EXPLANATORY STATEMENT

APPLICATION A534

MAXIMUM RESIDUE LIMITS (MARCH, APRIL, MAY 2004)

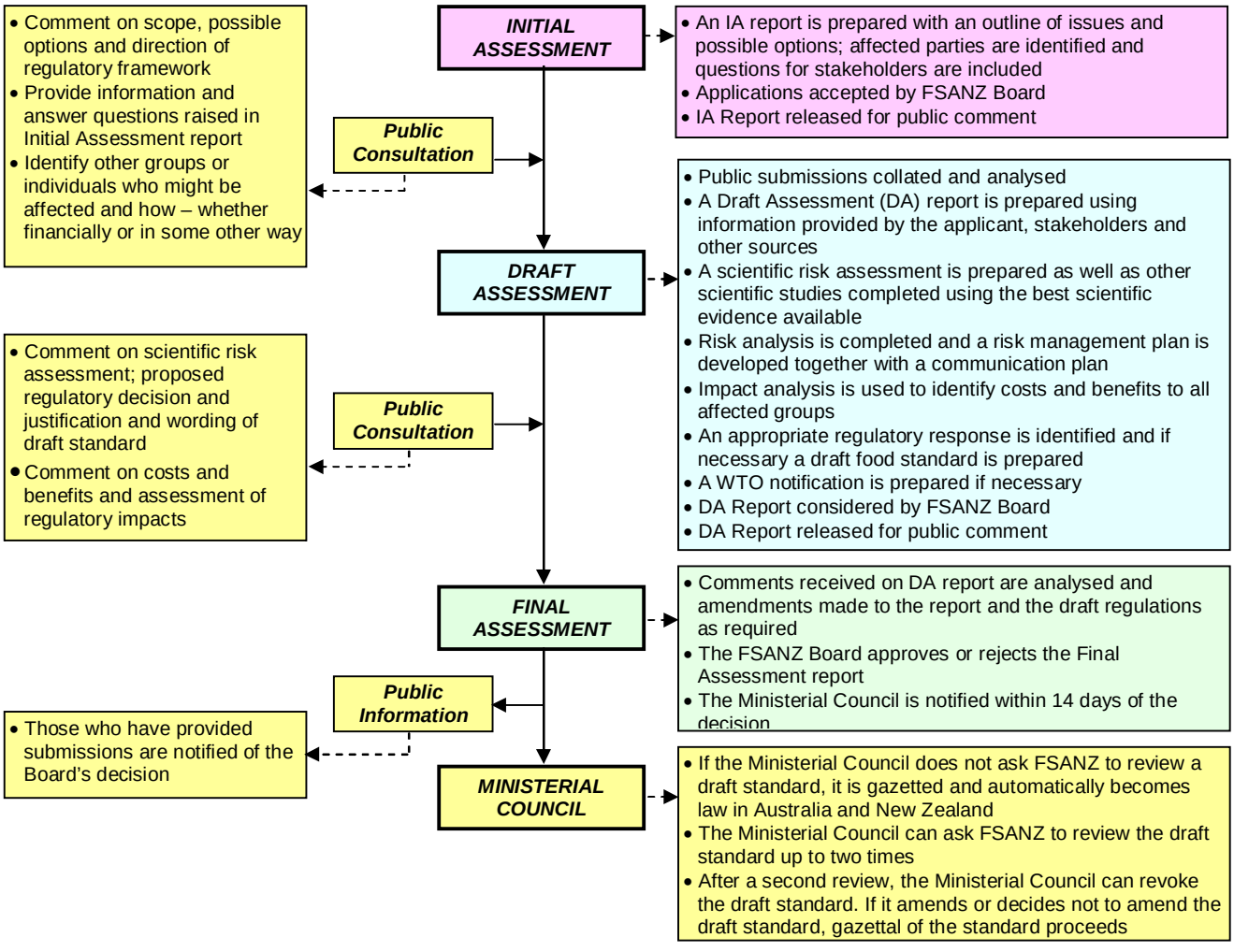
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Final Assessment Stage (s.36)

FSANZ has now completed the assessment of Application A534 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
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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 (A534) 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 Pesticides and Veterinary Medicines Authority (APVMA), to update the Code in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

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

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

There are no MRLs for antibiotic residues in this Application.

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

Statement of Reasons

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.

- 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 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 30 March, 15 April and 18 May 2004 seeking amendments to Standard 1.4.2 – Maximum Residue Limits, 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 addition of the MRLs for the new chemicals epoxiconazole and pyraclofos;
- the deletion of MRLs for certain foods for the chemicals fenvalerate, sethoxydim and spinosad;
- the addition of MRLs for certain foods for the chemicals diafenthiuron, dimethoate, diphenylamine, fenvalerate, fipronil, sethoxydim, spinosad and triclabendazole;
- the changing of MRLs for certain foods for the chemicals chlorpyrifos, diphenylamine, fenvalerate, flumethrin, glyphosate, methomyl, sethoxydim, spinosad, tebufenozide and triclabendazole; and
- the addition of temporary MRLs for certain foods for the chemicals azoxystrobin, bifenthrin, buprofezin, captan, carbaryl, carfentrazone-ethyl, chlorpyrifos, cyhalothrin, fludioxonil, imidacloprid, spinosad and trifloxystrobin.

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

1.2 Antibiotic MRLs

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

2. Regulatory Problem

2.1 Current Regulations

APVMA has approved the use of the agricultural and veterinary chemical products associated with the MRLs in this Application, and made consequent amendments to its 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:

[1] A chemical inhibitor of the growth of organisms produced by a microorganism..

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

- where APVMA has included MRLs for new chemicals or for additional foods that are not included in the Code, the particular food cannot be legally sold under food legislation if it contains any detectable residues of the particular chemical; and

- where APVMA has decreased or deleted MRLs, food may be legally sold under food legislation if it contains residues that are inconsistent with the current registered uses of chemical products.

3. Objective

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

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

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

3.1.1 The protection of public health and safety

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

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

This is not relevant for this Application.

3.1.3 The prevention of misleading or deceptive information

This is not relevant for this Application.

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

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

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

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

3.1.5 The promotion of consistency between domestic and international food standards

This is addressed in section 9.

3.1.6 The desirability of an efficient and internationally competitive food industry

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

3.1.7 The promotion of fair trading in food

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

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

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

4. Background

4.1 The use of agricultural and veterinary chemicals

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

Before registering such a product, APVMA must be satisfied that the use of the product will not result in residues that would be an unacceptable 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 the 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 (Ministerial Council) of the adoption of the variation to the Code. If the Ministerial Council accepts the changes made by FSANZ, the MRLs are automatically adopted by reference under the food laws of the Australian States and Territories.

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

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

4.3 Maximum Residue Limits

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

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

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

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

In summary, the MRLs in 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 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 website at www.apvma.gov.au/ or by contacting APVMA on +61 2 6272 5158.

5. Evaluation Raised in Public Comment

Submissions were received from Food Technology Association of Victoria (FTAV), the Victorian Department of Human Services, Queensland Health and the United States of America.

The submission from FTAV supported the Application.

5.1 Submission from Queensland Health

The submission from Queensland Health brought to FSANZ'S attention an anomaly in the residue definition of sethoxydim. The drafting has been corrected to remove this anomaly.

The anomaly does not affect the proposed maximum residue limits for sethoxydim, or the estimated dietary exposure to the potential residues associated with the proposed MRLs for this chemical. Therefore, FSANZ considers that the proposed MRLs for sethoxydim do not represent an unacceptable risk to public health and safety.

5.2 Submission from the Victorian Department of Human Service

The submission from the Victorian Department of Human Service questioned the definition of antibiotics used in this Report. In this Report the term antibiotic refers to a chemical inhibitor of the growth of organisms produced by a microorganism.

FSANZ considers that there are no proposed MRLs for antibiotics in this Application.

FSANZ is in the process of investigating, with APVMA, the possible inclusion of a definition of the term 'antibiotic' that could be included in both Standard 1.4.2 and the APVMA MRL Standard.

5.3 Submission from the United States of America

As a result of the SPS Notification for this Application the United States of America requested the scientific data supporting the proposed MRLs for diphenylamine and fenvalerate.

As it is APVMA which has the responsibility to register the use of agricultural or veterinary chemicals, FSANZ forwarded this request to APVMA. APVMA will respond directly to the Australian SPS contact point regarding the request received from the United States of America.

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 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.

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 the 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 the 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 the 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 11.5.3 and data on imported foods are addressed in section 11.5.4. FSANZ invites comments from importers on the impacts of the deletions or reduction of MRLs; and

- for the 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 the 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 the Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable costs, although there may be minimal impacts associated with slight changes to residue monitoring programs.

8.4 Conclusion

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

- potential substantial costs to primary producers that may have a negative impact on their viability and in turn the viability of the rural and regional communities that depend upon the sale of the agricultural produce; and

- discrepancies between agricultural and food legislation which could have negative impacts on the compliance costs of primary producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

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

9. Consultation

Submissions were received from Food Technology Association of Victoria (FTAV), the Victorian Department of Human Services, Queensland Health and the United States of America. The Submissions received are addressed in section 5 of this Report

9.1 World Trade Organization Notification

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

This Application contains variations to MRLs which are addressed in the international Codex standard. MRLs in this Application also relate to chemicals used in the production of heavily traded agricultural commodities that may indirectly have a significant effect on trade of derivative food products between WTO members.

This Application was notified as an 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 to the WTO notification on this Application made by the United States of America is addressed in section 5.3 of this Report

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. This Application contains variations to MRLs which are addressed in the international Codex standard. The table below illustrates the proposed MRLs in this Application that differ from Codex MRLs.

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
Fenvalerate		
Edible offal (mammalian)	0.05	0.02
Milks	0.1	0.2
Imidacloprid		
Lettuce, head	5	2

FSANZ requested comment as to any possible ramifications of the proposed MRLS differing from those of the Codex Alimentarius Commission. The United States of America requested the scientific data supporting the proposed MRL fenvalerate.

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 that states the imported quantity of relevant foods for the years 2002 and 2003. These data are for foods for which deletions or reductions of MRLs are proposed.

Chemical Food	**2002** **Tonnes**	**2003** **Tonnes**
Spinosad Radish[2]	14	89
Tebufenozide Persimmon, Japanese	No recorded imports	No recorded imports

FSANZ requested comment as to any possible ramifications for imports of the deletion or reductions of the MRLs in this Application. No submissions were received addressing the proposed deletion or reduction of the MRLs for the relevant agricultural chemicals in imported food.

10. Conclusion and Recommendation

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

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.

- 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.

[2] The Australian Bureau of Statistics data does not include the individual import figures for radish. The import figures used include salad beetroot, salsify, celeriac, radishes and similar edible roots (excl. carrots and turnips), fresh or chilled.

- 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 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.

11. Implementation and Review

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

- State and Territory residue monitoring programs;

- Australian Government programs such as the National Residue Survey; and

- dietary exposure surveys such as the Australian Total Diet Survey.

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

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

Attachments

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

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 *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
SETHOXYDIM	SUM OF SETHOXYDIM AND METABOLITES CONTAINING THE 5-(2-ETHYLTHIOPROPYL)CYCLOHEXENE-3-ONE AND 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES AND THEIR SULFOXIDES AND SULFONES, EXPRESSED AS SETHOXYDIM

[1.2] *inserting in* Schedule 1 –

EPOXICONAZOLE EPOXICONAZOLE	
AVOCADO	0.5
BANANA	1
EDIBLE OFFAL (MAMMALIAN)	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.001
PYRACLOFOS PYRACLOFOS	
SHEEP FAT	T*0.1
SHEEP KIDNEY	T*0.1
SHEEP LIVER	T*0.1
SHEEP MEAT	T*0.1

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

FENVALERATE FENVALERATE, SUM OF ISOMERS	
CATTLE MEAT (IN THE FAT),	0.2
GOAT MEAT (IN THE FAT)	0.5
MILKS (IN THE FAT)	0.2
SHEEP MEAT (IN THE FAT)	0.5
SETHOXYDIM SUM OF SETHOXYDIM AND METABOLITES CONTAINING THE 5-(2-ETHYLTHIOPROPYL)CYCLOHEXENE-3-ONE AND 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES AND THEIR SULFOXIDES AND SULFONES, EXPRESSED AS SETHOXYDIM	
HERBS	T0.1

SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
ASSORTED TROPICAL AND SUB-TROPICAL FRUITS – INEDIBLE PEEL	T0.5
MIZUNA	T5
PEAS	T0.2
POTATO	T*0.01
RADISH	*0.05

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

AZOXYSTROBIN AZOXYSTROBIN	
COTTON SEED	T*0.01
BIFENTHRIN BIFENTHRIN	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	T1
COMMON BEAN (PODS AND/OR IMMATURE SEEDS)	T0.5
LETTUCE, HEAD	T2
BUPROFEZIN BUPROFEZIN	
OLIVES	T0.5
OLIVE OIL, CRUDE	T2
PERSIMMON, JAPANESE	T1
CAPTAN CAPTAN	
PITAYA (DRAGON FRUIT)	T20
CARBARYL CARBARYL	
GALANGAL, RHIZOMES (FRESH)	T5
TURMERIC, ROOT (FRESH)	T5
CARFENTRAZONE-ETHYL CARFENTRAZONE-ETHYL	
COTTON SEED	T*0.05
CHLORPYRIFOS CHLORPYRIFOS	
PITAYA (DRAGON FRUIT)	T*0.05
CYHALOTHRIN CYHALOTHRIN, SUM OF ISOMERS	
CHARD	T0.5

DIAFENTHIURON SUM OF DIAFENTHIURON; N-[2,6-BIS(1-METHYLETHYL)- 4-PHENOXYPHENYL]-N'-(1,1-DIMETHYLETHYL)UREA; AND N-[2,6-BIS(1-METHYLETHYL)-4-PHENOXYPHENYL]- N'-(1,1-DIMETHYLETHYL)CARBODIIMIDE, EXPRESSED AS DIAFENTHIURON	
EGGS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT (IN THE FAT)	*0.02
DIMETHOATE SUM OF DIMETHOATE AND OMETHOATE, EXPRESSED AS DIMETHOATE *SEE ALSO* OMETHOATE	
MANGO	1
DIPHENYLAMINE DIPHENYLAMINE	
EDIBLE OFFAL (MAMMALIAN) [EXCEPT LIVER]	*0.01
EGGS	0.05
LIVER OF CATTLE, GOATS, PIGS AND SHEEP	0.05
MEAT (MAMMALIAN) (IN THE FAT)	*0.01
MILKS (IN THE FAT)	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT (IN THE FAT)	*0.01
FENVALERATE FENVALERATE, SUM OF ISOMERS	
EGGS	0.02
MEAT (MAMMALIAN) (IN THE FAT)	1
MILKS	0.2
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT (IN THE FAT)	0.05
FIPRONIL SUM OF FIPRONIL, THE SULPHENYL METABOLITE (5-AMINO-1-[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-4-[(TRIFLUOROMETHYL) SULPHENYL]-1H-PYRAZOLE-3-CARBONITRILE), THE SULPHONYL METABOLITE (5-AMINO-1-[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-4-[(TRIFLUOROMETHYL)SULPHONYL]-1H-PYRAZOLE-3-CARBONITRILE), AND THE TRIFLUOROMETHYL METABOLITE (5-AMINO-4-TRIFLUOROMETHYL-1-[2,6-DICHLORO-4-(TRIFLUOROMETHYL)PHENYL]-1H-PYRAZOLE-3-CARBONITRILE)	
SWEDE	0.1
TURNIP, GARDEN	0.1
FLUDIOXONIL FLUDIOXONIL	
COTTON SEED	T*0.05

IMIDACLOPRID SUM OF IMIDACLOPRID AND METABOLITES CONTAINING THE 6-CHLOROPYRIDINYMETHYLENEMOIETY, EXPRESSED AS IMIDACLOPRID	
LETTUCE, HEAD	T5
LETTUCE, LEAF	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 SULFONES, EXPRESSED AS SETHOXYDIM	
HERBS [EXCEPT THYME]	*0.1
THYME	0.5
SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
ASSORTED TROPICAL AND SUB TROPICAL FRUITS – INEDIBLE PEEL [EXCEPT BANANA AND KIWIFRUIT]	T0.5
BANANA	0.2
CUCUMBER	0.2
KIWIFRUIT	0.3
JAPANESE GREENS	5
PEAS (PODS AND SUCCULENT, IMMATURE SEEDS)	0.5
ROOT AND TUBER VEGETABLES	0.02
SOYA BEAN	T0.05
TRICLABENDAZOLE TRICLABENDAZOLE	
FAT (MAMMALIAN)	1
TRIFLOXYSTROBIN SUM OF TRIFLOXYSTROBIN AND ITS ACID METABOLITE ((E,E)-METHOXYIMINO-[2-[1-(3-TRIFLUOROMETHYLPHENYL)-ETHYLIDENEAMINOOXYMETHYL]PHENYL] ACETIC ACID), EXPRESSED AS TRIFLOXYSTROBIN EQUIVALENTS	
STRAWBERRY	T2

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

CHLORPYRIFOS CHLORPYRIFOS	
PERSIMMON, JAPANESE	0.5
DIPHENYLAMINE DIPHENYLAMINE	
APPLE	10

FENVALERATE FENVALERATE, SUM OF ISOMERS	
EDIBLE OFFAL (MAMMALIAN)	0.05
FLUMETHRIN FLUMETHRIN, SUM OF ISOMERS	
CATTLE, EDIBLE OFFAL OF	0.05
CATTLE MEAT (IN THE FAT)	0.2
MILKS	0.05
GLYPHOSATE GLYPHOSATE	
COTTON SEED	10
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL *SEE ALSO* THIODICARB	
AVOCADO	*0.1
SETHOXYDIM SUM OF SETHOXYDIM AND METABOLITES CONTAINING THE 5-(2-ETHYLTHIOPROPYL)CYCLOHEXENE-3-ONE AND 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES AND THEIR SULFOXIDES AND SULFONES, EXPRESSED AS SETHOXYDIM	
BERGAMOT	*0.1
BURNET, SALAD	*0.1
CHERVIL	*0.1
CORIANDER (LEAVES, STEM, ROOTS)	*0.1
CORIANDER SEED	*0.1
DILL, SEED	*0.1
FENNEL, SEED	*0.1
KAFFIR LIME LEAVES	*0.1
LEMON GRASS	*0.1
LEMON VERBENA (FRESH WEIGHT)	*0.1
MIZUNA	*0.1
ROSE AND DIANTHUS (EDIBLE FLOWERS)	*0.1
RUCOLA (ROCKET)	*0.1
TURMERIC, ROOT	1
SPINOSAD SUM OF SPINOSYN A AND SPINOSYN D	
BEANS [EXCEPT BROAD BEAN AND SOYA BEAN]	0.5
BERGAMOT	5
BERRIES AND OTHER SMALL FRUITS [EXCEPT GRAPES]	0.7
BURNET, SALAD	5
CHERVIL	5
CORIANDER (LEAVES, STEM, ROOTS)	5
CORIANDER, SEED	5
DILL, SEED	5
EGG PLANT	0.2
FENNEL, SEED	5
GALANGAL, GREATER	0.02

HERBS	5
KAFFIR LIME LEAVES	5
LEMON GRASS	5
LEMON VERBENA (DRY LEAVES)	5
POME FRUITS	0.5
PULSES	T0.05
RUCOLA (ROCKET)	5
STONE FRUITS	0.7
TURMERIC, ROOT	0.02
TEBUFENOZIDE	
TEBUFENOZIDE	
PERSIMMON, JAPANESE	0.1
TRICLABENDAZOLE	
TRICLABENDAZOLE	
KIDNEY (MAMMALIAN)	1
LIVER (MAMMALIAN)	2

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*

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.

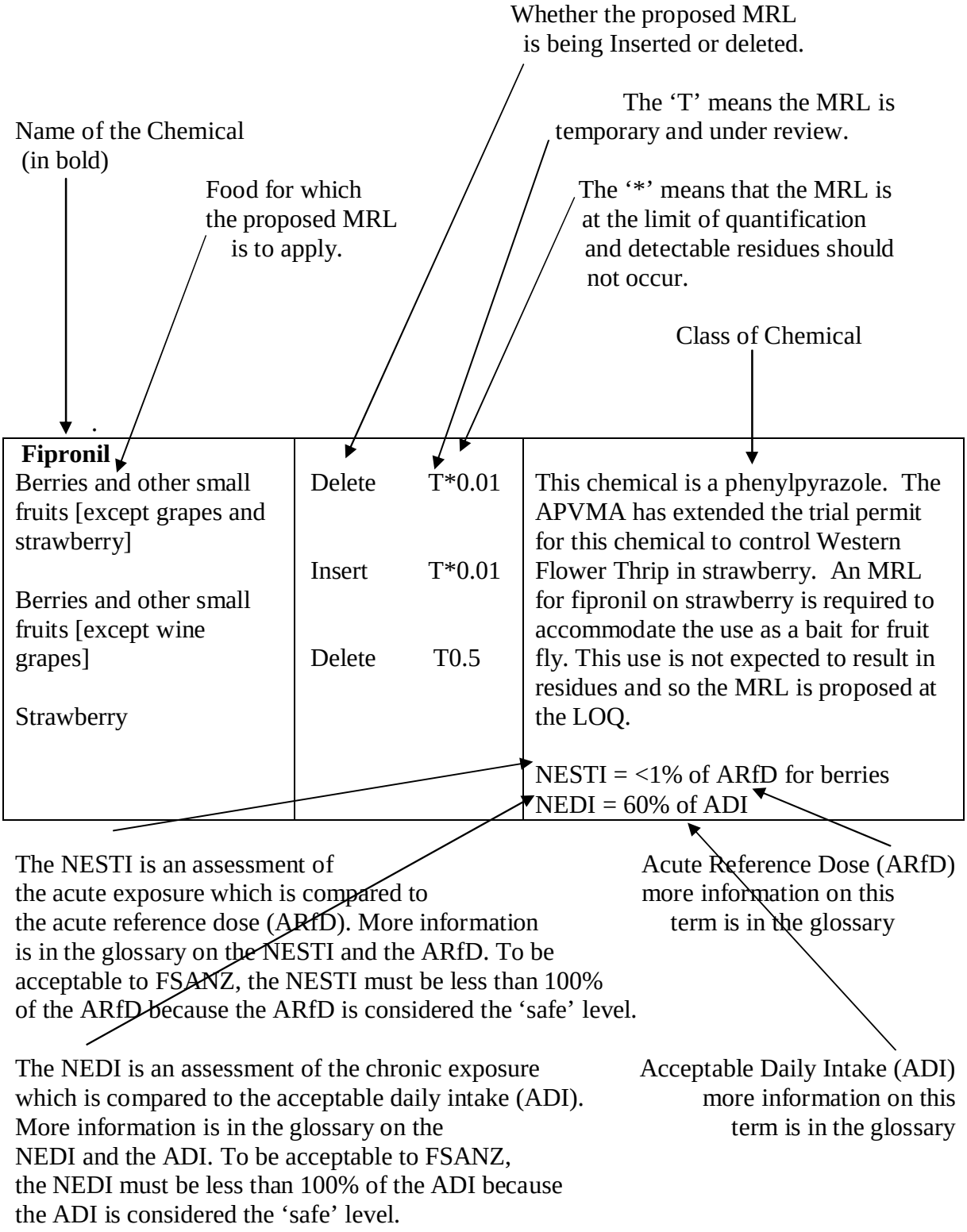
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

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.



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	Insert	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

SUMMARY OF THE REQUESTED MRLS FOR APPLICATION A534 - MRLS

Chemical Food	**Action**	**MRL**	**Comments**
Azoxystrobin			
Cotton seed	Insert	T*0.01	This chemical is a strobilin fungicide. The APVMA has issued a permit for this chemical to be used to control fungal diseases on cotton crops. NEDI = <1% of ADI.
Bifenthrin			
Brassica (cole or cabbage) vegetables, Head cabbages, Flower head brassicas	Insert	T1	This chemical is a synthetic pyrethroid insecticide. The APVMA have issued a permit for this chemical to be used to control insects on vegetable crops. The 20th ATDS (2000) dietary exposure estimate for bifenthrin, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 72% of the ADI.
Common bean (pods and/or immature seeds)	Insert	T0.5	
Lettuce, head	Insert	T2	
Buprofezin			
Olives	Insert	T0.5	This chemical is an insecticide and an acaracide. The APVMA have issued a permit for this chemical to be used to control insects on olive and persimmon trees. NEDI = 11% of the ADI.
Olive oil, crude	Insert	T2	
Persimmon, Japanese	Insert	T1	
Captan			
Pitaya (dragon fruit)	Add	T20	This chemical is a phthalimide fungicide. The APVMA have issued a permit for this chemical to be used to control fungal attacks on pitaya crops. The 20th ATDS (2000) dietary exposure estimate for captan, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 8% of the ADI.
Carbaryl			
Galangal, rhizomes (fresh)	Insert	T5	This chemical is a carbamate insecticide. The APVMA have issued a permit for this chemical to be used to control insects on galangal and turmeric crops. This chemical is currently under review by the APVMA. Its use on galangal and turmeric will make negligible difference to the current estimated chronic dietary exposure. The 20th ATDS (2000) dietary exposure estimate for carbaryl, as a percentage of the ADI is equivalent to <1% for the adult males and 5% of ADI for 2-6 y.o. NESTI calculations were undertaken based on spice consumption using ginger portion sizes.
Turmeric, root (fresh)	Insert	T5	

Carbaryl (cont)			Spices (root) NESTI = 20% of ARfD for 2 to 6 y.o. and 12% of the ARfD for the whole population. Spices (root – dry – processed) NESTI = 22% of ARfD for 2 to 6 y.o. and 13% of the ARfD for the whole population. Spices (root – dry – individual) NESTI = 65 % of ARfD for 2 to 6 y.o. and 39% of the ARfD for the whole population. NEDI = 45% of the ADI.
Carfentrazone-ethyl Cotton seed	Insert	T*0.05	This chemical is a triazolinone herbicide. The APVMA have issued a permit for this chemical to be used a pre-harvest defoliant in cotton. NEDI = 2% of the ADI.
Chlorpyrifos Persimmon, Japanese Pitaya (dragon fruit)	Delete Substitute Insert	T*0.05 0.5 T*0.05	This chemical is an organophosphate insecticide used to control insects on various crops. NESTI for persimmon, Japanese = 1% of ARfD for 2 to 6 y.o. and 2% of the ARfD for the whole population. The APVMA have issued a permit for this chemical to be used to control ants on pitaya crops. NESTI calculations for pitaya were undertaken based on pineapple consumption. NESTI = 5% of ARfD for 2 to 6 y.o. and 1% of the ARfD for the whole population. 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 the ADI.
Cyhalothrin Chard	Insert	T0.5	This chemical is a synthetic pyrethroid insecticide. The APVMA have issued a permit for this chemical to be used to control insects in silver beet crops. NEDI = 3% of the ADI.
Diafenthiuron Eggs Poultry, edible offal of Poultry meat (in the fat)	Insert Insert Insert	*0.02 *0.02 *0.02	This chemical is a thiourea miticide; it is used to control insects on cotton crops. NEDI = 7% of the ADI.

Dimethoate			
Mango	Insert	1	This chemical is an organophosphate insecticide used to control insects on fruit crops. The 20th (2000) ATDS dietary exposure estimate for dimethoate as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NESTI for mango is equivalent to 96% of ARfD for 2 to 6 y.o. There are less than 39 consumers of mango in the age group 2-6 y.o. Therefore, the consumption figure for banana was used. This value is an extreme situation, as it assumes that more consumers would eat banana than mango. NESTI for 2 years and above = 40% of the ARfD. NEDI = 80% of the ADI.
Diphenylamine			
Apple	Delete Substitute	5 10	This chemical is a fungicide; it is used to control scald on apples. As apple processing waste may be used as animal feed, it is proposed to establish animal commodity MRLs for this chemical. The 20th ATDS (2000) dietary exposure estimate for diphenylamine as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 20% of the ADI.
Edible offal (mammalian) [except liver]	Insert	*0.01	
Eggs	Insert	0.05	
Liver of cattle, goats, sheep and pigs	Insert	0.05	
Meat (mammalian) (in the fat)	Insert	*0.01	
Milks (in the fat)	Insert	*0.01	
Poultry, edible offal of	Insert	*0.01	
Poultry meat (in the fat)	Insert	*0.01	
Epoxiconazole			
Avocado	Insert	0.5	This chemical is a triazole fungicide; it is used to control fungal attacks on banana and avocado crops. Avocado NESTI = 10% of ARfD for 2 to 6 y.o. and 2% of the ARfD for the whole population. Banana NESTI = 4 % of ARfD for 2 to 6 y.o. and 1% of the ARfD for the whole population. Edible offal (mammalian) NESTI = <1 % of ARfD for 2 to 6 y.o. and <1% of the ARfD for the whole population. Meat (mammalian) NESTI = <1 % of ARfD for 2 to 6 y.o. and <1% of the ARfD for the whole population. Milk NESTI = <1 % of ARfD for 2 to 6 y.o. and <1% of the ARfD for the whole population. NEDI = 2% of the ADI
Banana	Insert	1	
Edible offal (mammalian)	Insert	*0.01	
Meat (mammalian)	Insert	*0.01	
Milks	Insert	*0.001	

Fenvalerate			
Cattle meat (in the fat)	Delete	0.2	This chemical is a synthetic pyrethroid; it is used to control insects on various crops. The proposed MRLs for animal commodities are in relation to the APVMA's Stockfeed Guideline project. The 19th ATDS (1998) dietary exposure estimate for fenvalerate as a percentage of the ADI is equivalent to <1% of ADI for the whole population. In the 20th (2000) ATDS the concentrations of residues of fenvalerate in surveyed foods were less than the LOQ. NEDI = 88% of the ADI.
Edible offal (mammalian)	Delete	0.02	
	Substitute	0.05	
Eggs	Insert	0.02	
Goat meat (in the fat)	Delete	0.5	
Meat, mammalian (in the fat)	Insert	1	
Milks	Insert	0.2	
Milks (in the fat)	Delete	0.2	
Poultry, edible offal of	Insert	*0.02	
Poultry meat (in the fat)	Insert	0.05	
Sheep meat (in the fat)	Delete	0.5	
Fipronil			
Swede	Insert	0.1	This chemical is a phenylpyrazole insecticide; it is used to control insects on swede and turnip crops. Swede NESTI = 8% of ARfD for 2 to 6 y.o. and 13% of the ARfD for the whole population. Turnip NESTI = 8% of ARfD for 2 to 6 y.o. and 5% of the ARfD for the whole population. NEDI = 77% of the ADI.
Turnip, garden	Insert	0.1	
Fludioxonil			
Cotton seed	Insert	T*0.05	This chemical is a phenylpyrrole fungicide. The APVMA has issued a permit for this chemical to be used to control various fungal diseases on cotton crops. NEDI = 1.2% of ADI.
Flumethrin			
Cattle, edible offal of	Delete	T0.05	This chemical is a synthetic pyrethroid insecticide used to control ticks, lice and mites on cattle. The 19th ATDS (1998) dietary exposure estimate for flumethrin as a percentage of the ADI is equivalent to <1% of ADI for the whole population. In the 20th (2000) ATDS the concentrations of residues of flumethrin in surveyed foods were less than the LOQ. NEDI = 10% of the ADI
	Substitute	0.05	
Cattle meat (in the fat)	Delete	T0.2	
	Substitute	0.2	
Milks	Delete	T0.05	
	Substitute	0.05	
Glyphosate			
Cotton seed	Delete	1	This chemical is a glycine derivative herbicide; it is used is to control weeds on cotton crops. The proposed MRL of 10 mg/kg is consistent with the MRLs established by the Codex Alimentarius Commission, Japan and European Union. NEDI = 6% of ADI.
	Substitute	10	

Imidacloprid Lettuce, head Lettuce, leaf	 Insert Insert	 T5 T5	This chemical is a neonicotinoid insecticide: it is used to control thrips and aphids on brassica leafy vegetable crops. APVMA has issued a permit for this chemical to be used to control insects on lettuce crops. NESTI for lettuce is equivalent to 5% of ARfD for 2 to 6 y.o. and 3% of the ARfD for the whole population. NEDI = 7% of ADI
Methomyl Avocado	 Delete Substitute	 T0.1 *0.1	This chemical is a carbamate insecticide; it is used to insects on avocado crops. In the 19th (1998) ATDS methomyl residues were not detected in any surveyed foods. At this time the OCS has not set an Australian ARfD. The NESTI was calculated using the Codex ARfD NESTI = 16% of ARfD for 2 to 6 y.o. and 5% of the ARfD for the whole population. NEDI = 83% of the ADI.
Pyraclofos Sheep fat Sheep kidney Sheep liver Sheep meat	 Insert Insert Insert Insert	 T*0.1 T*0.1 T*0.1 T*0.1	This chemical is an organophosphate. The APVMA have issued a permit for this chemical to be used control gastrointestinal roundworms, large lungworms, tape worms and to aid in the control of liver fluke. NEDI = 2% of the ADI.
Sethoxydim Bergamot Chervil Coriander (leaves, stem and roots) Coriander seed Dill seed Fennel seed Herbs Herbs [except thyme] Kaffir lime leaves	 Delete Substitute Delete Substitute Delete Substitute Delete Substitute Delete Substitute Delete Substitute Delete Insert Delete Substitute	 T0.1 *0.1 T0.1 *0.1 T0.1 *0.1 T0.1 *0.1 T0.1 *0.1 T0.1 *0.1 T0.1 *0.1 T0.1 *0.1	This chemical is a cyclohexanedione oxime herbicide; it is used to control grasses in various crops.

Lemon grass	Delete Substitute	T0.1 *0.1	
Lemon verbena (fresh weight)	Delete Substitute	T0.1 *0.1	
Mizuna	Delete Substitute	T0.1 *0.1	
Rose and dianthus (edible flowers)	Delete Substitute	T0.1 *0.1	
Rucola (rocket)	Delete Substitute	T0.1 *0.1	
Salad burnet	Delete Substitute	T0.1 *0.1	
Thyme Turmeric, root	Insert Delete Substitute	0.5 T1 1	NEDI = 25% of ADI.
Spinosad Assorted tropical and sub tropical fruits-inedible peel Assorted tropical and sub tropical fruits-inedible peel [except banana and kiwifruit] Banana	Delete Insert Insert	T0.5 T0.5 0.2	This chemical is a spinosyn; it is used to control arthropods in various crops.
Beans, except broad bean and soya bean	Delete Substitute	T0.2 0.5	
Bergamot	Delete Substitute	T5 5	
Berries and other small fruits [except grapes]	Delete Substitute	T0.5 0.7	
Chervil	Delete Substitute	T5 5	
Coriander (leaves, stem, roots)	Delete Substitute	T5 5	
Coriander, seed	Delete Substitute	T5 5	
Cucumber Dill, seed	Insert Delete Substitute	0.2 T5 5	
Egg plant	Delete Substitute	T0.1 0.2	

Fennel, seed	Delete Substitute	T5 5	
Galangal, greater	Delete Substitute	T*0.01 0.02	
Herbs	Delete Substitute	T5 5	
Japanese greens	Insert	5	
Kaffir lime leaves	Delete Substitute	T5 5	
Kiwifruit	Insert	0.3	
Spinosad (cont) Lemongrass	Delete Substitute	T5 5	
Lemon verbena (dry leaves)	Delete Substitute	T5 5	
Mizuna	Delete	T5	
Peas	Delete	T0.2	
Peas (pods and succulent and immature seed)	Insert	0.5	
Pome fruits	Delete Substitute	0.2 0.5	
Pulses	Delete Substitute	T*0.01 T0.05	The APVMA have issued a permit for this chemical to be used control insects in pulse crops.
Potato	Delete	T*0.01	
Radish	Delete	*0.05	
Root and tuber vegetables	Insert	0.02	
Rucola (rocket)	Delete Substitute	T5 5	
Salad burnet	Delete Substitute	T5 5	
Soya bean	Insert	T0.05	
Stone fruit	Delete Substitute	T0.2 0.7	
Turmeric, root	Delete Substitute	T*0.01 0.02	NEDI = 33% of the ADI.
Tebufenozide Persimmon, Japanese	Delete Substitute	T1 0.1	This chemical is a diacylhydrazine insecticide; it is used to control insects on persimmon crops. NEDI = 22% of ADI.

Triclabendazole Fat (mammalian) Kidney (mammalian) Liver (mammalian)	 Insert Delete Substitute Delete Substitute	 1 0.5 1 0.5 2	 This chemical is a benzimidazole anthelmintic; it used to treat liver fluke in cattle. NEDI = 48% of the ADI.
Trifloxystrobin Strawberry	Insert	T2	This chemical is a strobilurin fungicide. The APVMA have issued a permit for this chemical to be used to control powdery mildew and downy mildew on strawberries. 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 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 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 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.