

EXPLANATORY STATEMENT

APPLICATION A612

MAXIMUM RESIDUE LIMITS DIMETRIDAZOLE (ANTIBIOTIC)

For information on matters relating to this Assessment Report or the assessment process generally, please refer to: <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

Application A612 seeks to reduce maximum residue limits (MRLs) for pig and poultry commodities and add an MRL for eggs¹ for the antibiotic veterinary chemical dimetridazole in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* (the Code). It is a routine Application from the Australian Pesticides and Veterinary Medicines Authority (APVMA) to update the Code in order to reflect the current registration status in Australia of dimetridazole following the APVMA chemical review. The requested MRLs are temporary and at the limit of analytical quantification (LOQ) of *0.0001 mg/kg (0.1 ppb). The APVMA anticipates requesting Food Standards Australia New Zealand (FSANZ) omit the temporary MRLs from the Code after the two year phase out period for the use of this chemical.

The National Health and Medical Research Council (NHMRC) provides advice on risk assessments for new antibiotics and extensions of indications of currently registered antibiotics. The NHMRC provides this advice with reference to the Expert Advisory Group on Antimicrobial Resistance (EAGAR). The APVMA has advised that as the use of dimetridazole is being phased out, information on changes to the use pattern and MRL variations was not required to be provided to the NHMRC.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits and to support industry and compliance agencies by maintaining current MRLs in the Code. As a result of the review by the APVMA, dimetridazole is being phased out and uses in food-producing animals have been cancelled. This has also occurred at an international level. The APVMA has advised that residues are expected to be well below the LOQ, essentially zero residues. Since a dietary risk assessment accompanied the approval of dimetridazole at the time of registration, incorporating MRLs in the Code at the LOQ does not warrant conducting another dietary exposure assessment. FSANZ considers that the Application raises no safety concerns from a dietary exposure or microbiological perspective.

The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty), excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

Purpose

The purpose of this Application is to update the Code by incorporating MRLs at the LOQ for certain commodities for the antibiotic dimetridazole. This will protect public health and safety by providing a compliance tool in line with MRLs determined by the APVMA following a review of dimetridazole.

¹ An MRL was not previously established for eggs as it was assumed that eggs from breeder birds would not be made available for human consumption. The APVMA has taken into account that such eggs may be sold or processed for human consumption and recommended an MRL.

Decision

FSANZ has made an assessment and approves the draft variations to Standard 1.4.2 – Maximum Residue Limits to incorporate temporary dimetridazole MRLs for pig and poultry commodities and eggs at the LOQ.

Reasons for Decision

FSANZ approves the draft variations to Standard 1.4.2 for the following reasons:

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- The proposed variations will benefit stakeholders by maintaining public health and safety. Incorporating the proposed temporary dimetridazole MRLs at the LOQ in the Code poses no adverse consequences to human health.
- The proposed variations would update the Code in line with the recommendations of the APVMA chemical review of dimetridazole.
- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary and cost-effective.
- The proposed draft variations would remove discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory compliance agencies.
- The proposed changes are consistent with the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) section 18 objectives.

Consultation

FSANZ has now completed the assessment of Application A612 and held a single round of public consultation under section 36 of the FSANZ Act (as was in force prior to 1 July 2007.) The Board has approved the draft amendments to the Code and this decision has been notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

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

CONTENTS

INTRODUCTION.....	2
1. BACKGROUND.....	3
1.1 Current Standard	3
1.2 Use of Agricultural and Veterinary Chemicals.....	3
1.3 Maximum Residue Limit Applications.....	3
1.4 Australia and New Zealand Joint Food Standards	4
1.5 Proposed Variations to Standard 1.4.2 - Maximum Residue Limits	4
1.6 Antimicrobial Resistance.....	6
2. THE ISSUE / PROBLEM.....	6
3. OBJECTIVES.....	7
4. ASSESSMENT APPROACH	8
RISK ASSESSMENT	8
5. SAFETY ASSESSMENT	8
RISK MANAGEMENT.....	8
6. OPTIONS	8
6.1 Option 1 – no change to existing dimetridazole MRLs in Standard 1.4.2.....	8
6.2 Option 2 – vary Standard 1.4.2 to incorporate temporary dimetridazole MRLs and amend the residue definition as proposed.....	8
7. IMPACT ANALYSIS	9
7.1 Affected Parties	9
7.2 Benefit Cost Analysis.....	9
7.3 Comparison of Options	10
COMMUNICATION AND CONSULTATION STRATEGY.....	10
8. COMMUNICATION	10
9. CONSULTATION.....	11
9.1 Summarised submission from the Food Technology Association of Australia Inc.	11
9.2 Summarised submission from the Country Women’s Association of NSW	11
9.3 Summarised submission from the Australian Food and Grocery Council.....	12
9.4 Summarised submission from the NSW Food Authority	13
9.5 Summarised submission from the Queensland Government	13
9.6 World Trade Organization (WTO).....	14
9.7 New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008	14
9.8 Imported Foods	15
CONCLUSION	15
10. CONCLUSION AND DECISION	15
10.1 Reasons for Decision.....	16
11. IMPLEMENTATION AND REVIEW.....	16
ATTACHMENT 1 - DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	18
ATTACHMENT 2 – SUMMARY OF SUBMISSIONS.....	19

INTRODUCTION

A notification was received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 20 August 2007 seeking to vary the *Australia New Zealand Food Standards Code* (the Code). The proposed variations to Standard 1.4.2 – Maximum Residue Limits align maximum residue limits (MRLs) in the Code for the antibiotic dimetridazole with the MRLs in the APVMA MRL Standard.

Food Standards Australia New Zealand's (FSANZ) role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits and to support producers, importers and compliance agencies by maintaining current MRLs in the Code.

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 the chemical per kilogram (mg/kg) of the food.

FSANZ will not agree to adopt MRLs into the Code where dietary exposure to residues of a chemical presents a risk to public health and safety. Dimetridazole is being phased out over a two year period, and uses in food-producing animals have been cancelled. The APVMA has advised that residues are expected to be well below the limit of quantification (LOQ), essentially zero residues. Since a dietary risk assessment accompanied the approval of dimetridazole at the time of registration, incorporating MRLs in the Code at the LOQ does not warrant conducting another dietary exposure assessment. FSANZ considers that the Application raises no safety concerns from a dietary exposure or microbiological perspective.

The proposed MRLs are at the LOQ and are indicated by an * in front of each MRL. 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. MRLs at the LOQ mean 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.

The proposed MRLs are temporary and are indicated by a 'T' in front of the MRL. The APVMA has advised that it anticipates notifying FSANZ in December 2009 to remove all dimetridazole MRLs from the Code.

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. 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 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.

1. Background

1.1 Current Standard

Currently there are dimetridazole MRLs in the Code for pig meat and offal and poultry meat and offal and not for eggs. These MRLs are at the level of *0.005 mg/kg and are indicated as being at the LOQ. The APVMA has undertaken a review of registrations and label approvals for products containing dimetridazole associated with the MRLs in this Application, and made amendments to the APVMA MRL Standard accordingly. Consequently there are discrepancies between the MRL Standard and the MRLs in Standard 1.4.2 of the Code.

The APVMA has established temporary MRLs for pig meat and offal and poultry meat and offal and eggs at the level of T*0.0001 mg/kg. The then Pesticides and Agricultural Chemicals Standing Committee of the National Health and Medical Research Council (NHMRC) did not establish an MRL for eggs when residues of dimetridazole in poultry commodities were considered previously as it was assumed that eggs from breeder birds would not be made available for human consumption. In conducting the review, the APVMA has taken into account that such eggs may be sold or processed for human consumption. The APVMA has selected the most sensitive available analytical method in establishing the temporary MRLs with a view of aiming for zero residues. The LOQ of this method is lower than the LOQ of the regulatory analytical method selected when the current dimetridazole MRLs were established.

1.2 Use of Agricultural and Veterinary Chemicals

In Australia, the APVMA is responsible for assessing and registering agricultural and veterinary chemical products, and regulating them up to the point of sale. Following the sale of such products, the use of the chemicals is regulated by State and Territory 'control of use' legislation.

Before registering a product, the APVMA independently evaluates its safety and performance, making sure that the health and safety of people, animals and the environment are protected. This evaluation includes a dietary exposure assessment where appropriate. When a chemical product is registered for use or a permit for use approved, the APVMA includes MRLs in the MRL Standard.

MRLs assist States and Territories in regulating the use of agricultural and veterinary chemicals.

The APVMA has advised that all dimetridazole uses in food-producing animals have been cancelled and new instructions on product handling and use have been issued in relation to treatment of breeder chickens, breeder turkeys and breeder pigs and the withholding period has been extended from 5 to 28 days. Dimetridazole has been registered for use in the treatment and control of swine dysentery in pigs, blackhead in poultry and game birds and canker in pigeons and caged birds.

1.3 Maximum Residue Limit Applications

After registering or reviewing agricultural or veterinary chemical products, based on scientific evaluations, the APVMA notifies FSANZ to incorporate the MRL variations in Standard 1.4.2.

FSANZ reviews information provided by the APVMA and validates whether the estimated dietary exposure is within appropriate safety limits. If satisfied that the residues are within safety limits and subject to adequate resolution of any issues raised during public consultation, FSANZ will agree to incorporate the proposed MRLs in Standard 1.4.2.

FSANZ notifies the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) when variations to the Code are approved. If the Ministerial Council does not request a review of the draft variations to Standard 1.4.2, the MRLs are automatically adopted by reference into the food laws of the Australian States and Territories.

1.4 Australia and New Zealand Joint Food Standards

The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty), excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

The Trans Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand commenced on 1 May 1998. The following provisions apply under the TTMRA.

- Food produced or imported into Australia that complies with Standard 1.4.2 of the Code can be legally sold in New Zealand.
- Food produced or imported into New Zealand that complies with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards, 2008 (and amendments) can be legally sold in Australia.

New Zealand MRLs are discussed further in section 9.2 of this report.

1.5 Proposed Variations to Standard 1.4.2 - Maximum Residue Limits

The variations under consideration in Application A612 are incorporating dimetridazole MRLs for the required animal commodities at the equivalent of the current LOQ and amending the residue definition to include the hydroxy metabolite of the parent compound. The requested changes are outlined in the table below and the draft variations to the Code are at **Attachment 1**.

In considering the issues associated with MRLs it should be noted that MRLs and variations to MRLs in the Code do not permit or prohibit the use of agricultural and veterinary chemicals. Other Australian Government, State and Territory legislation regulates use and control of agricultural and veterinary chemicals.

Requested MRLs	Dietary Exposure Estimates																							
<p>Dimetridazole</p> <p>Dimetridazole is a 5-nitroimidazole antibiotic. The antimicrobial activity of 5-nitroimidazole compounds is associated with metabolic reduction of the nitro group during microbial metabolism. This produces reactive metabolites that interact with DNA, leading to subsequent inhibition of nucleic acid and protein synthesis. Dimetridazole has been registered for the treatment and prevention of blackhead (caused by <i>Histomonas meleagridis</i>) in game birds, poultry and other caged birds; the treatment and prevention of swine dysentery (caused by <i>Brachyspira hyodysenteriae</i>) in pigs; and treatment of canker (caused by <i>Trichomonas gallinae</i>) in pigeons and caged birds. 5-nitroimidazoles are used in human therapeutics in Australia, generally for the treatment and prevention of protozoal infections. There are alternative chemical treatments available for this purpose. All uses in food-producing animals have been cancelled. After the two year phase out period for use of dimetridazole, the temporary MRLs are to be omitted from the Code. The APVMA has issued new instructions on product handling and use in relation to treatment of breeder chickens, breeder turkeys and breeder pigs and the withholding period has been extended from 5 to 28 days. An MRL was not previously established for eggs as it was assumed that eggs from breeder birds would not be made available for human consumption. The APVMA has taken into account that such eggs may be sold or processed for human consumption. The recommended temporary MRLs are at the LOQ. The recommended MRL variations are a result of the APVMA review of dimetridazole. The final review report and regulatory decision on the reconsideration of registrations of products containing dimetridazole and their associated approved labels is available on the APVMA website at: http://www.apvma.gov.au/chemrev/dimetridazole.shtml</p> <p>Amendment to residue definition</p> <p>Omit: Dimetridazole</p> <p>Substitute: Sum of dimetridazole and its hydroxy metabolite (2-hydroxymethyl-1-methyl-5-nitroimidazole), expressed as dimetridazole</p> <table border="0" data-bbox="199 1668 981 1966"> <tr> <td>Eggs</td> <td>Insert</td> <td>T*0.0001</td> </tr> <tr> <td rowspan="2">Pig meat</td> <td>Omit</td> <td>*0.005</td> </tr> <tr> <td>Substitute</td> <td>T*0.0001</td> </tr> <tr> <td rowspan="2">Pig, edible offal of</td> <td>Omit</td> <td>*0.005</td> </tr> <tr> <td>Substitute</td> <td>T*0.0001</td> </tr> <tr> <td rowspan="2">Poultry meat</td> <td>Omit</td> <td>*0.005</td> </tr> <tr> <td>Substitute</td> <td>T*0.0001</td> </tr> <tr> <td rowspan="2">Poultry, edible offal of</td> <td>Omit</td> <td>*0.005</td> </tr> <tr> <td>Substitute</td> <td>T*0.0001</td> </tr> </table>	Eggs	Insert	T*0.0001	Pig meat	Omit	*0.005	Substitute	T*0.0001	Pig, edible offal of	Omit	*0.005	Substitute	T*0.0001	Poultry meat	Omit	*0.005	Substitute	T*0.0001	Poultry, edible offal of	Omit	*0.005	Substitute	T*0.0001	<p>Dietary exposure assessment not required. A dietary risk assessment accompanied the approval of dimetridazole at the time of registration, the recommended MRLs are at a lower LOQ and detectable residues should not occur.</p>
Eggs	Insert	T*0.0001																						
Pig meat	Omit	*0.005																						
	Substitute	T*0.0001																						
Pig, edible offal of	Omit	*0.005																						
	Substitute	T*0.0001																						
Poultry meat	Omit	*0.005																						
	Substitute	T*0.0001																						
Poultry, edible offal of	Omit	*0.005																						
	Substitute	T*0.0001																						

1.6 Antimicrobial Resistance

Dimetridazole is a nitroimidazole antibiotic; it is a derivative of 5-nitroimidazole. Products containing dimetridazole have been approved for use in animals to treat and prevent diseases caused by certain infectious organisms. Products can be applied as in-feed medication and/or by addition to drinking water. Dimetridazole has been approved for treatment and prevention of blackhead in game birds, poultry and other caged birds and treatment of canker in pigeons and caged birds. Blackhead is caused by a protozoan species, *Histomonas meleagridis*. Canker is caused by another protozoan species, *Trichomonas gallinae*. Dimetridazole has also been approved for treatment and prevention of swine dysentery in pigs. This condition is caused by the bacterial species, *Brachyspira hyodysenteriae*. Dimetridazole is no longer used in food-producing animals and is not used in human therapeutics in Australia. Other nitroimidazoles are used as both prophylactic and therapeutic agents in human medicine.

With reference to the Expert Advisory Group on Antimicrobial Resistance (EAGAR), the NHMRC provides advice to government and regulatory agencies on antimicrobial resistance and measures to reduce the risks of antimicrobial resistance. In the EAGAR Importance Ratings and Summary of Antibiotic Uses in Humans in Australia, the nitroimidazoles metronidazole and tinidazole are classified as antibiotics of medium importance. This indicates that there are alternative agents available to treat bacterial infections, but fewer than for those classified as of low importance. Metronidazole and tinidazole are major agents for treatment and prevention of anaerobic infections in hospitals and principal agents for treatment of giardiasis and trichomoniasis.

The NHMRC provides advice on risk assessments for new antibiotics and extensions of indications of currently registered antibiotics. The APVMA has advised that as the use of dimetridazole is being phased out, information on changes to the use pattern and MRL variations was not required to be provided to the NHMRC.

As the requested MRLs are at the equivalent of the LOQ and the APVMA has advised that dimetridazole residues in edible commodities are expected to be well below the 0.0001 mg/kg method LOQ, i.e. essentially zero residues, FSANZ has concluded that there are no anticipated antimicrobial resistance concerns arising from this Application. The proposed variations pose no adverse consequences to human health.

2. The Issue / Problem

There are discrepancies between the MRL Standard and Standard 1.4.2 of the Code. Including MRLs in the Code has the effect of allowing legally treated produce to be sold legally, where any residues do not exceed MRLs. 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. As a result of the APVMA chemical review of dimetridazole, use of the chemical is being phased out and the APVMA has recommended lower temporary dimetridazole MRLs at the LOQ. The APVMA has established these MRLs aiming for zero residues to further limit dietary exposure to dimetridazole residues.

3. Objectives

In assessing this Application FSANZ aims to ensure that approving the proposed draft variations does not present public health and safety concerns. The APVMA has already established temporary dimetridazole MRLs at the equivalent of the LOQ under its legislation, and now seeks to have the relevant amendments made in the Code.

Subsection 18(1) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) provides that the objectives (in descending order of priority) of FSANZ in developing or reviewing food regulatory measures and variations of food regulatory measures 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.

Subsection 18(2) provides that 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.

The Ministerial Council has endorsed a Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food², which has been provided to FSANZ. In consultation with stakeholders, FSANZ is exploring alternative options for regulating chemical residues in food. To ensure appropriate consultation, this process will take some time to complete.

For the reasons set out in this Report, the proposed draft variations to Standard 1.4.2 are consistent with the FSANZ Act section 18 objectives of food regulatory measures, including the Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food.

2

[http://www.health.gov.au/internet/wcms/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/\\$File/pol-g-line-reg-res.pdf](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/$File/pol-g-line-reg-res.pdf) accessed 1 April 2008.

4. Assessment Approach

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 present public health and safety concerns.

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

As noted above, Application A612 seeks to incorporate temporary dimetridazole MRLs at the equivalent of the LOQ for pig meat and offal, poultry meat and offal and eggs in Standard 1.4.2 to support the phase out of all dimetridazole products in line with the recommendations of the APVMA chemical review. A dietary risk assessment accompanied the approval of dimetridazole at the time of registration, and as the recommended MRLs are at the LOQ, conducting another dietary exposure assessment is not required in this case.

RISK ASSESSMENT

5. Safety Assessment

The variations under consideration in Application A612 are incorporating MRLs for the required animal commodities at the equivalent of the LOQ and amending the residue definition to support this and facilitate the phase out of all dimetridazole products in line with the recommendations of the APVMA chemical review. Based on available residues decline data for pigs and poultry, the concentrations of dimetridazole residues (dimetridazole and its hydroxy metabolite) in edible commodities are expected to be well below the 0.0001 mg/kg method LOQ. The APVMA has selected the most sensitive available analytical method in establishing the MRLs and extended the withholding period from 5 to 28 days aiming for zero residues. Detectable residues should not occur. FSANZ considers that the Application raises no safety concerns from a dietary exposure or microbiological perspective.

RISK MANAGEMENT

6. Options

6.1 Option 1 – no change to existing dimetridazole MRLs in Standard 1.4.2

Under this option, there would be no changes to existing dimetridazole MRLs or the residue definition in the Code.

6.2 Option 2 – vary Standard 1.4.2 to incorporate temporary dimetridazole MRLs and amend the residue definition as proposed

Under this option, the current dimetridazole entries would be deleted and the proposed temporary dimetridazole MRLs and amended residue definition would be approved for inclusion in the Code.

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 proposed changes, and the potential impacts of any regulatory or non-regulatory provisions. Information from public submissions is needed to make a Final Assessment of the proposed change.

7.1 Affected Parties

The parties affected by proposed MRL amendments include:

- consumers;
- growers and producers of domestic and export food commodities;
- importers of agricultural produce and foods; 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.

7.2 Benefit Cost Analysis

7.2.1 *Option 1 – no change to existing dimetridazole MRLs in Standard 1.4.2*

No benefits to industry, consumers or government regulators have been identified.

For producers of domestic and export food commodities and Australian Government, State and Territory agencies, discrepancies between agricultural and food standards may create uncertainty, inefficiency and confusion.

7.2.2 *Option 2 – vary Standard 1.4.2 to incorporate temporary dimetridazole MRLs and amend the residue definition as proposed*

FSANZ has not identified any health or safety concerns in relation to incorporating temporary dimetridazole MRLs at the level of T*0.0001 for pig meat and offal and poultry meat, offal and eggs in the Code. FSANZ does not consider there to be any dietary exposure or microbiological implications associated with the proposed approval. Incorporating the MRLs in the Code as proposed in line with the recommendations of the APVMA chemical review will support the phase out of use of this chemical and contribute to maintaining consumer confidence in the food supply in relation to residues of agricultural and veterinary chemicals. No additional costs to consumers have been identified.

Consistency between agricultural and food standards potentially minimises compliance costs for producers of domestic and export food products. Amendments to the label instructions for products containing dimetridazole came into effect from 3 July 2007. For producers, this option is unlikely to result in any costs as changes in use patterns are made as required, proper use resulting in compliance with proposed MRLs already.

For importers, removing the discrepancy between agricultural and food standards would promote certainty and move toward consistency with international food standards. The existing MRLs were set at the then current LOQ indicating that no detectable residues of the chemical should occur. The proposed MRLs represent a lowering of the LOQ as more sensitive methods of analysis are now available. It is unlikely that progressing this option would result in costs for importers as dimetridazole has been widely withdrawn from use in food-producing animals internationally.

For Australian Government, State and Territory agencies, this option would foster community confidence that regulatory authorities are maintaining standards to minimise residues in the food supply and removing the discrepancy between agricultural and food standards would create certainty and allow efficient enforcement of regulations. The proposed variations are unlikely to result in a significant additional cost burden, although there would need to be an awareness of changes in the standards for residues in food and there may be minimal impacts associated with slight changes to residue monitoring programs.

7.3 Comparison of Options

In assessing MRL applications, FSANZ considers the impact of various options on all sectors of the community, including consumers, food industries and governments in Australia. For Application A612, there are no options other than varying Standard 1.4.2.

FSANZ recommends approving option 2 – to vary Standard 1.4.2 to incorporate temporary dimetridazole MRLs and amend the residue definition as proposed for the following reasons:

- FSANZ has not identified any public health or safety concerns associated with the proposed MRL amendments (this benefit also applies to option 1).
- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.
- The proposed change would update the Code by removing discrepancies between agricultural and food standards assisting compliance agencies.

The proposed draft variations would remove discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory compliance agencies. The benefits of progressing option 2 outweigh any associated costs.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

Applications by the APVMA to amend MRLs in the Code do not normally generate public interest. FSANZ adopts a basic communication strategy, with a focus on alerting the community that a change to the Code is being contemplated.

FSANZ publishes the details of the Application and subsequent assessment reports on its website, notifies the community of the period of public consultation through newspaper advertisements, and issues media releases drawing attention to proposed Code amendments. Once the Code has been amended, FSANZ incorporates the changes in the website version of the Code and, through its email and telephone information service, responds to industry enquiries.

Should the media show an interest in the assessment, FSANZ or the APVMA can provide background information and other advice, as required.

9. Consultation

FSANZ decided, pursuant to section 36 of the FSANZ Act (as was in force prior to 1 July 2007), not to invite public submissions in relation to Application A612 prior to making a Draft Assessment. FSANZ made this decision under section 36 because it was satisfied that Application A612 raised issues of minor significance or complexity only. Section 63 of the FSANZ Act (as was in force prior to 1 July 2007) provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for review of the decision to omit to invite public submissions prior to making a Draft Assessment, may be made to the Administrative Appeals Tribunal.

Public comment was sought on any cost/benefit impacts of the proposed deletions of specific MRLs; any public health and safety considerations; and any other affected parties to this Application.

Submissions were received from the Food Technology Association of Australia Inc. (FTAA), the Country Women's Association of NSW, the Australian Food and Grocery Council (AFGC), the NSW Food Authority and the Queensland Government. Submissions received are summarised at **Attachment 3**.

Submissions from the FTAA, AFGC and NSW Food Authority support approving the proposed draft variations.

9.1 Summarised submission from the Food Technology Association of Australia Inc.

The FTAA supports varying Standard 1.4.2 to incorporate temporary MRLs for dimetridazole and amend the residue definition as proposed.

9.2 Summarised submission from the Country Women's Association of NSW

The CWA notes that in view of concerns regarding antibiotic resistance, the CWA would only support the Application on the grounds that rigorous independent scientific testing has already been carried out to prove there are no health or safety concerns.

9.2.1 FSANZ Evaluation

FSANZ's decision in relation to approving the proposed draft variations is based on ensuring that there are no health and safety concerns and that the Code is maintained with current MRLs.

The risk of development of antibiotic resistance and issues in relation to the effectiveness of antibiotics in human therapeutics are important considerations in registration decisions for antibiotics for use in food producing animals. In Australia dimetridazole is no longer permitted for use in food producing animals and is not used in human medicine.

The APVMA reviewed scientific studies including toxicology, residue, animal transfer, processing and metabolism studies in relation to the dimetridazole MRL variations proposed through this Application. The Office of Chemical Safety (OCS) undertook a toxicological evaluation of dimetridazole as part of the APVMA reconsideration of registrations of products containing dimetridazole and their associated approved labels. The OCS and the APVMA data requirements include stringent criteria concerning rigor and independence of studies evaluated in their assessments.

In assessing the public health and safety implications of chemical residues in food, FSANZ considers the dietary exposure from potentially treated foods. The MRLs under consideration in this Application are at a level equivalent of the limit of analytical quantification. This means that the APVMA has established the MRLs at the lowest concentration that can be reliably identified and measured in the required foods and that detectable dimetridazole residues should not occur in food. The data indicate that for pigs and poultry, the concentrations of dimetridazole residues (dimetridazole and its hydroxy metabolite) in edible commodities are expected to be well below the limit of analytical quantification. The APVMA has selected the most sensitive available analytical method in establishing the MRLs and instituted long withholding periods aiming for zero residues.

Based on the data provided and the findings of the APVMA chemical review of dimetridazole, FSANZ has concluded that there are no anticipated antimicrobial resistance concerns or other adverse consequences to human health arising from this Application.

9.3 Summarised submission from the Australian Food and Grocery Council

The AFGC supports varying Standard 1.4.2 to incorporate temporary dimetridazole MRLs and amend the residue definition as proposed in line with the recommendations of the APVMA chemical review.

The AFGC notes that safety concerns about the unnecessary use of antibiotics, in particular the development of antibiotic resistance, have led to the restricted use of antibiotics in the food supply. The AFGC supports the responsible use of veterinary chemicals.

The AFGC notes that Australia imports significant quantities of pork and that Canada is a major source. The submission states that the Canadian Government has deleted dimetridazole from its Compendium of Medicating Ingredients Brochures effective 2004. The submission cites the Canadian report on 'Pesticides, Agricultural Chemicals, Veterinary Drugs, Environmental Pollutants and Other Impurities in Agri-Food Commodities of Animal Origin for 2004 – 2005' noting that that ninety six pork muscle meat samples were analysed for the presence of dimetridazole and none was detected. The AFGC considers that the importation of pork from Canada is unlikely to be affected by the proposed variations.

The AFGC does not consider that concentrations of dimetridazole residues in edible commodities would exceed the 0.0001 mg/kg method LOQ.

9.4 Summarised submission from the NSW Food Authority

The NSW Food Authority supports progression of this Application.

The Authority notes that the proposed variations do not present any public health or safety concerns and that the Application seeks to reduce the limit of dimetridazole residues in pig and poultry products to allow the sale of animal products treated with this antibiotic where extensive withholding periods are required following treatment. The Authority is satisfied that consultation with EAGAR has not occurred as the MRLs are reductions. The Authority notes that the dimetridazole MRLs will be reviewed in conjunction with the planned phase out of dimetridazole.

9.5 Summarised submission from the Queensland Government

The Queensland Government does not support the Application.

The submission questions whether the proposed MRLs are protective of the consumer and the rationale for not conducting a dietary risk assessment. The submission contends that a dietary exposure assessment was not conducted because there is no ADI for dimetridazole. The previous ADI was withdrawn in 2003. The submission states that such compounds should be kept out of the food chain and that allowing use on food-producing animals and setting MRLs is probably not protective of the consumer. The submission recommends cancelling all uses of dimetridazole that might produce residues, including non-detectable residues, in food and varying MRLs by the normal procedure once uses are cancelled.

9.5.1 FSANZ Evaluation

The APVMA has introduced a controlled phase out of dimetridazole taking into account standard regulatory practice that recognises that there are supplies of products containing dimetridazole that have been purchased legitimately and in good faith. The scope of use of dimetridazole has been reduced and the withholding period extended to effectively remove dimetridazole residues from the diet of consumers. The APVMA has advised that these measures will protect the consumer and during the phase out of dimetridazole.

The APVMA advised that there are no expected residues in edible commodities following the permitted uses after observance of the withholding period. The withholding period was established to allow greater than twenty half lives of dimetridazole in tissues to elapse and reduce residues from concentrations of parts per 10^6 to parts per 10^{12} . This effectively allows residues to decline to zero and avoids exposure of consumers to dimetridazole during the phase out period of registered or approved products. The safety of the consumer is assured by the long withholding period.

In summary, FSANZ considers that progressing the Application supports the APVMA phase out of dimetridazole which is expected to be finalised in December 2009. The recommended MRLs are consistent with the reduction of residues of dimetridazole in food. FSANZ has not conducted a dietary exposure assessment because the recommended MRLs are at the current lower LOQ and residues are not expected to occur in food. On the basis that the changes to dimetridazole use will effectively eliminate residues in food, FSANZ considers the recommended MRLs do not raise any public health or safety concerns.

A number of other issues were raised in the submission concerning the APVMA chemical review of dimetridazole and use of chemical products containing dimetridazole. These matters are beyond the scope of this Application and FSANZ's role in the agricultural and veterinary chemical regulatory framework. FSANZ provided the submission to the APVMA so that the APVMA can consider the concerns raised by Biosecurity Queensland.

9.6 World Trade Organization (WTO)

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 the relevant MRL set out in the Code cannot legally be supplied in Australia.

Application A612 requested incorporating temporary MRLs for dimetridazole for pig meat and offal, poultry meat and offal and eggs at the current lower LOQ of *0.0001 mg/kg. Codex Alimentarius Commission (Codex) standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. There are no dimetridazole MRLs in the international Codex standard.

Dimetridazole residues may have an effect on trade in food products between WTO members. The existing MRLs in the Code for dimetridazole were set at the then current LOQ of *0.005 mg/kg. Incorporating MRLs in the Code at the lower level would prohibit the sale of treated food products with detectable residues. Dimetridazole is not authorised for use in veterinary medicine or approved as a feed additive in the European Union. Use of dimetridazole in food-producing animals is not permitted in Canada or the United States. It is considered unlikely that the proposed variations will have an effect on trade as dimetridazole has been withdrawn from use in food-producing animals in several countries. For these reasons it was determined that there was no need to notify this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures.

9.7 New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008

All imported and domestically produced food sold in New Zealand (except for food imported from Australia) must comply with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2008 and amendments (the New Zealand MRL Standards).

Under the New Zealand MRL Standards, agricultural chemical residues in food must comply with the specific MRLs listed in the Standards. The New Zealand MRL Standards also include a provision for residues of up to 0.1 mg/kg for agricultural chemical / commodity combinations not specifically listed or, if the food is imported, it may comply with Codex MRLs. Further information about the New Zealand MRL Standards is available on the New Zealand Food Safety Authority (NZFSA) website at <http://www.nzfsa.govt.nz/acvm/registers-lists/nz-mrl/index.htm>.

MRLs in the Code and in the New Zealand MRL Standards may differ for a number of legitimate reasons including differing use patterns for chemical products as a result of varying pest and disease pressures and varying climatic conditions.

The Agricultural Compounds and Veterinary Medicines (ACVM) Group of the NZFSA has included dimetridazole on a list of substances prohibited from use in food-producing animals by some trading partners. The ACVM Group will no longer approve the registration of products containing dimetridazole with label claims for use in cattle, deer, goats, sheep, llamas, ostriches, emus or fish unless tagging or tracking programs are instituted.

The following table lists the proposed variations to MRLs in Application A612 and includes the corresponding MRL in the New Zealand MRL Standards. Notwithstanding the provision for residues of up to 0.1 mg/kg in the New Zealand MRL Standards, New Zealand has established an MRL of 0.1 mg/kg for dimetridazole in pig meat.

Chemical Food	Proposed MRL mg/kg	NZ MRL mg/kg
Dimetridazole Pig meat	T*0.0001	0.1

9.8 Imported Foods

Internationally, countries set MRLs according to good agricultural practice (GAP) or good veterinary practice (GVP). Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because product use patterns differ. This means that residues in imported foods may be different from those in domestically produced foods.

Deletions or reductions of MRLs may impact imported foods that may comply with existing MRLs even though these existing MRLs are no longer required for domestically produced food. This is because imported foods may contain residues consistent with the MRLs proposed for deletion or reduction.

It is considered unlikely that the proposed variations will have an effect on trade as dimetridazole has been widely withdrawn from use in food-producing animals internationally and MRLs varied accordingly.

The requested changes are outlined in section 1.5 of this report and the draft variations to the Code are at **Attachment 1**.

CONCLUSION

10. Conclusion and Decision

This Application has been assessed against the considerations provided for in the FSANZ Act. FSANZ approves the draft variations to Standard 1.4.2. – Maximum Residue Limits.

The recommendation is to adopt option 2 to vary Schedule 1 of Standard 1.4.2 as proposed.

Decision

FSANZ has made an assessment and approves the draft variations to Standard 1.4.2 – Maximum Residue Limits to incorporate temporary dimetridazole MRLs for pig and poultry commodities and eggs at the LOQ.

10.1 Reasons for Decision

FSANZ approves the draft variations to Standard 1.4.2 for the following reasons:

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- The proposed variations will benefit stakeholders by maintaining public health and safety. Incorporating the proposed temporary dimetridazole MRLs at the LOQ in the Code poses no adverse consequences to human health.
- The proposed variations would update the Code in line with the recommendations of the APVMA chemical review of dimetridazole.
- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary and cost-effective.
- The proposed draft variations would remove discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory compliance agencies.
- The proposed changes are consistent with the FSANZ Act section 18 objectives.

11. Implementation and Review

The APVMA anticipates notifying FSANZ to omit the temporary dimetridazole MRLs from the Code after the two year phase out period for the use of this chemical.

The use of chemical products and MRLs are under constant review as part of the APVMA Chemical Review Program. In addition, regulatory agencies continue to monitor health, agricultural and environmental issues associated with chemical product use. 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 studies such as the Australian Total Diet Study.

These monitoring programs and the continual review of the use of agricultural and veterinary chemicals mean that there is considerable scope to review MRLs.

It is proposed that the MRL amendments in this Application should take effect on gazettal and that the MRLs be subject to existing monitoring arrangements.

ATTACHMENTS

1. Draft Variations to the *Australia New Zealand Food Standards Code*
2. Summary of Submissions

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

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act 2003 and are not subject to disallowance or sunseting.

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 the chemical residue definition for the chemical appearing in Column 1 of the Table to this sub-item, substituting the chemical residue definition appearing in Column 2 –*

COLUMN 1	COLUMN 2
DIMETRIDAZOLE	SUM OF DIMETRIDAZOLE AND ITS HYDROXY METABOLITE (2-HYDROXYMETHYL-1-METHYL-5-NITROIMIDAZOLE), EXPRESSED AS DIMETRIDAZOLE

[1.2] *inserting in alphabetical order in Schedule 1, the food and associated MRL for the following chemical –*

DIMETRIDAZOLE	
SUM OF DIMETRIDAZOLE AND ITS HYDROXY METABOLITE (2-HYDROXYMETHYL-1-METHYL-5-NITROIMIDAZOLE), EXPRESSED AS DIMETRIDAZOLE	
EGGS	T*0.0001

[1.3] *omitting from Schedule 1, under the entry for the following chemical, the maximum residue limit for the food, substituting –*

DIMETRIDAZOLE	
SUM OF DIMETRIDAZOLE AND ITS HYDROXY METABOLITE (2-HYDROXYMETHYL-1-METHYL-5-NITROIMIDAZOLE), EXPRESSED AS DIMETRIDAZOLE	
PIG, EDIBLE OFFAL OF	T*0.0001
PIG MEAT	T*0.0001
POULTRY, EDIBLE OFFAL OF	T*0.0001
POULTRY MEAT	T*0.0001

Summary of Submissions

Submitter	Comments
Food Technology Association of Australia Inc.	Supported this Application.
Country Women's Association of New South Wales	Notes that in view of concerns regarding antibiotic resistance, the CWA would only support the Application on the grounds that rigorous independent scientific testing has already been carried out to prove there are no health or safety concerns.
Australian Food and Grocery Council	Supported this Application. The AFGC notes that safety concerns about the unnecessary use of antibiotics, in particular the development of antibiotic resistance, have led to the restricted use of antibiotics in the food supply. The AFGC supports the responsible use of veterinary chemicals. The AFGC notes that Australia imports significant quantities of pork and that Canada is a major source. The AFGC considers that the importation of pork from Canada is unlikely to be affected by the proposed variations. The AFGC does not consider that concentrations of dimetridazole residues in food would exceed the method LOQ.
New South Wales Food Authority	Supported this Application. The Authority notes that the proposed variations do not present any public health or safety concerns and that the Application seeks to reduce the limit of dimetridazole residues in pig and poultry products to allow the sale of animal products treated with this antibiotic where extensive withholding periods are required following treatment. The Authority is satisfied that consultation with EAGAR has not occurred as the MRLs are reductions. The Authority notes that the dimetridazole MRLs will be reviewed in conjunction with the planned phase out of dimetridazole.
Queensland Government	Did not support the Application. QLD questions whether the proposed MRLs are protective of the consumer and the rationale for not conducting a dietary risk assessment. The submission contends that a dietary exposure assessment was not conducted because there is no ADI for dimetridazole. The submission states that such compounds should be kept out of the food chain and that allowing use on food-producing animals and setting MRLs is probably not protective of the consumer. The submission recommends cancelling all uses of dimetridazole and then varying the MRLs.