

**1-05**  
**9 February 2005**

## **FINAL ASSESSMENT REPORT**

### **APPLICATION A526**

### **MAXIMUM RESIDUE LIMITS (JANUARY, FEBRUARY 2004)**

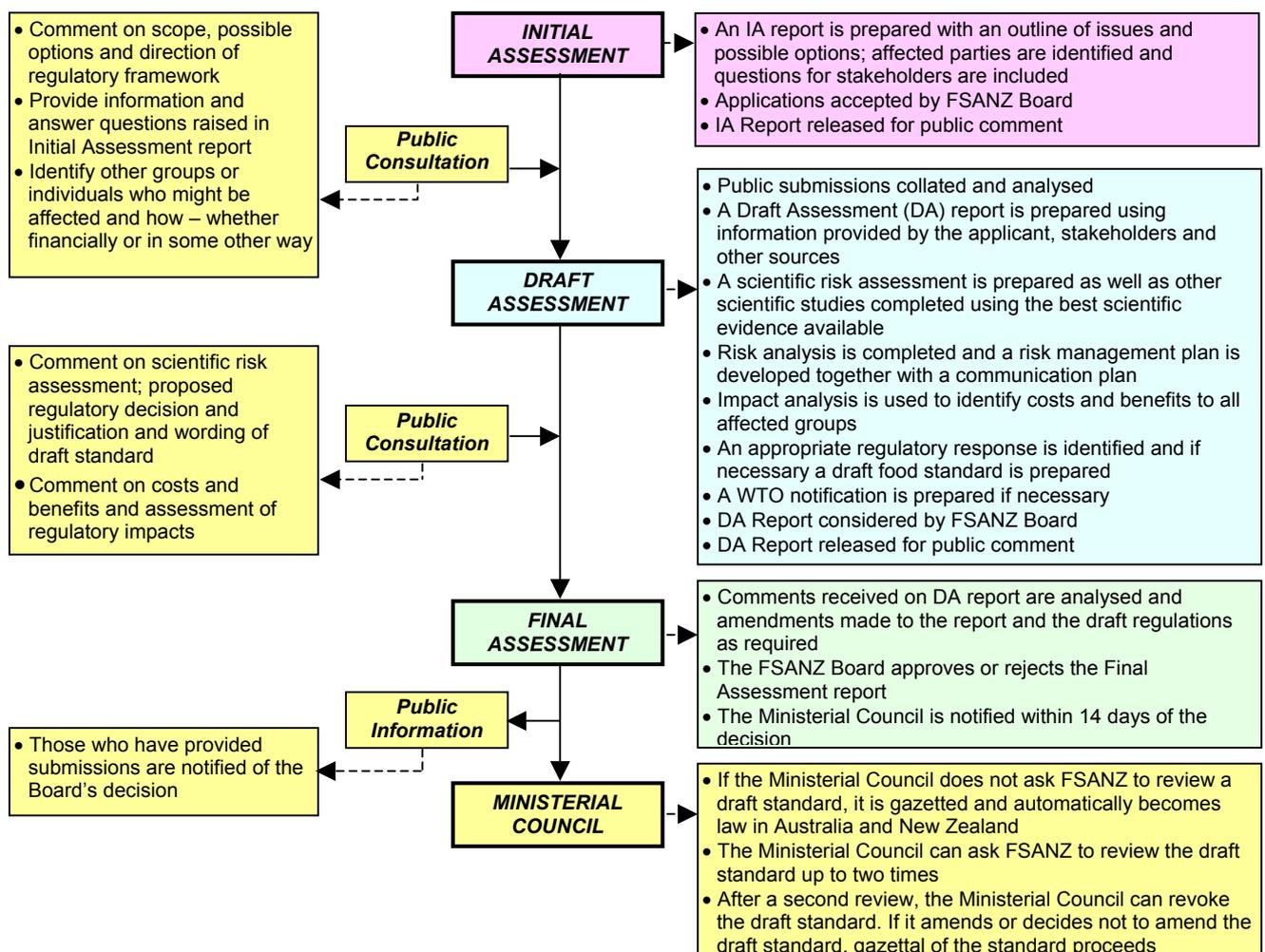
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



## **Final Assessment Stage (s.36)**

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

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

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

## **Further Information**

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

**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)**

Assessment reports are available for viewing and downloading from the FSANZ website [www.foodstandards.gov.au](http://www.foodstandards.gov.au) or alternatively paper copies of reports can be requested from FSANZ's Information Officer at [info@foodstandards.gov.au](mailto:info@foodstandards.gov.au) including other general enquiries and requests for information.

## CONTENTS

<b>EXECUTIVE SUMMARY AND STATEMENT OF REASONS .....</b>	<b>6</b>
<b>1. INTRODUCTION.....</b>	<b>7</b>
1.1 SUMMARY OF PROPOSED MRLS.....	7
1.4 ANTIBIOTIC MRLS.....	7
<b>2. REGULATORY PROBLEM.....</b>	<b>7</b>
2.1 CURRENT REGULATIONS.....	7
<b>3. OBJECTIVE .....</b>	<b>8</b>
3.1 CONSIDERATION OF ISSUES UNDER SECTION 10 OF THE <i>FOOD STANDARDS AUSTRALIA NEW ZEALAND ACT 1991</i> .....	8
<b>4. BACKGROUND .....</b>	<b>9</b>
4.1 THE USE OF AGRICULTURAL AND VETERINARY CHEMICALS .....	9
4.2 MAXIMUM RESIDUE LIMIT APPLICATIONS .....	9
4.3 MAXIMUM RESIDUE LIMITS .....	10
4.4 FOOD STANDARDS-SETTING IN AUSTRALIA AND NEW ZEALAND.....	11
4.5 TRANS TASMAN MUTUAL RECOGNITION ARRANGEMENT .....	11
4.6 LIMIT OF QUANTIFICATION .....	11
4.7 MRLS FOR PERMITS .....	11
<b>5. EVALUATION OF ISSUES RAISED IN PUBLIC COMMENT.....</b>	<b>12</b>
5.1 RACTOPAMINE RESIDUES IN PORK COMMODITIES.....	12
5.2 IDENTIFICATION OF NEW CHEMICALS.....	12
5.3 LEGISLATION GOVERNING THE REGISTRATIONS AND ENFORCEMENT OF USE OF AGRICULTURAL AND VETERINARY CHEMICALS. ....	12
5.4 EXCEEDANCE OF THE MRLS .....	13
5.5 POSSIBILITY OF THE OCCURRENCE OF SYNERGISTIC EFFECTS .....	13
<b>6. REGULATORY OPTIONS.....</b>	<b>14</b>
6.1 OPTION 1 – STATUS QUO – NO CHANGE TO THE EXISTING MRLS IN THE CODE .....	14
6.2 OPTION 2(A) – ADOPT THE CHANGE TO MRLS TO DELETE OR DECREASE SOME EXISTING MRLS.....	14
6.3 OPTION 2(B) – ADOPT THE CHANGES TO MRLS TO INCLUDE NEW OR INCREASE SOME EXISTING MRLS.....	14
<b>7. AFFECTED PARTIES.....</b>	<b>14</b>
<b>8. IMPACT ANALYSIS .....</b>	<b>15</b>
8.1 OPTION 1 – STATUS QUO – NO CHANGE TO THE EXISTING MRLS IN THE CODE .....	15
8.2 OPTION 2(A) – ADOPT THE CHANGES TO MRLS TO DELETE AND DECREASE SOME EXISTING MRLS.....	16
8.3 OPTION 2(B) – ADOPT THE CHANGES TO MRLS TO INCLUDE NEW AND INCREASE SOME EXISTING MRLS .....	17
8.4 CONCLUSION.....	17
<b>9. CONSULTATION .....</b>	<b>18</b>
9.1 WORLD TRADE ORGANIZATION NOTIFICATION .....	18
<b>10. CONCLUSION AND RECOMMENDATION .....</b>	<b>19</b>

<b>11. IMPLEMENTATION AND REVIEW .....</b>	<b>19</b>
<b>ATTACHMENT 1 - DRAFT VARIATIONS TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>.....</b>	<b>21</b>
<b>ATTACHMENT 2 - A SUMMARY OF THE REQUESTED MRLS FOR EACH CHEMICAL AND AN OUTLINE OF THE INFORMATION SUPPORTING THE REQUESTED CHANGES TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> .....</b>	<b>24</b>
<b>ATTACHMENT 3 - BACKGROUND TO DIETARY EXPOSURE ASSESSMENTS ..</b>	<b>30</b>
<b>ATTACHMENT 4 - SUMMARY OF SUBMISSIONS RECEIVED.....</b>	<b>33</b>

## **Executive Summary and Statement of Reasons**

This Application (A526) seeks to amend Maximum Residue Limits (MRLs) for non-antibiotic agricultural and veterinary chemicals in the Code. It is a routine application from the Australian Pesticide and Veterinary Medicines Authority (APVMA), to update the Code in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

*The Agreement between the Commonwealth of Australia and the Government of New Zealand to establish a system for the development of joint food standards (the Treaty)*, excluded MRLs for agricultural and veterinary chemicals in food from the joint Australia New Zealand food standards setting system. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

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

There are no MRLs for antibiotic residues in this Application.

FSANZ made a Sanitary and Phytosanitary notification to the World Trade Organization.

### **Statement of Reasons**

FSANZ recommends progressing this Application for the following reasons:

- The dietary exposure assessments, where appropriate, indicate that the residues associated with the MRLs do not represent an unacceptable risk to public health and safety. APVMA has already registered the chemical products associated with the MRLs in this Application and the rejection of the MRLs would result in legally treated food not being able to be legally sold. Therefore, the requested changes will benefit all stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.
- APVMA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the use of chemicals on commodities as outlined in this Application.
- The Office of Chemical Safety (OCS) of the Therapeutic Goods Administration (TGA) of the Australian Government Department of Health and Ageing has undertaken an appropriate toxicological assessment of the chemical products and has established relevant acceptable daily intakes (ADI) and where applicable, acute reference doses (ARfD).
- FSANZ has undertaken a regulation impact assessment process. That process concluded that the amendment to the Code is necessary, cost-effective and of benefit to both producers and consumers.
- None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed changes.

## **1. Introduction**

Applications were received from APVMA on 13 January and 10 February 2004 seeking amendments to Standard 1.4.2 of the Code. The proposed amendments to the Standard would align MRLs in the Code, for non-antibiotic agricultural and veterinary chemicals with the MRLs in APVMA's MRL Standard.

### **1.1 Summary of proposed MRLs**

The MRL amendments under consideration in this Application are:

- the changing of the residue definitions for the chemicals glyphosate, ractopamine and thiamethoxam;
- the addition of the MRL for the new chemical acibenzolar-s-methyl;
- the deletion of MRLs for certain foods for the chemicals glyphosate and spinosad;
- the addition of MRLs for certain foods for the chemicals bifenazate, methomyl and thiamethoxam;
- the changing of MRLs for certain foods for the chemicals glyphosate, permethrin, ractopamine, spinosad and thiacloprid; and
- the addition of temporary MRLs for certain foods for the chemicals azoxystrobin, imazamox, isoxaflutole, metolachlor and spinosad.

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

### **1.4 Antibiotic MRLs**

There are no MRLs for antibiotic residues in this Application.

## **2. Regulatory Problem**

### **2.1 Current Regulations**

APVMA has approved the use of the agricultural and veterinary chemical products associated with the MRLs in this Application, and made consequent amendments to APVMA's MRL Standard. The approval of the use of these products now means that there is a discrepancy between the residues associated with the use and the MRLs in the Code. In turn, this means that:

- where APVMA has increased MRLs, food cannot be legally sold under food legislation if it contains residues in excess of the existing MRLs in the Code;

- where APVMA has included MRLs for new chemicals or for additional foods that are not included in the Code, the particular food cannot be legally sold under food legislation if it contains any detectable residues of the particular chemical; and
- where APVMA has decreased or deleted MRLs, food may be legally sold under food legislation if it contains residues that are inconsistent with the current registered uses of chemical products.

### **3. Objective**

The objective of this Application is to ensure that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety and that the proposed MRLs permit the legal sale of food that has been legally treated. APVMA has already established MRLs under the APVMA's legislation, and now seeks, by way of this Application to include the amendments in the Code.

#### **3.1 Consideration of Issues under section 10 of the *Food Standards Australia New Zealand Act 1991***

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

##### *3.1.1 The protection of public health and safety*

The OCS establishes the ADI and, where applicable, the ARfD for the agricultural and veterinary chemicals. APVMA and FSANZ carry out estimations of dietary exposure to agricultural and veterinary chemicals and compare them to the ADI. Based on dietary exposure assessments, the residues associated with the proposed MRLs in this Application do not represent an unacceptable risk to public health and safety.

##### *3.1.2 The provision of adequate information relating to food to enable consumers to make informed choices*

This is not relevant for this Application.

##### *3.1.3 The prevention of misleading or deceptive information*

This is not relevant for this Application.

In addition to these objectives, subsection 10(2) requires FSANZ to have regard to a number of matters set out in paragraphs 10(2)(a) to (d). Each of these matters is discussed below.

##### *3.1.4 The need for standards to be based on risk analysis using the best available scientific evidence*

FSANZ considers proposed MRLs in accordance with the best available scientific evidence. The procedures adopted by FSANZ, the TGA and APVMA are based on a comprehensive examination of detailed scientific information.

That includes a rigorous toxicological assessment and dietary exposure assessments undertaken in accordance with international protocols.

### *3.1.5 The promotion of consistency between domestic and international food standards*

This is addressed in section 9.

### *3.1.6 The desirability of an efficient and internationally competitive food industry*

The inclusion of the requested MRLs would assist in permitting the legal sale of legally treated food. Varying the Code to include the proposed MRLs would promote trade and commerce and allow food industries to continue to be efficient and competitive.

### *3.1.7 The promotion of fair trading in food*

As the MRLs in the Code apply to all food whether produced domestically or imported, the inclusion of the MRLs would benefit all producers equally.

### *3.1.8 Any written guidelines formulated by the Ministerial Council for the purposes of this paragraph and notified to FSANZ*

To date the Ministerial Council has not made a written notification to FSANZ of any policy guidelines that are relevant to this Application.

## **4. Background**

### **4.1 The use of agricultural and veterinary chemicals**

In Australia, APVMA is responsible for registering agricultural and veterinary chemical products, granting permits for use of chemical products and regulating the sale of agricultural and veterinary chemical products. Following the sale of these products, the use of the chemicals is then regulated by State and Territory ‘control of use’ legislation.

Before registering such a product, APVMA must be satisfied that the use of the product will not result in residues that would be an undue risk to the safety of people, including people using anything containing its residues.

When a chemical product is registered for use or a permit for use granted, APVMA includes MRLs in its APVMA MRL Standard. These MRLs are then adopted into control of use legislation in some jurisdictions and assist States and Territories in regulating the use of agricultural and veterinary chemicals.

### **4.2 Maximum Residue Limit applications**

After registering the agricultural or veterinary chemical products, based on their scientific evaluations, APVMA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews the information provided by APVMA and validates whether the dietary exposure is within agreed safety limits.

If satisfied that the residues do not represent an unacceptable risk to public health and safety and subject to adequate resolution of any issues raised during public consultation, FSANZ will then agree to adopt the proposed MRLs into Standard 1.4.2 of the Code.

FSANZ then notifies the Ministerial Council of the adoption of the variation to the Code. If the Ministerial Council accepts the changes made by FSANZ, the MRLs are automatically adopted by reference under the food laws of the Australian States and Territories.

The inclusion of the MRLs in the Code has the effect of allowing legally treated produce to be legally sold, provided that the residues in the treated produce do not exceed the MRL. Changes to Australian MRLs reflect the changing patterns of agricultural and veterinary chemicals available to farmers. These changes include both the development of new products and crop uses, and the withdrawal of older products following review.

Appropriate toxicology, residue, animal transfer, processing and metabolism studies were provided to APVMA in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997* to support the MRLs in the commodities as outlined in this Application. Full evaluation reports for individual chemicals are available upon request from the relevant Project Coordinator at FSANZ on +61 2 6271 2222.

### **4.3 Maximum Residue Limits**

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

MRLs assist in indicating whether an agricultural or veterinary chemical product has been used according to its registered use and if the MRL is exceeded then this indicates a likely misuse of the chemical product.

MRLs are also used as standards for the international trade in food. In addition, MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases. As stated above, APVMA includes MRLs in its APVMA MRL Standard when it registers a chemical product for use or grant a permit for use. APVMA then notifies FSANZ of these MRLs so that FSANZ may consider them for inclusion in the Code. In relation to MRLs, FSANZ's role is to ensure that the potential residues in food do not represent an unacceptable risk to public health and safety.

FSANZ will not agree to adopt MRLs into the Code where the dietary exposure to the residues of a chemical could represent an unacceptable risk to public health and safety. In assessing this risk, FSANZ conducts dietary exposure assessments in accordance with internationally accepted practices and procedures.

In summary, the MRLs in APVMA MRL Standard are used in some jurisdictions to assist in regulating the use of agricultural and veterinary chemical products under State and Territory 'control-of-use' legislation.

Whereas the MRLs in the Code apply in relation to the sale of food under State and Territory food legislation and the inspection of imported foods by the Australian Quarantine and Inspection Service.

#### **4.4 Food Standards-setting in Australia and New Zealand**

The Treaty excluded MRLs for agricultural and veterinary chemicals in food from the joint food standards setting system. Australia and New Zealand separately and independently develop MRLs for agricultural and veterinary chemicals in food.

#### **4.5 Trans Tasman Mutual Recognition Arrangement**

Following the commencement of the Trans Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand on 1 May 1998:

- food produced or imported into Australia, which complies with Standard 1.4.2 of the Code can be legally sold in New Zealand; and
- food produced or imported into New Zealand, which complies with the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard, 1999* can be legally sold in Australia.

#### **4.6 Limit of Quantification**

Some of the proposed MRLs in this Application are at the limit of quantification (LOQ) and are indicated by an \* in the ‘Summary of the Requested MRLs for each Chemical...’ (Attachment 2). The LOQ is the lowest concentration of an agricultural or veterinary chemical residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. The inclusion of the MRLs at the LOQ means that no detectable residues of the relevant chemical should occur. FSANZ incorporates MRLs at the LOQ in the Code to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

#### **4.7 MRLs for Permits**

Some of the proposed MRLs in this Application are temporary and are indicated by a ‘T’ in the ‘Summary of the Requested MRLs for each Chemical...’ (Attachment 2). 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 APVMA’s website at [www.apvma.gov.au/](http://www.apvma.gov.au/) or by contacting APVMA on +61 2 6272 5158.

## **5. Evaluation of Issues Raised in Public Comment**

Submissions were received from:

- Kelly Bullock.
- Food Technology Association of Victoria.
- Queensland Health.
- Kumara de Silva.
- New South Wales Food Authority.

The submissions from Kelly Bullock, Food Technology Association of Victoria, the New South Wales Food Authority and Queensland Health supported this Application.

The submission from Kumara de Silva did not support the establishment MRLs for new agricultural and veterinary chemicals.

### **5.1 Ractopamine residues in pork commodities**

In relation to the proposed MRLs for ractopamine, the submission from Queensland Health asked whether the consumption of pork containing residues of ractopamine would result in weight gain.

#### *5.1.1 Evaluation*

As part of its assessment of this chemical, APVMA has carried out a review of the toxicology of ractopamine. Their advice to FSANZ was that the dietary exposure to residues of this chemical would not be high enough to permit any physiological or pharmacological effects i.e. there would be no weight gain in humans.

Additionally, ractopamine is rapidly metabolised (the elimination half-life in humans is <4 hours), which means that chronic dietary exposure to potential residues of ractopamine will not lead to accumulation of the drug in the body nor any physiological effects in humans.

### **5.2 Identification of New Chemicals**

Kumara de Silva was concerned that the assessment reports did not clearly identify whether the proposed MRLs are for existing chemicals or new chemicals.

#### *5.2.1 Evaluation*

FSANZ has taken steps to remedy this in that in the future Attachment 2 (A Summary of the Requested MRLs for Each Chemical...) of the assessment reports will indicate the inclusion of proposed MRLs for new chemicals.

### **5.3 Legislation governing the registrations and enforcement of use of agricultural and veterinary chemicals.**

The submission from Kumara de Silva commented on the 'chemical usage in agricultural'.

### 5.3.1 Evaluation

FSANZ does not regulate nor enforce the use of agricultural and veterinary chemicals in Australia and has no legislative power to control to do so. FSANZ does not have any statutory role in questioning the merits of or enforcement of the use of agricultural or veterinary chemicals.

In Australia, APVMA is responsible for registering agricultural and veterinary chemical products, granting permits for use of chemical products and regulating the sale of agricultural and veterinary chemical products. Following the sale of these products, the use of the chemicals is then regulated by State and Territory 'control of use' legislation.

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ ensures that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. In assessing this risk, FSANZ conducts dietary exposure assessments in accordance with internationally accepted practices and procedures. FSANZ will not agree to adopt MRLs into the *Australia New Zealand Food Standards Code* (the Code) where the dietary exposure to the residues of a chemical could represent an unacceptable risk.

The inclusion or exclusion of an MRL in the Code has limited impact on whether or not a chemical product is used. Chemical products are used in accordance with registered labels or permit approvals and are not used on the basis of the MRLs in the Code. The only significance of an MRL is that treated produce cannot be legally sold unless the treated produce complies with the MRLs in the Code.

## 5.4 Exceedance of the MRLs

The submission from Kumara de Silva stated that 'although it seems to be safe from the point of view of legal requirements, there are many instances around the world, where chemicals proved to be particularly dangerous to human health'.

### 5.4.1 Evaluation

Although a residue exceedance of the MRL in a food is in breach of the Code, it does not necessarily indicate a risk to public health and safety from the dietary exposure. It is the comparison of the estimated dietary exposure to the acceptable daily intake (ADI) and, where appropriate, the acute reference dose (ARfD), and not the MRL, which is the measure of risk to public health and safety from dietary exposure.

FSANZ has reviewed the information provided by APVMA and has validated that the estimated dietary exposure for the proposed MRLs in this Application is within agreed safety limits. FSANZ is satisfied that the potential residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

## 5.5 Possibility of the Occurrence of Synergistic Effects

The submission from Kumara de Silva stated that 'the combined effect of a number of chemicals is not well understood.'

### 5.5.1 Evaluation

The reasons why testing for these effects are not carried out are as follows:

- The low levels of residues in food are unlikely to have any significant effect on metabolism or toxicity of other chemicals and the mechanisms of action are quite different in most cases; and
- There is very little scientific evidence of true synergy between pesticide residues in relation to potential toxicity from the data available. For testing of synergistic effects to be appropriate there would need to be a reasonable explanation for the mechanism of this synergy - in most cases this explanation does not exist.

FSANZ has written to Kumara de Silva addressing his concerns. However, given that many of this Submitter's concerns relate to the use of agricultural and veterinary chemicals, FSANZ has encouraged the submitter to consider providing submissions directly to the APVMA as part of its statutory consultation processes in its review of this chemical.

## 6. Regulatory Options

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

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

### 6.2 Option 2(a) – adopt the change to MRLs to delete or decrease some existing MRLs

Under this option, only those variations that were reductions and deletions would be approved for inclusion into the Code. The proposed increases and inclusions of new MRLs would not be approved.

### 6.3 Option 2(b) – adopt the changes to MRLs to include new or increase some existing MRLs

Under this option, only those variations that were increases and additions of MRLs would be approved for inclusion into the Code. The proposed decreases and deletions of MRLs would not be approved.

Option 2 has been arranged into two sub-options because the impacts of each sub-option are different. Splitting the option into two sub-options also allows a more detailed impact analysis. However, FSANZ cannot legally separate these two sub-options and may only accept or reject the Application.

## 7. Affected Parties

The parties affected by proposed MRL amendments include:

- consumers, including domestic and overseas customers;

- 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.

## **8. Impact Analysis**

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

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

#### *8.1.1 Benefits*

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of agricultural and veterinary chemicals;
- for growers and producers of domestic and export food commodities, the adoption of this option would not result in any discernable benefits;
- for importers, the adoption of this option would not result in any discernable benefits; and
- for Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable benefits.

#### *8.1.2 Costs*

- for consumers there are unlikely to be any discernable costs as the unavailability of some food from certain growers is likely to be seen as typical seasonal fluctuations in the food supply;
- for growers and producers of domestic and export food commodities, the adoption of this option would result in costs resulting from not being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Primary producers do not produce food or use chemical products to comply with MRLs. They use chemical products to control pests and diseases in accordance with the prescribed label conditions, and expect that the resulting residues will be acceptable and that the legally treated food can be legally sold. If the legal use of chemical products results in the production of food that cannot be legally sold under food legislation then primary producers will incur substantial losses. Major losses for primary producers would in turn impact negatively upon rural and regional communities;
- for importers, the adoption of this option would not result in any discernable costs; and

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

## **8.2 Option 2(a) – adopt the changes to MRLs to delete and decrease some existing MRLs**

### *8.2.1 Benefits*

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of agricultural and veterinary chemicals;
- for growers and producers of domestic and export food commodities, the adoption of this option would not result in any discernable benefits;
- for importers, the adoption of this option would not result in any discernable benefits; and
- for Australian Government, State and Territory agencies, the adoption of this option would foster community confidence that regulatory authorities are maintaining the standards to minimise residues in the food supply.

### *8.2.2 Costs*

- for consumers there are unlikely to be any discernable costs as the unavailability of some food from certain importers is likely to be seen as typical seasonal fluctuations in the food supply;
- for growers and producers of domestic and export food commodities, the adoption of this option is unlikely to result in any costs, as reductions in MRLs are adopted where this is practically achievable, with little or no impact on production costs;
- for importers, the adoption of this option may result in costs, as foods may not be able to be imported if these foods contained residues consistent with the MRLs proposed for deletion or reduction. Any MRL deletions or reductions have the potential to restrict the importation of foods and could potentially result in higher food costs and a reduced product range available to consumers, as foods that exceed the new, lower MRLs could not be legally imported or sold to consumers. To identify any restrictions and possible trade impacts, Codex MRLs and data on imported foods are addressed in section 9; and
- for Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable costs, although there would need to be an awareness of changes in the standards for residues in food.

### **8.3 Option 2(b) – adopt the changes to MRLs to include new and increase some existing MRLs**

#### *8.3.1 Benefits*

- for consumers, the major benefit would be potential flow on benefits resulting from the price and availability of food if growers can legally sell food containing residues consistent with increased MRLs or MRL additions;
- for growers and producers of domestic and export food commodities, the benefits of this option would result from being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Other benefits include the consistency between agricultural and food legislation thereby minimising compliance costs to primary producers;
- for importers, the adoption of this option would result in the benefit that food could be legally imported if it contained residues consistent with increased MRLs or MRL additions; and
- for Australian Government, State and Territory agencies, the benefits of this option would include the removal of discrepancies between agricultural and food legislation thereby creating certainty and allowing efficient enforcement of regulations.

#### *8.3.2 Costs*

- for consumers there are no discernable costs;
- for growers and producers of domestic and export food commodities, the adoption of this option would not result in any discernable costs;
- for importers, the adoption of this option would not result in any discernable costs; and
- for Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable costs, although there may be minimal impacts associated with slight changes to residue monitoring programs.

### **8.4 Conclusion**

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

- potential substantial costs to primary producers that may have a negative impact on their viability and in turn the viability of the rural and regional communities that depend upon the sale of the agricultural produce; and
- discrepancies between agricultural and food legislation which could have negative impacts on the compliance costs of primary producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

FSANZ's preferred approach is adopt Options 2(a) and 2(b) – to adopt the change to MRLs in the Code to include new or increase some existing MRLs and to decrease or delete some existing MRLs. FSANZ prefers this approach because:

- the residues associated with the MRL amendments would not result in an unacceptable risk to public health and safety (this benefit also applies to Option 1);
- the changes would minimise the potential costs to primary producers and rural and regional communities in terms of legally being able to sell legally treated food;
- the changes would minimise residues consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases; and
- the changes would remove discrepancies between agricultural and food legislation and assist enforcement.

Adopting option 2(a) may result in compliance costs for importers and industry where there are decreases or deletions of MRLs. However, there is no information to suggest how these costs would be incurred.

## **9. Consultation**

### **9.1 World Trade Organization Notification**

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

This Application contains variations to MRLs which are addressed in the international Codex standard. MRLs in this Application 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 Application was notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO SPS agreement because the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment. No WTO member made a submission in response to the notification.

#### *9.1.1 Codex MRLs*

The standards of the Codex Alimentarius Commission are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. FSANZ identified the proposed glyphosate MRL for rapeseed of 2 mg/kg to be more restrictive than the relevant Codex MRL of 10 mg/kg.

FSANZ recognised that the proposed deletion of this MRL may have had implications for the importation of food. FSANZ requested comments on the significance of the differences of the proposed MRL from the Codex MRL for imported foods. No submission was received addressing this difference.

### 9.1.2 *Imported Foods*

Agricultural and veterinary chemicals are used differently in countries other than in Australia because of different pests or diseases or because different products may be used. This means that residues in imported food may still be safe for human consumption, but may be different from those in domestically produced food.

Deletions or reductions of MRLs may affect the importation of foods. FSANZ has identified the commodities of rapeseed, rape seed oil and soya bean oil which may have residues complying with existing MRLs even though the relevant MRLs are no longer required for domestically produced food. This is because imported food may contain residues consistent with the MRLs proposed for deletion or reduction.

To assist in identifying possible impacts where imported food may be affected, FSANZ requested comment as to any possible ramifications for imports of the deletion or reductions of the MRLs in this Application. No submissions were received that addressed the proposed MRLs of the relevant agricultural chemicals in imported food.

## **10. Conclusion and Recommendation**

The dietary exposure assessments indicate that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. APVMA has already registered the chemical products and rejection of the MRLs would result in legally treated food not being able to be legally sold. Therefore, accepting the requested changes will benefit all stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

## **11. Implementation and Review**

The use of chemical products and MRLs are under constant review as part of APVMA's Existing Chemical Review Program. In addition, regulatory agencies involved in the regulation of chemical products continue to monitor health, agricultural and environmental issues associated with the use of chemical products. The residues in food are also monitored through:

- State and Territory residue monitoring programs;
- Australian Government programs such as the National Residue Survey; and
- dietary exposure surveys such as the Australian Total Diet Survey.

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

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

## ATTACHMENTS

1. Draft Variations to the *Australia New Zealand Food Standards Code*.
2. A Summary of the Requested MRLs for each Chemical and an Outline of the Information Supporting the Requested Changes to the *Australia New Zealand Food Standards Code*.
3. Background to Dietary Exposure Assessments.
4. Summary Submissions Received.

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

To commence: on gazettal

[1] *Standard 1.4.2 of the Australia New Zealand Food Standards Code is varied by –*[1.1] *omitting from Schedule 1 under the entry for the following chemicals the chemical residue definitions, substituting –*

<b>GLYPHOSATE</b> SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
<b>RACTOPAMINE</b> RACTOPAMINE	
<b>THIAMETHOXAM</b> COMMODITIES OF PLANT ORIGIN: THIAMETHOXAM COMMODITIES OF ANIMAL ORIGIN: SUM OF THIAMETHOXAM AND N-(2-CHLORO- THIAZOL-5-YLMETHYL)-N'-METHYL-N'-NITRO- GUANIDINE, EXPRESSED AS THIAMETHOXAM	

[1.2] *inserting in Schedule 1 –*

<b>ACIBENZOLAR-S-METHYL</b> SUM OF ACIBENZOLAR-S-METHYL AND BENZO[1,2,3]THIADIAZOLE-7-CARBOXYLIC ACID METABOLITE, EXPRESSED AS ACIBENZOLAR-S- METHYL	
COTTON SEED	T*0.02

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

<b>GLYPHOSATE</b> SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
RAPE SEED OIL, CRUDE	T0.05
<b>SPINOSAD</b> SUM OF SPINOSYN A AND SPINOSYN D	
SORGHUM	T*0.01

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

<b>AZOXYSTROBIN</b> AZOXYSTROBIN	
BARLEY	T*0.02
WHEAT	T*0.02
<b>BIFENAZATE</b> SUM OF BIFENAZATE AND BIFENAZATE DIAZENE (DIAZENECARBOLIC ACID, 2-(4-METHOXY-[1,1'- BIPHENYL-3-YL] 1-METHYLETHYL ESTER), EXPRESSED AS BIFENAZATE	
APRICOT	0.5
NECTARINE	0.5
PEACH	2
PLUM (INCLUDING PRUNES)	0.5
<b>IMAZAMOX</b> IMAZAMOX	
BROAD BEANS (DRY) (FAVA BEANS)	T*0.05
<b>ISOXAFLUTOLE</b> THE SUM OF ISOXAFLUTOLE, 2- CYCLOPROPYLCARCONYL-3-(2-METHYLSULFONYL- 4-TRIFLUOROMETHYLPHENYL)-3- OXOPROPANENITRILE AND 2-METHYLSULFONYL-4- TRIFLUOROMETHYLBENZOIC ACID EXPRESSED AS ISOXAFLUTOLE	
CEREAL GRAINS	T*0.05
EGGS	T*0.05
POULTRY, EDIBLE OFFAL OF	T*0.05
POULTRY MEAT	T*0.05
<b>METHOMYL</b> SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL <i>SEE ALSO</i> THIODICARB	
CELERY	3
<b>METOLACHLOR</b> METOLACHLOR	
TOMATO	T*0.01
<b>SPINOSAD</b> SUM OF SPINOSYN A AND SPINOSYN D	
CEREAL GRAINS	T1
<b>THIAMETHOXAM</b> COMMODITIES OF PLANT ORIGIN: THIAMETHOXAM COMMODITIES OF ANIMAL ORIGIN: SUM OF THIAMETHOXAM AND N-(2-CHLORO- THIAZOL-5-YLMETHYL)-N'-METHYL-N'-NITRO- GUANIDINE, EXPRESSED AS THIAMETHOXAM	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.005

POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02

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

<b>GLYPHOSATE</b> SUM OF GLYPHOSATE AND AMINOMETHYLPHOSPHONIC ACID (AMPA) METABOLITE, EXPRESSED AS GLYPHOSATE	
RAPE SEED	2
<b>PERMETHRIN</b> PERMETHRIN, SUM OF ISOMERS	
MEAT (MAMMALIAN) (IN THE FAT)	1
<b>RACTOPAMINE</b> RACTOPAMINE	
PIG FAT	0.05
PIG, KIDNEY	0.2
PIG, LIVER	0.2
PIG MEAT	0.05
<b>SPINOSAD</b> SUM OF SPINOSYN A AND SPINOSYN D	
EDIBLE OFFAL (MAMMALIAN)	T0.2
MEAT (MAMMALIAN) (IN THE FAT)	T1
MILKS	T0.1
<b>THIACLOPRID</b> THIACLOPRID	
STONE FRUITS	2

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

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

#### **NOTES ON TERMS USED IN THE TABLE**

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

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

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

NEDI - National Estimated Dietary Intake - The NEDI represents a more realistic estimate of dietary exposure and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions; the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials other than the MRL to represent pesticide residue levels. In most cases the NEDI is still an overestimation because the above data is often not available and in these cases the MRL is used.

NESTI - National Estimated Short Term Intake - The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated based on consumption of raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis. FSANZ has used ARfDs set by OCS and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey (NNS) and the MRL when the STMR is not available to calculate the NESTIs.

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.

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

<p><b>Fipronil</b> Berries and other small fruits [except grapes and strawberry]</p> <p>Berries and other small fruits [except wine grapes]</p> <p>Strawberry</p>	<p>Delete</p> <p>Add</p> <p>Delete</p>	<p>T*0.01</p> <p>T*0.01</p> <p>T0.5</p>	<p>This chemical is a phenylpyrazole. APVMA has extended the trial permit for this chemical to control Western Flower Thrip in strawberry. An MRL for fipronil on strawberry is required to accommodate the use as a bait for fruit fly. This use is not expected to result in residues and so the MRL is proposed at the LOQ.</p> <p>NESTI = &lt;1% of ARfD for berries</p> <p>NEDI = 60% of ADI</p>
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The NESTI is an assessment of the acute exposure which is compared to the acute reference dose (ARfD). More information is in the glossary on the NESTI and the ARfD. To be acceptable to FSANZ, the NESTI must be less than 100% of the ARfD because the ARfD is considered the 'safe' level.

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

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

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

Name of the Chemical (in bold)

Food for which the proposed MRL is to apply.

Whether the proposed MRL is being added or deleted.

The 'T' means the MRL is temporary and under review.

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

Class of Chemical

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

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

<p><b>Chlorpyrifos</b> Coffee beans</p>	<p>Add</p>	<p>T0.5</p>	<p>APVMA extension of the permit for use for the control of pests. The 18<sup>th</sup> ATDS (1996) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to 0.53% of ADI for adult males and up to 1.42% for 2 year olds. The 19<sup>th</sup> ATDS (1998) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to 0.51% of ADI for adult males and up to 2.55% of ADI for 2 year olds. NEDI = 83% of ADI</p>
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Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and typically result because of the different range of foods in the individual surveys.

### Glossary

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

**SUMMARY OF THE REQUESTED MRLS FOR APPLICATION A526 - MRLs**

<b>Chemical</b> Food	<b>MRL</b> (mg/kg)	<b>INFORMATION</b>
<b>Acibenzolar-S-methyl</b> Cotton seed	Insert      T*0.02	This is a new chemical. It is a plant host defence inducer, fungicide. APVMA has issued a permit for this chemical to be used to control fungal diseases on cotton plants. NESTI = <1% of ARfD. NEDI = <1% of ADI.
<b>Azoxystrobin</b> Barley Wheat	Insert      T*0.02 Insert      T*0.02	This chemical is a strobilin fungicide. APVMA has issued a permit for this chemical to be used to control fungal diseases on cereal crops. NEDI = <1% of ADI.
<b>Bifenazate</b> Apricot Nectarine Peach Plum (including prunes)	Insert      0.5 Insert      0.5 Insert      2 Insert      0.5	This chemical is a biphenyl miticide used to control mites on Stone fruit crops. Apricot NESTI = 7% of ARfD for 2 to 6 y.o. and 1% of the ARfD for the whole population. Nectarine NESTI = 5 % of ARfD for 2 to 6 y.o. and 2% for the whole population. Peach NESTI = 29 % of ARfD for 2 to 6 y.o. and 9% for the whole population. Plum (including prunes) NESTI = 2 % of ARfD for 2 to 6 y.o. and <1% for the whole population. NEDI = 4% of ADI.
<b>Glyphosate</b> Rape seed  Rape seed oil, crude	Omit      T5 Substitute      2  Delete      T0.05	This chemical is a glycine derivative used to control weeds on rape seed and soya bean crops. NEDI = 6% of ADI.

<b>Imazamox</b> Broad beans (dry) (fava beans)	Insert	T*0.05	This chemical is an imidazolinone, herbicide. APVMA has issued a permit for this chemical to be used to control weeds on broad bean crops. NEDI = <1% of ADI.
<b>Isoxaflutole</b> Cereal Grains Eggs Poultry, edible offal of Poultry meat	Insert Insert Insert Insert	T*0.05 T*0.05 T*0.05 T*0.05	This chemical is an isoxazole, herbicide. APVMA has issued a permit for this chemical to be used to control weeds prior to planting cereal crops. NEDI = 3% of ADI.
<b>Methomyl</b> Celery	Insert	3	This chemical is a carbamate insecticide used to control thrips on celery crops. In the 19 <sup>th</sup> (1998) ATDS methomyl residues were not detected in any surveyed foods. At this time the OCS has not set an Australian ARfD. The NESTI calculated using the Codex ARfD. NESTI = 68 % of ARfD for 2 to 6 y.o. and 21% of ARfD for the whole population. NEDI = 82% of ADI.
<b>Metolachlor</b> Tomato	Insert	T*0.01	This chemical is a chloroacetamide, herbicide. APVMA has issued a permit for this chemical to be used to control weeds prior to planting tomato crops NEDI = <1% of ADI
<b>Permethrin</b> Meat (mammalian) (in the fat)	Omit Substitute	0.3 1	This chemical is a synthetic pyrethroid insecticide used to control insects on herbs. The 20 <sup>th</sup> ATDS (2000) dietary exposure estimate for permethrin, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 16% of ADI.
<b>Ractopamine</b> Pig fat  Pig, kidney  Pig, liver  Pig meat	Omit Substitute  Omit Substitute  Omit Substitute  Omit Substitute	T0.02 0.05  T0.1 0.2  T0.05 0.2  T0.02 0.05	This chemical is a phenethanolamine ( $\beta$ -agonist) used to increase the rate of weight gain in pigs. NESTI for pig fat = <1% of ARfD for 2-6 years old and the whole population. NESTI for pig meat = 25% of ARfD for 2-6 years old and 13% for the whole population. NESTI for pig offal = 43 % of ARfD for 2-6 years old and 67% for the whole population. NEDI = 2% of ADI

<p><b>Spinosad</b> Cereal grains Edible offal (mammalian)</p> <p>Meat (mammalian) (in the fat)</p> <p>Milks</p> <p>Sorghum</p>	<p>Insert T1 Omit 0.05 Substitute T0.2</p> <p>Omit 0.2 Substitute T1</p> <p>Omit 0.02 Substitute T0.1</p> <p>Delete T*0.01</p>	<p>This chemical is an insecticide. APVMA has issued a permit for this chemical to be used to control arthropod pests in stored grain. Livestock may consume treated grain, and animal feeding studies support changing some of the animal commodity MRLs.</p> <p>NEDI = 29% of ADI</p>
<p><b>Thiacloprid</b> Stone fruits</p>	<p>Omit T2 Substitute 2</p>	<p>This chemical is neonicotinoid insecticide used to control insects on stone fruit crops. A WHP of 14 days has been set for stone fruits except peach, which a WHP of 21 days has been established. At a WHP 14 days the NESTI were as follows: Apricot NESTI = 65 % of ARfD for 2 to 6 y.o. and 24% for the whole population. Cherry NESTI = 40 % of ARfD for 2 to 6 y.o. and 5% of the ARfD for the whole population. Nectarine NESTI = 69 % of ARfD for 2 to 6 y.o. and 29% for the whole population. Plums (including prunes) NESTI = 61% of ARfD for 2 to 6 y.o. and 22% for the whole population. At a WHP of 21 days the NESTI for peach was 27 % of ARfD for 2 to 6 y.o. and 11% of the ARfD for the whole population. NEDI = 11% of ADI.</p>
<p><b>Thiamethoxam</b> Edible offal (mammalian) Eggs Meat (mammalian) Milks Poultry, edible offal of Poultry meat</p>	<p>Insert *0.02 Insert *0.02 Insert *0.02 Insert *0.005 Insert *0.02 Insert *0.02</p>	<p>This chemical is neonicotinoid insecticide used to control flies in animal housings.</p> <p>NEDI = &lt;1% of ADI.</p>

## Background to Dietary Exposure Assessments

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code, 1994 (Ag Vet Code Act)* requires APVMA to be satisfied that there will not be any appreciable risk to the consumer, to the person handling, applying or administering the chemical, to the environment, to the target crop or animal or to trade in an agricultural commodity.

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

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

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

### Determination of the residues of a chemical in a treated food

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

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

### Determination of the acceptable health standard for a chemical in food

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

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

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

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

### **Calculating the dietary exposure**

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

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

### **Chronic Dietary Exposure Assessment**

The National Estimated Daily Intake (NEDI) represents a realistic estimate of chronic dietary exposure if the chemical residue data are available and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions and the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials rather than the MRL to represent pesticide residue levels. When adequate information is available, monitoring and surveillance data or total diet studies may also be used such as the Australian Total Diet Survey (ATDS).

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

In conducting chronic dietary exposure assessments, APVMA and FSANZ consider the residues that could result from the use of a chemical product on all foods. If specific data on the residues are not available then a cautious approach is taken and the MRL is used. The residues that are likely to occur in all foods are then multiplied by the daily consumption of these foods derived from individual dietary records from the latest 1995 National Nutrition Survey (NNS). These calculations provide information on the level of a chemical that is consumed for each food and take into account the consumption of processed foods e.g. apple pie and bread. These calculations for each food are added together to provide the total dietary exposure to a chemical from all foods.

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

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

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

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

### **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 when an ARfD has been determined for a chemical. 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. The residues of a chemical in a specific food is multiplied by 97.5 percentile food consumption of that food, a variability factor is applied and this result is compared to the ARfD. NESTIs are calculated from ARfDs set by the OCS and the Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey and the MRL when the data on the actual residues in foods are not available. FSANZ considers that the acute dietary exposure to the residues of a chemical is acceptable where the acute dietary exposure does not exceed the ARfD.

**Summary of Submissions Received**

<b>Submitter</b>	<b>Comments raised</b>
Kelly Bullock	Supported this Application.
Kumara de Silva	Did not support the establishment of MRLs for new chemicals.
Food Technology Association of Victoria.	Supported this Application.
New South Wales Food Authority	Supported this Application.
Queensland Health	Supported this Application.