

09/02
8 May 2002

FINAL ASSESSMENT REPORT
(INQUIRY - S. 17)

APPLICATION A422

MAXIMUM RESIDUE LIMITS - ANTIBIOTICS

EXECUTIVE SUMMARY

- This Application seeks to amend Maximum Residue Limits (MRL) for antibiotic residues in the *Food Standards Code*.
- The current Application (A422) is a routine Application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the *Food Standards Code* in order to reflect current registration status of antibiotics in veterinary use in Australia.
- 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 Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Ageing has undertaken an appropriate toxicological assessment of the antibiotics and has established relevant acceptable daily intakes (ADI).
- The NRA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Agricultural and Veterinary Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this application.
- ANZFA is satisfied from the dietary modelling that the residues associated with the proposed MRLs 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 represent an unacceptable risk to public health and safety.
- None of ANZFA's section 10 objectives of food regulatory measures are compromised by the proposed changes. The requested variation to the *Food Standards Code* should commence on gazettal.
- ANZFA at initial assessment made a Sanitary and Phytosanitary notification to the World Trade Organization. No WTO Member has made a submission.

1. ISSUES

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

- include limit of quantification (LOQ) MRLs for a new antibiotic, avilamycin for poultry meat and poultry offal;
- delete MRLs for the antibiotics, benzyl G penicillin, and procaine penicillin for poultry meat, poultry offal and eggs;
- delete MRLs for the antibiotic, erythromycin for eggs; and
- include a temporary MRL for the antibiotic, oxytetracycline (OTC) for honey.

2. BACKGROUND

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

The MRL is the highest concentration of a chemical residue that is legally permitted or accepted in a food. The MRL does not indicate the amount of chemical that is always present in a treated food but it does indicate the highest residue that could result from the registered conditions of use. The concentration is expressed in milligrams per kilogram (mg/kg) of the food. MRLs are indicators of whether an agricultural or veterinary chemical product has been used according to its registered use and if the MRL is exceeded then this indicates a likely misuse of the chemical product. However, MRLs are not established for specific commodities if the residues resulting from the use of the chemical product could represent an unacceptable risk to public health and safety.

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

2.1 Food Standards Setting in Australia and New Zealand

2.1.1 *Treaty between the Commonwealth of Australia and New Zealand*

The agreement between the Commonwealth of Australia and the Government of New Zealand to establish a system for the development of joint food standards (the Treaty) excluded MRLs for agricultural and veterinary chemicals in food. Australia and New Zealand 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.

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

The NRA has informed ANZFA of anomalies between the NRA MRL Standard and the *Food Standards Code* for the antibiotics benzyl G penicillin, erythromycin, and procaine penicillin. This application includes proposed amendments to correct these anomalies.

2.3 **Limit of Quantification**

Some of the proposed MRLs in this Application are at the limit of quantification LOQ and are indicated by an * in the Summary of the Requested MRLs for 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 MRLs at the LOQ means that no detectable residues of the relevant chemical should occur. ANZFA incorporates MRLs at the LOQ in the *Food Standards Code* to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

3. **DIETARY EXPOSURE ASSESSMENT**

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

There are a number of methods for estimating dietary exposure based on the type of information that is available. The one that was considered in this application was the National Estimated Daily Intake (NEDI).

3.1 **Toxicology of agricultural and veterinary chemicals**

The Chemicals and Non-prescription Medicines Branch of the 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 does not exceed the ADI.

3.3 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 agricultural and veterinary chemical residue levels. When adequate information is available, monitoring and surveillance data or total diet studies may also be used such as the Australian Total Diet Survey (ATDS).

3.4 Food Consumption Data

The NRA and ANZFA have recently agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the NRA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest 1995 National Nutrition Survey (NNS). The Australian Bureau of Statistics with the Commonwealth Department of Health and Aged Care undertook the NNS survey over a 12-month period (1995-early 1996). The sample of 13,858 respondents aged 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. EVALUATION OF ISSUES RAISED IN RESPONSE TO THE INITIAL ASSESSMENT REPORT

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

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

Each of these is examined in turn below.

4.1 Importation of foods

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

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

4.2 Deletion of antibiotic MRLs

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

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

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

4.3 Potential resistance development and JETACAR recommendations

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

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

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

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

4.4 The use of and approval for antibiotics in agriculture

The submission from Queensland Health stated that 'European countries are withdrawing antibiotics from use in animal feeds' and also commented on the requirements of field trials, the efficacy and labelling of formulations, and the appropriateness of withholding periods. The NRA approves the use of agricultural and veterinary chemicals, assesses labels and trial data and determines permit conditions. As the NRA is in a better position to answer these concerns, ANZFA has forwarded a copy of the Queensland Health submission to the NRA for them to reply to Queensland Health. The NRA has not advised that the proposed MRLs should be withdrawn and ANZFA has continued to progress them through the statutory process.

4.5 Potential toxicity of antibiotics

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

The proposed MRL for oxytetracycline in honey is temporary to allow research and field trials into the treatment of European Foul Brood in bees and is indicated by a 'T' in the Summary of the Requested MRLs for A442 (Attachment 2).

ANZFA does not issue permits or grant permission for the temporary use of agricultural and veterinary chemicals. Further information on MRLs for permits can be found on the website of the NRA at <http://www.nra.gov.au> or by contacting the NRA on +61 2 6272 5158.

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

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

4.6 Penicillins as allergens

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

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

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

the role of ANZFA	antibiotics in agriculture
antimicrobial resistance	article in the <i>Adelaide Advertiser</i>
development of antimicrobial resistance	imports of honey
notification of the application	permits for use of antibiotics
Regulation Impact Statements	relationship between the NRA and ANZFA
residues in honey	synergy
timetable for comments	

Each of these is examined in turn below.

5.1 Role of ANZFA

Submissions from the National Council of Women of Australia (NCWA) and the South Australian Apiarist Association were concerned with the use of agricultural and veterinary chemicals. ANZFA has no role in regulating the use of agricultural and veterinary chemicals and food legislation does not regulate the use of agricultural and veterinary chemicals. ANZFA develops food regulatory measures for inclusion in the *Food Standards Code*, which is then adopted in Commonwealth, State, Territory and New Zealand food legislation. ANZFA's focus is the public health implications the residues in treated food and ensuring that 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.

The NCWA submission stated that 'When considering food additives, ANZFA has to consider technological justification for the additive's use'. The NCWA submission then asked where the technological justification is for the use of avilamycin. The use of food additives in food is regulated by food legislation but the use of agricultural and veterinary chemicals is not. This means that while ANZFA can consider the technological justification for food additives in food it cannot consider the technological justification for the use of agricultural and veterinary chemicals. The NRA considers the efficacy and need for agricultural and veterinary chemicals and both the NRA and ANZFA considers the public health implications of the residues in food.

Furthermore, MRLs do not control, permit or prevent the use of agricultural and veterinary chemicals. This is because MRLs are only indicators of the maximum residues that may occur not the typical residues. Many uses of agricultural and veterinary chemicals do not result in detectable residues and this means that the MRL does not control or prevent their use.

The MRLs for avilamycin demonstrate that the use of avilamycin should not result in detectable residues and so the MRLs do not control the use of this chemical. In addition, the proposed MRLs for avilamycin are at the LOQ and as a result the effect is to continue the restriction applied by the current standard i.e. no detectable residues 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.

5.2 Antibiotics in agriculture

Submissions from the NCWA and Mr J. Carapiet expressed concerns about the general use of antibiotics in agriculture and both stated that the uses of antibiotics are either being phased out or banned overseas. This is not the case and not all antibiotics are an issue in terms of antimicrobial resistance. For example, the European Union has not banned the use of avilamycin (the subject of this application) as an antimicrobial growth promotant but has phased out the use of some other antibiotics.

This issue was previously addressed in sections 4.3 and 4.4 of this document.

5.3 An article in the Adelaide Advertiser

The submission from the Australian Honey Bee Industry Council (AHBIC) referred to an advertisement and a major article in the *Adelaide Advertiser* that concerned them in relation to the use of antibiotics in agricultural. ANZFA did not place an advertisement and did not contribute to the article in this newspaper. While recognising that this article may have caused concern to AHBIC, ANZFA cannot be held accountable for this article over which ANZFA has no control.

5.4 Development of antimicrobial resistance

The NCWA submission stated that ‘ANZFA consulted the Commonwealth Interdepartmental JETACAR Implementation Group’ about the issue of antibiotic resistance and questioned the use of the word ‘appear’ in their advice.

ANZFA did not consult the ‘Commonwealth Interdepartmental JETACAR Implementation Group’ about these MRLs. The Commonwealth Interdepartmental JETACAR Implementation Group is responsible for implementing the Commonwealth Government’s response to the JETACAR Report. This Group is not responsible for providing advice on individual MRLs and the potential for the development of antimicrobial resistance.

The potential for the development of antimicrobial resistance has been previously been addressed in section 4.3 of this document.

5.5 Imports of Honey

The submission from the AHBIC questioned the quantity of honey imported into Australia. ANZFA quotes import data in its reports that were purchased from the Australian Bureau of Statistics. The ABS has subsequently supplied corrected data on honey imports.

5.6 Notification of the Application

The AHBIC was concerned that they were not given any notice of Application A422. The AHBIC is included in ANZFA’s subscriber database and ANZFA records indicate that the relevant information circular for this Application was provided to them.

However, the title of the Application may not have been sufficiently detailed to identify that the application contained MRLs for OTC in honey. Given the number of MRLs in Applications this precludes ANZFA from detailing every chemical and every food in the title of an application.

5.7 Permits for use of antibiotics

The NCWA submission raised matters that would be addressed in ‘use’ permits. As the NRA grants permits for use and as ANZFA does not regulate use, these matters were appropriately referred to the NRA for their consideration. The NRA has not advised that the proposed MRLs should be withdrawn and ANZFA has continued to progress them through the statutory processes.

5.8 Regulation Impact Statements

The NCWA made a number of general comments about the Regulation Impact Statement. These statements are in the process of being reviewed and the NCWA’s comments will be considered when these assessments are reviewed.

The NCWA submission raised concerns about the use of the terms ‘if’ and ‘could’ in the Regulation Impact Statement. These terms are used because the statement is assessing the impacts of possible future regulation paths. For this reason any impacts are always going to be ‘potential’ or ‘possible’. ANZFA considers that it is appropriate to use these terms.

5.9 Relationship between the NRA and ANZFA

The NCWA questioned the relationship between the NRA and ANZFA. The NCWA also considered that by having two regulatory agencies for determining MRLs this places consumers in an ‘impossible situation’ and that a ‘better method’ for determining MRLs is needed. ANZFA and the NRA regularly discuss issues related to dietary exposure assessments and both agencies use agreed approaches based upon internationally recognised protocols when assessing dietary exposure. Additionally, the legislation of both the NRA and ANZFA have similar wording which requires both agencies to ensure that public health and safety is not compromised. Nevertheless, ANZFA has to independently assure itself that the residues in food are safe before it recommends MRLs for inclusion in the *Food Standards Code*.

The current processes for developing MRLs mean that two regulatory agencies are responsible for independently assessing the public health and safety aspects of residues in food. However, it is recognised that this is not the most practical or efficient means by which the residues in food can be considered. A Commonwealth Interdepartmental Committee is considering the issue and is in the process of considering an optimal MRL setting system.

5.10 Residues in of oxytetracycline in honey

The submission from the South Australian Apiarists Association Inc. expressed concerns about the occurrence of residues of OTC in honey, and in particular the possible trade implications. As previously mentioned in section 5.1 of this document, ANZFA’s primary focus is the public health implications of the dietary exposure to potential residues in treated food and ensuring that these residues 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. ANZFA considers that the residues associated with the proposed MRL for OTC in honey do not represent an unacceptable risk to public health and safety.

Food sold or imported into Australia must comply with the MRLs stipulated in the *Food Standards Code*. Where the *Food Standards Code* does not include an MRL for a chemical in a food then this means that there must be no detectable residues of that chemical in that food. Currently an MRL for OTC in honey does not exist in the *Food Standards Code* and this means that honey cannot legally be imported into or sold in Australia if it contains detectable residues of OTC.

The NRA has advised ANZFA that the use of OTC products in hives can result in detectable residues in honey. This is supported by data from the Report on the Australian National Residue Survey Results, 1999 - 2000 where residues of OTC were reported in honey (Attachment 5).

Where the residues associated with the legal use of a chemical product do not represent an unacceptable risk to public health and safety, ANZFA considers that the MRL associated with the legal use should be included in the *Food Standards Code*. ANZFA considers that this is appropriate so that the legally treated produce can be legally sold under food legislation. Therefore, if the existing use of OTC is retained, ANZFA considers that it is necessary to include the relevant MRL so that honey from legitimately treated hives can be legally sold under food legislation.

It is recognised that South Australia may not have the same honey bee diseases or need for chemical products as other jurisdictions. However, the *Food Standards Code* is a national standard intended to apply throughout Australia. It is therefore appropriate that this national standard reflect the residues that may occur in food produced in all parts of Australia. This means that it is necessary for all relevant MRLs to be included in the *Food Standards Code* even though the associated chemical uses may not be relevant to certain jurisdictions.

5.11 Synergy

The NCWA submission requested information as to ‘What is known about synergy with other chemicals given to poultry’. There are several reasons why testing for these effects are not carried out:

- chemicals are not generally used simultaneously;
- the low levels of residues in food are unlikely to have any significant effect on metabolism or toxicity of other chemicals and the mechanisms of action are quite different in most cases; and
- there is very little scientific evidence of true synergy between agricultural and veterinary chemical residues in relation to potential toxicity from the data available. For testing of synergistic effects to be appropriate there would need to be a reasonable explanation for the mechanism of this synergy - in most cases this explanation does not exist.

5.12 Timetable for comment

The submission from the AHBIC and the NCWA expressed concerns about the timetable for comment on Application A422. 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 has accepted late submissions in this case. 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 and the food supply.

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 two Options:

Option 1: - to accept the requests made by the NRA and vary the *Food Standards Code*.

Option 2: - to reject the requests and make no changes to the *Food Standards Code*.

6.3 Affected parties

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

6.4 Costs and benefits

6.4.1 Costs of making the changes sought by the NRA

- there will be a cost of disposal, replacement and dissemination of information about proscribed agricultural and veterinary chemicals;
- initially enforcement agencies, food manufacturers and importers may have an administrative burden with complying and enforcing the proposed MRLs;
- importers will no longer be able to rely on existing MRLs; and

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

6.4.2 *Benefits of making the changes sought by the NRA*

- poultry producers and apiculturists will be legally able to sell produce legally treated with chemicals intended to improve stock and yields as well as controlling diseases and pests;
- it will ensure consistency between the health and agricultural regulations;
- it will benefit all stakeholders by maintaining public health and safety; and
- consumers may receive the potential benefits of improved stock production through cheaper or better quality produce.

6.4.3 *Costs of not of making the changes sought by the NRA*

- producers will not be able to legally sell produce that has been legally treated with chemicals intended to increase productivity by improving feed efficiency and weight gain;
- there may be increased production costs for manufacturers and ultimately increased costs to consumers if commodities which have been legally treated to improve productivity and/or control pests and disease cannot be legally sold; and
- the discrepancies between the *Food Standards Code* and the NRA MRL Standard would become greater leading to confusion for producers, consumers and government agencies.

6.4.4 *Benefits of not of making the changes sought by the NRA*

- importers may potentially benefit by filling a possible domestic production shortfall by local producers resulting from potential reduction in domestic agricultural productivity; and
- products complying with the existing MRLs could continue to be legally sold.

6.5 Conclusion and recommended option

The proposed deletion of the MRLs of erythromycin, benzyl G penicillin and procaine penicillin is consistent with the fact that products containing these chemicals are no longer registered and has public support.

The dietary exposure calculations indicate that the ADIs for avilamycin and OTC will not be exceeded. The NRA has already registered these antibiotics for which new MRLs are proposed in this application and rejection of the MRLs would result in legally treated food not being able to be legally sold.

Therefore the requested changes will benefit all stakeholders by maintaining public health and safety while permitting the appropriate use of antibiotics in agriculture and veterinary treatment.

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

7. ANZFA SECTION 10 OBJECTIVES

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

(a) The protection of public health and safety

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

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

This is not relevant for this Application.

(c) Prevention of misleading or deceptive conduct

This is not relevant for this Application.

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

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

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

(b) The promotion of consistency between domestic and international food standards

The proposed MRLs in this Application reflect the domestic use of agricultural and veterinary chemicals, details of overseas uses were not available. Because agricultural conditions vary from one geographic location to another, differences in national MRLs are to be expected. These proposed variations represent some move away from consistency between Codex and domestic standards.

(c) The desirability of an efficient and internationally competitive food industry

The requested MRLs are necessary to allow the legal sale of legally treated food. Varying the *Food Standards Code* to include the proposed MRLs would promote trade and commerce.

(d) The promotion of fair trading in food

As the MRLs in the *Food Standards Code* apply to all food produced or imported for sale or in Australia, the inclusion of the MRLs would benefit all producers equally.

8. CONCLUSION

The dietary exposure calculations indicate that the ADI for each chemical will not be exceeded. The proposed deletion of the MRLs of erythromycin, benzyl G penicillin and procaine penicillin is consistent with the fact that the relevant chemicals are no longer registered for use. The NRA has already registered the antibiotics in this Application and rejection of the MRLs for oxytetracycline would result in legally treated food not being able to be legally sold. The MRLs for avilamycin are at the LOQ and detectable residues should not occur. EAGAR has advised ANZFA that they consider that the residues associated with the proposed MRLs in this application do not represent an unacceptable risk to public health and safety. Including the MRLs would assist in identifying and practical benchmarking for enforcement and allow for future analytical method developments. Therefore the requested changes will benefit all stakeholders by maintaining public health and safety while permitting the appropriate use of antibiotics.

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

9. 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.

10. CODEX MRLS

The standards of the Codex Alimentarius Commission are used as the relevant international standards or basis as to whether a new or changed standard requires a WTO notification. The following table sets out the proposed MRLs, in the NRA application, which are more restrictive than the Codex MRL.

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

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

ANZFA recognises that changes to MRLs have implications for the importation of food, particularly where MRLs are deleted and therefore no detectable residue is permitted. No submissions were received in relation to the Codex MRLs.

11. IMPORTED FOODS

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

Food	1999 tonnes	2000 tonnes
Honey	101	181
Poultry Eggs	672	353
Poultry meat	142	143

The submission from the Australian Honey Bee Industry Council questioned the quantity of honey imported into Australia. ANZFA quoted import data in its reports that was purchased from the Australian Bureau of Statistics (ABS). The ABS has provided corrected import data which are included above.

12. 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. Draft Variations to the *Food Standards Code*.
2. Summary of proposed MRLs for A422.
3. Statement of Reasons.
4. Summary of Public Submissions Received at Draft Assessment.
5. Extract from the Report on the Australian National Residue Survey Results 1999 – 2000.

DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

A422 - MAXIMUM RESIDUE LIMITS

To commence: On gazettal

[1] *Standard A14 of Volume 1 of the Food Standards Code is varied by -*

[1.1] *inserting in columns 1 and 2 respectively of Schedule 1 each chemical (shown in bold type) and its associated food and maximum residue limit for that food -*

Chemical

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

Explanatory Note: These are new MRLs for a new chemical not previously listed.

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

Chemical

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

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

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

Chemical

Food	MRL
Oxytetracycline	
Honey	0.3

Explanatory Note: This is a new MRL for the existing chemical, but for a food that is not currently listed.

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

[2.1] *inserting in columns 1 and 2 respectively of Schedule 1 each chemical (shown in bold type) and its associated food and maximum residue limit for that food -*

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

Explanatory Note: These are new MRLs for a new chemical not previously listed.

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

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

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

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

OXYTETRACYCLINE INHIBITORY SUBSTANCE, IDENTIFIED AS OXYTETRACYCLINE	
HONEY	T0.3

Explanatory Note: This is a new MRL for the existing chemical, but for a food that is not currently listed.

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

CHEMICAL Food	MRL (mg/kg)	INFORMATION
Avilamycin Poultry meat Poultry, Edible offal of	Add * ¹ 0.05 Add *0.05	NRA has advised that this is a new active ingredient in poultry feed premix to improve feed efficiency by modifying gut microflora populations. No detectable residues should occur. NEDI ² = <1% of ADI ³ .
Benzyl G Penicillin Eggs Poultry, Edible offal of Poultry meat	Delete 0.018 Delete 0.06 Delete 0.06	As these are deletions no NEDI has been calculated
Erythromycin Eggs	Delete 0.3	As this is a deletion no NEDI has been calculated
Oxytetracycline Honey	Add T ⁴ 0.3	The NRA has issued a permit to facilitate additional research and field trials to support the current registered use for the control of European Foul Brood in honey bees. NEDI = 38.3% of the ADI
Procaine Penicillin Eggs Poultry, Edible offal of Poultry meat	Delete 0.03 Delete 0.1 Delete 0.1	As these are deletions no NEDI has been calculated

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

³ 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.

⁴ Temporary MRL

STATEMENT OF REASONS

APPLICATION A422

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

The Australia New Zealand Food Authority (ANZFA) has before it Application A422 (received 6 September 2000), from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) seeking to amend Standards A14 and 1.4.2 for the *Food Standards Code*.

ANZFA has completed a final assessment of the Application, and prepared draft variations to Standard A14 in Volume 1 and Standard 1.4.2 in Volume 2 of the *Food Standards Code*.

ANZFA recommends progressing the Application for the following reasons:

- The current Application (A422) is a routine application from the NRA, to update the *Food Standards Code* in order to reflect current registration status of antibiotics in veterinary use in Australia.
- The Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Ageing has undertaken an appropriate toxicological assessment of the antibiotics and has established relevant acceptable daily intakes (ADI).
- ANZFA is satisfied from the dietary modelling performed that the changes to the *Food Standards Code* for the chemicals in this application will not cause the ADI to be exceeded.
- 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 represent an unacceptable risk to public health and safety.
- None of ANZFA's Section 10 objectives of food regulatory measures are compromised by the proposed changes. The requested variation to the *Food Standards Code* should commence on gazettal.
- ANZFA has made a Sanitary and Phytosanitary notification to the World Trade Organization. No WTO member has made a submission to this Application.

A SUMMARY OF THE REQUESTED MRLS

CHEMICAL Food	MRL (mg/kg)	INFORMATION
Avilamycin Poultry meat Poultry, Edible offal of	Add * ⁵ 0.05 Add *0.05	NRA has advised that this is a new active ingredient in poultry feed premix to improve feed efficiency by modifying gut microflora populations. No detectable residues should occur.. NEDI ⁶ = <1% of ADI ⁷ .
Benzyl G Penicillin Eggs Poultry, Edible offal of Poultry meat	Delete 0.018 Delete 0.06 Delete 0.06	As these are deletions no NEDI has been calculated
Erythromycin Eggs	Delete 0.3	As this is a deletion no NEDI has been calculated
Oxytetracycline Honey	Add T ⁸ 0.3	The NRA has issued a permit to facilitate additional research and field trials to support the current registered use for the control of European Foul Brood in honey bees. NEDI = 38.3% of the ADI
Procaine Penicillin Eggs Poultry, Edible offal of Poultry meat	Delete 0.03 Delete 0.1 Delete 0.1	As these are deletions no NEDI has been calculated

REGULATION IMPACT

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.

⁵ 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.

⁶ NEDI - National Estimated Dietary Intake - The 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 because the above data is often not available and in these cases the MRL is used.

⁷ 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.

⁸ Temporary MRL.

CODEX MRLS

The standards of the Codex Alimentarius Commission are used as the relevant international standards or basis as to whether a new or changed standard requires a WTO notification. The following table sets out the proposed MRLs, in the NRA application, which are more restrictive than the Codex MRL.

In its initial assessment ANZFA, in error, stated that the deletion of the MRLs for benzyl G penicillin and procaine penicillin would not result in MRLs that were more restrictive than Codex. To allow additional public consultation on these MRLs ANZFA sought a second round of public consultation under section 17(3)(a) of the Act. No submissions were received relating to residues associated with Codex MRLs.

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

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

IMPORTED FOODS

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

Food	1999	2000
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Poultry meat	142 tonnes	143 tonnes

The submission from the Australian Honey Bee Industry Council questioned the quantity of honey imported into Australia. ANZFA quoted import data in its reports that was purchased from the ABS. The ABS has provided corrected import data which are included above.

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 as the primary objective of the measure is to support regulating the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment. No WTO Member has made a submission.

DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

Please see Attachment 1 of the Final Assessment Report.

SUMMARY OF PUBLIC SUBMISSIONS RECEIVED AT DRAFT ASSESSMENT

Submitter	Comments raised
Australian Honey Bee Industry Council	Supports the approval of an MRL for oxytetracycline in honey.
Mr J. Carapiet	Opposes the approval of new MRLs for avilamycin being used for poultry.
Consumers' Association of South Australia Inc	Supports the submission made by the National Council of Women of Australia
Department of Agriculture, Fisheries and Forestry - Australia	Supports option one to accept the request made by the NRA and vary the <i>Food Standards Code</i> .
Food Technology Association - Victoria	Accepts option one to vary the MRLs in accordance with the NRA Application
Informed Systems Ltd	Supports option one to vary the MRLs in accordance with the NRA Application.
National Council of Women of Australia	Opposes the approval of an MRL for oxytetracycline in honey and MRLs for avilamycin for poultry. Supports the deletion of MRLs for benzyl g and procaine penicillin.
New Zealand Ministry of Health	Has no particular concerns about the Application
South Australian Apiarists Association Inc	Opposes the introduction of an MRL for oxytetracycline in honey.
South Australian Farmers Federation	Supported the submission made by the South Australian Apiarists Association Inc.