

- The NRA have assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this application.

- The Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aged Care has undertaken a toxicological assessment of the antibiotic cloxacillin and has established an acceptable daily intake (ADI).

- The issue of the potential of antimicrobial resistance developing as a result of dietary exposure to these antibiotic residues in food has recently been reviewed by the Expert Advisory Group on Antimicrobial Resistance (EAGAR), which did not raise any objections to these MRLs.

- The NRA has assessed the allergenicity of antibiotic residues in food commodities. While evidence for residues of antibiotics in foods causing allergic reactions is sparse, there is some evidence for rare occurrences of allergic reactions to the β-lactam antibiotics. For this reason β-lactam antibiotics are only used as therapeutic treatments for individual animals and not as a mass medication. Furthermore cattle milk is a blended food which means that the undetectable residues in milk from treated animals will be blended with the milk from untreated animals thereby reducing any residues even further. Therefore the potential for allergic reactions to residues of β-lactam antibiotics is considered to be very low.

- 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 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.

A summary of the proposed MRLs is in Attachment 1 of the Initial/Draft Assessment.

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 primarily the registered conditions of use that act to 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 MRLs also act as trading standards. 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 will make 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.

The proposed Draft Variations are in Attachment 2 of the Initial/Draft Assessment.