10/02
26 June 2002

FINAL ASSESSMENT REPORT
(INQUIRY - SECTION 17)

APPLICATION A460

MAXIMUM RESIDUE LIMITS - ANTIBIOTICS

THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY

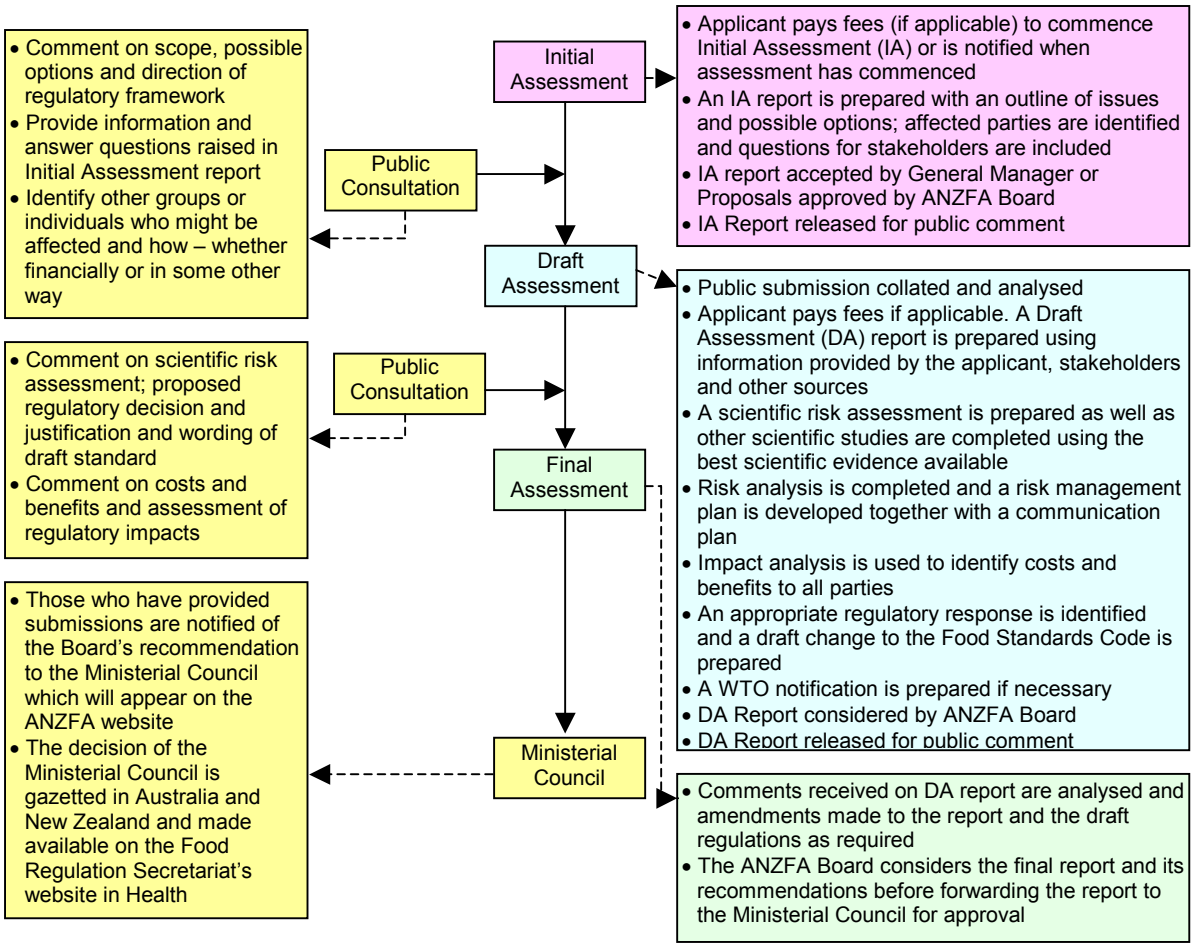
The Australia New Zealand Food Authority's (ANZFA) is a partnership between the Commonwealth Government, Australian State and Territory governments and the New Zealand Government. ANZFA is a bi-national, statutory body whose role, in association with others, is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply.

ANZFA seeks to achieve this goal by developing, varying and reviewing standards for food available for sale in Australia and New Zealand and through a range of other functions including national food surveillance and recall systems, conducting research, assessing policies about imported food and developing codes of practice with industry.

In developing and reviewing food standards for both Australia and New Zealand, ANZFA makes recommendations to change the food standards to the Australia New Zealand Food Standards Council, a Ministerial Council made up of Commonwealth, State and Territory and New Zealand Health Ministers. If the Council approves the recommendations made by ANZFA, the food standards are automatically adopted as regulations into the food laws of the Australian States and Territories and New Zealand.

STEPS IN DEVELOPING AND REVIEWING FOOD STANDARDS

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Australia New Zealand Food Authority Act 1991* (ANZFA Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



CONTENTS

Executive Summary

- This Application (A460) seeks to include new Maximum Residue Limits (MRLs) for the antibiotic cephapirin in cattle meat, milk and offal and semduramicin in chicken fat/skin, kidney, liver and meat in the *Food Standards Code*. The National Registration Authority for Agricultural and Veterinary Chemicals (NRA), seeks to update the *Food Standards Code* in order to reflect current registration status of cephapirin and semduramicin in use in Australia. The proposed MRLs for cephapirin are at the limit of quantification (LOQ).

- On 24 November 2000, the Australia New Zealand Food Standards Council adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). On 24 May 2002, the Ministerial Council agreed to vary the *Food Standards Code* to amend Standard A14 (Volume 1) by deleting schedules 1, 2 and 3 of that Standard and referring the schedules in Standard A14 to the MRL schedules of Standard 1.4.2. This created a single set of schedules for MRLs. Subsequently all applications to amend MRLs will now be incorporated into schedules 1,2 and 3 of Standard 1.4.2 of the *Food Standards Code*. Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

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

- The Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Ageing has undertaken a toxicological assessment of the antibiotics cephapirin and semduramicin and has established acceptable daily intakes (ADI).

- The Expert Advisory Group on Antimicrobial Resistance (EAGAR) has considered the issue of the potential for antimicrobial resistance developing as a result of dietary exposure to cephapirin and semduramicin residues in food. EAGAR did not raise any objections in terms of either the use or the residues associated with the use of these antibiotics.

- The dietary exposure assessments indicate that the residues associated with the proposed new MRLs for cephapirin and semduramicin do not represent an unacceptable risk to public health and safety.

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

- ANZFA has made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO) at the Initial / Draft Assessment (Preliminary Assessment - s.13 / Full Assessment - s.15). No submissions have been received from WTO members.

1. Introduction

An application was received from the NRA on 29 November 2001 and 12 December 2001 seeking to include new MRLs in Standard 1.4.2 for the *Food Standards Code*. The proposed amendments to Schedule 1 of the Standard to include new MRLs for cephapirin and semduramicin would align the MRLs in the *Food Standards Code* with the MRLs in the NRA MRL Standard.

The Application from the NRA seeks the inclusion of new MRLs for the new antibiotics, cephapirin in cattle meat, milk and offal and semduramicin in chicken fat/skin, kidney, liver and meat. The proposed MRLs for cephapirin are at the limit of quantification (LOQ).

Appropriate toxicology, residue, animal transfer, processing and metabolism studies were provided to the NRA in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997* to support the use of cephapirin and semduramicin on commodities as outlined in this application. Full evaluation reports for individual chemicals are available upon request from the relevant Project Manager at ANZFA.

2. Regulatory Problem

2.1 Current Regulations

The NRA has approved the use of the agricultural and veterinary chemical products associated with the MRLs in this Application, and made consequent amendments to the NRA MRL Standard. The approval of the use of these products result in there being a discrepancy between the residues associated with the use and the MRLs in the *Food Standards Code* meaning that:

- where the NRA has increased MRLs, food cannot be legally sold under food legislation if it contains residues in excess of the existing MRLs in the *Food Standards Code*;

- where the NRA has included MRLs for new chemicals or for additional foods that are not included in the *Food Standards Code*, the particular food cannot be legally sold under food legislation if it contains any detectable residues of the particular chemical; and

- where the NRA has decreased or deleted MRLs, food may be legally sold under food legislation if it contains residues that are inconsistent with the current registered uses of chemical products.

3. Objective

The objective of this application is to ensure that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety and that the proposed MRLs permit the legal sale of food that has been legally treated.

3.1 Consideration of Issues under Section 10 of the *Australia New Zealand Food Authority Act 1991*

In developing or varying a food standard, ANZFA is required by its legislation to meet three primary objectives which are set out in Section 10 of the *Australia New Zealand Food Authority Act 1991*. These are:

3.1.1 The protection of public health and safety

The Chemicals and Non-prescription Medicines Branch of the TGA have established the ADIs for cephapirin and semduramicin. The NRA and ANZFA have carried out estimations of dietary exposure to agricultural and veterinary chemicals and compared them to the TGA standards. Based on dietary exposure assessments, the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

The issues of potential allergenicity and the potential for the development of antimicrobial resistance are discussed in section 5 of this document.

3.1.2 The provision of adequate information relating to food to enable consumers to make informed choices

This is not relevant for this Application.

3.1.3 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.

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

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

3.1.5 The promotion of consistency between domestic and international food standards

This is not relevant for this Application because there are no Codex MRLs for cephapirin and semduramicin.

3.1.6 The desirability of an efficient and internationally competitive food industry

The inclusion of the requested MRLs would assist in permitting the legal sale of legally treated food. Varying the *Food Standards Code* to include the proposed MRLs for cephapirin and semduramicin would promote trade and commerce and allow food industries to continue to be efficient and competitive.

3.1.7 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 new MRLs would benefit all producers equally.

4. Background

4.1 The use of agricultural and veterinary chemicals

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

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

4.2 Maximum Residue Limits applications

After registering the agricultural or veterinary chemical products, based on their scientific evaluations, the NRA makes applications to ANZFA to include MRLs in the *Food Standards Code*. ANZFA reviews the information provided by the NRA and validates whether the dietary exposure is within agreed safety limits. If satisfied that the residues do not represent an unacceptable risk to public health and safety ANZFA recommends that the Ministerial Council adopt a draft variation to the *Food Standards Code* and include the MRLs in the *Food Standards Code*.

The inclusion of the MRLs in the *Food Standards Code* has the effect of allowing treated produce to be legally sold, provided that the residues in the treated produce are less than or equal to the MRL.

Changes to Australian MRLs reflect the changing patterns of agricultural and veterinary chemicals available to farmers. These changes include both the development of new products and crop uses, and the withdrawal of older products following review.

4.3 Maximum Residue Limits

The MRL is the highest concentration of a chemical residue that is legally permitted or accepted in a food. The MRL does not indicate the amount of chemical that is always present in a treated food but it does indicate the highest residue that could possibly result from the registered conditions of use. The concentration is expressed in milligrams per kilogram (mg/kg) of the food.

MRLs assist in indicating whether an agricultural or veterinary chemical product has been used according to its registered use and if the MRL is exceeded then this indicates a likely misuse of the chemical product.

MRLs are also used as standards for the international trade in food. MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.

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

In relation to MRLs, ANZFA's role is to ensure that the potential residues in treated food do not represent an unacceptable risk to public health and safety. ANZFA will not recommend MRLs for inclusion in the *Food Standards Code* where the dietary exposure to the residues of a chemical could represent an unacceptable risk to public health and safety. In assessing this risk, ANZFA conducts dietary exposure assessments in accordance with internationally accepted practices and procedures. In addition, for antibiotics ANZFA accepts the advice of EAGAR in relation to the potential for the development of antimicrobial resistance.

In summary, the MRLs in the NRA MRL Standard are used in some jurisdictions to assist in regulating the use of agricultural and veterinary chemical products under State and Territory 'control-of-use' legislation. Whereas the MRLs in the *Food Standards Code* apply in relation to the sale of food under State and Territory food legislation and the inspection of imported foods by the Australian Quarantine and Inspection Service.

4.4 Food standards-setting in Australia and New Zealand

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

4.5 Trans Tasman Mutual Recognition Arrangement

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

- food produced or imported into Australia, which complies with Standard 1.4.2 of the *Food Standards Code* can be legally sold in New Zealand; and

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

4.6 *Food Standards Code*

On 24 November 2000, the Australia New Zealand Food Standards Council adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). On 24 May 2002, the Ministerial Council agreed to vary the *Food Standards Code* to amend Standard A14 (Volume 1) by deleting schedules 1, 2 and 3 of that Standard and referring the schedules in Standard A14 to the MRL schedules of Standard 1.4.2. This created a single set of schedules for MRLs.

Subsequently all applications to amend MRLs will now be incorporated into schedules 1,2 and 3 of Standard 1.4.2 of the *Food Standards Code*. Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

4.7 Limit of Quantification

Some of the proposed MRLs in this application are at the 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.

5. MRLs for Antibiotics

5.1 Antimicrobial resistance

The issue of the potential of antimicrobial resistance developing as a result of dietary exposure to these antibiotic residues in food has been considered by the Working Party on Antibiotics (WPA), which did not raise any objections to these proposed MRLs. However, EAGAR has superseded the WPA.

The EAGAR has considered the issue of the potential for antimicrobial resistance developing as a result of dietary exposure to cephapirin and semduramicin residues in food. EAGAR did not raise any objections in terms of either the use or the residues that arise from with the use of these antibiotics.

5.2 β-lactams as Allergens

The NRA has assessed the allergenicity of antibiotic residues in food commodities. Cephapirin is a β-lactam antibiotic 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 for individual animals and not as a mass medication. Furthermore, the proposed MRLs are at the LOQ (see Section 4.7) and no residues should occur. Therefore, ANZFA considers that the potential for allergic reactions to residues cephapirin to be very low. Semduramicin is not a β-lactam antibiotic and there is no evidence of allergenicity resulting from dietary exposure to residues of this chemical.

5.3 Use of these antibioics in human medicine

Neither if these chemicals are registered for use in human medicine in Australia.

6. Evaluation of Issues Raised in Public Comment

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

- antimicrobial Resistance;
- blending of milk from treated animals with untreated animals;
- harmonisation of the MRL setting process between ANZFA and the NRA;
- health and safety considerations in setting MRLs for inclusion in the *Food Standards Code*;
- potential for allergenic reactions to residues of antibiotics in foods;
- relationship between ANZFA and the NRA; and
- use of agricultural and veterinary chemicals.

6.1 Antimicrobial Resistance

The submission from the National Council of Women of Australia (NCWA) included concerns about the potential for antimicrobial resistance from the use of antibiotics in 'industry'.

ANZFA relies on the expertise of the EAGAR and its predecessor the WPA for the advice on the issue of the potential for antimicrobial resistance developing as a result of dietary exposure to residues of antibiotics in food. EAGAR did not raise any objections in terms of either the use or the residues associated with the use of the antibiotics in this application.

6.2 Blending of milk from treated animals with untreated animals

The Food Technology Association of Victoria (FTAV) considered that the blending of milk from treated animals with the milk of untreated animals was supposition 'as a majority or high proportion of milk may come from treated animals and as such is not an acceptable reason for agreeing with the use of this chemical'.

As the NRA is responsible for registering agricultural and veterinary chemical products, granting permits for use of chemical products and regulating the sale of agricultural and veterinary chemical products, any concerns about the use of agricultural and veterinary chemicals should be directed to the NRA. However, ANZFA understands that milk, at the point of sale, is considered to be a blended product. The proposed MRL for cephapirin in milk has been set at the LOQ and no residues should occur in the final product.

6.3 Harmonisation of the MRL-setting process

FTAV raised concerns about the time taken by ANZFA to progress applications from the NRA, and that this has led to temporary discrepancies between the ANZFA and NRA MRL standards. ANZFA progresses an application from the NRA to vary the *Food Standards Code* in accordance with statutory requirements stipulated in the *Australia New Zealand Food Authority Act 1991*. This process results in ANZFA making a recommendation to the Ministerial Council on whether the MRLs in the application should be included in the *Food Standards Code* and adopted into State and Territory food law.

Industry has indicated on many occasions that it needs a more timely process for establishing MRLs. These concerns have been highlighted in a number of reviews of food regulatory arrangements, including the Food Regulation Review (the Blair Review) and the Regulatory Reform Taskforce. These reviews reported that there are problems with the 'dual' assessment processes for MRLs in foods.

In order to streamline the safety assessment process the NRA and ANZFA have signed a Memorandum of Understanding (MoU) which describes the agreed process for undertaking dietary exposure assessments based on Australian food consumption information. The terms of the MoU also require the NRA to undertake dietary exposure assessments and to provide these to ANZFA prior to making an application to vary the *Food Standards Code*. While removing unnecessary duplication and inefficiencies, this arrangement does not mean that ANZFA recommends the approval of an MRL simply on the basis of the NRA doing so. ANZFA exercises due diligence in its processes, as is required under its statutory obligations.

The primary concern with the current system is the significant delay between permission being granted for use of a chemical product, and the legal allowance for a residue of the chemical to be present in foods for sale. To address this situation a committee involving relevant Commonwealth Government agencies has been established to examine the current MRL setting process in Australia, and to make recommendations for change. The Committee is in the process of identifying the most appropriate mechanism for resolving this issue and recognises that legislative change to the NRA and/or ANZFA legislation is required. However, the Committee has recognised that the Ministerial Council retains a statutory duty to remain engaged in the establishment of MRLs.

6.4 Health and safety considerations in setting MRLs for inclusion in the *Food Standards Code*

FTAV stated that 'health and safety considerations are the primary foundations of creation of Food Standards'. As mentioned above (Section 4.1), before an agricultural or veterinary chemical is registered by the NRA, 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.

In relation to MRLs, ANZFA's responsibility is to ensure that the potential residues in treated food do not represent an unacceptable risk to public health and safety. ANZFA will not recommend MRLs for inclusion in the *Food Standards Code* where the dietary exposure to the residues of a chemical could represent an unacceptable risk to public health and safety. In assessing this risk, ANZFA conducts dietary exposure assessments in accordance with internationally accepted practices and procedures.

When an application includes a proposed MRL for an antibiotic ANZFA accepts the advice of the EAGAR in relation to the potential for the development of antimicrobial resistance (see Section 5.1). EAGAR raised no objections in terms of either the use or the residues associated with the use of the antibiotics cephapirin and semduramicin.

6.5 Potential for allergenic reactions to residues of antibiotics in foods

FTAV had concerns of the potential of allergenic reactions to residues of antibiotics in foods. Cephapirin is a β-lactam antibiotic and there is some evidence in the scientific literature for rare occurrences of allergic reactions to the residues of β-lactam antibiotics.
The NRA and ANZFA have concluded that these reactions can potentially occur following the consumption of very low concentrations of residues of these antibiotics in food.

In light of the potential for allergic reactions to residues of β-lactam antibiotics, the NRA permits these antibiotics only to be used as therapeutic treatments under veterinary supervision for specific conditions and not as mass medication in farm animals, and applies strict statutory restrictions on their use. These restrictions are applied so that generally detectable residues of β-lactam antibiotics should not occur in food.

The NRA usually establishes MRLs at LOQ for the particular antibiotic. These limits then provide a benchmark for enforcement purposes and a monitoring tool to determine whether primary producers follow the use restrictions. The proposed MRLs for cephapirin are prefixed with an asterisk (*), which indicates that the MRLs are at the LOQ and no residues should occur.

6.6 Relationship between ANZFA and the NRA

The submission from NCWA questioned the role that ANZFA plays in assessing the NRA MRLs. MRLs recommended by ANZFA are usually consistent with those determined by the NRA. This is because the NRA and ANZFA 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 require both agencies to ensure that public health and safety is not compromised. Nevertheless, ANZFA independently ensures that the residues in food are safe for human consumption, before MRLs are recommended for inclusion in the *Food Standards Code*.

In summary, the NRA assesses the residues resulting from a proposed use and they will not register a product until they are satisfied that the residues do not represent an unacceptable risk to public health and safety. ANZFA validates this assessment and makes recommendations to the Ministerial Council concerning the inclusion of MRLs in the *Food Standards Code*.

6.7 The use of agricultural and veterinary chemicals

NCWA had concerns about use of antibiotic chemicals and their effect on human health. While recognising that that NCWA has legitimate concerns about the use antibiotics, it must be noted that ANZFA does not have any statutory role in questioning the merits or the use of agricultural or veterinary chemicals, including antibiotics. ANZFA's role is to ensure that the potential residues in treated food do not represent an unacceptable risk to public health and safety. The NRA has the statutory role for the registered use of agricultural and veterinary chemical, including antibiotics and concerns about the use of these chemicals in agriculture and animal husbandry should be directed to the NRA. Concerns about other uses of antibiotics should be directed to the relevant agency.

7. Options and Impact Analysis

7.1 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*.

7.2 Affected parties

The parties affected by this application are government, producers, food manufacturers and consumers of primary produce and foods imported into Australia. In considering these proposed MRLs, it should be noted that all the MRLs for cephapirin in cattle products and the MRL for semduramicin in chicken meat are at the LOQ.

7.3 Costs and benefits

7.3.1 Costs of accepting the NRA application (Option 1)

- initially enforcement agencies and food manufacturers may have costs associated with compliance and enforcement of MRLs following the proposed inclusions; 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.

7.3.2 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;

- 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.

7.3.3 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.

7.3.4 Benefits of not accepting the application (Option 2)

- There are no perceived benefits associated with not accepting the application.

7.4 Conclusion and recommended option

The inclusion of the proposed MRLs in the *Food Standards Code* is consistent with the current registered uses of cephapirin and semduramicin. The dietary exposure assessments indicate that the residues of these chemicals associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. In addition, EAGAR considered the potential for the development of antimicrobial resistance and did not raise any objections in terms of either the use or the residues associated with the use of these antibiotics.

The NRA has already registered these chemicals and rejection of the proposed MRLs would result in legally treated food not being able to be legally sold. In addition, rejection of the proposed MRLs would create discrepancies between agricultural and health legislation. Therefore including the proposed MRLs (Option 1) 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.

8. Consultation

8.1 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. Additionally, MRLs assist in ensuring that residues are no higher than is necessary for effective control of pests and disease. MRLs are also used as standards for the international trade in food.

This Application contains proposed MRLs which are not addressed in the international Codex standard. The proposed 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.

Therefore, a WTO notification for this application was made following the endorsement of the Initial/Draft Assessment Report.

This Application has been notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO SPS agreement as the primary objective of the measure is to support regulating the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment. No WTO member has made a submission.

9. Conclusion and Recommendation

The inclusion of the proposed MRLs is consistent with the current registered uses of the chemical products. The dietary exposure assessments indicate that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. In addition, EAGAR considered the potential for the development of antimicrobial resistance and did not raise any objections in terms of either the use or the residues associated with the use of these antibiotics. Therefore including the proposed MRLs 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. Implementation and review

The use of chemical products and MRLs are subject to review as part of the NRA's Existing Chemical Review Program. In addition, regulatory agencies involved in the regulation of chemical products continue to monitor health, agricultural and environmental issues associated with the use of chemical products. The residues in food are also monitored through:

- State and Territory residue monitoring programs;
- Commonwealth programs such as the National Residue Survey; and
- dietary exposure surveys such as the Australian Total Diet Survey.

These monitoring programs and the continual review of the use of agricultural and veterinary chemicals mean that considerable scope exists to review MRLs on a continual basis.

It is recommended that the proposed MRLs should come into effect upon gazettal and continue to be monitored by the same means as other residues in food.

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: nz.reception@anzfa.gov.au

Assessment reports are available for viewing and downloading from the ANZFA website www.anzfa.gov.au . People without access to internet facilities may request paper copies of reports from the Information Officer.

ATTACHMENTS

1. Draft Variation to the *Food Standards Code*
2. A Summary of the Requested MRLs for Each Chemical
3. Statement of Reasons
4. Dietary Exposure Assessment
5. Summary of Public Submissions
6. Glossary Of Acronyms

ATTACHMENT 1

DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

A460 - MAXIMUM RESIDUE LIMITS

To commence: On gazettal

[1] ***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 *each chemical (shown in bold type) and its associated food and maximum residue limit for that food -*

CEPHAPIRIN CEPHAPIRIN AND DES-ACETYLCEPHAPIRIN, EXPRESSED AS CEPHAPIRIN	
CATTLE, EDIBLE OFFAL OF	*0.02
CATTLE MEAT	*0.02
CATTLE MILK	*0.01
SEMDURAMICIN SEMDURAMICIN	
CHICKEN FAT/SKIN	0.5
CHICKEN KIDNEY	0.2
CHICKEN LIVER	0.5
CHICKEN MEAT	*0.05

Explanatory Note: These are new MRLs for the new chemicals and foods.

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*.

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

Chemical Food		**MRL** (mg/kg)	**Information**
Cephapirin			
Cattle, edible offal of	Add	*0.02[1]	This chemical is used for the intra-uterine treatment of susceptible bacterial infections in cows. NEDI[2] = <1% of ADI[3].
Cattle meat	Add	*0.02	
Cattle milk	Add	*0.01	
Semduramicin			
Chicken fat/skin	Add	0.5	This chemical is used as an anticoccidial feed additive for broiler chickens. NEDI = <1% of ADI.
Chicken meat	Add	*0.05	
Chicken kidney	Add	0.2	
Chicken liver	Add	0.5	

[1] **Limit of Quantification**

The * indicates that this proposed MRL is at the limit of quantification. The LOQ is the lowest concentration of an agricultural or veterinary chemical that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

[2] **National Estimated Dietary Intake**

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

[3] **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.

ATTACHMENT 3

STATEMENT OF REASONS

APPLICATION A460 – MAXIMUM RESIDUE LIMITS – ANTIBIOTICS

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

This Application (A460) seeks to include new Maximum Residue Limits (MRLs) for the antibiotic cephapirin in cattle meat, milk and offal and semduramicin in chicken fat/skin, kidney, liver and meat in the *Food Standards Code*. The National Registration Authority for Agricultural and Veterinary Chemicals (NRA), seek to update the *Food Standards Code* in order to reflect current registration status of cephapirin and semduramicin in use in Australia. The proposed MRLs for cephapirin are at the limit of quantification (LOQ).

On 24 November 2000, the Australia New Zealand Food Standards Council adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). On 24 May 2002, the Ministerial Council agreed to vary the *Food Standards Code* to amend Standard A14 (Volume 1) by deleting schedules 1, 2 and 3 of that Standard and referring the schedules in Standard A14 to the MRL schedules of Standard 1.4.2. This created a single set of schedules for MRLs. Subsequently all applications to amend MRLs will now be incorporated into schedules 1,2 and 3 of Standard 1.4.2 of the *Food Standards Code*. Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

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

ANZFA has completed a Final Assessment (Inquiry s.17) of the Application, and prepared draft variations to Standard 1.4.2 in Volume 2 of the *Food Standards Code*.

ANZFA recommends progressing the new MRLs for cephapirin and semduramicin for the following reasons:

- The dietary exposure assessments indicate that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. The NRA has already registered the chemical products in this application and the rejection of the proposed 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 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 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 an appropriate toxicological assessment of the chemical products and has established relevant acceptable daily intakes and where applicable, acute reference doses.

- The Expert Advisory Group on Antimicrobial Resistance (EAGAR) has considered the issue of the potential for antimicrobial resistance developing as a result of dietary exposure to cephapirin and semduramicin residues in food. EAGAR did not raise any objections in terms of either the use or the residues associated with the use of these antibiotics.

- None of ANZFA's section 10 objectives of food regulatory measures are compromised by the proposed changes.

- 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 A460

Please see Attachment 2 of the Final 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 of pests and diseases. MRLs also act as trading standards. This application contains MRLs which relate to antibiotics used in the production of heavily traded agricultural commodities which may indirectly have a significant effect on trade of derivative food products between WTO members.

ANZFA 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 VARIATION TO THE *FOOD STANDARDS CODE*

Please see Attachment 1 of the Final Assessment Report.

ATTACHMENT 4

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.

Comparing the dietary exposure with the relevant health standard assesses the potential public health implications. There are a number of methods for estimating dietary exposure based on the type of information that is available. In this application, ANZFA considered the National Estimated Daily Intake (NEDI) and the National Estimated Short Term Intake (NESTI).

National Estimated Daily Intake

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

The chronic dietary risk estimated by the NEDI calculation encompasses all registered/temporary uses of MRLs and dietary intake data from the 1995 National Nutrition Survey of Australia. The calculation has been made in accordance with the Guidelines for predicting dietary intake of pesticide residues (revised) (World Health Organization, 1997).

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 based on all the known facts at the time of the evaluation of the chemical. The ADI 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 or is less than the ADI.

National Estimated Short Term Intake

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

The NESTI calculation incorporates a large portion (97.5 percentile) of food consumption data and can take into account such factors as:

- the highest residue on a composite sample of an edible portion;
- the supervised trials median residue (STMR) that represents typical residues in an edible portion resulting from the maximum permitted pesticide use pattern;
- processing factors which affect changes from the raw commodity to the consumed food; and
- the variability factor.

ANZFA has used the ARfD set by the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey (NNS) and the MRL when the STMR is not available to calculate the NESTIs. The ARfD of a chemical is the estimate of the amount of a substance in food, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer, on the basis of all the known facts at the time of evaluation. ANZFA considers that the acute dietary exposure to the residues of a chemical is acceptable where the acute dietary exposure does not exceed the ARfD.

Food Consumption Data

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

A computer program developed by ANZFA derives raw commodity consumption data used in the NRA dietary exposure assessments. The program accesses the 13,858 individual dietary records from the 1995 NNS, and applies recipes to all mixed foods consumed by each individual to enable the total amounts of raw commodity equivalents consumed per individual person to be calculated. Population statistics (mean consumption, all respondents) are then derived from these individual raw commodity totals for use in NRA dietary exposure assessments.

However, for all new chemicals, review chemicals and those where the initial dietary exposure assessment based on mean consumption data appears to approach or exceed the ADI, the ANZFA computer program is used to calculate the total dietary exposure to a given chemical for each individual in the survey. Population statistics such as mean chemical exposure are then derived, thus taking into account as much as possible, individual dietary patterns from a diverse and representative sample of the Australian population. This program also enables high consumers of a given chemical to be identified, as well as the major foods contributing to total dietary exposure for that chemical.

ATTACHMENT 5

SUMMARY OF PUBLIC SUBMISSIONS

Submitter	Comments raised
Consumers' Association of South Australia	Did not support the application
National Council of Women of Australia	Did not support the application
Dairy Food Safety Victoria	Supported the proposed MRL for cephapirin
Food Technology Association of Victoria	Did not support the application
New Zealand Ministry of Health	Had no particular concerns about this application

ATTACHMENT 6

GLOSSARY OF ACRONYMS

ADI	Acceptable Daily Intake
ANZFA	Australia New Zealand Food Authority
AQIS	Australian Quarantine and Inspection Service
ARfD	Acute Reference Dose
Codex	Codex Alimentarius Commission
DHA	Health and Ageing, Department of
EAGAR	Expert Advisory Group on Antimicrobial Resistance
FSC	*Food Standards Code*
FTAV	Food Technology Association of Victoria
JETACAR	Joint Expert Technical Advisory Committee on Antibiotic Resistance
LOQ	Limit of Quantification
MRL	Maximum Residue Limit
NCWA	National Council of Women of Australia
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short Term Intake
NNS	National Nutrition Survey
NRA	National Registration Authority for Veterinary and Agricultural Chemicals
RIS	Regulation Impact Statement
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
TGA	Therapeutic Goods Administration
TTMRA	Trans-Tasman Mutual Recognition Arrangement
WHO	World Health Organization
WPA	Working Party on Antibiotics
WTO	World Trade Organization