FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

**4-05**
**25 May 2005**

# INITIAL / DRAFT ASSESSMENT REPORT

# APPLICATION A550

# MAXIMUM RESIDUE LIMITS – SULPHAQUINOXALINE (ANTIBIOTIC)

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 July 2005**
**SUBMISSIONS RECEIVED AFTER THIS DEADLINE**
**WILL NOT BE CONSIDERED**
*(See 'Invitation for Public Submissions' for details)*

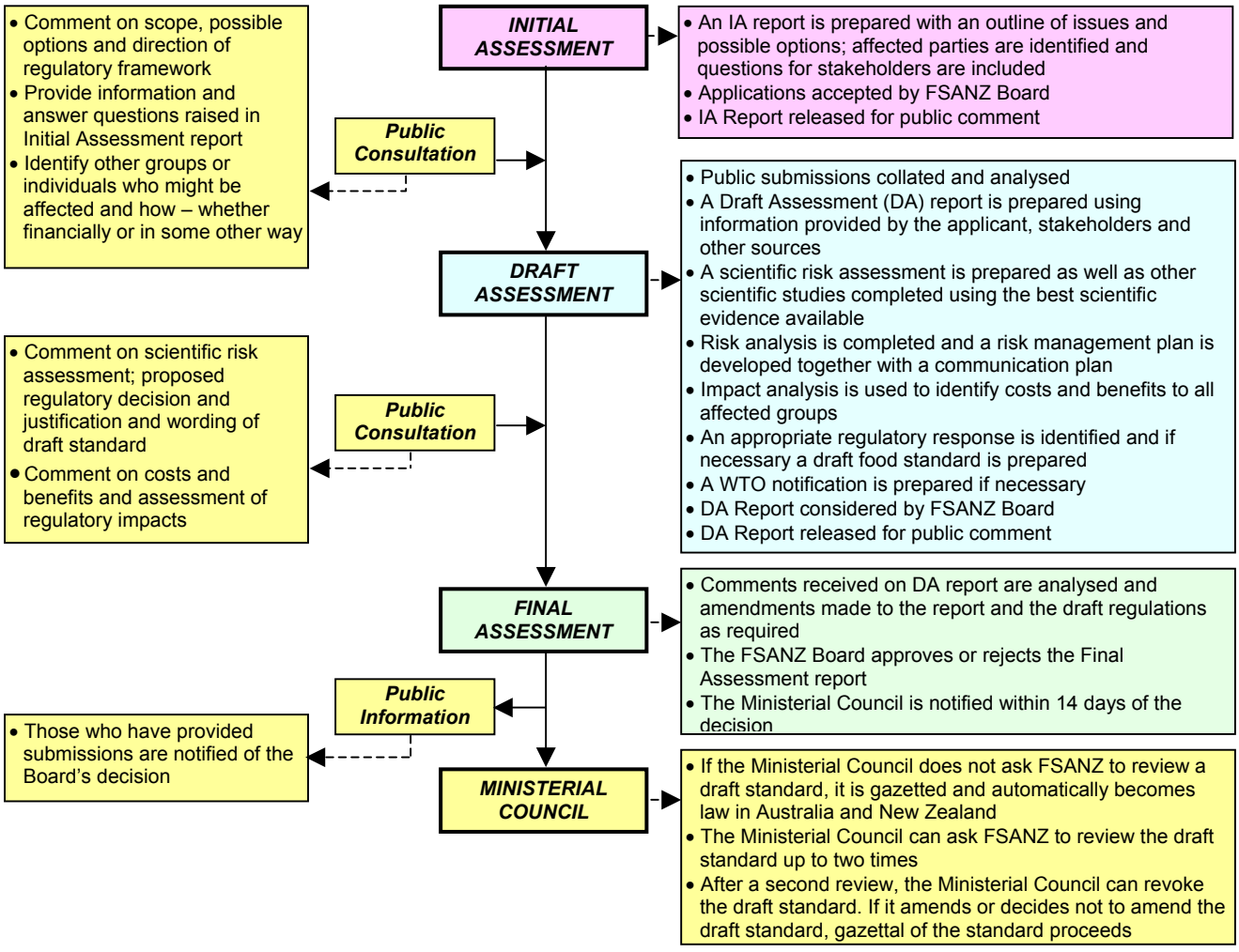
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Commonwealth; 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 Commonwealth, 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 Commonwealth, 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* 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.



## INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial / Draft Assessment Report of Application A550, which includes the identification and discussion of the key issues and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code). FSANZ invites public comment on this Initial / Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing a Final Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ 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.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand**
**PO Box 7186**
**Canberra BC ACT 2610**
**AUSTRALIA**
**Tel (02) 6271 2222**
**www.foodstandards.gov.au**

**Food Standards Australia New Zealand**
**PO Box 10559**
**The Terrace WELLINGTON 6036**
**NEW ZEALAND**
**Tel (04) 473 9942**
**www.foodstandards.govt.nz**

**Submissions need to be received by FSANZ by 6pm (Canberra time) 6 July 2005.**

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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## Executive Summary and Statement Of Reasons

This Application (A550) seeks to vary the Maximum Residue Limits (MRLs) for poultry meat and poultry offal, for the antibiotic sulphaquinoxaline in the *Australia New Zealand Food Standards Code* (the Code). It is an application from the Australian Pesticides and Veterinary Medicines Authority (APVMA) to update the Code in order to reflect the current registration status of sulphaquinoxaline in use in Australia.

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 independently and separately develop MRLs for agricultural and veterinary chemicals in food.

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

FSANZ will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization.

**Statement of Reasons**

This Application has been assessed against the requirements for Initial / Draft Assessment in sections 13 and 15 of the FSANZ Act. FSANZ recommends accepting and progressing this Application for the following reasons:

- The dietary exposure assessment indicates that the residues associated with the proposed MRLs for sulphaquinoxaline for poultry meat and poultry offal would be the same as already established for this chemical and, therefore, do not represent an unacceptable risk to public health and safety.

- APVMA's proposed changes to the MRLs for sulphaquinoxaline for poultry commodities are of an administrative nature. There has been no change in the usage pattern for this chemical and the proposed MRLs would no longer be the subject of a permit.

- As there is no proposed change in the limit of the residues permitted by either the APVMA MRL Standard or the Code, the rejection of the application would not result in legally treated poultry commodities not being legally sold. However, acceptance of the proposed MRLs would remove the current anomalies between the APVMA MRL Standard and the Code and this would benefit all stakeholders by maintaining public confidence in the system of establishing MRLs.

- 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 sulphaquinoxaline for poultry.

- The Office of Chemical Safety (OCS) of the Therapeutic Goods Administration (TGA) has undertaken an appropriate toxicological assessment of sulphaquinoxaline and has established it's acceptable daily intake (ADI).

- The Expert Advisory Group on Antimicrobial Resistance (EAGAR) has evaluated the impact of the potential residues of sulphaquinoxaline in the food supply and has concluded that the use pattern of the sulphaquinoxaline product for poultry is acceptable.

- FSANZ has undertaken a preliminary regulation impact assessment process. That process concluded that the amendment to 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 15 October 2004 seeking amendments to Standard 1.4.2 of the Code. The proposed amendments to the Standard would align MRLs in the Code for the antibiotic sulphaquinoxaline with the MRLs in the APVMA MRL Standard.

## 1.1 Summary of the proposed MRLs for sulphaquinoxaline

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

| **Chemical**<br>Food | **MRL**<br>**(mg/kg)** | **Information** |
|---|---|---|
| **Sulphaquinoxaline** | | |
| Poultry meat | Omit T0.1<br>Substitute 0.1 | Sulphaquinoxaline is a sulphonamide antibiotic used to prevent and treat coccidiosis in poultry. This is an administrative change to the MRL. |
| Poultry, edible offal of | Omit T0.1<br>Substitute 0.1 | No changes to the use pattern of this chemical are proposed. EAGAR agreed that APVMA's proposal to covert these MRLs from temporary to permanent are acceptable.<br>Sulphaquinoxaline does not have a human analogue.<br>NEDI = <1% of ADI. |

## 1.2 The National Estimated Dietary Intake

The National Estimated Dietary Intake (NEDI) for sulphaquinoxaline is equivalent to <1% of the ADI. This calculation is considered to be a gross overestimate of the actual consumption of sulphaquinoxaline as it assumes all slaughtered poultry were treated and contain residues at the MRL. This calculation used summary food consumption figures derived from the National Nutrition Survey 1995 data. It is concluded that the chronic dietary exposure is less than the ADI and the risk is acceptable.

## 1.3 Acute dietary exposure

Neither the OCS nor the Joint FAO/WHO Expert Committee on Food Additives, have set an acute reference dose for sulphaquinoxaline.

## 1.4 Stop clock for sulphaquinoxaline

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.

On 16 December 2004, pursuant to section 34 of the FSANZ Act, FSANZ requested that the APVMA:

- seek written advice from EAGAR as to whether EAGAR supports the proposed amendments of the sulphaquinoxaline MRLs; and

- advise FSANZ of EAGAR's opinion as to whether the risk of the development of resistance in human pathogenic bacteria, arising from the human consumption of poultry commodities containing residues of sulphaquinoxaline at the levels that arise from the Australian approved uses, is acceptable.

On 12 April 2005, APVMA supplied a letter from EAGAR in which EAGAR stated:

> *Members agreed that the APVMA proposal to convert two temporary MRLs for poultry commodities to permanent MRLs is acceptable to EAGAR.*

FSANZ then re-commenced assessment of this Application on 13 April 2005.

### 1.5 Antibiotics as allergens

APVMA assesses the potential allergenicity of antibiotic residues in food commodities. 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.

Sulphaquinoxaline belongs to the sulphonamide group of antibiotics and not to the β-lactam group of antibiotics. Therefore, allergic reactions to the residues of sulphaquinoxaline in poultry meat and/or offal are not expected to occur. However, FSANZ recognises that the proposed MRLs for sulphaquinoxaline may be of concern to some of our stakeholders.

**FSANZ requests data on the occurrence of allergic reactions to residues of sulphaquinoxaline in poultry meat and poultry offal.**

## 2. Regulatory Problem

### 2.1 Current Regulations

APVMA has amended the MRLs for sulphaquinoxaline for poultry meat and poultry offal in its APVMA MRL Standard. These changes are of an administrative nature and APVMA has made no changes to the use pattern for this chemical; the only changes are that the proposed MRLs are no longer the subject of a permit. Therefore, there is now a discrepancy between the APVMA MRL Standard and the Code for the MRLs for sulphaquinoxaline for poultry meat and poultry offal. As there is no change in the limit of the residues permitted by either the APVMA MRL Standard or the Code legally treated poultry commodities can still be legally sold.

## 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 to 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 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 sulphaquinoxaline for poultry meat and offal.

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. As stated above, APVMA includes MRLs in its APVMA MRL Standard when they register a chemical product for use or grant a permit for use. APVMA then notifies FSANZ of these MRLs so that FSANZ may consider them for inclusion in the Code.

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 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 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.

## 5. Options

### 5.1 Option 1 – *status quo* – no change to the existing MRLs for sulphaquinoxaline in the Code

Under this option, the status quo would be maintained and there would be no changes in the existing MRLs to the Code.

### 5.2 Option 2 – adopt the changes to include the new MRLs for sulphaquinoxaline

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

## 6. 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.

## 7. 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 proposal, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make a final assessment of this proposal will include information from public submissions.

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

*7.1.1 Benefits*

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of sulphaquinoxaline;
- for producers of domestic and export poultry products, the adoption of this option would not result in any discernable benefits;
- for importers, 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.

*7.1.2 Costs*

- for consumers, the adoption of this option would not result in any discernable costs;
- for producers of domestic and export poultry products, 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 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.

### 7.2 Option 2 – adopt the changes to the MRLs for sulphaquinoxaline

*7.2.1 Benefits*

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of sulphaquinoxaline;

- for producers of domestic and export poultry products, the adoption of this option would not result in any discernable benefits;

- for importers, the adoption of this option would result in the benefit that poultry products could be legally imported if it contained residues consistent with MRL additions; 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.

*7.2.2 Costs*

- for consumers, the adoption of this option would not result in any discernable costs;

- for producers of domestic and export poultry products, 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.

## 8. Consultation

FSANZ has decided, pursuant to section 36 of the FSANZ Act, to omit to invite public submissions in relation to the application prior to making a Draft Assessment. However, FSANZ now invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to any submissions received.

FSANZ was satisfied that omitting to invite public submissions prior to making a draft assessment was warranted as the application raises matters of minor significance or complexity. Furthermore, FSANZ considered that omitting to invite public submissions prior to making a Draft Assessment would not significantly adversely affect the interests of any person or body.

Section 63 of the FSANZ Act provides that subject to the *Administrative Appeals Act 1975*, application may be made to the Administrative Appeals Tribunal for review of a decision of FSANZ under section 36 of the FSANZ Act not to do something.

In addition to the public consultation that is undertaken for all applications and proposals, and as the preferred option has some potential impacts for importers of food and associated industries, comment on the impacts of the proposed MRLs will be sought from them.

### 8.1 World Trade Organization Notification

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

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

This Application will be notified as an SPS measure 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.

## 9. Conclusion

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

- 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 – adopt the changes to include new MRLs for sulphaquinoxaline. FSANZ prefers this approach because:

- the residues associated with the MRL amendments would not result in an unacceptable risk to public health and safety (this benefit also applies to Option 1);

- the changes would remove discrepancies between agricultural and food legislation and assist enforcement.

## 10. 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 Survey.

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

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.

## 11. Recommendation

FSANZ recommends progressing this Application for the following reasons:

- The dietary exposure assessment indicates that the residues associated with the proposed MRLs for sulphaquinoxaline for poultry meat and poultry offal would be the same as already established for this chemical and, therefore, do not represent an unacceptable risk to public health and safety.
- APVMA's proposed changes to the MRLs for sulphaquinoxaline for poultry commodities are of an administrative nature. There has been no change in the usage pattern for this chemical and the proposed MRLs would no longer be the subject of a permit.
- As there is no proposed change in the limit of the residues permitted by either the APVMA MRL Standard or the Code, the rejection of the application would not result in legally treated poultry commodities not being legally sold. However, acceptance of the proposed MRLs would remove the current anomalies between the APVMA MRL Standard and the Code and this would benefit all stakeholders by maintaining public confidence in the system of establishing MRLs.
- 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 sulphaquinoxaline for poultry.

- OCS has undertaken an appropriate toxicological assessment of sulphaquinoxaline and has established an ADI.

- EAGAR has evaluated the impact of the potential residues of sulphaquinoxaline in the food supply and has concluded that the use pattern of the sulphaquinoxaline product for poultry is acceptable.

- FSANZ has undertaken a preliminary regulation impact assessment process. That process concluded that the amendment to 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 the *Australia New Zealand Food Standards Code*
2. Notes on Terms
3. Background to Dietary Exposure Assessments

**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] *omitting from* Schedule 1*, under the entries for the following chemicals, the maximum residue limit for the food, substituting –*

| **SULPHAQUINOXALINE**<br>SULPHAQUINOXALINE | |
|---|---|
| POULTRY, EDIBLE OFFAL OF | 0.1 |
| POULTRY MEAT | 0.1 |

**Attachment 2**

## Notes on Terms

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 National Nutrition Survey (NNS) and the MRL when the STMR is not available to calculate the NESTIs.

## 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 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 <u>if the chemical residue data are available</u> 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).

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.