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FINAL ASSESSMENT REPORT

APPLICATION A510

MAXIMUM RESIDUE LIMITS (AUGUST, SEPTEMBER, OCTOBER 2003)

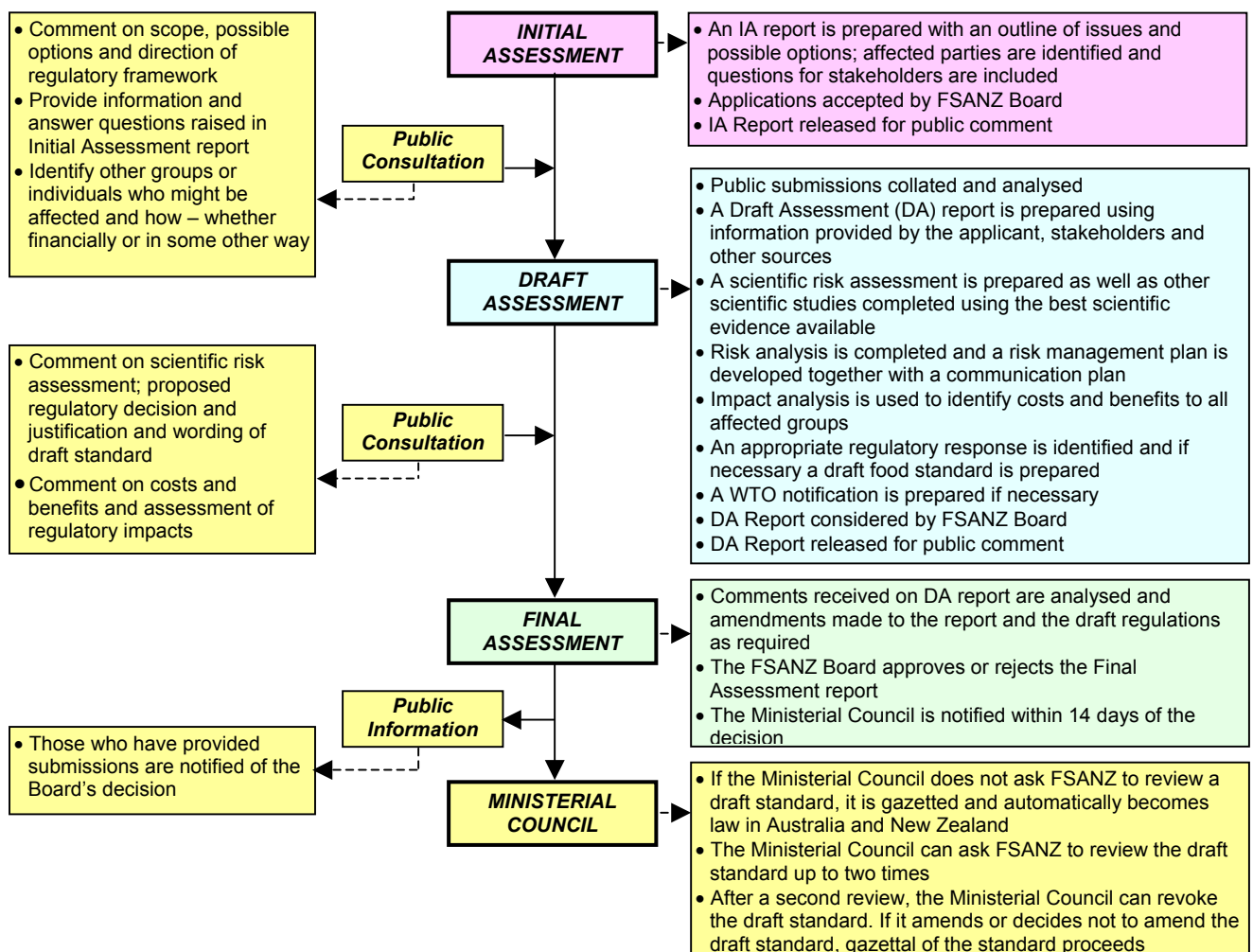
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Commonwealth; 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 Commonwealth, 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 Commonwealth, 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 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:

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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 (A510) 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 expected residues associated with the proposed changes to the MRLs do not represent an unacceptable public health and safety risk.

There are no MRLs for antibiotics in this Application.

FSANZ made a Sanitary and Phytosanitary notification to the World Trade Organization. The People's Republic of China made a submission requesting relevant scientific evidence on the proposed deletion of the MRLs for bioresmethrin.

Statement of Reasons

FSANZ recommends progressing this Application for the following reasons:

- The dietary exposure assessments indicate that the expected residues associated with the proposed changes to the MRLs do not represent an unacceptable public health and safety risk. APVMA has already registered the chemical products associated with the MRLs in this Application and the rejection of the proposed 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 of the Therapeutic Goods Administration (OCS) of the Commonwealth Department of Health and Ageing has undertaken an appropriate toxicological assessment of the chemicals and has established, where appropriate, an acceptable daily intake (ADI) and a acute reference dose (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 11 August, 10 September and 14 October 2003 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 deletion of all the MRLs for the chemicals bioresmethrin and phoxim;
- the deletion of MRLs for certain foods for the chemicals aminoethoxyvinylglycine and permethrin;
- the addition of MRLs for certain foods for the chemicals aminoethoxyvinylglycine, azoxystrobin, carfentrazone-ethyl, cyfluthrin, cyhalothrin, cyprodinil, pirimiphos-methyl, sethoxydim, spinosad and terbufos;
- the changing of MRLs for certain foods for the chemicals azoxystrobin, bupirimate, buprofezin, cyprodinil, fluazinam, permethrin and procymidone; and
- the addition of temporary MRLs for certain foods for the chemicals fludioxonil, methomyl, oxycarboxin, permethrin, propiconazole and thiamethoxam.

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 Commonwealth, State and Territory legislation.

1.2 Antibiotic MRLs

There are no MRLs for antibiotics 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 the APVMA 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 public health and safety risk 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.

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 Office of Chemical Safety (OCS) of the Therapeutic Goods Administration (TGA) establishes the ADI and, where applicable, the ARfD for agricultural and veterinary chemicals. APVMA and FSANZ carry out estimations of dietary exposure to agricultural and veterinary chemicals and compare them to the TGA standards. 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 Council for the purposes of this paragraph and notified to the Authority

To date the Ministerial Council has not made a written notification to the Authority 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 Australia and New Zealand Food Regulation Ministerial Council of the adoption of the variation to the Code. If the 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 Manager 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 the 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 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's website at 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:

- Australian Food and Grocery Council (AFGC);
- Australian Pork Limited;
- Department of Agriculture, Fisheries and Forestry (DAFF);
- Food Technology Association; and
- People's Republic of China (PRC).

The submissions from Australian Pork Limited and the Food Technology Association supported this Application.

5.1 Australian Food and Grocery Council

The AFGC identified potential problems for importers of grain and pork commodities from the proposed deletion of MRLs for bioresmethrin and phoxim and informed FSANZ that it was in the process of seeking information from their members of the effects of the proposed deletion of these MRLs. There are a number of points that need to be made in this regard.

Firstly, FSANZ can only accept or reject an Application in its entirety. This means that FSANZ must progress all the MRL amendments in the Application from APVMA or reject all the MRL amendments. In the case of this Application it means that FSANZ cannot retain certain MRLs while progressing the other MRL amendments in this Application.

Secondly, a demonstrated need for an MRL is required to retain an MRL, as this ensures that all MRLs in the Code are relevant and that residues are kept as low as reasonably achievable. It also ensures that MRLs in the Code have a sound scientific basis e.g. the deletion of MRLs resulting from temporary permit for the use of the chemical expiring. While the AFGC has expressed reservations about these deletions, there is no evidence to suggest that these deletions would cause difficulties. Therefore, to maintain the relevancy of the Code and to maintain residues as low as reasonably possible, it is important that these amendments are progressed.

Lastly, retaining MRLs proposed for deletion by APVMA would result in an inconsistency between domestic food and agricultural legislation. This would create complications for enforcement which would undermine the efficiency of domestic food production. Some inconsistency may be warranted where there is specific evidence indicating that a difference is required. However, AFGC has provided no such evidence and therefore it would be inappropriate to retain these MRLs and create an inconsistency.

5.1.1 *Bioresmethrin*

There are Codex MRLs for this chemical for wheat and wheat commodities, for the post harvest treatment of wheat, and it was thought that the proposed deletion may have implications for the importation of wheat and wheat products. Therefore, FSANZ requested comment on the significance of the difference from the Codex MRLs.

AFGC informed FSANZ that several AFGC members had responded to this proposed deletion of the MRLs for bioresmethrin. They had all advised that only Australian wheat was used in their food products. On this basis, AFGC has removed its objection to the proposed deletion of the bioresmethrin MRLs.

5.1.2 *Phoxim*

There are no Codex MRLs for this chemical and the majority of the MRLs proposed for deletion for phoxim are at the limit of quantification (LOQ). 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 in the Code at the LOQ means that no detectable residues of the relevant chemical should occur in these commodities. Therefore, the proposed deletion of these MRLs from the Code for this chemical will have no effect on the importation of commodities because in the case of those MRLs at LOQ no detectable residues should occur and there are no internationally recognised MRLs for this chemical.

As at 13 February 2004, the AFGC had not received any responses from its members on the proposed deletion of the MRLs for phoxim. AFGC is not prepared to remove its objection to the proposed deletion of these MRL, as it considers that in the future the LOQ may be revised.

In summary, there are costs in retaining MRLs proposed for deletion and based upon the information provided in submissions, there is little evidence to suggest that the MRLs proposed for deletion should be retained. On this basis, FSANZ considers that all the MRL amendments as proposed by APVMA should be progressed.

5.2 Submission by the Department of Agriculture Fisheries and Forestry

DAFF's preferred option would be to adopt the changes to MRLs to include new or increase some existing MRLs. DAFF believes that this option would allow food imported into Australia to still meet MRLs for agricultural and veterinary chemicals that can be safely used in other countries even when these same chemicals are not registered for use in Australia. DAFF's submission did not discuss the option of deleting or decreasing some existing MRLs.

FSANZ's preferred approach is to adopt changes to MRLs in the Code to include new or increase some existing MRLs and to delete or decrease some existing MRLs. The reasons for this are addressed in section 8.4.

5.3 Submission by the People’s Republic of China

The People’s Republic of China (PRC) requested that FSANZ provide it with the relevant scientific evidence on the proposed deletion of the MRLs for bioresmethrin.

As it is APVMA which has the responsibility to register the use of agricultural or veterinary chemicals, FSANZ has forwarded the PRC request for information on bioresmethrin to APVMA. APVMA will respond directly to the Australian Sanitary and Phytosanitary contact point regarding the request received from the PRC.

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
- Commonwealth, 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 included 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 Commonwealth, 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 Commonwealth, 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 Commonwealth, 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 9.3.1 and data on imported foods are addressed in section 9.3.2. FSANZ invites comments from importers on the impacts of the deletions or reduction of MRLs; and
- for Commonwealth, 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.

Codex MRLs

Codex MRLS are addressed in section 9.

Imported Food

Issues relating to imported foods are addressed in section 9.

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 Commonwealth, 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 Commonwealth, 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 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 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 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.

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.

In administrative terms and consistent with international practice, MRLs assist in regulating the use of agricultural and veterinary chemical products. MRLs indicate whether agricultural and veterinary chemical products have been used in accordance with the registered conditions of use.

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. MRLs are also used as standards for the international trade in food.

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.

The submission from the People’s Republic of China requesting data on the reasons for the proposed deletion of the MRLs for bioresmethrin is addressed in section 5.

9.3.1 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 sets out the proposed MRLs to be deleted, in the APVMA’s application, which are more restrictive than the relevant Codex MRL.

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Bioresmethrin		
Cereal Grains	MRLs proposed for deletion	1 (Wheat)
Wheat bran, unprocessed	MRLs proposed for deletion	5
Wheat germ	MRLs proposed for deletion	3

FSANZ recognises that the proposed deletion of these MRLs may have implications for the importation of food. Therefore, FSANZ requested comments on the significance of the differences from Codex MRLs for imported foods. No WTO member has made a submission on the trade impact of the proposed deletion of MRLs.

9.3.2 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 that 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 that states the imported quantity of relevant foods for the years 2000 and 2001. These data are for foods for which deletions or reductions of MRLs are proposed. FSANZ requested comment as to any possible ramifications for imports of the deletion or reductions of the MRLs in this Application.

Food	2000 Tonnes	2001 Tonnes
Cereal Grains	74466	79027
Edible offal, mammalian	7350	7729
Eggs	352	272
Herbs	155	477
Meat (mammalian)	44370	38658
Milks	19345	20057
Pig, edible offal	447	668
Pig fat	0.5	1.5
Pig meat	37701	32269
Pome fruits	13323	20803
Potato	18920	21933
Poultry, edible offal	143	506
Rape seed oil	3166	3859
Stone fruits	7972	6113

FSANZ requested comment as to any possible ramifications for imports of the deletion or reductions of the MRLs in this Application. The submission from AFGC about the effect of the proposed deletion of bioresmethrin and phoxim on imported food is addressed in section 5.

10. Conclusion

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

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.

ATTACHMENT 1

Draft Variations to *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 -*

Bioresmethrin

Phoxim

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

AMINOETHOXYVINYLGLYCINE AMINOETHOXYVINYLGLYCINE	
NECTARINE	0.2
PEACH	0.2
STONE FRUITS [EXCEPT AS OTHERWISE LISTED]	T0.2
PERMETHRIN PERMETHRIN, SUM OF ISOMERS	
LEMON BALM	T5
MIZUNA	T5

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

AMINOETHOXYVINYLGLYCINE AMINOETHOXYVINYLGLYCINE	
STONE FRUITS [EXCEPT CHERRIES]	0.2
AZOXYSTROBIN AZOXYSTROBIN	
AVOCADO	1
LEEK	0.5
CARFENTRAZONE-ETHYL CARFENTRAZONE-ETHYL	
GRAPES	*0.05
OLIVES	*0.05
POME FRUITS	*0.05
STONE FRUITS	*0.05
TREE NUTS	*0.05
CYFLUTHRIN CYFLUTHRIN, SUM OF ISOMERS	
COTTONSEED OIL, CRUDE	0.02

CYHALOTHRIN	
CYHALOTHRIN, SUM OF ISOMERS	
BEETROOT	*0.01
CYPRODINIL	
CYPRODINIL	
DRIED STONE FRUITS	0.05
FLUDIOXONIL	
FLUDIOXONIL	
MAIZE	T*0.02
SORGHUM	T*0.05
SUNFLOWER SEED	T*0.02
SWEET CORN (CORN-ON-THE-COB)	T*0.02
METHOMYL	
METHOMYL	
MANGO	T*0.05
OXYCARBOXIN	
OXYCARBOXIN	
BLUEBERRIES	T10
PERMETHRIN	
PERMETHRIN, SUM OF ISOMERS	
CORIANDER (LEAVES AND STEMS)	T10
PIRIMIPHOS-METHYL	
PIRIMIPHOS-METHYL	
TRITICALE	10
PROPICONAZOLE	
PROPICONAZOLE	
CELERY	T5
SETHOXYDIM	
SUM OF SETHOXYDIM AND METABOLITES CONTAINING THE 5-(2-ETHYLTHIOPROPYL)CYCLOHEXENE-3-ONE AND 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES AND THEIR SULFOXIDES AND SULFOXIDES AND SULFONES, EXPRESSED AS SETHOXYDIM	
WHEAT	*0.1
SPINOSAD	
SUM OF SPINOSYN A AND SPINOSYN D	
RADISH	*0.05
TERBUFOS	
SUM OF TERBUFOS, ITS OXYGEN ANALOGUE AND THEIR SULFOXIDES AND SULFONES, EXPRESSED AS TERBUFOS	
SWEET CORN (CORN-ON-THE-COB)	*0.05
THIAMETHOXAM	
THIAMETHOXAM	
CITRUS FRUITS	T0.2

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

AZOXYSTROBIN AZOXYSTROBIN	
MANGO	0.5
PASSIONFRUIT	0.5
POPPY SEED	*0.02
BUPIRIMATE BUPIRIMATE	
FRUITING VEGETABLES, CUCURBITS	1
BUPROFEZIN BUPROFEZIN	
TOMATO	1
CYPRODINIL CYPRODINIL	
DRIED STONE FRUITS	*0.01
FLUAZINAM FLUAZINAM	
POME FRUITS	*0.01
PERMETHRIN PERMETHRIN	
HERBS	T10
KAFFIR LIME LEAVES	T10
LEMON GRASS	T10
PROCYMIDONE PROCYMIDONE	
RAPE SEED OIL, CRUDE	T2

[1.5] omitting from Schedule 3 all entries for the following chemicals -

Bioresmethrin
Phoxim

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.

<p>Fipronil 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 = <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>Chlorpyrifos Coffee beans</p>	<p>Add T0.5</p>	<p>APVMA extension of use for the control of pests. The 18th 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 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. 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.

SUMMARY OF THE REQUESTED MRLS FOR APPLICATION A510

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. **ECRP** Existing Chemical Review Program
6. **LOQ** Limit of Analytical Quantification.
7. **NEDI** National Estimated Daily Intake.
8. **NESTI** National Estimated Short Term Intake.
9. **NNS** National Nutrition Survey of Australia 1995
10. **LOQ** MRL set at or about the limit of quantification.
11. **T** Temporary MRL.

Chemical Food	MRL (mg/kg)	Information
Aminoethoxyvinylglycine Nectarine Peach Stone fruits [except as other wise listed] Stone fruits [except cherries]	Delete 0.2 Delete 0.2 Delete T0.2 Add 0.2	This chemical is a plant growth regulator; it is used to regulate the growth in apples and stone fruits. NEDI = 46% of ADI.
Azoxystrobin Avocado Leek Mango Passionfruit Poppy seed	Add 1 Add 0.5 Delete T0.5 Substitute 0.5 Delete T0.5 Substitute 0.5 Delete T*0.02 Substitute *0.02	This chemical is a strobilurin fungicide; it is used to control various fungal diseases of horticultural crops. NEDI = <1% of ADI.
Bioresmethrin Cereal grains Edible offal, mammalian Eggs Meat (mammalian)(in the fat) Milks Poultry, edible offal of Poultry meat (in the fat) Wheat bran, unprocessed Wheat germ	Delete 5 Delete T*0.01 Delete T0.05 Delete T0.5 Delete T0.05 Delete T*0.01 Delete T0.5 Delete T10 Delete T10	This chemical is a synthetic pyrethroid insecticide; it used as a grain protectant. APVMA has withdrawn all the uses for bioresmethrin. It is proposed that the MRLs for this chemical in cereal grains and related animal products be deleted.
Bupirimate Fruiting vegetables, cucurbits	Delete T1 Substitute 1	This chemical is a pyrimidine fungicide; it is used to control various fungal diseases of vegetable crops. NEDI = 3% of ADI.
Buprofezin Tomato	Delete T1 Substitute 1	This chemical is an insecticide; it is used to control greenhouse whitefly on greenhouse tomatoes. NEDI = 11% of ADI.
Carfentrazone-ethyl Grapes Olives Pome fruits Stone fruits Tree nuts	Add *0.05 Add *0.05 Add *0.05 Add *0.05 Add *0.05	This chemical is a phenyl triazolene herbicide; it is used to control weeds in various tree and vine crops. NEDI = 2% of ADI
Cyfluthrin Cottonseed oil, crude	Add 0.02	This chemical is a synthetic pyrethroid insecticide; it is used to control insect pests on various crops. In the 20 th (2000) ATDS the concentrations of residues of cyfluthrin in surveyed foods were less than the LOQ. NEDI = 66% of ADI.

Cyhalothrin Beetroot	Add	*0.01	This chemical is a synthetic pyrethroid insecticide; it is used to control insects on beetroot. In the 20 th (2000) ATDS the concentrations of residues of diazinon in surveyed foods were less than the LOQ. NEDI = 3% of ADI.
Cyprodinil Dried stone fruits Stone fruits	Add Delete Substitute	0.05 T0.5 *0.01	This chemical is an anilinopyrimidine fungicide; it is used to control various fungal diseases of horticultural crops. NEDI = 10% of ADI.
Fluazinam Pome fruits	Delete Substitute	T*0.05 *0.01	This chemical is a phenylpyridinamine fungicide; it is used to control various fungal diseases on dormant and seedling pome trees. NEDI = 1% of ADI.
Fludioxonil Maize Sorghum Sunflower seed Sweet corn (corn-on-the-cob)	Add Add Add Add	T*0.02 T*0.05 T*0.02 T*0.02	This chemical is a phenylpyrrole fungicide. APVMA has issued a permit for this chemical to be used to control various fungal diseases vegetable and grain crops. NEDI = 1% of ADI.
Methomyl Mango	Add	T*0.05	This chemical is a carbamate insecticide; it is used to control insects on mango trees during the flowering period only. In the 19 th (1998) ATDS methomyl residues were not detected in any surveyed foods. NEDI = 87% of ADI.
Oxycarboxin Blueberries	Add	T10	This chemical is a carboxanilide fungicide. APVMA has issued a permit for this chemical to be used to control rust on blueberries. NEDI = <1% of ADI.
Permethrin Coriander (leaves and stems) Herbs Kaffir lime leaves Lemon balm Lemon grass Mizuna	Add Delete Substitute Delete Substitute Delete Delete Substitute Delete	T10 T5 T10 T5 T10 T5 T5 T10 T5	This chemical is a synthetic pyrethroid insecticide; it is used to control insects on herbs. NEDI = 16% of ADI.

Phoxim Potato Pig, edible offal of Pig fat Pig meat	Delete Delete Delete Delete	*0.05 *0.01 0.5 *0.01	This chemical is an organophosphorous. APVMA has withdrawn the registration of all phoxim products. It is proposed that the MRLs for this chemical in potato and pig commodities be deleted.
Pirimiphos-methyl Triticale	Add	10	This chemical is an organophosphorous insecticide; it is used to control insects in stored triticale. NEDI = 46% of ADI.
Procymidone Rape seed oil, crude	Delete Substitute	T3 T2	This chemical is a dicarboximide fungicide. APVMA has issued a permit for this chemical to be used to control fungal diseases in canola. In the 20 th (2000) ATDS the concentrations of residues of procymidone in surveyed foods were estimate at being less than 1% of the ADI for the groups assessed. NEDI = 24% of ADI.
Propiconazole Celery	Add	T5	This chemical is a triazole fungicide. APVMA has issued a permit for this chemical to be used to control fungal diseases in celery crops. In the 20 th (2000) ATDS the dietary exposure to residues of procymidone in surveyed foods was estimated to be less than 1% of the ADI for all groups assessed. NEDI = 4% of ADI.
Sethoxydim Wheat	Add	*0.1	This chemical is a cyclohexanedione oxime herbicide; it is used to control grasses in broad-leaved crops. NEDI = 1% of ADI.
Spinosad Radish	Add	*0.05	This chemical is an insecticide; it is used to control diamond back moth, cabbage white butterfly and Heliothis in radish. NEDI = 12% of ADI.
Terbufos Sweet corn (corn-on-the-cob)	Add	*0.05	This chemical is an organophosphorous insecticide; it is used to control insects during planting of maize crops. NEDI = 10% of ADI.
Thiamethoxam Citrus fruits	Add	T0.2	This chemical is a neonicotinoid insecticide. APVMA has issued a permit for this chemical to be used to control mealy bugs, scale, thrips, aphids and leaf miners on citrus. NEDI = 2% of ADI.

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

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 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 the 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 Commonwealth 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.

ATTACHMENT 4

SUMMARY OF SUBMISSIONS RECEIVED

Submitter	Comments raised
Australian Food and Grocery Council.	Opposed the deletion and reduction of MRLs.
Australian Pork Limited.	Supported the Application.
Department of Agriculture Fisheries and Forestry.	Supported the Application.
Food Technology Association of Victoria.	Supported the Application.
People's Republic of China.	Requested data on bioresmethrin.