EXPLANATORY STATEMENT

APPLICATION A547

MAXIMUM RESIDUE LIMITS (SEPTEMBER, OCTOBER, NOVEMBER, DECEMBER 2004)

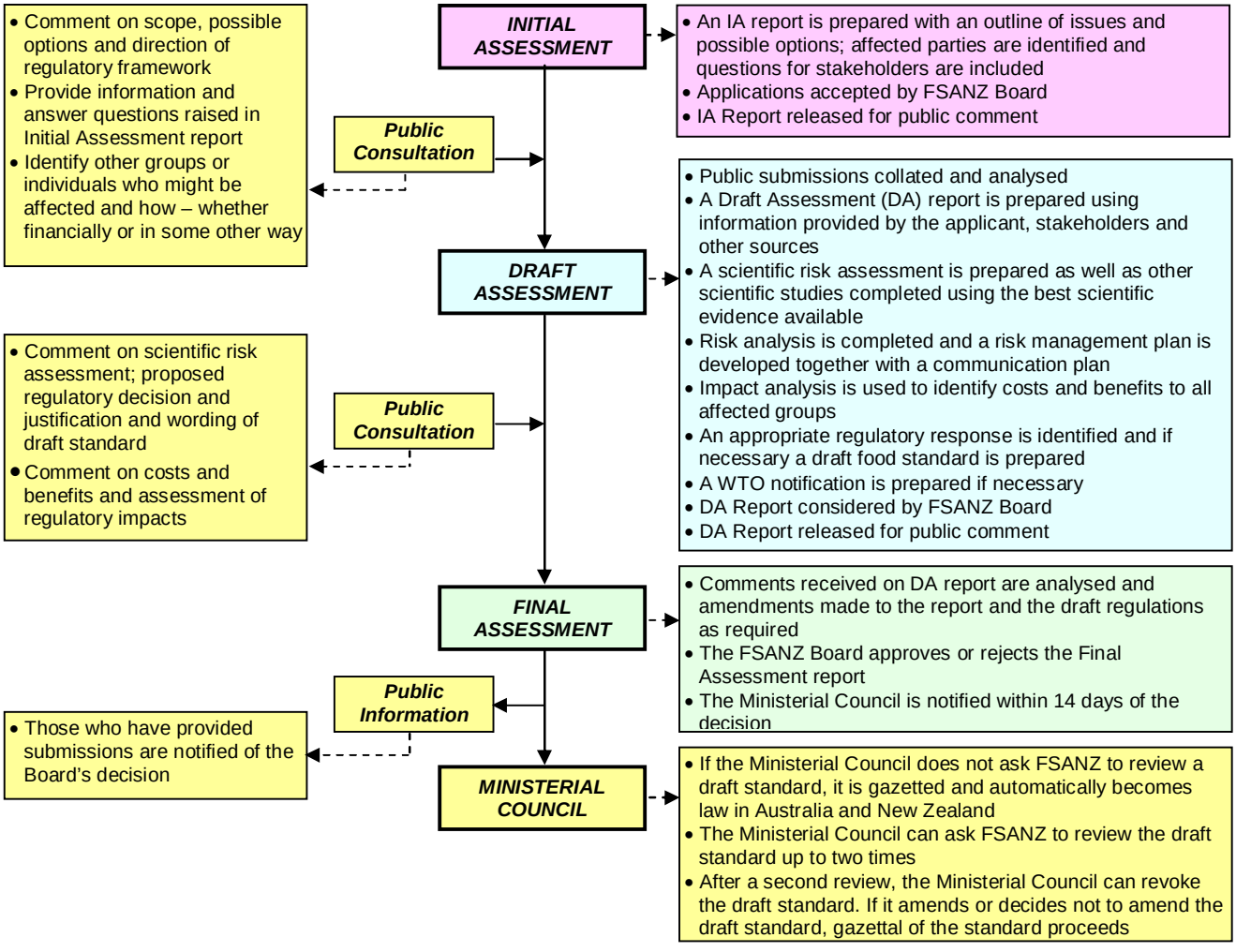
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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* (the 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 A547 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.

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

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

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

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Executive Summary and Statement of Reasons

This Application (A547) seeks to amend Maximum Residue Limits (MRLs) for non-antibiotic agricultural and veterinary chemicals in Standard 1.4.2 – Maximum Residue Limits of the Code. It is a routine application from the Australian Pesticide and Veterinary Medicines Authority (APVMA), to update the *Australia New Zealand Food Standards Code* (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. No submissions were received from WTO Members.

Decision

The MRL amendments under consideration in this Application are:

- the changing of the residue definitions for; abamectin, dinitolmide, fluometuron and imidacloprid;
- the addition of the MRLs for the new chemicals fenbuconazole and flumioxazin;
- the deletion of all entries for the chemical fenchlorazole-ethyl;
- the deletion of MRLs for certain foods for the chemical spinosad;
- the addition of MRLs for certain foods for the chemicals chlorothalonil, cyproconazole, difenoconazole, etoxazole and fluazifop-butyl;
- the changing of MRLs for certain foods for the chemicals azoxystrobin, cyproconazole, dithiocarbamates, etoxazole, imidacloprid, methidathion, spinosad and trifloxystrobin; and
- the addition of temporary MRLs for certain foods for the chemicals abamectin, azoxystrobin, chlorpyrifos, dimethomorph and spinosad.

Refer to Attachment 1 of Final Assessment Report for MRL levels.

Statement of Reasons

FSANZ recommends accepting and progressing this Application for the following reasons:

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

- This Application is not so similar to any previous application that it ought not be accepted.

- The 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 of the Therapeutic Goods Administration (OCS) 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, an acute reference dose (ARfD).

- FSANZ has undertaken a regulation impact assessment and 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 17 September, 15 October, 8 November and 9 December 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 the APVMA MRL Standard.

1.1 Summary of proposed MRLs

The MRL amendments under consideration in this Application are:

- the changing of the residue definitions for; abamectin, dinitolmide, fluometuron and imidacloprid;
- the addition of the MRLs for the new chemicals fenbuconazole and flumioxazin;
- the deletion of all entries for the chemical fenchlorazole-ethyl;
- the deletion of MRLs for certain foods for the chemical spinosad;
- the addition of MRLs for certain foods for the chemicals chlorothalonil, cyproconazole, difenoconazole, etoxazole and fluazifop-butyl;
- the changing of MRLs for certain foods for the chemicals azoxystrobin, cyproconazole, dithiocarbamates, etoxazole, imidacloprid, methidathion, spinosad and trifloxystrobin; and
- the addition of temporary MRLs for certain foods for the chemicals abamectin, azoxystrobin, chlorpyrifos, dimethomorph and spinosad.

In considering the issues associated with MRLs it should be noted that MRLs and amendments to MRLs in the Code 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.

1.2 Use of the ARfD of the Joint Meeting on Pesticide Residue for Imidacloprid

The OCS has not established an Australian ARfD for imidacloprid. However, the Joint Meeting on Pesticide Residues (JMPR) has established an ARfD of 0.4 mg/kg body weight for this chemical. OCS has suggested that the APVMA formally request that the OCS consider the establishment an Australian ARfD for this chemical.

In the interim, while this request is being considered, FSANZ has carried out an estimated short term dietary exposure for the potential residues of imidacloprid for citrus fruits and sugar associated with the proposed MRLs using the JMPR ARfD. FSANZ has concluded that there is no unacceptable risk to public health and safety from the estimated short term dietary exposure to the potential residues of this chemical associated at the proposed MRLs for imidacloprid.

1.3 Antibiotic MRLs

There are no MRLs for antibiotic[1] residues in this Application.

1.4 Deleting spinosad MRL for sorghum

As part of this Application APVMA has requested that FSANZ delete the MRL for spinosad for sorghum at T0.05 mg/kg from the Code. However, the latest edition of the Code (Amendment No. 76) includes an MRL for spinosad for sorghum at *0.01 mg/kg; this MRL is to be omitted as part of a previous application (A526). Therefore, as there is no MRL for spinosad for sorghum at T0.05 mg/kg in the Code and the current entry is to be omitted as part of a previous application, FSANZ will not be deleting the MRL for spinosad for sorghum 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 its APVMA MRL Standard. The approval of the use of these products now means that there is a discrepancy between the potential residues associated with the use of the relevant agricultural and/or veterinary chemical and the MRLs in the Code. This has led to the possibility that legally treated food may not comply with the Code.

2.2 This draft variation

The draft variations for particular chemicals, chemical definitions, Maximum Residue Limits and commodities in Attachment 1 to this Assessment Report, may differ form that which is in the current gazetted version of Schedule 1 of Standard 1.4.2 of the Food Standards Code. The draft variation for spinosad and etoxazole, anticipates changes to the Food Standard Code as promulgated in previous applications.

3. Objective

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

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

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

[1] An antibiotic is a chemical inhibitor of the growth of organisms produced by a microorganism.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed MRLs.

4. Background

4.1 The use of agricultural and veterinary chemicals

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

Before registering such a product, APVMA must be satisfied that the use of the product will not result in residues that would be an unacceptable risk to the safety of people, including occupational health and safety issues.

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

FSANZ then notifies the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) of the 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. 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, 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 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 the APVMA website at www.apvma.gov.au or by contacting APVMA on +61 2 6272 5158.

5. EVALUATION OF ISSUES RAISED IN PUBLIC SUBMISSIONS

Submissions were received from Queensland Health, Food Technology Association of Victoria (FTAV), the Victorian Department of Human Services and the Australian Food and Grocery Council.

The submission from FTAV supported the Application. FTAV supported option 2(a) to decrease and delete existing MRLs and option 2(b) to adopt changes to MRL to include new and increase existing MRLs.

5.1 Submission from Queensland Health

Supports option 2(a) and 2 (b) to adopt changes to MRLs to include new or increase existing MRLs. The submission from Queensland Health brought to FSANZ's attention an anomaly under the listing for 'spinosad' where the current amendments do not include cucumber and soya bean (dry), which are proposed to be deleted.

The same anomaly was observed for azoxystrobin, where the current Code does not include 'barley' and 'wheat' and the MRLs listed under etoxazole.

5.1.1 Evaluation

The Queensland Health submission is correct that anomalies do exist for spinosad and etoxazole (but not for azoxystrobin) [2] where the Code does not include those commodities requested for deletion. This is because a previous Application had requested insertion of specific foods for those chemicals and this Application (A547) requested an amendment to delete those commodities.

FSANZ receives new amendments to MRLs, notified by the APVMA each month and currently batches together 3 months of MRLs applications. In order to facilitate a greater degree of harmonisation with the APVMA MRL standard and the Code, FSANZ drafts amendments to the Code as FSANZ becomes aware of the new proposed changes to any MRL. In practice, this occasionally means that amendments progress through the system with a new Application, updating a particular MRL for a chemical/food commodity combination, although the previous MRL may not have been currently Gazetted in the Code.

This arises due to the legislated procedural requirements in the current MRL setting of FSANZ, and in addition, the 60-day notification and consideration of the Ministerial Council. FSANZ considers that the consideration of MRL amendments to the Code should parallel the APVMA MRL Standard amendments even if this means consulting upon amendments to existing MRLs that have not yet been gazetted in the Code. This ensures that all MRL amendments are consulted upon, facilitates the legal and correct usage of the chemical and ensures an orderly consideration of MRL amendments.

5.2 Submission from the Victorian Department of Human Services

Supports option 2(a) and 2(b). Notes that the approach to include the sum of all isomers and metabolites of each chemical differs from the approach taken by Codex.

5.2.1 Evaluation

Although the residue definition may not be consistent with Codex, FSANZ incorporates the residue definition that the APVMA prescribes in Standard 1.4.2 as being the most up-to-date and relevant for the chemical registered in Australia by the APVMA.

5.3 Submission from the Australian Food and Grocery Council

The AFGC support Option 2(a) and identified a few potential problems for Option 2(a), however suggested that FSANZ determine the potential impact on importation of soya beans and on the oil crushing industry if spinosad is deleted. The deletion of fenchlorazole-ethyl is unlikely to impact imports of barley, chick peas and wheat as Australia is the net exporter.

[2] MRLs exist for barley and wheat of T0.02 in the Code

5.3.1 Evaluation

MRL deletions have the potential to restrict the importation of foods and could potentially result in a reduced product range available to consumers, as foods could not be legally imported or sold to consumers. However, no submissions were received from specific industry sectors that addressed the likely effects on trade or importation for the relevant food commodities if the proposed deletion of spinosad for soya beans takes place.

6. 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 omit or decrease some existing MRLs.

Under this option, only those variations that were reductions and omissions 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 insert new or increase some existing MRLs.

Under this option, only those variations that were increases and insertions of MRLs would be approved for inclusion into the Code. The proposed decreases and omissions 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 this 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. The information needed to make a final assessment of this proposal will include information from public submissions.

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 are addressed in section 9.1.1 and data on imported foods are addressed in section 9.1.2; 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.

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. MRLs prescribed in the Code constitute a mandatory requirement applying to all food products of a particular class whether produced domestically or imported. Food products exceeding their relevant MRL set out in the Code cannot legally be supplied in Australia.

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.

FSANZ made a Sanitary and Phytosanitary notification to the WTO for this Application 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 on this Application.

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. The following table lists the variations to MRLs in this Application which are addressed in the international Codex standard.

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
Fenbuconazole		
Banana	0.5	0.05
Edible offal (mammalian)	*0.01	*0.05 (Cattle kidney and liver)
Eggs	*0.01	*0.05
Meat (mammalian)	*0.01	*0.05 (Cattle meat)
Milks	*0.01	*0.05 (Cattle milk)
Nectarine	0.5	
Poultry, edible offal of	*0.01	*0.05
Poultry meat	*0.01	*0.05
Stone fruits [except nectarine]	T1	0.5 (Apricots)

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 imported food which may be complying with existing MRLs even though these existing 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 has compiled the following table of foods that have MRLs that are proposed for deletion and/or reduction and sought comment on any impacts of these reductions or deletions.

Chemical Food
Fenchlorazole-ethyl
Barley
Chick-pea (dry)
Rye
Triticale
Wheat
Spinosad
Sorghum
Soya bean

10. 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 to adopt Options 2(a) and 2(b) –change MRLs in the Code to include new or increase some existing MRLs and to delete or decrease 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 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.

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.

12. Recommendation

FSANZ recommends progressing this Application for the following reasons:

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

- This Application is not so similar to any previous application that it ought not be accepted.

- The 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 of the Therapeutic Goods Administration (OCS) 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, an acute reference dose (ARfD).

- FSANZ has undertaken a preliminary regulation impact assessment process. That process concluded that the amendment to the Code is necessary, cost-effective and of benefit to both producers and consumers.

- None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed changes.

Attachments

1. Draft 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.

Attachment 1

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 *all entries for the following chemicals –*

Fenchlorazole-ethyl

[1.2] *omitting from* Schedule 1 *the residue definition for the chemical appearing in* Column 1 *of the Table to this sub-item, substituting the residue definition appearing in* Column 2 –

COLUMN 1	COLUMN 2
ABAMECTIN	SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B
DINITOLMIDE	SUM OF DINITOLMIDE AND ITS METABOLITE 3-AMINO-5-NITRO-O-TOLUAMIDE, EXPRESSED AS DINITOLMIDE EQUIVALENTS
FLUOMETURON	SUM OF FLUOMETURON AND 3-TRIFLUOROMETHYLANILINE, EXPRESSED AS FLUOMETURON
IMIDACLOPRID	SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID

[1.3] *inserting in* Schedule 1 –

FENBUCONAZOLE FENBUCONAZOLE	
BANANA	0.5
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
NECTARINE	0.5
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
STONE FRUITS [EXCEPT NECTARINE]	T1
FLUMIOXAZIN FLUMIOXAZIN	
BROAD BEAN (DRY)	*0.1
CEREAL GRAINS	*0.05
CHICK-PEA (DRY)	*0.1
COTTON SEED	*0.1
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
FIELD PEA (DRY)	*0.1
LENTIL (DRY)	*0.1
LUPIN (DRY)	*0.1
MEAT (MAMMALIAN)	*0.01

MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
RAPE SEED	*0.1

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

SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
CUCUMBER	0.2
SOYA BEAN (DRY)	T0.05

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

ABAMECTIN SUM OF AVERMECTIN B1A, AVERMECTIN B1B AND (Z)-8,9 AVERMECTIN B1A, AND (Z)-8,9 AVERMECTIN B1B	
GROUND CHERRIES	T0.01
AZOXYSTROBIN AZOXYSTROBIN	
BANANA	T0.5
CHLOROTHALONIL CHLOROTHALONIL	
PEAS (PODS AND SUCCULENT, IMMATURE SEEDS)	10
CHLORPYRIFOS CHLORPYRIFOS	
PEPPERS, SWEET	T1
CYPROCONAZOLE CYPROCONAZOLE, SUM OF ISOMERS	
EGGS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
DIFENOCONAZOLE DIFENOCONAZOLE	
MACADAMIA NUTS	*0.01
DIMETHOMORPH SUM OF E AND Z ISOMERS OF DIMETHOMORPH	
SHALLOT	T0.5
ETOXAZOLE ETOXAZOLE	
APPLE	0.2

FLUAZIFOP-BUTYL FLUAZIFOP-BUTYL	
SHALLOT	0.05
SPRING ONION	0.05
SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
FRUITING VEGETABLES, CUCURBITS	T0.2

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

AZOXYSTROBIN AZOXYSTROBIN	
BARLEY	*0.02
WHEAT	*0.02
CYPROCONAZOLE CYPROCONAZOLE, SUM OF ISOMERS	
BARLEY	*0.02
EDIBLE OFFAL (MAMMALIAN)	1
MEAT (MAMMALIAN)	0.03
WHEAT	*0.02
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
CHICK-PEA (DRY)	0.5
LENTIL (DRY)	0.5
ETOXAZOLE ETOXAZOLE	
COTTON SEED	0.2
EDIBLE OFFAL (MAMMALIAN)	*0.01
EGGS	*0.01
MEAT (MAMMALIAN)(IN THE FAT)	*0.02
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT (IN THE FAT)	*0.02
IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYLMETHYLENE MOIETY, EXPRESSED AS IMIDACLOPRID	
CITRUS FRUITS	T2
SUGAR CANE	*0.05
METHIDATHION METHIDATHION	
PERSIMMON, JAPANESE	0.5
SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
PULSES	0.01

TRIFLOXYSTROBIN SUM OF TRIFLOXYSTROBIN AND ITS ACID METABOLITE ((E,E)-METHOXYIMINO-[2-[1-(3-TRIFLUOROMETHYLPHENYL)-ETHYLIDENEAMINOOXYMETHYL]PHENYL] ACETIC ACID), EXPRESSED AS TRIFLOXYSTROBIN EQUIVALENTS	
BANANA	0.5

Attachment 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 Manager 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.

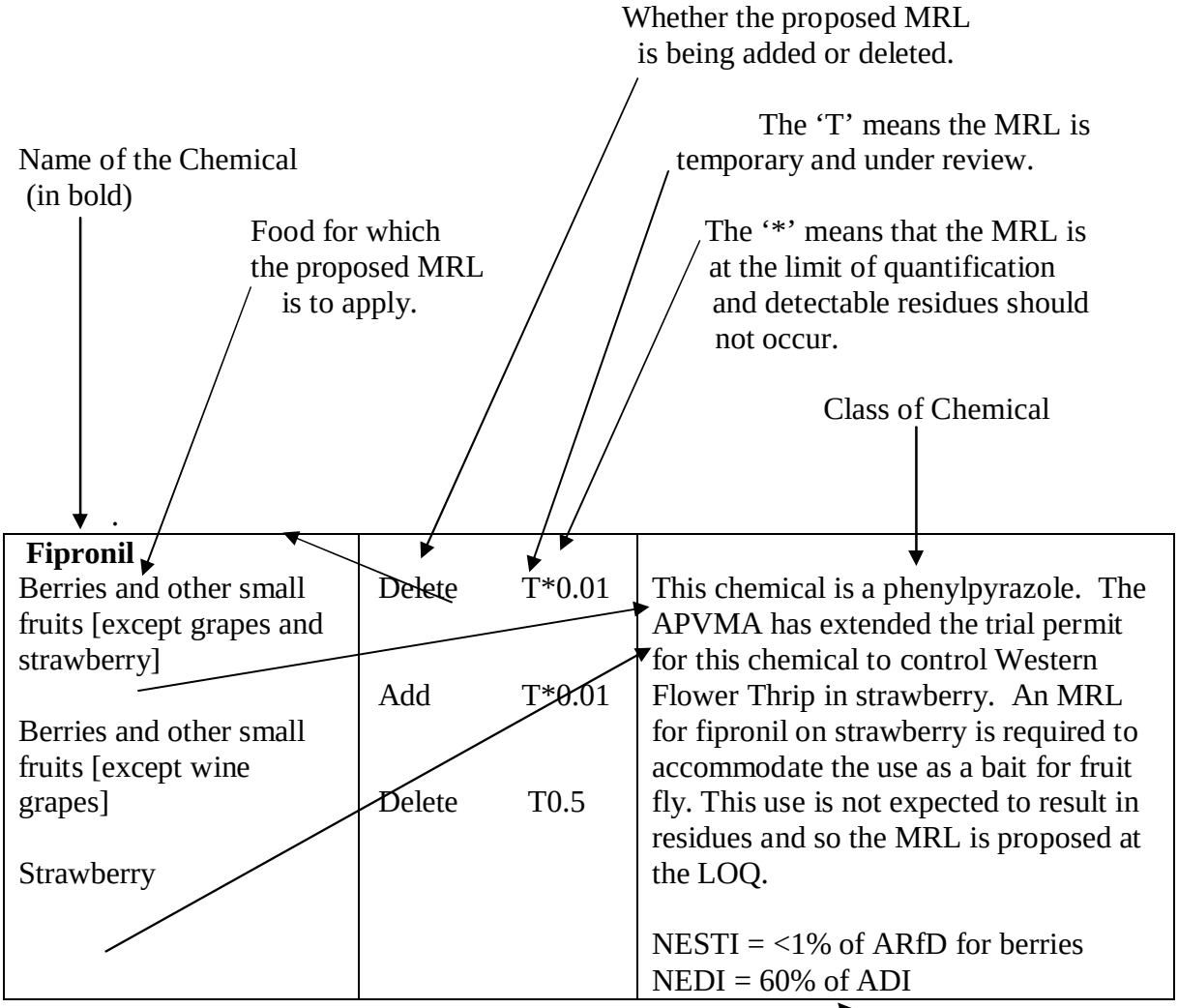
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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 the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey (NNS) and the MRL when the STMR is not available to calculate the NESTIs.

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.



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.

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

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.

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

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.

Chlorpyrifos Coffee beans	Add	T0.5	APVMA extension of use for the control of pests. The 19th 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. The 20th ATDS (2000) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 83% of ADI

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.
14.	**WHP**	With Holding Period

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

SUMMARY OF THE REQUESTED MRLS FOR APPLICATION A547

Abamectin Ground cherries	Insert	T0.01	**Omit** residue definition**:** Sum of avermectin B1A, avermectin B1B and D-8,9 isomer of avermectin B1A **Substitute** residue definition: Sum of avermectin B1A, avermectin B1B and (Z)-8,9 avermectin B1A, and (Z)-8,9 avermectin B1B This chemical is an insecticide. APVMA have issued a permit for this chemical to be used to control Two Spotted Mites on ground cherries. NESTI for whole population 2 years and above, and the 2 to 6 y.o. age group = <1% of the ARFD. NEDI = 46% of the ADI.
Azoxystrobin Banana Barley Wheat	Insert Omit Substitute Omit Substitute	T0.5 T*0.02 *0.02 T*0.02 *0.02	This chemical is a strobilurin fungicide used to control fungal diseases on grain crops. APVMA have issued a permit for this chemical to be used to control Yellow Sigatoka on banana crops. NEDI = <1% of the ADI.
Chlorothalonil Peas (pods and succulent, immature seeds)	Insert	10	This chemical is a chloronitrile fungicide used to control fungal diseases on pea crops. The 20th ATDS (2000) dietary exposure estimate for chlorothalonil, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 85% of the ADI
Chlorpyrifos Peppers, sweet	Insert	T1	This chemical is an organophosphate insecticide. APVMA have issued a permit for this chemical to be used to control insects on sweet pepper crops. The 20th ATDS (2000) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NESTI for the whole population 2 years and above for Peppers, sweet = 2% of the ARFD. NESTI for the 2 to 6 y.o. age group for Peppers, sweet = 5 % of ARfD. NEDI = 85% of the ADI

Cyproconazole			
Barley	Omit	T*0.02	This chemical is a triazole fungicide used to control fungal diseases on grain crops.
	Substitute	*0.02	
Edible offal (mammalian)	Omit	T1	
	Substitute	1	
Eggs	Insert	*0.01	
Meat (mammalian)	Omit	T0.03	
	Substitute	0.03	
Poultry meat	Insert	*0.01	
Poultry, edible offal of	Insert	*0.01	
Wheat	Omit	T*0.02	
	Substitute	*0.02	NEDI = 8% of the ADI.
Difenoconazole			
Macadamia nuts	Insert	*0.01	This chemical is an azole fungicide used to control fungal diseases on macadamia crops. In the 20th (2000) ATDS residues of difenoconazole were not detected in surveyed foods. NEDI = 11% of ADI.
Dimethomorph			
Shallot	Insert	T0.5	This chemical is a cinnamic acid fungicide. APVMA has issued a permit for this chemical to be used to control fungal diseases on shallot crops. In the 20th (2000) residues of dimethomorph were not detected in surveyed foods. NEDI = 3% of ADI.
Dinitolmide			**Omit** residue definition: Dinitolmide **Substitute** residue definition: Sum of dinitolmide and its metabolite 3-amino-5-nitro-O-toluamide, expressed as dinitolmide equivalents
Dithiocarbamates (Mancozeb)			Dithiocarbamates are fungicides used to control fungal diseases on crops. In the 19th (1998) ATDS the estimated dietary exposure to thiram (the dithiocarbamate with the lowest ADI) was at 63% of the ADI two year olds and 20% of the ADI for adult males. On the basis of results from the 1998 ATDS and that mancozeb has higher ADIs than thiram; FSANZ considers that the residues associated with the proposed MRL would not represent an unacceptable risk to public health and safety. NEDI for mancozeb = 85% of ADI
Chick-pea (dry)	Omit	T0.5	
	Substitute	0.5	
Lentil (dry)	Omit	T0.5	
	Substitute	0.5	

Etoxazole			
Apple	Insert	0.2	This chemical is an insecticide used to control insects on apple crops. NESTI for the whole population 2 years and above, and the age group 2-6 year old for all relevant commodities = <1% of the ARfD.
Cotton seed	Omit	T0.2	
	Substitute	0.2	
Edible offal (mammalian)	Omit	T*0.01	
	Substitute	*0.01	
Eggs	Omit	T*0.01	
	Substitute	*0.01	
Meat (mammalian) (in the fat)	Omit	T*0.01	
	Substitute	*0.02	
Milks	Omit	T*0.01	
	Substitute	*0.01	
Poultry, edible offal of	Omit	T*0.01	
	Substitute	*0.01	
Poultry meat (in the fat)	Omit	T*0.01	
	Substitute	*0.02	NEDI = <1% of the ADI.
Fenbuconazole			
Banana	Insert	0.5	This new chemical is a triazole fungicide used to control fungal diseases on nectarine and banana crops. The anticipated exposure to livestock from their consumption of culled bananas or grazing in treated orchards is considered negligible. Therefore, the proposed MRLs for animal commodities are at the LOQ. NESTI for the whole population 2 years and above, and the 2 to 6 y.o. age group and for: • Bananas = <1 % of the ARfD; • Edible offal (mammalian) = <1% of the ARfD; • Eggs = <1% of the ARfD; • Meat (mammalian) = <1% of the ARfD; • Milks = <1% of the ARfD; • Poultry meat = <1 % of the ARfD; and • Poultry, edible offal = <1 % of the ARfD. • Plums = <1 % of the ARfD. NESTI for the whole population 2 year and above for Apricot = <1 % of the ARfD; NESTI for the 2 to 6 y.o. age group for Apricot = 4 % of the ARfD.
Edible offal (mammalian)	Insert	*0.01	
Eggs	Insert	*0.01	
Meat (mammalian)	Insert	*0.01	
Milks	Insert	*0.01	
Nectarine	Insert	0.5	
Poultry, edible offal of	Insert	*0.01	
Poultry meat	Insert	*0.01	
Stone fruits [except nectarine]	Insert	T1	

			NESTI for the whole population 2 year and above for Cherries = <1 % of the ARfD; NESTI for the 2 to 6 y.o. age group for Cherries = 5 % of the ARfD. NESTI for the whole population 2 year and above for Nectarine = 3 % of ARfD; NESTI for the 2 to 6 y.o. age group for Nectarine = 6 % of ARfD. NESTI for the whole population 2 year and above for Peach = 3 % of ARfD; NESTI for the 2 to 6 y.o. age group for Peach = 8 % of ARfD. NEDI = 3% of the ADI
Fenchlorazole-ethyl Barley Chick-pea (dry) Rye Triticale Wheat	 Omit Omit Omit Omit Omit	 *0.05 *0.05 *0.05 *0.05 *0.05	This chemical is a herbicide safener. As there are no registered products containing this chemical the MRL is no longer required.
Fluazifop-butyl Shallot Spring Onion	 Insert Insert	 0.05 0.05	This chemical is a propionate herbicide used to control grasses in onion crops. NEDI = 69% of ADI.
Flumioxazin Broad bean (dry) Cereal grains Chick-pea (dry) Cotton seed Edible offal (mammalian) Eggs Field pea (dry) Lentil (dry) Lupin (dry) Meat (mammalian) Milks Poultry, edible offal of Poultry meat Rape seed	 Insert Insert Insert Insert Insert Insert Insert Insert Insert Insert Insert Insert Insert Insert	 *0.1 *0.05 *0.1 *0.1 *0.01 *0.01 *0.1 *0.1 *0.1 *0.01 *0.01 *0.01 *0.01 *0.1	This new chemical is a herbicide used to control weeds prior to planting of cereals, oilseeds and pulses. NESTI for whole population 2 years and above, and the 2 to 6 y.o. age group for: • Edible offal = <1% of ARfD; • Eggs = <1% of ARfD; • Meat (mammalian) = <1% of ARfD; • Oilseed = <1 % of ARfD; • Poultry, edible offal = <1 % of ARfD; and • Poultry meat = <1 % of ARfD. NESTI for the whole population 2 years and above for Cereal grains = 3 % of the ARfD. NESTI for the 2 to 6 y.o. age group for Cereal grains = 4 % of ARfD. NESTI for the whole population 2 years and above for Pulses = <1% of the ARfD. NESTI for the 2 to 6 y.o. age group for Pulses = 3 % of ARfD. NESTI for the whole population 2 years and above for Milks = <1% of the ARfD. NESTI for the 2 to 6 y.o. age group for Milks = 3 % of ARfD. NEDI =9% of the ADI.

Fluometuron			**Omit** residue definition: Sum of fluometuron and 4-trifluoromethylaniline, expressed as fluometuron **Substitute** residue definition: Sum of fluometuron and 3-trifluoromethylaniline, expressed as fluometuron
Imidacloprid			
Citrus fruits	Omit Substitute	T0.5 T2	**Delete** residue definition: Sum of imidacloprid and metabolites containing the 6-chloropyridinymethylenemoiety, expressed as imidacloprid **Substitute** residue definition: Sum of imidacloprid and metabolites containing the 6-chloropyridinylmethylene moiety, expressed as imidacloprid.
Sugar cane	Omit Substitute	T*0.05 *0.05	This chemical is a chloronicotinyls insecticide. APVMA has issued a permit for the use of this chemical to control insects on citrus fruit trees. NESTI for the whole population 2 years and above for Citrus fruit = 8% of the ARFD. NESTI for 2 to 6 y.o. age group Citrus fruit = 22 % of the ARfD. Imidacloprid is used to control insects in sugarcane crops. NESTI for the whole population 2 years and above and the 2 to 6 y.o. age group for Sugar cane = <1% of the ARFD. NEDI = 9% of the ADI
Methidathion			
Persimmon, Japanese	Omit Substitute	T0.5 0.5	This chemical is an organophosphate insecticide used to control insects in Persimmon crops. In the 20th (2000) ATDS the estimated dietary exposure to methidathion was at <1% for the whole population. NESTI for the 2 to 6 y.o. age group for Persimmon, Japanese = 5 % of ARfD. NESTI for the whole population 2 years and above for Persimmon Japanese = 3% of the ARFD NEDI = <88% of the ADI.
Spinosad			
Cucumber Fruiting vegetables, cucurbits	Omit Insert	0.2 T0.2	This chemical is a spinosyn insecticide used to control insects in various crops.
Pulses	Omit Substitute	T0.05 0.01	
Soya bean (dry)	Omit	T0.05	NEDI = 32% of the ADI.

Trifloxystrobin Banana	Omit Substitute	T0.1 0.5	This chemical is a strobilurin fungicide used to control black Sigatoka, yellow Sigatoka and Cordana Leaf Spot on banana. NEDI = 3% of the ADI.

Attachment 3

BACKGROUND TO DIETARY EXPOSURE ASSESSMENTS

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

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 *Food Standards 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

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 an unacceptable risk to public health and safety.

Determination of the acceptable health standard for a chemical in food

The Office of Chemical Safety of the Therapeutic Goods Administration assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where applicable, the ARfD for a chemical.

Both the 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

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 Joint FAO/WHO Meeting on Pesticide Residues has established an ARfD.

The APVMA and FSANZ have recently 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 1995 National Nutrition Survey (NNS). The Australian Bureau of Statistics with the Australian Government Department of Health and Aged Care undertook the NNS survey over a 13-month period (1995 to early 1996). The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns were reported.

Chronic Dietary Exposure Assessment

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

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

In conducting chronic dietary exposure assessments, the 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.