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FINAL ASSESSMENT REPORT

APPLICATION A559

MAXIMUM RESIDUE LIMITS (APRIL, MAY, JUNE 2005)

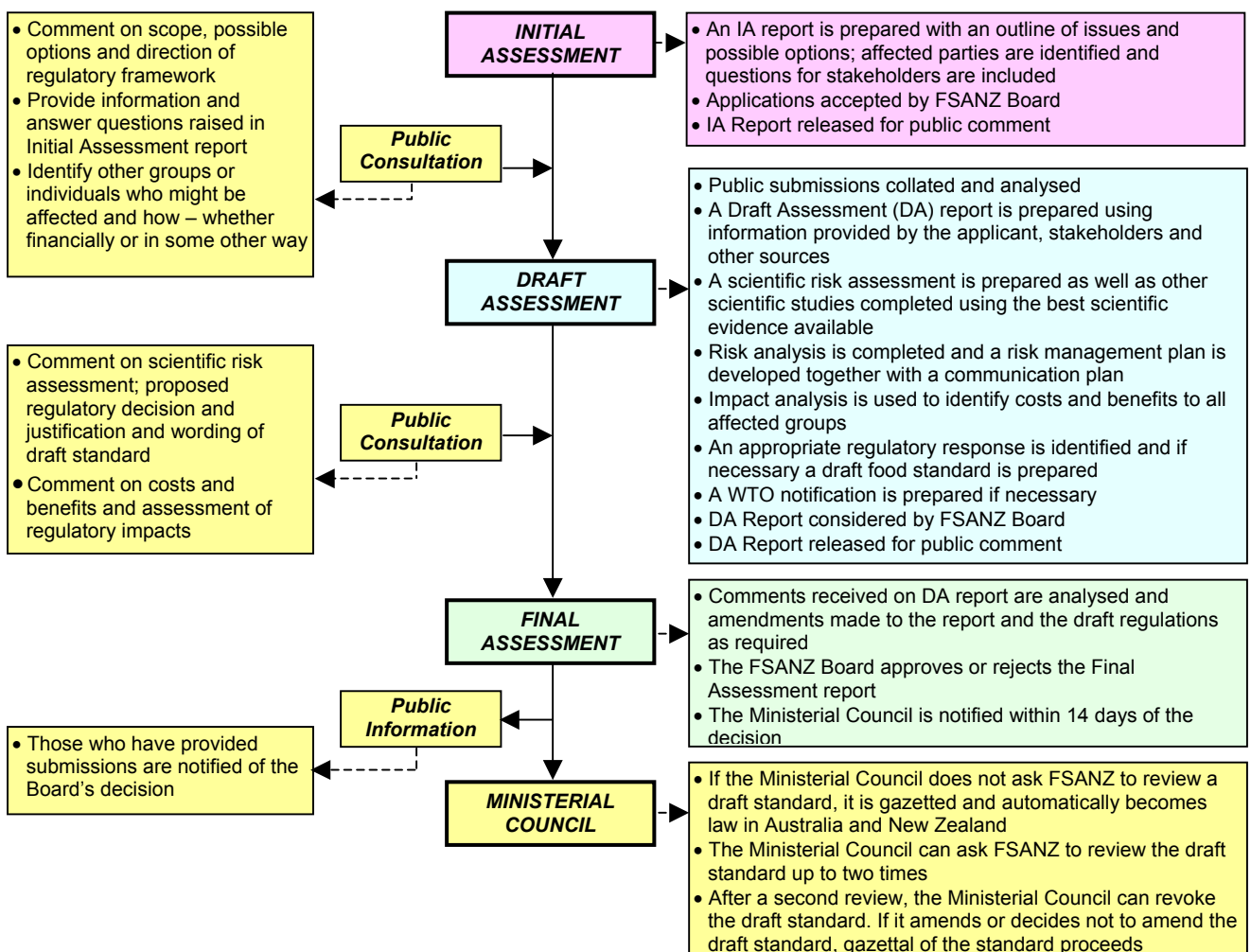
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Final Assessment Stage (s.36)

FSANZ has now completed the assessment of Application A559 and held a single round of public consultation under section 36 of the FSANZ Act. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

Further Information

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

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Executive Summary

This Application (A559) seeks to amend Maximum Residue Limits (MRLs) for agricultural and veterinary chemicals in Standard 1.4.2 – Maximum Residue Limits of the Code. It is a routine application from Australian Pesticide and Veterinary Medicines Authority (APVMA), to update the *Australia New Zealand Food Standards Code* (the Code) in order to reflect the current registration status of agricultural and veterinary chemicals in use in Australia.

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

The dietary exposure assessments indicate that setting the residues as proposed does not represent any public health and safety concerns.

There are no MRLs for antibiotic residues in this Application.

FSANZ made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO). No submissions were received from WTO Members.

FSANZ Decision

FSANZ has undertaken an assessment and recommends approving the draft variations to Standard 1.4.2 – Maximum Residue Limits.

Statement of Reasons

FSANZ recommends approving the draft variations to Standard 1.4.2 Maximum Residue Limits for the following reasons:

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- The dietary exposure assessments indicate that setting the residues as proposed does not present any public health and safety concerns.
- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.
- APVMA has assessed appropriate 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.

- Office of Chemical Safety (OCS) has undertaken an appropriate toxicological assessment of the chemicals and has established relevant acceptable daily intakes (ADI) and where applicable, an acute reference dose (ARfD).
- FSANZ has undertaken a regulation impact assessment and concluded that the draft variations to Standard 1.4.2 Maximum Residue Limits are necessary, cost-effective and will benefit producers and consumers.
- The proposed draft variations would remove any discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.
- None of FSANZ's section 10 objectives are compromised by the proposed changes.

1. Introduction

Applications were received from Australian Pesticides and Veterinary Medicines Authority (APVMA) on 7 April, 12 May and 16 June 2005 seeking variations to Standard 1.4.2 of the Code. The proposed variations to the Standard would align MRLs in the Code for non antibiotic agricultural and veterinary chemicals with the MRLs in the APVMA MRL Standard.

1.1 Summary of proposed MRLs

The MRL amendments under consideration in this Application are:

- changing the residue definition for tylosin from tylosin to tylosin A
- adding MRLs for new chemicals clothianidin, flumiclorac pentyl and forchlorfenuron
- deleting all entries for the chemicals alloxydim, alloxydim sodium, diclobutrazol, diofenolan, diphenamid, methazole and promecarb
- deleting MRLs for certain foods for benfluralin, cyproconazole, difenoconazole, dimethomorph, ethoprophos, fenoxycarb, metalaxyl, procymidone and propachlor
- adding MRLs for certain foods for meloxicam, propachlor and sethoxydim
- changing MRLs for certain foods for azoxystrobin, cypermethrin, dithiocarbamates, dodine, fludioxonil, fluvalinate, halosulfuron-methyl, imazapic, procymidone, trichlorfon, trifloxystrobin
- adding temporary MRLs for certain foods for azoxystrobin, boscalid, bupirimate, cyhalothrin, cypermethrin, dimethomorph, ethephon, iprodione, phenmedipham, procymidone and tolylfluanid.

In considering the issues associated with MRLs it should be noted that MRLs and amendments to MRLs in the Code do not permit or prohibit the use of agricultural and veterinary chemicals. Other Australian Government, State and Territory legislation regulates use and control of agricultural and veterinary chemicals.

1.2 APVMA review of procymidone

APVMA announced the commencement of the review of procymidone in December 2004. An assessment of the chemical identified public health and safety concerns associated with its use, in relation to persons working with this chemical; specifically (for women of child bearing age) following acute occupational exposure to procymidone (e.g. during spraying, dipping, packing).

On the basis of an assessment of available residue data, APVMA considered that the acute reference dose (ARfD)¹ could be exceeded for some commodities. The registrations and label approvals for all procymidone products were suspended and new instructions for use issued.

¹ Confirmed by FSANZ

It was determined that the use of procymidone was inappropriate for the following commodities:

- beans: all uses i.e. uses for control of Sclerotinia rot and Sclerotinia post-harvest rot;
- grapes: to control for grey mould for table grapes and grapes to be used for dried fruit production;
- lettuce: all uses;
- stone fruit: to control brown rot and post-harvest use for control of brown rot and transit rot;
- strawberry: all uses; and
- tomato: all uses.

In addition, a 9-day re-entry interval was established by OCS to ensure protection of workers. For a number of previous uses, the label withholding periods (WHP) were shorter than 9 days i.e. nil for fava beans and navy beans, 5 days for grapes, 7 days for potatoes. Withholding periods currently shorter than 9 days were amended to 9 days to coincide with the 9 day re-entry interval.

Therefore, the use on green beans, at a late and post-harvest stage on stone fruit and table grapes is no longer allowed according to APVMA's suspension notice. Uses such as on wine grapes² and on stone fruit at the flowering stage (early stage) and dry beans only are still permitted on the label (http://www.apvma.gov.au/chemrev/procymidone_poster.pdf). The use of procymidone on lettuce, strawberries, table grapes and tomatoes is no longer permitted and the MRLs have been deleted. The MRLs for beans, wine grapes and stone fruits remain as temporary (T) until the APVMA assesses new data as part of the review of procymidone (http://www.apvma.gov.au/chemrev/procymidone_scope.pdf). APVMA has also withdrawn permits issued for the use of procymidone on brassicas and cucurbits.

1.2.1 Dietary exposure assessments

Due to specific occupational health and safety concerns for women of child-bearing age, FSANZ undertook a National Estimated Short Term Intake (NESTI) and a National Estimated Dietary Intake (NEDI) calculation to ascertain whether any public health and safety concerns existed from residues of procymidone for this target group (females aged 16 to 44 years).

1.2.2 NESTI

Previous calculations of the NESTI for procymidone in December 2004 indicated that there may be a potential for the ARfD to be exceeded for women of childbearing age. In the worst case NESTI, the ARfD was exceeded for beans, cucurbits, lettuce, nectarine and peach. In a modified NESTI calculation the ARfD was exceeded for cucurbits, nectarine and peach.

These preliminary calculations were done in the absence of up to date residue data, and only provide a guide as to the likely risk.

² This does not include use on table grapes or grapes used for production of dried fruit

On the basis of the NESTI conducted by FSANZ, there appeared to be a small risk for consumers of nectarines, peaches and cucurbits. However, when a balanced diet containing a range of healthy foods is consumed (including a broad range of fruit and vegetables) FSANZ concluded that the risk to public health and safety from residues of procymidone on those foods was low.

In addition, recent reports of surveys of residues in foods carried out in Victoria, Western Australia and South Australia indicate a very high compliance rate with procymidone MRLs in the Code, with only two breaches of Standard 1.4.2 detected on samples of lettuce and broccoli for procymidone. Although the actual levels were not stated in the reports, this data suggests that there are limited procymidone residues in foods.

In summary, APVMA has recently undertaken the following actions in relation to procymidone:

- deleted the uses for specific commodities (green beans and wine grapes and at a late and post-harvest stage on stone fruit). MRLs are now temporary in these commodities until APVMA completes its review;
- deleted the use and the subsequent MRL of procymidone in lettuce, strawberry, table grapes and tomatoes;
- withdrawn the permits for brassicas and cucurbits. The associated MRLs have been requested to be deleted in the September 2005 APVMA notifications;
- revised use patterns for the remaining commodities and increased the WHP to 9 days for stone fruit, wine grapes and dry beans (Fava and Navy).

Therefore, residues from the current remaining existing uses are now not expected to exceed the ARfD for any commodity with residues of procymidone. Consequently there are no expected public health and safety concerns. APVMA and FSANZ will be in a position to perform a revised NESTI once additional residue data is available following the review of procymidone.

1.2.3 NEDI

The current National Estimated Dietary Intake (NEDI) of residues of procymidone (based on the MRL) in food for women of childbearing age is 40% of the acceptable daily intake (ADI). Further, in the 18th, 19th and 20th Australian Total Diet Surveys (ATDS) the estimated dietary exposure to procymidone was less than 1% of the ADI for adult females 25-34 years of age³. On the basis of results from the NEDI and the results from the ATDSs, FSANZ considers that chronic dietary exposure to the potential residues associated with MRLs for procymidone would not present a risk to the health and safety of women of child-bearing age.

³ Data was not available for the age groups 35 to 46 years

1.3 Antibiotic MRLs

There are no MRLs for antibiotic⁴ residues in this Application.

1.4 Revised ethephon notification

Following late advice from APVMA current permissions for use of ethephon on barley, wheat and triticale will be maintained. APVMA had requested that the ethephon MRLs of T1 for each of barley, triticale and wheat be deleted. APVMA has now withdrawn this request, as the registered use is still current on the label. The NEDI for ethephon is equivalent to 79% of the ADI.

2. Regulatory Problem

2.1 Current Regulations

APVMA has approved the use of the agricultural and veterinary chemical products associated with the MRLs in this Application, and made amendments to its APVMA MRL Standard accordingly. Consequently there are discrepancies between the potential residues associated with the use of the relevant agricultural and/or veterinary chemicals and the MRLs in the Code.

3. Objective

This Application aims to ensure that the proposed MRLs do not present a risk to public health and safety and that the sale of legally treated food is permitted. APVMA has already established MRLs under its legislation, and now seeks to have the amendments included in Standard 1.4.2 Maximum Residue Limits through this application.

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

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

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

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

⁴ An antibiotic is a chemical inhibitor of the growth of organisms produced by a micro-organism.

None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed draft variations to Standard 1.4.2 Maximum Residue Limits.

4. Background

4.1 The use of agricultural and veterinary chemicals

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

Before registering a product, APVMA independently evaluates its safety and performance, making sure that the health and safety of people, animals and the environment are protected.

When a chemical product is registered for use or a permit for use granted, APVMA includes MRLs in its APVMA MRL Standard. These MRLs are then adopted into control of use legislation in some jurisdictions and assist States and Territories in regulating the use of agricultural and veterinary chemicals.

4.2 Maximum Residue Limit applications

After registering agricultural or veterinary chemical products, based on scientific evaluations, APVMA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews information provided by APVMA and validates whether the dietary exposure is within appropriate safety limits. If satisfied that the residues are within safety limits and subject to adequate resolution of any issues raised during public consultation, FSANZ will agree to incorporate the proposed MRLs into Standard 1.4.2 of the Code.

FSANZ notifies the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) of the adoption of the variation to the Code. If the Ministerial Council does not request a review of the draft variations to Standard 1.4.2 Maximum Residue Limits, the MRLs are automatically adopted by reference into the food laws of the Australian States and Territories.

Including MRLs in Standard 1.4.2 of the Code has the effect of allowing legally treated produce to be legally sold, provided that the residues in the treated produce do not exceed the MRL. Changes to Australian MRLs reflect the changing patterns of agricultural and veterinary chemicals available to farmers. These changes include both the development of new products and crop uses, and the withdrawal of older products following review.

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

4.3 Maximum Residue Limits

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

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

MRLs are also used as standards for international trade in food. In addition, MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases. In relation to MRLs, FSANZ's role is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits.

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

In summary, MRLs in the Code apply in relation to the sale of food under State and Territory food legislation and the inspection of imported foods by the Australian Quarantine and Inspection Service.

4.4 Food Standards-setting in Australia and New Zealand

The Treaty excluded MRLs for agricultural and veterinary chemicals in food from the joint food standards setting system. Australia and New Zealand separately and independently develop MRLs for agricultural and veterinary chemicals in food.

4.5 Trans Tasman Mutual Recognition Arrangement

Following the commencement of the Trans Tasman Mutual Recognition Arrangement between Australia and New Zealand on 1 May 1998:

- food produced or imported into Australia, which complies with Standard 1.4.2 of the Code can be legally sold in New Zealand
- food produced or imported into New Zealand, which complies with the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard, 1999* can be legally sold in Australia.

4.6 Limit of Quantification

Some of the proposed MRLs in this Application are at the limit of quantification (LOQ) and are indicated by an * in the 'Summary of the Requested MRLs...' (Attachment 2).

The LOQ is the lowest concentration of an agricultural or veterinary chemical residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. The inclusion of the MRLs at the LOQ means that no detectable residues of the relevant chemical should occur. FSANZ incorporates MRLs at the LOQ in the Code to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

4.7 MRLs for Permits

Some of the proposed MRLs in this Application are temporary and are indicated by a ‘T’ in the ‘Summary of the Requested MRLs for each Chemical...’ (Attachment 2). These MRLs may include uses associated with:

- the APVMA minor use program
- off-label permits for minor and emergency uses
- trial permits for research.

FSANZ does not issue permits or grant permission for the temporary use of agricultural and veterinary chemicals. Further information on permits for the use of agricultural and veterinary chemicals can be found on the APVMA website at www.apvma.gov.au or by contacting APVMA on +61 2 6272 5158.

5. EVALUATION OF ISSUES RAISED IN PUBLIC SUBMISSIONS

Submissions were received from Queensland Health, Food Technology Association of Victoria (FTA), the Department of Human Services Victoria, Department of Health South Australia and Australian Food and Grocery Council (AFGC).

The submissions from Queensland Health, FTA, Department of Human Services Victoria and Department of Health South Australia supported the Application. Queensland Health, FTA, Department of Human Services Victoria and Department of Health South Australia support option 2(a) to decrease and delete existing MRLs and option 2(b) adopt changes to MRLs to include new and increase existing MRLs.

5.1 Submission from Australian Food and Grocery Council

AFGC supports Option 2(b) and does not support Option 2(a) to vary Standard 1.4.2 to delete and decrease some existing MRLs until there has been adequate consultation with industry to ensure that imported produce will not be adversely affected. AFGC expressed concern that foods may not be able to be imported if these foods contained residues consistent with the MRLs proposed for deletion or reduction.

United Kingdom legislation and European Union legislation currently permit a level of certain residues at the point of detection for the chemicals proposed for deletion or reduction: ethephon for barley, triticale and wheat; ethoprophos for grapes; and procymidone for carrot, strawberry, tomato and lettuce head.

5.1.1 Evaluation

MRL deletions have the potential to restrict the importation of foods and could potentially result in a reduced product range available to consumers, as foods could not be legally imported or sold to consumers. FSANZ publicly advertises any proposed changes to MRL as part of the round of public consultation and lists all amendments on the FSANZ website to assist industry sectors in identifying any impacts following deletions or reductions of specific MRLs.

However, no submissions were received from specific industry sectors that addressed the likely effects on trade or importation for the relevant food commodities if the proposed deletion of ethephon for barley, triticale and wheat; ethoprophos for grapes; and procymidone for carrot, strawberry, tomato and lettuce head were progressed. In addition, Member countries following the WTO Notification raised no issues in regard to the proposed deletions.

Furthermore, the deletion for specific commodities for procymidone was part of a package to reduce any possible risks to public health and safety for specific consumers. FSANZ concurs with APVMA that this is appropriate.

6. Options

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

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

6.2 Option 2(a) – adopt the change to MRLs to omit or decrease some existing MRLs.

Under this option, only those variations that were reductions and omissions would be approved for inclusion into the Code. The proposed increases and inclusions of new MRLs would not be approved.

6.3 Option 2(b) – adopt the changes to MRLs to insert new or increase some existing MRLs.

Under this option, only those variations that were increases and insertions of MRLs would be approved for inclusion into the Code. The proposed decreases and omissions of MRLs would not be approved.

Option 2 has been arranged into two sub-options because the impacts of each sub-option are different. Splitting the option into two sub-options also allows a more detailed impact analysis. However, FSANZ cannot legally separate these two sub-options and may only accept or reject this Application.

7. Affected Parties

The parties affected by proposed MRL amendments include:

- consumers, including domestic and overseas customers;
- growers and producers of domestic and export food commodities;
- importers of agricultural produce and foods; and
- Australian Government, State and Territory agencies involved in monitoring and regulating the use of agricultural and veterinary chemicals in food and the potential resulting residues.

8. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposal, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make a final assessment of this proposal includes information from public submissions.

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

8.1.1 Benefits

- For consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of agricultural and veterinary chemicals.
- For growers and producers of domestic and export food commodities, the adoption of this option would not result in any discernable benefits.
- For importers, adopting this option would not result in any discernable benefits.
- For Australian Government, State and Territory agencies, adopting this option would not result in any discernable benefits.

8.1.2 Costs

- For consumers there are unlikely to be any discernable costs as the unavailability of some food from certain growers is likely to be seen as typical seasonal fluctuations in the food supply.
- For growers and producers of domestic and export food commodities, adopting this option would result in costs resulting from not being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Primary producers do not produce food or use chemical products to comply with MRLs. They use chemical products to control pests and diseases in accordance with the prescribed label conditions, and expect that the resulting residues will be acceptable and that the legally treated food can be legally sold. If the legal use of chemical products results in the production of food that cannot be legally sold under food legislation then primary producers will incur substantial losses. Major losses for primary producers would in turn impact negatively on rural and regional communities.

- For importers, adopting this option would not result in any discernable costs.
- For Australian Government, State and Territory agencies, adopting this option would create discrepancies between agricultural and food legislation thereby creating uncertainty, inefficiency and confusion in the enforcement of regulations.

8.2 Option 2(a) – adopt the changes to MRLs to delete and decrease some existing MRLs.

8.2.1 Benefits

- For consumers the major benefit would be maintaining the existing confidence in the food supply in relation to residues of agricultural and veterinary chemicals.
- For growers and producers of domestic and export food commodities, adopting this option would not result in any discernable benefits.
- For importers, adopting this option would not result in any discernable benefits.
- For Australian Government, State and Territory agencies, adopting this option would foster community confidence that regulatory authorities are maintaining the standards to minimise residues in the food supply.

8.2.2 Costs

- For consumers there are unlikely to be any discernable costs as the unavailability of some food from certain importers is likely to be seen as typical seasonal fluctuation in the food supply.
- For growers and producers of domestic and export food commodities, adopting this option is unlikely to result in any costs, as reductions in MRLs are adopted where this is practically achievable, with little or no impact on production costs.
- For importers, adopting this option may result in costs, as foods may not be permitted to be imported if these foods contain residues consistent with the MRLs proposed for deletion or reduction. Any MRL deletions or reductions have the potential to restrict the importation of foods and could potentially result in higher food costs and a reduced product range available to consumers, as foods that exceed the new, lower MRLs could not be legally imported or sold to consumers.
- For Australian Government, State and Territory agencies, adopting this option would not result in any discernable costs, although there would need to be an awareness of changes in the standards for residues in food.

8.3 Option 2(b) – adopt the changes to MRLs to include new and increase some existing MRLs.

8.3.1 Benefits

- For consumers the major benefit would be potential flow on benefits resulting from the price and availability of food if growers can legally sell food containing residues consistent with increased MRLs or MRL additions.
- For growers and producers of domestic and export food commodities, the benefits of this option would result from being able to legally sell food containing residues consistent with increased MRLs or MRL additions. Other benefits include the consistency between agricultural and food legislation thereby minimising compliance costs to primary producers.
- For importers, adopting this option would result in the benefit that food could be legally imported if it contained residues consistent with increased MRLs or MRL additions.
- For Australian Government, State and Territory agencies, the benefits of this option would include the removal of discrepancies between agricultural and food legislation thereby creating certainty and allowing efficient enforcement of regulations.

8.3.2 Costs

- For consumers there are no discernable costs.
- For growers and producers of domestic and export food commodities, adopting this option would not result in any discernable costs.
- For importers, adopting this option would not result in any discernable costs.
- For Australian Government, State and Territory agencies, adopting this option would not result in any discernable costs, although there may be minimal impacts associated with slight changes to residue monitoring programs.

9. Consultation

9.1 World Trade Organization Notification

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

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

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

FSANZ made a Sanitary and Phytosanitary (SPS) notification to the WTO for this Application in accordance with the WTO SPS agreement because the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment. No WTO member has made a submission on this Application.

9.1.1 Codex MRLs

The standards of the Codex Alimentarius Commission are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table lists the variations to MRLs in this Application that are addressed in the international Codex standard.

Chemical Food	Proposed MRL mg/kg	Codex MRL mg/kg
Dithiocarbamates		
Almonds	3	0.1
Potato	1	0.2
Strawberry	3	5
Dodine		
Stone fruits	*0.05	2 (Cherries) 2 (Nectarine) 5 (Peach)
Ethephon		
Walnuts	T0.05	0.5
Ethoprophos		
Grapes	Omit T*0.01	0.02
Iprodione		
Onion Bulb	T0.2	0.2
Metalaxyl		
Cereal grains	Omit T*0.05	0.05
Procymidone		
Adzuki Bean (Dry)	T0.2	5
Peppers	T2	1
Beans [except broad bean and soya bean]	T10	5
Wine grapes	T2	5
Lettuce, head	Omit 2	0.2
Onion, bulb	T0.2	
Stone fruits	T10	10 (Cherries) 2 (Peach) 2 (Plum)
Strawberry	Omit 5	10
Tomato	Omit 2	5
Trichlorfon		
Peppers	0.2	0.2 (capsicum and chillies)

FSANZ requested comment on any possible ramifications of the proposed MRLs differing from Codex. No submitters raised any issues in relation to these differences between the Code and Codex MRLs.

9.1.2 Imported Foods

Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because different products may be used. This means that residues in imported food may still be safe for human consumption, but may be different from those in domestically produced food.

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

To assist in identifying possible impacts where imported food may be affected, FSANZ compiled the following table of foods that have MRLs that are proposed for deletion and/or reduction and sought comment on any impacts of these reductions or deletions at Initial/Draft Assessment. AFGC made a submission on these impacts, which is discussed in section 5.1 above.

Chemical Food
Alloxydim Beetroot Bulb vegetables [alliums] Carrot Fruiting vegetables, cucurbits Poppy seed Potato Strawberry Tomato
Alloxydim Sodium This is a consequential amendment arising from the proposed deletion Alloxydim (see above).
Benfluralin Edible offal (mammalian) Meat (mammalian) Milks
Cyproconazole Banana Grapes
Diclobutrazol Wheat
Difenoconazole Cereal grains

Chemical
Food
Diofenolan Avocado Citrus fruits Macadamia nuts Mango Papaya Pome fruits Stone fruits
Diphenamid Tomato
Dodine Stone fruits
Ethoprophos Grapes
Fenoxycarb Grapes Stone fruits
Metalaxyl Cereal grains
Methazole Onion, Bulb
Procymidone Carrot Strawberry Tomato Lettuce, Head Lettuce, Leaf Table grapes
Promecarb Beans, except broad and soya bean Broad bean (green pods and immature seeds) Citrus fruits Fruiting vegetables, cucurbits Grapes Onion, Bulb Stone fruits
Trichlorfon Peppers

10. Conclusion

Option 1 is a viable but undesirable option.

- Potential substantial costs to primary producers may result. Additional costs may impact negatively on their viability and in turn the viability of the rural and regional communities that depend upon the sale of the agricultural produce.
- Consequent discrepancies between agricultural and food legislation could have negative impacts on the compliance costs for primary producers, perception problems in export

markets and undermine the efficient enforcement of standards for chemical residues.

FSANZ's preferred approach is adopt Options 2(a) and 2(b) – to change MRLs in Standard 1.4.2 of the Code to include new or increase some existing MRLs and to delete or decrease some existing MRLs.

- There are no public health and safety concerns associated with the proposed MRL amendments (this benefit also applies to Option 1).
- The changes would minimise the potential costs to primary producers and rural and regional communities in terms of legally being able to sell legally treated food.
- The changes would minimise residues consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases.
- The changes would remove discrepancies between agricultural and food legislation and provide certainty enforcement.

Adopting option 2(a) may result in compliance costs for importers and industry where there are decreases or deletions of MRLs.

11. Implementation and Review

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

- State and Territory residue monitoring programs
- Australian Government programs such as the National Residue Survey
- dietary exposure surveys such as the Australian Total Diet Study.

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 MRL amendments in this Application should take effect on gazettal and that the MRLs be subject to existing monitoring arrangements.

12. Recommendation

FSANZ recommends approving the draft variations to Standard 1.4.2 Maximum Residue Limits for the following reasons:

- MRLs serve to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases.
- The dietary exposure assessments indicate that setting the residues as proposed does not present any public health and safety concerns.

- The proposed variations will benefit stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.
- APVMA has assessed appropriate 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.
- Office of Chemical Safety (OCS) has undertaken an appropriate toxicological assessment of the chemicals and has established relevant acceptable daily intakes (ADI) and where applicable, an acute reference dose (ARfD).
- FSANZ has undertaken a regulation impact assessment and concluded that the draft variations to Standard 1.4.2 Maximum Residue Limits are necessary, cost-effective and will benefit producers and consumers.
- The proposed draft variations would remove any discrepancies between agricultural and food legislation and provide certainty and consistency for growers and producers of domestic and export food commodities, importers and Australian, State and Territory enforcement agencies.
- None of FSANZ's section 10 objectives are compromised by the proposed changes.

Attachments

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

Draft Variations to the Australia New Zealand Food Standards Code**To commence: On gazettal****[1] Standard 1.4.2 of the Australia New Zealand Food Standards Code is varied by –****[1.1] omitting from Schedule 1 all entries for the following chemicals –**

Alloxydim
 Alloxydim Sodium
 Diclobutrazol
 Diofenolan
 Diphenamid
 Methazole
 Promecarb

[1.2] inserting in Schedule 1 –

CLOTHIANIDIN	
<i>COMMODITIES OF PLANT ORIGIN: CLOTHIANIDIN</i>	
<i>COMMODITIES OF ANIMAL ORIGIN: SUM OF</i>	
<i>CLOTHIANIDIN, 2-CHLOROTHIAZOL-5-</i>	
<i>YLMETHYLGUANIDINE, 2-CHLOROTHIAZOL-5-</i>	
<i>YLMETHYLUREA, AND THE PYRUVATE DERIVATIVE</i>	
<i>OF N⁷-(2-CHLOROTHIAZOL-5-YLMETHYL)-N⁷-</i>	
<i>METHYLGUANIDINE, EXPRESSED AS CLOTHIANIDIN</i>	
COTTON SEED	T*0.02
EDIBLE OFFAL (MAMMALIAN)	T*0.02
MEAT (MAMMALIAN) (IN THE FAT)	T*0.02
MILKS	T*0.01
FLUMICLORAC PENTYL	
FLUMICLORAC PENTYL	
COTTON SEED	T0.1
EDIBLE OFFAL (MAMMALIAN)	T*0.01
EGGS	T*0.01
MEAT (MAMMALIAN)	T*0.01
MILKS	T*0.01
POULTRY, EDIBLE OFFAL OF	T*0.01
POULTRY MEAT	T*0.01
FORCHLORFENURON	
FORCHLORFENURON	
GRAPES	T*0.01

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

COLUMN 1	COLUMN 2
TYLOSIN TYLOSIN	TYLOSIN TYLOSIN A

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

BENFLURALIN BENFLURALIN	
EDIBLE OFFAL (MAMMALIAN)	T*0.01
MEAT (MAMMALIAN)	T*0.01
MILKS	T*0.01
CYPROCONAZOLE CYPROCONAZOLE, SUM OF ISOMERS	
BANANA	T0.5
GRAPES	T0.5
DIFENOCONAZOLE DIFENOCONAZOLE	
CEREAL GRAINS	T*0.01
DIMETHOMORPH SUM OF E AND Z ISOMERS OF DIMETHOMORPH	
CHARD (SILVER BEET)	T2
LETTUCE, LEAF	T2
ETHOPROPHOS ETHOPROPHOS	
GRAPES	T*0.01
FENOXYCARB FENOXYCARB	
GRAPES	T2
STONE FRUITS	T0.5
METALAXYL METALAXYL	
CEREAL GRAINS	T*0.05
PROCYMIDONE PROCYMIDONE	
CARROT	T1
GRAPES	2
LETTUCE, HEAD	2
LETTUCE, LEAF	2
STRAWBERRY	5
TOMATO	2
PROPACHLOR PROPACHLOR	
CEREAL GRAINS	*0.05
TRICHLORFON TRICHLORFON	
PEPPERS, SWEET	T0.5

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

AZOXYSTROBIN AZOXYSTROBIN	
OLIVES	T2
BOSCALID <i>COMMODITIES OF PLANT ORIGIN:</i> BOSCALID <i>COMMODITIES OF ANIMAL ORIGIN:</i> SUM OF BOSCALID, 2-CHLORO-N-(4'-CHLORO-5-HYDROXYBIPHENYL-2-YL) NICOTINAMIDE AND GLUCURONIDE CONJUGATE OF 2-CHLORO-N-(4'-CHLORO-5-HYDROXYBIPHENYL-2-YL) NICOTINAMIDE, EXPRESSED AS BOSCALID EQUIVALENTS	
ONION, BULB	T1.0
BUPIRIMATE BUPIRIMATE	
PEPPERS	T1
CYHALOTHRIN CYHALOTHRIN, SUM OF ISOMERS	
CUCUMBER	T0.05
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
CORIANDER (LEAVES, STEM, ROOTS)	T1
CORIANDER, SEED	T1
PARSLEY	T1
DIMETHOMORPH SUM OF E AND Z ISOMERS OF DIMETHOMORPH	
LEAFY VEGETABLES [EXCEPT LETTUCE HEAD]	T2
ETHEPHON ETHEPHON	
WALNUTS	T0.5
IPRODIONE IPRODIONE	
ONION, BULB	T0.2
MELOXICAM MELOXICAM	
PIG FAT/SKIN	0.1
PIG KIDNEY	*0.01
PIG LIVER	*0.01
PIG MEAT	0.02
PHENMEDIPHAM PHENMEDIPHAM	
LETTUCE, HEAD	T0.2
LETTUCE, LEAF	T0.2

PROCYMIDONE PROCYMIDONE	
PEPPERS	T2
ROOT AND TUBER VEGETABLES [EXCEPT POTATO]	T1
WINE GRAPES	T2
PROPACHLOR PROPACHLOR	
CEREAL GRAINS [EXCEPT SORGHUM]	0.05
EDIBLE OFFAL (MAMMALIAN)	0.1
EGGS	*0.02
MEAT (MAMMALIAN) (IN THE FAT)	*0.02
MILKS	*0.02
POULTRY, EDIBLE OFFAL OF	*0.02
POULTRY MEAT (IN THE FAT)	*0.02
SORGHUM	0.2
SWEET CORN (CORN-ON-THE-COB)	0.05
SETHOXYDIM SUM OF SETHOXYDIM AND METABOLITES CONTAINING THE 5-(2- ETHYLTHIOPROPYL)CYCLOHEXENE-3-ONE AND 5-HYDROXYCYCLOHEXENE-3-ONE MOIETIES AND THEIR SULFOXIDES AND SULFONES, EXPRESSED AS SETHOXYDIM	
BARLEY	*0.1
TOLYLFLUANID TOLYLFLUANID	
DRIED GRAPES	T0.2
GRAPES	T*0.05
TRICHLORFON TRICHLORFON	
PEPPERS	0.2

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

AZOXYSTROBIN AZOXYSTROBIN	
COTTON SEED	*0.01
CYPERMETHRIN CYPERMETHRIN, SUM OF ISOMERS	
LINOLA OIL, EDIBLE	0.1
LINOLA SEED	0.1
DITHIOCARBAMATES TOTAL DITHIOCARBAMATES, DETERMINED AS CARBON DISULPHIDE EVOLVED DURING ACID DIGESTION AND EXPRESSED AS MILLIGRAMS OF CARBON DISULPHIDE PER KILOGRAM OF FOOD	
ALMONDS	3
BEETROOT	1

CITRUS FRUITS	0.2
POME FRUITS	3
POTATO	1
STRAWBERRY	3
DODINE DODINE	
STONE FRUITS	*0.05
FLUDIOXONIL <i>COMMODITIES OF ANIMAL ORIGIN: SUM OF FLUDIOXONIL AND OXIDISABLE METABOLITES, EXPRESSED AS FLUDIOXONIL</i> <i>COMMODITIES OF PLANT ORIGIN: FLUDIOXONIL</i>	
COTTON SEED	*0.05
RAPE SEED	*0.01
FLUVALINATE FLUVALINATE, SUM OF ISOMERS	
COTTON SEED	0.1
HALOSULFURON-METHYL HALOSULFURON-METHYL	
EDIBLE OFFAL (MAMMALIAN)	0.2
MEAT (MAMMALIAN)	*0.01
MILKS	*0.01
IMAZAPIC SUM OF IMAZAPIC AND ITS HYDROXYMETHYL DERIVATIVE	
EGGS	*0.01
POULTRY, EDIBLE OFFAL OF	*0.01
POULTRY MEAT	*0.01
PROCYMIDONE PROCYMIDONE	
ADZUKI BEAN (DRY)	T0.2
BEANS [EXCEPT BROAD BEAN AND SOYA BEAN]	T10
EDIBLE OFFAL (MAMMALIAN)	T0.05
EGGS	T*0.01
GARLIC	T5
LUPIN (DRY)	T*0.01
MEAT (MAMMALIAN) (IN THE FAT)	T0.2
MILKS	T0.02
ONION, BULB	T0.2
POME FRUITS	T1
POTATO	T0.1
POULTRY, EDIBLE OFFAL OF	T*0.01
POULTRY MEAT (IN THE FAT)	T0.1
SNOW PEAS	T5
STONE FRUITS	T10
TRICHLORFON TRICHLORFON	
MILKS	*0.05

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

A Summary of the Requested MRLs for Each Chemical and an Outline of the Information Supporting the Requested Changes to the *Australia New Zealand Food Standards Code*

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

NOTES ON TERMS USED IN THE TABLE

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

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

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

NEDI - National Estimated Dietary Intake - The NEDI represents a more realistic estimate of dietary exposure and is the preferred calculation. It may incorporate more refined food consumption data including that for specific sub-groups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated; residues in edible portions; the effects of processing and cooking on residue levels; and may use median residue levels from supervised trials other than the MRL to represent pesticide residue levels. In most cases the NEDI is still an overestimation because the above data is often not available and in these cases the MRL is used.

NESTI - National Estimated Short Term Intake - The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated based on consumption of raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis. FSANZ has used ARfDs set by the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey (NNS) and the MRL when the supervised trials median residue (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; STMR, representing typical residue in an edible portion resulting from the maximum permitted pesticide use pattern; processing factors which affect changes from the raw commodity to the consumed food and the variability factor.

The following are examples of entries and the proposed MRLs listed are not part of this Application.

<p>Fipronil Berries and other small fruits [except grapes and strawberry]</p> <p>Berries and other small fruits [except wine grapes]</p> <p>Strawberry</p>	<p>Delete</p> <p>Add</p> <p>Delete</p>	<p>T*0.01</p> <p>T*0.01</p> <p>T0.5</p>	<p>This chemical is a phenylpyrazole. APVMA has extended the trial permit for this chemical to control Western Flower Thrip in strawberry. An MRL for fipronil on strawberry is required to accommodate the use as a bait for fruit fly. This use is not expected to result in residues and so the MRL is proposed at the LOQ.</p> <p>NESTI = <1% of ARfD for berries</p> <p>NEDI = 60% of ADI</p>
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The NESTI is an assessment of the acute exposure which is compared to the acute reference dose (ARfD). More information is in the glossary on the NESTI and the ARfD. To be acceptable to FSANZ, the NESTI must be less than 100% of the ARfD because the ARfD is considered the 'safe' level.

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

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

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

Name of the Chemical (in bold)

Food for which the proposed MRL is to apply.

Whether the proposed MRL is being added or deleted.

The 'T' means the MRL is temporary and under review.

The '*' means that the MRL is at the limit of quantification and detectable residues should not occur.

Class of Chemical

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

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

<p>Chlorpyrifos Coffee beans</p>	<p>Add T0.5</p>	<p>APVMA extension of use for the control of pests. The 19th ATDS (1998) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to 0.51% of ADI for adult males and up to 2.55% of ADI for 2 year olds. The 20th ATDS (2000) dietary exposure estimate for chlorpyrifos, as a percentage of the ADI is equivalent to <1% of ADI for the whole population. NEDI = 83% of ADI</p>
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Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and typically result because of the different range of foods in the individual surveys.

Glossary:

- 1. **ADI** Acceptable Daily Intake
- 2. **APVMA** Australian Pesticides and Veterinary Medicines Authority
- 3. **ARfD** Acute Reference Dose
- 4. **ATDS** Australian Total Diet Study
- 5. **FSC** *Australia New Zealand Food Standards Code*
- 6. **JMPR** Joint FAO/WHO Meeting on Pesticide Residues
- 7. **LOQ** Limit of Analytical Quantification
- 8. **NEDI** National Estimated Daily Intake
- 9. **NESTI** National Estimated Short Term Intake
- 10. **NNS** National Nutrition Survey of Australia 1995
- 11. **T** Temporary MRL
- 12. **WHP** Withholding Period

**SUMMARY OF THE REQUESTED MRLS FOR APPLICATION A559
(APRIL, MAY, JUNE MRL AMENDMENTS)**

Alloxydim Beetroot Bulb vegetables [alliums] Carrot Fruiting vegetables, Cucurbits Poppy seed Potato Strawberry Tomato	Omit Omit Omit Omit Omit Omit Omit Omit	T0.1 T0.1 T0.2 T*0.1 T0.3 T0.1 T0.1 T0.2	Deletion. No dietary exposure report required.
Alloxydim sodium			Consequential amendment
Azoxystrobin Cotton seed Olives	Omit Substitute Insert	T*0.01 *0.01 T2	This chemical is a strobilin fungicide. APVMA has issued a permit for this chemical to be used to control fungal diseases on lettuce and bean crops. NEDI = 2% of ADI.
Benfluralin Edible offal (mammalian) Meat (mammalian) Milks	Omit Omit Omit	T*0.01 T*0.01 T*0.01	Deletion. No dietary exposure report required.
Boscalid Onion, Bulb	Insert	T1.0	This chemical is a fungicide used to control Neck rot (<i>Botrytis allii</i>) in onions. NESTI 2 years (+) <1% of ARfD. NESTI 2-6 years <1% of ARfD. NEDI = 6% of ADI.
Bupirimate Peppers	Insert	T1	This chemical is used for disruption of sporulation in the target pest. NEDI = 3% of ADI.

Clothianidin Cotton seed Edible offal (mammalian) Meat (mammalian) (in the fat) Milks	Insert Insert Insert Insert	T*0.02 T*0.02 T*0.02 T*0.01	This is a new chemical. It is an insecticide for the control of cotton aphid in cotton. NESTI 2 years (+) Oil seed <1% ARfD Edible offal (mammalian) <1% ARfD Meat (mammalian in the fat) <1% ARfD Milks <1% ARfD NESTI 2-6 years Oil seed <1% ARfD Edible offal (mammalian) <1% ARfD Meat (mammalian in the fat) <1% ARfD Milks <1% ARfD NEDI = <1% of ADI.
Cyhalothrin Cucumber	Insert	T0.05	This chemical is an insecticide with contact and stomach action and repellent properties. NEDI = 4% ADI.
Cypermethrin Coriander (leaves, stem, roots) Coriander, seed Parsley Linola oil, edible Linola oil, edible Linola seed Linola seed	Insert Insert Insert Omit Substitute Omit Substitute	T1 T1 T1 T0.1 0.1 T0.1 0.1	This chemical is a pyrethroid, non-systemic insecticide with contact and stomach action. It is used to control a wide range of chewing and sucking insect pests in horticulture and fruit production. APVMA has also received a minor use permit application for alpha-cypermethrin treatment to control insect pests on parsley and coriander. NEDI = 9% of ADI.
Cyproconazole Banana Grapes	Omit Omit	T0.5 T0.5	Deletion. No dietary exposure report required.
Diclobutrazol Wheat	Omit	T0.05	Deletion. No dietary exposure report required.
Difenoconazole Cereal grains	Omit	T*0.01	Deletion. No dietary exposure report required.
Dimethomorph Chard (silver beet) Lettuce, Leaf Leafy vegetables (except head lettuce)	Omit Omit Substitute	T2 T2 T2	Dimethomorph is a local systematic fungicide with good protectant antispore activity. NEDI = 4% of ADI.

Diofenolan Avocado Citrus fruits Macadamia nuts Mango Papaya Pome fruits Stone fruits	Omit Omit Omit Omit Omit Omit Omit	T0.5 T0.5 T0.5 T0.5 T0.5 T0.5 T0.5	Deletion. No dietary exposure report required.
Diphenamid Tomato	Omit	T*0.1	Deletion. No dietary exposure report required.
Dithiocarbamates Almonds Beetroot Citrus fruits Pome fruits Potato Strawberry	Omit Substitute Omit Substitute Omit Substitute Omit Substitute Omit Substitute Omit Substitute	T3 3 T1 1 T0.2 0.2 T3 3 T1 1 T3 3	Administrative change from temporary to permanent MRLs. No dietary exposure report required as was previously evaluated. In the 19 th (1998) ATDS the estimated dietary exposure to thiram (which has the lowest ADI of all dithiocarbamate chemicals) was at 63% of the ADI for two year olds and 20% of the ADI for adult males.
Dodine Stone fruits	Omit Substitute	5 *0.05	For the prevention and control of leaf curl (<i>Taphrina deformans</i>) and blossom blight (<i>Monilinia fructicola</i>) in stone fruits. NEDI = 6% of ADI.
Ethephon Walnuts	Insert	T0.5	This chemical is used to promote nut-fall in walnuts. It decomposes to ethylene in plant tissues. Walnut NESTI 2 years (+) <1% of ARfD and NESTI 2-6 years <1% of ARfD. NEDI = 79% of ADI.
Ethoprophos Grapes	Omit	T*0.01	Deletion. No dietary exposure report required.
Fenoxycarb Grapes Stone fruits	Omit Omit	T2 T0.5	Deletion. No dietary exposure report required.
Fludioxonil Cotton seed Rape seed [canola seed]	Omit Substitute Omit Substitute	T*0.05 *0.05 T*0.01 *0.01	Administrative change from temporary to permanent MRLs. No dietary exposure report required as was previously evaluated.

Flumiclorac pentyl Cotton seed Edible offal (mammalian) Eggs Meat (mammalian) Milks Poultry, Edible offal of Poultry meat	Insert Insert Insert Insert Insert Insert Insert	T0.1 T*0.01 T*0.01 T*0.01 T*0.01 T*0.01 T*0.01	This is a new chemical. It is a N-phenylamide herbicide used for defoliation and boll opening of cotton. NEDI = <1% of ADI.
Fluvalinate Cotton seed	Omit Substitute	T0.1 0.1	Administrative change from temporary to permanent MRLs. No dietary exposure report required as was previously evaluated.
Forchlorfenuron Grapes	Insert	T*0.01	This is a new chemical. {T} Forchlorfenuron This chemical is a phenylurea type cytokinin plant growth regulator. Forchlorfenuron acts as a cytokinin plant growth regulator, that stimulates cell division, leading to increases in fruit size. NEDI = <1% of ADI.
Halosulfuron-methyl Edible offal (mammalian) Meat (mammalian) Milks	Omit Substitute Omit Substitute Omit Substitute	T0.2 0.2 T*0.01 *0.01 T*0.01 *0.01	Administrative change from temporary to permanent MRLs. No dietary exposure report required as was previously evaluated.
Imazapic (formerly known as Imazameth) Eggs Poultry, Edible offal of Poultry meat	Omit Substitute Omit Substitute Omit Substitute	T*0.01 *0.01 T*0.01 *0.01 T*0.01 *0.01	Administrative change from temporary to permanent MRLs. No dietary exposure report required as was previously evaluated.
Iprodione Onion, Bulb	Insert	T0.2	Fungicide for the control of Neck rot (<i>Botrytis allii</i>) in onions. NEDI = 43% of ADI.

Meloxicam Pig fat/skin Pig kidney Pig liver Pig meat	Insert Insert Insert Insert	0.1 *0.01 *0.01 0.02	Meloxicam is to be used in pigs to: (i) reduce the symptoms of lameness and inflammation associated with non-infectious locomotor disorders; and (ii) reduce clinical signs of inflammation, oppose the effects of endotoxins, and hasten recovery in cases of puerperal septicaemia and toxemia (mastitis-metritis-agalactia syndrome), when used in combination with appropriate antibiotic therapy. NESTI 2 years (+) Pig fat/skin <1% ARfD Pig meat 2 % ARfD Pig kidney 0% ARfD Pig liver <1% ARfD NESTI 2-6 years Pig fat/skin <1% ARfD Pig meat 4 % ARfD Pig offal 0% ARfD NEDI = 69 % of ADI.
Metalaxyl Cereal grains	Omit	T*0.05	Deletion. No dietary exposure report required.
Methazole Onion, Bulb	Omit	T*0.1	Deletion. No dietary exposure report required.
Phenmedipham Lettuce, Head Lettuce, Leaf	Insert Insert	T0.2 T0.2	Herbicide for control of broadleaf weeds in lettuce (minor use permit). NEDI = 1% of ADI.

<p>Procymidone Carrot Peppers Root and tuber vegetables (except potato)</p>	<p>Omit Insert Insert</p>	<p>T1 T2 T1</p>	<p>Fungicide - Inhibition of triglyceride synthesis in the target pest.</p> <p>The NEDI for procymidone includes contributions from MRLs established as a result of the proposed use pattern.</p> <p>NESTI 2 years +</p> <p>Peppers, sweet 17% ARfD Peppers, chilli 2% ARfD Beetroot 14% ARfD Parsnip 14% ARfD Radish 15% ARfD Swede 24% ARfD Turnip, garden 9% ARfD</p> <p>NESTI 2-6 years</p> <p>Peppers, sweet 63% ARfD Peppers, chilli 19% ARfD Beetroot 35% ARfD Parsnip 13% ARfD Radish 22% ARfD Swede 30% ARfD Turnip, garden 15% ARfD</p> <p>For all existing and proposed uses, including those on the next page NEDI = 44% of ADI.</p>
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Procymidone			
Adzuki beans (dry)	Omit	0.2	As part of the new label instructions for procymidone (APVMA Gazette, December 2004), the following permanent MRLs have been changed to temporary MRLs.
	Substitute	T0.2	
Beans, except broad beans and soya bean	Omit	10	The use of procymidone on lettuce, strawberry, table grapes and tomato is no longer permitted, consequently, the MRLs are to be omitted from the Code.
	Substitute	T10	
Edible offal (mammalian)	Omit	0.05	The NEDI for procymidone includes contributions from MRLs established as a result of the proposed use pattern.
	Substitute	T0.05	
Eggs	Omit	*0.01	
	Substitute	T*0.01	
Garlic	Omit	5	
	Substitute	T5	
Grapes	Omit	2	
Lettuce, Head	Omit	2	
Lettuce, Leaf	Omit	2	
Lupin (dry)	Omit	*0.01	
	Substitute	T*0.01	
Meat (mammalian)(in the fat)	Omit	0.2	
	Substitute	T0.2	
Milks	Omit	0.02	
	Substitute	T0.02	
Onion, Bulb	Omit	0.2	
	Substitute	T0.2	
Pome fruits	Omit	1	
	Substitute	T1	
Potato	Omit	0.1	
	Substitute	T0.1	
Poultry, Edible offal of	Omit	*0.01	
	Substitute	T*0.01	
Poultry meat (in the fat)	Omit	0.1	
	Substitute	T0.1	
Snow-peas	Omit	5	
	Substitute	T5	
Stone fruits	Omit	10	For all existing and proposed uses, including those on the page prior NEDI = <44% of ADI.
	Substitute	T10	
Strawberry	Omit	5	
Tomato	Omit	2	
Wine Grapes	Insert	T2	
Promecarb			
Beans, except broad and soya bean	Omit	T0.5	Deletion. No dietary exposure report required.
Broad bean (green pods and immature seeds)	Omit	T0.5	
Citrus fruits	Omit	T1	
Fruiting vegetables, Cucurbits	Omit	T0.5	
Grapes	Omit	T0.2	
Onion, Bulb	Omit	T0.5	
Stone fruits	Omit	T0.5	

Propachlor Cereal grains Cereal grains [except sorghum] Edible offal (mammalian) Eggs Meat (mammalian)(in the fat) Milks Poultry, Edible offal of Poultry meat (in the fat) Sorghum Sweet corn (corn-on-the-cob)	Omit Substitute Insert Insert Insert Insert Insert Insert Insert Insert	*0.05 0.05 0.1 *0.02 *0.02 *0.02 *0.02 *0.02 0.2 0.05	This chemical is a chloroacetamide herbicide used to control weeds in radish, swede and turnip crops. NEDI = 7% of ADI.
Sethoxydim Barley	Insert	*0.1	Control of grasses in broad-leafed crops. Selective systemic herbicide, absorbed predominantly by the foliage, and, to a lesser extent, by the roots. NEDI = 28% of ADI.
Tolyfluanid Dried grapes Grapes	Insert Insert	T0.2 T*0.05	Fungicide on grapes Inactivation of essential enzymes by reaction with -SH bonds For all existing and proposed uses NEDI = <1% of ADI.
Trichlorfon Milks Peppers	Omit Substitute Omit Substitute	0.05 *0.05 T0.5 0.2	This chemical is an organophosphate insecticide used to control Haemonchus spp. on goats. NEDI = 84% of ADI.
Trifloxystrobin Strawberry	Omit Substitute	T2 2	Fungicide on strawberries for control of powdery mildew and downy mildew. Inhibition of mitochondrial respiration by blocking electron transfer. NEDI = 3% of ADI.
Tylosin	Omit Substitute		Tylosin Tylosin A

BACKGROUND TO DIETARY EXPOSURE ASSESSMENTS

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

FSANZ's primary role in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential residues in treated food do not present public health and safety concerns. In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from all foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will not approve MRLs for inclusion in the *Food Standards Code* where the dietary exposure to the residues of a chemical could represent a 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:

- 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 (ADI) and/or the acute reference dose (ARfD))
- calculating the dietary exposure to a chemical from all foods, using food consumption data from nutrition surveys and comparing this to the acceptable health standard.

Determination of the residues of a chemical in a treated food

APVMA assesses a range of data when considering the proposed use of a chemical product on a food. These data enable APVMA to determine what the likely residues of a chemical will be on a treated food. These data also enable APVMA to determine what the maximum residues will be on a treated food if the chemical product is used as proposed and from this, APVMA determines an MRL.

The MRL is the maximum level of a chemical that may be in a food and it is not the level that is usually present in a treated food. However, incorporating the MRL into food legislation means that the residues of a chemical are minimised (i.e. must not exceed the MRL), irrespective of whether the dietary exposure assessment indicates that higher residues would not represent a risk to public health and safety.

Determination of the acceptable health standard for a chemical in food

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

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

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

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

Calculating the dietary exposure

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

APVMA and FSANZ have recently agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by APVMA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest 1995 National Nutrition Survey (NNS). The Australian Bureau of Statistics with the Australian Government Department of Health and Aged Care undertook the NNS survey over a 13-month period (1995 to early 1996). The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns were reported.

Chronic Dietary Exposure Assessment

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

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

In conducting chronic dietary exposure assessments, APVMA and FSANZ consider the residues that could result from the use of a chemical product on all foods. If specific data on the residues are not available then a cautious approach is taken and the MRL is used.

The residues that are likely to occur in all foods are then multiplied by the daily consumption of these foods derived from individual dietary records from the latest 1995 National Nutrition Survey (NNS). These calculations provide information on the level of a chemical that is consumed for each food and take into account the consumption of processed foods e.g. apple pie and bread. These calculations for each food are added together to provide the total dietary exposure to a chemical from all foods.

This figure is then divided by the average Australian's bodyweight to provide the amount of chemical consumed per day per kg of human bodyweight. This is compared to the ADI. It is therefore the overall dietary exposure to a chemical that is compared to the ADI - not the MRL. FSANZ considers that the chronic dietary exposure to the residues of a chemical is acceptable where the best estimate of this exposure does not exceed the ADI.

Further, where these calculations use the MRL they are considered to be overestimates of dietary exposure because they assume that:

- the chemical will be used on all crops for which there is a registered use
- treatment occurs at the maximum application rate
- the maximum number of permitted treatments have been applied
- the minimum withholding period has been applied
- this will result in residues at the maximum residue limit.

In agricultural and animal husbandry this is not the case, but for the purposes of undertaking a risk assessment, it is important to be conservative in the absence of reliable data to refine the dietary exposure estimates further.

Acute Dietary Exposure Assessment

The National Estimated Short Term Intake (NESTI) is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated for raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis.

The NESTI is calculated in a similar way to the chronic dietary exposure. The residues of a chemical in a specific food are multiplied by the 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 OCS and the Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey and the MRL when the data on the actual residues in foods are not available. FSANZ considers that the acute dietary exposure to the residues of a chemical is acceptable where the acute dietary exposure does not exceed the ARfD.

SUMMARY OF SUBMISSIONS RECEIVED

Submitter	Comments raised
Australian Food and Grocery Council	Supported option 2(b) to include new or increase some existing MRLs, however raised the possibility that negative impacts may result if option 2(a) to decrease or delete some existing MRLs is adopted. AFGC suggested that FSANZ should determine potential impacts on importation of commodities for which decreased and deleted MRLs have been proposed.
Department of Health South Australia	Supported this Application.
Department of Human Services Victoria	Supported this Application.
Food Technology Association of Victoria	Supported this Application.
Queensland Health	Supported this Application.