FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

5-05
3 August 2005

FINAL ASSESSMENT REPORT

PROPOSAL P297

MAXIMUM RESIDUE LIMITS – 2,4-D IN GRAPES

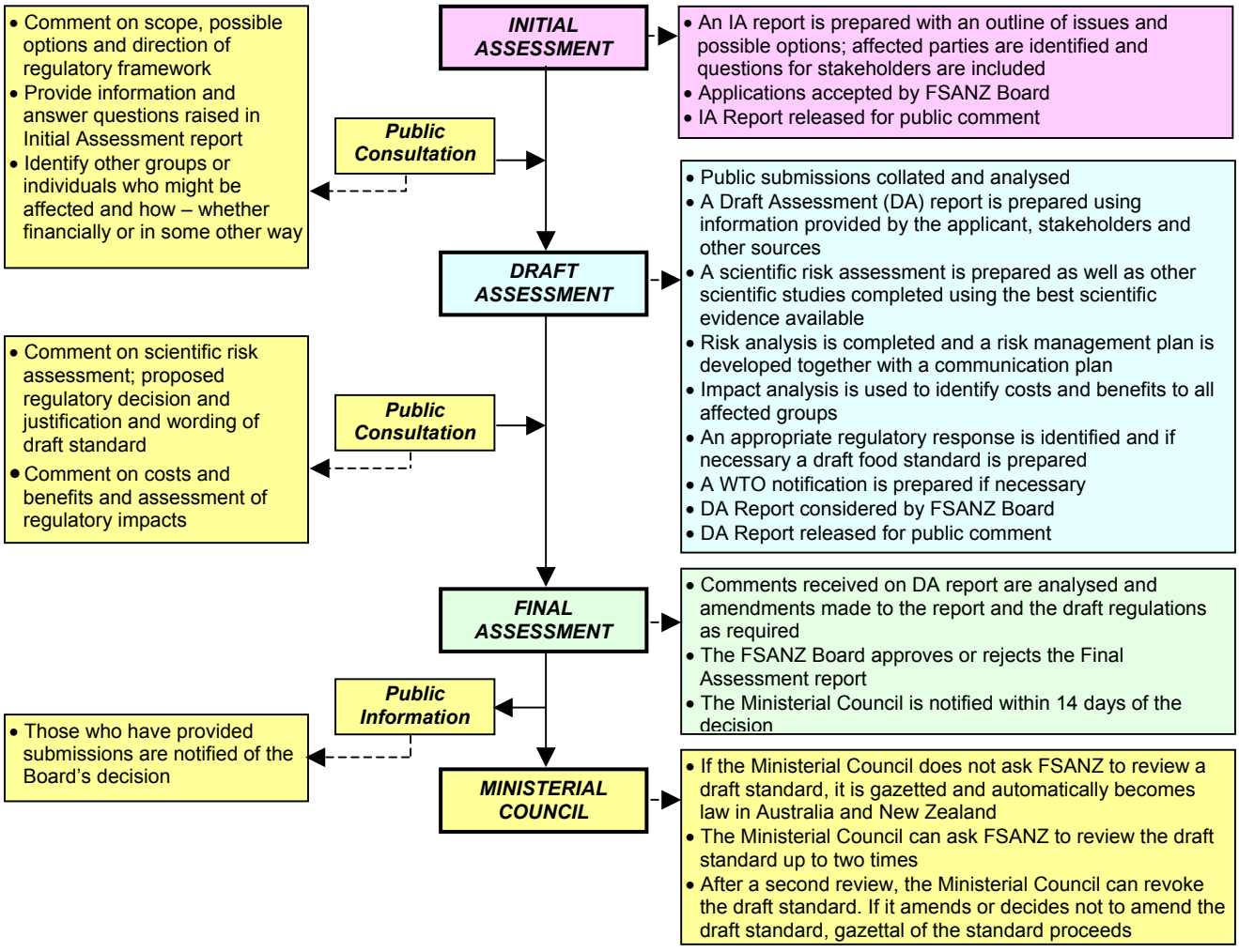
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Final Assessment Stage (s.36)

FSANZ has now completed the assessment of Proposal P 297 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.

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

Further Information

Further information on this Proposal and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general inquiries and requests for information.

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Executive Summary and Statement of Reasons

This Proposal (P297) seeks to establish a maximum residue limit (MRL) of *0.05 mg/kg[1] for 2,4-D in grapes in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* (the Code). The APVMA has issued a temporary permit for use of 2,4-D in vineyards and published an associated temporary MRL in grapes in the APVMA MRL Standard of *0.05 mg/kg. The Australian Pesticides and Veterinary Medicines Authority (APVMA) have submitted an Application to update the Code in order to reflect the proposed use of 2,4-D in vineyards in Australia.

In addition, low-level residues of 2,4-D have been detected in wine grapes. While the source of these residues has not been confirmed, the residues do not represent an unacceptable risk to public health and safety. The proposed temporary MRL in the Code also fortuitously addresses the problems created by the detection of these residues in food, and is considered an appropriate interim provision until policy is developed concerning low levels of residues in food. 2,4-D is a widely used herbicide and a number of MRLs already exist for 2,4-D in a range of foods.

The estimated chronic dietary exposure assessment indicates that residues associated with the proposed residue limit for 2,4-D for grapes do not represent an unacceptable risk to public health and safety.

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.

FSANZ made an SPS notification to the World Trade Organization.

Statement of Reasons

FSANZ recommends the establishment of a temporary MRL for the following reasons:

- The dietary exposure assessment indicates that the residues associated with the proposed temporary MRL of *0.05 mg/kg in grapes for 2,4-D does not represent an unacceptable risk to public health and safety.

- APVMA has assessed appropriate studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the temporary MRL of 2,4-D in grapes.

- The Office of Chemical Safety of the Therapeutic Goods Administration (OCS) of the Australian Government Department of Health and Ageing has undertaken an appropriate toxicological assessment of 2,4-D products and has established a relevant acceptable daily intake (ADI) of 0.01 mg/kg Bodyweight/Day.

[1] * refers to the establishment of an MRL at the Limit of Quantification as detailed in Section 1.2.

- FSANZ has undertaken a regulation impact assessment process. That process concluded that the amendment to the Code is necessary, cost-effective and of benefit to both producers and consumers.

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

1. Introduction

This Proposal (P297) seeks to establish a temporary maximum residue limit (MRL) of *0.05 mg/kg for 2,4-D in grapes in Standard 1.4.2 – Maximum Residue Limits of the Code. The APVMA has issued a temporary permit for use of 2,4-D in vineyards and submitted an Application to FSANZ to amend the Code in order to reflect the proposed use of 2,4-D in Australian vineyards.

Table 1

2,4-D Grapes	Insert T*0.05	2,4-D is a phenoxycarboxylic acid herbicide. APVMA have issued a permit for 2,4-D to be used to control weeds around dormant wine grape vines. Based upon the information provided to FSANZ about the residues detected in wine grapes, a temporary limit of *0.05 mg/kg would be appropriate. NEDI = 53% of the ADI.

2,4-D is used as a post-emergence herbicide. Products containing 2,4-D are used to control broadleaf and grass weeds in an extensive range of crops and non-cropping situations. Aerial, handheld and ground methods of application are used. Major agricultural uses of 2,4-D include pasture, stubble and fallow maintenance, cereal crops (including wheat, oats, barley, rye, triticale), grain crops (including sorghum, millet, maize) and oilseed crops (safflower, canola, rape). Other agricultural uses include cotton, citrus crops (particularly to inhibit post harvest abscission of buttons), sugar cane, sweet corn, peanuts and control of banana suckers. 2,4-D is also used extensively for weed control in non-cropping situations, including commercial and industrial areas, turf, forestry and aquatic areas.

1.1 Phenoxycarboxylic acid

2,4-D belongs to the phenoxycarboxylic acid class of herbicides; other chemicals in this class include 2,4-DB, clomeprop, dichlorprop, dichlorprop-P, MCPA and MCPB.

1.2 Limit of Quantification

The proposed MRL for 2,4-D in grapes is at the limit of quantification (LOQ) and is indicated by an *. 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. 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.

1.3 MRLs for Permits

The proposed MRL for 2,4-D in grapes is temporary and is indicated by a ‘T’. These MRLs may include uses associated with:

- the APVMA minor use program;
- off-label permits for minor and emergency uses; or

- trial permits for research.

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

2. Regulatory Problem

2.1 Current Standard

Currently in Standard 1.4.2, 2,4-D has well established MRLs in a range of commodities (Table 2). Therefore, residues are expected in a range of foods currently on the Australian market.

Table 2

2,4-D 2, 4-D	
CEREAL GRAINS	0.2
CITRUS FRUITS	5
EDIBLE OFFAL (MAMMALIAN)	2
EGGS	*0.05
LEGUME VEGETABLES	*0.05
LUPIN (DRY)	*0.05
MEAT (MAMMALIAN)	0.2
MILKS	*0.05
OILSEED	*0.05
PEAR	*0.05
POTATO	0.1
POULTRY, EDIBLE OFFAL OF	*0.05
POULTRY MEAT	*0.05
PULSES	*0.05

In respect of 2,4-D residues in grapes, the APVMA has amended the MRLs in its APVMA MRL Standard as a result of recently granting a temporary permit for 2,4-D in vineyards. Therefore, there will be a discrepancy between the APVMA MRL Standard and the Code for MRLs of 2,4-D in grapes.

3. Objective

The objective of this Proposal 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 temporary permit the legal sale of food that has been legally treated. The APVMA has established a temporary MRL for 2,4-D under the APVMA's legislation, and FSANZ seeks to include the amendments in the Code.

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

- the protection of public health and safety;

- the provision of adequate information relating to food to enable consumers to make informed choices; and

- the 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; and

- any written policy guidelines formulated by the Ministerial Council.

None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed establishment of this new MRL for 2,4-D in grapes in Standard 1.4.2.

4. Issues

4.1 2,4-D in grapes

4.1.1 Use of 2,4-D in vineyards

As a result of recently issuing a temporary permit for proposed use of 2,4-D in vineyards, the APVMA is making an Application to FSANZ for a temporary MRL of *0.05 mg/kg for 2,4-D in grapes.

4.1.2 2,4-D residues in wine grapes

Low level residues of 2,4-D have been detected in wine grapes. While not the intention of the APVMA's proposed MRL, the proposed temporary MRL fortuitously addresses the problems created by the detection of these residues, and is considered an appropriate interim provision until policy regarding low levels of residues in food is developed.

4.2. Public Health and Safety Considerations

4.2.1 Toxicological assessment

The Office of Chemical Safety advised FSANZ that the Australian ADI for 2,4-D is 0.01 mg/kg bw/day, based on a No-Observed-Effect-Level (NOEL) of 1 mg/kg bw/day in 2-year (chronic dosing) feeding study in rats. The Joint Meeting on Pesticides Residues (JMPR) conducted various reviews on 2,4-D from the period in 1970s to 1998. JMPR concluded in 1998 that that the intake of residues of 2,4-D resulting from uses considered by JMPR is unlikely to present a public health concern in the long-term.

JMPR also considered short-term exposure in 2000 and concluded that there was unlikely to be a risk to consumers in the short-term.

4.2.2 Estimated dietary exposure assessments

No acute reference dose (ARfD) has been established for 2,4 D, therefore a National Short Term Estimated Intake (NESTI) was not calculated by FSANZ. There have also been no recent surveys of residue levels of 2,4-D for grapes in the 18th, 19th or 20th Australian Total Diet Surveys (ATDS).

The current National Estimated Dietary Intake (NEDI) of the potential residues of 2,4-D in food is 53% of the ADI[2]. The NEDI was calculated by incorporating the proposed APVMA MRL of 0.05 mg/kg for 2,4-D in grapes and using supervised median trial residue data from JMPR (1991) for all food commodities with an established MRL in the Code.

On the basis of results from the NEDI, FSANZ considers that chronic dietary exposure to the potential residues associated with MRLs for 2,4-D would not represent an unacceptable risk to public health and safety for any population group. Furthermore, the use of the APVMA proposed temporary MRL of 0.05 mg/kg covers the range of residue levels for 2,4-D detected in Australian wine grapes.

In conclusion, on the evidence available on residues of 2,4-D in grapes and wine from the wine industry, FSANZ does not believe that there are any public health and safety issues associated with the consumption of the grapes or grape products.

5. BACKGROUND

5.1 Maximum Residue Limits

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

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

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

[2] The ADI is the level at which there are no public health and safety concerns following prolonged exposure to a chemical in the diet.

In summary, the MRLs in APVMA's MRL Standard are used in some jurisdictions to assist in regulating the use of agricultural and veterinary chemical products under State and Territory 'control-of-use' legislation. Whereas the MRLs in the Code apply in relation to the sale of food under State and Territory food legislation and the inspection of imported foods by the Australian Quarantine and Inspection Service.

5.2 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.

5.3 Trans Tasman Mutual Recognition Arrangement

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

- food produced or imported into Australia, which complies with Standard 1.4.2 of the Code can be legally sold in New Zealand; and

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

5.4 International regulation of 2,4-D in grapes

MRLs are in place overseas for the use of 2,4-D on grapes. A limit of 0.05 mg/kg is in place in the EU (including Belgium, Finland, Greece, Ireland, Poland and the UK), Kenya and the Netherlands. Spain has an established MRL of 0.1 mg/kg and the USA, Japan and Korea have set an MRL of 0.5 mg/kg. The Codex standard is 0. 1 mg/kg for residues of 2,4-D in berries and other small fruits.

5.5 Analytical Methods

While a variety of methods may be used, a common method for detection of 2,4- D residues involves homogenising the sample, followed by alkaline hydrolysis and then clean-up of the filtered supernatant with solid phase extraction (SPE) cartridges. The SPE cartridges are washed and 2,4-D residues are eluted with methanol, dichloromethane/methanol containing tetrabutyl ammonium chloride which is then evaporated to dryness. The residues are then acidified and extracted into pentane/ether, which is then evaporated. The residues are then dissolved in acetonitrile and tetrabutyl ammonium fluoride and residues are quantified by liquid chromatography / mass spectrometry / mass spectrometry.

6. Issues raised in public submissions

Fourteen submissions were received during the period 2 to 12 May 2005 (Attachment 4). Seven submissions were in support with seven opposed to the establishment of an MRL for 2,4-D in grapes.

6.1 Submissions from AFGC, Queensland Health, NSW Food Authority, Department of Human Services (Victoria), FT Victoria, SA Department of Health, Winemakers' Federation of Australia supporting establishment of an MRL for 2,4-D in grapes

These submissions supported the temporary permit and establishment of an MRL for 2,4-D in grapes based on the grounds that there are no identified public health and safety issues and that the use is controlled by the APVMA on a restricted basis. One of the submitters suggested that the MRL should only be granted on the proviso that the residue levels of 2,4-D in grapes and grape products be assessed in the 25th Australian Total Diet Survey (ATDS).

6.1.1 Evaluation

FSANZ will consider the inclusion of 2,4-D in a future ATDS in consultation with State and Territories, as one of the options available for monitoring of 2,4-D in wine grapes.

6.2 Submissions from Organic Federation of Australia, SA Genetic Food Information Food Network, Seedsavers, Organic Vignerons, Environmental Defenders Office (SA), Temple Bruer Wines Pty Ltd, Soil Association of South Australia Inc. opposed to the establishment of an MRL for 2,4-D I grapes

The submissions were opposed to the MRL on the following basis:

- The MRL should not be established due to public health and safety issues;

- Australian regulatory authorities should concentrate on stopping the source of the contamination rather than trying to legitimise the contamination. Approval of the MRL will threaten existing certified organic grape growers/winemakers if residues of 2,4-D are founds and result in Australian grape growers and wineries losing access to the worlds fastest growing market, the organic market;

- The legal consequences for sectors of the industry (e.g. organic growers) in regard to organic certification and the subsequent loss of markets.

6.2.1 Evaluation

FSANZ considers that there are no public health and safety concerns from dietary exposure to 2,4-D at the residue levels reported in these grapes as detailed in Section 4.2. The OCS has undertaken an extensive toxicological evaluation and an ADI is established. FSANZ undertook an exposure evaluation and concluded that the ADI was not exceeded and consequently there are no public health and safety issues in regard to exposure to 2,4-D in grapes in the diet (this dietary exposure evaluation also included other commodities where residues of 2,4-D may be found).

In addition, an international recognised Committee (JMPR) concluded in 1998 that the intake of residues of 2,4-D resulting from uses considered by JMPR is unlikely to present a public health concern in the long-term. The State Health Departments that made a submission to FSANZ, also supported FSANZ's conclusions on public health and safety.

Although control of the source of contamination is not an issue that FSANZ can address, FSANZ has been advised that the APVMA is investigating the issue of vapour and/or spray drift[3] onto vineyards. The investigation may result in changes to agricultural practice, to ensure grape crops are not inadvertently contaminated. The Department of Agriculture Fisheries and Forestry Australia is also liaising with its State and Territory counterparts on the issue of vapour and/or spray drift.

FSANZ notes concerns about the potential consequences for particular industry sectors if an MRL for 2,4-D in grapes is approved, and in particular the potential effect on organic certification of growers. However, such growers may take appropriate action to seek compensation for damages resulting from the consequences of use of chemicals by third parties, under statute or common law. FSANZ notes that the MRL will not have retrospective effect.

7. Options

7.1 Option 1 – *Status quo* – no change to the existing MRLs for 2,4-D 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.

7.2 Option 2 – adopt the changes to include new MRLs for 2,4-D in grapes

Under this option, the temporary residue limit for 2,4-D would be approved for inclusion into the Code.

8. Affected Parties

The parties affected by proposed MRL amendments include:

- consumers, including domestic and overseas customers;
- growers and producers of domestic and export grape products;
- importers of grape products; 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.

[3] Spray drift can occur at the time of application of the pesticide. It is the movement of chemical droplets/particles through the air to an area outside the area intending to be sprayed. It can occur as a result of either aerial or ground application.
Some pesticides are more volatile than others and may be prone to vapour drift. Vapour drift occurs after the chemical has been sprayed on the target. Under certain environmental conditions the pesticide may vaporise from the target and move outside the target area.

9. 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.

9.1 Option 1 – *Status quo* – no change to the existing MRLs in the Code

9.1.1 Benefits

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to potential residues of the relevant agricultural and veterinary chemicals in food;

- for producers of food for both the domestic and export markets, the adoption of this option would not result in any discernable benefits;

- for importers of food, the adoption of this option would not result in any discernable benefits; and

- for Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable benefits.

9.1.2 Costs

- for consumers there are unlikely to be any immediate discernable costs as the unavailability of food from certain producers is likely to be seen as typical seasonal fluctuations in the food supply;

- for producers of grapes for both the domestic and export markets, the adoption of this option would result in costs resulting from not being able to legally sell food containing residues consistent with the proposed temporary residue limit. However, if the occurrence of these residues results in grapes that cannot be legally sold under food legislation then primary producers will incur substantial losses. Losses for primary producers would in turn impact negatively upon rural and regional communities; and

- for importers of food, the adoption of this option would not result in any discernable costs.

9.2 Option 2 – adopt the changes to include new MRLs for 2,4-D in grapes

9.2.1 Benefits

- for consumers, the major benefit would be potential flow on benefits resulting from the price and availability of food if producers can legally sell such products containing residues consistent with the temporary residue limit;

- for producers of food for both the domestic and export markets, the benefits of this option would result from being able to legally sell food containing residues consistent with the temporary residue limit;

- for importers, the adoption of this option would result in the benefit that food products which contained residues consistent with MRL additions could be legally imported; and

- for Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable benefits.

9.2.2 Costs

- for consumers there are no discernable costs;

- for producers of food for both the domestic and export markets, the adoption of this option would not result in any discernable costs;

- for importers, the adoption of this option would not result in any discernable costs; and

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

10. Consultation

10.1 World Trade Organization

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

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

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

MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases. MRLs are also used as standards for the international trade in food.

This Proposal contains MRLs, which are addressed in the international Codex Standard. The proposed MRLs also relate to production of traded grape products that may indirectly have a significant effect on trade between WTO members.

FSANZ made a Sanitary and Phytosanitary 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 made a submission on this Application.

10.1.1 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 Proposal, which are addressed in the international Codex standard.

Table 3

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
2,4-D Grapes	T*0.05	0.1 (Berries and other small fruit)

The proposed MRL is lower than the Codex MRL as the lower level is consistent with the proposed use of 2,4-D in vineyards and addresses the problems associated with the low level residues that have been detected in wine grapes.

11. Conclusion

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

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

FSANZ's preferred approach is to adopt Option 2 – adopt the changes to include a new MRL for 2,4-D for grapes.

FSANZ prefers this approach because:

- the residues associated with the MRL amendments would not result in an unacceptable risk to public health and safety (this benefit also applies to Option 1);

- the changes would remove discrepancies between agricultural and food legislation and assist enforcement.

12. Implementation and Review

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

- State and Territory residue monitoring programs;

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

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

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

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

13. Recommendation

FSANZ recommends the establishment of a temporary MRL for the following reasons:

- The dietary exposure assessment indicates that the residues associated with the proposed temporary MRL of *0.05 mg/kg in grapes for 2,4-D does not represent an unacceptable risk to public health and safety.

- APVMA has assessed appropriate studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the temporary MRL of 2,4-D in grapes.

- The Office of Chemical Safety of the Therapeutic Goods Administration (OCS) of the Australian Government Department of Health and Ageing has undertaken an appropriate toxicological assessment of 2,4-D products and has established a relevant acceptable daily intake (ADI) of 0.01 mg/kg Bodyweight/Day.

- FSANZ has undertaken a regulation impact assessment process. That process concluded that the amendment to the Code is necessary, cost-effective and of benefit to both producers and consumers.

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

ATTACHMENTS

1. Draft Variation to the *Australia New Zealand Food Standards Code*
2. Notes on Terms
3. Background to Dietary Exposure Assessments
4. Summary of submissions

Attachment 1

Draft Variation 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 inserting in alphabetical order in* Schedule 1*, the food and associated MRL for the following chemical –*

2,4-D 2, 4-D	
GRAPES	T*0.05

Attachment 2

Notes on Terms

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

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

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

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

NESTI - National Estimated Short Term Intake - The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated based on consumption of raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis. FSANZ has used ARfDs set by the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey (NNS) and the MRL when the STMR is not available to calculate the NESTIs.

Attachment 3

Background To Dietary Exposure Assessments

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

FSANZ's primary role in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential residues in treated food do not represent an unacceptable risk to public health and safety. In assessing the public health and safety implications of chemical residues, FSANZ considers the dietary exposure to chemical residues from all foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will not approve MRLs for inclusion in the Code where the dietary exposure to the residues of a chemical could represent an unacceptable risk to public health and safety. In assessing this risk, FSANZ conducts dietary exposure assessments in accordance with internationally accepted practices and procedures.

The three steps undertaken in conducting a dietary exposure assessment are the:

- determination of the residues of a chemical in a treated food;
- determination of the acceptable health standard for a chemical in food (i.e. the acceptable daily intake and/or the acute reference dose); and
- calculating the dietary exposure to a chemical from all foods, using food consumption data from nutrition surveys and comparing this to the acceptable health standard.

Determination of the residues of a chemical in a treated food

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

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

Determination of the acceptable health standard for a chemical in food

TGA assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where applicable, the ARfD for a chemical.

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

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

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

Calculating the dietary exposure

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

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

Chronic Dietary Exposure Assessment

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

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

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

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

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

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

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

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

Attachment 4

SUMMARY OF SUBMISSIONS

Submitter	Comment
Winemakers' Federation of Australia (WFA)	**Supports** the establishment of an MRL of 0.05 mg/kg for 2,4-D in grapes. The WFA strongly supports a review of existing controls on the use of 2,4-D.
Australian Food and Grocery Council	**Supports** the temporary permit for 2,4-D in grapes on the grounds that there are no identified public health and safety issues and the use is controlled by the APVMA on a restricted basis.
Environmental Health Unit, Queensland Health	**Supports** option 2 on the proviso that the residue levels of 2,4-D in grapes and grape products be assessed in the 25th Australian Total Diet Survey. Supports the need for action to control spray drift.
NSW Food Authority	**Supports** option 2-setting of a temporary MRL for wine and grapes
Department of Human Services Victoria	**Supports** option 2 based on no public health and safety risks and that the proposal contains MRLs addressed in the Codex Standard.
Food technology Association of Victoria	**Supports** option 2 to adopt the changes to Standard 1.4.2 to include an MRL for 2,4-D in grapes.
Environmental Health Service of the SA Department of health	**Supports** option 2 as there are no identified health issues.
Organic Federation of Australia	**Opposes** the proposed MRL and believes that Australian regulatory authorities should concentrate on stopping the source of the contamination rather than trying to legitimise the contamination. Approval of the MRL will threaten existing certified organic grape growers/winemakers if residues of 2,4-D are found and result in Australian grape growers and wineries losing access to the worlds fastest growing market, the organic market.
SA Genetic Food Information Food Network	**Opposes** option 2 because 2,4-D has potential adverse health effects, it is inappropriate to establish an MRL in grapes to legitimise spray drift and is compromises the sale of organic wine overseas.
Seedsavers	**Opposes** option 2 because 2,4-D has potential adverse health effects, it is inappropriate to establish an MRL in grapes to legitimise vapour drift and it compromises the sale of organic wine overseas.
Organic Vignerons	**Opposes** option 2 . The Australian Wine Industry should stand firm and accept a zero residue. Wine with 2,4-D residues should be discarded, rather than an MRL established. Organic wine industry will be affected and the source of the contamination should be dealt with to stop this situation occurring.

Submitter	Comment
Environmental Defenders Office (SA)	**Opposes** option 2 based on adverse effects to the environment and public health. Particularly concerned that setting an MRL will have legal consequences for that section of the industry that seeks to minimise or avoid chemical use. Organic producers are at risk of compromising their organic certification, which can have serious economic consequences for producers.
Temple Bruer Wines Pty Ltd	**Opposes** option 2. Does not agree with the toxicological assessment. Organic certifiers will tolerate no residues of 2,4-D in grapes. Recommend to FSANZ and APVMA to move immediately to ban the sale, possession and use of 2,4-D Australia wide and that no MRL for 2,4-D be established on wine.
Soil Association of South Australia Inc.	**Opposes** option 2. Permitting an MRL for 2,4-D in grapes will place Australia's wine industry at risk and also Australia's 'clean and green' image. Raised similar issues to previous submitters in regard to public health and safety issues and the economic consequences for organic growers if the MRL is approved.