09/02
8 May 2002

FINAL ASSESSMENT REPORT
[INQUIRY – S.17]

APPLICATION A440

MAXIMUM RESIDUE LIMITS - ANTIBIOTICS

EXECUTIVE SUMMARY

- This Application seeks to amend Maximum Residue Limits (MRLs) for the antibiotics ampicillin and cloxacillin in cattle milk in the *Food Standards Code*.

- The current Application (A440) 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.

- 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. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

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

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

- The proposed MRL for ampicillin is at the limit of quantification (LOQ) and as detectable residues should not occur, ANZFA is satisfied that the residues associated with the proposed MRL do not represent an unacceptable risk to public health and safety.

- The Expert Advisory Group on Antimicrobial Resistance (EAGAR) has advised ANZFA that they consider that the residues associated with the proposed MRLs in this Application do not appear to pose a resistance risk.

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

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

- 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 LOQ.

1. ISSUES

The NRA has registered chemical products for the uses associated with the MRLs in Application A440 and is now seeking to amend the MRLs in the *Food Standards Code* to:

- change the MRL for the antibiotic cloxacillin in cattle milk to reflect the achievable 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 should occur 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.

1.1 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

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 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.

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 independently and 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.

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.

3.1 Toxicology of agricultural and veterinary chemicals

The Chemicals and Non-prescription Medicines Branch of the 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. However, The TGA has not established an acceptable daily intake for ampicillin and as a result a dietary exposure assessment could not be conducted. The proposed MRL has been set at the limit of quantification, this means that detectable residues of ampicillin should not occur in cattle milk.

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 Limit of Quantification

The proposed MRL in this Application is at the LOQ and is indicated by an * in the 'Summary of the Requested MRL for each Chemical' (Attachment 2). The LOQ is the lowest concentration of an agricultural or veterinary chemical residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. The inclusion of the MRL at the LOQ means that no detectable residues of the relevant chemical should occur. ANZFA incorporates MRLs at the LOQ in the *Food Standards Code* to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

3.4 National Estimated Daily Intake

The NEDI estimate of dietary exposure 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 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 Age Care undertook the NNS survey over a 12-month period (1995-early 1996). The sample of 13,858 respondents aged two years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns 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

The NRA has advised that:

- ampicillin and cloxacillin formulations are only registered for use to control summer mastitis in cows during the dry period;
- treated cows have been dried-off i.e. they are not lactating and no milk is being produced for human consumption;
- detectable residues of these chemicals should not occur in cattle milk; and
- the MRLs for cattle milk are needed to assist in enforcement of the veterinary product.

4.1 Antimicrobial resistance

The issue of potential antimicrobial 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. EAGAR's role 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.

4.2 Penicillins as allergens

The NRA has assessed the allergenicity of antibiotic residues in food commodities. Ampicillin and cloxacillin are β-lactam antibiotics, and 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 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. On this basis, the MRL has been established at the limit of analytical quantification to:

- assist in the policing of any possible misuse, as residues above 0.01mg/kg would only occur if the ampicillin formulations were misused; and

- assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

4.4 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.

Dairy Food Safety Victoria (DFSV), the Commonwealth Department of Agriculture Fisheries and Forestry – Australia and the Commonwealth Department of Health and Ageing have informed ANZFA that there is an analytical method available to detect residues of cloxacillin at 0.01 mg/kg. On this basis, ANZFA considers that the MRL of 0.01 mg/kg 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. EVALUATION OF ISSUES RAISED IN RESPONSE TO THE DRAFT ASSESSMENT REPORT

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

- ability to detect residues of cloxacillin;

- MRLs in other countries;

- residues of antibiotics in food;

- timetable for comment;

- use of ampicillin; and

- use of the term 'blended' to describe cattle milk.

Each of these is examined in turn below.

5.1 Ability to detect residues of cloxacillin

The submission from DSM Food Specialties expressed support for the NRA decision to raise the MRL for cloxacillin in cattle milk from 0.01 mg/kg to 0.02 mg/kg, as this would bring it within the detection limits for the DSM Food Specialties screening and testing product 'Delvo-test SP'. Submissions from the DFSV, the Commonwealth Department of Agriculture Fisheries and Forestry – Australia and the Commonwealth Department of Health and Ageing state that there is an analytical method available to detect residues of cloxacillin at 0.01 mg/kg. While recognising that this limit may be beyond the Delvo-test SP method, ANZFA considers that the MRL of 0.01 mg/kg 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.

The DFSV submission referred to the detection limits for test kits not correlating well with Australian MRLs for milk. Their submission recommended that in the MRL setting process that consideration is given to the current routine testing methods utilised by the dairy industry. They also referred to the unavailability of confirmatory test methods for antibiotic testing and recommended that confirmatory test methods be made more readily available to laboratories before a drug is registered and MRLs set.

These general issues relating to the registration of products and the enforcement of limit issues are considered during the registration process but are beyond the scope of this individual application. ANZFA has forwarded a copy of this submission to the NRA for their consideration.

5.2 MRLs in other countries

The submission from DFSV stated that the process for setting MRLs in other countries is different and that it may be premature to adopt the same levels as other countries. ANZFA acknowledged that countries may develop MRLs in different mechanisms from Australia and also may have different levels to account for different uses. However, in terms of determining achievable limits of quantification, it is legitimate to consider the lowest limits that are achievable in other countries to determine whether these limits of quantification can also be achieved in Australia. In this regard, ANZFA looked to the limits set in other countries to determine what was an achievable limit of quantification.

The submission from DSM Food Specialties stated that international bodies are setting different levels and it would be appropriate for these levels and the methods of setting them to be aligned. However, MRLs are dependent upon the use of agricultural and veterinary chemicals and the availability of detection methods. This means that different levels reflect different uses of agricultural and veterinary chemicals or different methods of detection.

In the case of the MRL for cloxacillin and ampicillin, the NRA has informed ANZFA that the uses of cloxacillin and ampicillin formulations are such that detectable residues should not occur.

As stated previously, ANZFA has been advised by the DFSV, the Commonwealth Department of Agriculture Fisheries and Forestry – Australia and the Commonwealth Department of Health and Ageing that a LOQ of 0.01 mg/kg for cloxacillin and ampicillin residues in milk is achievable. In this situation it is usual for the relevant MRL to be established at the LOQ. Therefore, ANZFA considers that the MRL of 0.01 mg/kg 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, and an MRL of 0.01 mg/kg is appropriate for ampicillin in cattle milk.

5.3 Residues of antibiotics in food

The submissions from Ms O'Driscoll and Ms Christian of Westland, New Zealand raised concerns about the amount of antibiotic residues in the food supply. 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 or where ANZFA is advised that the associated residues in food could lead to the development of antibiotic resistance in human pathogens. ANZFA routinely seeks the advice of EAGAR 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 EAGAR has advised ANZFA that they consider that the residues associated with the proposed MRLs in this application do not appear to pose a resistance risk.

The proposed MRLs in this application are at the LOQ and detectable residues should not occur. 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.

5.4 Timetable for comment

The submission from the National Council of Women of Australia expressed concerns about the timetable for comment on Application A440. ANZFA has statutory timeframes for progressing applications and these timeframes mean that ANZFA must limit the amount of time for which public comment can be accepted. This means that ANZFA normally allows four weeks for public comment on applications. However, ANZFA recognised that the MRLs associated with this application were potentially contentious and arranged for the public comment period to extend to six weeks.

ANZFA is also flexible in terms of timeframes with potential submitters and accepts late submissions in some circumstances. In addition, ANZFA must progress MRL applications in a timely manner, particularly when it is recognised that the use of the chemical products has already been registered and as a result producers could potentially be producing food containing residues in excess of the existing MRLs.

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

5.5 Use of ampicillin

The DFSV submission brought to ANZFA's attention that ampicillin is not only used as a therapeutic intended for single animal use but is also used as a whole herd treatment of dry cows (cows not producing milk for human consumption). The NRA has confirmed this and the Final Assessment Report has been adjusted accordingly.

5.6 Use of the term 'blended' to describe cattle milk

The DFSV questioned ANZFA's use of the term 'blended'. ANZFA's use of the term 'blended' is in relation to the blending of milk from one animal with the milk from another. It is in this context in which the term 'blended' was used, rather than to describe the blending of one producer's milk with another.

The submission from DSM Food Specialties stated that the practice of blending should not be encouraged from a public health point of view, but also from the perspective 'that product thus contaminated may result in penalties with international trading parties and affect future trade'. ANZFA documentation does not promote the practice of blending milk products but notes that it occurs. The assessment of dietary exposure is based upon the exposure from non-blended milk containing the highest possible level of the relevant antibiotics, and the practice of blending was mentioned as an additional factor that would reduce exposure further. In relation to trade, it should be noted that the use of ampicillin and cloxacillin are such that detectable residues should not occur and therefore trade concerns should not result.

6. REGULATION IMPACT ANALYSIS

6.1 OBJECTIVE

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

6.2 There are three 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.

6.3 Affected parties

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

6.4 Costs and benefits

6.4.1 Costs of accepting the 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.

6.4.2 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 and this benefit is unlikely to be significant;

- 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, although this benefit is unlikely to be significant.

6.4.3 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.

6.4.4 Benefits of not accepting the application (Option 2)

- No perceived benefits.

6.4.5 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.

6.4.6 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 and this benefit is unlikely to be significant;

- consumers may receive the potential benefits of improved crop and stock production through cheaper or better quality product, although this benefit is unlikely to be significant; and

- residues of cloxacillin will be minimised.

6.5 Conclusion and recommended option

The inclusion of the NRA's proposed MRLs is consistent with the current registered uses of the chemical products. The proposed MRL for ampicillin is at the limit of quantification (LOQ) and as detectable residues should not occur, ANZFA is satisfied that the residues associated with the proposed MRL do not represent an unacceptable risk to public health and safety. EAGAR has advised ANZFA that they consider that the residues associated with the proposed MRLs in this Application do not appear to pose a resistance risk. 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.

7. CONSIDERATION OF ISSUES UNDER SECTION 13 OF THE *AUSTRALIA NEW ZEALAND FOOD AUTHORITY ACT 1991*

Subsection 13(1) of the *Australia New Zealand Food Authority Act 1991* (ANZFA Act) requires ANZFA to make 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.

7.1 Paragraph 13(2)(a)

This Application relates to a matter that may warrant a variation to a food regulatory measure, because the application seeks an amendment of a standard. Under the ANZFA Act, a standard, by definition, is a food regulatory measure.

7.2 Paragraph 13(2)(b)

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

7.3 Paragraph 13(2)(c)

The Application does not suggest that the proposed amendment would present any further costs to the community, Government or industry. ANZFA has reviewed the application and has not identified any adverse health effects that would result from the variations being made.

7.4 Paragraph 13(2)(d)

The nature of the Application is such that only an amendment to a standard (i.e. a food regulatory measure) can bring about what the applicant is seeking. No other measures appear to be available.

7.5 Paragraph 13(2)(e)

Other relevant matters for consideration by ANZFA are as follows.

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

7.5.1.1 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.

7.5.1.2 Regulation 12b

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

7.5.2 World Trade Organization Notification

As a member of the WTO Australia is obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The MRLs prescribed in the *Food Standards Code* constitute a mandatory requirement applying to all food products of a particular class whether produced domestically or imported. Food products exceeding their relevant MRL set out in the *Food Standards Code* cannot legally be supplied in Australia.

In administrative terms and consistent with international practice, MRLs assist in regulating the use of agricultural and veterinary chemical products. MRLs indicate whether agricultural and veterinary chemical products have been used in accordance with the registered conditions of use. MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control pests and diseases. MRLs are also used as standards for the international trade in food.

This Application contains variations to MRLs which are not addressed in the international Codex standard. MRLs in this Application also relate to chemicals used in the production of heavily traded agricultural commodities which may indirectly have a significant effect on trade of derivative food products between WTO members.

ANZFA made a Sanitary and Phytosanitary (SPS) notification in accordance with the WTO SPS agreement. No WTO member has made a submission.

8. CONSIDERATION OF ISSUES UNDER SECTION 15 OF THE *AUSTRALIA NEW ZEALAND FOOD AUTHORITY ACT 1991*

Subsection 15(1) of the ANZFA Act requires ANZFA to make a Draft Assessment 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.

8.1 Paragraph 15(3)(a)

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

8.2 Paragraph 15(3)(b)

Section 10 (1), paragraphs (a) to(c) of the ANZFA Act sets out the objectives of food regulatory measures and variations to food regulatory matters. Each of these measures is discussed below.

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

The Chemicals and Non-prescription Medicines Branch of the TGA establish the ADI 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. The proposed MRL for ampicillin is at the limit of quantification (LOQ) and as detectable residues should not occur, ANZFA is satisfied that the residues associated with the proposed MRL do not represent an unacceptable risk to public health and safety. EAGAR has advised ANZFA that they consider that the residues associated with the proposed MRL in this Application do not appear to pose a resistance risk

8.2.2 Paragraph 10(1)(b) the provision of adequate information relating to food to enable consumers to make informed choices

This is not relevant for this Application.

8.2.3 Paragraph 10(1)(c) the prevention of misleading or deceptive information

This is not relevant for this Application.

In addition to these objectives, subsection 10(2) requires ANZFA to have regard to a number of matters set out in paragraphs 10(2)(a) to (d). Each of these matters is discussed below.

8.2.3 Paragraph 10(2)(a) the need for standards to based on risk analysis using the best available scientific evidence

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

8.2.4 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.

8.2.5 Paragraph 10(2)(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.

8.2.6 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.

8.3 Paragraph 15(3)(c)

ANZFA has undertaken a regulation impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the *Food Standards Code* is necessary, cost effective and of benefit to both producers and consumers.

8.4 Paragraph 15(3)(d)

The nature of the Application is such that only an amendment to a standard (i.e. a food regulatory measure) can bring about what the applicant is seeking. No other measures appear to be available.

8.5 Paragraph 15(3)(e)

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

9. CONCLUSION

The inclusion of the proposed MRLs is consistent with the current registered uses of the chemical products. The proposed MRL for ampicillin is at the limit of quantification (LOQ) and as detectable residues should not occur, ANZFA is satisfied that the residues associated with the proposed MRL do not represent an unacceptable risk to public health and safety.

EAGAR has advised ANZFA that they consider that the residues associated with the proposed MRLs in this application do not appear to pose a resistance risk. 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.

10. 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/Draft assessment. No WTO member has made a submission.

11. FURTHER INFORMATION

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

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

Australia New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2258
email: slo@anzfa.gov.au

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

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

ATTACHMENTS

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

ATTACHMENT 1

DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

A440 - MAXIMUM RESIDUE LIMITS

To commence: On gazettal

[1] ***Standard A14 of*** *Volume 1 of the Food Standards Code is varied by inserting in columns 1 and 2 respectively of* Schedule 1*, in relation to the chemical (shown in bold type), the food and the maximum residue limit for that food -*

Chemical Food	MRL
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] ***Standard 1.4.2 of*** *Volume 2 of the Food Standards Code is varied by inserting in columns 1 and 2 respectively of Schedule 1, in relation to the chemical (shown in bold type), the food and the maximum residue limit for that food -*

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 2

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

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

NOTES ON TERMS USED IN THE TABLE

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.

CHEMICAL Food		**MRL** (mg/kg)	**INFORMATION**
Ampicillin Cattle milk	Add	*[1]0.01	The TGA has not established an ADI[2] for ampicillin and as a result a dietary exposure assessment has not been conducted. The NRA has advised that: • ampicillin formulations are only registered for use to control summer mastitis in cows during the dry period; • treated cows have been dried-off i.e. they are not lactating and no milk is being produced for human consumption; • detectable residues of ampicillin should not occur in cattle milk; and • the MRLs for cattle milk are needed to assist in enforcement of the veterinary product. On this basis, the MRL has been established at the LOQ to assist: • in the policing of any possible misuse, as residues in excess of 0.01mg/kg would only occur if the ampicillin formulation was misused; and • in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

[1] The * indicates that the MRL is at the Limit of Quantification. This 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

[2] 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.

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 a Full Assessment (Inquiry - s.17) 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:

- ANZFA has been informed that analytical methods to detect cloxacillin at 0.01mg/kg are available.

- The proposed MRL for ampicillin is at the limit of quantification (LOQ) and as detectable residues should not occur, ANZFA is satisfied that the residues associated with the proposed MRL 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 Ageing has undertaken a toxicological assessment of the antibiotic cloxacillin and has established an acceptable daily intake (ADI).

- The Expert Advisory Group on Antimicrobial Resistance (EAGAR) has advised ANZFA that they consider that the residues associated with the proposed MRLs in this application do not appear to pose a resistance risk.

- 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 regulation impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the *Food Standards Code* is necessary, cost effective and of benefit to both producers and consumers.

A SUMMARY OF THE REQUESTED MRLS IN APPLICATION A440

Please see Attachment 2 of the Full Assessment Report.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

As a member of the WTO Australia is obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

MRLs prescribed in the *Food Standards Code* constitute a mandatory requirement applying to all food products of a particular class whether produced domestically or imported. Food products exceeding their relevant MRL set out in the *Food Standards Code* cannot legally be supplied in Australia.

In administrative terms and consistent with international practice, MRLs assist in regulating the use of agricultural and veterinary chemical products. MRLs indicate whether agricultural and veterinary chemical products have been used in accordance with the registered conditions of use, and it is primarily the registered conditions of use that act to protect human, animal and plant health and the environment. MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control pests and diseases. MRLs are also used as standards for the international trade in food. 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. No WTO member has made a submission.

DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

Please see Attachment 1 of the Final Assessment Report.

ATTACHMENT 4

SUMMARY OF PUBLIC SUBMISSIONS RECEIVED AT DRAFT ASSESSMENT

Submitter	Comments raised
Ms Anji Christian	Did not support the application. States that there is 'more than enough antibiotic additions to the food supply'.
Commonwealth Department of Health and Ageing	Supports option three to accept the request made by the NRA for ampicillin but not for cloxacillin and vary the *Food Standards Code*.
Dairy Food Safety Victoria	Supports option three to accept the request made by the NRA for ampicillin but not for cloxacillin and vary the *Food Standards Code*.
Commonwealth Department of Agriculture, Fisheries and Forestry - Australia	Supports option three to accept the request made by the NRA for ampicillin but not for cloxacillin and vary the *Food Standards Code*.
DSM Food Specialties	Supports option one to accept the request made by the NRA for ampicillin and cloxacillin and vary the *Food Standards Code*.
Food Technology Association	The Technical Sub-committee of the Association accepted this Application without further comment.
National Council of Women of Australia	The Council was unable to supply a submission due to their offices being closed.
Ms Leah O'Driscoll	Did not support the application. States that there is 'more than enough antibiotic additions to the food supply'.
Queensland Health	Supports option three to accept the request made by the NRA for ampicillin but not for cloxacillin and vary the *Food Standards Code*.