



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

**12 December 2007**  
**[8-07]**

## **INITIAL/DRAFT ASSESSMENT REPORT**

### **APPLICATION A612**

### **MAXIMUM RESIDUE LIMITS – DIMETRIDAZOLE (ANTIBIOTIC)**

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 February 2008**  
**SUBMISSIONS RECEIVED AFTER THIS DEADLINE**  
**WILL NOT BE CONSIDERED**

*(See 'Invitation for Public Submissions' for details)*

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 eggs<sup>1</sup> 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 notifying Food Standards Australia New Zealand (FSANZ) to 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 Expert Advisory Group on Antimicrobial Resistance (EAGAR) 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 EAGAR.

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 the required commodities for the antibiotic dimetridazole. This will protect public health and safety by further minimising dimetridazole residues in foods and remove discrepancies between agricultural and food standards.

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<sup>1</sup> 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.

## **Preferred Approach**

FSANZ recommends accepting Application A612 and the proposed 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 Preferred Approach**

This Application has been assessed against the requirements for Initial and Draft Assessments in sections 13 and 15 respectively, of the FSANZ Act. FSANZ recommends accepting this Application and the proposed 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.

## **Consultation**

FSANZ decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), not to invite public submissions in relation to Application A612 prior to making a Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only.

FSANZ is seeking public comment on this Initial / Draft Assessment Report to assist in assessing the Application. Comments on, but not limited to, any impacts (costs/benefits) of the proposed variations, in particular the likely impacts on importation of food if the variations are advanced; any public health and safety considerations associated with the proposed MRLs; and any other affected parties to this Application would be useful.

Further details on making submissions are provided in the Invitation for Public Submissions section of this Report.

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## **INVITATION FOR PUBLIC SUBMISSIONS**

FSANZ invites public comment on this Initial / Draft Assessment Report based on regulation impact principles and the draft variations 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 the Final Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 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 confidential commercial information. Section 114 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](http://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](http://www.foodstandards.govt.nz)**

**Submissions need to be received by FSANZ by 6pm (Canberra time) 6 February 2007.**

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 [standards.management@foodstandards.gov.au](mailto:standards.management@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](mailto:info@foodstandards.gov.au).

## **INTRODUCTION**

A notification was received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 20 August 2007 seeking to vary the Code. The proposed variations to Standard 1.4.2 – Maximum Residue Limits would align maximum residue limits (MRLs) 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 its MRL Standard accordingly. 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 (NH&MRC) 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. Consequently there are discrepancies between the MRL Standard and the MRLs in Standard 1.4.2 of the Code.

### **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 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 of the Code.

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, 2007 (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><b>Dimetridazole</b>            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: <a href="http://www.apvma.gov.au/chemrev/dimetridazole.shtml">http://www.apvma.gov.au/chemrev/dimetridazole.shtml</a></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 1964"> <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																						
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	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.

The NH&MRC established the Expert Advisory Group on Antimicrobial Resistance (EAGAR) to provide 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.

EAGAR 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 EAGAR.

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. 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.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act:

- 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.

The Ministerial Council has endorsed a Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food<sup>2</sup>, 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.

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.

### **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.

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[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 27 September 2007.

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:

- domestic and international 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 discernable 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 advice 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, to omit inviting public submissions in relation to Application A612 prior to making a Draft Assessment. However, FSANZ invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to submissions received.

FSANZ made its 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 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.

FSANZ is seeking public comment on this Initial / Draft Assessment Report to assist in assessing the Application. Comments on, but not limited to, any impacts (costs/benefits) of the proposed variations, in particular the likely impacts on importation of food if the variations are advanced; any public health and safety considerations associated with the proposed MRLs; and any other affected parties to this Application would be useful.

### **9.1 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 requests 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 is 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.

## 9.2 New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

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 2007 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

## 9.3 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 Preferred Approach**

This Application has been assessed against the requirements for Initial and Draft Assessments in sections 13 and 15 respectively, of the FSANZ Act. FSANZ recommends accepting this Application and approving the proposed draft variations to Standard 1.4.2. – Maximum Residue Limits.

The preferred approach is to adopt option 2 to vary MRLs in Schedule 1 of Standard 1.4.2 as proposed.

#### **Preferred Approach:**

FSANZ recommends accepting Application A612 and the proposed 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 Preferred Approach**

FSANZ recommends accepting this Application and the proposed 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 use of chemical products and MRLs are under constant review as part of the APVMA Existing 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*

**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