EXPLANATORY STATEMENT

APPLICATION A558

MAXIMUM RESIDUE LIMITS (ANTIBIOTICS)

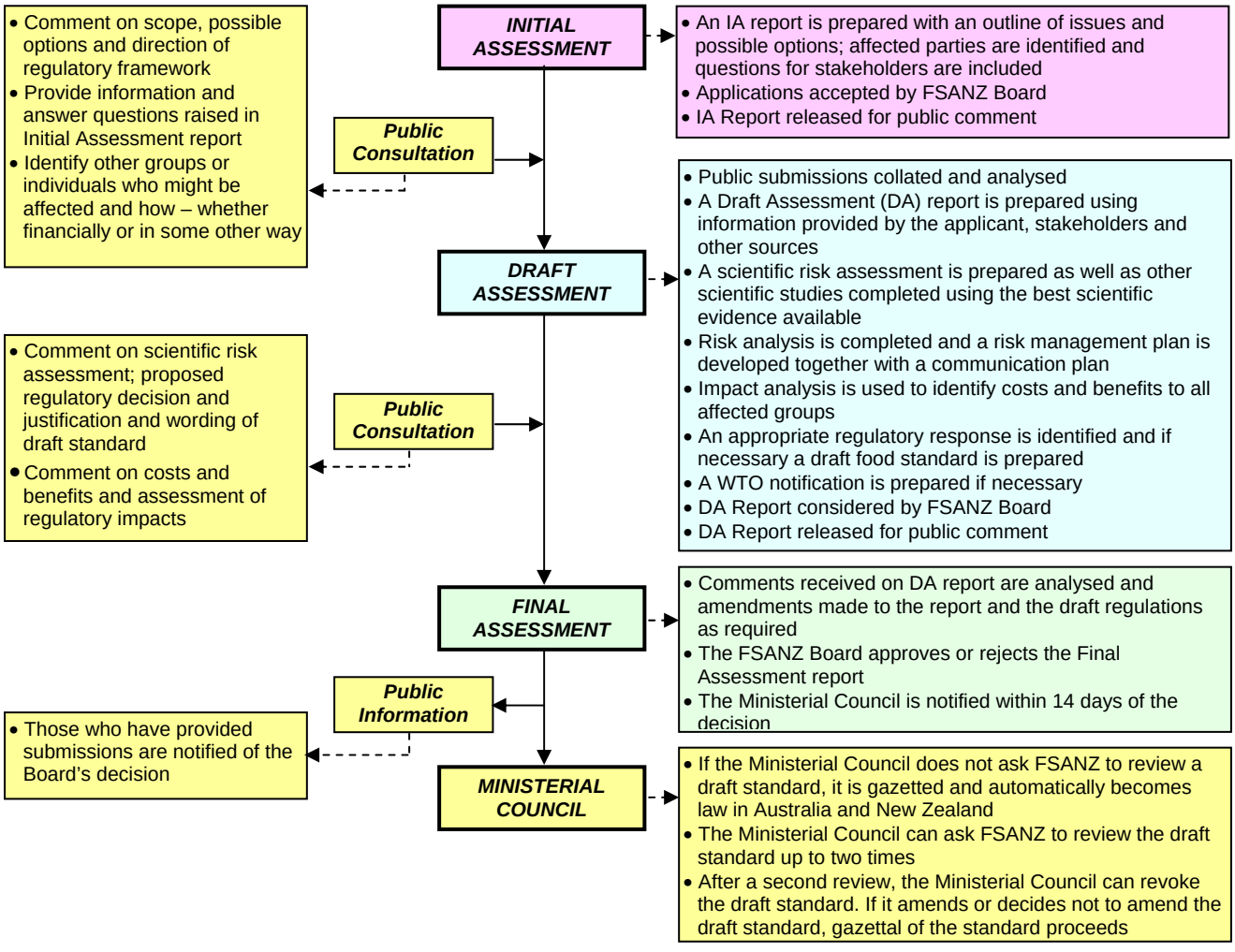
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ 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.



Final Assessment Stage (s.36)

FSANZ has now completed the assessment of the Application A558 and held a single round of public consultation under section 36 of the FSANZ Act. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:

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Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary

This Application (A558) seeks to vary the Maximum Residue Limits (MRLs) for eggs, for various antibiotics in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* (the Code). It is an application from the Australian Pesticides and Veterinary Medicines Authority (APVMA) to update Standard 1.4.2 of the Code in order to reflect the current registration status of various antibiotics in use in Australia.

The *Agreement between the Government 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 independently and separately develop MRLs for agricultural and veterinary chemicals in food.

The chronic dietary exposure assessment indicates that residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

FSANZ made a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO). No WTO Members made a submission.

FSANZ Decision

FSANZ has undertaken an assessment and review of the proposed range of MRLs for the antibiotics amoxicillin, sulphadiazine, sulphadimidine, sulphaquinoxaline and trimethoprim and considers that the draft variations to Standard 1.4.2-Maximum Residue Limits, varying MRLs for eggs, for various antibiotics are approved 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 APVMA has already registered the chemical products associated with the MRLs 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 APVMA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.

- The Office of Chemical Safety of the Therapeutic Goods Administration (OCS) of the Australian Government Department of Health and Ageing has undertaken an appropriate toxicological assessment of the chemical products and has established relevant acceptable daily intakes (ADI).

- The Expert Advisory Group on Antimicrobial Resistance (EAGAR) has evaluated the impact of the potential residues of the proposed antibiotics in the food supply and supported the changes to MRLs in this Application.

- FSANZ has undertaken a regulation impact assessment and concluded that the amendment to Standard 1.4.2 of the Code is necessary, cost-effective and of benefit to both producers and consumers.

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

1. Introduction

This Application was received from APVMA on 3 February 2005 seeking amendments to Standard 1.4.2 of the Code. The proposed amendments to the Standard would align MRLs in Standard 1.4.2 of the Code for the relevant antibiotics for eggs with the MRLs in the APVMA MRL Standard.

1.1 Summary of the proposed MRLs

The MRL amendments under consideration in this Application are as follows:

Chemical (Antibiotic)	Proposed MRL	Purpose and use of the antibiotics in animals and humans
Amoxycillin Eggs	T*0.01	Off-label, minor use permit to allow the use of amoxycillin in replacement pullets (layers and breeders) prior to the onset of egg production for the **treatment** of bacterial diseases caused by organisms that are susceptible to amoxycillin. According to the JETACAR[1] Report (*The use of antibiotics in food-producing animals: antibiotic-resistant bacteria in animals and humans,* 1999), amoxycillin is used for treatment in humans and food-producing animals. For **humans**, amoxycillin is classed as a Category C antibiotic, indicating that there are a reasonable number of alternative agents in different classes that are available to treat most infections. In contrast, for **poultry**, amoxycillin is classed as a Category A antibiotic, which is essential for the treatment or prevention of infections where there are few or no alternatives for many infections.
Sulphadiazine Eggs	T*0.02	Proposed use under the permit is for the **treatment** of bacterial infections sensitive to sulfadiazine. According to the JETACAR Report (*The use of antibiotics in food-producing animals: antibiotic-resistant bacteria in animals and humans,* 1999), sulfadiazine is used for treatment in humans and food-producing animals. For **humans**, sulfadiazine is classed as a Category C antibiotic, indicating that there are a reasonable number of alternative agents in different classes that are available to treat most infections.

[1] Joint Expert Advisory Committee on Antibiotic Resistance (JETACAR).

Chemical (Antibiotic)	Proposed MRL	Purpose and use of the antibiotics in animals and humans
		In contrast, for **poultry**, the sulphonamides are classed as Category A antibiotics, which are essential for the treatment or prevention of infections where there are few or no alternatives for many infections.
Sulphadimidine Eggs	T*0.01	Proposed use (under permit) in replacement pullets for the **treatment** of bacterial infections caused by organisms that are sensitive to sulphadimidine. According to the JETACAR Report (*The use of antibiotics in food-producing animals: antibiotic-resistant bacteria in animals and humans,* 1999), sulphadimidine is only used in the treatment of food-producing animals, although other sulphonamide antibiotics are used in human medicine. For **humans**, the sulphonamides are classed as Category C antibiotics, indicating that there are a reasonable number of alternative agents in different classes that are available to treat most infections. In contrast, for **poultry**, the sulphonamides (including sulphadimidine) are classed as Category A antibiotics, which are essential for the treatment or prevention of infections where there are few or no alternatives for many infections.
Sulphaquinoxaline Eggs	T*0.01	Proposed use (under permit) in replacement pullets is for the **prevention and treatment** of coccidiosis. According to the JETACAR Report (*The use of antibiotics in food-producing animals: antibiotic-resistant bacteria in animals and humans,* 1999), sulphaquinoxaline is only used in the treatment of food-producing animals, although other sulphonamide antibiotics are used in human medicine. For **humans**, the sulphonamides are classed as Category C antibiotics, indicating that there are a reasonable number of alternative agents in different classes that are available to treat most infections. In contrast, for **poultry**, the sulphonamides (including sulphaquinoxaline) are classed as Category A antibiotics, which are essential for the treatment or prevention of infections where there are few or no alternatives for many infections.

Chemical (Antibiotic)	Proposed MRL	Purpose and use of the antibiotics in animals and humans
Trimethoprim Eggs	T*0.02	Off-label permit to use trimethoprim in combination with sulphonamide antibiotics in replacement pullets, for the **treatment** of infections caused by organisms that are sensitive to these drugs. According to the JETACAR Report (*The use of antibiotics in food-producing animals: antibiotic-resistant bacteria in animals and humans,* 1999), trimethoprim (in combination with sulphonamides) is used for treatment in humans and food-producing animals. For **humans,** the trimethoprim/sulphonamide combinations are classed as Category C drugs, indicating that there are a reasonable number of alternative agents in different classes that are available to treat most infections. In contrast, for **poultry**, the trimethoprim/sulphonamide combinations are classed as Category A antibiotics, which are essential for the treatment or prevention of infections where there are few or no alternatives for many infections.

1.2 Acute dietary exposure

Neither the OCS nor the Joint FAO/WHO Expert Committee on Food Additives has established acute reference doses for the chemicals associated with the proposed MRLs.

1.3 Expert Advisory Group on Antimicrobial Resistance (EAGAR)

The National Health and Medical Research Council established EAGAR to provide advice to government and regulatory agencies on antibiotic resistance and especially measures to reduce the risks of antibiotic resistance.

1.3.1 Amoxycillin

As part of its Application for the inclusion of amoxycillin MRLs for eggs in Standard 1.4.2 of the Code, APVMA has supplied a letter from EAGAR in which EAGAR states:

> *Members agreed that amoxycillin is a very important antibiotic in laying hens and were of the view that the risk of resistance developing in human pathogenic bacteria arising from the consumption of edible commodities containing amoxycillin residues was low. EAGAR therefore agreed to support the granting of an off-label minor use permit*.

1.3.2 Sulphadiazine, sulphadimidine and sulphaquinoxaline

As part of its Application for the inclusion of sulphadiazine, sulphadimidine and sulphaquinoxaline MRLs for eggs in Standard 1.4.2 of the Code, APVMA has supplied a letter from EAGAR in which EAGAR states:

> *Members agreed that the proposed use does not constitute a significant risk of antimicrobial resistance to humans and supported the granting of an off-label minor use permit*.

1.3.3 Trimethoprim

As part of its Application for the inclusion of trimethoprim MRLs for eggs in the Code, APVMA has supplied a letter from EAGAR in which EAGAR states:

> *Members agreed that the proposed use does not constitute a significant risk of antimicrobial resistance to humans and supported the granting of an off-label minor use permit*.

1.5 Antibiotics as allergens

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.

1.5.1 β-lactam group of antibiotics

Amoxycillin belongs to the β-lactam group of antibiotics. However, the proposed MRL for eggs is at the limit of quantification and this means that no detectable residues of this chemical should occur. Therefore, allergic reactions to the residues of this chemical are not expected to occur. It should also be noted that currently all amoxycillin MRLs in Standard 1.4.2 of the Code are at the Limit of Quantification (LOQ).

1.5.2 Sulphonamide antibiotics

Sulphadiazine, sulphadimidine and sulphaquinoxaline belong to the sulphonamide group of antibiotics and not to the β-lactam group of antibiotics. Further, the proposed MRL for eggs is at the limit of quantification and this means that no detectable residues of the relevant chemical should occur. Therefore, allergic reactions to the residues of these chemicals in eggs are not expected to occur.

1.5.2 Diaminopyrimidines

Trimethoprim is a diaminopyrimidine drug and does not belong to the β-lactam group of antibiotics. Further, the proposed MRL for eggs is at the limit of quantification and this means that no detectable residues of this chemical should occur. Therefore, allergic reactions to the residues of this chemical in eggs are not expected to occur.

2. Regulatory Problem

2.1 Current Regulations

APVMA has approved permits for the use of the antibiotic products associated with the MRLs in this Application, and made consequent amendments to its APVMA MRL Standard. The approval of the use of these products now means that there is a discrepancy between the potential residues associated with the use of the antibiotic products and the MRLs in Standard 1.4.2 of the Code. This has led to the possibility that legally treated food may not comply with the Code.

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. APVMA has already established MRLs under the APVMA's legislation, and now seeks by way of this Application to include the amendments in Standard 1.4.2 of the Code.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 10 of the FSANZ Act. 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, FSANZ 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;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed antibiotic MRLs.

4. Background

4.1 The use of agricultural and veterinary chemicals

In Australia, APVMA 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, APVMA 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, APVMA includes MRLs in its APVMA 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 Limit applications

After registering the agricultural or veterinary chemical products, based on their scientific evaluations, APVMA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews the information provided by APVMA 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 subject to adequate resolution of any issues raised during public consultation, FSANZ will then agree to adopt the proposed MRLs into Standard 1.4.2 of the Code.

FSANZ then notifies the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) of the proposed adoption of the variation into the Code. If the Ministerial Council does not request FSANZ to review its decision, the MRLs are automatically adopted by reference under the food laws of the Australian States and Territories, after gazettal by FSANZ.

The inclusion of the MRLs in Standard 1.4.2 of the Code has the effect of allowing legally treated produce to be legally sold, provided that the residues in the treated produce do not exceed 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.

Appropriate toxicology, residue, animal transfer, processing and metabolism studies were provided to APVMA in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997* to support the proposed MRLs for amoxycillin, sulphadiazine, sulphadimidine, sulphaquinoxaline and trimethoprim for eggs.

Full evaluation reports for individual chemicals are available upon request from the relevant Project Coordinator at FSANZ on +61 2 6271 2222.

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 of chemical 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. In addition, 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. In relation to MRLs, FSANZ's role is to ensure that the potential residues in food do not represent an unacceptable risk to public health and safety.

FSANZ will not agree to adopt MRLs into Standard 1.4.2 of the 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, APVMA and FSANZ conduct dietary exposure assessments in accordance with internationally accepted practices and procedures.

In considering the issues associated with MRLs it should be noted that MRLs and amendments to MRLs do not permit or prohibit the use of agricultural and veterinary chemicals. The approvals for the use of agricultural and veterinary chemicals and the control of the use of agricultural and veterinary chemicals are regulated by other Australian Government, State and Territory legislation.

In summary, the MRLs in APVMA's 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 Standard 1.4.2 of the 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 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 Limit of Quantification

All 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. FSANZ incorporates MRLs at the LOQ in the 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.

4.7 MRLs for Permits

All of the proposed MRLs in this Application are temporary and are indicated by a 'T' in this report. These MRLs may include uses associated with:

- the APVMA minor use program;
- off-label permits for minor and emergency uses; or
- trial permits for research.

FSANZ does not issue permits or grant permission for the temporary use of agricultural and veterinary chemicals. Further information on permits for the use of agricultural and veterinary chemicals can be found on the APVMA website at www.apvma.gov.au or by contacting APVMA on +61 2 6272 5158.

5. Issues raised in public submissions

Three submissions were received during the period 25 May to 6 July 2005 (**Attachment 4**). There was overall support for the proposed MRLs. Submitters raised a range of issues, which have been evaluated by FSANZ below.

5.1 FSANZ has not provided any details on overseas permission for use of antibiotics (AFGC)

5.1.1 Evaluation

There are no Codex MRLs, US tolerances or EU MRLs for any of the proposed antibiotics in eggs.

5.2 MRL are established only for good agricultural practice in Australia (AFGC)

FSANZ should consider the issue of international aspects of MRLs and that MRLs should not be purely set on the basis of good agricultural practice in Australia only. This is an ongoing issue for the food industry, which has had products rejected at point of import.

5.2.1 Evaluation

MRL changes (in particular deletions) have the potential to restrict the importation of foods and could potentially result in a reduced product range available to consumers, as foods could not be legally imported or sold to consumers. In the case of Application A558, MRLs are to be inserted into Standard 1.4.2 of the Code for eggs for a range of various antibiotics. Therefore, this would expect to facilitate imports of eggs into Australia with those particular residues, rather than restrict trade.

No submissions were received from specific industry sectors that addressed the likely effects on trade or importation for the relevant food commodities if the proposed additions were approved.

A Food Regulation Standing Committee (FRSC) interdepartmental working group consisting of representatives from FSANZ, the Australian Pesticides and Veterinary Medicines Authority (APVMA), Department of Health and Aging (DoHA) and the Australian Department of Agriculture Fisheries and Forestry (DAFF) is currently considering some options for regulating AG/VET chemicals without MRLs, including issues associated with the adoption of Codex MRLs and MRLs specifically for imported foods. The proposed strategy is that discussions with the relevant agencies continue and a policy on these issues is recommended for consideration by the Food Regulation Standing Committee at its December 2005 meeting.

5.3 Out of date dietary exposure data used to calculate the NEDI (Queensland Health)

Concerns were expressed over the use of out-of-date dietary data to calculate the NEDI for the proposed antibiotics.

5.3.1 Evaluation

FSANZ is aware of the lapse of time since the last National Nutrition Survey (NNS) and of the need to generate new survey data that documents the changes that may have occurred in the eating patterns of consumers over the last decade. However, when considering the foods encompassed by the current Application (namely eggs) FSANZ considers that minimal change is likely to have occurred since the mid 1990s in terms of consumption of eggs, as they were already established staple foods in Australia. The data and information provided by the previous NNS in this case is likely to be appropriate and valid for current times. Where necessary FSANZ looks for additional data on consumption or market sales/volumes for new foods, however for the purpose of this application it was not necessary.

6. Options

6.1 Option 1 – *status quo* – do not include the new MRLs for the relevant antibiotics for eggs

Under this option, the *status quo* would be maintained and there would be no changes in the existing MRLs in Standard 1.4.2 of the Code.

6.2 Option 2 – vary Standard 1.4.2 to include the new MRLs for the relevant antibiotics for eggs

Under this option, the addition of the proposed MRLs for eggs would be approved for inclusion into Standard 1.4.2 of the Code.

7. Affected Parties

The parties affected by proposed MRL amendments include:

- consumers, including domestic and overseas customers;
- growers and producers of domestic and export poultry products;
- importers of poultry products; and
- Australian Government, State and Territory agencies involved in monitoring and regulating the use of agricultural and veterinary chemicals in food and the potential resulting residues.

8. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the Application, and the potential impacts of any regulatory or non-regulatory provisions.

8.1 Option 1 – *status quo* – no change to the existing MRLs in the Code

8.1.1 Benefits

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to potential residues of the relevant antibiotics in eggs and egg products;
- for producers of eggs and egg products for both the domestic and export markets, the adoption of this option would not result in any discernable benefits;
- for importers of eggs and egg products, the adoption of this option would not result in any discernable benefits; and

- for Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable benefits.

8.1.2 Costs

- for consumers there are unlikely to be any discernable costs as the unavailability of eggs and some egg products from certain producers is likely to be seen as typical seasonal fluctuations in the food supply;

- for producers of eggs and egg products for both the domestic and export markets, the adoption of this option would result in costs resulting from not being able to legally sell eggs and egg products containing residues consistent with the proposed MRLs. Primary producers do not produce eggs or use antibiotics to comply with MRLs. They use antibiotics to treat diseases in accordance with the prescribed label conditions, and expect that any resulting residues will be acceptable and that products from the legally treated poultry can be legally sold. If the legal use of antibiotics results in the production of eggs and egg products that cannot be legally sold under food legislation then primary producers will incur substantial losses. Losses for primary producers would in turn impact negatively upon rural and regional communities;

- for importers of eggs and egg products, the adoption of this option would not result in any discernable costs; and

- for Australian Government, State and Territory agencies, the adoption of this option would create discrepancies between agricultural and food legislation thereby creating uncertainty, inefficiency and confusion in the enforcement of regulations.

8.2 Option 2 – vary Standard 1.4.2 to include the new MRLs for the relevant antibiotics for eggs

8.2.1 Benefits

- for consumers, the major benefit would be potential flow on benefits resulting from the price and availability of eggs and egg products if producers can legally sell such products containing residues consistent with MRL additions;

- for producers of eggs and egg products for both the domestic and export markets, the benefits of this option would result from being able to legally sell eggs containing residues consistent with MRL additions. Other benefits include the consistency between agricultural and food legislation thereby minimising compliance costs to primary producers;

- for importers, the adoption of this option would result in the benefit that eggs and egg products which contained residues consistent with MRL additions could be legally imported; and

- for Commonwealth, State and Territory agencies, the benefits of this option would include the removal of discrepancies between agricultural and food legislation thereby creating certainty and allowing efficient enforcement of regulations.

8.2.2 Costs

- for consumers there are no discernable costs;
- for producers of eggs and egg products for both the domestic and export markets, the adoption of this option would not result in any discernable costs;
- for importers, the adoption of this option would not result in any discernable costs; and
- for Commonwealth, State and Territory agencies, the adoption of this option would not result in any discernable costs, although there may be minimal impacts associated with slight changes to residue monitoring programs.

9. Consultation

9.1 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.

MRLs prescribed in Standard 1.4.2 of the 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 Code cannot legally be supplied in Australia.

In administrative terms and consistent with international practice, MRLs assist in regulating the use of agricultural and veterinary chemical products. MRLs indicate whether agricultural and veterinary chemical products have been used in accordance with the registered conditions of use.

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

This Application contains MRLs which are not addressed in the international Codex standard. The proposed MRLs also relate to production of traded poultry products that may indirectly have a significant effect on trade between WTO members.

FSANZ made a Sanitary and Phytosanitary notification to the WTO for this Application in accordance with the WTO SPS agreement because the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment. No WTO member made a submission on this Application.

10. The Decision

FSANZ has undertaken an assessment and review of the proposed range of MRLs for the antibiotics amoxicillin, sulphadiazine, sulphadimidine, sulphaquinoxaline and trimethoprim and considers that the MRLs are appropriate for the following reasons:

- a detailed dietary risk assessment has been undertaken by the APVMA and FSANZ and it was concluded that there are no public health and safety concerns;

- advice from the Expert Advisory Group on Antimicrobial Resistance (EAGAR) confirmed that the proposed MRLs are supported;

- following an assessment of the Application, the proposed changes would remove any discrepancies between agricultural and food legislation and provide certainty and consistently for enforcement;

- the changes would minimise the potential costs to primary producers and rural and regional communities in terms of legally being able to sell legally treated food; and

- the changes would minimise residues consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases.

Option 1 is a viable option but its adoption would result in:

- potential substantial costs to primary producers that may have a negative impact on their viability and in turn the viability of the rural and regional communities that depend upon the sale of the agricultural produce; and

- discrepancies between agricultural and food legislation which could have negative impacts on the compliance costs of primary producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

FSANZ's preferred approach is to adopt Option 2 – vary Standard 1.4.2 to include new MRLs for the relevant antibiotics.

11. Implementation and Review

The use of chemical products and MRLs are under constant review as part of APVMA'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;

- Australian Government programs such as the National Residue Survey; and

- dietary exposure surveys such as the Australian Total Diet Study.

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.

At this time it is proposed that the proposed MRL amendments should come into effect upon gazettal and continue to be monitored by the same means as other residues in food.

12. Recommendation

The draft variations to Standard 1.4.2-Maximum Residue Limits, varying MRLs for eggs, for various antibiotics is approved 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 APVMA has already registered the chemical products associated with the MRLs 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 APVMA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.

- The Office of Chemical Safety of the Therapeutic Goods Administration (OCS) of the Australian Government Department of Health and Ageing has undertaken an appropriate toxicological assessment of the chemical products and has established relevant acceptable daily intakes (ADI).

- The Expert Advisory Group on Antimicrobial Resistance (EAGAR) has evaluated the impact of the potential residues of the proposed antibiotics in the food supply and supported the changes to MRLs in this Application.

- FSANZ has undertaken a regulation impact assessment and concluded that the amendment to Standard 1.4.2 of the Code is necessary, cost-effective and of benefit to both producers and consumers.

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

ATTACHMENTS

1. Draft variation to Standard 1.4.2 of the *Australia New Zealand Food Standards Code.*
2. A Summary of the Requested MRLs for Each Chemical and an Outline of the Information Supporting the Requested Changes to the *Australia New Zealand Food Standards Code*.
3. Background to Dietary Exposure Assessments.
4. Summary of submissions

Attachment 1

Draft Variation to the *Australia New Zealand Food Standards Code*

To commence: on gazettal

[1] ***Standard 1.4.2*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *inserting in alphabetical order in* Schedule 1, *the foods and associated MRLs for the following chemicals –*

AMOXYCILLIN INHIBITORY SUBSTANCE, IDENTIFIED AS AMOXYCILLIN	
EGGS	T*0.01
SULPHADIAZINE SULPHADIAZINE	
EGGS	T*0.02
SULPHADIMIDINE SULPHADIMIDINE	
EGGS	T*0.01
SULPHAQUINOXALINE SULPHAQUINOXALINE	
EGGS	T*0.01
TRIMETHOPRIM TRIMETHOPRIM	
EGGS	T*0.02

Attachment 2

A Summary of the Requested MRLs for Each Chemical and an Outline of the Information Supporting the Requested Changes to the *Australia New Zealand Food Standards Code*

The Full Evaluation Reports for individual chemicals are available upon request from the relevant Project Manager at FSANZ.

NOTES ON TERMS USED IN THE TABLE

ADI – Acceptable Daily Intake - The ADI is the daily intake of an agricultural or veterinary chemical, which, during the consumer's entire lifetime, appears to be without appreciable risk to the health of the consumer. This is 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.

ARfD – Acute Reference Dose - The ARfD 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.

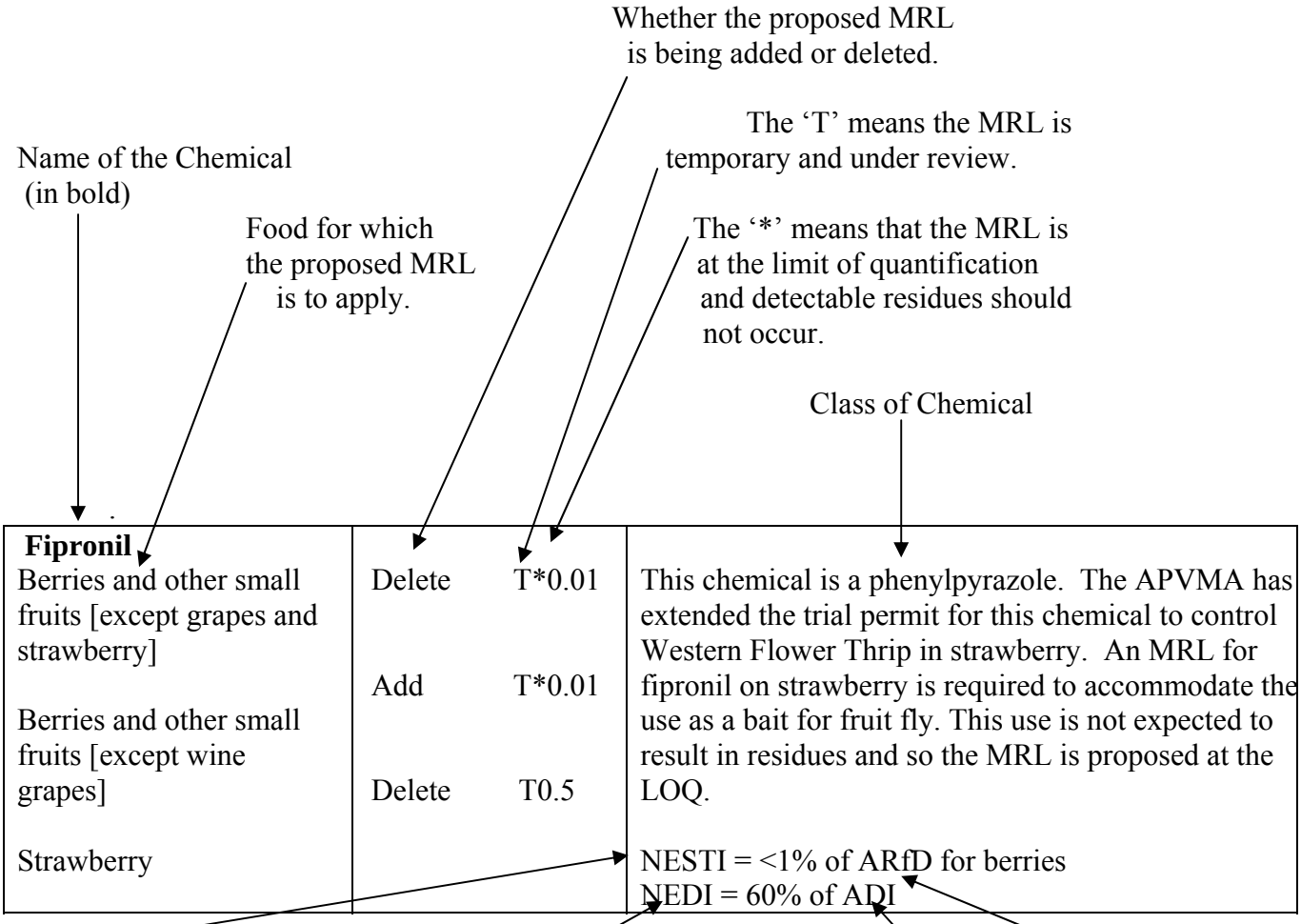
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

NEDI - National Estimated Dietary Intake - The NEDI represents a more realistic estimate of dietary exposure 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; the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials other than the MRL to represent pesticide residue levels. In most cases the NEDI is still an overestimation because the above data is often not available and in these cases the MRL is used.

NESTI - National Estimated Short Term Intake - The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an 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. FSANZ has used ARfDs set by the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 Australian National Nutrition Survey (NNS) and the MRL when the STMR is not available to calculate the NESTIs.

The NESTI calculation incorporates the large portion (97.5^{th} percentile) 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), representing typical residue 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.

The following are examples of entries and the proposed MRLs listed are not part of this Application.



Fipronil			
Berries and other small fruits [except grapes and strawberry]	Delete	T*0.01	This chemical is a phenylpyrazole. The APVMA has extended the trial permit for this chemical to control Western Flower Thrip in strawberry. An MRL for fipronil on strawberry is required to accommodate the use as a bait for fruit fly. This use is not expected to result in residues and so the MRL is proposed at the LOQ. NESTI = <1% of ARfD for berries NEDI = 60% of ADI
Berries and other small fruits [except wine grapes]	Add	T*0.01	
Strawberry	Delete	T0.5	

The NESTI is an assessment of the acute dietary exposure which is compared to the acute reference dose (ARfD). More information is in the glossary on the NESTI and the ARfD. To be acceptable to FSANZ, the NESTI must be less than 100% of the ARfD because the ARfD is considered the 'safe' level.

Acute Reference Dose (ARfD) more information on this term is in the glossary

The NEDI is an assessment of the chronic exposure which is compared to the acceptable daily intake (ADI). More information is in the glossary on the NEDI and the ADI. To be acceptable to FSANZ, the NEDI must be less than 100% of the ADI because the ADI is considered the 'safe' level.

Acceptable Daily Intake (ADI) more information on this term is in the glossary

Information about the use of the chemical is provided so consumers can see the reason why the residues may occur in food.

Data from the Australian Total Diet Study (ATDS) is provided when available because it provides an indication of the typical exposure to chemicals in table ready foods. The ATDS results are more realistic because the NEDI and NESTI calculations are theoretical calculations that conservatively overestimate exposure.

Chlorpyrifos Coffee beans	Add	T0.5	APVMA extension of use for the control of pests. The 19th ATDS (1998) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to 0.51% of ADI for adult males and up to 2.55% of ADI for 2 year olds. The 20th ATDS (2000) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 83% of ADI

Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and typically result because of the different range of foods in the individual surveys.

Glossary;

1. **ADI** Acceptable Daily Intake.
2. **APVMA** Australian Pesticides and Veterinary Medicines Authority
3. **ARfD** Acute Reference Dose.
4. **ATDS** Australian Total Diet Study.
5. **FSC** *Australia New Zealand Food Standards Code.*
6. **JMPR** Joint FAO/WHO Meeting on Pesticide Residues
7. **LOQ** Limit of Analytical Quantification.
8. **NEDI** National Estimated Daily Intake.
9. **NESTI** National Estimated Short Term Intake.
10. **NNS** 1995 Australian National Nutrition Survey
11. **JMPR** Joint FAO/WHO Meeting on Pesticide Residues
12. **T** Temporary MRL.
13. **WHP** With Holding Period

The Full Evaluation Reports for individual chemicals are available upon request from the relevant Project Manager at FSANZ.

Amoxycillin Eggs	Insert T*0.01	Amoxycillin is a beta-lactam antibiotic. APVMA has issued a permit to allow the use of amoxycillin to treat bacterial diseases in replacement pullets (layers and breeders). To cover this use pattern, it is recommended that a temporary MRL at the LOQ be established for amoxycillin in eggs. The inclusion of the MRLs at the LOQ means that no detectable residues of amoxycillin in eggs should occur. NEDI = <1% of the ADI.
Sulphadiazine Eggs	Insert T*0.02	Sulfadiazine is a sulphonamide antibiotic. APVMA has issued a permit to allow the use of sulfadiazine to treat bacterial diseases in poultry. Sulfadiazine is currently registered as a medicated water preparation for use in chickens and turkeys (broiler/meat birds only). The registered use rate is identical to that proposed for use in replacement pullets. Therefore, the existing sulfadiazine MRLs for poultry meat and edible offal adequately covers the occurrence of sulfadiazine residues in edible tissues from treated replacement pullets. To cover this use pattern, it is recommended that a temporary MRL at the LOQ be established for sulfadiazine in eggs. NEDI = 6% of the ADI.
Sulphadimidine Eggs	Insert T*0.01	Sulphadimidine is a sulphonamide antibiotic. APVMA has issued a permit to allow the use of sulphadimidine to treat bacterial diseases in poultry. Sulphadimidine is currently registered as a medicated water preparation for use in chickens and turkeys (broiler/meat birds only). The registered use rate is identical to that proposed for use in replacement pullets. Therefore, the existing sulphadimidine MRLs for poultry meat and edible offal adequately covers the occurrence of sulfadiazine residues in edible tissues from treated replacement pullets. To cover this use pattern, it is recommended that a temporary MRL at the LOQ be established for sulphadimidine in eggs. NEDI = 1% of the ADI.

Sulphaquinoxaline Eggs	Insert T*0.01	Sulphaquinoxaline is a sulphonamide antibiotic. APVMA has issued a permit to allow the use of sulphaquinoxaline to prevent and treat coccidiosis in poultry. Sulphaquinoxaline is currently registered as a medicated water preparation for use in chickens and turkeys (broiler/meat birds only). The registered use rate is identical to that proposed for use in replacement pullets. Therefore, the existing sulphaquinoxaline MRLs for poultry meat and edible offal adequately covers the occurrence of sulphaquinoxaline residues in edible tissues from treated replacement pullets. To cover this use pattern, it is recommended that a temporary MRL at the LOQ be established for sulphaquinoxaline in eggs. NEDI = <1% of the ADI.
Trimethoprim Eggs	Insert T*0.02	Trimethoprim is a diaminopyrimidine drug which potentiates the actions of sulphonamide antibiotics. APVMA has issued a permit to allow the use of trimethoprim in combination with sulphonamide antibiotics to treat bacterial diseases in poultry. Trimethoprim is currently registered as a medicated water preparation for use in chickens and turkeys (broiler/meat birds only). The registered use rate is identical to that proposed for use in replacement pullets. Therefore, the existing trimethoprim MRLs for poultry meat and edible offal adequately covers the occurrence of trimethoprim residues in edible tissues from treated replacement pullets. To cover this use pattern, it is recommended that a temporary MRL at the LOQ be established for trimethoprim in eggs. NEDI = 3% of the ADI.

Attachment 3

Background To Dietary Exposure Assessments

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code, 1994* (*Ag Vet Code Act*) requires APVMA 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.

FSANZ's primary role in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential residues in treated food do not represent an unacceptable risk to public health and safety. In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from all foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will not approve MRLs for inclusion in the 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, FSANZ conducts dietary exposure assessments in accordance with internationally accepted practices and procedures.

The three steps undertaken in conducting a dietary exposure assessment are the:

- determination of the residues of a chemical in a treated food;
- determination of the acceptable health standard for a chemical in food (i.e. the acceptable daily intake and/or the acute reference dose); and
- calculating the dietary exposure to a chemical from all foods, using food consumption data from nutrition surveys and comparing this to the acceptable health standard.

Determination of the residues of a chemical in a treated food

APVMA assesses a range of data when considering the proposed use of a chemical product on a food. These data enable APVMA to determine what the likely residues of a chemical will be on a treated food. These data also enable APVMA to determine what the maximum residues will be on a treated food if the chemical product is used as proposed and from this, APVMA determines an MRL.

The MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. However, incorporating the MRL into food legislation means that the residues of a chemical are minimised (i.e. must not exceed the MRL), irrespective of whether the dietary exposure assessment indicates that higher residues would not represent an unacceptable risk to public health and safety.

Determination of the acceptable health standard for a chemical in food

TGA assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where applicable, the ARfD for a chemical.

Both APVMA and FSANZ use these health standards in dietary exposure assessments.

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.

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.

Calculating the dietary exposure

APVMA and FSANZ undertake chronic dietary exposure assessments for all agricultural and veterinary chemicals and undertake acute dietary exposure assessments where either the OCS or Joint FAO/WHO Meeting on Pesticide Residues has established an ARfD.

APVMA and FSANZ have recently agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by APVMA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest 1995 Australian National Nutrition Survey (NNS). The Australian Bureau of Statistics with the Australian Government Department of Health and Aged Care undertook the NNS survey over a 13-month period (1995 to 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 were reported.

Chronic Dietary Exposure Assessment

The National Estimated Daily Intake (NEDI) represents a realistic estimate of chronic dietary exposure if the chemical residue 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 Study (ATDS).

Where the data is not available on the specific residues in a treated food then a cautious approach is taken and the MRL is used. The use of the MRL in dietary exposure estimates may result in considerable overestimates of exposure because it assumes that the entire national crop is treated with a pesticide and that the entire national crop contains residues equivalent to the MRL. In reality, only a portion of a specific crop is treated with a pesticide; most treated crops contain residues well below the MRL at harvest; and residues are usually reduced during storage, preparation, commercial processing and cooking. It is also unlikely that every food for which an MRL is proposed will have been treated with the same pesticide over the lifetime of consumers.

In conducting chronic dietary exposure assessments, APVMA and FSANZ consider the residues that could result from the use of a chemical product on all foods. If specific data on the residues are not available then a cautious approach is taken and the MRL is used.

The residues that are likely to occur in all foods are then multiplied by the daily consumption of these foods derived from individual dietary records from the latest 1995 National Nutrition Survey (NNS). These calculations provide information on the level of a chemical that is consumed for each food and take into account the consumption of processed foods e.g. apple pie and bread. These calculations for each food are added together to provide the total dietary exposure to a chemical from all foods.

This figure is then divided by the average Australian's bodyweight to provide the amount of chemical consumed per day per kg of human bodyweight. This is compared to the ADI. It is therefore the overall dietary exposure to a chemical that is compared to the ADI - not the MRL. FSANZ considers that the chronic dietary exposure to the residues of a chemical is acceptable where the best estimate of this exposure does not exceed the ADI.

Further where these calculations use the MRL they are considered to be overestimates of dietary exposure because they assume that:

- the chemical will be used on all crops for which there is a registered use;
- treatment occurs at the maximum application rate;
- the maximum number of permitted treatments have been applied;
- the minimum withholding period has been applied; and
- this will result in residues at the maximum residue limit.

In agricultural and animal husbandry this is not the case but for the purposes of undertaking a risk assessment, it is important to be conservative in the absence of reliable data to refine the dietary exposure estimates further.

Attachment 4

SUMMARY OF SUBMISSIONS

Submitter	Comment
Australian Food and Grocery Council	The AFGC **supports** the proposed MRLs. The AFGC consider that there is a conflict in the use of the FSANZ Act in relation to MRLs to support decisions of the APVMA on the domestic use of agricultural and veterinary chemicals. The AFGC urges FSANZ to consider the issue of international aspects of MRLs and that MRLs should not be purely set on the basis of good agricultural practice in Australia only. FSANZ has not provided any details on overseas permission for use of antibiotics.
Department of Human Services Victoria	**Supports** options 2 (a), (b) and (c) and agrees that the Food Standards Code should be consistent with the APVMA MRL Standard.
Environmental Health Unit, Queensland Health	Queensland Health **supports** options 2 (a), (b) and (c) but expresses concerns over the use of out-of-date dietary data to calculate the NEDI for the proposed antibiotics.