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

05/03
20 November 2002

INITIAL/DRAFT ASSESSMENT REPORT (s.36)

APPLICATION A478

DELETION OF CERTAIN BRASSICA AND LEAFY VEGETABLE MRLs FOR ENDOSULFAN

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
15 January 2003
(See "Invitation for Public Submissions" for details)

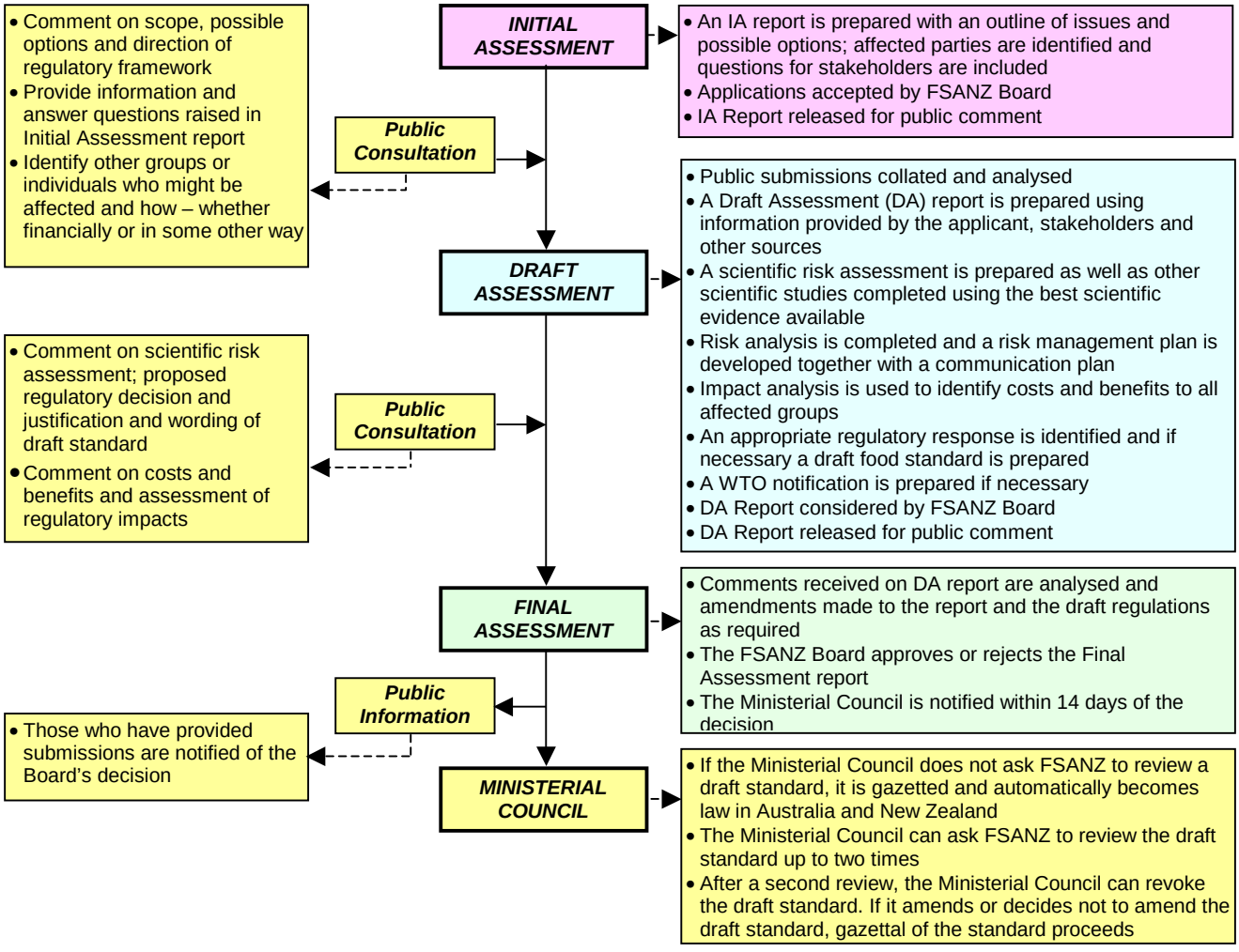
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 *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.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared an Initial/Draft Assessment Report for Application A478, which includes the identification and discussion of the key issues; and prepared a draft variation to Volume 2 of the *Food Standards Code.*

The Authority invites public comment on this Report based on regulation impact principles and the draft variation to Volume 2 of the *Food Standards Code* for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Final Assessment for this Application. Submissions should, where possible, address the objectives of the Authority as set out in Section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Food Standards Code* (the Code) from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority to treat in confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word "Submission" and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942

Submissions should be received by the Authority by: **15 January 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing **slo@foodstandards.gov.au**.

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

Further Information

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

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
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CONTENTS

Executive Summary and Statement of Reasons

Executive Summary

- This Application (A478) seeks to amend the Maximum Residue Limits (MRLs) for the insecticide endosulfan in brassica and leafy vegetables in the *Food Standards Code*. It is an application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the *Food Standards Code* in order to reflect the current registration status of endosulfan use in Australia and to remove those MRLs that may result in an unacceptable risk to public health and safety.

- On 1 October 2002, the NRA amended the registration for the use of endosulfan on brassica vegetables and leafy vegetables. Since the registration for the uses have been changed, legal residues will only occur in domestically grown broccoli, cabbages and cauliflower. Furthermore, the NRA will be amending their MRLs for endosulfan and will gazette the amendments to the MRLs for this chemical in the November 2002 NRA Gazette.

- On 24 November 2000, the then Australia New Zealand Food Standards Council adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). On 24 May 2002, the Ministerial Council agreed to vary the *Food Standards Code* to amend Standard A14 (Volume 1) by deleting schedules 1, 2 and 3 of that Standard and referring the schedules in Standard A14 to the MRL schedules of Standard 1.4.2. This created a single set of schedules for MRLs. Consequently, all amendments to MRLs are incorporated into schedules 1, 2 and 3 of Standard 1.4.2 of the *Food Standards Code* and all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

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

- The Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Ageing has undertaken an appropriate toxicological assessment of the agricultural chemical, endosulfan, and has established an acceptable daily intake (ADI) and the Acute Reference Dose (ARfD).

- 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.

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

- FSANZ will make a Sanitary and Phytosanitary notification to the World Trade Organization.

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, choi 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 *Food Standards 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 acaracide endosulfan from Schedule 1 of Standard 1.4.2 of the *Food Standards Code*. The proposed amendments to the Standard would align MRLs for this chemical in the *Food Standards 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 of the Agricultural and Veterinary Chemical Program. This review has shown that the current use of endosulfan on certain commodities may result in an unacceptable risk to public health and safety.

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

1.1 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, flowerhead brassicas; and
- Leafy vegetables (including brassica leafy vegetables).

This Application proposes that endosulfan MRLs for vegetable groups Brassica and leafy vegetables be deleted from, and entries for the individual brassica vegetables: Broccoli, Cabbage head and Cauliflower be included, in the *Food Standards Code*. 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	
Cabbages, head.	Add	T2	
Cauliflower.	Add	T2	
Leafy vegetables (including Brassica leafy vegetables).	Delete	T2	

2. REGULATORY PROBLEM

2.1 Current Regulations

The NRA has amended the registration for the use of endosulfan associated with the MRLs in this Application, and will gazette the consequent amendments to the NRA MRL Standard in the November 2002 NRA Gazette.

This will mean that there will be a discrepancy between the residues associated with the use and the MRLs in the *Food Standards 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 proposed MRLs permit the legal sale of food that has been legally treated. The NRA is planning to establish the proposed MRLs under the NRA's MRL Standard, and now seeks by way of this Application to include the amendments in the *Food Standards Code*.

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 Existing Chemical Review Program 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 Ministerial 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 acute estimated dietary exposure exceeds ARfD. The NRA has taken action to amend the use of endosulfan on brassica and leafy vegetables to ensure that legal residues only occur in domestically grown broccoli, cabbage head and cauliflower.

4.2 Maximum Residue Limit applications

The NRA is now making an application to FSANZ to adopt the proposed MRLs for endosulfan in Standard 1.4.2 of the *Food Standards Code*. FSANZ will review the information provided by the NRA and validate whether the dietary exposure is within agreed safety limits. If satisfied that there is no unacceptable risk to public health and safety associated with this Application, and following consultation, FSANZ will then agree to adopt the proposed MRLs into Standard 1.4.2 of the *Food Standards Code*.

FSANZ will then 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 *Food Standards Code*. If the Council accepts the changes made by FSANZ, the MRLs are automatically adopted by reference under the food laws of the Australian States and Territories.

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

In relation to MRLs, FSANZ's role is to ensure that the potential residues in food do not represent an unacceptable risk to public health and safety. FSANZ will not recommend MRLs for inclusion in the *Food Standards Code* where the dietary exposure to the residues of a chemical could represent an unacceptable risk to public health and safety. In assessing this risk, FSANZ conducts dietary exposure assessments in accordance with internationally accepted practices and procedures.

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

4.4 Food Standards-setting in Australia and New Zealand

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

4.5 Trans Tasman Mutual Recognition Arrangement

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

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

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

4.6 *Food Standards Code*

On 24 November 2000, the then Australia New Zealand Food Standards Council adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). On 24 May 2002, the Ministerial Council agreed to vary the *Food Standards Code* to amend Standard A14 (Volume 1) by deleting schedules 1, 2 and 3 of that Standard and referring the schedules in Standard A14 to the MRL schedules of Standard 1.4.2. This created a single set of schedules for MRLs. Subsequently all applications to amend MRLs will now be incorporated into schedules 1,2 and 3 of Standard 1.4.2 of the *Food Standards Code*. Consequently, all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

4.7 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. 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.

5.1 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.

5.2 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 is 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.

5.3 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.

5.4 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 Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 National Nutrition Survey and the MRL when the supervised trial meridian 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; 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.

NESTI calculations have been undertaken for those food 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 year old:

- broccoli was equal to 89% of the ARfD;
- cabbages, head 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;
- cabbages, head 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.

5.5 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.

6. REGULATORY OPTIONS

6.1 Option 1 – accept the proposed changes to the existing MRLs in the *Food Standards Code*.

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

6.2 Option 2 – status quo – do not accept the application and therefore no change to the existing MRLs in the *Food Standards Code*.

Under this option, the status quo would be maintained and the *Food Standards Code* would not change and a recommendation would not be made to include any changes in the existing MRLs for endosulfan.

7. IMPACT ANALYSIS

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

7.1 Costs and benefits

7.1.1 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.

7.1.2 Benefits of accepting the application

- the deletion of the endosulfan MRLs will result in a reduction of the risk to public health and safety from the possible exposure to residues of this chemical;

- 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.

7.1.3 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 *Food Standards Code* and the NRA MRL Standard would become greater, leading to confusion for producers, consumers and government agencies.

7.1.4 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.

8. CONSIDERATION OF ISSUES UNDER SECTION 13 OF THE *FOOD STANDARDS AUSTRALIA NEW ZEALAND ACT 1991*

Subsection 13(1) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) requires FSANZ to make a preliminary assessment of an application. In making that preliminary assessment, subsection 13(2) requires FSANZ to have regard to a number of matters set out in paragraphs 13(2)(a) to (e). Each of these matters is discussed below.

8.1 Paragraph 13(2)(a)

This Application relates to a matter that may warrant a variation to a food regulatory measure, because the application seeks an amendment of a standard. Under the FSANZ Act, a standard is, by definition, a food regulatory measure.

8.2 Paragraph 13(2)(b)

This Application is not so similar to a previous application that it ought not be accepted.

8.3 Paragraph 13(2)(c)

The Application does not suggest that the proposed amendment would present any further costs to the community, Government or industry. FSANZ has reviewed the Application and has not identified any adverse health effects that would result from the variations being made.

8.4 Paragraph 13(2)(d)

The nature of the Application is such that only an amendment to a standard (i.e. a food regulatory measure) can bring about what the applicant is seeking. No other measures appear to be available.

8.5 Paragraph 13(2)(e)

Other relevant matters for consideration by FSANZ are as follows.

8.5.1 Consideration of issues under Regulation 12 of the Food Standards Australia New Zealand Regulations 1994 which prescribes matters for the purpose of paragraph 13(2)(e) of the FSANZ Act.

8.5.1.1 Regulation 12(a)

Because it is a simple variation of a food regulatory matter requiring only the updating of a standard set out in the *Food Standards Code* this matter will be in category 2.

8.5.1.2 Regulation 12(b)

FSANZ considers that this Application will not confer an exclusive capturable commercial benefit on the applicant.

8.5.2 World Trade Organization Notification

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

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

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

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

The primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment. Therefore, this application will be notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO SPS agreement, in order to enable other member countries to comment on standards which may have a significant impact on them.

8.5.3 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: • 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 requests comments on the significance of the proposed departures from Codex MRLs and the possible impact on imported foods.

8.5.4 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 requests comment as to any possible ramifications for imports of the deletion of the MRLs in this Application.

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

9. CONSIDERATION OF ISSUES UNDER SECTION 15(3) OF THE *FOOD STANDARDS AUSTRALIA NEW ZEALAND ACT 1991*

Subsection 15(1) of the FSANZ Act requires FSANZ to make a Draft Assessment of an application accepted under Section 13A of the Act. In making that Draft Assessment, subsection 15(3) requires FSANZ to have regard to a number of matters set out in paragraphs 15(3)(a) to (e). Each of these matters is discussed below.

9.1 Paragraph 15(3)(a)

As this Application raises issues of minor significance and complexity only, FSANZ has not invited written submissions for the purposes of making the Initial / Draft Assessment. However, FSANZ will invite written submissions for the purpose of the Final Assessment under s. 17(3)(c) of the FSANZ Act and will have regard to any submissions received.

9.2 Paragraph 15(3)(b)

Section 10(1), paragraphs (a) to (c) of the FSANZ Act sets out the objectives of food regulatory measures and variations to food regulatory matters. Each of these objectives is discussed below.

9.2.1 Paragraph 10(1)(a) the protection of public health and safety

The Chemicals and Non-prescription Medicines Branch of the TGA have established the ADI and ARfD for endosulfan. The NRA and FSANZ have carried out estimations of dietary exposure to endosulfan and have compared them to the TGA standards. Based on dietary exposure assessments, the residues associated with the proposed MRLs for endosulfan do not represent an unacceptable risk to public health and safety.

9.2.2 Paragraph 10(1)(b) the provision of adequate information relating to food to enable consumers to make informed choices

This is not relevant for this Application.

9.2.3 Paragraph 10(1)(c) 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 (e). Each of these matters is discussed below.

9.2.4 Paragraph 10(2)(a) the need for standards to be based on risk analysis using the best available scientific evidence

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

9.2.5 Paragraph 10(2)(b) the promotion of consistency between domestic and international food standards

This is addressed in section 8.5.

9.2.6 Paragraph 10(2)(c) the desirability of an efficient and internationally competitive food industry

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

9.2.7 Paragraph 10(2)(d) the promotion of fair trading in food

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

9.2.8 Paragraph 10(2)(e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority

To date the Council has not made a written notification to the Authority of any policy guidelines that are relevant to this Application.

9.3 Paragraph 15(3)(c)

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

9.4 Paragraph 15(3)(d)

The nature of the Application is such that only an amendment to a standard (i.e. a food regulatory measure) can bring about what the applicant is seeking. No other measures appear to be available.

9.5 Paragraph 15(3)(e)

This is addressed in section 8.5.

10. CONSULTATION

FSANZ has decided, pursuant to section 36 of the *Australia New Zealand Food Authority Act 1991,* to omit to invite public submissions in relation to the Application prior to making a Draft Assessment. However, FSANZ now invites written submissions for the purpose of the Final Assessment under s.17 (3)(c) of the FSANZ Act and will have regard to any submissions received. FSANZ was satisfied that omitting to invite public submissions prior to making a draft assessment was warranted as the Application raises matters of a mechanical nature that are of minor significance or complexity. Furthermore, the Authority considered that omitting to invite public submissions prior to making a Draft Assessment would not significantly adversely affect the interests of any person or body. Subject to the *Administrative Appeals Tribunal Act 1975*, an application may be made to the Administrative Appeals Tribunal, for review of the decision (under section 36 of that Act) by a person whose interests are affected by the decision.

In addition to the public consultation that is undertaken for all Applications and Proposals, and as the preferred option has some potential impacts for importers of food and associated industries, comment on the impact of the proposed MRLs will be sought from them.

10.1 World Trade Organization (WTO) Notification

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

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

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

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

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

This Application will be 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.

11. RECOMMENDATION

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, choi 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 *Food Standards 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.

12. IMPLEMENTATION AND REVIEW

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

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

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

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

ATTACHMENTS

1. Draft Variations to the *Food Standards Code*.
2. The National Estimated Dietary Intake for Endosulfan.
3. The National Estimated Short Term Intake for Endosulfan.

ATTACHMENT 1

DRAFT VARIATIONS TO THE *FOOD STANDARDS CODE*

To commence: On gazettal

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

[1.1] *omitting from* Schedule 1 *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

THE NATIONAL ESTIMATED DIETARY INTAKE FOR ENDOSULFAN

Calculation of NEDI of endosulfan
(ADI for endosulfan is 0.006 mg/kg of body weight)

		Commodity	Food Consumption g/kg bw/day Total population	MRL/HR /STMR mg/kg	Dietary intake mg/kg bw/day Total population	% ADI	Notes
FC	0001	Citrus fruits	2.1336	T0.25	0.0005334	8.9%	
FB	0018	Grapes	0.7939	T0.38	0.0003017	5.0%	
FI	0030	Assorted tropical and sub-tropical fruits – inedible peal	0.7442	T0.69	0.0005135	8.6%	HR
FP	0009	Pome fruits	1.1687	T0.79	0.0009233	15.4%	HR
FS	0012	Stone fruits	0.2788	T1	0.0002788	4.6%	#1
FT	0026	Assorted tropical and sub-tropical fruits – edible peel	0.0048	T2	0.0000096	0.2%	
GC	0080	Cereal grains	0.4	T0.2	0.00008	1.3%	except rice
CF		Cereal grain fractions	1.8953	T0.2	0.0003791	6.3%	except rice
CM		Early milling products	0.0249	T0.2	4.98E-06	0.1%	except rice
GC	0649	Rice	0.0145	T0.1	1.45E-06	0.0%	
CF	0649	Rice bran, processed	0.0001	T0.1	1E-08	0.0%	
CM		Rice, husked, polished, unprocessed bran	0.2338	T0.1	2.338E-05	0.4%	
ML	0106	Milks [in the fat]	0.359732	T0.5	0.0001799	3.0%	
MM	0095	Meat (mammalian)[in the fat]	0.17556	0.2	3.511E-05	0.6%	
OC	0691	Cotton seed oil, crude	0.0001	T0.5	5E-08	0.0%	
PE	0112	Eggs	0.2228	T*0.05	1.114E-05	0.2%	
PM	0110	Poultry meat [in the fat]	0.05596	0.2	1.119E-05	0.2%	
PO	0111	Poultry, Edible offal of	0.0024	0.2	4.8E-07	0.0%	
SO	0088	Oilseed	0.0542	T0.31	1.68E-05	0.3%	HR
TN	0085	Tree nuts	0.0772	T0.005	3.86E-07	0.0%	HR
VA	0385	Onion, Bulb	0.2767	T0.2	5.534E-05	0.9%	
VA	0388	Shallots	0.0061	T2	0.0000122	0.2%	
VB	**0400**	**Broccoli**	**0.1221**	**T0.17**	**2.076E-05**	**0.35%**	**STMR**
VB	**0041**	**Cabbage, head**	**0.0648**	**T0.17**	**1.102E-05**	**0.18%**	**STMR**
VB	**0404**	**Cauliflower**	**0.0775**	**T0.17**	**1.318E-05**	**0.22%**	**STMR**
VD	0070	Pulses	0.0863	T0.35	3.021E-05	0.5%	HR
VO	0045	Fruiting vegetables, cucurbits	0.4375	T0.55	0.0002406	4.0%	HR
VO	0050	Fruiting vegetables, other than cucurbits	1.0579	T0.17	0.0001798	3.0%	HR
VP	0060	Legume vegetables	0.2751	T0.7	0.0001926	3.2%	HR
VR	0075	Root and tuber vegetables	1.3287	T0.39	0.0005182	8.6%	HR
VS	0078	Stalk and stem vegetables	0.0799	T1.2	9.588E-05	1.6%	HR
		Total			0.004674 mg/kg body weight**	78%	

**** Equivalent to 77.89942 % of the ADI**

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

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

Glossary of terms

NEDI - National Estimated Dietary Intake
ADI - Acceptable Daily Intake (Chemicals Safety Unit, Commonwealth Department of Human Services and Health)
HR - Highest Residue
MRL - Maximum Residue Limit
STMR - Supervised Trial Meridian Residue
T - temporary MRL
* At or about the limit of quantitation
#1: Current labels do not allow use on stone fruit, however the MRL remains until a final decision is made.

ATTACHMENT 3

THE NATIONAL ESTIMATED SHORT TERM INTAKE FOR ENDOSULFAN

Endosulfan Acute Dietary Intake _ 2 years +

Acute RfD 0.02 mg/kg bw

Name	MRL mg/kg	STMR or STMR-P, mg/kg	Process factor	HR or HR-P, mg/kg	Large portion, g/kg bw	Body weight, kg	Large portion, kg	Unit weight, g	% edible portion	Unit weight, edible portion, kg	Variability factor	Case	NESTI, mg/kg bw/day	% ARfD
Broccoli	2	2		0.29	3.127	67	0.210	318	56	0.178	7	2b	0.0063	31.739
Cabbage	2	2		0.11	3.246	67	0.217	950	84	0.798	7	2b	0.0025	12.497
Cauliflower	2	2		0.05	2.627	67	0.176	575	100	0.575	7	2b	0.0009	4.597

Case 1. Composite sampling data reflect the residue level in the food, based upon HR or HR-P
Case 2. Composite residue data do not reflect the residue level in individual food commodity units.
Case 2a. Unit weight edible portion is less than large portion weight.
Case 2b. Unit weight edible portion exceeds large portion weight.
Case 3. Processed commodity, where bulking or blending means that the STMR-P represents the likely highest residue

Processing factor of 0.33 is used for boiling.
B**r**occoli: HR(0.9) x 0.33 = 0.29 mg/kg
Cabbage: HR (0.32) x 0.33 = 0.11 mg/kg
Cauliflower: HR (0.14) x 0.33 = 0.05 mg/kg

Endosulfan Acute Dietary Intake _ 2-6 years

Acute RfD 0.02 mg/kg bw

Name	MRL mg/kg	STMR or STMR-P, mg/kg	Process factor	HR or HR-P, mg/kg	Large portion , g/kg bw	Body weight, kg	Large portion , kg	Unit weight, g	% edible portion	Unit weight, edible portion, kg	Variability factor	Case	NESTI, mg/kg bw/day	% ARfD
Broccoli	2	2		0.29	8.798	19	0.167	318	56	0.178	7	2b	0.0179	89.300
Cabbage	2	2		0.11	4.357	19	0.083	950	84	0.798	7	2b	0.0034	16.774
Cauliflower	2	2		0.05	6.947	19	0.132	100	57	0.057	7	2b	0.0024	12.157

Case 1. Composite sampling data reflect the residue level in the food, based upon HR or HR-P
Case 2. Composite residue data do not reflect the residue level in individual food commodity units.
Case 2a. Unit weight edible portion is less than large portion weight.
Case 2b. Unit weight edible portion exceeds large portion weight.
Case 3. Processed commodity, where bulking or blending means that the STMR-P represents the likely highest residue

Processing factor of 0.33 is used for boiling.
B**r**occoli: HR(0.9) x 0.33 = 0.29 mg/kg
Cabbage: HR (0.32) x 0.33 = 0.11 mg/kg
Cauliflower: HR (0.14) x 0.33 = 0.05 mg/kg