APPLICATION A460 – MAXIMUM RESIDUE LIMITS

INITIAL/DRAFTASSESSMENT

(PRELIMINARY/FULL ASSESSMENT - SS.13/15 - S.36)

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:**24 April 2002** (See "Invitation for Public Submissions" for details)

THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY

The Australia New Zealand Food Authority's (ANZFA) role is to protect the health and safety of people in Australia and New Zealand by maintaining a safe food supply. ANZFA is a partnership between the Commonwealth Government, Australian States and Territories governments and the New Zealand Government.

As an independent expert body, ANZFA is responsible for 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, 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.

ANZFA's OBJECTIVES

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:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, ANZFA must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry; and
- the promotion of fair trading in food.

OTHER REGULATORY OBJECTIVES

At the same time ANZFA must ensure that the regulations it develops are the most efficient and effective possible. It does this by looking at the possible impact that the regulation might have on consumers, business and other groups in our community or whether there are alternative options to formal regulations such as codes of practice. In addition, as Australia and New Zealand are members of the World Trade Organization (WTO), ANZFA must ensure that the regulations are consistent with the obligations of both countries as members of the WTO.

INVITATION FOR PUBLIC SUBMISSIONS

The Authority has made an Initial/Draft Assessment on Application A460 (referred to as the 'Preliminary Assessment'/ 'Full Assessment' in the *Australia New Zealand Food Authority Act 1991)*, which includes a Draft Assessment; and draft variation to Volumes 1 and 2 of the *Food Standards Code.* The Authority will conduct a Final Assessment (referred to as 'Inquiry' in section 17 of the *Australia New Zealand Food Authority Act 1991*).

The Authority invites public comment on the Initial/Draft Assessment, the draft variations to Volume 1 and Volume 2 of the *Food Standards Code*; and the Regulation Impact Assessment for the purpose of preparing a Final Assessment report finalising the matter for recommendation to the Australia New Zealand Food Standards Council.

Written submissions containing technical or other relevant information that will assist the Authority in preparing the Final assessment for this Proposal are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

All correspondence and submissions on this matter should be addressed to the

Project Manager - Application A460 at one of the following addresses:

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Submissions should be received by the Authority **by 24 April 2002**

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on slo@anzfa.gov.au. Requests for more general information on the Authority can be directed to the Information Officer at the above addresses.

EXECUTIVE SUMMARY

- This Application (A460) seeks to amend 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*. It is a routine application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the *Food Standards Code* in order to reflect current registration status of cephapirin and semduramicin in use in Australia.

- On 24 November 2000, the Australia New Zealand Food Standards Council (ANZFSC) adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). Subsequently, all applications to amend MRLs will now also be incorporated into Volumes 1 and 2 of the *Food Standards Code* (Standard A14 and Standard 1.4.2 respectively). Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

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

- The Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aged Care has undertaken a toxicological assessment of the 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 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 will make a Sanitary and Phytosanitary notification to the World Trade Organization at the Initial / Draft Assessment (Preliminary Assessment - s.13 / Full Assessment - s.15).

1. ISSUES

An application was received from the NRA on 29 November 2001 and 12 December 2001 seeking amendment to Standards A14 and 1.4.2 for the *Food Standards Code*. The proposed amendments to Schedule 1 of the Standards would align MRLs for cephapirin and semduramicin in the *Food Standards Code* with the MRLs in the NRA MRL Standard.

The Application from the NRA seeks the inclusion of add a new MRLs for the new antibiotics, cephapirin in cattle meat, milk and offal and semduramicin in chicken fat/skin, kidney, liver and meat.

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 BACKGROUND

2.1 The use of agricultural and veterinary chemicals

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

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

2.2 Maximum Residue Limits applications

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

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

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

2.3 Maximum Residue Limits

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

MRLs assist in indicating whether an agricultural or veterinary chemical product has been used according to its registered use and if the MRL is exceeded then this indicates a likely misuse of the chemical product. MRLs are also used as standards for the international trade in food. MRLs, 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.

2.4 Food standards settings in Australia and New Zealand

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

2.5 Trans Tasman Mutual Recognition Arrangement

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

- food produced or imported into Australia, which complies with Standard A14 or Standard 1.4.2 of the *Food Standards Code* can be legally sold in New Zealand; and

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

2.6 *Food Standards Code*

On 24 November 2000, the Australia New Zealand Food Standards Council (ANZFSC) adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). Subsequently all applications to amend MRLs will now also be incorporated into Volumes 1 and 2 of the *Food Standards Code* (Standard A14 and Standard 1.4.2 respectively). Consequently all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

2.7 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, 1994* requires the NRA to be satisfied that there will not be any appreciable risk to the consumer, to the person handling, applying or administering the chemical, to the environment, to the target crop or animal or to trade in an agricultural commodity. ANZFA's responsibility is to ensure that the residues in food resulting from the use of agricultural and veterinary chemical products do not represent an unacceptable risk to public health and safety.

The potential public health impacts are assessed by considering the dietary exposure and comparing this to the relevant health standard. There are a number of methods for estimating dietary exposure based on the type of information that is available. The one that was considered in this application was the National Estimated Daily Intake (NEDI).

3.1 Toxicology of agricultural and veterinary chemicals

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

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

3.2 Acceptable Daily Intake

The ADI is the daily intake of an agricultural or veterinary chemical which, during the consumer's entire lifetime, appears to be without appreciable risk to the health of the consumer. This is on the basis of all the known facts at the time of the evaluation of the chemical. It is expressed in milligrams of the chemical per kilogram of body weight.

ANZFA considers that the dietary exposure to the residues of a chemical is acceptable where the best estimate of dietary exposure is less than the ADI.

3.3 National Estimated Daily Intake

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

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

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

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

4. MRLS FOR ANTIBIOTICS

4.1 Antimicrobial resistance

The issue of the potential of antimicrobial resistance developing as a result of dietary exposure to these antibiotic residues in food has been considered by the WPA, which did not raise any objections to these MRLs. However, the Expert Advisory Group on Antimicrobial Resistance (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 associated with the use of these antibiotics.

4.2 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 cattle milk is a blended food which means that the undetectable residues in milk from treated animals will be blended with the milk from untreated animals thereby reducing any residues even further. Therefore the potential for allergic reactions to residues of β-lactam antibiotics is considered to be very low.

5. REGULATION IMPACT ANALYSIS

5.1 OBJECTIVE

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

5.2 Options

Option 1: - to accept the requests made by the NRA and vary the *Food Standards Code*.
Option 2: - to reject the requests and make no changes to the *Food Standards Code*.

5.3 Affected parties

The parties affected by this application are consumers, government, producers, food manufacturers and consumers of primary produce and foods 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.

5.4 Costs and benefits

5.4.1 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 amendments; and

- some consumers may consider that any residues of agricultural and veterinary chemicals in food are not in the public interest and may regard the presence of any chemical residues in foods, including undetectable residues, as a cost.

5.4.2 Benefits of accepting the NRA application (Option 1)

- food producers will be legally able to sell produce legally treated with chemicals intended to improve stock and yields as well as controlling diseases and pests;

- it will ensure consistency between the health and agricultural regulations; and

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

5.4.3 Costs of not accepting the application (Option 2)

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

5.4.4 Benefits of not accepting the application (Option 2)

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

5.5 Conclusion and recommended option

The inclusion of the NRA's proposed MRLs 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, the Expert Advisory Group on Antimicrobial Resistance (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 MRLs would result in legally treated food not being able to be legally sold. In addition, rejection of the 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.

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

Subsection 13(1) of the *Australia New Zealand Food Authority Act 1991* (ANZFA Act) requires ANZFA to make an Initial Assessment of an application. In making that Initial Assessment, subsection 13(2) requires ANZFA to have regard to a number of matters set out in paragraphs 13(2)(a) to (e). Each of these matters is discussed below.

6.1 Paragraph 13(2)(a)

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

6.2 Paragraph 13(2)(b)

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

6.3 Paragraph 13(2)(c)

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

6.4 Paragraph 13(2)(d)

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

6.5 Paragraph 13(2)(e)

Other relevant matters for consideration by ANZFA are as follows.

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

6.5.1.1 Regulation 12a

Because it is a simple variation of a food regulatory matter requiring only the updating of a standard set out in the *Food Standards Code* this matter will be in category 2.

6.5.1.2 Regulation 12b

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

6.5.2 World Trade Organization Notification

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

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

In administrative terms and consistent with international practice, MRLs assist in regulating the use of agricultural and veterinary chemical products. MRLs indicate whether agricultural and veterinary chemical products have been used in accordance with the registered conditions of use. Additionally, MRLs assist in ensuring that residues are no higher than is necessary for effective control of pests and disease. MRLs are also used as standards for the international trade in food.

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

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

The application **will be** notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO SPS agreement as the primary objective of the measure is to support regulating the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment.

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

Subsection 15(1) of the ANZFA Act requires ANZFA to make a Draft Assessment of an application. In making that Draft Assessment, subsection 15(3) requires ANZFA to have regard to a number of matters set out in paragraphs 15(3)(a) to (e). Each of these matters is discussed below.

7.1 Paragraph 15(3)(a)

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

7.2 Paragraph 15(3)(b)

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

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

The Chemicals and Non-prescription Medicines Branch of the TGA have established the ADIs for cephapirin and semduramicin. The NRA and ANZFA carry out estimations of dietary exposure to agricultural and veterinary chemicals and compare them to the their standards.

On the basis of dietary exposure assessments, the residues associated with the proposed MRLs for these chemicals do not represent an unacceptable risk to public health and safety.

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

This is not relevant for this application.

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

This is not relevant for this application.

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

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

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

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

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

7.2.5 Paragraph 10(2)(c) the desirability of an efficient and internationally competitive food industry

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

7.2.6 Paragraph 10(2)(d) the promotion of fair trading in food

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

7.3 Paragraph 15(3)(c)

ANZFA has undertaken a preliminary 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.

7.4 Paragraph 15(3)(d)

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

7.5 Paragraph 15(3)(e)

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

8. CONCLUSION

The inclusion of the proposed MRLs is consistent with the current registered uses of the chemical products. The dietary exposure assessments indicate that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. In addition, the Expert Advisory Group on Antimicrobial Resistance (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 the chemical products and rejection of the MRLs would result in legally treated food not being able to be legally sold and it would also create discrepancies between agricultural and health legislation. Therefore including the proposed MRLs for these chemical products 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.

ATTACHMENTS

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

ATTACHMENT 1

DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

A460 - MAXIMUM RESIDUE LIMITS

To commence: On gazettal

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

Chemical Food	**MRL**
Cephapirin	
Cattle, edible offal of	0.02
Cattle meat	0.02
Cattle milk	0.01
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 chemicals not previously listed.

[2] ***Standard 1.4.2 of*** *Volume 2 of the Food Standards Code is varied by inserting in columns 1 and 2 respectively of* Schedule 1 *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* IS PROVIDED BELOW.

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 STANDARDS A14 AND STANDARD 1.4.2 - MAXIMUM RESIDUE LIMITS - ANTIBIOTICS.

This Application (A460) seeks to amend 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*. It is a routine application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the *Food Standards Code* in order to reflect current registration status of cephapirin and semduramicin in use in Australia.

On 24 November 2000, the Australia New Zealand Food Standards Council (ANZFSC) adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). Subsequently, all applications to amend MRLs will now also be incorporated into Volumes 1 and 2 of the *Food Standards Code* (Standard A14 and Standard 1.4.2 respectively). Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

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

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

- The dietary exposure assessments indicate that the residues associated with the MRLs do not represent an unacceptable risk to public health and safety. The NRA has already registered the chemical products in this application and the 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 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 Aged Care 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 preliminary 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 Initial/Draft 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 will make a Sanitary and Phytosanitary (SPS) notification in accordance with the WTO SPS agreement as the primary objective of the measure is to support regulating the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment.

DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

Please see attachment on of the Initial/Draft Assessment Report.