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FINAL ASSESSMENT REPORT

APPLICATION A461

MAXIMUM RESIDUE LIMITS

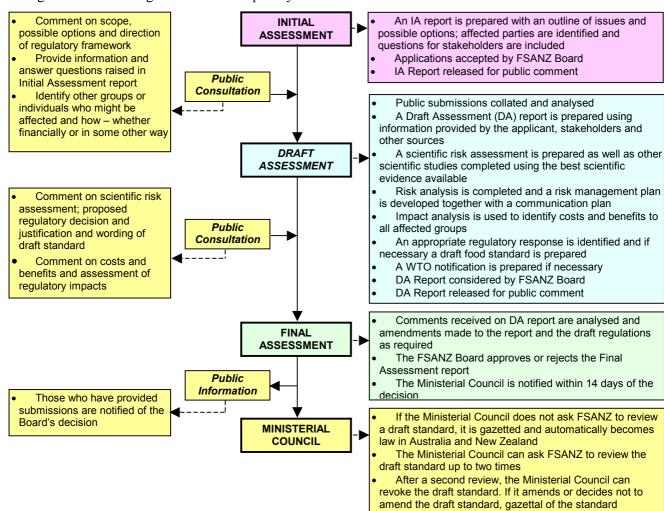
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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, 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 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 *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.



Submissions

No submissions on this matter are sought as the Authority has notified the Australia New Zealand Food Regulation Ministerial Council that it has approved the draft standard.

Further Information

Further information on this and other matters should be addressed to the Standards Liaison Officer at Food Standards Australia New Zealand at one of the following addresses:

Food Standards Australia New Zealand Food Standards Australia New Zealand

PO Box 7186 PO Box 10559

Canberra BC ACT 2610 The Terrace WELLINGTON 6036

AUSTRALIA NEW ZEALAND Tel (02) 6271 2258 Tel (04) 473 9942

www.foodstandards.gov.nz www.foodstandards.govt.nz

Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from 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

Executive Summary

- This Application (A461) seeks to amend Maximum Residue Limits (MRLs) for nonantibiotic agricultural and veterinary chemicals in the *Food Standards Code*. It is a routine application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the *Food Standards Code* in order to reflect current registration status of agricultural and veterinary chemicals in use in Australia.
- On 24 November 2000, the Australia New Zealand Food Standards Council adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). On 24 May 2002, the Ministerial Council agreed to vary the *Food Standards Code* to amend Standard A14 (Volume 1) by deleting schedules 1, 2 and 3 of that Standard and referring the schedules in Standard A14 to the MRL schedules of Standard 1.4.2. This created a single set of schedules for MRLs. Subsequently all applications to amend MRLs will now be incorporated into schedules 1,2 and 3 of Standard 1.4.2 of the *Food Standards Code*. Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.
- 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 Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aging has undertaken an appropriate toxicological assessment of the agricultural and veterinary chemicals and has established relevant acceptable daily intakes (ADI).
- The dietary exposure assessments indicate that the residues associated with the proposed MRLs for agricultural and veterinary chemicals do not represent an unacceptable risk to public health and safety.
- None of the Food Standards Australia New Zealand's (FSANZ's) section 10 objectives of food regulatory measures are compromised by the proposed changes.
- There are no MRLs for antibiotic residues in this Application.
- FSANZ has made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO). No WTO member has made a submission.
- The Australia New Zealand Food Authority (ANZFA) to FSANZ transitional requirements for an application at full (draft) assessment stage have been followed. ANZFA has not received additional submissions in relation to his application and to date it has not been notified of any Ministerial Council policy guidelines relevant to this proposal.

Statement Of Reasons

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

A Summary of the Requested MRLs

Please see Attachment 2 of the Final Assessment Report.

World Trade Organization (WTO) 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 *Food Standards 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 *Food Standards 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 made a submission.

1. Introduction

Applications were received from the NRA on 13 February, 5 March, 9 April and 7 May 2002 seeking amendment to Standard 1.4.2 of the *Food Standards Code*. The proposed amendments to the Standard would align MRLs for non-antibiotic agricultural and veterinary chemicals, in the *Food Standards Code* with the MRLs in the NRA MRL Standard.

1.1 Transitional requirements

This Application reached full (draft) assessment stage under the operation of the *Australia New Zealand Food Authority Act 1991* (ANZFA Act), and will be finalised in accordance with the provisions of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

FSANZ has therefore been required to:

- 1. give the Applicant the opportunity to request deferral of consideration (by 29 July 2002) of the application in order to provide any additional information;
- 2. give notice under section 13A or 14 of the FSANZ Act; and
- 3. review the full (draft) assessment having regard to any new submissions received in response to the above notice as well as any written policy guidelines that have been notified by the Ministerial Council.

1.2 Summary of proposed MRLs

The MRL amendments under consideration in this Application are:

- remove the chemical febantel and all associated foods;
- delete MRLs for certain foods for the chemicals, butafenacil, procymidone, profenofos and pymetrozine;

- add MRLs for certain foods for the new chemicals ethametsulfuron methyl, flutolanil, pyriproxyfen, spiroxamine and thiacloprid;
- add MRLs for certain foods for the chemicals butafenacil, pirimiphos-methyl, profenofos, pymetrozine and tebufenozide;
- change MRLs for certain foods for 2,4-D, bifenthrin, butafenacil, ethylene dichloride, fipronil, imazapic, procymidone, tebufenozide and trifluralin; and
- add temporary MRLs for certain foods for abamectin, benalaxyl, bifenthrin, buprofezin, chlorpyrifos, doramectin, fenoxaprop-ethyl, fluazifop-butyl, fludioxonil, fluquinconazole, procymidone, propiconazole, spinosad, triadimenol and trifluralin.

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.

1.3 Antibiotic MRLs

There are no MRLs for antibiotic residues in this Application.

1.4 MRL for Dithiocarbamates in Vetch

The NRA made an Application for a proposed temporary MRL for mancozeb in Vetch at T0.5 mg/kg in February 2002.

The term 'vetch', describes many plant species belonging to the genus *Vicia*. This genus is very large and includes Faba beans and Narbon beans. In general the term Vetch describes a large group of prostrate or trailing species that have been used for fodder or grain for stock feed.

Vetch has no history of use in Australia as a human food and is usually used as a farm animal food item. Vetch has a known potential for adverse effects in humans in that it contains a toxin called cyanoalanine. Vetch cannot be considered a traditional food and FSANZ cannot accept an MRL for a commodity that is not used as a food for humans in Australia.

The NRA MRL Standard has listed Vetch in Table 1 as the Codex commodity classification AL 1029. The AL prefix is usually associated with Table 4 - MRLs for Pesticides in Animal Feed Commodities.

Although Vetch is listed in Schedule 4 of the Standard 1.4.2 – Maximum Residue Limits of the *Food Standards Code*, the listing is anomalous and that clause 1(2) of the *Food Standards Code* provides that:

Commodity names specified in Schedule 4 apply only for the purposes of this Standard and Standard 1.4.1.

Because the *Food Standards Code* only applies to food for human consumption, it follows that an MRL for vetch can only be included in Standard 1.4.2 – Maximum Residue Limits of the *Food Standards Code* if vetch is a food used for human consumption. The listing of vetch will be removed when these provisions are reviewed.

Given the above, the NRA has agreed to withdraw the proposed MRL for mancozeb in Vetch

1.5 Proposed MRLs for Bitertanol

The NRA made an application for proposed MRLs for bitertanol in a variety of foods in April 2002

FSANZ has noticed discrepancies between the NRA application and the NRA gazettal to amend the NRA MRL Standard for the proposed MRLs for eggs and strawberry for this chemical. After discussions between FSANZ and the NRA, the NRA withdrew the application for the proposed MRLs and made a new application in June 2002.

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 mean that there is a discrepancy between the residues associated with the use and the MRLs in the *Food Standards Code* meaning 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 *Food Standards Code*;
- where the NRA has included MRLs for new chemicals or for additional foods that are not included in the *Food Standards Code*, the particular food cannot be legally sold under food legislation if it contains <u>any</u> 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 *Food Standards Code*.

3.1 Consideration of Issues under Section 10 of the *Food Standards Australia New Zealand Food 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 *Australia New Zealand Food Authority Act 1991*. 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

The procedures used by FSANZ, the TGA and the NRA rely on the comprehensive examination of detailed scientific information, including a rigorous toxicological assessment. The dietary exposure assessments are undertaken in accordance with international protocols.

3.1.5 The promotion of consistency between domestic and international food standards

This is addressed in section 7

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 *Food Standards 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 *Food Standards 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 policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority

The Ministerial Council has not notified FSANZ of any relevant policy guidelines.

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 include the MRLs Standard 1.4.2 of the *Food Standards 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 taking into account public submissions, FSANZ will then approve the inclusion of the proposed MRL into Standard 1.4.2 of the *Food Standards Code*.

FSANZ then notifies the Australia New Zealand Food Regulation Ministerial Council, which includes the Ministers of the Commonwealth, Australian States and Territories and New Zealand, of it approval of the MRL variation to the *Food Standards Code*. The Ministerial Council may request a review of the inclusion of the MRL approved by FSANZ. At the conclusion of the Ministerial Council process, if the MRL variation stands, it will be automatically adopted by reference under the food laws of the Australian States and Territories.

The inclusion of the MRLs in the *Food Standards 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.

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 <u>not</u> 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. 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 *Food Standards 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 <u>not</u> recommend 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.

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

Whereas the MRLs in the *Food Standards Code* apply in relation to the <u>sale</u> of food under State and Territory food legislation and the <u>inspection</u> of imported foods by the Australian Quarantine and Inspection Service.

4.4 Dietary Exposure Assessments

FSANZ evaluates the chronic, and where appropriate the acute, dietary exposure assessments for all MRL applications. These are compared to the relevant health standard i.e. the ADI and the ARfD. FSANZ will only recommend proposed MRLs to the Board, where the estimated dietary exposure to the potential residue does not exceed the relevant health standard. Further details of the dietary exposure assessments are outlined in Attachment 3 of this report.

4.5 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.

4.6 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 *Food Standards 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.

4.7 Food Standards Code

On 24 November 2000, the Australia New Zealand Food Standards Council adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). On 24 May 2002, the Ministerial Council agreed to vary the *Food Standards Code* to amend Standard A14 (Volume 1) by deleting schedules 1, 2 and 3 of that Standard and referring the schedules in Standard A14 to the MRL schedules of Standard 1.4.2. This created a single set of schedules for MRLs.

Subsequently all applications to amend MRLs will now be incorporated into schedules 1,2 and 3 of Standard 1.4.2 of the *Food Standards Code*. Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

4.8 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 *Food Standards 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.

4.9 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.

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

5. Evaluation of issues raised in public comment

The submission from the Food Technology Association of Victoria accepted the recommendation to progress this Application. The submissions from the Australian Food and Grocery Council and the Western Australian Food Advisory Committee supported the recommendation to progress this Application.

5.1 Australian Food and Grocery Council

The submission from the Australian Food and Grocery Council suggested that, after the proposed MRLs are approved for inclusion the *Food Standards Code*, FSANZ should ensure that the MRLs are then referred to the relevant Codex Alimentarius Committee for inclusion in the Codex Standards.

Codex Alimentarius Committee MRLs are not universally adopted in all countries and are limited in terms of the chemicals and foods to which they apply.

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) bases pesticide MRLs on a detailed international evaluation of a comprehensive scientific data package, including residue trials. Details of the data required and the procedure for the submission of these data to the FAO Secretary to the JMPR are given in the "Manual on the Submission and Evaluation of Pesticide Residues Data, 2002". This Manual is available from the JMPR website at http://www.fao.org/ag/agp/agpp/pesticid/jmpr/pm_jmpr.htm

The data holder who is usually the agricultural chemical company makes submissions of residues data to the JMPR. The JMPR will not recommend MRLs that are not supported by a scientific data package and the Codex Committee on Pesticides Residues (CCPR) will only consider MRL that have been recommended by the JMPR based on their scientific evaluation. Once the JMPR has recommended these MRLs to the CCPR, then the Australian Commonwealth government agencies (incl. FSANZ) that attend the CCPR can assist in ensuring the adoption of these MRLs into Codex Standards.

A similar procedure is in place for MRLs for veterinary drugs, with the Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommending MRLs, based on a scientific assessment of available data, to the Codex Committee for Residues of Veterinary Drugs in Food (CCRVDF). In common with the JMPR, the JECFA will not recommend MRLs to the CCRVDF unless adequate supporting scientific data are submitted to it.

5.2 Food Services Environmental Health Unit

The submission from the Food Services Environmental Health Unit of Queensland Health raised concerns about:

- the proposed increase in the maximum residue limit (MRL) for the insecticide, bifenthrin;
- the validity of using the National Estimated Dietary Intake (NEDI) to estimate the potential ingestion of residues of bifenthrin in vegetables which are then eaten raw;
- residue data from crop surveys carried out in Queensland; and
- changes in the Australian diet being reflected in the consumption figures.

As discussed in this paper previously, the Queensland Department of Primary Industry had provided data on bifenthrin to the NRA. These data indicated that the original temporary MRLs recommended for herbs, mizuna and rocket may be exceeded when this chemical is used according to the minor use permit. The proposed increase in the MRLs will avoid unnecessary violations of the temporary MRLs, while industry generates additional residue data for this chemical.

The NEDI for bifenthrin is an over-estimate of the chronic dietary exposure to the residues of this chemical. The NEDI is calculated as a percentage of the acceptable daily intake, using MRLs and the consumption data from the National Nutrition Survey. 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 a consumer.

Processing factors, such as data on the effect of washing raw vegetables and fruits on the level of chemical residues are taken into account when calculating the NEDI. No processing factors were supplied for bifenthrin in herbs, mizuna and rocket. However, safe food practices recommend that all fresh fruit and vegetables should be at least rinsed in cold water before being consumed. In the case of rocket, one source stated to prepare rocket:

wash in cold water, drain well, and then pat dry in a clean tea towel.

This submission stated that the Queensland Health Scientific Services was involved in agricultural chemical residue trials, that there was an increase in the consumption of herbs and an increase in vegetarian diets. However, the submission did not supply data in support of the above statements.

6. Options and Impact Analysis

6.1 Options

Option 1 – status quo – no change to the existing MRLs in the *Food Standards Code*. Option 2(a) – recommend changes to MRLs to delete or decrease some existing MRLs. Option 2(b) – recommend changes to MRLs to include new MRLs or increase some existing MRLs.

6.2 Affected parties

The parties affected by this application are consumers, government, producers and food manufacturers of primary produce and foods imported into Australia.

6.3 Costs and benefits

6.3.1 Costs of accepting the application

- There will be a cost of disposal, replacement and dissemination of information about proscribed agricultural and veterinary chemicals;
- Initially, enforcement agencies, food manufacturers may have costs associated with compliance and enforcement of MRLs following the proposed amendments;
- Some consumers may consider that any residues of agricultural and veterinary chemicals in food are not in the public interest and may regard the presence of any chemical residues in foods as a cost.

6.3.2 Benefits of accepting the Application

- Food producers will be legally able to sell produce legally treated with chemicals intended to improve stock and yields as well as controlling diseases and pests;
- It will ensure consistency between the health and agricultural regulations; and
- Consumers may receive the potential benefits of improved crop and stock production through cheaper or better quality produce.

6.3.3 Costs of not accepting the application

- Producers will <u>not</u> be able to legally sell legally treated produce treated with chemicals intended to increase productivity and/or control disease and pests. This will have costs for primary producers with consequent potential impacts on regional Australia;
- There may be increased production costs for manufacturers and ultimately increased costs to consumers if commodities which have been legally treated to improve productivity and/or control pests and disease cannot be legally sold; and
- the discrepancies between the *Food Standards Code* and the NRA MRL Standard would become greater leading to confusion for producers, consumers and government agencies.

6.3.4 Benefits of not accepting the application

• Products complying with the existing MRLs could continue to be legally sold.

6.4 Conclusion and recommended option

The inclusion of the proposed MRLs is consistent with the current registered uses of the chemical products. 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 (Option 1) 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.

7. Consultation

No additional submissions were received in response to section 13A or 14 notice required under the ANZFA to FSANZ transitional provisions.

7.1 World Trade Organization Notification

As a member of the World Trade Organization (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.

The MRLs prescribed in the *Food Standards 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 *Food Standards 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 assist in ensuring that residues are no higher than is necessary for effective control of pests and diseases. MRLs are also used as standards for the international trade in food.

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. Therefore, this application was notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO SPS agreement, in order to enable other member countries to comment on standards which may have a significant impact on them. No WTO member made a submission.

7.2 Codex MRLs

The standards of the Codex Alimentarius Commission are used as the relevant international standards or basis as to whether a new or changed standard requires a WTO notification. There are no proposed MRLs in this application which have a relevant Codex MRL.

7.3 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 while still being safe for human consumption, may be different from that in domestically produced food.

Deletions or reductions of MRLs may affect imported food which may be complying with existing MRLs even though these existing MRLs are no longer required for domestically produced food. This is because imported food that may contain residues consistent with the MRLs proposed for deletion.

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 1999 and 2000. These data are for foods for which reductions and deletions of MRLs are proposed.

Food	1999	2000
	Tonnes	Tonnes
Apple	332	162
Cattle, edible offal of	1462	1847
Cattle meat	1376	1107
Cereal grains	71834	74466
Eggs	672	353
Goat meat	0	5
Meat (mammalian)	25992	40012
Milk fats	23527	22689
Milks	22033	19345
Peanut	6389	7716
Pome fruits	1652	1843
Poultry, edible offal of	142	143
Poultry meat	142	143
Pulses	172147	191741
Sheep meat	335	459
Strawberry	5165	5889
Sweet corn (kernels)	13745	12907

FSANZ received no submissions on any possible ramifications for imports of the changes of the MRLs in this Application.

8. Implementation and review

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

- State and Territory residue monitoring programs;
- Commonwealth programs such as the National Residue Survey; and

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

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

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.

9. Transitional issues

In accordance with the transitional requirements for an application which has reached full (draft) assessment prior to the commencement of the FSANZ Act, the full (draft) assessment has been reviewed. No relevant policy guidelines have been notified by the Ministerial Council and no additional submissions were received in response to the notice given under section 13A or 14.

10. Conclusion and Recommendation

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 chemicals in this application and 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.

ATTACHMENTS

- 1. Draft Variations to the *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 *Food Standards Code*.
- 3. Background to Dietary Exposure Assessments.
- 4. Summary of Public Submissions
- 5. Glossary Of Acronyms.

ATTACHMENT 1

DRAFT VARIATIONS TO THE 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 -

FEBANTEL
FEBANTEL

[1.2] inserting in Schedule 1–

ETHAMETSULFURON METHYL	
ETHAMETSULFURON METHYL	
EDIBLE OFFAL (MAMMALIAN)	T*0.02
EGGS	T*0.02
LUPIN (DRY)	T*0.02
MEAT (MAMMALIAN)	T*0.02
MILKS	T*0.02
POULTRY, EDIBLE OFFAL OF	T*0.02
POULTRY MEAT	T*0.02
FLUTOLANIL	
COMMODITIES OF PLANT ORIGIN: FLUTO	
COMMODITIES OF ANIMAL ORIGIN: FLUTOL	
METABOLITES HYDROLYSED TO 2	-
TRIFLUOROMETHYL-BENZOIC ACID AND EX	KPRESSED
AS FLUTOLANIL	
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.05
MEAT (MAMMALIAN) (IN THE FAT)	*0.05
MILKS	*0.05
Ротато	0.05
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT (IN THE FAT)	*0.05
Pyriproxyfen	
PYRIPROXYFEN PYRIPROXYFEN	
BEANS [EXCEPT BROAD BEAN AND	T0.2
SOYA BEAN]	
COTTON SEED	T0.1
COTTON SEED OIL, CRUDE	T*0.02
COTTON SEED OIL, EDIBLE	T*0.02
EDIBLE OFFAL (MAMMALIAN)	T*0.02
FRUITING VEGETABLES, CUCURBITS	T0.2
FRUITING VEGETABLES, OTHER	T0.2
THAN CUCURBITS	
MEAT (MAMMALIAN) (IN THE FAT)	T*0.02
MILKS	T*0.02

SPIROXAMINE		
COMMODITIES OF PLANT ORIGIN: SPIROXA	MINE	
COMMODITIES OF ANIMAL ORIGIN: SPIROXA	AMINE	
CARBOXYLIC ACID, EXPRESSED AS SPIROXAMINE		
DRIED GRAPES	3	
EDIBLE OFFAL (MAMMALIAN)	0.5	
GRAPES	2	
MAMMALIAN FATS [EXCEPT MILK	0.05	
FATS]		
MEAT (MAMMALIAN)	0.05	
MILKS	0.05	
THIACLOPRID		
THIACLOPRID		
POME FRUITS	T1	
STONE FRUITS	T2	

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

BUTAFENACIL	_
BUTAFENACIL	
CEREAL GRAINS [EXCEPT MAIZE;	T*0.02
SORGHUM; MILLET; AND RICE]	
PROCYMIDONE	
PROCYMIDONE	
BROCCOLI	T5
Profenofos	
Profenosos	
SWEET CORN (KERNELS)	*0.02
PYMETROZINE	
PYMETROZINE	
APRICOT	*0.05
NECTARINE	*0.05
PEACH	*0.05
PLUMS (INCLUDING PRUNES)	*0.05

 $[1.4] \quad \textit{inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals} \, - \,$

ABAMECTIN		
SUM OF AVERMECTIN B 1A, AVERMECTIN	B 1B AND	
D-8,9 ISOMER OF AVERMECTIN B	1A	
SOYA BEAN (DRY)	T*0.002	
BENALAXYL		
Benalaxyl		
SHALLOT	T0.5	
BIFENTHRIN		
BIFENTHRIN		
KAFFIR LIME LEAVES	T10	
LEMON BALM	T10	

I my sovy on a go	Т10
LEMON GRASS LEMON VERBENA	T10 T10
MIZUNA	T10
THE COUNT	110
BUPROFEZIN	
BUPROFEZIN COTTON SEED	T1
COTTON SEED OIL, CRUDE	T0.3
,	
BUTAFENACIL	
BUTAFENACIL CEREAL GRAINS [EXCEPT RICE]	*0.02
CEREAL GRAINS [EACE! I RICE]	0.02
CHLORPYRIFOS	
CHLORPYRIFOS PEDER MANY LABANESE	T*0.05
PERSIMMON, JAPANESE	1*0.03
DORAMECTIN	
DORAMECTIN	
CATTLE MILK	T0.06
FENOXAPROP-ETHYL	
SUM OF FENOXAPROP-ETHYL (ALL ISON	MERS) AND 2-
(4-(6-CHLORO-2-BENZOXAZOLYLOXY	
PROPANOATE AND 6-CHLORO-	
DIHYDROBENZOXAZOL-2-ONE, EXP	RESSED AS
FENOXAPROP-ETHYL RICE	T*0.02
RICE	1 0.02
FLUAZIFOP-BUTYL	
FLUAZIFOP-BUTYL	TO 1
PARSNIP	T0.1
FLUDIOXONIL	
FLUDIOXONIL	TENE OI
RAPE SEED	T*0.01
FLUQUINCONAZOLE	
FLUQUINCONAZOLE	
RAPE SEED	T*0.01
PIRIMIPHOS-METHYL	
PIRIMIPHOS-METHYL	
PEANUT	5
PEANUT OIL, EDIBLE	15
PROCYMIDONE	
PROCYMIDONE	
BRASSICA (COLE OR CABBAGE)	T5
VEGETABLES, HEAD CABBAGES,	
FLOWERHEAD BRASSICAS INDIAN MUSTARD	T2
MUSTARD GREENS	T2
PROFENOFOS PROFENOFOS	
CATTLE MILK	*0.01
EDIBLE OFFAL (MAMMALIAN)	*0.05
EGGS	*0.02

lac (400=
MEAT (MAMMALIAN)	*0.05
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
PROPICONAZOLE	
PROPICONAZOLE	
BLUEBERRIES	T2
Pymetrozine	
PYMETROZINE	
STONE FRUITS	*0.05
SPINOSAD	
SUM OF SPINOSYN A AND SPINOSYN D	
CELERY	T*0.25
CLEEKI	1 0.23
TERUFENOZIDE	
TEBUFENOZIDE TEBUFENOZIDE	_
TEBUFENOZIDE	*0.02
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN)	*0.02
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT)	*0.02
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN)	
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT) MILKS	*0.02
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT) MILKS TRIADIMENOL	*0.02
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT) MILKS TRIADIMENOL TRIADIMENOL	*0.02
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT) MILKS TRIADIMENOL TRIADIMENOL SEE ALSO TRIADIMEFON	*0.02 *0.01
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT) MILKS TRIADIMENOL TRIADIMENOL	*0.02
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT) MILKS TRIADIMENOL TRIADIMENOL SEE ALSO TRIADIMEFON PEPPERS	*0.02 *0.01
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT) MILKS TRIADIMENOL TRIADIMENOL SEE ALSO TRIADIMEFON PEPPERS TRIFLURALIN	*0.02 *0.01
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT) MILKS TRIADIMENOL TRIADIMENOL SEE ALSO TRIADIMEFON PEPPERS TRIFLURALIN TRIFLURALIN	*0.02 *0.01
TEBUFENOZIDE EDIBLE OFFAL (MAMMALIAN) MEAT (MAMMALIAN) (IN THE FAT) MILKS TRIADIMENOL TRIADIMENOL SEE ALSO TRIADIMEFON PEPPERS TRIFLURALIN	*0.02 *0.01

 $[1.5] \quad \textit{omitting from Schedule 1, under the entries for the following chemicals, the maximum residue limit for the food, substituting -$

2,4-D	
2,4-D	
CEREAL GRAINS	0.2
BIFENTHRIN	
BIFENTHRIN	
GALANGAL, RHIZOMES	T10
HERBS	T10
RUCOLA (ROCKET)	T10
TURMERIC, ROOT	T10
BUTAFENACIL	
BUTAFENACIL	
EDIBLE OFFAL (MAMMALIAN)	*0.02
EGGS	*0.01
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT	*0.01
I and the second	

ETHYLENE DICHLORIDE (EDC)	
1,2-dichloroethane	
CEREAL GRAINS *0	.1
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]-1F	1-
PYRAZOLE-3-CARBONITRILE)	0.1
SUNFLOWER SEEDS *0.0)1
IMAZAPIC	
SUM OF IMAZAPIC AND ITS HYDROXYMETHYL	
DERIVATIVE	
PEANUT *0	.1
PROCYMIDONE	
PROCYMIDONE	
RAPE SEED T	Γ1
RAPE SEED OIL, CRUDE	Γ3
TEBUFENOZIDE	
TEBUFENOZIDE	
LITCHI	Γ2
LONGAN	Γ2
POME FRUITS	1
Trifluralin	
Trifluralin	
VEGETABLES [EXCEPT AS 0.0)5
OTHERWISE LISTED UNDER THIS	
CHEMICAL]	

A SUMMARY OF THE REQUESTED MRLS FOR EACH CHEMICAL AND AN OUTLINE OF THE INFORMATION SUPPORTING THE REQUESTED CHANGES TO THE FOOD STANDARDS CODE.

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

NOTES ON TERMS USED IN THE TABLE

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

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

LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue 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.

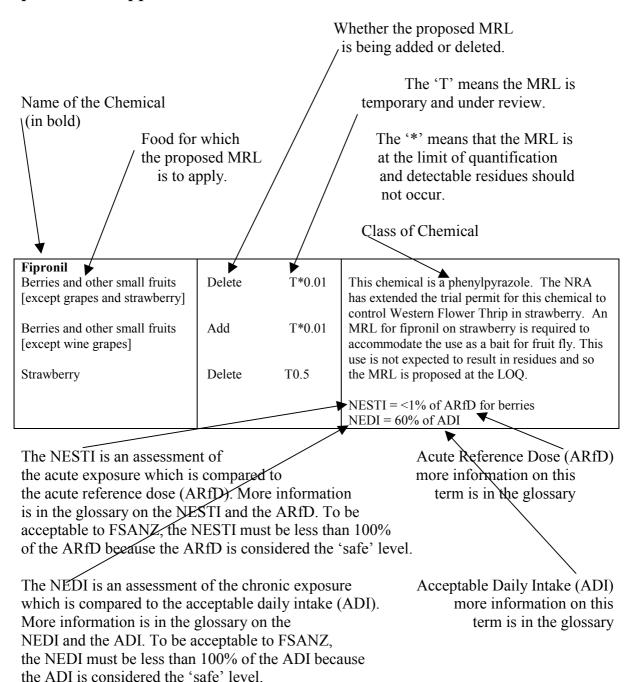
NEDI - National Estimated Dietary Intake - The NEDI represents a more realistic estimate of dietary exposure and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such 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 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 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.

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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	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

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.	JMPR	Joint FAO/WHO Meeting on Pesticide Residues
5.	LOQ	Limit of Analytical Quantification.
6.	NEDI	National Estimated Daily Intake.
7.	NESTI	National Estimated Short Term Intake.
8.	*	MRL set at or about the limit of quantification.
9.	T	Temporary MRL.

Chemical	MRL		Information
Food	(mg/kg)		
Abamectin Soya bean (dry)	Add T*0.002		This chemical is an avermectin. It is used as an insecticide and an acaricide. The NRA has issued a permit for a trial of this chemical to control insects on
			soya bean crops. NEDI = 48% of ADI

2,4-D			
Cereal grains	Delete Substitute	T2 0.2	This chemical is an aryloxyalkanoic acid. It is used as an herbicide to control weeds in cereal crops. JMPR Data (1998) was used for citrus fruits high residue in post harvest dipped lemons was 0.6 mg/kg NEDI = 65% of ADI
Benalaxyl Shallot	Add	T0.5	This chemical is a phenylamide. It is used as a fungicide. The NRA has issued a permit for this chemical to be used to control fungal diseases in shallots. NEDI = 1% of ADI
Bifenthrin			
Galangal, rhizomes	Delete Substitute	T0.5 T10	This chemical is a pyrethroid. It is used as an insecticide and an acaricide to control insects on herb crops. The
Herbs	Delete Substitute	T0.5 T10	Queensland Department of Primary Industry has provided residue monitoring data indicating that the
Kaffir lime leaves	Delete Substitute	T0.5 T10	original temporary MRLs recommended for herbs may be exceeded when bifenthrin is used according to the minor
Lemon balm	Delete Substitute	T0.5 T10	use permit. To avoid unnecessary violations the temporary MRLs will be increased in the interim period while the
Lemon grass	Delete Substitute	T0.5 T10	industry generates additional residue data. The contribution of herbs to the dietary intake of bifenthrin is negligible.
Lemon verbena	Delete Substitute	T0.5 T10	The temporary MRLs may be revised downwards once new data are available. Raising the MRLs for herbs has made
Mizuna	Delete Substitute	T0.5 T10	negligible difference to the NEDI (<1% increase). As it is recognised that the NEDI calculation is a conservative
Rucola (rocket)	Delete Substitute	T0.5 T10	indicator of dietary exposure, FSANZ concludes that there is no unacceptable risk to public health and safety
Turmeric, root	Delete Substitute	T0.5 T10	NEDI = 89% of ADI
Buprofezin			
Cottonseed Cotton seed oil, crude	Add Add	T1 T0.3	This chemical is a chitin synthesis inhibitor. It is used as an insecticide and an acaricide. The NRA has issued a permit for this chemical to be used to control insects on cotton plants. NEDI = 2% of ADI.

Butafenacil			
Cereal grains [except maize, sorghum, millet and rice]	Delete	T*0.02	This chemical is a uracil. It is used as an herbicide to control broad leaf weeds and some grass weeds in cereal
Cereal grains [except rice]	Add	*0.02	crops.
Edible offal (mammalian)	Delete	T*0.02	
	Substitute	*0.02	
Eggs	Delete	T*0.01	
	Substitute	*0.01	
Meat (Mammalian)	Delete	T*0.01	
	Substitute	*0.01	
Milks	Delete	T*0.01	
	Substitute	*0.01	
Poultry, Edible offal of	Delete	T*0.02	
	Substitute	*0.02	
Poultry meat	Delete	T*0.01	NEDY 404 CARY
Chlarnyrifas	Substitute	*0.01	NEDI = 4% of ADI
Chlorpyrifos Persimmon, Japanese	Add	T*0.05	This chemical is an organophosphorous. It used as an insecticide. The NRA has issued permit for this chemical to be used to control ant nests under persimmon trees. In the 19 th (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 level of consumption of Persimmon, Japanese, 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 and 2% of ARfD for children

Doramectin			
Cattle milk	Add	T0.06	This chemical is a macrocyclic lactone. It is used as an antiparasitic agent. The NRA has issued a permit for this chemical to be used to control parasites on and in dairy cattle and then to conduct a milk residue study. When the proposed MRL was included in the NEDI, the estimated chronic dietary intake of this chemical was 114% of the ADI, with 108% of this total being associated with the consumption of cattle milk. The potential dietary risks associated with the use of this chemical in dairy cattle have been reduced by applying the following conditions to the permit approval: • A maximum of 50 diary cattle are to be used in the residue trials associated with this permit i.e. 25 animals in the treatment group and 2 treatment groups (injection/pour on) = 50 animals; and • The milk from the treated animals must be co-mingled with milk from an equal (or higher) number of untreated animals at the dairy (in the farm vat). Restricting the dairy cattle being exposed to this chemical largely mitigates the potential risk to human health. The requirement to co-mingle milk from treated animals with milk from untreated animals effectively reduces the maximum level of this chemical in milk to half the proposed MRL (0.03 mg/kg), thereby reducing the NEDI calculation to 68% of the ADI. Subsequent dilution (in the milk tanker) and processing of the milk (separation and pasteurisation) are likely to reduce the level of any residues of this chemical even further.

Doramectin (cont)			Therefore, the dietary exposure assessment indicates that the residues associated with this chemical do not represent an unacceptable risk to public health and safety. Expected NEDI = 68% of ADI.
Ethametsulfuron methyl Edible offal (Mammalian) Eggs Lupin (dry) Meat (Mammalian) Milks Poultry, Edible offal of Poultry meat	Add Add Add Add Add Add Add	T*0.02 T*0.02 T*0.02 T*0.02 T*0.02 T*0.02 T*0.02	This chemical is a sulfonylurea. It is used as an herbicide to control weeds in lupin. NEDI = <1% of ADI
Ethylene dichloride Cereal grains	Delete Substitute	50 *0.1	This chemical is a fumigant insecticide. It is used to fumigate rice milling equipment. No ADI has been set for this chemical. However, FSANZ considers dietary exposure does not represent an unacceptable risk to public health and safety, as the rice grains are not treated directly with this chemical and the proposed MRL has been set at the LOQ. Therefore, detectable residues are not expected in rice or its processed fractions following the treatment of the rice milling equipment with this chemical.
Febantel Cattle, Edible offal of Cattle meat Goat, Edible offal of Goat meat Milk fats Milks Sheep, Edible offal of Sheep meat Fenoxaprop-ethyl	Delete Delete Delete Delete Delete Delete Delete Delete Delete	0.5 0.1 0.5 0.1 4 0.5 0.5 0.1	This chemical is a benzimidazole. It is used as anthelmintic. It is no longer registered for use in food producing animals, so MRLs for this chemical are no longer required. As this a deletion of the chemical no NEDI is required.
Rice	Add	T*0.02	This chemical is a 2-(4-aryloxyphenoxy)propionic acid. It is used as an herbicide. The NRA has issued a permit for this chemical to be used to control weeds in rice crops. NEDI = 7% of ADI.

Fipronil			
Sunflower seed	Delete Substitute	T*0.01 *0.01	This chemical is a phenylpyrazole. It is used as an insecticide to control insects on sunflower seed. There is an ARfD for this chemical. However, an acute dietary exposure was not carried out as no detectable residues are expected in seed grown from treated seed. NEDI = 27% of ADI.
Fluazifop-butyl Parsnip	Add	T0.1	This chemical is a
•	7 Kdd	10.1	2-(4-aryloxyphenoxy)propionic acid. It is used as an herbicide. The NRA has issued a permit for this chemical to be used to control grass weeds in parsnip crops. NEDI = 69% of ADI.
Fludioxonil Rape seed	Add	T*0.01	This chemical is a phenylpyrrole. It is used as a fungicide. The NRA has issued a permit for this chemical to be used to control fungal diseases on rape seed. NEDI = 2% of ADI
Fluquinconazole Rape seed	Add	T*0.01	This chemical is an azole. It is used as a fungicide. The NRA has issued a permit for a field trial for the use of this chemical to control blackleg in rape seed crops. NEDI = 22% of ADI
Flutolanil			1 2 2
Edible offal (Mammalian)	Add	*0.05	This chemical is a carboxamide. It is
Eggs Meat (Mammalian) (in the fat)	Add Add	*0.05 *0.05	used as fungicide control fungal diseases in potato.
Milks	Add	*0.05	
Potato	Add	0.05	
Poultry meat (in the fat)	Add	*0.05	
Poultry, Edible offal of	Add	*0.05	NEDI = 3% of ADI
Imazapic Peanut	Delete Substitute	T*0.1 *0.1	This chemical is an imidazolinone. It is used as an herbicide to control weeds in peanut crops. NEDI = <1% of ADI.

Pirimiphos-methyl			
Peanut	Add	5	This chemical is an
Peanut oil, edible	Add	15	organophosphorous. It is used as an
Teanut on, earoic	7 tuu	13	insecticide to control insects on
			peanuts.
			NEDI = 46% of ADI.
Procymidone			NEDI – 40/0 01 ADI.
Brassica (cole or cabbage)	Add	T5	This chemical is as dicarboximide. It
vegetables, Head cabbages,	Tuu	13	is used as a fungicide to control fungal
Flowerhead brassicas			diseases in various plants.
Broccoli	Delete	T5	diseases in various plants.
Indian mustard	Add	T2	
Mustard greens	Add	T2	
Rape seed	Delete	1	
Kape seed	Substitute	T1	
	Substitute	11	
Rape seed oil, crude	Delete	3	
rape seed on, erade	Substitute	T3	NEDI = 20% of ADI
Profenofos			
Cattle milk	Add	*0.01	This chemical is an
Edible offal (Mammalian)	Add	*0.05	organophosphorous. It is used to
Eggs	Add	*0.02	control insects on cotton crops.
Meat (Mammalian)	Add	*0.05	Available residue data for cotton and
Poultry meat	Add	*0.05	animal feed items have been reviewed
Poultry, Edible offal of	Add	*0.05	as part of the NRA's Stockfeed
Sweet corn (kernels)	Delete	*0.02	Guideline project. Entries are deleted
			for commodities for which there are no
			registered or approved uses. Animal
			commodity MRLs are reviewed based
			on anticipated dietary exposure of
			livestock to profenofos residues and
			available animal transfer studies. No
			changes to current use patterns are
			proposed.
			NEDI = 34% of ADI
Propiconazole			
Blueberries	Add	T2	This chemical is an azole. It is used as
			a fungicide. The NRA has issued a
			permit for this chemical to be used to
			control fungi on blueberries.
			NEDI = 5% of ADI.
Pymetrozine			
Apricot	Delete	*0.05	This chemical is an azomethine. It is
Nectarine	Delete	*0.05	use as an insecticide to control insects
Peach	Delete	*0.05	on stone fruits.
Plums (including prunes)	Delete	*0.05	NEDY 50/ CADA
Stone fruits	Add	*0.05	NEDI = 5% of ADI.

D			
Pyriproxyfen Danie Fernand Inno 1 Inno 1	A 1.1	TO 2	This should be a formation of the same of
Beans [except broad bean	Add	T0.2	This chemical is a juvenile hormone
and soya bean]			mimic. It is used as an insecticide.
Cotton seed	Add	T0.1	The NRA have issued an emergency
Cotton seed oil, crude	Add	T*0.02	permit for this chemical to be used to
Cotton seed oil, edible	Add	T*0.02	control white fly on cotton crops and
Edible offal (Mammalian)	Add	T*0.02	have issued a permit for this chemical
Fruiting vegetables,	Add	T0.2	to be used to control silver leaf whitefly
cucurbits			on various vegetable crops.
Fruiting vegetables, other	Add	T0.2	The state of the s
than cucurbits	1144	10.2	
Meat (Mammalian) (in the	Add	T*0.02	
	Auu	1 0.02	
fat)	A 11	T*0.03	NEDI (10/ CADI
Milks	Add	T*0.02	NEDI = <1% of ADI.
Spinosad			
Celery	Add	T*0.25	This chemical is a macrocylic lactone.
			It is used as an insecticide. The NRA
			has issued a permit for this chemical to
			be used to control insects on celery.
			NEDI = 11% of ADI
Spiroxamine			
Dried grapes	Add	3	This chemical is a morpholine. It is
Edible offal (Mammalian)	Add	0.5	used as used as a fungicide to control
	Add		
Grapes		2	powdery mildew on grapes. The MRLs
Mammalian fats [except	Add	0.05	for animal products are included as
milk fats]			grape pomace is fed to livestock.
Meat (Mammalian)	Add	0.05	The highest NESTI calculated was for
Milks	Add	0.05	grapes in infants (2 - 6 years) and is
			equivalent to 17 % of the ARfD. The
			NESTI for grapes consumed by adults (7
			years and above) is equivalent to 7% of
			the ARfD. NESTIs for all other
			commodities were ≤2% of the ARfD.
			NEDI = 4% of ADI
Tebufenozide			T/0 01/10/1
	A 4.4	*0.02	This chamical is a disculturation of the
Edible offal (Mammalian)	Add	*0.02	This chemical is a diacylhydrazine. It is
Litchi	Delete	T1	used as an insecticide to control
	Substitute	T2	lightbrown apple moths in apples and
			pears and codling moth on apples.
Longan	Delete	T1	The NRA has issued a permit for this
	Substitute	T2	chemical to control insects on litchi and
			longans. Animal commodity MRLS are
Meat (Mammalian) (in the	Add	*0.02	recommended as a result of the use of
fat)			apple and pear pomace as animal feed
Milks	Add	*0.01	commodities.
Pome fruit	Delete	T2	
1 one muit	Substitute	12	NEDI = 11% of ADI.
	Substitute	1	NEDI = 11/0 01 ADI.

Thiacloprid			
Pome fruits	Add	T1	This chemical is a chloronicotinyl. The
Stone fruits	Add	Т2	NRA has issued a permit for this chemical to control codling moth and oriental fruit moth on stone and pome fruits. The NESTI was calculated using raw fruit consumption figures, and was, as a maximum, 26 % of the ARfD for the whole population and 80 % of the ARfD for children. NEDI = 18% of ADI.
Triadimenol			
Peppers	Add	T0.5	This chemical is an azole. It is used as a fungicide. The NRA has issued a permit for this chemical to be used to control powdery mildew on capsicum. NEDI =2% of ADI
Trifluralin			
Parsnip	Add	T0.5	This chemical is a 2,6-dinitroaniline. It
Vegetables [except carrot;	Delete	0.05	is used as an herbicide. The NRA has
fennel bulb; and galangal,			issued a permit for this chemical to be
greater]			used to control winter grasses in
Vegetables [except carrot;	Add	0.05	parsnip crops.
fennel bulb; galangal,			
greater; and parsnip]			NEDI =7% 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, 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 <u>not</u> recommend 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); an
- calculating the dietary exposure to a chemical from <u>all</u> 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 have established an ARfD.

The NRA and FSANZ have 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 Aged Care undertook the NNS survey over a 12-month period (1995 to early 1996) by 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 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 NRA and FSANZ consider the residues that could result from the use of a chemical product on <u>all</u> 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 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 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 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.

National Estimated Daily Intake (NEDI) for

Abamectin

 $16 \ \text{Jan } 2002$ Calculation of NEDI (ADI for abamectin = 0.0005 mg/kg of body weight)

Commodity	Food Consumption g/kg bodyweight/day		MRL mg/kg	NEDI %ADI mg/kg bw/day
apple	0.9466		0.01	0.00000947 1.89%
blackcurrant	0.0222	T	0.02	0.00000044 0.09%
cattle, edible offal of	0.0016		0.1	0.00000016 0.03%
cattle fat	0.1106		0.1	0.00001106 2.21%
cattle meat	1.0839		0.005	0.00000542 1.08%
cattle milk	9.0007		0.02	0.00018001 36.00%
citrus fruits	2.1336		0.01	0.00002134 4.27%
cotton seed	0.0001	*	0.01	0.00000000 0.00%
egg plant	0.0075	T	0.02	0.00000015 0.03%
Hops, dry	0.0001		0.1	0.00000001 0.00%
pear	0.1642		0.01	0.00000164 0.33%
peppers	0.0469	*	0.02	0.00000094 0.19%
Pig kidney	0.0001		0.01	0.00000044 0.09%
Pig liver	0.0001		0.02	0.00000015 0.03%
Pig meat [in the fat]	0.0435		0.02	0.00000042 0.08%
sheep, Edible offal of	0.0077		0.05	0.00000039 0.08%
sheep meat [in the fat]	0.02085		0.05	0.00000104 0.21%
soybean	0.0304	T*	0.002	0.00000006 0.01%
strawberry	0.0299		0.02	0.00000060 0.12%
tomato	0.8185		0.01	0.00000819 1.64%
Total (mg/kg bw/day)				0.00024192 48.38%

* At or about the limit of determination

Equivalent to 48% of the ADI

The food consumption figures are derived from the 1995 National Nutrition Survey of Australia for people 2 years and above (the mean consumption figures shown are from all respondents) NEDI - National Estimated Daily Intake

MRL - Maximum Residue Limit

These calculations have been made in accordance with 'Food consumption and exposure assessment of chemicals. Report of a FAO/WHO Consultation, Geneva, Switzerland 10 - 14 February 1997' T signifies that the MRL is associated with a temporary use pattern

National Estimated Daily Intake (NEDI) for 2,4-D

Calculation of NEDI (ADI for 2,4-D =

0.01 mg/kg of body weight)

Commodity	•	nd Consumption MRL g/kg bodyweight/daymg/kg		NEDI mg/kg bw/day	%ADI	
Cereal Grains	2.5686		0.2	0.00051372	5.14%	CF+CM+G
Citrus fruits	2.1336		0.6	0.00128016	12.80%	Note 1
Edible offal	0.0157		2	0.00003140	0.31%	
Eggs	0.2228	*	0.05	0.00001114	0.11%	
Legumes vegetables	0.2751	*	0.05	0.00001376	0.14%	
Lupin dry	0.0001	*	0.05	0.00000001	0.00%	Default
Meat (mammalian)	1.7276		0.2	0.00034552	3.46%	
Milks	8.9933	*	0.05	0.00044967	4.50%	
Oilseed	0.05452	*	0.05	0.00000273	0.03%	
Pears	0.1537	*	0.05	0.00000769	0.08%	
Potato	0.9821		0.1	0.00009821	0.98%	
Poultry, edible offal of	0.0024	*	0.05	0.00000012	0.00%	
Poultry meat	0.5596	*	0.05	0.00002798	0.28%	
Pulses	0.0863	*	0.05	0.00000432	0.04%	
Sugar cane	0.7328		5	0.00366400	36.64%	
Total (mg/kg bw/day)				0.00645040	64.50%	

* At or about the limit of determination

Equivalent to 65 % of the ADI

The food consumption figures are derived from the 1995 National Nutrition Survey of Australia for people 2 years and above (the mean consumption figures shown are from all respondents)

Note 1 JMPR Data (1998) high residue in post harvest dipped lemons (MRL=5mg/kg)

* Limit of Quantification

ADI - Acceptable Daily Intake

National Estimated Daily Intake (NEDI) for benalaxyl

Calculation of NEDI (ADI for benalaxyl =

0.05 mg/kg of body weight)

Commodity	od Consumption MRL g/kg bodyweight/daymg/kg	NEDI %ADI mg/kg bw/day
Fruiting vegetables, cucurbits	0.4375 0.2	0.00008750 0.18%
Garlic	0.0019 0.1	0.00000019 0.00%
Grapes (including wine)	0.7939 0.5	0.00039695 0.79%
Lettuce, head	0.1273 * 0.01	0.00000127 0.00%
Lettuce, leaf	0.0001 * 0.01	0.00000000 0.00%
Onion, bulb	0.2767 0.1	0.00002767 0.06%
Shallots	0.0061 T 0.5	0.00000305 0.01%
Total (mg/kg bw/day)		0.00051358 1.03%

* At or about the limit of determination Equivalent to 1 % of the ADI

The food consumption figures are derived from the 1995 National Nutrition Survey of Australia for people 2 years and above (the mean consumption figures shown are from all respondents)

NEDI - National Estimated Daily Intake

ADI - Acceptable Daily Intake (Chemicals and Non-prescription Drugs Branch, Department of Health and Aged Care)

MRL - Maximum Residue Limit

These calculations have been made in accordance with 'Food consumption and exposure assessment of chemicals. Report of a FAO/WHO Consultation, Geneva, Switzerland 10 - 14 February 1997'

T signifies that the MRL is associated with a temporary use pattern

Appendix 1: NEDI for Bifenthrin

(ADI for bifenthrin = 0.01 mg/kg of body weight)

Dietary intakes taken from ANZFA figures, all respondents 2 years and above

Commodity	Food Consumption g/kg BW/day		MRL ng/kg	NEDI mg/kg BW/day	
FP 0226 Apple	0.9466	*	0.05	0.00004733	
FI 0326 Avocados	0.0306	T	0.1	0.00000306	
FI 0327 Banana	0.3515		0.1	0.00003515	
MO 0812 Cattle, Edible offal of	0.0016		0.5	0.0000008	
MM 0812 Cattle meat [in the fat]	0.1106		2	0.0002212	fat+10% of meat intake
GC Cereal grains (except wheat)	0.8801		2	0.0017602	see note below
Wheat flour (white)	1.5482		0.6	0.00092892	PF x MRL
Wheat flour (wholemeal))	0.1721		1.66	0.000285686	PF x MRL
Wheat bran (unprocessed)	0.0075		7	0.0000525	PF x MRL
VL 0465 Chervil	0.0001	T	10	0.000001	default consumption
FC Citrus fruits	2.1336	*	0.05	0.00010668	
SO 0691 Cotton seed	0.0001		0.1	0.00000001	default consumption
PE 0112 Eggs	0.2228	*	0.05	0.00001114	
VO 0440 Eggplant	0.0075	T	0.5	0.00000375	
VD 0561 Field pea (dry)	0.0001	T*	0.01	0.000000001	default consumption
VC 0045Fruiting Vegetables, cucurbits	0.4375	T*	0.1	0.00004375	
HS 0783 Galangal, rhizomes	0.0001	T	10	0.000001	default consumption
MO 0814 Goat, Edible offal of	0.0001		0.5	0.00000005	default consumption
MM 0814 Goat meat [in the fat]	0.0001		2	0.0000002	default consumption
FB 0269 Grapes	0.7939	*	0.01	0.000007939	including wine
HH 0092 Herbs #	0.0067	T	10.00	0.000067	
VD 0545 Lupin (dry)	0.0001	T*	0.02	0.000000002	default consumption
ML 0106 Milks	8.9933		0.5	0.00449665	
Mizuna	0.0001	T	10	0.000001	default consumption
VO 0442 Okra	0.0018	T	0.5	0.0000009	
FP 0230 Pear	0.1642		0.5	0.0000821	
VO 0051 Peppers,	0.06	T	0.5	0.00003	
PO 0111 Poultry, Edible offal of	0.0024	*	0.05	0.00000012	
PM 0110 Poultry meat [in the fat]	0.05596	*	0.05	0.000002798	10% of poultry meat
VD 0070 Pulses [except for field pea, dry;	0.0861	*	0.02	0.000001722	
SO 0494 Rape seed	0.0001	*	0.02	0.000000002	default consumption
Rocket (Rucola)	0.0001	T	10	0.000001	default consumption
MO 0822 Sheep, Edible offal of	0.0076		0.5	0.0000038	kidney + liver intakes
MM 0822 Sheep meat [in the fat]	0.0208		2	0.0000416	10% of sheep meat
FS 0012 Stone Fruit	0.2788	T	1	0.0002788	
GS 0659 Sugar cane	0.7328	*	0.01	0.000007328	sugarcane molasses intal
VO 0448 Tomato	0.8185		0.5	0.00040925	

Total 0.008934438 mg/kg BW/day

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimated Daily Intake

ADI - Acceptable Daily Intake

^{*} At or about the limit of determination

^{**} Equivalent to 89.34 % of the ADI

^{# -} Since there is unlikely to be significant contribution from the similar minor use commodities (kaffir lime leaves, lemon balm, lemon grass, lemon verbena, tumeric) the dietary intakes from these commodities are included in the herbs entry

Calculation of NEDI for Buprofezin

ADI for buprofezin = 0.01 mg/kg of body weight)

Commodity	Food Consumption g/kg bodyweight/day	MRL/STMR mg/kg	Intake mg//kg bw/day	
Citrus fruits	0.2873	0.18	0.000051714	STMR for whole fruit
Citrus fruits (juices)	1.8463	0.0306	5.64968E-05	STMR x PF
cottonseed	0.0001	0.21	0.000000021	default intake, STMR=0.21
cottonseed oil (crude+refined)	0.0001	0.05	5.25E-09	default intake, cottonseed STMRxPF 0.2
Mango	0.0663	0.01	0.000000663	STMR in pulp = <0.01
Milks	8.9933	* 0.01	0.000089933	STMR = 0.01
Meat (mammalian)[in the fat]	0.1756	* 0.05	0.00000878	10% of MM + MF
Edible offal (mammalian)	0.0157	* 0.05	0.000000785	STMR = 0.05
	0	0	0	
Total			0.000208398	mg/kg bodyweight**

^{*} At or about the limit of determination

% of the ADI

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimate of Daily Intake using ANZFA mean intake figures for all respondents 2 years and above (November 2000).

ADI - Acceptable Daily Intake

MRL - Maximum Residue Limit

Notes: MRL for citrus fruit = 2 mg/kg; MRL for mango = 0.2; MRL for cottonseed = 1 mg/kg; MRL for cottonseed oil = 0.3 mg/kg

^{**} Equivalent to

^{2.1}

NEDI for butafenacil

ADI = 0.004 mg/kg of body weight)

Dietary intakes from 1995 National Nutrition Survey of Australia, mean intake, all respondents 2 years and above

Commodity	Food Consumption g/kg BW/day	MRL mg/kg	NEDI mg/kg BW/day	Note
Cereal Grains (total)	2.5686	* 0.02	0.0000514	1
Offal, mammalian	0.0157	* 0.02	0.0000003	
Poultry eggs	0.2228	* 0.01	0.0000022	
Meat, mammalian	1.7276	* 0.01	0.0000173	
Milk	8.9933	* 0.01	0.0000899	
Poultry offal	0.0024	* 0.02	0.0000000	
Poultry meat	0.5596	* 0.01	0.0000056	
Total			0.0001668	mg/kg BW/day**

^{*} At or about the limit of determination

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimated Daily Intake

ADI - Acceptable Daily Intake

MRL - Maximum Residue Limit

1. Sum of CF + CM + GC. Includes rice, although the product will not be registered on rice.

^{**} Equivalent to 4.17 % of the ADI

NEDI for chlorpyrifos

NEDI for chlorpyrifos	ADI for chlorpyrifos	=		4-Sep-01 0.003	mg/kg of body weight	
Commodity	Food Consumption g/kg bw/day		MRL mg/kg	MRL or expected residue mg/kg	NEDI mg/kg bw/day	
Asparagus	0.0109	T	0.5	0.5	0.00000545	
Avocado	0.0306		0.5	0.5	0.00001530	
Banana	0.3515	T	0.5	0.014	0.00000492	Note 1
Brassica (cole or cabbage) vegetables.	0.3249	T	0.5	0.5	0.00016245	
Cassava	0.0016	T*	0.02	0	0.00000000	Note 2
Celery	0.0578	T	5	5	0.00028900	
Cereal grains (except sorghum)	2.5686	T	0.1	0.1	0.00025686	
Citrus fruits	0.2873	T	0.5	0.5	0.00014365	Note 3
Citrus fruits (juice)	1.64			0.01	0.00001640	Note 4
Coffee Bean	0.0506	T	0.5	0.5	0.00002530	
Cotton seed	0.0001		0.05	0.05	0.00000001	Note 5
Cotton seed oil, crude (see oilseed)	0.0001		0.2	0.2	0.00000002	
Dried fruit	0.1094	T	2	1	0.00010940	Note 6
Edible offal (mammalian)	0.0151	T	0.1	0	0.00000000	Note 7
Eggs	0.2228	T*	0.01	0.01	0.00000223	
Ginger, root	0.0001		0.05	0.05	0.00000001	Note 5
Grapes (raw)	0.1059	T	1	1	0.00010590	Note 3
Grapes (wine only)	0.688		_	0.04	0.00002752	Note 8
Kiwifruit	0.0225	_	2	2	0.00004500	
Leeks	0.0058	T *	5	5	0.00002900	
Mango	0.0663		0.05	0.05	0.00000332	
Meat (mammalian) [in the fat]	0.1756	T	0.5	0	0.00000000	Note 7
Milks [in the fat]	0.3597	T	0.2	0.2	0.00007194	Note 9
Oilseed	0.0542	T T*	0.01	0.01	0.00000054	Note 10
Olive	0.0104	*	0.05	0.05	0.00000052	Note 11
Passion fruit Persimmon	0.0106 0.05	T*	0.05 0.05	0.05 0.05	0.00000053 0.00000250	Note 12 Note 16
	0.03	T	0.03	0.03	0.00000230	Note 16
Pineapple Pome fruits	1.1687	T	0.5	0.5		
Potato	0.9821	1	0.05	0.3	0.00058435 0.00000000	Note 2
Poultry, edible offal of	0.9821	Т	0.03	0	0.00000000	Note 7
Poultry meat [in the fat]	0.05596	T	0.1	0	0.0000000	Note 7
Sorghum	0.0001	T	3	3	0.00000000	Note 5
Stone fruits	0.2788	T	1	1	0.00000030	Note 3
Strawberry	0.0299	1	0.05	0.05	0.00027880	
Sugar cane	0.7328	T	0.03	0.05	0.00000130	Note 13
Sweet potato	0.0081	T	0.05	0	0.00000000	Note 2
Tomato (whole)	0.3683	T	0.05	0.5	0.00018415	Note 3
Tomato (whole)	0.4502	T	0.5	0.02	0.00018413	Note 14
Vegetables (except asparagus, brassica vegetable; cassava, celery,	0.4302			0.02	0.00000900	11010 14
potato, tomato)	2.04121	T*	0.01	0.01	0.00002041	Note 15
Total					0.00250487	-

The NEDI is equivalent to 83 % of the ADI

These calculations have been made in accordance with 'Guidelines for Predicting Dietary
Intake of Pesticide Residues' (World Health Organization)
Food consumption data derived from the 1995 National Nutrition Survey, mean consumption, all respondents, 2 years and above
NEDI - National Estimate of Dietary Intake
ADI - Acceptable Daily Intake
MRL - Maximum Residue Limit
* - At or about the limit of determination
T - Temporary

corrected for residue in pulp soil treatment, nil residue situation consumption figure for fruit processing factor for juice (0.002) applied to MRL default consumption, not consumed in 1995 NNS processing factors in range 0.5-1 for dried grapes (MRLs 0.5 or 1 for raw pome, stone, grape) NRS Survey data indicates negligible residue detections wine data variable consumption figure corrected for fat content (4%) excludes cotton seed consumption figure =sum of olive and olive oil nil residue expected in edible portion consumption figure for molasses, soil treatment, nil residue processing factor for sauce + juice (0.04) applied to MRL. Consumption figure for all vegetables except those excluded soil treatment, nil residue situation Note 1 Note 2 Note 3 Note 4 Note 5 Note 6 Note 7 Note 8 Note 9 Note 10 Note 11 Note 12 Note 13 Note 15 Note 15 Note 15

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CASE 2a
Persimmon & Chlorpyrifos

		NOTE 1	NOTE 2
ARfD	2 yrs +	Date 1:0 consumption	Banana 1.0 consumption
HR (uncorr) Processing factor HR		0.05 1 0.050	0.05 1 0.050
LP (g/kg bw/day kg bw LP (kg))	2.525 67 0.169	67
U (uncorr, g) Edible portion U (corr, kg)		179 69% 0.124	69%
v		5	5
NESTI % ARfD		0.00049 0.5%	0.00056 1%
pieces (number o	f fruit)	1	2
ARfD	2 - 6 years	0.1	0.1
HR (uncorr) Processing factor HR	-	0.05 1 0.050	0.05 1 0.050
LP (g/kg bw/day kg bw LP (kg))	2.968 19 0.056	19
U (uncorr, g) Edible portion U (corr, kg)		179 69% 0.124	69%
v		5	5
NESTI % ARfD		0.00145 1%	0.00201 2%
pieces (number o	f fruit)	0.5	2

NOTE 1 Consumption data for persimmon are not available from the 1995 NNS. NESTI calculated using consumption data for dates, which belong to the same Codex food group.

NOTE 2 NESTI calculated using consumption data for bananas, another subtropical fruit.

Calculation of NEDI

Doramectin

ADI for doramectin

= 0.0005 mg/kg of body weight

Commodity	Food Consumption g/kg bw/day	MRL mg/kg	NEDI mg/kg bw/day	% ADI
Cattle, edible offal of	0.0016	0.1	0.00000016	0.032
*Cattle fat	0.1106	0.1	0.00001106	2.212
Cattle meat	1.0839	0.01	0.00001084	2.168
Cattle milk	9.0007	T 0.06	0.00054004	108.008
ΦPig, edible offal	0.003	0.05	0.00000015	0.030
Pig meat [in the fat]	0.04353	0.1	0.00000435	0.871
Sheep, edible offal of	0.0001	0.05	0.00000001	0.001
*Sheep fat	0.02095	0.1	0.00000210	0.419
Sheep meat	0.2085	0.02	0.00000417	0.834
Total			0.000572874	mg/kg bw/day

NEDI - National Estimate of Dietary Intake

(Chemicals Safety Unit, Commonwealth Department of Human Services and Health)

^{*} At or about the limit of determination

^{**} Equivalent to 114.6 % of the ADI

Food consumption of pig meat [in the fat] is comprised of 10% of the meat intake (ie 10% of 0.4293 g/kg/day), plus the pig fat intake of 0.0006 g/kg/day.

Φ Consumption figure for pig, edible offal includes both pig liver and pig kidney.

^{*} Cattle/sheep fat consumption figures are calculated as 10 % of the meat intake, plus the relevant fat intake figure.

^{*}NC, default intake

[#] ADI - Acceptable Daily Intake

Calculation of NEDI for Ethametsulfuron methyl

ADI for ethametsulfuron methyl = 0.21 mg/kg of body weight

Commodity	Food Consumption g/kg bw/day		MRL ng/kg	NEDI mg/kg bw/day	
Edible offal (mammalian)	0.0151	*	0.02	0.000000302	
Meat (mammalian)	1.7276	*	0.02	0.000034552	
Milks	8.9933	*	0.02	0.000179866	
Eggs	0.2228	*	0.02	0.000004456	
Poultry meat	0.5596	*	0.02	0.000011192	
poultry, edible offal of	0.0024	*	0.02	0.000000048	
lupin, dry	0.0001	*	0.02	0.000000002	default consumption
Total				0.000230418 0.015438006	mg/kg bw/day mg/person/day

^{*} At or about the limit of determination

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimate of Dietary Intake

Mean body weight 67 kg

ADI - Acceptable Daily Intake

(Chemicals Safety Unit, Commonwealth Department of Human Services and Health)

^{**} Equivalent to 0.1 % of the ADI

Calculation of NEDI for Fenoxaprop-ethyl

(ADI for fenoxaprop = 0.004 mg/kg of body weight)

Dietary intakes taken from ANZFA figures, all respondents 2 years and above

Commodity	Food Consumption g/kg BW/day	MRL mg/kg	NEDI mg/kg BW/day
GC 0640 Barley	0.0052	* 0.01	0.00000052
VD 0524 Chick-pea (dry)	0.0033	* 0.01	0.000000033
MO 0812 Edible offal, mammalian	0.0151	0.2	0.00000302
PE 0112 Eggs	0.2228	* 0.02	0.000004456
MM 0812 Meat, mammalian	1.7276	0.05	0.00008638
ML 0106 Milks	8.9933	0.02	0.000179866
PO 0111 Poultry, edible offal of	0.0024	* 0.1	0.00000024
PM 0110 Poultry meat	0.5596	* 0.01	0.000000033
GC 0649 Rice	0.0145	T*0.02	0.000000302
GC 0650 Rye	0.0001	* 0.01	0.000002228 default consumption
GC 0653 Triticale	0.0001	* 0.01	0.000017276 default consumption
GC 0654 Wheat	1.771	* 0.01	0.000089933 CF0654+CF1210+CF1211+CF1212+CM0654
Total			0.000273995 mg/kg BW/day

^{*} At or about the limit of determination

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimated Daily Intake

ADI - Acceptable Daily Intake

MRL - Maximum Residue Limit

Last updated 13/12/01

^{**} Equivalent to 6.85 % of the ADI

Calculation of NEDI for Fipronil

(ADI for fipronil = 0.0002 mg/kg of body weight)

Dietary intakes taken from ANZFA figures, all respondents 2 years and above

Commodity	Food consumption g/kg bw/day		MRL mg/kg	Expected mg/kg	NEDI mg/kg bw/day	
Asparagus	0.0109	T	0.5	0.5	0.00000545	
Assorted tropical and subtropical frui	0.3927	T*	0.01	0.0016	6.2832E-07	nil residue situation, bait spray, <lod< td=""></lod<>
Berries and other small fruit [except	0.1961	T*	0.01	0.0016	3.1376E-07	nil residue situation, bait spray, <lod< td=""></lod<>
Bananas	0.3515	*	0.01	0	0	nil residue situation
Brassica vegetables	0.3249	T	0.05	0.05	0.000016245	
Citrus fruit	2.1336	T*	0.01	0.0016	3.41376E-06	nil residue situation, bait spray, <lod< td=""></lod<>
Cottonseed	0.0001	*	0.01	0.01	0.000000001	default intake
Cottonseed oil	0.0001	*	0.01	0.01	0.000000001	
Edible offal (mammalian)	0.0151		0.02	0	0	no residues expected
Eggs	0.2228		0.02	0	0	
Herbs, spices, various entries	0.01	T	0.10	0.1	0.000001	see comment below
Maize	0.0522	T*	0.01	0	0	nil residue situation
Meat (mammalian) [in the fat]	0.1756		0.10	0.1	0.00001756	fat intake+10% of meat intake
Milk	8.9933		0.01	0	0	no residues expected
Mushrooms	0.049		0.02	0.02	0.00000098	
Peanut	0.0434	T*	0.01	0	0	nil residue situation
Peanut oil	0.0001	*	0.01	0	0	nil residue situation
Pecans	0.0082	T*	0.01	0	0	nil residue situation
Peppers	0.06	T	0.10	0.1	0.000006	
Pome fruit	1.1687	T*	0.01	0.0016	1.86992E-06	nil residue situation, bait spray, <lod< td=""></lod<>
Potatoes	0.9821	*	0.01	0	0	nil residue situation
Poultry, edible offal	0.0024	*	0.01	0	0	no residues expected
Poultry meat [in the fat]	0.05596		0.01	0	0	no residues expected
Rape seed	0.0001	*	0.01	0.00	0	nil residue situation
Rice	0.2533	*	0.01	0	0	nil residue situation, GC0649+CM1205+CM1206+GC
Sorghum	0.0001		0.01	0.01	0.000000001	
Stone fruit	0.2788	T*	0.01	0.0016	4.4608E-07	nil residue situation, bait spray, <lod< td=""></lod<>
Sugarcane	0.7328	*	0.01	0.00	0	nil residue situation
Sunflower	0.0019	T*	0.01	0.00	0	nil residue situation
Sweet potato	0.0081	T*	0.01	0.00	0	nil residue situation
Wine grapes	0.6766	T*	0.01	0.00	0	nil residue situation

Total 5.39098E-05 mg/kg BW/day

Equivalent to 27 % of the ADI

NEDI- National Estimated Daily Intake ADI - Acceptable Daily Intake

FLUAZIFOP-P-BUTYL

Dietary Inlake Calculation

(ADI for fluazifop = 0.003 mg/kg of body weight)

Commodity	Food Consumption		MRL	Dietary Intake	% ADI	•
	g/kg bw/day		mg/kg	mg/kg bw/day		
	Total Population					
DH 1100 Hops (dry)	0.0001		0.05	0.00000001	0.00%	default intake
FB 0018 Berries and other small fruits	0.8727		0.2		5.82%	
FC 0001 Citrus fruits	2.1336	*	0.02	0.00004267	1.42%	
FI 0030 Assorted tropical and sub-						
tropical fruits - inedible peel	0.3621		0.05	0.00001811	0.60%	
FI 0326 Avocado	0.0306	*	0.02	0.00000061	0.02%	
FI 0327 Banana	0.3515	*	0.02	0.00000703	0.23%	
FP 0009 Pome fruits	1.1687	*	0.01	0.00001169	0.39%	
FS 0012 Stone fruits	0.2788		0.05	0.00001394	0.46%	
FT 0305 Olives	0.0067	Τ	0.05	0.00000034	0.01%	
GS 0659 Sugar cane	0.7328	T*	0.1	0.00007328	2.44%	
HH 0092 Herbs#	0.0067	Τ	1	0.00000670	0.22%	
HS 0784 Ginger, root	0.0001	Т	0.05	0.0000001	0.00%	default intake
ML 0106 Milks	8.9933		0.1	0.00089933	29.98%	
MM 0095 Meat (mammalian)	1.7276	*	0.05	0.00008638	2.88%	
MO 0105 Edible offal (mammalian)	0.0151	*	0.05	0.00000076	0.03%	
PE 0112 Eggs	0.2228	*	0.05	0.00001114	0.37%	
PM 0110 Poultry meat	0.5596	*	0.05	0.00002798	0.93%	
PO 0111 Poultry, Edible offal of	0.0024	*	0.05	0.00000012	0.00%	
SB 0716 Coffee Beans	0.0506	Т	1	0.00005060	1.69%	
SO 0088 Oliseed	0.0542		0.5	0.00002710	0.90%	
VA 0381 Garlic	0.0019		0.05	0.00000010	0.00%	
VA 0384 Leeks	0.0058	Т	0.5		0.10%	
VA 0385 Onion, Bulb	0.2767		0.05	0.00001384	0.46%	
VB 0040 Brassica (cole or cabbage)						
vegetables	0.3249		1	0.00032490	10.83%	
VD 0545 Lupin (dry)	0.0001		0.1	0.00000001	0.00%	default intake
VD 0070 Pulses	0.0863		0.5	0.00004315	1.44%	
VC 0045 Fruiting vegetables, Cucurbi	0.4375		0.1	0.00004375	1.46%	
VL 0476 Endive	0.0016		0.05	0.00000008	0.00%	
VL 0482 Lettuce, Head	0.1273		0.05	0.00000637	0.21%	
VL 0483 Lettuce, Leaf	0.0000		0.05	0.00000000	0.00%	
						all lettuce considered
						under lettuce, head
VO 0445 Peppers, sweet [capsicum]	0.0600	*	0.02	0.00000120	0.04%	•
VO 0448 Tomato	0.8185		0.1	0.00008185	2.73%	
VP 0060 Legume vegetables	0.2751		0.1	0.00002751	0.92%	
VR 0577 Carrot	0.2707		0.1	0.00002707	0.90%	
VR 0589 Potato	0.9821		0.05	0.00004911	1.64%	
VS 0624 Celery	0.0578	*	0.02		0.04%	
VS 0627 Rhubarb	0.0088	*	0.02		0.01%	
VR 0588 Parsnip	0.0085	Т	0.1	0.00000085	0.03%	
Total				0.00207547	69.21%	1
				mg/kg b.w.**	02.2170	
				5		

^{*} At or about the limit of determination

** Equivalent to 69 % of the ADI

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

ADI - Acceptable Daily Intake MRL - Maximum Residue Limit

Date of Calculation: 11 January 2002

T - Temporary MRL

^{# -} Since there is unlikely to be significant contribution from the similar minor use commodities, the dietary intakes from these commodities are included in the herbs entry
Intake for all pulses used although the product is not registered for use on all pulses.

Calculation of NEDI for FLUDIOXONIL

(ADI for fludioxonil = = 0.03 mg/kg of body weight)

Commodity	Food Consumption g/kg BW/day		MRL mg/kg	Intake mg/kg BW/day
VR 0589 Potato	0.9821		0.02	0.000019642
FB 0269 Grapes	0.1199		2	0.0002398
MM 0812 Meat (mammalian)	1.7276	*	0.01	0.000017276
MO 0812 Edible offal (mammalian)	0.0151	*	0.05	0.000000755
ML 0812 Milk	8.9933	*	0.01	0.000089933
SO 0495 Rape seed (canola seed)	0.0001	*	0.02	0.000000002
Total				0.000367406

^{*} At or about the limit of determination

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

ADI - Acceptable Daily Intake

MRL - Maximum Residue Limit

Consumption figures are from the 1995 National Nutrition Survey of Australia (via ANZFA).

^{**} Equivalent to 1.22 % of the ADI

Calculation of NEDI for FLUQUINCONAZOLE~17/05/2000

Calculation of NEDI (ADI for fluquinconazole = 0.005 mg/kg of body weight)

Commodity	Food Consumption g/kg bw/day		NEDI g mg/kg bw/day	% of ADI	
MO 0105 Edible offal					
(mammalian)	0.0151	0.2	0.00000302	0%	
PE 0112 Eggs	0.2228	* 0.02	0.000004456	0%	
MM 0095 Meat (mammalian) [in					
the fat]	0.17276	0.5	0.00008638	8%	10% fat
ML 0106 Milks	8.9933	0.1	0.00089933	84%	
FP Pome Fruits	1.1687	* 0.05	0.000058435	5%	
PO 0111 Poultry, Edible offal of	0.0024	* 0.02	0.000000048	0%	
PM 0110 Poultry meat[in the fat]	0.05596	* 0.02	1.1192E-06		10% fat
SO 495 Rape seed	0.0001	T*0.01	0.000000001	0%	
Wheat	1.771	*0.02	0.00003542	3%	CF0654+CF1210+CF12 11+CF1212+CM0654
Total			0.001080733	mg/kg	bw/day**

^{*} At or about the limit of determination

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimated Daily Intake

ADI - Acceptable Daily Intake (Chemicals and Non-Prescription Drugs Branch, Therapeutic Goods Administration)

^{**} Equivalent to 21.6% of the ADI

Calculation of NEDI for FLUTOLANIL

(ADI for flutolanil = 0.02 mg/kg of body weight)

Dietary intakes taken from ANZFA figures, all respondents 2 years and above

Commodity	Food Consumption g/kg BW/day	MRL mg/kg	NEDI mg/kg BW/day
MO 0812 Edible offal, mammalian	0.0151	* 0.05	0.000000755
PE 0112 Eggs	0.2228	* 0.05	0.00001114
MM 0812 Meat, mammalian (in the fat)	0.1756	* 0.05	0.00000878 10% of MM +MF
ML 0106 Milks	8.9933	* 0.05	0.000449665
VR 0589 Potato	0.9821	0.05	0.000049105
PO 0111 Poultry, edible offal of	0.0024	* 0.05	0.00000012
PM 0110 Poultry meat (in the fat)	0.05596	* 0.05	0.000002798 10% of PM (poultry fat NC)
Total			0.000522363 mg/kg BW/day

^{*} At or about the limit of determination

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimated Daily Intake

ADI - Acceptable Daily Intake

^{**} Equivalent to 2.61 % of the ADI

NEDI for imazapic

Consumption data from 1995 NNS, all respondents 2 years and above.

ADI of imazapic = 0.3 mg/kg of body weight

Commodity	Food Consumption g/kg bw/day		MRL mg/kg	NEDI mg/kg bw/day	
Edible offal (mammalian)	0.0151	*	0.05	0.000000755	
Eggs	0.2228	*T	0.01	0.000002228	
Meat (mammalian)[in the fat]	0.1756	*	0.05	0.00000878	10% fat + fat,mammalian
Milks	8.9933	*	0.01	0.000089933	
Peanuts	0.0434	*	0.1	0.00000434	
Poultry, edible offal	0.0024	T*	0.01	0.000000024	
Poultry meat	0.5596	T*	0.01	0.000005596	
Rape seed	0.0001	*	0.05	0.000000005	
Sugar cane	0.7328	*	0.05	0.00003664	
Wheat	1.771	*	0.05	0.00008855	
Total				0.000236851	mg/kg bw/day

Equivalent to 0.079 % of the ADI

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimated Daily Intake

ADI - Acceptable Daily Intake

(Chemicals Safety Unit, Commonwealth Department of Human Services and Health)

MRL - Maximum Residue Limit

Intake for wheat is CF0654+CF1211+CF1210+CF1212+CM0654 Meat [in fat] = 10% of MM + MF

^{*} At or about the limit of determination

National Estimated Daily Intake for pirimiphos-methyl

Food consumption data from 1995 National Nutrition Survey of Australia (all respondents, 2 years and above)

ADI for pirimiphos-methyl

= 0.02

Commodity	Food Consumption g/kg bw/day	Proc. Factor		MRL or STMR mg/kg	NEDI mg/kg bw/day	
Barley	0.2804			7	0.0019628	
Bran, unprocessed of cereal grain	0.0175			20	0.00035	CM0081
Edible offal (mammalian)	0.0151		*	0.05	0.000000755	
Eggs	0.2228		*	0.05	0.00001114	
Kiwifruit	0.0025			2	0.000005	
Maize	0.0522			7	0.0003654	maize flour
Meat [mammalian]	1.7276		*	0.05	0.00008638	
Milks	8.9933		*	0.05	0.000449665	
Millet	0.0001			10	0.000001	
Oats	0.1064			7	0.0007448	
Peanut	0.0434			5	0.000217	
Peanut oil, edible	0.0001			15	0.0000015	
Poultry, Edible offal of	0.0024		*	0.05	0.00000012	
Poultry meat	0.5596		*	0.05	0.00002798	
Rice	0.0145			10	0.000145	
Rice, husked	0.0001			2	0.0000002	Note 1
Rice, polished	0.2333			1	0.0002333	
Rye	0.0001			10	0.000001	default consumption
Sorghum	0.0001			10	0.000001	default consumption
Wheat				10		Note 2
Wheat bran	0.0393			20	0.000786	
White flour	1.5482	0.17		10	0.00263194	CF1211
Wholemeal flour	0.1721	0.59		10	0.00101539	CF1212
Wheat germ	0.0039			30	0.000117	
Total					0.00915437	mg/kg bw/day

0.00915437 mg/kg bw/day

46

% of the ADI

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues (revised 1997, WHO)

Note 1- Default consumption figure for rice husked. All rice consumption included in rice, polished

Note 2- MRL of 10 mg/kg is for wheat grain. Consumption figures have been split into white flour, wholemeal flour and wheat bran processed Consumption of processed wheat bran is not otherwise captured in calculation

Processing factors for flours from JMPR 1974 (mean of several trials), residue in wheat bran processed assumed to be present at MRL for unprocessed cereal brans

^{*-} denotes residue level "at or about the limit of analytical determination"

ADI - Acceptable Daily Intake

MRL - Maximum Residue Limit

T- denotes temporary MRL

NEDI for procymidone

TVEDT for procyminating	ADI for procyr		=		mg/kg of body weigh	
Commodity		g/kg		MRL	NEDI	Notes
		bw/day		mg/kg		
Beans, except Broad beans and Soya	beans	0.1133		10	0.001133	
Broad bean (green pods and immatur		0.0001		10	0.000001	
Broccoli	,	0.1221	T	5	0.0006105	
Snowpea pod, raw		0.001		5	0.000005	
Eggs		0.2228	*	0.01	0.000002228	
Edible offal (Mammalian)		0.0157	*	0.01	0.000000157	
Galangal		0.0001	T	0.5	0.00000005	2
Grapes		0.7939		2	0.0015878	
Herbs		0.0067	T	3	0.0000201	
Coriander (leaves, stems and roots)		0.0001	T	3	0.0000003	2
Lemon grass		0.0001	T	3	0.0000003	2
Kaffir lime leaves		0.0001	T	3	0.0000003	2
Salad burnet		0.0001	T	3	0.0000003	2
Bergamot		0.0001	T	3	0.0000003	2
Rose and dianthus (edible flowers)		0.0001	T	3	0.0000003	2
Coriander seed		0.0009	T	3	0.0000027	all spices
Dill seed			T	3	0	see above
Fennel seed			T	3	0	see above
Furmeric, root (fresh)		0.0001	T	0.5	0.00000005	2
Rucola (rocket), chervil, mizuna		0.0001	T	2	0.0000002	2
Lemon verbena (fresh leaves)		0.0024	T	3	0.0000072	
Lettuce, Head		0.1273		2	0.0002546	
Lettuce, leaf		0		2	0	1
Lupin (dry)		0.0001	*	0.01	0.000000001	2
Meat of cattle, pigs and sheep (in the	fat)	0.17496	*	0.01	1.7496E-06	3
Milks	,	8.9933	*	0.01	0.000089933	
Fennel, bulb		0.0003	T	1	0.0000003	
Onion, bulb		0.2767		0.2	0.00005534	
Garlic		0.0019		5	0.0000095	
Pome fruits		1.1687		1	0.0011687	
Potato		0.9821		0.1	0.00009821	
Poultry meat (in the fat)		0.05596	*	0.01	5.596E-07	4
Poultry, Edible offal of		0.0024	*	0.01	0.000000024	
Rape seed		0.0001	Τ	1	0.0000001	2
Rape seed oil, crude		0.0001	T	3	0.0000003	5
Spinach		0.0148	T	2	0.0000296	-
Stone fruits		0.2788		10	0.002788	
Strawberries		0.0299		5	0.0001495	
Tomato		0.8185		2	0.001637	
Carrot		0.2707	T	2.00	0.0005414	
ΓΟΤΑL mg/kg bodyweight					0.010196596	

The NEDI is equivalent to

20.39 % of the ADI

Notes

- 1. All lettuce considered under lettuce, head
- 2. Not consumed in 1995 NNS, default intake used (0.0001)
- 3. Sum of 10% MM0097 + MF0812 + MF0818 (sheep fat not consumed)
- 4. 10% of poultry meat (poultry fat NC)
- 5. Figure for rape seed oil, edible used.
- 6. Not reported by 1995 NNS, default intake used (0.0001)

NEDI calculations for PROFENOFOS

	#ADI (mg/kg	g)	0.0001		
Commodity	Food consum	p1 MRL	MRL or	NEDI	%ADI
	g/kg bw/day	mg/kg	pected resid	d mg/kg bw/day	
	total populati	on	mg/kg		
SO 0691 Cotton seed	0.0001	1	1	0.00000010	0.10% Not consumed in 1995 NNS
OR 0691 Cotton seed oil, edible	0.0001	0.3	0.3	0.00000003	0.03% Not consumed in 1995 NNS
ML 0812 Cattle milk	8.9933 *	0.01	0.001	0.00000899	8.99% NOTE 1
Meat [mammalian]	1.7276 *	0.05	0.005	0.00000864	8.64% NOTE 1
MO 0105 Edible offal (mammalian)	0.0151 *	0.05	0.025	0.00000038	0.38% NOTE 2
PM 0110 Poultry meat	0.5596 *	0.05	0.025	0.00001399	13.99% NOTE 2
PO 0111 Poultry, Edible offal of	0.0024 *	0.05	0.025	0.00000006	0.06% NOTE 2
PE 0112 Eggs	0.2228 *	0.02	0.01	0.00000223	2.23% NOTE 2
TOTAL mg/kg bw/day				0.00003442	34.42%
	% ADI			34%	

These calculations have been made in accordance with 'Food consumption and exposure assessment of chemicals. Report of a FAO/WHO Consultation, Geneva, Switzerland 10 - 14 February 1997'

NEDI - National Estimated Daily Intake

Acceptable Daily Intake (Chemicals & Non-Prescription Drug Branch, Therapeutic Goods Administration, Commonwealth Department of Health and Aged Care)

MRL - Maximum Residue Limit

¥mean Australian consumption 2 years and over, 1995 National Nutrition Survey

NOTE 1 The anticipated dietary exposure for mammals is 0.3 ppm. Cattle data indicate no residues in milk or meat at a feeding level of 25 ppm (LOQ 0.05 mg/kg) and sheep data indicate no residue in meat at a feeding level of 25 ppm (LOQ 0.01). The NEDI is based on residues occuring at 10% of the MRL.

NOTE 2 Feeding data at levels higher than expected in mammals and poultry indicate that residues in mammalian offal, poultry meat and offal, and eggs are not expected. The NEDI is based on residues occuring at half MRL.

Calculation of NEDI for propiconazole

(ADI for pesticide Propiconazole) = 0.04 mg/kg of body weight)

Intakes from ANZFA figures, all respondents 2 years and above, mean food consumption.

Commodity	Food Consumption g/kg BW/day	MRL mg/kg	TMDI mg/kg BW/day	
Avocado	0.0306	* 0.02	0.000000612	
Banana	0.3515	0.2	0.0000703	
Blueberries	0.0013	T 2	0.0000026	
Cereal grains	2.5632	* 0.05	0.00012816	
Grapes	0	1	0	no current registration or permit
Edible offal (mammalian)	0.7939	1	0.0007939	
Meat (mammalian)	1.7276	0.1	0.00017276	
Milks	8.9933	* 0.01	0.000089933	
Mint oil	0.0001	* 0.02	0.000000002	
Mushrooms	0.049	* 0.05	0.00000245	
Peanut	0.0434	* 0.05	0.00000217	
Persimmons (Inedible peel)	0.0001	T 0.2	0.00000002	
Pineapple	0.1176	0.05	0.00000588	
Poppy seed	0.0001	* 0.01	0.000000001	
	0	0	0	
Poultry, edible offal of	0.0024	0.1	0.00000024	
Poultry, meat	0.5596	0.1	0.00005596	
Stone fruits	0.2704	2	0.0005408	
	0.0001	* 0.02	0.000000002	

^{*} At or about the limit of determination

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

TMDI - Theoretical Maximum Daily Intake

ADI - Acceptable Daily Intake

(Chemicals Safety Unit, Commonwealth Department of Human Services and Health)

^{**} Equivalent to 4.7 % of the ADI

NEDI Calculation for Pymetrozine

08/Oct/2001

(ADI for Pymetrozine = 0.006 mg/kg of body weight)

Dietary consumption figures from 1995 National Nutrition Survey of Australia, mean intakes, all respondents 2 years and above.

		Commodity	Food Consumption g/kg bw/day		MRL (or STMR) mg/kg	Dietary intake mg/kg bw/day	% ADI	Notes
FS	0012	Stone fruit	0.2788	*	0.05	0.00001394	0.23%	1
ML	0106	Milks	8.9933	T*	0.01	0.00008993	1.50%	
MM	0095	Meat (mammalian)	1.7276	T*	0.01	0.00001728	0.29%	
MO	0105	Edible offal (mammalian)	0.0151	T*	0.01	0.00000015	0.00%	
SO	0691	Cottonseed	0.0001	T	0.1	0.00000001	0.00%	2
SO	0691	Cottonseed oil, edible	0.0001	T*	0.02	0.00000000	0.00%	2
VB	0040	Brassicas (cole or cabbage) vegetables,	0.3249	*	0.02	0.00000650	0.11%	
		Head cabbages, Flowerhead brassicas						
VC	0045	Cucurbits	0.4375	T	0.1	0.00004375	0.73%	
VL	0053	Leafy vegetables	0.1716	T	0.5	0.00008580	1.43%	
VO	0445	Peppers, sweet	0.06	T*	0.02	0.00000120	0.02%	
VR	0589	Potato	0.9821	*	0.02	0.00001964	0.33%	
		Total				0.00027820	4.64%	

National estimated daily intake is equivalent to 4.64 % of the ADI

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimated Daily Intake

* At or about the limit of determination

ADI - Acceptable Daily Intake

MRL - Maximum Residue Limit

T - temporary

Notes

- 1. STMR used in calculation
- 2. default intake, not consumed in 1995 National Nutrition Survey of Australia

NEDI Calculation for Pyriproxyfen

Date

09-01-2002

ADI for Pyriproxyfen = 0.07 mg/kg of body weight

		Commodity	g/ kg bw/day			MRL mg/kg	NEDI	% of ADI	Comment
							mg/kg bw/day		
SO	0691	Cotton seed	0.0001	T		0.1	0.00000001	0.00%	NC
OC	0691	Cotton seed oil, crude		T	*	0.02	0.00000000	0.00%	included in edible fraction
OR	0691	Cotton seed oil, edible	0.0001	T	*	0.02	0.00000000	0.00%	NC
MO	0105	Edible offal (mammalian)	0.0151	T	*	0.02	0.00000030	0.00%	
MM	0095	Meat [mammalian][in the fat]	0.17276	T	*	0.02	0.00000346	0.00%	
ML	0106	Milks	8.9933	T	*	0.02	0.00017987	0.26%	
		Total		·			0.000183623	0.26%	

^{*} At or about the limit of determination

NC - not consumed

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI = National Estimated Daily Intake

ADI - Acceptable Daily Intake

T = MRL for a temporary use-patten.

NEDI calculations for spinosad

Dietary intakes from 1995 National Nutrition Survey of Australia, all respondents 2 years and above $ADI = 0.02 \, mg/kg \, bw/day$

	ADI-		0.02	mg/kg bw/day
Commodity	Food consumption g/kg bw/day total population		MRL mg/kg	NEDI mg/kg bw/day
FI 0030 Assorted tropical and sub-	TO THE POPULATION			
tropical fruits-inedible peel	0.7442	T	0.5	0.00037210
VB 0040 Brassica vegetables	0.3249		0.5	0.00016245
VP 0061 Beans, except broad bean and	0.1133	T	0.2	0.00002266
soya bean FB 0018 Berries and other small fruit	0.1133	T	0.2	0.00002288
[excluding grapes]	0.0788	1	0.3	all berries minus grape (0.8727-0.7939)
VS 0624 Celery	0.0578	*	0.25	0.00001445
FC 0001 Citrus fruits	2.1336	T	0.1	0.00021336
SO 0691 Cotton seed	0.0001	*	0.01	0.00000000 default intake used
MO 0105 Edible offal [mammalian]	0.0151		0.05	0.0000076
PE 0012 Eggs	0.2228	T	0.05	0.00001114
VO 0440 Eggplant	0.0075	T	0.1	0.00000075
FB 0629 Grapes (including wine)	0.7939		0.04	0.00003176 STMR
HH 0092 Herbs	0.0067	T	5	0.00003350
Coriander (leaves, stems, roots)	0.0001	T	5	0.00000050 default intake used
Lemon grass	0.0001	T	5	0.00000050 default intake used
Kaffir lime leaves	0.0001	T	5	0.00000050 default intake used
Salad Burnett	0.0001	T	5	0.00000050 default intake used
Bergamot	0.0001	T	5	0.00000050 default intake used
HS 0779 Coriander seed	0.0001	T	5	0.00000050 default intake used
HS 0730 Dill seed	0.0001	T	5	0.00000050 default intake used
HS 0731 Fennel seed	0.0001	T	5	0.00000050 default intake used
HS 0794 Turmeric, root	0.0001	T*	0.01	0.00000000 default intake used
DT 1111 Lemon verbena	0.0001	T	5	0.00000050 default intake used
Edible flowers (rose and dianthus)	0.0001	T	5	0.00000050 default intake used
VL 0053 Leafy vegetables			5	
Chinese cabbage§	0.0074		5	0.00003700
				sum of pak-choi, pak- choi, pe-tsai and Chinese cabbage
Lettuce§	0.1273		5	0.00063650
Spinach§	0.0148		5	0.00007400
VL 0465 Chervil	0.0001	T	5	0.00000050 default intake used
VL 0496 Rucola (rocket)	0.0001	T	5	0.00000050 default intake used
Mizuna	0.0001	T	5	0.00000050 default intake used
VR 0581 Galangal, greater	0.0001	T*	0.01	0.00000000 default intake used
MM 0095 Meat (mammalian)[in the fat]	0.1756		0.2	0.00003512
VC 0046 Melons, except watermelon	0.0678	T	0.2	0.00001356
ML 0106 Milks	8.9933		0.02	0.00017987

VP 0063 Peas	0.161	T	0.2	0.00003220
				intake for garden pea shelled used. Includes green and snow peas.
VO 0051 Peppers	0.0621		0.2	0.00001242 sum of sweet capsicums + chilli
FP 0009 Pome fruits	1.1687		0.05	0.00005844 STMR
VR 0589 Potato	0.9821	T*	0.01	0.00000982
PO 0111 Poultry, edible offal	0.0024		0.05	0.00000012
Poultry fat/skin	0.0001	T	0.2	0.00000002
PM 0110 Poultry meat	0.5596	*	0.01	0.00000560
VD 0070 Pulses	0.0863	T*	0.01	0.00000086
GC 0651 Sorghum	0.0001	T*	0.01	0.00000000
FS 0012 Stone fruit	0.2788	T	0.2	0.00005576
VO1275 Sweetcorn	0.0881		0.02	0.00000176
VO 0448 Tomatoes	0.8185		0.2	0.00016370
TN 0085 Tree nuts	0.0772	T*	0.01	0.00000077
TOTAL mg/kg bw/day		·		0.00222634

Equivalent to 11.13% of the ADI

These calculations have been made in accordance with Guidelines for Predicting Dietary Intake of Pesticide Residues (World Health Organisation)

NEDI = National Estimated Daily Intake

ADI = Acceptable Daily Intake (Chemicals Safety Unit, Commonwealth

Department of Human Services

and Health)

MRL = Maximum Residue Limit

\$leafy vegetable MRL has been separated into the registered crops, i.e. only lettuce, spinach and Chinese cabbage

^{*} at or about the limit of determination

NEDI for spiroxamine

Commodity

Dietary consumption figures from 1995 National Nutrition Survey of Australia, mean intakes, all respondents, 2 years and above

Food Consumption

ADI for spiroxamine = 0.02 mg/kg of body weight

MRL STMR

NEDI

	g/kg bw/day	mg/kg	mg/kg	mg/kg bw/day	
grapes (incl. wine)	0.7939	2	0.5	0.00039695	<u> </u>
dried grapes	0.0597	3	2	0.0001194	
edible offal (mammalian)	0.015	0.5	0.2	0.000003	
meat (mammalian)	1.7276	0.05	0.02	0.000034552	
fat (mammalian)	0.0028	0.05	0.02	0.000000056	
milks	8.9933	0.05	0.02	0.000179866	
Total				0.000733824	mg/kg bw/day
			Equivalent to	3.7	% of the ADI

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimated Daily Intake, assumes residues present at STMR where available

ADI - Acceptable Daily Intake

MRL - Maximum Residue Limit

T - temporary

* - at or about limit of analytical quantitation

- The figure for dried grapes represents the highest residue observed in three trials

NESTI	FOR		XAMINE												
Name A	Acute RfD	MRL	mg/kg bw STMR or STMR-P, mg/kg		,	Large portion, g/kg bw	Body weight, kg	Large portion, g	Unit weight g	% edible portion	Unit weight, edible portion	Variability	Case	NESTI, mg/kg bw/day	% acute RfD
grape		2	0.5	1	1	33.01	19	627			0		Case 1	0.03301	17
dried grapes		3	2	1	2	2.418	19	46			0		Case 1	0.00484	2
edible offal		0.5	0.2	1	0.2	0.884	19	17			0		Case 1	0.00018	0
(mammalian)															
meat (mammal	ian)	0.05	0.02	1	0.02	13.72	19	261			0		Case 1	0.00027	0
milks		0.05	0.02	1	0.02	76.33	19	1450			0		Case 1	0.00153	1
Fat (mammalia	ın)	0.05	0.02	1	0.02	0.252	19	5			0		Case 1	0.00001	0
grape		2	0.5	1	1	14.43	70	1010			0		Case 1	0.01443	7
dried grapes		3	2	1	2	0.646		45			0		Case 1	0.00129	1
edible offal		0.5	0.2	1	0.2	3.054		214			0		Case 1	0.00061	0
(mammalian)		0.5	0.2	1	0.2	5.054	70	217			0		Cusc 1	0.00001	U
meat (mammal	ian)	0.05	0.02	1	0.02	7.521	70	526			0		Case 1	0.00015	0
milks		0.05	0.02	1	0.02	28.78	70	2014			0		Case 1	0.00058	0
Fat (mammalia	n)	0.05	0.02	1	0.02	0.286	70	20			0		Case 1	0.00001	0

Case 1. Composite sampling data reflect the residue level in the food.

Case 2. Composite residue data do not reflect the residue level in individual food commodity units.

Case 2a. Unit weight edible portion is less than large portion weight.

Case 2b. Unit weight edible portion exceeds large portion weight.

Case 3. Processed commodity, where bulking or blending means that the STMR-P represents the likely highest residue

Tebufenozide

Calculation of NEDI

(ADI for tebufenozide = 0.02 mg/kg of body weight)

Commodity	Food Consumption g/kg bw/day Total population		MRL mg/kg	NEDI mg/kg bw/day Total population	
FI 0326 Avocado	0.0306	T	0.5	0.00001530	
SB 0716 Coffee beans	0.0506	T	0.05	0.00000253	
FI 0332 Custard apple	0.0030	T	0.3	0.00000090	
DF 0269 Dried Grapes	0.0597		4	0.00023880	
FB 0269 Grapes	0.7939		2	0.00158780	
FI 0341 Kiwifruit	0.0225	T	1	0.00002250	
FI 0342 Longan	0.0001	T	2	0.00000020	default intake
FI 0343 Litchi	0.0001	T	2	0.00000020	default intake
TN 0669 Macadamia nuts	0.0007	T	0.05	0.00000004	
FS 0247 Peaches	0.1266	T	1	0.00012660	
FS 0245 Nectarines	0.0639	T	1	0.00006390	
FT 0307 Persimmon, Japanese	0.0018	T	1	0.00000180	consumption f
FP 0009 Pome fruits	1.1687		0.24	0.00028049	STMR
Total				0.00205877	_

* At or about the limit of determination

** Equivalent to 10.3 % of the ADI

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

NEDI - National Estimate of Daily Intake using ANZFA mean intake figures for all respondents 2 years and above

ADI - Acceptable Daily Intake

MRL - Maximum Residue Limit

T - Temporary MRL

STMR - Supervised Trial Median Residue

NEDI calculatic Thiacloprid 02-Oct-2001 #ADI (mg/kg) Commodity Food consumptic MRL NEDI %ADI g/kg bw/day mg/kg mg/kg bw/day total population FP Pome fruit 0.00117600 11.76% includes dried apple and dried pear 1.176 1 FS Stone fruit 0.30661 T 2 0.000613226.13% includes dried stone fruit 0.00000000 0.00% 0.00000000 0.00% TOTAL mg/kg bw/day 0.00178922 17.89% 18% % ADI

These calculations have been made in accordance with 'Food consumption and exposure assessment of chemicals. Report of a FAO/WHO Consultation, Geneva, Switzerland 10 - 14 February 1997'

NEDI - National Estimated Daily Intake

Acceptable Daily Intake (Chemicals & Non-Prescription Drug Branch, Therapeutic Goods Administration, Commonwealth Department of Health and Aged Care)

MRL - Maximum Residue Limit

¥mean Australian consumption 2 years and over, 1995 National Nutrition Survey

calculated cells		Case	2a	Case 1	Cas	e 2a	
	2 yrs +; Raw Stone Fruit					2 yrs +; R	aw pome fru
	Peach	Apricot	Plum	Nectarine	Cherry	Apples	Pears
See Note:							
ARfD	0.03	0.03	0.03	0.03	0.03	0.03	0.03
HR (uncorr)	0.5	0.5	0.5	0.5	0.5	0.4	0.4
% edible	96%	94%	96%	96%	85%	92%	89%
HR-P	0.365	0.372	0.365	0.365	0.412	0.320	0.320
LP (g/kg bw/day)	8.029	8.442	7.029	9.015	7.172	6.328	6.149
kg bw	67	67	67	67	67	67	67
LP (kg)	0.538	0.566	0.471	0.604	0.481	0.424	0.412
U (uncorr, g)	153	56	88	126	6	166	180
U (corr, kg)	0.147	0.053	0.084	0.121	0.005	0.153	0.160
· · · · · · · · · · · · · · · · · · ·							
•	7	7	7	7		7	7
NESTI	0.00772	0.00490	0.00532	0.00724	0.00295	0.00640	0.00656
% ARfD	26%	16%	18%	24%	10%	21%	22%
		o				Pome Frui	
	2 - 6 yrs; R			N4 - nin -	Ob	2 - 6 yrs;	
\ DfD		Apricot	Plum	Nectarine	•	Apples	Pears
ARfD	0.03	0.03	0.03	0.03	0.03	0.03	0.03
HR (uncorr)	0.5	0.5	0.5	0.5	0.5	0.4	0.4
% edible	96%	94%	96%	96%	85%	92%	89%
IR-P	0.365	0.372	0.365	0.365	0.412	0.320	0.320
₋P (g/kg bw/day)	16.605	21.811	17.095	16.605	17.095	17.474	24.468
g bw	19	19	19	19	19	19	19
_P (kg)	0.315	0.414	0.325	0.315	0.325	0.332	0.465
(9)							
J (uncorr, g)	153	56	88	126	6	166	180

NOTES

NESTI

% ARfD

7

0.02296

77%

7

0.01431

48%

7

0.01596

53%

7

0.01998

67%

HR - P (corrected) for stone fruit: Residues in stone fruit are determined after the removal of the stone, but are expressed on a whole fruit basis, including the stone. Hence the residue concentration in the edible portion is higher than that reported in the residue studies. The highest residue in stone fruit observed in the residue trials was 0.5 mg/kg. The 0.5 mg/kg was adjusted for the reduction in residues expected from

0.02102

70%

0.00704

23%

7

0.02402

80%

NEDI Calculation for Triadimenol

Calculation of dietary intake (ADI for triadimenol = 0.06 mg/kg of body weight)

Commodity	Food Consumption ##		MRL	NEDI	% ADI
	g/kg BW/day		mg/kg	mg/kg bw/day	
Broccoli	0.1221		0.2	0.00002442	0.04
Cabbages, head	0.0648		0.50	0.0000324	0.05
Berries (excluding grapes)	0.0788	T	0.50	0.0000394	0.07
Cauliflower	0.0775		0.20	0.0000155	0.03
Cereal grains	2.5686	*	0.01	0.000025686	0.04
Cottonseed	0.0001	T	0.01	0.000000001	0.00
Cottonseed oil	0.0001	T	0.05	0.000000005	0.00
Edible offal (mammalian)	0.0151	*	0.01	0.000000151	0.00
Eggs	0.2228	*	0.01	0.000002228	0.00
Fruiting Vegetables, Cucurbits	0.4375		0.5	0.00021875	0.36
Grapes	0.7939		0.5	0.00039695	0.66
Meat (Mammalian)	1.7276	*	0.01	0.000017276	0.03
Milks	8.9933	*	0.01	0.000089933	0.15
Papaya [pawpaw]	0.0001		0.2	0.00000002	0.00
Peppers [all]	0.0469	T	0.5	0.00002345	0.04
Poultry meat	0.5596	*	0.01	0.000005596	0.01
Poultry, Edible offal of	0.0024	*	0.01	0.000000024	0.00
Sugar cane	0.7328	*	0.01	0.000007328	0.01
Tomato	0.8185		0.2	0.0001637	0.27

Total 0.001062818 mg/kg bw**

** Equivalent to 1.77 % of the ADI

These calculations have been made in accordance with 'Guidelines for Predicting Dietary Intake of Pesticide Residues' (World Health Organization)

T temporary MRLs

ADI - Acceptable Daily Intake

MRL - Maximum Residue Limit

Food consumption data taken from the 1995 National Nutrition Survey of Australia

^{*} At or about the limit of determination

ATTACHMENT 4

SUMMARY OF PUBLIC SUBMISSIONS

Submitter	Comments raised
Australian Food and	The AFGC supports the approval of this application.
Grocery Council	
Western Australian Food	Supports the application.
Advisory Committee	
Food Technology	The Technical Sub-committee of the Association accepts the
Association of Victoria	recommendation to progress this Application.
Queensland Health	Supports the application with the exception of the proposed
	temporary increase of the MRLs for bifenthrin.
Western Australia Food	The Committee supports the recommendation to progress this
Advisory Committee	Application.

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ATTACHMENT 5

GLOSSARY OF ACRONYMS

ADI Acceptable Daily Intake

ANZFA Australia New Zealand Food Authority

AQIS Australian Quarantine and Inspection Service

ARfD Acute Reference Dose

CAC Codex Alimentarius Commission

CCPR Codex Committee on Pesticide Residues

CCRVDF Codex Committee on Residues of Veterinary Drugs in Food

DHA Health and Ageing, Department of

FSANZ Food Standards Australia New Zealand

FSC Food Standards Code

JECFA Joint FAO/WHO Expert Committee on Food Additives

JMPR Joint FAO/WHO Meeting on Pesticide Residues

LOQ Limit of Quantification

MRL Maximum Residue Limit

NEDI National Estimated Dietary Intake

NESTI National Estimated Short Term Intake

NNS National Nutrition Survey

NRA National Registration Authority for Veterinary and Agricultural

Chemicals

RIS Regulation Impact Statement
SPS Sanitary and Phytosanitary
TBT Technical Barriers to Trade

TGA Therapeutic Goods Administration

TTMRA Trans-Tasman Mutual Recognition Arrangement

WHO World Health Organization
WTO World Trade Organization