

**6 August 2008**  
**[13-08]**

## **PROPOSAL M1002**

### **Maximum Residue Limits (January, February, March 2008)**

### **ASSESSMENT REPORT**

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#### **Executive Summary**

##### **Purpose**

The purpose of this Proposal is to consider incorporating maximum residue limits (MRLs) for agricultural and veterinary chemicals that may legitimately occur in food in Standard 1.4.2 of the *Australia New Zealand Food Standards Code* (the Code). This includes MRLs gazetted by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in January, February and March 2008. This will permit the sale of treated foods and protect public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

Food Standards Australia New Zealand's (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.

Dietary exposure assessments indicate that in relation to current reference health standards, setting the MRLs as proposed does not present any public health and safety concerns. This Proposal includes consideration of an MRL for the antibiotic florfenicol in fish. The proposed MRL does not pose a risk in terms of antimicrobial resistance.

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.

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

Submissions are now invited on this Report to assist FSANZ make an assessment.

This Proposal is being assessed under the General Procedure.

### **Assessing the Proposal**

In assessing the Proposal, FSANZ has had regard to the section 18 objectives and the following matters as prescribed in section 59 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure;
- whether other measures would be more cost-effective than a variation to a food regulatory measure;
- any relevant New Zealand standards; and
- any other relevant matters.

### **Preferred Approach**

FSANZ recommends approving the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits. The residues associated with the proposed MRL variations do not present any public health and safety concerns and the proposed draft variations are necessary, cost-effective and will benefit consumers, Government and industry. Approving the proposed draft variations will permit the sale of legitimately treated foods.

### **Reasons for Preferred Approach**

This Proposal has been assessed against the considerations provided for in section 59 of the FSANZ Act. FSANZ recommends approving 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.
- Dietary exposure assessments indicate that setting the MRLs as proposed does not present any public health and safety concerns.
- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.
- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in this Proposal.
- The Office of Chemical Safety (OCS) has undertaken a toxicological assessment of each chemical and has established an acceptable daily intake (ADI) and where appropriate an acute reference dose (ARfD).
- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and beneficial.
- The proposed draft variations would remove discrepancies between agricultural and food standards and provide certainty and consistency for producers, importers and Australian, State and Territory compliance agencies.
- The proposed changes are consistent with the FSANZ Act section 18 objectives.

## Consultation

FSANZ is seeking public comment on this Assessment Report to assist in assessing the Proposal. Comments would be welcome 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.

## Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles 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 further considering this Proposal. 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, separate it from your submission and provide justification for treating it as confidential commercial material. 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. 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. Alternatively, you may email your submission directly to the Standards Management Officer at [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au). There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 3 September 2008**

**SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED**

Submissions received after this date will only be considered if 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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

If you are unable to submit your submission electronically, hard copy 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**

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

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## **INTRODUCTION**

Notifications were received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 5 February, 19 February and 6 March 2008 seeking to vary the *Australia New Zealand Food Standards Code* (the Code). The proposed variations to the Australia only Standard 1.4.2 – Maximum Residue Limits would align maximum residue limits (MRLs) in the Code for certain agricultural and veterinary chemicals with the APVMA MRLs listed in The MRL Standard and permit the sale of relevant foods legitimately treated during production.

This Proposal includes consideration of MRLs for azoxystrobin, bifenazate, bifenthrin, chlorpyrifos, closantel, clothianidin, cyanamide, cyprodinil, dimethenamid-P (new chemical), florfenicol (antibiotic), fludioxonil, fluorine (inorganic salts), glyphosate, isoxaben, maldison, methomyl, metsulfuron-methyl, phosphorous acid, propiconazole, prosulfocarb, prothioconazole, pyrasulfotole, ractopamine, sulfurly fluoride (new chemical) thiamethoxam, toltrazuril and tolylfluanid.

This Proposal does not include an MRL for mancozeb in herbs gazetted by the APVMA in March 2008. Consideration of the requested MRL is ongoing. Rather than delay progressing the other requested MRLs, the mancozeb MRL has been excluded from this Proposal.

The draft variations to the Code are at **Attachment 1** and the proposed variations and dietary exposure estimates are outlined in **Attachment 2**. The safety assessment methodology is outlined in **Attachment 3**; this includes an explanation of terms used in this Report.

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 producers, importers and compliance agencies by maintaining current MRLs in the Code.

In considering the issues associated with MRLs, it should be noted that the MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. However, incorporating the MRL into food legislation means that the residues of a chemical are minimised (i.e. must not exceed the MRL), irrespective of whether the dietary exposure assessment indicates that higher residues would not risk public health and safety.

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.

## **1. The Issue / Problem**

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. Where residues do not pose health or safety concerns, MRLs are also varied in line with international standards to reflect requirements for legitimately treated foods to be imported. Internationally, farmers face different pest and disease pressures and so agricultural and veterinary chemical use patterns may vary.

## **2. Current Standard**

### **2.1 Background**

Standard 1.4.2 lists the limits for agricultural and veterinary chemical residues which may occur in foods. A dietary exposure assessment is conducted before the Standard is varied to ensure that proposed MRLs do not present any public health or safety concerns. If an MRL is not listed for a particular agricultural or veterinary chemical/commodity combination, there must be no detectable residues of that chemical in that food. This general prohibition means that in the absence of the relevant MRL in the Standard, legitimately treated produce may not be sold where there are detectable residues. Amendments to the Standard are required to permit the sale of foods legitimately treated during production.

Further background information on MRLs, the regulatory framework for agricultural and veterinary chemicals and the FSANZ assessment process for incorporating MRLs, including MRLs for antibiotic substances, in the Code is provided at **Attachment 4**.

## **3. Objectives**

In assessing this Proposal, FSANZ aims to ensure that approving the proposed draft variations does not present public health and safety concerns and that the sale of legally treated food is permitted.

Subsection 18(1) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) provides that the objectives (in descending priority order) 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.

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.

#### **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 are within reference health standards. FSANZ conducts and reviews dietary exposure assessments in accordance with internationally accepted practices and procedures.

In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from potentially treated foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will not approve MRLs for inclusion in the Code where dietary exposure to the residues of a chemical could risk public health and safety.

The steps undertaken in conducting a dietary exposure assessment are:

- determination of the residues of a chemical in a treated food; and
- calculating the dietary exposure to a chemical from relevant foods, using food consumption data from national nutrition surveys and comparing this to the acceptable reference health standard.

The estimated dietary exposure to a chemical is compared to the relevant reference health standard/s for that chemical in food (i.e. the acceptable daily intake (ADI) and/or the acute reference dose (ARfD)). FSANZ considers that dietary exposure to the residues of a chemical is acceptable where the best estimate of this exposure does not exceed the relevant standard/s.

The safety assessment methodology is further outlined in **Attachment 3**.



## **RISK ASSESSMENT**

### **5. Risk Assessment Summary**

FSANZ has reviewed the dietary exposure assessments submitted by the APVMA and conducted dietary exposure assessment on sulfur dioxide to assess the MRLs requested. Using the best available scientific data and internationally recognised risk assessment methodology, including other dietary sources of sulfur dioxide, FSANZ concluded that in relation to current reference health standards, setting the MRLs as proposed does not present any public health and safety concerns.

The additional safety factors inherent in calculation of the ADI and ARfD mean that there is negligible risk to public health and safety when estimated exposures are below these reference health standards.

The proposed MRL for antibiotic substance florfenicol does not pose a risk in terms of antimicrobial resistance.

## **RISK MANAGEMENT**

### **6. Options**

1. Option 1 – approve the draft variations
2. Option 2 – approve the draft variations subject to such amendments as the Authority considers necessary
3. Option 3 – reject the draft variations

### **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 affected parties and any alternative options consistent with the objective of the proposed changes. Information from public submissions is needed to further assess the proposed changes.

FSANZ has not identified any health or safety concerns associated with the proposed approval.

The draft variations may be amended and option 2 recommended for approval where the need is identified. For example, an MRL may be retained rather than reduced or deleted where the necessity for the MRL to continue to allow for the importation and sale of safe food is identified through consultation. Further information to assist in identifying implications for imported foods is provided in section 9 of this Report and the requested MRL variations are outlined in **Attachment 2**.

## **7.1 Affected Parties**

The parties affected by proposed MRL amendments include:

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

## **7.2 Benefit Cost Analysis**

FSANZ has conducted an Office of Best Practice Regulation Preliminary Assessment and concluded that business compliance costs and other impacts on business, individuals, regulatory agencies and the economy are low or nil. The regulatory proposal does not impose impacts on business, individuals, regulatory agencies or the economy that warrant further analysis. The changes to regulation are mechanical in nature involving technical variations to the Standard which will not have appreciable impacts and are consistent with existing policy.

## **7.3 Comparison of Options**

In assessing proposed variations to the Code, FSANZ considers the impact of various regulatory and non-regulatory options on all sectors of the community, including consumers, food industries and governments in Australia.

FSANZ recommends approving Option 1 – approve the draft variations for the following reasons:

- There are no public health and safety concerns associated with the proposed MRL variations.
- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.
- The changes would minimise potential costs to primary producers, rural and regional communities and importers in terms of permitting the sale of legitimately treated food.
- The changes would minimise residues in food consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases.
- The changes would remove discrepancies between agricultural and food standards and assist compliance agencies.

Option 2 may be recommended in the Approval Report subject to the need for any required amendments being identified through consultation or further assessment.

Option 3 is an undesirable option. Potential substantial costs to primary producers may result. Additional costs may impact negatively on their viability and in turn the viability of the rural and regional communities that depend upon the sale of agricultural produce. This option may restrict the opportunity for importers to source safe produce or foods internationally and potentially impact consumers through higher food prices and limited choice. Also, consequent discrepancies between agricultural and food legislation could have negative impacts on compliance costs for producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

The benefits of progressing Option 1 outweigh any associated costs.

## **COMMUNICATION AND CONSULTATION STRATEGY**

### **8. Communication**

FSANZ consideration of amending MRLs in the Code does 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 proposed changes 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 any of the chemicals being assessed, FSANZ or the APVMA can provide background information and other advice, as required.

### **9. Consultation**

FSANZ is seeking public comment on the proposed changes to the Code outlined in this Report to assist in finalising the assessment. Comments on, but not limited to, any impacts (costs/benefits) of the proposed variations, in particular the likely impacts on importation of food if specific 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**

As a member of the World Trade Organization (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.

This Proposal includes consideration of varying MRLs in the Code that are addressed in the international Codex standard. MRLs in the Proposal also relate to chemicals used in the production of heavily traded agricultural commodities that may indirectly have a significant effect on trade of derivative food products between WTO members.

This Proposal will be notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures as the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment.

## 9.2 Codex Alimentarius Commission MRLs

Codex standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table lists proposed MRLs where there is a corresponding MRL in the international Codex standard.

<b>Chemical</b> Food	<b>Proposed MRL</b> mg/kg	<b>Codex MRL</b> mg/kg
<b>Closantel</b>		
Cattle fat	T <sup>a</sup> 3	3
Cattle kidney	T3	3
Cattle liver	T1	1
Cattle muscle	T1	1
<b>Cyprodinil</b>		
Cucumber	T0.2	0.2
Lettuce, head	T10	10
Peppers, Sweet	T0.5	0.5
<b>Fludioxonil</b>		
Cucumber	T0.3	0.3
Lettuce, head	T10	10
Peppers, Sweet	T2	1
<b>Sulfuryl fluoride</b>		
Cereal grains	0.05	0.05
Dried fruits	0.07	0.06
Tree nuts	7	3
<b>Tolyfluanid</b>		
Cucumber	T2	1

<sup>a</sup> 'T' indicates the MRL is temporary

**FSANZ requests comment on any possible ramifications of the proposed MRLs differing from Codex Alimentarius Commission MRLs.**

### 9.3 New Zealand MRL Standards

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 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 following table lists the proposed variations to MRLs and includes the corresponding MRL in the New Zealand MRL Standards.

Chemical Food	Proposed MRL mg/kg	NZ MRL mg/kg
<b>Azoxystrobin</b> Maize	T <sup>b</sup> * <sup>c</sup> 0.01	*0.01
<b>Closantel</b> Cattle fat Cattle kidney Cattle liver Cattle muscle	T3 T3 T1 T1	3 3 1 1
<b>Clothianidin</b> Edible offal (mammalian) Meat (mammalian) Milks	*0.02 *0.02 *0.01	Mammalian kidney *0.01 Mammalian liver 0.02 *0.01 *0.01
<b>Maldison</b> Shallot Spring onion	T5 T5	Vegetables 8
<b>Prothioconazole</b> Wheat	*0.05	Cereal grains *0.02

<sup>b</sup> 'T' indicates the MRL is temporary

<sup>c</sup> '\*' indicates that the MRL is at the limit of quantification

<b>Chemical</b> Food	<b>Proposed MRL</b> mg/kg	<b>NZ MRL</b> mg/kg
<b>Toltrazuril</b>		
Cattle fat	1	0.15
Cattle kidney	1	0.25
Cattle liver	2	0.5
Cattle muscle	0.25	0.1

**FSANZ requests comment on the proposed MRLs in relation to the corresponding New Zealand MRLs.**

#### 9.4 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 legitimately 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.

FSANZ is committed to ensuring that the implications of MRL variations are considered. Under the current process for considering variations to the Code, FSANZ encourages submissions including specific data demonstrating a need for certain MRLs to be retained or varied. FSANZ will consider retaining MRLs proposed for deletion or reduction where these MRLs are necessary to continue to allow the sale of safe food; and where the MRLs are supported by adequate data or information demonstrating that the residues associated with these MRLs do not raise any public health or safety concerns. Further information on data requirements may be obtained from FSANZ.

To assist in identifying possible impacts on imported foods, FSANZ has compiled the following table of foods where the MRLs are proposed for deletion or reduction. All the proposed MRL variations to the Code are at **Attachment 1** and the requested changes are outlined in more detail in **Attachment 2**.

<b>Chemical</b> Food
<b>Fludioxonil</b> Sorghum
<b>Fluorine (inorganic salts)</b> Fruit Vegetables

<b>Chemical</b>
Food
<b>Methomyl</b>
Bergamot
Burnet, Salad
Chervil
Coriander (leaves, stem, roots)
Coriander, seed
Dill, seed
Fennel, seed
Galangal, Greater
Kaffir lime leaves
Lemon grass
Lemon verbena (dry leaves)
Mizuna
Rose and dianthus (edible flowers)
Rucola (rocket)
Turmeric, root
<b>Prothioconazole</b>
Milks
<b>Ractopamine</b>
Cattle fat
Cattle kidney
Cattle meat

**FSANZ requests comment on any possible ramifications of the proposed deletion or reduction of MRLs in this Application for imported foods.**

## **9.5 Commodity classifications for MRLs notified for veterinary chemicals**

This Proposal includes consideration of an MRL notified by the APVMA for 'Cattle muscle'. This commodity classification is consistent with the Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA) approach for determining residue limits for veterinary chemicals in food. The JECFA approach is internationally accepted as best practice for setting MRLs for veterinary chemicals.

The APVMA adopted the approach used by the JECFA for setting MRLs for veterinary chemicals in July 2006. The decision to adopt the JECFA approach followed a review of evaluation processes conducted by an external body and consultation with industry and regulatory authorities.

FSANZ and the APVMA are currently discussing implementation issues associated with incorporating JECFA commodity classifications in the Code for MRLs notified for veterinary chemicals. Commodity classifications used for veterinary and agricultural chemicals differ, reflecting the different approaches used to determine MRLs in agricultural as opposed to veterinary situations.

As an interim measure FSANZ has decided to progress the MRLs requested by the APVMA with JECFA commodity classifications. These may be varied through a future Proposal depending on the outcome of considerations and further consultation on the practical implications of including JECFA commodity classifications in the Code.

## **CONCLUSION**

### **10. Conclusion and Preferred Option**

This Proposal has been assessed against the considerations provided for in section 59 of the FSANZ Act.

The preferred approach is to adopt option 1 to approve the draft variations.

#### **Preferred Approach**

FSANZ recommends approving the proposed draft variations to Standard 1.4.2 – Maximum Residue Limits. The residues associated with the proposed MRL variations do not present any public health and safety concerns and the proposed draft variations are necessary, cost-effective and will benefit consumers, Government and industry. Approving the proposed draft variations will permit the sale of legitimately treated foods.

#### **10.1 Reasons for Preferred Approach**

FSANZ recommends approving 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.
- Dietary exposure assessments indicate that setting the MRLs as proposed does not present any public health and safety concerns.
- This approach ensures openness and transparency in relation to the residues that could reasonably occur in food.
- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.



- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of chemicals on commodities as outlined in this Proposal.
- The Office of Chemical Safety (OCS) has undertaken a toxicological assessment of each chemical and has established an acceptable daily intake (ADI) and where appropriate an acute reference dose (ARfD).
- FSANZ has undertaken a preliminary regulation impact assessment and concluded that the proposed draft variations are necessary, cost-effective and beneficial.
- The proposed draft variations would remove discrepancies between agricultural and food standards and provide certainty and consistency for producers, 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 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 variations in this Proposal 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. A Summary of MRLs under consideration in Proposal M1002
3. Safety Assessment Methodology
4. Background Information

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

*Subsection 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but 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 –*

<b>COLUMN 1</b>	<b>COLUMN 2</b>
CLOTHIANIDIN	CLOTHIANIDIN

[1.2] *inserting in Schedule 1 –*

<b>DIMETHENAMID-P</b>	
SUM OF DIMETHENAMID-P AND ITS (R)-ISOMER	
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MAIZE	*0.02
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
PEAS	*0.02
POPPY SEED	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
PULSES	*0.02
PUMPKINS	*0.02
SWEET CORN (CORN-ON-THE-COB)	*0.02
<b>SULFURYL FLUORIDE</b>	
SULFURYL FLUORIDE	
CEREAL GRAINS	0.05
DRIED FRUITS	0.07
PEANUT	7
TREE NUTS	7

[1.3] *omitting from Schedule 1 the foods and associated MRLs for each of the following chemicals –*

<b>BIFENTHRIN</b> BIFENTHRIN	
LETTUCE, HEAD	T2
<b>CLOTHIANIDIN</b> <i>COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN</i> <i>COMMODITIES OF ANIMAL ORIGIN: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'-METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN</i>	
MEAT (MAMMALIAN) (IN THE FAT)	T*0.02
<b>FLUORINE (INORGANIC SALTS)</b> FLUORIDE ION	
FRUIT	7
VEGETABLES	7
<b>GLYPHOSATE</b> SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
OILSEED [EXCEPT COTTON AND RAPE SEED]	*0.1
<b>MALDISON</b> MALDISON	
VEGETABLES [EXCEPT AS OTHERWISE LISTED UNDER THIS CHEMICAL]	2
<b>METHOMYL</b> SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL <i>SEE ALSO THIODICARB</i>	
BERGAMOT	T5
BURNET, SALAD	T5
CHERVIL	T5
CORIANDER (LEAVES, STEM, ROOTS)	T10
CORIANDER, SEED	T5
DILL, SEED	T5
FENNEL, SEED	T5
GALANGAL, GREATER	T*0.02
KAFFIR LIME LEAVES	T5
LEMON GRASS	T5
LEMON VERBENA (DRY LEAVES)	T5
MIZUNA	T5
ROSE AND DIANTHUS (EDIBLE FLOWERS)	T5
RUCOLA (ROCKET)	T5
TURMERIC, ROOT	T*0.02

<b>RACTOPAMINE</b> RACTOPAMINE	
CATTLE FAT	T*0.02
CATTLE KIDNEY	T0.1
CATTLE MEAT	T*0.02

[1.4] inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals –

<b>AZOXYSTROBIN</b> AZOXYSTROBIN	
MAIZE	T*0.01
<b>BIFENAZATE</b> SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOXYLIC ACID, 2-(4-METHOXY-[1,1'- BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
PEAS	T0.5
<b>BIFENTHRIN</b> BIFENTHRIN	
LEAFY VEGETABLES [EXCEPT CHERVIL; MIZUNA; RUCOLA (ROCKET)]	T2
<b>CLOSANTEL</b> CLOSANTEL	
CATTLE FAT	T3
CATTLE KIDNEY	T3
CATTLE LIVER	T1
CATTLE MUSCLE	T1
<b>CLOTHIANIDIN</b> COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN COMMODITIES OF ANIMAL ORIGIN: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5- YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5- YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N'- METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
<b>CYANAMIDE</b> CYANAMIDE	
APPLE	*0.02
BLUEBERRIES	*0.05
<b>CYPRODINIL</b> CYPRODINIL	
CUCUMBER	T0.2
LETTUCE, HEAD	T10
PEPPERS, SWEET	T0.5

<b>FLORFENICOL</b>	
SUM OF FLORFENICOL AND ITS METABOLITES FLORFENICOL ALCOHOL, FLORFENICOL OXAMIC ACID, MONOCHLOROFORFENICOL AND FLORFENICOL AMINE EXPRESSED AS FLORFENICOL AMINE	
FISH	T0.5
<b>FLUDIOXONIL</b>	
<i>COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL</i>	
<i>COMMODITIES OF PLANT ORIGIN: FLUDIOXONIL</i>	
CUCUMBER	T0.3
LETTUCE, HEAD	T10
PEPPERS, SWEET	T2
<b>FLUORINE (INORGANIC SALTS)</b>	
FLUORIDE ION	
DRIED FRUITS	5
PEANUT	30
TREE NUTS	30
WHEAT GERM	10
<b>GLYPHOSATE</b>	
SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
LINSEED	T5
OILSEED [EXCEPT COTTON SEED; LINSEED; RAPE SEED]	T*0.1
<b>ISOXABEN</b>	
ISOXABEN	
BARLEY	*0.01
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
TRITICALE	*0.01
WHEAT	*0.01
<b>MALDISON</b>	
MALDISON	
SHALLOT	T5
SPRING ONION	T5
VEGETABLES [EXCEPT BEANS (DRY); CAULIFLOWER; CHARD (SILVERBEET); EGG PLANT; GARDEN PEA; KALE; KOHLRABI; LENTIL (DRY); PEPPERS, SWEET; ROOT AND TUBER VEGETABLES; SHALLOT; SPRING ONION; TOMATO; TURNIP, GARDEN]	2

<b>PHOSPHOROUS ACID</b> PHOSPHOROUS ACID	
FLOWERHEAD BRASSICAS	T50
<b>PROPICONAZOLE</b> PROPICONAZOLE	
SPINACH	T0.1
<b>PROSULFOCARB</b> PROSULFOCARB	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
<b>THIAMETHOXAM</b> COMMODITIES OF PLANT ORIGIN: THIAMETHOXAM COMMODITIES OF ANIMAL ORIGIN: SUM OF THIAMETHOXAM AND N-(2-CHLORO-THIAZOL-5- YLMETHYL)-N <sup>1</sup> -METHYL-N <sup>1</sup> -NITRO-GUANIDINE, EXPRESSED AS THIAMETHOXAM	
SUGAR CANE	T*0.02
<b>TOLTRAZURIL</b> SUM OF TOLTRAZURIL, ITS SULFOXIDE AND SULFONE, EXPRESSED AS TOLTRAZURIL	
CATTLE FAT	1
CATTLE KIDNEY	1
CATTLE LIVER	2
CATTLE MUSCLE	0.25
<b>TOLYLFLUANID</b> TOLYLFLUANID	
CUCUMBER	T2

[1.5] omitting from Schedule 1, under the entries for the following chemicals, the Maximum Residue Limit for the food, substituting –

<b>CHLORPYRIFOS</b> CHLORPYRIFOS	
PARSLEY	0.05
<b>CLOTHIANIDIN</b> COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN COMMODITIES OF ANIMAL ORIGIN: SUM OF CLOTHIANIDIN, 2-CHLOROTHIAZOL-5- YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5- YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE OF N-(2-CHLOROTHIAZOL-5-YLMETHYL)-N <sup>1</sup> - METHYLGUANIDINE EXPRESSED AS CLOTHIANIDIN	
APPLE	0.5
BANANA	*0.02
COTTON SEED	*0.02
EDIBLE OFFAL (MAMMALIAN)	*0.02
MILKS	*0.01

NECTARINE	2
PEACH	2
PEAR	0.5
<b>FLUDIOXONIL</b>	
<i>COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL</i>	
<i>COMMODITIES OF PLANT ORIGIN: FLUDIOXONIL</i>	
SORGHUM	*0.01
<b>METSULFURON-METHYL</b>	
METSULFURON-METHYL	
LINSEED	*0.02
<b>PROSULFOCARB</b>	
PROSULFOCARB	
BARLEY	*0.01
WHEAT	*0.01
<b>PROTHIOCONAZOLE</b>	
<i>COMMODITIES OF PLANT ORIGIN: SUM OF PROTHIOCONAZOLE AND PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1H-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE</i>	
<i>COMMODITIES OF ANIMAL ORIGIN: SUM OF PROTHIOCONAZOLE, PROTHIOCONAZOLE DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLOROPHENYL)-3-(1H-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), PROTHIOCONAZOLE-3-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-3-HYDROXYPHENYL)-3-(1H-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL) AND PROTHIOCONAZOLE-4-HYDROXY-DESTHIO (2-(1-CHLOROCYCLOPROPYL)-1-(2-CHLORO-4-HYDROXYPHENYL)-3-(1H-1,2,4-TRIAZOL-1-YL)-PROPAN-2-OL), EXPRESSED AS PROTHIOCONAZOLE</i>	
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.01
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MILKS	*0.004
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT (IN THE FAT)	*0.05
WHEAT	*0.05
<b>PYRASULFOTOLE</b>	
SUM OF PYRASULFOTOLE AND (5-HYDROXY-3-METHYL-1H-PYRAZOL-4-YL)[2-MESYL-4-(TRIFLUOROMETHYL)PHENYL]METHANONE, EXPRESSED AS PYRASULFOTOLE	
CEREAL BRAN, UNPROCESSED	0.03
CEREAL GRAINS	*0.02
EDIBLE OFFAL (MAMMALIAN)	0.5
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01

## Attachment 2

### A summary of MRLs under consideration in Proposal M1002

A guide to the summary table is provided at **Attachment 4**

Requested MRLs		mg/kg	Dietary Exposure Estimates	
<p><b>Azoxystrobin</b> Azoxystrobin is a fungicide that acts by inhibition of mitochondrial respiration through blocking electron transfer between cytochrome B and cytochrome C<sub>1</sub> at the ubiquinol oxidising site. The APVMA has issued a permit for its use to control polysora rust (<i>Puccinia polysora</i>) in maize. The recommended MRL is at the limit of quantification (LOQ).</p>			NEDI = 4% of ADI	
Maize	Insert	T*0.01		
<p><b>Bifenazate</b> Bifenazate is a non-systemic acaricide absorbed primarily by contact. It is used to control the egg and motile stages of phytophagous mites. The APVMA has issued a permit for its use in peas to control two spotted mite (<i>Tetranychus urticae</i>), European red mite (<i>Panonychus ulmi</i>) and Bryobia mite (<i>Brobia rubrioculus</i>).</p>			NEDI = 8% of ADI	
Peas	Insert	T0.5	NESTI as % of ARfD	
			<u>2-6 years</u>	<u>2 years &amp; above</u>
			<1	<1
<p><b>Bifenthrin</b> Bifenthrin is an insecticide that acts on the nervous system through interaction with the sodium channel. The APVMA has issued a permit for its use to control quarantine pests on selected nursery stocks of culinary herbs and leafy vegetables entering Western Australia from other states. Residues of bifenthrin in leafy vegetables are expected to be significantly less than the MRLs as it will be 8 – 10 weeks between treatment and harvest for human consumption.</p>			NEDI = 75% of ADI	
			Mean estimated daily dietary exposure based on mean analytical results:	
			20 <sup>th</sup> ATDS – <1% of ADI for all population groups assessed	
Leafy vegetables [except chervil; mizuna; rucola (rocket)]	Insert	T2		
Lettuce, head	Omit	T2		



Requested MRLs		mg/kg	Dietary Exposure Estimates
<p><b>Chlorpyrifos</b> Chlorpyrifos is a non-systemic insecticide with contact, stomach, and respiratory action. It is a cholinesterase inhibitor. The APVMA has issued a permit for its use to control vegetable weevil (<i>Listroderes obliquus</i>) on parsley.</p> <p>Parsley</p> <p>Omit T0.05</p> <p>Substitute 0.05</p>			Dietary exposure assessment not required
<p><b>Closantel</b> Closantel is an anthelmintic. It acts as a potent uncoupler of oxidative phosphorylation in parasite mitochondria. The APVMA has issued a permit for its use in cattle for the treatment and control of gastrointestinal nematodes, liver fluke (immature and adult), lungworms, eyeworms, screw worm fly, sucking lice, mites and cattle tick.</p> <p>Cattle fat Insert T3</p> <p>Cattle kidney Insert T3</p> <p>Cattle liver Insert T1</p> <p>Cattle muscle Insert T1</p>			NEDI = 6% of ADI

Requested MRLs	mg/kg	Dietary Exposure Estimates		
<p><b>Clothianidin</b>  Clothianidin is an insecticide; it is an agonist of the nicotinic acetylcholine receptor, affecting the synapses in the insect central nervous system. The APVMA has issued permits for its use to control pests in apples, pears, peaches, nectarines, bananas and cotton. The recommended animal commodity MRLs are at the LOQ.</p> <p><u>Note:</u> Some of the MRLs proposed for deletion were approved through Proposal M1001. It is anticipated that the MRLs will be gazetted in August 2008.</p> <p>Omit residue definition:</p> <p><i>Commodities of plant origin:</i> Clothianidin  <i>Commodities of animal origin:</i> Sum of clothianidin, 2-chlorothiazol-5-ylmethylguanidine, 2-chlorothiazol-5-ylmethylurea, and the pyruvate derivative of N-(2-chlorothiazol-5-ylmethyl)-N'-methylguanidine expressed as clothianidin</p> <p>Insert residue definition:</p> <p>Clothianidin</p>		NEDI = 2% of ADI		
		NESTI as % of ARfD		
		<u>2-6 years</u>		<u>2 years &amp; above</u>
Apple	Omit T0.5			
	Substitute 0.5	15		4
Banana	Omit T*0.02			
	Substitute *0.02	<1		<1
Cotton seed	Omit T*0.02			
	Substitute *0.02	<1	Oilseed	<1
Edible offal (mammalian)	Omit T*0.02			
	Substitute *0.02	<1		<1
Eggs	Insert *0.02	<1		<1
Meat (mammalian) (in the fat)	Omit T*0.02			
Meat (mammalian)	Insert *0.02	<1		<1
Milks	Omit T*0.01			
	Substitute *0.01	<1		<1
Nectarine	Omit T2			
	Substitute 2	29		13
Peach	Omit T2			
	Substitute 2	32		11
Pear	Omit T0.5			
	Substitute 0.5	10		3
Poultry, edible offal of	Insert *0.02	<1		<1
Poultry meat	Insert *0.02	<1		<1

Requested MRLs	mg/kg	Dietary Exposure Estimates
<p><b>Cyanamide</b>  Cyanamide is a plant growth regulator. It act as a catalase inhibitor, requiring the plant to detoxify hydrogen peroxide by other routes, which affects the oxidative pentose phosphate pathway. This in turn, leads to an increase in reduced nucleotide production, ultimately affecting bud break. It is used in apples to regulate bud dormancy, and in blueberries to promote vegetative bud break and earlier leaf development. The recommended MRLs are at the LOQ.</p> <p>Apple                                      Insert                                      *0.02  Blueberries                                      Insert                                      *0.05</p>		<p>NEDI = 5% of ADI</p>
<p><b>Cyprodinil</b>  Cyprodinil is a systemic fungicide. It is a proposed inhibitor of the biosynthesis of methionine and the secretion of fungal hydrolytic enzymes. It is transported throughout the tissue and acropetally in the xylem. It inhibits penetration and mycelial growth both inside the plant and on leaf surfaces. The APVMA has issued permits for its use to control butyris rots (<i>Botrytis cinerea</i>) in cucumbers, glasshouse grown capsicums and lettuce as well as bottom rot (<i>Rhizoctonia sp.</i>) in glasshouse lettuce.</p> <p>Cucumber                                      Insert                                      T0.2  Lettuce, head                                      Insert                                      T10  Peppers, Sweet                                      Insert                                      T0.5</p>		<p>NEDI = 18% of ADI</p>

Requested MRLs	mg/kg	Dietary Exposure Estimates	
<p><b>Dimethenamid-P</b> Dimethenamid-P is a herbicide. It acts as a cell division inhibitor. It is used for pre-emergent or early post-emergent control of weeds in pulse, oilseed and vegetable crops. The recommended MRLs are at the LOQ.</p> <p>New Chemical</p> <p>Insert residue definition:</p> <p>Dimethenamid-P: Sum of dimethenamid-P and its (<i>R</i>)-isomer</p>		<p>NEDI =&lt;1% of ADI</p> <p>NESTI as % of ARfD</p>	
		<u>2-6 years</u>	<u>2 years &amp; above</u>
Common bean (pods and/or immature seeds)	Insert *0.02	<1	<1
Edible offal (mammalian)	Insert *0.01	<1	<1
Eggs	Insert *0.01	<1	<1
Maize	Insert *0.02	<1	<1
Meat (mammalian)	Insert *0.01	<1	<1
Milks	Insert *0.01	<1	<1
Peas	Insert *0.02	<1	<1
Poppy seed	Insert *0.01	<1	<1
Poultry, edible offal of	Insert *0.01	<1	<1
Poultry meat	Insert *0.01	<1	<1
Pulses	Insert *0.02	<1	<1
Pumpkins	Insert *0.02	<1	<1
Sweet corn (corn-on-the-cob)	Insert *0.02	<1	<1
<p><b>Florfenicol</b> Florfenicol is an amphenicol antibiotic. Amphenicols are broad-spectrum antibiotics with a range of activity that includes Gram-positive and Gram-negative bacteria, rickettsia and Chlamydiae. Amphenicols bind to the 50S ribosomal subunit and inhibit the transpeptidyl-transferase step in protein synthesis. The APVMA has issued a permit for the use of florfenicol to treat bacterial diseases in salmon, trout, barramundi, silver perch, yellow tail and kingfish. The NHMRC has advised that the proposed florfenicol MRLs do not pose a risk in terms of antimicrobial resistance. Florfenicol is currently registered for use in fish in the UK/Europe, the United States, Canada, Japan and Chile.</p>		<p>NEDI = 44% of ADI</p>	
Fish	Insert T0.5		

Requested MRLs	mg/kg	Dietary Exposure Estimates																								
<p><b>Fludioxonil</b> Fludioxonil is a non-systemic fungicide with long residual activity. The uptake into the plant tissues and the curative properties are generally limited. It inhibits mainly the germination of conidia and, to a lesser extent, the germ tube and mycelial growth. It inhibits MAP kinase, in osmotic signal transduction. It is used in sorghum to control damping off and rot caused by <i>Pythium</i> and <i>Fusarium</i>. The APVMA has issued permits for its use to control botrytis rots (<i>Botrytis cinerea</i>) in cucumbers, glasshouse grown capsicums and lettuce as well as bottom rot (<i>Rhizoctonia sp.</i>) in glasshouse lettuce. The recommended sorghum MRL is at LOQ.</p> <table> <tr> <td>Cucumber</td> <td>Insert</td> <td>T0.3</td> </tr> <tr> <td>Lettuce, head</td> <td>Insert</td> <td>T10</td> </tr> <tr> <td>Peppers, Sweet</td> <td>Insert</td> <td>T2</td> </tr> <tr> <td>Sorghum</td> <td>Omit</td> <td>T*0.05</td> </tr> <tr> <td></td> <td>Substitute</td> <td>*0.01</td> </tr> </table>	Cucumber	Insert	T0.3	Lettuce, head	Insert	T10	Peppers, Sweet	Insert	T2	Sorghum	Omit	T*0.05		Substitute	*0.01		NEDI =7% of ADI									
Cucumber	Insert	T0.3																								
Lettuce, head	Insert	T10																								
Peppers, Sweet	Insert	T2																								
Sorghum	Omit	T*0.05																								
	Substitute	*0.01																								
<p><b>Fluorine (inorganic salts)</b> (See also sulfuryl fluoride) Fluoride ion residues arising from the use of sulfuryl fluoride are listed under fluorine (inorganic salts) in the Code. Sulfuryl fluoride is hydrolysed to sulphate ions and fluoride ions in plant and animal tissue. Sulphate ions are not of toxicological concern. Sulfuryl fluoride and inorganic fluoride ions are determined separately.</p> <table> <tr> <td>Dried fruits</td> <td>Insert</td> <td>5</td> </tr> <tr> <td>Fruit</td> <td>Omit</td> <td>7</td> </tr> <tr> <td>Peanut</td> <td>Insert</td> <td>30</td> </tr> <tr> <td>Tree nuts</td> <td>Insert</td> <td>30</td> </tr> <tr> <td>Vegetables</td> <td>Omit</td> <td>7</td> </tr> <tr> <td>Wheat germ</td> <td>Insert</td> <td>10</td> </tr> </table>	Dried fruits	Insert	5	Fruit	Omit	7	Peanut	Insert	30	Tree nuts	Insert	30	Vegetables	Omit	7	Wheat germ	Insert	10		Fluoride ion NEDI as % of UL <table> <tr> <td><u>2-6 years</u></td> <td><u>7 years</u></td> </tr> <tr> <td>76</td> <td><u>&amp; above</u></td> </tr> <tr> <td></td> <td>31</td> </tr> </table>	<u>2-6 years</u>	<u>7 years</u>	76	<u>&amp; above</u>		31
Dried fruits	Insert	5																								
Fruit	Omit	7																								
Peanut	Insert	30																								
Tree nuts	Insert	30																								
Vegetables	Omit	7																								
Wheat germ	Insert	10																								
<u>2-6 years</u>	<u>7 years</u>																									
76	<u>&amp; above</u>																									
	31																									
<p><b>Glyphosate</b> Glyphosate is a herbicide. It inhibits the biosynthesis of aromatic amino acids. The APVMA has issued a permit for its use to desiccate linseed crops at harvest. Residues are significantly reduced on processing of linseed to oil. A separate MRL is therefore not required for linseed oil.</p> <table> <tr> <td>Linseed</td> <td>Insert</td> <td>T5</td> </tr> <tr> <td>Oilseed [except cotton seed and rape seed]</td> <td>Omit</td> <td>*0.1</td> </tr> <tr> <td>Oilseed [except cotton seed, linseed and rape seed]</td> <td>Insert</td> <td>T*0.1</td> </tr> </table>	Linseed	Insert	T5	Oilseed [except cotton seed and rape seed]	Omit	*0.1	Oilseed [except cotton seed, linseed and rape seed]	Insert	T*0.1		NEDI = 6% of ADI															
Linseed	Insert	T5																								
Oilseed [except cotton seed and rape seed]	Omit	*0.1																								
Oilseed [except cotton seed, linseed and rape seed]	Insert	T*0.1																								

Requested MRLs	mg/kg	Dietary Exposure Estimates																											
<p><b>Isoxaben</b> Isoxaben is a herbicide used to control various broadleaf weeds in barley, triticale and wheat. It inhibits biosynthesis of cellulose. The recommended MRLs are at the LOQ.</p> <table border="0"> <tr> <td>Barley</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Edible offal (mammalian)</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Eggs</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Meat (mammalian)</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Milks</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Poultry, edible offal of</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Poultry meat</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Triticale</td> <td>Insert</td> <td>*0.01</td> </tr> <tr> <td>Wheat</td> <td>Insert</td> <td>*0.01</td> </tr> </table>		Barley	Insert	*0.01	Edible offal (mammalian)	Insert	*0.01	Eggs	Insert	*0.01	Meat (mammalian)	Insert	*0.01	Milks	Insert	*0.01	Poultry, edible offal of	Insert	*0.01	Poultry meat	Insert	*0.01	Triticale	Insert	*0.01	Wheat	Insert	*0.01	<p>NEDI = &lt;1% of ADI</p>
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Wheat	Insert	*0.01																											
<p><b>Maldison</b> Maldison is a non systemic insecticide and acaricide with contact, stomach and respiratory action. It acts as a cholinesterase inhibitor and proinsecticide. It is used to control pests in a wide range of crops.</p> <table border="0"> <tr> <td>Shallot</td> <td>Insert</td> <td>T5</td> <td>2</td> <td>&lt;1</td> </tr> <tr> <td>Spring onion</td> <td>Insert</td> <td>T5</td> <td>1</td> <td>&lt;1</td> </tr> <tr> <td>Vegetables [except as otherwise listed under this chemical]</td> <td>Omit</td> <td>2</td> <td></td> <td></td> </tr> <tr> <td>Vegetables [except beans (dry); cauliflower; chard (silverbeet); egg plant; garden pea; kale; kohlrabi; lentil (dry); peppers, sweet; root and tuber vegetables; shallot; spring onion; tomato; turnip, garden]</td> <td>Insert</td> <td>2</td> <td></td> <td></td> </tr> </table>		Shallot	Insert	T5	2	<1	Spring onion	Insert	T5	1	<1	Vegetables [except as otherwise listed under this chemical]	Omit	2			Vegetables [except beans (dry); cauliflower; chard (silverbeet); egg plant; garden pea; kale; kohlrabi; lentil (dry); peppers, sweet; root and tuber vegetables; shallot; spring onion; tomato; turnip, garden]	Insert	2			<p>NEDI = 82% of ADI</p> <p>Mean estimated daily dietary exposure based on mean analytical results:</p> <p>20<sup>th</sup> ATDS – &lt;1% of ADI for all population groups assessed</p> <p>19<sup>th</sup> ATDS – not detected in any foods sampled</p> <p>NESTI as % of ARfD</p> <table border="0"> <tr> <td><u>2-6 years</u></td> <td><u>2 years &amp; above</u></td> </tr> <tr> <td>2</td> <td>&lt;1</td> </tr> <tr> <td>1</td> <td>&lt;1</td> </tr> </table>	<u>2-6 years</u>	<u>2 years &amp; above</u>	2	<1	1	<1	
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Requested MRLs	mg/kg	Dietary Exposure Estimates
<p><b>Methomyl</b> Methomyl is a carbamate insecticide and acaricide with contact and stomach action. It is a cholinesterase inhibitor. Methomyl is used to control a wide range of insects and spider mites on fruit, vines, vegetables and field crops. The APVMA permit for its use to control grass hoppers and budworms on culinary herbs has expired.</p>		
Bergamot	Omit	T5
Burnet, salad	Omit	T5
Chervil	Omit	T5
Coriander (leaves, stem, roots)	Omit	T10
Coriander, seed	Omit	T5
Dill, seed	Omit	T5
Fennel, seed	Omit	T5
Galangal, Greater	Omit	T*0.02
Kaffir lime leaves	Omit	T5
Lemon grass	Omit	T5
Lemon verbena (dry leaves)	Omit	T5
Mizuna	Omit	T5
Rose and dianthus (edible flowers)	Omit	T5
Rucola (rocket)	Omit	T5
Turmeric, root	Omit	T*0.02
<p><b>Metsulfuron-methyl</b> Metsulfuron-methyl is a post-emergent herbicide. It inhibits the synthesis of branched chain amino acids such as valine and isoleucine, halting cell division and plant growth. It is used to control a wide range of grass and broad leaf weeds in cereal, pulse and oilseed crops. The recommended MRL is at the LOQ.</p>		
Linseed	Omit	T*0.02
	Substitute	*0.02
<p><b>Phosphorous acid</b> Phosphorus acid is a selective systemic phosphonate fungicide with multi-site activity. It is used to control fungal diseases on fruit and vegetables.</p>		
Flowerhead brassicas	Insert	T50

Requested MRLs	mg/kg	Dietary Exposure Estimates			
<p><b>Propiconazole</b>  Propiconazole is a systemic fungicide with protective and curative action. It inhibits the biosynthesis of ergosterol by fungi. It is used to control certain fungal diseases in cereal crops and various horticultural situations.</p>		<p>NEDI = 6% of ADI</p> <p>Mean estimated daily dietary exposure based on mean analytical results:</p> <p>20<sup>th</sup> ATDS – &lt;1% of ADI for all population groups assessed</p>			
Spinach	Insert	T0.1			
<p><b>Prosulfocarb</b>  Prosulfocarb is a S-benzyl thiocarbamate selective herbicide, absorbed by the leaves and roots. It inhibits lipid synthesis in the meristematic region. It is used to control annual ryegrass and toad rust in barley and wheat. Detectable residues are not expected in animal feeds. The recommended MRLs are set at the LOQ.</p>		<p>NEDI = 1% of ADI</p> <p>NESTI as % of ARfD</p> <p><u>2-6 years</u>                      <u>2 years &amp; above</u></p>			
Barley	Omit	T*0.01	<1	Barley grain	<1
	Substitute	*0.01	<1	Barley beer	<1
Edible offal (mammalian)	Insert	*0.02	<1		<1
Eggs	Insert	*0.02	<1		<1
Meat (mammalian)	Insert	*0.02	<1		<1
Milks	Insert	*0.02	<1		<1
Poultry, edible offal of	Insert	*0.02	<1		<1
Poultry meat	Insert	*0.02	<1		<1
Wheat	Omit	T*0.01	<1		<1
	Substitute	*0.01	<1	Wheat bran, processed	<1
			<1	Wheat bran, unprocessed	<1
			<1	Wheat flour	<1
			<1	Wheat germ	<1
			<1	Wheat wholemeal	<1



Requested MRLs	mg/kg	Dietary Exposure Estimates
<p><b>Prothioconazole</b>  Prothioconazole is a systemic fungicide with protective, curative, eradicated and long-lasting activity. It inhibits ergosterol biosyntheses by affecting steroid demethylation. It is used to treat Common Bunt (<i>Tilletia spp.</i>). Residues and feeding studies data support MRLs at the LOQ for wheat grain and animal commodities.</p> <p>Note: Prothioconazole MRLs were approved through Application A610. It is anticipated that the MRLs will be gazetted in August 2008.</p>		NEDI = 2% of ADI
Edible offal (mammalian)	Omit	T*0.05
	Substitute	*0.05
Eggs	Omit	T*0.01
	Substitute	*0.01
Meat (mammalian) (in the fat)	Omit	T*0.01
	Substitute	*0.01
Milks	Omit	T*0.01
	Substitute	*0.004
Poultry, edible offal of	Omit	T*0.05
	Substitute	*0.05
Poultry meat (in the fat)	Omit	T*0.05
	Substitute	*0.05
Wheat	Omit	T*0.05
	Substitute	*0.05

Requested MRLs	mg/kg	Dietary Exposure Estimates	
<p><b>Pyrasulfotole</b>  Pyrasulfotole is a herbicide. It acts as an inhibitor of the 4-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme and blocks the pathway of prenylquinone biosynthesis in plants. It is used to control broadleaf weeds in cereal crops. The recommended MRLs for cereal grains, eggs, meat (mammalian), milks and poultry commodities are at the LOQ.</p> <p>Note: Pyrasulfotole MRLs were approved through Proposal M1001. It is anticipated that the MRLs will be gazetted in August 2008.</p>		<p>NEDI = 1% of ADI</p> <p>NESTI as a % of ARfD</p> <p><u>2-6 years</u>                      <u>2 years &amp; above</u></p>	
Cereal bran, unprocessed	Omit                      T0.03		
	Substitute                      0.03	<1	<1
Cereal grains	Omit                      T*0.02		
	Substitute                      *0.02	<1	<1
Edible offal (mammalian)	Omit                      T0.5		
	Substitute                      0.5	<1	<1
Eggs	Omit                      T*0.01		
	Substitute                      *0.01	<1	<1
Meat (mammalian)	Omit                      T*0.01		
	Substitute                      *0.01	<1	<1
Milks	Omit                      T0.01		
	Substitute                      *0.01	<1	<1
Poultry, edible offal of	Omit                      T*0.01		
	Substitute                      *0.01	<1	<1
Poultry meat	Omit                      T*0.01		
	Substitute                      *0.01	<1	<1
<p><b>Ractopamine</b>  Ractopamine is a phenethanolamine. It was used to increase weight gain, improve feed efficiency and increased carcass leanness in beef cattle. The APVMA permit for this use has expired.</p>		<p>Dietary exposure assessment not required</p>	
Cattle fat	Omit                      T*0.02		
Cattle kidney	Omit                      T0.1		
Cattle meat	Omit                      T*0.02		

Requested MRLs	mg/kg	Dietary Exposure Estimates																																																																																
<p><b>Sulfuryl fluoride</b> (see also fluorine (inorganic salts)) Sulfuryl fluoride is an insecticide. It is a fumigant used to control insect pests in various situations including grain storage silos and warehouses, in fumigation chambers and food processing facilities such as mills. It is also used for seed intended for sowing and for hay fumigation.</p> <p>New Chemical</p> <p>Insert residue definition: Sulfuryl fluoride</p> <table border="0" data-bbox="177 761 954 1536"> <tr> <td>Cereal grains</td> <td>Insert</td> <td>0.05</td> </tr> <tr> <td>Dried fruits</td> <td>Insert</td> <td>0.07</td> </tr> <tr> <td>Peanut</td> <td>Insert</td> <td>7</td> </tr> <tr> <td>Tree nuts</td> <td>Insert</td> <td>7</td> </tr> </table>		Cereal grains	Insert	0.05	Dried fruits	Insert	0.07	Peanut	Insert	7	Tree nuts	Insert	7	<p>NEDI = 2% of ADI</p> <p>NESTI as % of ARfD</p> <table border="0" data-bbox="957 672 1388 1536"> <thead> <tr> <th colspan="2"></th> <th><u>2-6 years</u></th> <th><u>2 years &amp; above</u></th> </tr> </thead> <tbody> <tr> <td>&lt;1</td> <td>Cereal grains</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Cereal grain fractions</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Early milling products</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Barley beer</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Wheat bran, processed</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Wheat bran, unprocessed</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Wheat flour</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Wheat germ</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Wheat wholemeal</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td></td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>4</td> <td></td> <td>2</td> <td>2</td> </tr> <tr> <td>3</td> <td></td> <td>2</td> <td>2</td> </tr> <tr> <td>&lt;1</td> <td>Almonds</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>2</td> <td>Pecan</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Pistachios</td> <td>&lt;1</td> <td>&lt;1</td> </tr> <tr> <td>&lt;1</td> <td>Walnuts</td> <td>&lt;1</td> <td>&lt;1</td> </tr> </tbody> </table>			<u>2-6 years</u>	<u>2 years &amp; above</u>	<1	Cereal grains	<1	<1	<1	Cereal grain fractions	<1	<1	<1	Early milling products	<1	<1	<1	Barley beer	<1	<1	<1	Wheat bran, processed	<1	<1	<1	Wheat bran, unprocessed	<1	<1	<1	Wheat flour	<1	<1	<1	Wheat germ	<1	<1	<1	Wheat wholemeal	<1	<1	<1		<1	<1	4		2	2	3		2	2	<1	Almonds	<1	<1	2	Pecan	<1	<1	<1	Pistachios	<1	<1	<1	Walnuts	<1	<1
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<p><b>Thiamethoxam</b> Thiamethoxam is a neonicotinoid insecticide. It is an agonist of the nicotinic acetylcholine receptor, affecting the synapses in the insect's central nervous system. It is used to control various insect pests on fruit, vegetable, cereal and oilseed crops. The APVMA has issued a research permit for its use in sugar cane to control soil and sucking insect pests. The recommended MRL is at the LOQ.</p> <table border="0" data-bbox="177 1859 954 1919"> <tr> <td>Sugar cane</td> <td>Insert</td> <td>T*0.02</td> </tr> </table>		Sugar cane	Insert	T*0.02	<p>NEDI = 11% of ADI</p>																																																																													
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Requested MRLs	mg/kg	Dietary Exposure Estimates	
<p><b>Toltrazuril</b>  Toltrazuril is a triazinetrione derivative coccidiostat. It causes obstruction of the wall-forming bodies of <i>Eimerian macrogamonts</i>, and induces changes in the fine structure of coccidian development stages, mainly due to a swelling of the endoplasmic reticulum and of the Golgi apparatus. It also causes abnormalities in the perinuclear space, leading to disturbances in nuclear division, and a reduction of enzymes of the respiratory chain of the parasites. It is used to treat and prevent coccidiosis caused by <i>Eimeria bovis</i> or <i>Eimeria zeurnii</i> in calves up to 9 months of age. It is not to be used in lactating or pregnant cows where milk or milk products may be used for human consumption.</p> <p>Cattle fat                      Insert                      1  Cattle kidney                      Insert                      1  Cattle liver                      Insert                      2  Cattle muscle                      Insert                      0.25</p>		<p>NEDI = 14% of ADI</p>	
<p><b>Tolyfluanid</b>  Tolyfluanid is a fungicide. It inhibits fungal cell respiration. It is used to control botrytis rot (<i>Botrytis cinerea</i>). The APVMA has issued a permit for its use on glass house and field cucumber.</p> <p>Cucumber                      Insert                      T2</p>		<p>NEDI = &lt;1% of ADI</p> <p>NESTI as % of ARfD</p> <p><u>2-6 years</u>                      <u>2 years &amp; above</u></p> <p>7                      2</p>	

### Safety Assessment Methodology

#### 1.1 Determination of the Residues of a Chemical in a Treated Food

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

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

#### 1.2 Determining the Acceptable Reference Health Standard for a Chemical in Food

The Office of Chemical Safety (OCS) assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where appropriate, the ARfD for a chemical. In the case that an Australian ADI or ARfD has not been established, a Joint Food and Agriculture Organization / World Health Organization Meeting on Pesticide Residues (JMPR) ADI or ARfD may be used for risk assessment purposes if the OCS advises this is appropriate.

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

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

The ARfD of a chemical is the estimate of the amount of a substance in food, expressed on a body weight basis that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer, on the basis of all the known facts at the time of evaluation.

#### 1.3 Calculating Dietary Exposure

The APVMA and FSANZ undertake chronic dietary exposure assessments for all agricultural and veterinary chemicals and undertake acute dietary exposure assessments where either the OCS or JMPR has established an ARfD.

The APVMA and FSANZ have agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the APVMA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest National Nutrition Survey (NNS). The Australian Bureau of Statistics with the then Australian Government Department of Health and Aged Care undertook the latest NNS over a 13-month period (1995 to early 1996). The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns was reported.

### *1.3.1 Chronic Dietary Exposure Assessment*

The National Estimated Daily Intake (NEDI) represents an estimate of chronic dietary exposure. Chemical residue data, as opposed to the MRL, are the preferred concentration data to use if they are available, as they provide a more realistic estimate of dietary exposure. The NEDI calculation may incorporate more specific data including food consumption data for particular sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions and the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials rather than the MRL to represent pesticide residue levels. Monitoring and surveillance data or data from total diet studies may also be used, such as the 19<sup>th</sup> and 20<sup>th</sup> Australian Total Diet Surveys (ATDS).

FSANZ is currently undertaking the 23rd ATDS (now the Australian Total Diet Study). The study will analyse the levels of various agricultural and veterinary chemicals in food and estimate the potential dietary exposure of population groups in Australia to those chemicals.

In conducting chronic dietary exposure assessments, the APVMA and FSANZ consider the residues in foods that could result from the permitted uses of a chemical product. Where data are not available on the specific residues in a food then a cautious approach is taken and the MRL is used. The use of the MRL in dietary exposure estimates may result in considerable overestimates of exposure because it assumes that the chemical will be used on all crops for which there is a registered use or an approved permit; treatment occurs at the maximum application rate; the maximum number of permitted treatments have been applied; the minimum withholding period applies; and that the entire national crop contains residues equivalent to the MRL. In agriculture and animal husbandry this is not the case, but for the purposes of undertaking a risk assessment, it is important to be conservative in the absence of reliable data to refine the dietary exposure estimates further. In reality, only a portion of a specific crop is treated with a pesticide; most treated crops contain residues well below the MRL at harvest; and residues are usually reduced during storage, preparation, commercial processing and cooking. It is also unlikely that every food for which an MRL is proposed will have been treated with the same pesticide over the lifetime of consumers.

The residues that are likely to occur in all foods are multiplied by the mean daily consumption of these foods derived from individual dietary records from the latest NNS for all survey respondents regardless of whether they consumed the food or not. These calculations provide information on the level of a chemical that is consumed for each food and take into account the consumption of processed foods e.g. apple pie and bread. The estimated exposure for each food is added together to provide the total mean dietary exposure to a chemical from all foods with MRLs.

The estimated mean dietary exposure is then divided by the average Australian's bodyweight to provide the amount of chemical consumed per day per kg of human bodyweight.

### *1.3.2 Acute Dietary Exposure Assessment*

The National Estimated Short Term Intake (NESTI) is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken where the OCS has determined an ARfD for a chemical or advised that a JMPR ARfD is appropriate. Acute dietary exposures are normally only estimated for raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis.

The NESTI is calculated in a similar way to the chronic dietary exposure. Generally, the residues of a chemical in a specific food are multiplied by the 97.5<sup>th</sup> percentile food consumption of that food based on consumers only, if appropriate the exposure is divided by a mean body weight for the population group being assessed and this result is compared to the ARfD. The exact equations for calculating the NESTIs differ depending on the type or size of the commodity. These equations are set and used internationally. NESTIs are calculated from ARfDs set by the OCS or JMPR, consumption data from the 1995 NNS and the MRL when the data on the actual residues in foods are not available.

The NESTI calculation incorporates the large portion (97.5 percentile) food consumption data and can take into account such factors as the highest residue on a composite sample of an edible portion; the supervised trials median residue (STMR), representing typical residue in an edible portion resulting from the maximum permitted pesticide use pattern; processing factors which affect changes from the raw commodity to the consumed food and the variability factor where appropriate.

### *1.3.3 Risk Characterisation*

The estimated mean chronic dietary exposure is compared to the ADI to characterise risk to the Australian population. FSANZ considers that the chronic and acute dietary exposure to the residues of a chemical is acceptable where the best estimates of mean chronic and acute dietary exposure do not exceed the ADI or ARfD.

### Background Information

#### 1.1 Maximum Residue Limits

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

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 consistent with the effective control of pests and diseases.

Some of the proposed MRLs in this Application are at the limit of quantification (LOQ) and are indicated by an \* in front of the 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. Future developments in methods of detection may lead to lowering these limits.

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

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

FSANZ does not issue permits or grant permission for the temporary use of agricultural and veterinary chemicals. Further information on permits for the use of agricultural and veterinary chemicals can be found on the APVMA website at [www.apvma.gov.au](http://www.apvma.gov.au) or by contacting the APVMA on +61 2 6210 4700.

#### 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 consumers, those handling, or applying the chemical, animals, crops 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.

### **1.3 Maximum Residue Limit Notifications and Submissions**

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

Appropriate toxicology, residue, animal transfer, processing and metabolism studies are provided to the APVMA in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the requested MRLs.

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

FSANZ is committed to ensuring that the implications of MRL variations are considered. Under the current process for considering variations to the Code, FSANZ encourages submissions including specific data demonstrating a need for certain MRLs to be retained or varied. FSANZ will consider retaining MRLs proposed for deletion or reduction where these MRLs are necessary to continue to allow the sale of safe food; and where the MRLs are supported by adequate data or information demonstrating that the residues associated with these MRLs do not raise any public health or safety concerns. Further information on data requirements may be obtained from FSANZ.

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.

FSANZ reviews the information provided 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 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 Antibiotics

Applicants seeking to register antibiotics for veterinary uses are required to provide suitable data to the Office of Chemical Safety to permit establishment of an ADI based on a microbiological endpoint as well as a toxicological one. The ADI is based on whichever is the most sensitive. This ensures that any antibiotic residues which may be present in food will not facilitate the development of antibiotic resistance in the microflora of the colon when ingested.

The National Health and Medical Research Council (NHMRC), with reference to the Expert Advisory Group on Antimicrobial Resistance (EAGAR), provides advice to government and regulatory agencies on antimicrobial resistance issues and measures designed to reduce the risk of antimicrobial resistance developing.

As part of its registration and chemical review processes, the APVMA seeks NHMRC advice on risk assessments for new antibiotics and extensions of indications. This advice considers the likely impact on the efficacy of antibiotics that are essential for human therapeutics.

FSANZ will incorporate MRLs for antimicrobial substances in the Code, only where the NHMRC has no objection to the use of the antimicrobial substance in food production. This process ensures that the potential for the development of antimicrobial resistance is rigorously considered.

## 1.5 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.

## 1.6 A guide to the summary table of requested MRLs

The following is an example of an entry and the proposed MRL is not being considered in this Proposal.

Data from the 19<sup>th</sup> and 20<sup>th</sup> ATDS are provided when available because they provide an indication of the typical exposure to chemicals in table ready foods.

The ATDS results are more realistic because analysed concentrations of the chemical in foods as consumed are used; the NEDI and NESTI calculations are theoretical calculations that conservatively overestimate exposure. Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and typically result because of the different range of foods in the individual studies.

Chemical name

The NEDI is an assessment of the chronic exposure which is compared to the acceptable daily intake (ADI).

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

**Chlorpyrifos**

Chlorpyrifos is an acaricide, nematocide and insecticide. The APVMA has approved an extension of use for the control of pests in coffee crops.

NEDI = 83% of ADI

Mean estimated daily dietary exposure based on mean analytical results:

20<sup>th</sup> ATDS = <1% of ADI for all population groups assessed

19<sup>th</sup> ATDS = 3% of ADI for toddlers 2 years and <1% of ADI for other population groups assessed

NESTI as % of ARfD

<u>2-6 years</u>	<u>2+ years</u>
------------------	-----------------

8

<1

Coffee beans

Insert

T\*0.5

Food/s for which the proposed MRL is to apply.

Whether the proposed MRL is being added or deleted.

The NESTI is an assessment of the acute exposure which is compared to the acute reference dose (ARfD).

The “\*” means that the MRL is at the limit of quantification and detectable residues should not occur.

The ‘T’ means the MRL is temporary and under review.