



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

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FINAL ASSESSMENT REPORT

APPLICATION A478

**DELETION OF CERTAIN BRASSICA AND LEAFY
VEGETABLES MRLS FOR ENDOSULFAN**

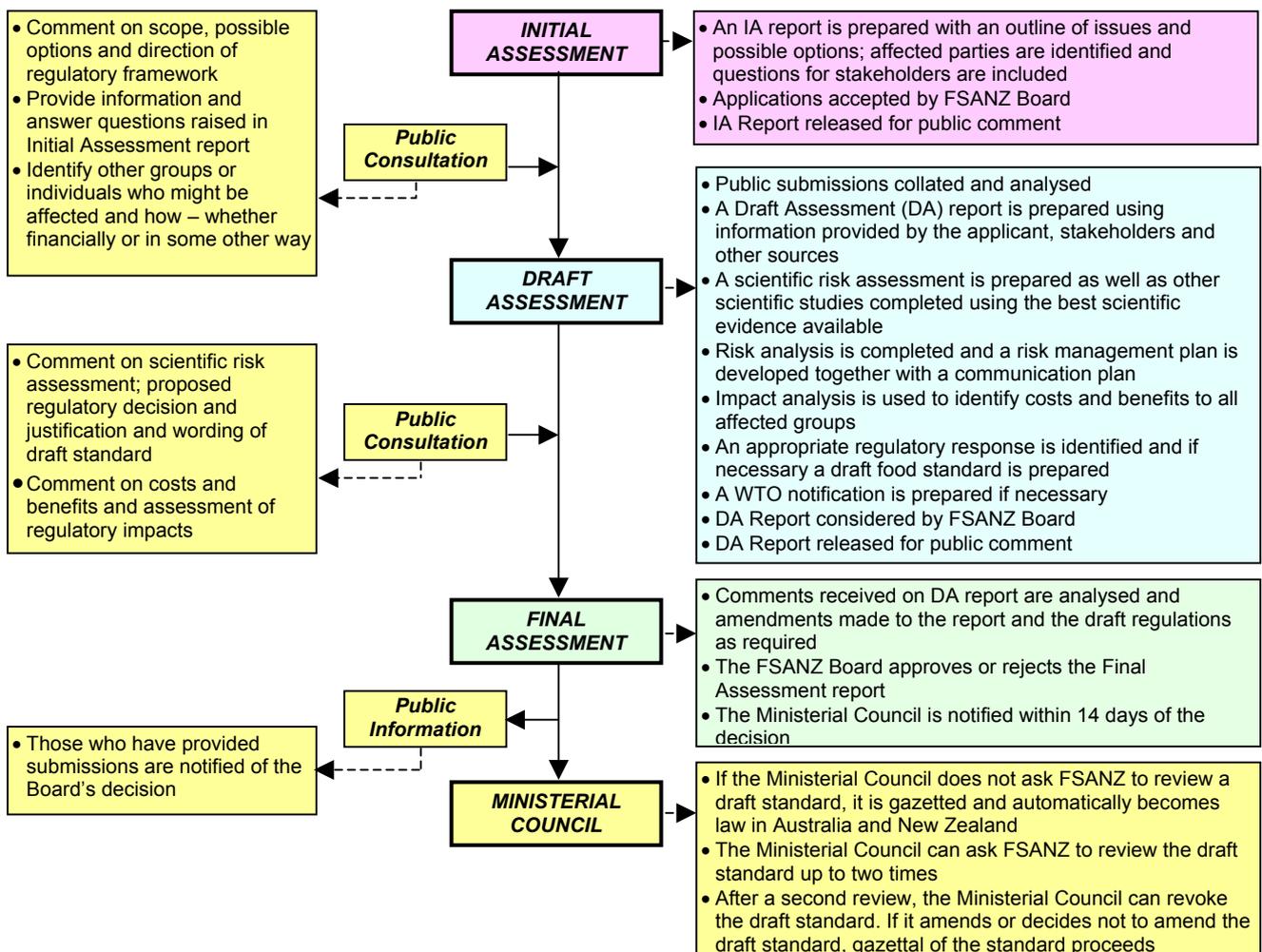
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Final Assessment Stage

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

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

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

Submissions

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

Further Information

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

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Executive Summary

This Application (A478) seeks to amend the Maximum Residue Limits (MRLs) for the insecticide endosulfan in brassica and leafy vegetables in the *Australia New Zealand Food Standards Code*. It is an application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the Code in order to reflect the current registration status of endosulfan use in Australia and to remove the MRLs that are no longer necessary.

The NRA has amended the registration of endosulfan products to prohibit their use on Brussels sprouts and leafy vegetables. As a result the NRA has proposed the deletion of endosulfan MRLs for these foods.

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

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

Statement of Reasons

FSANZ recommends progressing the Application for the following reasons:

- New residue trials data assessed by the NRA as part of its Existing Chemicals Review Program has shown that the current use of endosulfan on some vegetables may result in residues that represent an unacceptable risk to public health and safety. Specifically, estimates of the acute dietary exposure indicate that the acute reference dose may be exceeded from the current use on Brussels sprouts and the leafy vegetables, silver beet, Chinese cabbage, choy sum, all lettuce varieties, cress, Japanese greens (mizuna and Indian mustard), spinach, pak choi and bok choi.
- This Application proposes that the existing MRLs of 2 mg/kg for the commodity groups Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas and Leafy vegetables (including brassica leafy vegetables) be amended to specifically remove MRLs for all those commodities for which there may be an unacceptable risk to public health and safety. The MRLs for the specific commodities of broccoli, cabbage head and cauliflower need to be retained as the current use of endosulfan on these vegetables would result in residues that do not present an unacceptable risk to public health and safety.
- The dietary exposure assessments indicate that the residues associated with the proposed MRLs for endosulfan do not represent an unacceptable risk to public health and safety. The NRA has already amended the registration status of endosulfan and the rejection of the proposed MRLs would leave MRLs in the Code that do not reflect this amended registration status.

- The NRA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997*, to support the deletion of the use of this chemical on the commodities as outlined in this Application.
- The Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Ageing has undertaken an appropriate toxicological assessment of endosulfan and has established an ADI and the ARfD.
- None of FSANZ's section 10 objectives of food regulatory measures are compromised by the proposed changes.
- FSANZ has undertaken a preliminary regulation impact assessment process. That process has concluded that the amendment to the *Food Standards Code* is necessary, cost-effective and of benefit to both producers and consumers.

1. Introduction

An Application was received from the NRA on 25 September 2002 seeking to delete certain MRL entries for the insecticide and acaricide endosulfan from Schedule 1 of Standard 1.4.2 of the *Australia New Zealand Food Standards Code*. The proposed amendments to the Standard would align MRLs for this chemical in the Code with the registration status for this chemical and with the MRLs in the NRA MRL Standard.

The NRA has assessed the use of endosulfan as part of its Existing Chemical Review Program (ECRP). While the review is at an interim stage, the data reviewed by the NRA indicated the use of endosulfan on certain commodities may result in an unacceptable risk to public health and safety. As a result, the NRA prohibited the use of endosulfan on these commodities.

1.1 Summary of the proposed MRLs

Currently, Standard 1.4.2 includes temporary endosulfan MRLs of 2 mg/kg for the vegetable groups:

- Brassica (Cole or Cabbage) vegetables, head cabbages and flowerhead brassicas; and
- Leafy vegetables (including brassica leafy vegetables).

This Application proposes that endosulfan MRLs for the food group ‘Leafy vegetables (including Brassica leafy vegetables)’ and the commodity Brussels sprouts be deleted.

To give effect to the deletion of MRL for Brussels sprouts it is necessary to delete the group MRL entry for ‘Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas’ and then include entries for the individual brassica vegetables: broccoli, head cabbage and cauliflower. The proposed MRL changes are summarised in the following table.

Chemical Food	MRL (mg/kg)	Information	
Endosulfan			
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas.	Delete	T2	This chemical is a cyclodiene organochlorine and is used to control insects and acarids on vegetable, fruit and grain crops.
Broccoli.	Add	T2	
Head cabbages.	Add	T2	
Cauliflower.	Add	T2	
Leafy vegetables (including Brassica leafy vegetables).	Delete	T2	

The MRLs for broccoli, head cabbage and cauliflower remain unchanged by this Application.

2. Regulatory Problem

2.1 Current Regulations

The NRA has amended the registration of endosulfan products to prohibit their use on Brussels sprouts and leafy vegetables. As a result the NRA has deleted endosulfan MRLs for these foods from the NRA MRL Standard.

As a result there is now a discrepancy between the residues associated with the use and the MRLs in the Code. This will mean that food may be legally sold under food legislation even though they contain residues that are inconsistent with the current registered uses of endosulfan.

3. Objective

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

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

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 10 of the *Food Standards Australia New Zealand Act 1991*. These are:

3.1.1 The protection of public health and safety

The Office of Chemical Safety of the TGA establish the ADI and where applicable the ARfD for the agricultural and veterinary chemicals. The NRA and FSANZ carry out estimations of dietary exposure to agricultural and veterinary chemicals and compare them to the TGA standards. Based on dietary exposure assessments, the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

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

This is not relevant for this Application.

3.1.3 The prevention of misleading or deceptive information

This is not relevant for this Application.

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

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

FSANZ considers proposed MRLs in accordance with the best available scientific evidence. The procedures adopted by FSANZ, the TGA and the NRA are based on a comprehensive examination of up to date detailed scientific information. That includes a rigorous toxicological assessment and dietary exposure assessments undertaken in accordance with international protocols.

3.1.5 The promotion of consistency between domestic and international food standards

This is addressed in section 10.

3.1.6 The desirability of an efficient and internationally competitive food industry

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

3.1.7 The promotion of fair trading in food

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

4. Background

4.1 The use of agricultural and veterinary chemicals

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

The NRA's ECRP has reviewed the registration of endosulfan. This program reconsiders the registration of existing agricultural and veterinary chemicals in the market place where potential risks to safety and performance of chemicals has been identified. A review may be initiated when new research or evidence has raised concerns about the use and safety of a particular chemical.

In February 2001, the NRA made an Application (A426) to include temporary MRLs for Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas and Leafy vegetables (including brassica leafy vegetables). In that application the NRA stated that changes to the MRLs for endosulfan would allow the NRA to manage its use on an interim basis while more data on worker safety and commodity residues are developed to determine specific requirements in those areas necessary for its ongoing use. This Application was subsequently approved by the then Australia New Zealand Standards Council.

Recent assessment of new residue trials data generated from the NRA review of endosulfan has found that residues in some brassica vegetables and the group, leafy vegetables are in excess of the MRL and the estimated acute dietary exposure exceeds ARfD. As a result, the NRA has taken action to prohibit the use of endosulfan on Brussels sprouts and leafy vegetables.

4.2 Maximum Residue Limit applications

The NRA has made an application to FSANZ to adopt the proposed MRLs for endosulfan in Standard 1.4.2 of the Code. FSANZ has reviewed the information provided by the NRA and has validated that the dietary exposure is within agreed safety limits.

FSANZ is satisfied that residues associated with the proposed MRLS do not represent an unacceptable risk to public health and safety. FSANZ will now notify the Australia and New Zealand Food Regulation Ministerial Council, which is made up of Commonwealth, State and Territory and New Zealand Health Ministers, of the adoption of the variation to the Code. If the Council accepts the changes made by FSANZ, the MRLs are automatically adopted by reference under the food laws of the Commonwealth and the Australian States and Territories.

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

4.3 Maximum Residue Limits

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

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

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

As stated above, the NRA includes MRLs in its NRA MRL Standard when they register a chemical product for use or grant a permit for use. The NRA then notifies FSANZ of these MRLs so that FSANZ may consider them for inclusion into the Code.

In relation to MRLs, FSANZ's role is to ensure that the potential residues in food do not represent an unacceptable risk to public health and safety. FSANZ will not 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.

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

4.4 Food Standards-setting in Australia and New Zealand

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

4.5 Trans Tasman Mutual Recognition Arrangement

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

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

4.6 MRLs for Permits

The proposed MRLs in this Application are temporary and are indicated by a ‘T’ in the table in Section 1.1 of this report. These MRLs are still under review by the NRA and may be amended as further data is received.

FSANZ does not issue permits or grant permission for the temporary use of agricultural and veterinary chemicals. Further information on MRLs for permits can be found on the website of the NRA at <http://www.nra.gov.au> or by contacting the NRA on +61 2 6272 5158.

5. Evaluation of Issues Raised in Public Comment

The submission from the Food Technology Association of Victoria supported this Application. Submissions from the Australian Food and Grocery Council and the Department of Agriculture Fisheries and Forestry - Australia (AFFA) support the application. The submission from Public Health Services - Queensland Health sought clarification on the estimated acute dietary exposure.

Submissions expressed concerns about the following:

- clarification of acute dietary exposure estimates;
- Codex standards;
- cumulative effect of the estimated acute dietary exposure for the potential residues of endosulfan for broccoli, cabbage head and cauliflower;
- examination of the proposed MRL for endosulfan for broccoli
- imported vegetables; and
- residues resulting in potential soil contamination.

5.1 Clarification of acute dietary exposure estimates

Public Health Services of Queensland Health (PHS) sought clarification about acute dietary exposure estimates.

The ARfD is the estimate of the amount of a substance in a specific 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. The WHO/FAO Joint Meeting on Pesticide Residues (JMPR) and the Department of Health and Ageing establish the ARfDs.

The NRA and FSANZ have agreed protocols to estimate the dietary exposure for residues of chemicals in commodities. The agreed protocols are based on those used by the JMPR and endorsed by the Codex Committee on Pesticide Residues. Australia uses consumption data from the Australian NNS and the unit weights for the commodities from the *Information Gathered on Unit Weights of Individual Fruit and Vegetable Commodities* published by the Queensland Department of Primary Industries.

The estimated acute dietary exposure is likely to be an overestimation of the acute exposure to residues of a given chemical in a given commodity. This overestimation reflects the fact that FSANZ and the NRA include an assessment of the high consumers of particular foods. There are three factors that may result in this over estimation.

Firstly, the consumption figure used is the large portion consumed, that is the 97.5th percentile of eaters' consumption per day for the food. As this consumption is based on one-day dietary records, this figure is a conservative overestimation of the consumption. Secondly, where available, the estimation uses the highest residue of the edible portion found from the supervised trial data. However, on many occasions, where there are no residue data, the MRL is used and this results in an even greater overestimation of the acute dietary exposure as MRLs represent the maximum permitted level and not the levels actually found in the commodity. Finally the calculation incorporates a variability factor for the residues that provides an allowance to take into account higher residue levels than the values found.

Given these conservative assumptions and as the estimated acute dietary exposure for endosulfan for broccoli does not exceed the ARfD, FSANZ considers that the residues associated with broccoli do not represent an unacceptable risk to public health and safety.

5.2 Codex Standards

AFFA expressed concerns that:

That the departure from the Codex standard raises the question whether Australia should seek a review of the relevant Codex provision based on new scientific evidence.

The NRA as part of its ECRP is still reviewing the use of endosulfan. FSANZ considers that before Australia seeks a review of the relevant Codex provisions it would be prudent to await the final report from ECRP. FSANZ is also aware that the Joint FAO/WHO Meeting on Pesticide Residues will be carrying out a full review of this chemical in 2003.

5.3 Cumulative effect of the estimated acute dietary exposure for the potential residues of endosulfan for broccoli, cabbage head and cauliflower.

The PHS submission stated:

It is noted if a 2 to 6 year old was to consume the three vegetables in question, the NESTI would be well over 100%.

This is not correct because the estimated acute dietary exposure for food groups are not calculated in that manner. FSANZ has carried out an estimated acute dietary exposure for the brassica (cole or cabbage) vegetable group that includes broccoli, Brussels sprouts, cabbage, cauliflower and kohlrabi.

This estimation gave a result of 73% of the ARfD for the 2 to 6 year old population. This result came about because, using food consumption amounts measured in the NNS, an individual would not eat the large portion sizes of broccoli, Brussels sprouts, cabbage, cauliflower and kohlrabi in a single day. When an individual eats a large portion size of one commodity they then eat smaller portion sizes of the other related commodities.

Therefore, where an estimated acute dietary exposure is based on the highest consumption of one commodity it means that there would be a reduction in the amount of consumption of the other commodities when a cumulative estimated acute dietary exposure is calculated.

5.4 Examination of the proposed MRL for endosulfan for broccoli

The PHS had concerns that the proposed endosulfan MRL for broccoli may need ‘closer examination’. As stated in the Initial/Draft assessment Report the NRA is still assessing endosulfan as part of its ECRP. The NRA has stated that the proposed changes to the MRLs for this chemical would allow them to manage its use on an interim basis while more data on residues are developed. FSANZ will receive a copy of the final ECRP report for this chemical and expects, that at the end of the review, that the NRA will make further applications to amend the MRLs for this chemical.

5.5 Imported Vegetables

AFFA expressed concerns on the effect of the proposed deletion of these MRLs and the resultant possible trade implications for importers of food. Their submission advocated a transition period to minimise these implications. FSANZ proposes deleting these MRLs because the residues associated with the MRLs may pose an unacceptable risk to public health and safety, in that the ARfD may be exceeded. Given the public health and safety concerns, FSANZ considers that a transition period is inappropriate.

5.6 Residues Resulting in Potential Soil Contamination

AFFA expressed concerns about the possibility that residue levels of endosulfan in the soil may affect subsequent crops. This has occurred in the past with other organochlorine insecticides and Extraneous Maximum Residue Limits¹ (EMRLs) have been established in the *Food Standard Code* to address this. However, it would not be practicable for FSANZ to establish MRLs based on ‘possible’ soil contamination in the absence of supporting residue data on which EMRLs could be based.

¹ EMRL refers to a pesticide residue or contaminant arising from environmental sources (including former agricultural use) other than the use of a chemical or contaminant substance directly or indirectly on the commodity

6. FSANZ Assessment of the Proposed MRLs

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

6.1 The 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.

6.2 The National Estimated Dietary Intake

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

The NEDI for endosulfan is 78% of the ADI.

FSANZ considers that as the estimated chronic dietary exposure to the residues of endosulfan does not exceed the ADI there is no unacceptable risk to public health and safety.

6.3 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.

6.4 National Estimated Short Term Intake

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 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 the JMPR, the consumption data from the NNS, the MRL when the supervised trial meridian residue (STMR) is not available, and the unit weights for the commodities from the *Information Gathered on Unit Weights of Individual Fruit and Vegetable Commodities* published by the Queensland Department of Primary Industries to calculate the NESTIs.

The NESTI calculation incorporates the large portion (97.5 percentile) food consumption data and can take into account such factors as the highest residue on a composite sample of an edible portion; the 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.

To delete the MRL for Brussels sprouts it is necessary to delete the group MRL entry for 'Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas' and then include entries for the individual brassica vegetables: broccoli, head cabbage and cauliflower. NESTI calculations have been undertaken for those brassica commodities, which need to be retained following the deletion of their broader commodity group.

The following are the NESTIs for endosulfan for children 2 to 6 years old:

- broccoli was equal to 89% of the ARfD;
- head cabbages was equal to 17% of the ARfD; and
- cauliflower was equal to 12% of the ARfD.

The following are the NESTIs for endosulfan for the whole population:

- broccoli was equal to 32% of the ARfD;
- head cabbages was equal to 12% of the ARfD; and
- cauliflower was equal to 5% of the ARfD.

FSANZ considers that as the estimated acute dietary exposures to the residues of endosulfan in the above foods do not exceed the ARfDs, there is no unacceptable risk to public health and safety.

6.5 Australian Total Diet Survey

Data from the Australian Total Diet Survey (ATDS) are 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 calculations are theoretical calculations that conservatively overestimate exposure.

In the 18th (1996) ATDS the estimated dietary exposure to endosulfan was 2.72% of the ADI for children of 2 years old and 1.6% of ADI for the adult male population.

In the 19th (1998) ATDS the estimated dietary exposure to endosulfan was 1.1% of the ADI for boys of 12 years old and less than 1% of the ADI for the for the adult male population.

In the 20th (2000/2001) ATDS the estimated dietary exposure to endosulfan was less than 0.1% of the ADI for all population groups.

7. Options

7.1 Option 1 – accept the proposed changes to the existing MRLs in the *Australia New Zealand Food Standards Code*

Under this option, FSANZ would approve the changes to the MRLs for endosulfan in this Application.

7.2 Option 2 – status quo – do not accept the application and therefore no change to the existing MRLs in the *Australia New Zealand Food Standards Code*

Under this option, the status quo would be maintained and the *Food Standards Code* would not change and FSANZ would not approve any changes in the existing MRLs for endosulfan.

8. Affected Parties

The parties affected by proposed MRL amendments include:

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

9. Impact Analysis

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

9.1 Costs and benefits

9.1.1 Costs of accepting the application

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

9.1.2 Benefits of accepting the application

- the deletion of the endosulfan MRLs for Brussels sprouts and leafy vegetables (including Brassica leafy vegetables) will result in a reduction of the risk to public health and safety from the possible exposure to residues of this chemical;

- in the case of the MRLs for broccoli, head cabbage and cauliflower, produce treated with endosulfan will be able to be legally sold, resulting in improvements in public health and safety; and
- it will ensure consistency between the health and agricultural regulations.

9.1.3 Costs of not accepting the application

- the potential would exist for produce illegally treated with endosulfan to be sold, this may represent an unacceptable risk to public health and safety; and
- the discrepancies between the Code and the NRA MRL Standard would become greater, leading to confusion for producers, consumers and government agencies.

9.1.4 Benefits of not accepting the Application

- Products complying with the existing endosulfan MRLs could continue to be sold. This may represent an unacceptable risk to public health and safety.

9.2 Conclusion

The deletion of the endosulfan MRLs for Brussels sprouts and leafy vegetables (including Brassica leafy vegetables) is consistent with the current registered uses of endosulfan products. The dietary exposure assessments indicate that the residues associated with the proposed MRLs for broccoli, head cabbage and cauliflower do not represent an unacceptable risk to public health and safety. Therefore, accepting the requested changes (Option 1) will benefit all stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

10. Consultation

10.1 World Trade Organization Notification

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

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

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

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

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

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

10.2 Codex MRLs

The standards of the Codex Alimentarius Commission are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table sets out the proposed MRLs to be deleted, in the NRA application, that are more restrictive than the relevant Codex MRL.

Chemical Food	Proposed MRL	Codex MRL
Endosulfan Leafy vegetables (including Brassica leafy vegetables)	No detectable residues would be permitted.	The Codex MRLs are for: <ul style="list-style-type: none"> • Kale 1 mg/kg • Lettuce head 1 mg/kg • Lettuce, leaf 1 mg/kg • Spinach 2 mg/kg • Vegetables [except as otherwise listed] 2 mg/kg

FSANZ recognises that the proposed deletion of these MRLs may have implications for the importation of food. Therefore, FSANZ requested comments on the significance of the proposed departures from Codex MRLs and the possible impact on imported foods. No submissions were received specifically addressing concerns about the impact on imported foods having requirements more stringent than the relevant Codex MRLs.

10.3 Imported Foods

Agricultural and veterinary chemicals are used differently in countries other than in Australia because of different pests or diseases or because different products may be used. This means that residues in imported food, while still being safe for human consumption, may be different from that in domestically produced food.

Deletions or reductions of MRLs may affect imported food which may be complying with existing MRLs. That is, imported food may contain residues consistent with the MRLs proposed for deletion.

To assist in identifying possible impacts where imported food may be affected, FSANZ has compiled the following table that states the imported quantity of relevant foods for the years 2000 and 2001.

These data are for foods for which deletions of MRLs are proposed. FSANZ requested comment as to any possible ramifications for imports of the deletion of the MRLs in this Application. No submissions were received specifically addressing the importation of brassica or leafy vegetables.

Food	2000 Tonnes	2001 Tonnes
Brassica (cole or cabbage) vegetables, Head cabbages, flowerhead brassicas.	14	1
Leafy vegetables (including Brassica leafy vegetables)	2294	2680

11. Conclusion and Recommendation

The dietary exposure assessments indicate that the residues associated with the proposed MRLs for broccoli, head cabbages and cauliflower do not represent an unacceptable risk to public health and safety. The NRA has already restricted the use of endosulfan products and deletion of the endosulfan MRLs for Brussels sprouts and leafy vegetables (including Brassica leafy vegetables), from the Code, would reflect these restrictions. Therefore, accepting the requested changes will benefit all stakeholders by maintaining public health and safety while permitting the legal sale of food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

12. Implementation and Review

The use of endosulfan and its MRLs are the subject of the NRA's ECRP. In addition, regulatory agencies involved in the regulation of chemical products continue to monitor health, agricultural and environmental issues associated with the use of chemical products.

The residues in food are also monitored through:

- State and Territory residue monitoring programs;
- Commonwealth programs such as the National Residue Survey; and
- Dietary exposure surveys such as the Australian Total Diet Survey.

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

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

Attachments

1. Draft Variations to the *Australia New Zealand Food Standards Code*.
2. Summary of Public Submissions.
3. Glossary of Terms.

**DRAFT VARIATIONS TO THE
AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE**

To commence: On gazettal

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

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

ENDOSULFAN	
SUM OF A- AND B- ENDOSULFAN AND ENDOSULFAN SULPHATE	
BRASSICA (COLE OR CABBAGE) VEGETABLES, HEAD CABBAGES, FLOWERHEAD BRASSICAS	T2
LEAFY VEGETABLES (INCLUDING BRASSICA LEAFY VEGETABLES)	T2

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

ENDOSULFAN	
SUM OF A- AND B- ENDOSULFAN AND ENDOSULFAN SULPHATE	
BROCCOLI	T2
CABBAGE HEAD	T2
CAULIFLOWER	T2

ATTACHMENT 2

SUMMARY OF PUBLIC SUBMISSIONS

Submitter	Comments raised
Australian Food and Grocery Council	Supports the application.
The Department of Agriculture Fisheries and Forestry - Australia	Supports the application but suggested a phase in period.
Food Technology Association of Victoria	Supported the application
Public Health Services - Queensland Health	Sought clarification on the acute dietary exposure estimates.

GLOSSARY OF ACRONYMS

ADI	Acceptable Daily Intake
ANZFRMC	Australia and New Zealand Food Regulation Ministerial Council
AQIS	Australian Quarantine and Inspection Service
ARfD	Acute Reference Dose
ATDS	Australian Total Diet Survey
Codex	Codex Alimentarius Commission
DHA	Health and Ageing, Department of
ECRP	Existing Chemical Review Program
FSANZ	Food Standards Australia New Zealand
FSC	<i>Food Standards Code</i>
LOQ	Limit of Quantification
MRL	Maximum Residue Limit
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short Term Intake
NNS	National Nutrition Survey of Australia 1995
NRA	National Registration Authority for Veterinary and Agricultural Chemicals
RIS	Regulation Impact Statement
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
TGA	Therapeutic Goods Administration
TTMRA	Trans-Tasman Mutual Recognition Arrangement
WHO	World Health Organization
WTO	World Trade Organization