

08/03
19 March 2003

FINAL ASSESSMENT REPORT

APPLICATION A468

MAXIMUM RESIDUE LIMITS

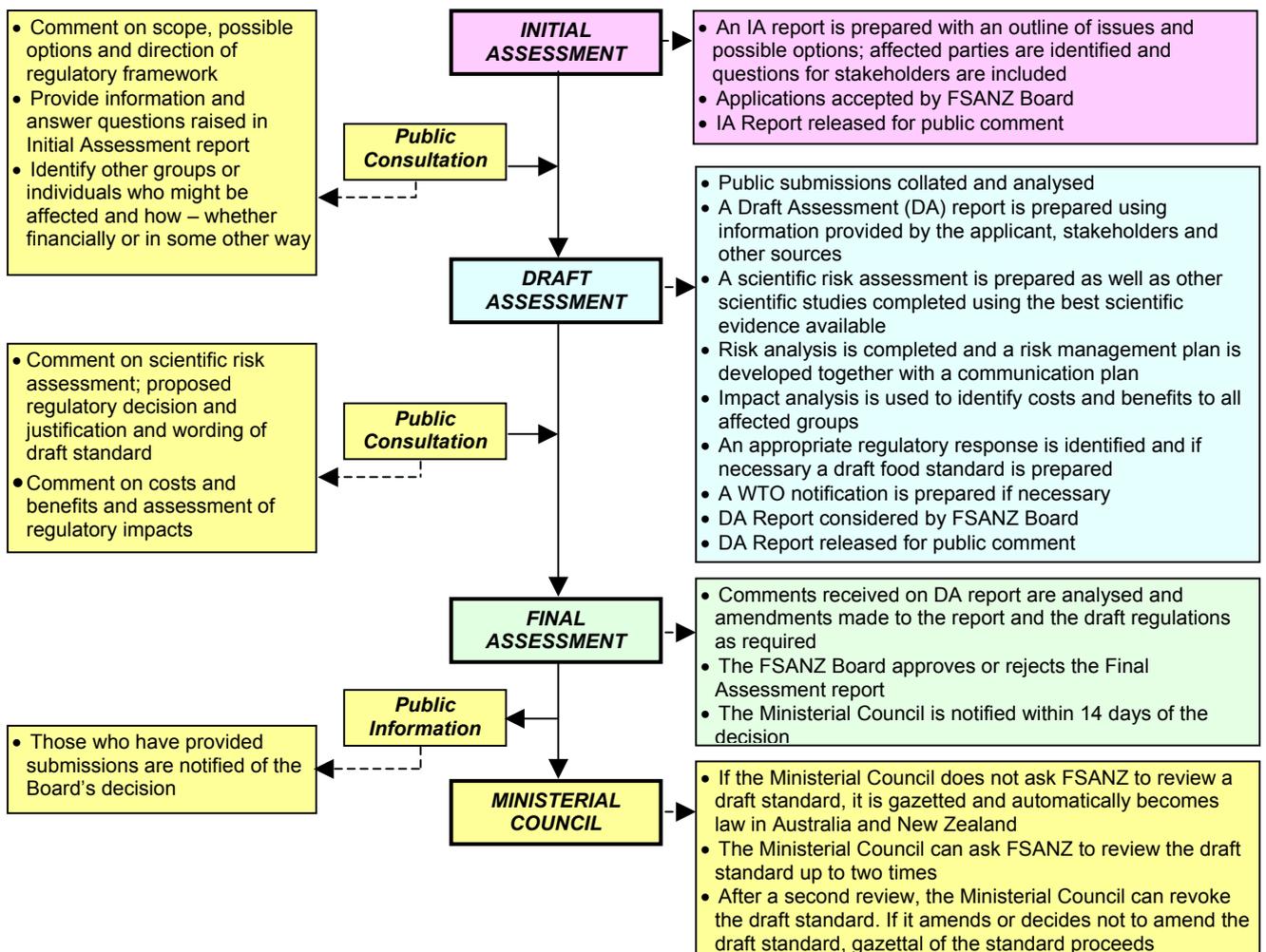
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 *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

The Authority 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 *Australia New Zealand Food Standards Code*, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

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

Submissions

No submissions on this matter are sought as the Authority has completed its assessment and the matter is now with the Australia and New Zealand Food Regulation Ministerial Council for consideration.

Further Information

Further information on this and other matters should be addressed to the Standards Liaison Officer at the Food Standards Australia New Zealand 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 the Authority'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 (A468) seeks to amend Maximum Residue Limits (MRLs) for non-antibiotic agricultural and veterinary chemicals in the *Australia New Zealand Food Standards Code* (Code). It is a routine application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the Code in order to reflect 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.

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 NRA 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 NRA 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 Therapeutic Goods Administration (TGA) of the Commonwealth 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, the acute reference dose (ARfD).
- FSANZ has undertaken a preliminary regulation impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the *Food Standards 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 the NRA on 3 June, 9 July, 12 August and 4 September 2002 seeking amendment 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 NRA MRL Standard.

1.1 Summary of proposed MRLs

The MRL amendments under consideration in this Application are:

- the removal all MRL entries for the chemicals monocrotophos, parathion and rafoxanide;
- the deletion of MRLs for certain foods for the chemicals bifenthrin, bitertanol, carbendazim, dithiocarbamates, fipronil, kresoxim-methyl, quizalofop-ethyl, quizalofop-p-tefuryl and triadimenol;
- the addition of MRLs for certain foods for the new chemicals ketoprofen and mesosulfuron-methyl;
- the addition of MRLs for certain foods for the chemicals bifenthrin, bitertanol, cyanazine, diflufenican, dithiocarbamates, fipronil, imazamox, kresoxim-methyl, pendimethalin, propachlor, propyzamide, quinoxifen, quizalofop-ethyl, quizalofop-p-tefuryl, simazine, tebufenozide and triadimenol;
- the changing of MRLs for certain foods for bitertanol, chlorpyrifos, deltamethrin, ethametsulfuron methyl, fluazifop-butyl, fluazinam, methabenzthiazuron, methomyl, pendimethalin, procymidone, quinoxifen, quizalofop-ethyl, quizalofop-p-tefuryl and tebufenozide; and
- the addition of temporary MRLs for certain foods for the chemicals azoxystrobin, carbendazim, cypermethrin, dithiocarbamates, methidathion, procymidone 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 antibiotic residues in this Application.

2. Regulatory Problem

2.1 Current Regulations

The NRA has approved the use of the agricultural and veterinary chemical products associated with the MRLs in this Application, and made consequent amendments to the NRA 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 the NRA 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 the NRA 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 the NRA 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. The NRA has already established MRLs under the NRA'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 Chemicals and Non-prescription Medicines Branch of the TGA establish the ADI and where applicable the ARfD for the agricultural and veterinary chemicals. The NRA 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 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 the NRA are based on a comprehensive examination of up to date 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.

4. Background

4.1 The use of agricultural and veterinary chemicals

In Australia, the NRA 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, the NRA 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, the NRA includes MRLs in its NRA 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, the NRA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews the information provided by the NRA 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.

FSANZ then notifies the Australia and New Zealand Food Regulation Ministerial Council, which is made up of Commonwealth, State and Territory and New Zealand Health Ministers, of its decision. If the Council does seek a review of the FSANZ decision, the MRLs are gazetted and automatically adopted by reference under the food laws of the Commonwealth and 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 the NRA 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 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, the NRA includes MRLs in its NRA MRL Standard when they register a chemical product for use or grant a permit for use. The NRA then notifies FSANZ of these MRLs so that FSANZ may consider them for inclusion into 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 MRLs 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 NRA 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 MRLs for permits can be found on the website of the NRA at <http://www.nra.gov.au> or by contacting the NRA on +61 2 6272 5158.

5. Evaluation of Issues Raised in Public Comment

The submission from the Food Technology Association of Victoria supported this Application. The submissions from the Australian Food And Grocery Council (AFGC) Australian Pork Limited (APL) and Nestlé Australia Limited expressed concerns about:

- an omission in Attachment 2 of the Initial/Draft Assessment Report;
- Codex Alimentarius Commission MRLs;
- Ethametsulfuron-methyl;
- imported food;
- MRLs and genetically modified organisms applications;
- MRLs permitted in other countries;
- retaining all the MRLs proposed for deletion;
- roles of the NRA and FSANZ in establishing MRLs;
- time taken to process applications;
- Trans Tasman Mutual Recognition Arrangement;
- use of group heading for commodities; and
- use of section 36 of the FSANZ Act.

Each of these is examined in turn below:

5.1 Omission in Attachment 2 of the Initial/Draft Assessment Report

AFGC, APL and Nestlé brought to FSANZ's attention that the entry in Attachment 2 - Summary of Requested MRLs, contains an omission for bitertanol for poultry edible offal. This entry has been corrected. This omission did not affect the entry for this proposed MRL in Attachment 1.

5.2 Codex Alimentarius Commission MRLs

Nestlé expressed concerns about Codex MRLs and the proposed deletion of MRLs for monocrotophos and parathion being inconsistent with Codex MRLs.

5.2.1 Monocrotophos

The relevant Codex MRLs for monocrotophos in this Application are all at the limit of quantification (LOQ). The LOQ is the lowest concentration of an agricultural and 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. This effectively means that no detectable residues of this chemical should occur in those commodities. Therefore, the proposed deletion of these MRLs from the Code for this chemical would have no effect on the importation of commodities that comply with the Codex MRL, as no residues should be detectable.

Further, at its 34th Session the Codex Committee on Pesticide Residues (CCPR) noted that this compound was no longer supported and has decided to consider revocation of the MRLs for this chemical at the next session of CCPR.

5.2.2 Parathion

The Joint Meeting of the FAO Panel of Experts on Pesticide Residues has recommended to the CCPR that the Codex MRLs for apricot and peach be withdrawn. At its 34th Session the CCPR agreed that all MRLs for this chemical should be withdrawn.

5.3 Ethametsulfuron-methyl

The AFGC submission noted that in the Initial/Draft assessment Report the spelling of the herbicide ethametsulfuron-methyl was not hyphenated. In all the documentation received from the Applicant, the name of this chemical was not hyphenated. After discussions with the Applicant, it was agreed that the correct spelling for this chemical includes a hyphen i.e. ethametsulfuron-methyl. FSANZ has corrected the assessment papers accordingly.

5.4 Imported Food

Nestlé stated that it had experienced problems with residues of pesticides in food exported from Malaysia to Australia. As discussed above, MRLs associated with residues in imported food can be considered by making an application to FSANZ to amend the Code to include the MRLs associated with the residues in imported food. FSANZ has already received applications of this type and would encourage an application to include MRLs that Nestlé consider should be included in the Code.

The AFGC submission stated that FSANZ is *ignoring the potential costs to importers and domestic manufacturers* by recommending certain MRL deletions.

The Initial/Draft Assessment Report specifically includes a regulatory impact section that specifically asks importers to identify the costs that may be associated with the proposed deletions and reductions.

To assist in identifying possible impacts where imported food may be affected, the Initial/Draft Assessment Report provided relevant data on the food imported for the past two years. FSANZ then requested comment as to any possible ramifications for imports from the proposed deletions or reduction. Further, FSANZ specifically targeted food importers that had previously made submissions and forwarded a copy of the assessment report to them.

Further, Australia as a member of WTO is obliged to notify WTO member nations where proposed mandatory regulation measures are inconsistent with any existing on imminent international standards and the proposed measure may have a significant effect on trade. FSANZ makes WTO notifications for all MRL applications and proposals.

Nestlé expressed concerns about the data in the table of imported food. These data are based on data supplied by the Australian Bureau of Statistics. FSANZ incorporates data on processed imported food commodities, where available, in the table.

AFGC and Nestlé raised concerns as to the effect of the variation on foods being imported into Australia. AFGC and Nestlé were advised of the effects of Amendment 61 to the Code on the potential impact of the MRL reductions or deletions. That amendment commenced on 20 December 2002, and provides a period of grace for any further variation to the Code for 'stock in trade'.

5.5 MRLs and genetically modified organisms applications

The AFGC had concerns that FSANZ is *exhibiting double standards* in the treatment of applications for MRLs as compared to the application for genetically modified foods. In assessing applications for foods derived from gene technology, FSANZ undertakes a specific assessment of each food. This specific assessment takes into account that such foods may be imported. In the same way specific MRLs associated with residues in imported food can be considered by making an application to FSANZ, together with supporting data to amend the *Code*.

5.6 MRLs permitted in other countries.

The AFGC had concerns that FSANZ had not addressed the issue of whether the proposed deletions or reductions were more restrictive than MRLs in other countries. The only appropriate approach for FSANZ in considering MRLs proposed for deletion or reduction is to consult as widely as possible on any MRL changes to the Code to determine the impacts that these changes may have. It is open to importers and domestic manufacturers to provide specific information on MRLs, use patterns and residue data to allow FSANZ to consider specific MRLs for imported foods.

In assessing MRLs, FSANZ has regard to the need for standards to be based upon risk analysis using the best available evidence. To fulfil this requirement and retain specific MRLs, FSANZ would need to be able to make a considered and proper assessment of the scientific evidence and the possible cost/benefits of retaining the specific MRLs. To make this assessment, FSANZ would require specific data for the chemical and commodity, relevant residue data from the importing country, including their MRL.

5.7 Retaining all the MRLs proposed for deletion

The AFGC submission stated:

However, on the basis that the prior approval of the MRLs which are proposed for removal, deletion and change was given consistent with the objective of the protection of public health and safety based on risk analysis and the best available science, consistency between domestic and international food standards, and the desirability of an efficient and internationally competitive food industry, the AFGC opposes these changes.

In addition, Nestlé's expressed concerns that food that is treated by some of the agricultural chemicals that are marked for deletion from the Code are currently able to be imported from some countries. Nestlé also supported Option 2(b) - Adopt the changes to MRLs to include and increase some existing MRLs for this Application and did not support Option 2(a) - Adopt the changes to MRLs to delete or increase some existing MRLs.

In considering MRLs, the NRA and FSANZ conduct dietary exposure assessments in accordance with the best available scientific evidence. To be consistent with the best available scientific evidence, the risk analysis only include those MRLs that are necessary; consistent with the principle that residues are kept as low as reasonably achievable. FSANZ considers that, based on the information currently available, that the MRLs proposed for deletion are unnecessary and that the AFGC and Nestlé have not provided any scientific evidence to support the retention of any specific MRL.

In addition, retaining all the MRLs proposed for deletion would result in a large inconsistency between domestic food and agricultural legislation. Some inconsistency may be warranted where there is specific evidence indicating that a difference is required. However, no such evidence has been provided and therefore it would be inappropriate to retain these MRLs and create an inconsistency between health and agricultural legislation. Furthermore, retaining all the MRLs proposed for deletion would create complications for enforcement that would undermine the efficiency of domestic food production. On this basis, FSANZ considers that retaining all the MRLs proposed for deletion would be inappropriate.

There are major costs in retaining all the MRLs proposed for deletion since this will undermine the effectiveness of MRLs which assist in controlling the use of agricultural and veterinary chemicals. FSANZ considers that these costs would be significant, substantial and unjustified where all MRLs are retained, even where there is no Australian use. However, for specific MRLs, the reasons for a difference between health and agricultural legislation may be justified, on the basis that the benefits may outweigh the costs. In this case, costs would be considered significant but not substantial. However, no submission supplied data supporting the retention of specific MRLs proposed for deletion or reduction.

5.8 Roles of the NRA and FSANZ in establishing MRLs

The APL submission sought clarification in the roles of the NRA and FSANZ in establishing MRLs. In Australia the NRA regulates the use of and labelling of agricultural and veterinary chemicals. Before registering any of these chemical products for use the NRA assesses the appropriate toxicological, residue, animal transfer, processing and metabolism studies. Following registration the NRA makes applications to FSANZ to amend MRLs for agricultural and veterinary chemicals 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 examines the estimated dietary exposures, carried out by the NRA, for all residues associated with a proposed MRL. FSANZ will not approve any MRL where the estimated dietary exposure exceeds the safety limits set by the ADI or, where appropriate the ARfD.

5.9 Time taken to process applications

The APL had concerns about the time taken to progress MRL applications. FSANZ is aware of the risks to producers using agricultural and veterinary chemicals for which the NRA has registered a use and established an MRL, but for which FSANZ has not established an MRL in the Code. However, FSANZ is a statutory authority that must develop food regulatory measures in accordance with the (FSANZ Act, which includes requirements for a regulatory impact analysis, public health and safety assessment and public consultation by FSANZ.

Following consultation and if satisfied, the FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines, where these are available, set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

Finally, jurisdictions on the Ministerial Council can ask for a review of the approved standard within a 60 day period further delaying the gazettal of the proposed MRLs into the Code. The time taken to progress MRL applications is a function of these statutory processes that FSANZ is obligated to follow.

5.10 Trans Tasman Mutual Recognition Arrangement

Nestlé had concerns that MRLs are not part of the *Trans Tasman agreement* (sic) and that commodities containing residues of parathion, that are permitted for sale in New Zealand would be illegal in Australia.

Nestlé is correct in that the *Agreement between the Commonwealth of Australia and the Government of New Zealand to establish a system for the development of joint food standards*, excludes MRLs for agricultural and veterinary chemicals in food from the joint Australia New Zealand food standards setting system. However, the Trans Tasman Mutual Recognition Arrangement permits food that is produced or imported into New Zealand and complies with the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard, 1999* can be legally sold in Australia.

5.11 Use of group heading for commodities

The APL submission endorsed the use of the *more generic MRL entry of “meat - mammalian”*.

The establishment of MRLs for specific commodities or for commodity groups is carried out on a case-by-case basis and only where appropriate studies support the proposed MRLs. In the case of the proposed MRLs for bifenthrin, quizalofop-ethyl and quizalofop-p-tefuryl the changes to the group heading of meat (mammalian) have resulted from the NRA Stockfeed Guideline Project. No changes in the use of these chemicals is involved and the estimated dietary exposures do not exceed the relevant ADIs. Further, the proposed MRLs for quizalofop-ethyl and quizalofop-p-tefuryl for meat mammalian are at the limit of quantification and therefore no detectable residues of these chemicals should occur in meat (mammalian).

5.12 Use of Section 36 of the FSANZ Act

The submission from Nestlé raised concerns that the application does raise issues of significance.

The FSANZ Act allows FSANZ to omit certain functions where:

- to omit the function with not have a significant adverse effect on the interests of anyone; or
- the application raises issues of minor significance or minor complexity.

Where appropriate, these provisions are used to minimise the time it takes for MRLs to be considered and adopted into the Code. MRLs are typically of minor complexity and on a case-by-case basis; one round of public comment for the purposes of the Initial/Draft Assessment may be omitted in assessing them.

The use of Section 36 simplifies the assessment of MRLs and does not impact on the assessment on the MRLs from a health perspective, and at least one round of public comment is sought.

6. Options

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

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

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 included in the final assessment of this application will include information from public submissions.

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

8.1.1 Benefits

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of agricultural and veterinary chemicals;
- for growers and producers of domestic and export food commodities, the adoption of this option would not result in any discernable benefits;
- for importers, the adoption of this option would not result in any discernable benefits; and
- for 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. FSANZ invited comment on whether these costs are likely to be discernable by consumers but no comments were received;
- 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. FSANZ invited comment on whether these costs are likely to be discernable by consumers FSANZ invited comment on whether these costs are likely to be discernable by consumers but no comments were received;
- for growers and producers of domestic and export food commodities, the adoption of this option is unlikely to result in any costs, as reductions in MRLs are adopted where this is practically achievable, with little or no impact on production costs;
- for importers, the adoption of this option may result in costs, as foods may not be able to be imported if these foods contained residues consistent with the MRLs proposed for deletion or reduction.

Any MRL deletions or reductions have the potential to restrict the importation of foods and could potentially result in higher food costs and a reduced product range available to consumers, as foods that exceed the new, lower MRLs could not be legally imported or sold to consumers. To identify any restrictions and possible trade impacts, Codex MRLs and data on imported foods have been considered in assessing the reductions and deletions within this proposal (see below). FSANZ invited comments from importers on the impacts of the deletions or reduction of MRLs and while general concerns were expressed, no specific data was provided to justify the retention of any specific 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 Foods

Issues relating to imported foods are addressed in section 9.

8.3 Option 2(b) – adopt the changes to MRLs to include 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. FSANZ invites comment as to whether this benefit is likely to be discernable;
- 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 programmes.

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 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. No WTO member has made a submission.

9.2 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 MRLs proposed to be deleted, in the NRA application, which are more restrictive than the relevant Codex MRL.

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Monocrotophos Cereal grains Cotton seed Edible offal (mammalian) Eggs Meat (mammalian) Milks Potato Poultry meat Poultry, edible offal of	MRLs proposed for deletion*	0.05 (maize) and *0.02(wheat) 0.1 *0.02 (edible offal of cattle, goats, pigs and sheep) *0.02 *0.02 (goat meat) *0.002 *0.05 *0.02 *0.02
Parathion Apricot Cereal grains Cotton seed Peach	MRLs proposed for deletion*	1.0 0.1 (maize) 1.0 1.0

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 and while general concerns were expressed, no specific data was provided to justify the retention of any specific MRLs.

9.3 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.

* MRLs proposed for deletion meaning that no detectable residues of this chemical are permitted in the 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.

Food	2000 Tonnes	2001 Tonnes
Cereal grains	74466	79027
Cotton seed	0	0
Cotton seed oil	220	705
Edible offal (mammalian)	7350	7729
Eggs	353	272
Fruits	107364	114997
Ginger, root	1926	1238
Meat (mammalian)	39275	33497
Milks	19345	20057
Peanut	7716	5384
Poultry, edible offal of, and poultry meat	143	502
Safflower seed (including oils)	9612	17564
Vegetables	420045	230807

FSANZ requested comment as to any possible ramifications for imports of the deletion or reductions of the MRLs in this Application and while general concerns were expressed, no specific data was provided to justify the retention of any specific MRLs.

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. The NRA 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 the NRA's Existing Chemical Review Programme. 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 programmes;
- Commonwealth programmes such as the National Residue Survey; and

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

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

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

Attachments

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

* MRLs proposed for deletion meaning that no detectable residues of this chemical are permitted in the food.

ATTACHMENT 1

DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

To commence: on gazettal

[1] *Standard 1.4.2 of Volume 2 of the Food Standards Code is varied by –*

[1.1] *omitting from Schedule 1 all entries for the following chemicals -*

Monocrotophos
Parathion
Rafoxanide

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

Monocrotophos
Parathion

[1.3] *inserting in Schedule 1–*

KETOPROFEN KETOPROFEN	
CATTLE, EDIBLE OFFAL OF	*0.05
CATTLE MEAT	*0.05
CATTLE MILK	*0.05
MESOSULFURON-METHYL MESOSULFURON-METHYL	
EDIBLE OFFAL (MAMMALIAN)	T*0.01
EGGS	T*0.01
MEAT (MAMMALIAN)	T*0.01
MILKS	T*0.01
POULTRY, EDIBLE OFFAL OF	T*0.01
POULTRY MEAT	T*0.01
WHEAT	T*0.02

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

BIFENTHRIN BIFENTHRIN	
CATTLE, EDIBLE OFFAL OF	0.5
CATTLE MEAT (IN THE FAT)	2
GOAT, EDIBLE OFFAL OF	0.5
GOAT MEAT (IN THE FAT)	2
SHEEP, EDIBLE OFFAL OF	0.5
SHEEP MEAT (IN THE FAT)	2

BITERTANOL BITERTANOL	
APPLE	1
BROAD BEAN (GREEN PODS AND IMMATURE SEEDS)	0.3
CEREAL GRAINS	*0.05
MILKS (IN THE FAT)	2
PEANUT	*0.2
PULSES	0.3
CARBENDAZIM SUM OF CARBENDAZIM AND 2-AMINOBENZIMIDAZOLE, EXPRESSED AS CARBENDAZIM	
MACADAMIA NUTS	T0.1
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
PEAS	T2
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)	
MAIZE	T*0.005
KRESOXIM-METHYL <i>COMMODITIES OF PLANT ORIGIN:</i> KRESOXIM-METHYL <i>COMMODITIES OF ANIMAL ORIGIN:</i> SUM OF A-(P-HYDROXY-O-TOLYLOXY)-O-TOLYL (METHOXYIMINO) ACETIC ACID AND (E)-METHOXYIMINO[A-(O-TOLYLOXY)-O-TOLYL]ACETIC ACID, EXPRESSED AS KRESOXIM-METHYL	
APPLE	0.1
QUIZALOFOP-ETHYL SUM OF QUIZALOFOP-ETHYL AND QUIZALOFOP ACID AND OTHER ESTERS, EXPRESSED AS QUIZALOFOP-ETHYL	
CATTLE, EDIBLE OFFAL OF	0.2
CATTLE MEAT	0.2
CHICKEN, EDIBLE OFFAL OF	*0.05
CHICKEN EGGS	*0.05
CHICKEN MEAT	*0.05
GOAT, EDIBLE OFFAL OF	0.2
GOAT MEAT	0.2
SAFFLOWER SEED	*0.01
SHEEP, EDIBLE OFFAL OF	0.2

SHEEP MEAT	0.2
QUIZALOFOP-P-TEFURYL SUM OF QUIZALOFOP-P-TEFURYL AND QUIZALOFOP ACID, EXPRESSED AS QUIZALOFOP-P-TEFURYL	
CATTLE, EDIBLE OFFAL OF	0.2
CATTLE MEAT	0.2
CHICKEN, EDIBLE OFFAL OF	*0.05
CHICKEN EGGS	*0.05
CHICKEN MEAT	*0.05
GOAT, EDIBLE OFFAL OF	0.2
GOAT MEAT	0.2
SAFFLOWER SEED	*0.01
SHEEP, EDIBLE OFFAL OF	0.2
SHEEP MEAT	0.2
TRIADIMENOL TRIADIMENOL <i>SEE ALSO TRIADIMEFON</i>	
BROCCOLI	0.2
CABBAGES, HEAD	0.5
CAULIFLOWER	0.2

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

AZOXYSTROBIN AZOXYSTROBIN	
PEANUT	T0.2
PEANUT OIL, CRUDE	T0.3
PISTACHIO NUT	T*0.01
BIFENTHRIN BIFENTHRIN	
EDIBLE OFFAL (MAMMALIAN)	0.5
MEAT (MAMMALIAN) (IN THE FAT)	2
BITERTANOL BITERTANOL	
MILKS	0.2
STRAWBERRY	*0.05
CARBENDAZIM SUM OF CARBENDAZIM AND 2- AMINOBENZIMIDAZOLE, EXPRESSED AS CARBENDAZIM	
TREE NUTS	T0.1
CYANAZINE CYANAZINE	
LEEK	0.05

CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
LEAFY VEGETABLES (EXCEPT LETTUCE HEAD AND LETTUCE LEAF)	T2
DIFLUFENICAN DIFLUFENICAN	
EGGS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
MACADAMIA NUTS	*0.2
PEAS (PODS AND SUCCULENT, IMMATURE SEEDS)	2
WASABI	T2
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)	
GINGER, ROOT	*0.01
IMAZAMOX IMAZAMOX	
EDIBLE OFFAL (MAMMALIAN)	*0.05
MEAT (MAMMALIAN)	*0.05
MILKS	*0.05
KRESOXIM-METHYL <i>COMMODITIES OF PLANT ORIGIN: KRESOXIM-METHYL</i> <i>COMMODITIES OF ANIMAL ORIGIN: SUM OF A-(P-HYDROXY-O-TOLYLOXY)-O-TOLYL (METHOXYIMINO) ACETIC ACID AND (E)-METHOXYIMINO[A-(O-TOLYLOXY)-O-TOLYL]ACETIC ACID, EXPRESSED AS KRESOXIM-METHYL</i>	
POME FRUIT	0.1
METHIDATHION METHIDATHION	
PERSIMMON, JAPANESE	T0.5
PENDIMETHALIN PENDIMETHALIN	
EDIBLE OFFAL (MAMMALIAN)	*0.01

EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILK	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
PROCYMIDONE PROCYMIDONE	
FRUITING VEGETABLES, CUCURBITS	T2
PROPACHLOR PROPACHLOR	
LEEK	*0.02
PROPYZAMIDE PROPYZAMIDE	
ENDIVE	*0.2
QUINOXYFEN QUINOXYFEN	
EDIBLE OFFAL (MAMMALIAN)	*0.01
MEAT (MAMMALIAN) (IN THE FAT)	0.1
MILKS	0.01
QUIZALOFOP-ETHYL SUM OF QUIZALOFOP-ETHYL AND QUIZALOFOP ACID AND OTHER ESTERS, EXPRESSED AS QUIZALOFOP- ETHYL	
EDIBLE OFFAL (MAMMALIAN)	0.2
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
QUIZALOFOP-P-TEFURYL SUM OF QUIZALOFOP-P-TEFURYL AND QUIZALOFOP ACID, EXPRESSED AS QUIZALOFOP-P-TEFURYL	
EDIBLE OFFAL (MAMMALIAN)	0.2
EGGS	*0.02
MEAT (MAMMALIAN)	*0.02
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
SIMAZINE SIMAZINE	
LEEK	*0.01
TEBUFENOZIDE TEBUFENOZIDE	
CITRUS FRUITS	1
THIAMETHOXAM THIAMETHOXAM	
SUNFLOWER SEED	T*0.02

TRIADIMENOL TRIADIMENOL <i>SEE ALSO TRIADIMEFON</i>	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	1

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

BITERTANOL BITERTANOL	
BEANS [EXCEPT BROAD BEAN AND SOYA BEAN]	0.5
EDIBLE OFFAL (MAMMALIAN)	3
MEAT (MAMMALIAN) (IN THE FAT)	0.3
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
CHLORPYRIFOS CHLORPYRIFOS	
GINGER, ROOT	*0.02
DELTAMETHRIN DELTAMETHRIN	
WHEAT GERM	3
ETHAMETSULFURON-METHYL ETHAMETSULFURON METHYL	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.02
LUPIN (DRY)	*0.02
MEAT (MAMMALIAN)	*0.02
MILKS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.02
FLUAZIFOP-BUTYL FLUAZIFOP-BUTYL	
LEEK	T0.5
FLUAZINAM FLUAZINAM	
WINE GRAPES	*0.05
METHABENZTHIAZURON METHABENZTHIAZURON	
LEEK	T0.2
METHOMYL SUM OF METHOMYL AND METHYL HYDROXYTHIOACETIMIDATE ('METHOMYL OXIME'), EXPRESSED AS METHOMYL <i>SEE ALSO THIODICARB</i>	
STRAWBERRY	3

PENDIMETHALIN PENDIMETHALIN	
OLIVES	*0.05
PROCYMIDONE PROCYMIDONE	
CARROT	T1
QUINOXYFEN QUINOXYFEN	
DRIED GRAPES	5
GRAPES	2
QUIZALOFOP ETHYL SUM OF QUIZALOFOP-ETHYL AND QUIZALOFOP ACID AND OTHER ESTERS, EXPRESSED AS QUIZALOFOP- ETHYL	
MILKS	0.1
QUIZALOFOP-P-TEFURYL SUM OF QUIZALOFOP-P-TEFURYL AND QUIZALOFOP ACID, EXPRESSED AS QUIZALOFOP-P-TEFURYL	
MILKS	0.1
TEBUFENOZIDE TEBUFENOZIDE	
AVOCADO	0.5
CUSTARD APPLE	0.3
KIWIFRUIT	2
MACADAMIA NUTS	0.05

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.

GLOSSARY OF 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 contaminant 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 are 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. To calculate the NESTIs FSANZ has used ARfDs set by the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 NNS and the MRL when the STMR is not available.

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

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. The NRA 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 NEDI = 60% of ADI</p>
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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.

The NESTI is an assessment of the acute exposure which is compared to the acute reference dose (ARfD). More information is in the glossary on the NESTI and the ARfD. To be acceptable to FSANZ, the NESTI must be less than 100% of the ARfD because the ARfD is considered the 'safe' level.

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

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

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

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

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

Chlorpyrifos Coffee beans	Add T0.5	NRA extension of use for the control of pests. The 18 th ATDS (1996) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to 0.53% of ADI for adult males and up to 1.42% for 2 year olds. The 19 th 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
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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 A461

Glossary;

1. **ADI** Acceptable Daily Intake.
2. **ARfD** Acute Reference Dose.
3. **ATDS** Australian Total Diet Survey.
4. **ECRP** Existing Chemical Review Program
5. **LOQ** Limit of Analytical Quantification.
6. **NEDI** National Estimated Daily Intake.
7. **NESTI** National Estimated Short Term Intake.
8. **NNS** National Nutrition Survey of Australia 1995
9. ***** MRL set at or about the limit of quantification.
10. **T** Temporary MRL.

Chemical Food	MRL (mg/kg)	Information
Azoxystrobin Peanut Peanut oil crude Pistachio nut	Add T0.2 Add T0.3 Add T*0.01	This chemical is a strobilurin fungicide. The NRA has issued permits for trials of this chemical to control fungus on peanut crops and pistachio nuts NEDI = <1% of ADI
Bifenthrin Cattle, Edible offal of Cattle meat (in the fat) Goat, Edible offal of Goat meat (in the fat) Sheep, Edible offal of Sheep meat (in the fat) Edible offal (mammalian) Meat (mammalian) (in the fat)	Delete 0.5 Delete 2 Delete 0.5 Delete 2 Delete 0.5 Delete 2 Add 0.5 Add 2	This chemical is a synthetic pyrethroid. It is used as an insecticide on various crops. The proposed MRLs have resulted from the NRA Stockfeed Guideline Project. No changes to the actual uses of the chemical are involved. NEDI = 68% of ADI
Bitertanol Apples Beans [except broad beans and soya bean] Broad bean (green pods and immature seeds) Cereal grains Edible offal (mammalian) Meat (mammalian) (in the fat) Milks Milks (in the fat) Peanut Poultry, Edible offal of Poultry meat Pulses Strawberry	Delete 1 Delete 0.3 Substitute 0.5 Delete 0.3 Delete *0.05 Delete 1 Substitute 3 Delete 1 Substitute 0.3 Add 0.2 Delete 2 Delete *0.2 Delete 0.1 Substitute *0.01 Delete 0.2 Substitute *0.01 Delete 0.3 Add *0.05	This chemical is a triazole fungicide. It is used to control fungus in various crops. In the 19 th (1998) ATDS the estimated dietary exposure to bitertanol was less than 1% of the ADI for the whole population. On the basis of the exposure assessment, FSANZ considers that the residues associated with the proposed MRLs would not represent an unacceptable risk to public health and safety. NEDI = 20% of ADI

<p>Carbendazim Macadamia nuts Tree nuts</p>	<p>Delete Add</p> <p>T0.1 T0.1</p>	<p>This chemical is a benzimidazole fungicide. The NRA has extended the permit for this chemical to be used to control fungus on tree nut crops. In the 19th (1998) ATDS the estimated dietary exposure to benomyl/carbendazim was less than 1% of the ADI for the whole population. On the basis of the exposure assessment, the level of consumption of tree nuts, the results from the 1998 ATDS and that this is an extension of an existing permit, FSANZ considers that the residues associated with the proposed MRL would not represent an unacceptable risk to public health and safety. NEDI = 84% of ADI</p>
<p>Chlorpyrifos Ginger, root</p>	<p>Delete Substitute</p> <p>T0.05 *0.02</p>	<p>This chemical is an organophosphorous insecticide. It is used as a pre-planting soil treatment to control Symphyla in ginger. In the 19th (1998) ATDS the estimated dietary exposure to chlorpyrifos was less than 1% of the ADI for adults and was 2.5% of the ADI for children of 2 years of age. On the basis of the exposure assessment, the level of consumption of ginger root, the results from the 1998 ATDS and the fact that this proposed MRL is at the LOQ and no residues should be detected, FSANZ considers that the residues associated with the MRL would not represent an unacceptable risk to public health and safety. NEDI = 83% of ADI NESTI = <1% of ARfD for the whole population.</p>
<p>Cyanazine Leek</p>	<p>Add</p> <p>0.05</p>	<p>This chemical is a 1,3,5-triazine. It is used as an herbicide to control weeds in leek crops. NEDI = 3% of ADI.</p>

Cypermethrin Leafy vegetables [except lettuce head and lettuce leaf]	Add	T2	This chemical is a synthetic pyrethroid. The NRA has issued a permit for the use of this chemical to control insects on leafy vegetable crops. NEDI = 9% of ADI.
Deltamethrin Wheat germ	Delete Substitute	T3 3	This chemical is a synthetic pyrethroid. This chemical is used as a grain protectant. NEDI = 56% of ADI.
Diflufenican Eggs Poultry, Edible offal of Poultry meat	Add Add Add	*0.02 *0.02 *0.02	This chemical is an anilide herbicide. It is used as a selective and residual herbicide for cereal grain and pulse crops which may then be fed to poultry. As these proposed MRLs are at the LOQ, no residues should be detected. NEDI = <1% of ADI
Dithiocarbamate Macadamia nuts Peas Peas (pods and succulent, immature seeds) Wasabi	Add Delete Add Add	*0.2 T2 2 T2	These MRLs relate to the dithiocarbamate class of compounds. It is used to control fungus on macadamia nuts. It is used to control fungus on pea crops. This proposed MRL is associated with the use of the dithiocarbamate, zineb The NRA has issued a permit for the dithiocarbamate, mancozeb to be used to control fungus on wasabi crops. In the 19 th (1998) ATDS the estimated dietary exposure to thiram (the dithiocarbamate with the lowest ADI) was at 63% of the ADI two year olds and 20% of the ADI for adult males. On the basis of the exposure assessment, the results from the 1998 ATDS and that both mancozeb and zineb have higher ADIs than thiram, FSANZ considers that the residues associated with the MRL would not represent an unacceptable risk to public health and safety. NEDI = 82% of ADI

Ethametsulfuron-methyl Edible offal (mammalian)	Delete Substitute	T*0.02 *0.02	This chemical is a sulfonyleurea and is used as a post emergent herbicide for lupin seed crops. As these proposed MRLs are at the LOQ, no residues should be detected. NEDI = <1% of the ADI
Eggs	Delete Substitute	T*0.02 *0.02	
Lupin (dry)	Delete Substitute	T*0.02 *0.02	
Meat (mammalian)	Delete Substitute	T*0.02 *0.02	
Milks	Delete Substitute	T*0.02 *0.02	
Poultry, edible offal of	Delete Substitute	T*0.02 *0.02	
Poultry meat	Delete Substitute	T*0.02 *0.02	
Fipronil Ginger, root Maize	Add Delete	*0.01 T*0.005	This chemical is a phenylpyrazole. It is used as a pre-planting soil treatment and ginger seed piece treatment to control Symphyla. As the proposed MRL for ginger root is at the LOQ, no residue should be detected. NEDI = 75 % of ADI. NESTI = <1% of ARfD for the whole population
Fluazinam Wine grapes	Delete Substitute	T*0.05 *0.05	This chemical is a 2,6 - Dinitroaniline. It is used as a fungicide for dormant wine grapes. As this proposed MRL is at the LOQ, no residue should be detected. NEDI = 2 % of ADI.
Fluazifop-butyl Leek	Delete Substitute	T0.2 T0.5	This chemical is a 2-(4-aryloxyphenoxy) propionic acid. The NRA has extended a permit for this chemical to be used to control weeds in leek crops. This exposure estimate is an overestimate because the MRLs have been used to calculate the NEDI, the exposure would be much lower if typical residue levels were used. NEDI = 69% of ADI.

Imazamox Edible offal (mammalian) Meat (mammalian) Milks	Add Add Add	*0.05 *0.05 *0.05	This chemical is an imidazolinone, and is used to control weeds in pastures. As these proposed MRLs are at the LOQ, no residues should be detected. NEDI = <1% of ADI.
Ketoprofen Cattle, Edible offal of Cattle meat Cattle milk	Add Add Add	*0.05 *0.05 *0.05	This chemical is a non-steroidal anti-inflammatory drug. It is used to treat ephemeral fever in cattle. The proposed MRLs are for a new chemical. These proposed MRLs are at the LOQ; therefore no residues should be detected. NEDI = 8% of ADI. NESTI = 18% of ARfD for the whole population and 45% for children 2-6 years of age.
Kresoxim-methyl Apple Pome fruit	Delete Add	0.1 0.1	This chemical is a strobilurin fungicide. It is used control black spot scab in pome fruits. NEDI = <1% of the ADI
Mesosulfuron-methyl Edible offal (mammalian) Eggs Meat (mammalian) Milks Poultry, Edible offal of Poultry meat Wheat	Add Add Add Add Add Add Add	T*0.01 T*0.01 T*0.01 T*0.01 T*0.01 T*0.01 T*0.02	This chemical is a sulfonylurea. The NRA has issued a permit for this chemical is used to control weeds in wheat crops. The proposed MRLs are for a new chemical. These proposed MRLs are at the LOQ; therefore no residues should be detected. NEDI = <1% of the ADI NESTI = <1% of the ARfD
Methabenzthiazuron Leek	Delete Substitute	T*0.05 T0.2	This chemical is a dimethylurea herbicide. The NRA has extended a permit for the use of this chemical to control broadleaf weeds in post emergent leeks. NEDI = 6% of ADI

<p>Methidathion Persimmon, Japanese</p>	<p>Add</p> <p>T0.5</p>	<p>This chemical is an organophosphorous insecticide. The NRA has issued a permit for this chemical to be used to control mealy bug, lightbrown apple moth, scale and fruitspotting bug on persimmon crops. In the 19th (1998) ATDS the dietary exposure to methidathion was not calculated, as the concentration of this chemical in all surveyed foods was less than the LOQ. On the basis of the exposure assessments, the level of consumption of persimmons, the results from the 1998 ATDS and that this is a permit, FSANZ considers that the residues associated with the MRL would not represent an unacceptable risk to public health and safety. NEDI = 62 % of ADI. Consumption data for persimmons is not available from the NNS1995. Therefore, the NESTI was calculated on the basis of consumption data for bananas. As a result this is an overestimate. However it is the best estimate of acute dietary exposure. NESTI = 11% of ARfD for the whole population and 40% for children 2-6 years of age.</p>
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Methomyl Strawberry	Delete 0.5 Substitute 3	<p>This chemical is an oxime carbamate. It is an insecticide on strawberry crops. In the 19th (1998) ATDS the dietary exposure to methomyl was not calculated, as the concentration of this chemical in all surveyed foods was less than the LOQ.</p> <p>NEDI = 83% of ADI. This exposure assessment is an overestimate because the MRLs have been used to calculate the NEDI; the exposure would be much lower if typical residues were used. In addition, this calculation uses the MRLs for both thiodicarb and methomyl because the metabolism of these compounds is similar. Methomyl has a lower ADI than thiodicarb and this lower ADI has been used in the combined NEDI. Where MRLs are established for both compounds the higher MRL has been used.</p>
Monocrotophos Apple Banana Beans [except broad bean and soya bean] Broad bean (green pods and immature seeds) Cereal grains Cotton seed Edible offal (mammalian) Eggs Meat (mammalian) Milks Pear Potato Poultry, Edible offal of Poultry meat Sweet corn (corn-on-the-cob) Tomato Vegetable oils, edible	Delete T0.5 Delete T0.5 Delete T0.2 Delete T0.2 Delete T*0.02 Delete T0.1 Delete T*0.02 Delete T*0.02 Delete T*0.02 Delete T*0.02 Delete T*0.002 Delete T0.5 Delete T0.1 Delete T*0.02 Delete T*0.02 Delete T*0.01 Delete T0.5 Delete T*0.05	<p>This chemical is an organophosphorous insecticide. It was used as an insecticide and acaricide. The deletion for all the MRLs for this chemical has resulted from a review as part of the NRA's Existing Chemical Review Program.</p>

Parathion			
Apricot	Delete	T1	This chemical is an organophosphorous insecticide. It was used as an insecticide. The deletion for all the MRLs for this chemical has resulted from a review as part of the NRA's Existing Chemical Review Program.
Carrot	Delete	T0.5	
Cereal grains	Delete	T0.5	
Cotton seed	Delete	T1	
Cotton seed oil, crude	Delete	T0.5	
Edible offal (mammalian)	Delete	T*0.05	
Fruits [except apricot and peach]	Delete	T0.5	
Meat (mammalian)	Delete	T*0.05	
Milks	Delete	T*0.05	
Peach	Delete	T1	
Vegetables [except carrot]	Delete	T0.7	
Pendimethalin			
Edible offal (Mammalian)	Add	*0.01	This chemical is a 2,6-dinitroaniline. It is used as an herbicide to control weeds under olive trees. As these proposed MRLs are at the LOQ, no residues should be detected.
Eggs	Add	*0.01	
Meat (Mammalian)	Add	*0.01	
Milk	Add	*0.01	
Olives	Delete Substitute	T*0.05 *0.05	
Poultry, Edible offal of	Add	*0.01	NEDI = <1% of ADI.
Poultry meat	Add	*0.01	
Procymidone			
Carrot	Delete Substitute	T2 T1	This chemical is a dicarboximide. It is used to control the fungus <i>Sclerotinia spp</i> on carrots and cucurbits. In both the 18 th (1996) and 19 th (1998) ATDSs the estimated dietary exposure to procymidone was less than 1% of the ADI for the whole population. On the basis of the exposure assessment, FSANZ considers that the residues associated with the proposed MRLs would not represent an unacceptable risk to public health and safety. NEDI = 24% of ADI.
Fruiting vegetables, cucurbits	Add	T2	
Propachlor			
Leek	Add	*0.02	This chemical is a chloracetanilide. It is used to control grass and broadleaf weeds in leek crops. As this proposed MRL is at the LOQ, no residue should be detected in leeks. NEDI = 5% of ADI.

Propyzamide Endive	Add	*0.2	This chemical is an amide herbicide. It is used to control weeds in endive crops. As this proposed MRL is at the LOQ, no residue should be detected in endive. NEDI = 2% of ADI.
Quinoxifen Dried grapes	Delete Substitute	T5 5	This chemical is a phenoxyquinoline. It is used to control powdery mildew on grape crops. The proposed meat, milk and offal MRLs are necessary to take into account the residues in animal commodities that may result from the feeding of grape pomace to livestock. NEDI = <1% of ADI.
Edible offal (Mammalian) Grapes	Add Delete Substitute	*0.01 T2 2	
Meat (Mammalian) (in the fat)	Add	0.1	
Milks	Add	0.01	
Quizalofop-ethyl Cattle, Edible offal of Cattle meat Chicken, edible offal of Chicken eggs Chicken meat Edible offal (mammalian) Eggs Goat, Edible offal of Goat meat Meat (mammalian) Milks Poultry, edible offal of Poultry meat Safflower seed Sheep, edible offal of Sheep meat	Delete Delete Delete Delete Delete Add Add Delete Delete Add Delete Substitute Add Add Delete Delete Delete	0.2 0.2 *0.05 *0.05 *0.05 0.2 *0.02 0.2 0.2 *0.02 0.2 0.1 *0.05 *0.05 *0.01 0.2 0.2	This chemical is a 2-(4-aryloxyphenoxy)propionic acid. It is used to control weeds in crops. Residue data were reviewed as part of the NRA's Stockfeed Guideline Project. The project focussed on animal feed commodities. However, animal transfer data for poultry and cattle were also reviewed. New animals MRLs were recommended based on anticipated livestock exposure determined as part of the feed commodity data. NEDI = 10% of ADI.

Quizalofop-p-tefuryl			
Cattle, Edible offal of	Delete	0.2	This chemical is a 2-(4-aryloxyphenoxy)propionic acid. It is used to control weeds in crops. Residue data were reviewed as part of the NRA's Stockfeed Guideline Project. The project focussed on animal feed commodities. However, animal transfer data for poultry and cattle were also reviewed. New animals MRLs were recommended based on anticipated livestock exposure determined as part of the feed commodity data. NEDI = 10% of ADI.
Cattle meat	Delete	0.2	
Chicken, edible offal of	Delete	*0.05	
Chicken eggs	Delete	*0.05	
Chicken meat	Delete	*0.05	
Edible offal (mammalian)	Add	0.2	
Eggs	Add	*0.02	
Goat, Edible offal of	Delete	0.2	
Goat meat	Delete	0.2	
Meat (mammalian)	Add	*0.02	
Milks	Delete	0.2	
	Substitute	0.1	
Poultry, edible offal of	Add	*0.05	
Poultry meat	Add	*0.05	
Safflower seed	Delete	*0.01	
Sheep, edible offal of	Delete	0.2	
Sheep meat	Delete	0.2	
Rafoxanide			
Cattle, Edible offal of	Delete	0.2	This chemical is a salicylanilide. This chemical was used to treat parasites in livestock. There are no longer any registered products for this chemical. Therefore, it is proposed that the MRLs be removed from the <i>Food Standards Code</i> .
Cattle fat	Delete	0.2	
Cattle meat	Delete	0.1	
Goat, Edible offal of	Delete	0.2	
Goat fat	Delete	0.2	
Goat meat	Delete	0.1	
Sheep, edible offal of	Delete	0.2	
Sheep fat	Delete	0.2	
Sheep meat	Delete	0.1	
Simazine			
Leek	Add	*0.01	This chemical is a 1,3,5 – triazine. It is used to control grass and broadleaf weeds in leek crops. As this proposed MRL is at the LOQ, no residue should be detected in leeks. NEDI = 26% of ADI.
Tebufenozide			
Avocado	Delete	T0.5	This chemical is a diacylhydrazine. It is used to control insects on crops. NEDI = 22% of ADI.
	Substitute	0.5	
Citrus fruits	Add	1	
Custard apple	Delete	T0.3	
	Substitute	0.3	
Kiwifruit	Delete	T1	
	Substitute	2	
Macadamia nuts	Delete	T0.05	
	Substitute	0.05	

Thiamethoxam Sunflower seed	Add T*0.02	This chemical is a nitromethylene. It is used as a seed dressing chemical to control early season soil and sucking pests in sunflowers. As this proposed MRL is at the LOQ, no residue should be detected. NEDI = <1% of ADI.
Triadimenol Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Broccoli Cabbages, Head Cauliflower	Add 1 Delete 0.2 Delete 0.5 Delete 0.2	This chemical is a triazole fungicide. It is used for the systemic control of the fungus, ring spot on Brassica vegetables. In the 19 th (1998) ATDS the dietary exposure to triadimenol was not calculated, as the concentration of this chemical in all surveyed food was less than the LOQ. 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 the NRA 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, considers the dietary exposure to chemical residues from all foods in the diet by comparing the overall dietary exposure with the relevant health standard. FSANZ will not adopt MRLs where the dietary exposure to the residues of a chemical could represent an unacceptable risk to public health and safety. In assessing this risk, 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); an
- calculating the dietary exposure to a chemical from all foods and comparing this to the acceptable health standard.

Determination of the residues of a chemical in a treated food

The NRA assesses a range of data when considering the proposed use of a chemical product on a food. These data enable the NRA to determine what the likely residues of a chemical will be on a treated food. These data also enable the NRA to determine what the maximum residues will be on a treated food if the chemical product is used as proposed and from this, the NRA 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 Chemicals and Non-prescription Medicines Branch of the Therapeutic Goods Administration assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where applicable, the ARfD for a chemical.

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

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

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

Calculating the dietary exposure

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

The NRA and FSANZ have recently agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the NRA 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 Ageing undertook the NNS survey over a 12-month period (1995 to early 1996). The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns was reported.

Chronic Dietary Exposure Assessment

The National Estimated Daily Intake (NEDI) represents a realistic estimate of chronic dietary exposure if the 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 are 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 NRA 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.

These calculations are overestimates of dietary exposure because they usually assume that all of a particular food will contain the proposed chemical. 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 are multiplied by the 97.5 percentile food consumption of that food (high consumer), a variability factor is applied and this result is compared to the ARfD. NESTIs are calculated from ARfDs set by the TGA 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 PUBLIC SUBMISSIONS

Submitter	Comments raised
Australian Food and Grocery Council	Supports the application.
Australian Pork Limited	Sought clarification on some matters
The Department of Agriculture Fisheries and Forestry - Australia	Supported the application.
Food Technology Association of Victoria	Supported the application
Nestlé Australia Limited	Only supported Option 2(b) – Adopt the changes to MRLs to include and increase some existing MRLs, of the application