10/02
26 June 2002

DRAFT / FINAL ASSESSMENT REPORT
(FULL ASSESSMENT - s.15)

APPLICATION A448

MAXIMUM RESIDUE LIMITS - BIORESMETHRIN

THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY

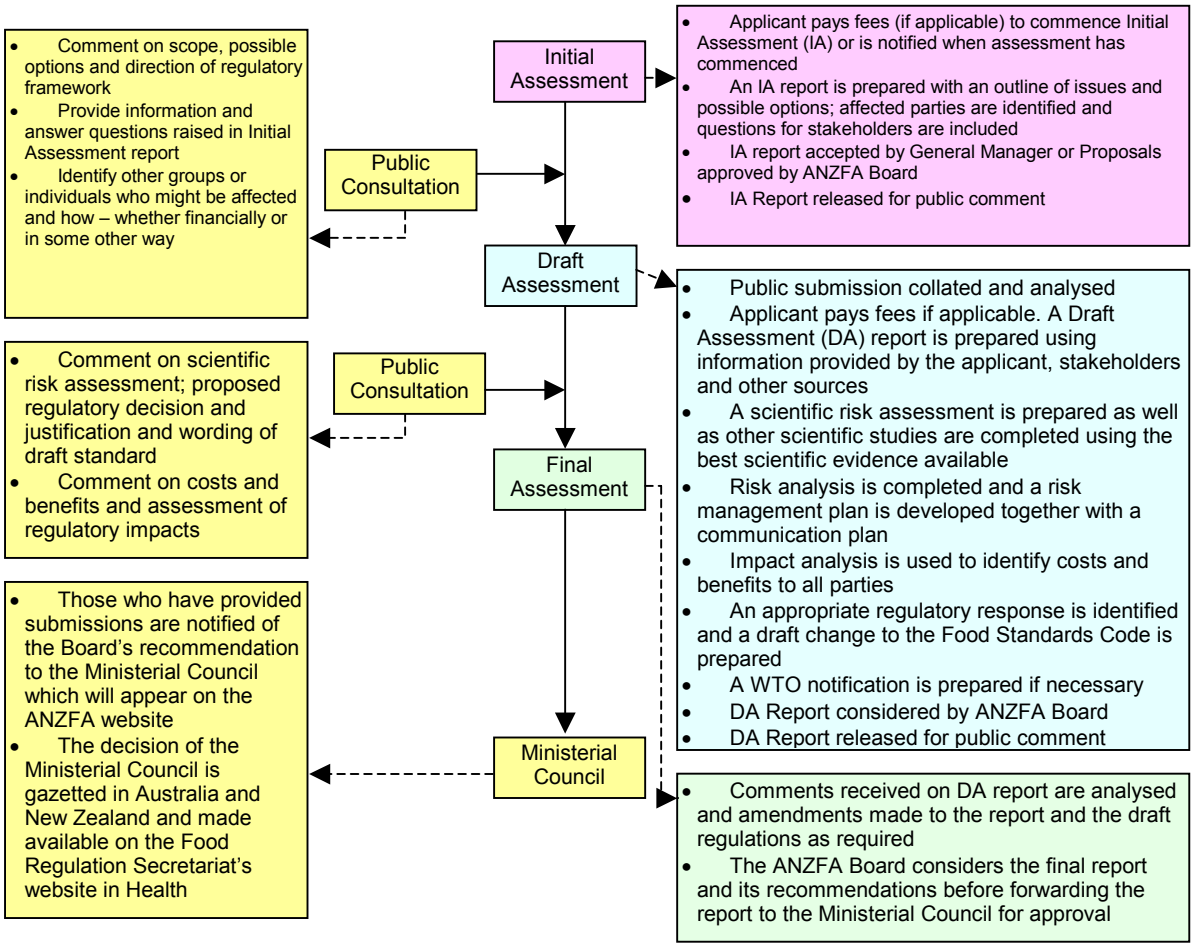
The Australia New Zealand Food Authority's (ANZFA) is a partnership between the Commonwealth Government, Australian State and Territory governments and the New Zealand Government. ANZFA is a bi-national, statutory body whose role, in association with others, is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply.

ANZFA seeks to achieve this goal by developing, varying and reviewing standards for food available for sale in Australia and New Zealand and through a range of other functions including national food surveillance and recall systems, conducting research, assessing policies about imported food and developing codes of practice with industry.

In developing and reviewing food standards for both Australia and New Zealand, ANZFA makes recommendations to change the food standards to the Australia New Zealand Food Standards Council, a Ministerial Council made up of Commonwealth, State and Territory and New Zealand Health Ministers. If the Council approves the recommendations made by ANZFA, the food standards are automatically adopted as regulations into the food laws of the Australian States and Territories and New Zealand.

STEPS IN DEVELOPING AND REVIEWING FOOD STANDARDS

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



SUBMISSIONS

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

FURTHER INFORMATION

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

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Assessment reports are available for viewing and downloading from the ANZFA website www.anzfa.gov.au. People without access to internet facilities may request paper copies of reports from the Information Officer.

EXECUTIVE SUMMARY

- This application seeks to include Maximum Residue Limits (MRLs) for bioresmethrin in eggs, mammalian meat (in the fat), mammalian offal, milk, poultry meat (in the fat) and poultry offal in the *Food Standards Code*.

- Bioresmethrin is used as an insecticide on grain crops. The feeding of cereal grain to livestock is consistent with the National Registration Authority for Agricultural and Veterinary Chemicals' (NRA's) current registered use of bioresmethrin. The proposed MRLs are required to cover potential residues in animal commodities through feeding of treated cereal grains.

- The current Application (**A448**) is a routine application from the NRA, to update the *Food Standards Code* in order to reflect the current registration status of bioresmethrin in agricultural use in Australia.

- On 24 November 2000, the Australia New Zealand Food Standards Council (ANZFSC) adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). Subsequently all applications to amend MRLs will now also be incorporated into Volumes 1 and 2 of the *Food Standards Code* (Standard A14 and Standard 1.4.2 respectively). Consequently all references throughout this document to the *Food Standards Code* are references to both Volumes 1 and 2 of the *Food Standards Code*.

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

- The Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health and Aged Care has undertaken an appropriate toxicological assessment of the bioresmethrin and has established an acceptable daily intake (ADI).

- ANZFA is satisfied from the dietary modelling performed that the changes to the *Food Standards Code* for bioresmethrin will not cause the ADI to be exceeded.

- None of ANZFA's section 10 objectives of food regulatory measures are compromised by the proposed changes. The requested variation to the *Food Standards Code* should commence on gazettal.

- ANZFA at initial assessment made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO) and no submissions have been received from WTO members.

1. ISSUES

The NRA has registered uses for the MRLs associated with Application A448 and is seeking to include the following MRLs in the *Food Standards Code.* -

Bioresmethrin	
Edible offal, mammalian	T*0.01
Eggs	T0.05
Meat (Mammalian) (in the fat)	T0.5
Milks	T0.05
Poultry, edible offal of	T*0.01
Poultry meat (in the fat)	T0.5

Bioresmethrin has been used as a grain protectant for many years and when it was originally registered the need for MRLs for animal commodities was not considered necessary. It is now routine to consider the establishment of MRLs for animal commodities where treated produce may be fed to animals. Including the proposed MRLs for these commodities in the *Food Standards Code* will correct the omission of animal commodity MRLs that occurred when bioresmethrin was originally registered.

2. BACKGROUND

In Australia, the NRA is responsible for registering agricultural and veterinary chemical products. Before registering such a product, they must be satisfied that the use of the product will not result in residues that would be an undue hazard to the safety of people, including people using anything containing its residues.

The maximum residue limit (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 result from the registered conditions of use. The concentration is expressed in milligrams per kilogram (mg/kg) of the food. MRLs are indicators of 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 assist in ensuring that residues are no higher than is necessary for effective control of pests and disease. However, MRLs are not established for specific commodities if the residues resulting from the use of the chemical product could represent an unacceptable risk to public health and safety.

On 24 November 2000, ANZFSC adopted the *Australia New Zealand Food Standards Code* (published as Volume 2 of the *Food Standards Code*). Subsequently all applications to amend MRLs will be incorporated into Volumes 1 and 2 of the *Food Standards Code* (Standard A14 and Standard 1.4.2 respectively). Consequently all references throughout this document to the *Food Standards Code* are references to Volumes 1 and 2.

2.1 Food Standards Setting in Australia and New Zealand

2.1.1 Treaty between the Commonwealth of Australia and New Zealand

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. Australia and New Zealand separately develop MRLs for agricultural and veterinary chemicals in food.

2.1.2 Trans Tasman Mutual Recognition Arrangement

Following the implementation of the Trans Tasman Mutual Recognition Arrangement on 1 May 1998:

- Food produced in Australia that complies with the MRLs in the *Food Standards Code* can be legally sold in New Zealand; and

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

3. DIETARY EXPOSURE ASSESSMENT

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code Act 1994* (Ag Vet Code Act) requires the NRA to be satisfied that there will not be any appreciable risk to the consumer, to the person handling, applying or administering the chemical, to the environment, to the target crop or animal or to trade in an agricultural commodity. ANZFA's responsibility is to ensure that the residues in food resulting from the use of agricultural and veterinary chemical products do not represent an unacceptable risk to public health and safety.

The potential public health implications are assessed by comparing the dietary exposure with the relevant health standard. There are a number of methods for estimating dietary exposure based on the type of information that is available. The one that was considered in this application was the National Estimated Daily Intake (NEDI).

3.1 Toxicology of agricultural and veterinary chemicals

The Chemicals and Non-prescription Medicines Branch of the Therapeutic Goods Administration (TGA) assess the toxicology of agricultural and veterinary chemicals and establish the ADI for a chemical. Both the NRA and ANZFA use these health standards in dietary exposure assessments.

Neither the NRA nor ANZFA will establish or recommend MRLs where the toxicology aspects have not been addressed to the satisfaction of the TGA.

3.2 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 on the basis of all the known facts at the time of the evaluation of the chemical. It is expressed in milligrams of the chemical per kilogram of body weight.

ANZFA considers that the dietary exposure to the residues of a chemical is acceptable where the best estimate of dietary exposure does not exceed the ADI.

3.3 Limit of quantification

Two of the proposed MRLs in this application are at the limit of quantification (LOQ) and are indicated by an '*'. The LOQ is the lowest concentration of a pesticide residue contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

3.4 Temporary MRLs

All of the proposed MRLs in this application are temporary and are indicated by a 'T' in the Summary of the Requested MRLs for A448 (Attachment 1). After the NRA receives the results of new studies, that are currently being planned, they may make an application to change these temporary MRLs. In the meantime, these MRLs are consistent with the available data.

3.5 National Estimated Daily Intake (NEDI)

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

The NEDI for bioresmethrin was calculated as 47% of the ADI. This estimate assumed that all cereal grains and all animal commodities contained bioresmethrin residues at the MRL. This is an overestimate and despite this over estimation the NEDI did not exceed the ADI. ANZFA does not consider that the residues of bioresmethrin in food represent an unacceptable risk to public health and safety.

3.6 Food Consumption Data

The NRA and ANZFA have recently agreed that all dietary exposure assessments for agricultural and veterinary chemicals undertaken by the NRA will be based on food consumption data for raw commodities, derived from individual dietary records from the latest 1995 National Nutrition Survey (NNS).

The Australian Bureau of Statistics, with the Commonwealth Department of Health and Aged Care, undertook the NNS survey over a 12-month period (1995-early 1996). The sample of 13,858 respondents aged 2 years and older was a representative sample of the Australian population and, as such, a diversity of food consumption patterns were reported.

A computer program developed by ANZFA derives raw commodity consumption data used in the NRA dietary exposure assessments. The program accesses the 13,858 individual dietary records from the 1995 NNS, and applies recipes to all mixed foods consumed by each individual to enable the total amounts of raw commodity equivalents consumed per individual person to be calculated. Population statistics (mean consumption, all respondents) are then derived from these individual raw commodity totals for use in NRA dietary exposure assessments.

However, for all new chemicals, review chemicals and those where the initial dietary exposure assessment based on mean consumption data appears to approach or exceed the ADI, the ANZFA computer program is used to calculate the total dietary exposure to a given chemical for each individual in the survey. Population statistics such as mean chemical exposure are then derived, thus taking into account as much as possible, individual dietary patterns from a diverse and representative sample of the Australian population. This program also enables high consumers of a given chemical to be identified, as well as the major foods contributing to total dietary exposure for that chemical.

3.7 19th (1998) Australian Total Diet Survey

As part of the 19th (1998) Australian Total Diet Survey, foods were analysed for bioresmethrin; however, residues were not reported in any foods.

4. EVALUATION OF ISSUES RAISED IN RESPONSE TO THE INITIAL ASSESSMENT REPORT (PRELIMINARY ASSESSMENT S.13)

The submissions made in response to the initial assessment expressed concerns about:

- whether all the current MRLs for bioresmethrin were included in the chronic dietary exposure estimates; and

- the use of bioresmethrin.

Each of these is examined in turn below.

4.1 The inclusion of current MRLs for bioresmethrin in the NEDI

The New Zealand Ministry of Health questioned whether the current MRLs for cereal grains, wheat bran and wheat germ and the proposed MRLs for bioresmethrin in the specified animal commodities were all included in the chronic dietary exposure assessment. This assessment included both the current and proposed MRLs for bioresmethrin. The chronic dietary exposure assessment for bioresmethrin is 47% of the ADI, and as the ADI will not be exceeded, ANZFA considers that there is no unacceptable risk to public health and safety from bioresmethrin residues in foods.

4.2 Use of bioresmethrin

W J Murray Consulting Services made a submission on behalf of:

- Grains Council of Australia;
- AWB Ltd;
- Grainco Ltd. Queensland;
- GrainCorp Ltd. NSW;
- Ausbulk Ltd. South Australia; and
- Stockfeed Manufacturers Association of Australia.

W J Murray Consulting Services stated that:

> The Grains Industry has been using bioresmethrin as a grain protectant for than 20 years, and during that time has received no customer complaints relating to residues of this compound from domestic or overseas markets. The protectant is of great value to the Industry as it an important component in an integrated resistance management strategy aimed at controlling resistant strains of the lesser grain borer, *Rhizopertha dominica*, which is the most serious insect pest of stored grains in Australia.

The submissions by W J Murray and Safemeat support the application.

The submission from the National Council of Women of Australia (NCWA) did not make a comment on this application. However, the NCWA considered that 'public consultation on matters of Maximum Residue Limits is an ineffective and time consuming exercise' and 'any comments to the contrary would be futile'. The late submission from the Consumers' Association of South Australia (CASA) supported the submission from the NWCA.

ANZFA has written to the NWCA and the CASA, explaining:

- ANZFA's legislative requirements and the process of progressing applications on MRLs;

- ANZFA's role in setting MRLs in the *Food Standards Code* and that ANZFA does not regulate the use of agricultural and veterinary chemicals; and

- how the concerns of the NWCA and CASA on the use of agricultural and veterinary chemicals can be addressed.

5. REGULATORY IMPACT ANALYSIS

5.1 Objective

To ensure that the residues associated with the proposed MRLs for bioresmethrin 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.

5.2 There are two Options:

Option 1: - to accept the requests made by the NRA and vary the *Food Standards Code*.
Option 2: - to reject the requests and make no changes to the *Food Standards Code*.

5.3 Affected parties

The identified parties affected by this application are consumers; meat, dairy and poultry producers; government through enforcement agencies; food manufacturers who use meat, dairy and poultry products, and exporters of meat, dairy and poultry products.

5.4 Costs and benefits

5.4.1 Costs of making the changes sought by the NRA

- Initially enforcement agencies, food manufacturers and importers may have an administrative burden of complying with and enforcing the proposed MRLs; 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.

5.4.2 Benefits of making the changes sought by the NRA

- It will benefit all stakeholders by maintaining public health and safety; and

- Meat, dairy and poultry producers will be legally able to sell produce from livestock which has been fed with bioresmethrin treated grain;

- It will ensure consistency between the health and agricultural regulations;

- Consumers may receive the potential benefits of improved stock production through cheaper or better quality produce.

5.4.3 Costs of not making the changes sought by the NRA

- Producers will not be able to legally sell or export animal commodities containing detectable residues of bioresmethrin;

- There may be increased production costs for manufacturers and ultimately increased costs to consumers if animal commodities containing detectable residues of bioresmethrin cannot be legally sold;

- The discrepancies between the *Food Standards Code* and the NRA MRL Standard would become greater leading to confusion for producers, consumers and government agencies; and

- As there are no unacceptable risks to public health and safety, consumers are not at risk if this application is not accepted.

5.4.4 Benefits of not making the changes sought by the NRA

- Importers may potentially benefit by filling a possible domestic production shortfall of animal commodities if local producers cannot legally sell their products; and

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

5.5 Conclusion and recommended option

The proposed inclusion of the MRLs is consistent with the current registered uses of bioresmethrin products. The dietary exposure calculations indicate that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. The NRA has already registered bioresmethrin products and rejection of the MRLs would result in legally treated food not being able to be legally sold. Therefore the requested changes (Option 1) will benefit all stakeholders by maintaining public health and safety while addressing the potential bioresmethrin residues in animal commodities that may occur following the feeding of treated cereal grains.

6. CONSIDERATION OF ISSUES UNDER SECTION 15 OF THE *AUSTRALIA NEW ZEALAND FOOD AUTHORITY ACT 1991*

Subsection 15(1) of the *Australia New Zealand Food Authority Act 1991* requires ANZFA to make a Draft Assessment (Full Assessment s.15) of an application. In making that Draft Assessment (Full Assessment s.15), subsection 15(3) requires ANZFA to have regard to a number of matters set out in paragraphs 15(3)(a) to (e). Each of these matters is discussed below.

6.1 Paragraph 15(3)(a)

ANZFA has had regard to the submissions made to this application and addressed them in section 4 of this document.

6.2 Paragraph 15(3)(b)

Section 10 (1), paragraphs (a) to (c) of the *Australia New Zealand Food Authority Act 1991* sets out the objectives of food regulatory measures and variations to food regulatory matters. Each of these is discussed below.

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

The Chemicals and Non-prescription Medicines Branch of the TGA establishes the ADI for the agricultural and veterinary chemicals. The NRA and ANZFA carry out estimations of dietary exposure to agricultural and veterinary chemicals and compare them to the TGA standards. On the basis of dietary exposure assessments, the residues associated with the proposed MRLs for bioresmethrin do not represent an unacceptable risk to public health and safety.

6.2.2 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.

6.2.3 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 ANZFA to have regard to a number of matters set out in paragraphs 10(2)(a) to (d). Each of these matters is discussed below.

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

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

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

The Codex Alimentarius Commission has not set any MRLs for bioresmethrin in meat, dairy and poultry products. The inclusion of MRLs for bioresmethrin does not restrict imported food commodities.

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

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

6.2.6 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.

6.3 Paragraph 15(3)(c)

ANZFA has undertaken a regulatory impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the *Food Standards Code* is necessary, cost effective and of benefit to both producers and consumers.

6.4 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.

6.5 Paragraph 15(3)(e)

Other relevant matters for consideration by ANZFA are as follows.

6.5.1 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.

The MRLs prescribed in the *Australia New Zealand 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 disease. MRLs are also used as standards for the international trade in food.

The Codex Alimentarius Commission has not set any MRLs for bioresmethrin in meat, dairy and poultry products. The inclusion of MRLs for bioresmethrin does not restrict imported food commodities.

At initial assessment ANZFA considered that this did constitute potential a Sanitary/Phytosanitary matter and therefore raised a WTO notification. No submissions were received from WTO members.

7. CONCLUSION

The dietary exposure calculations indicate that the ADI for bioresmethrin will not be exceeded. The proposed inclusion of the MRLs for bioresmethrin is consistent with current registered uses of this insecticide. The NRA has already registered bioresmethrin and rejection of the MRLs for bioresmethrin would result in legally treated food not being able to be legally sold.

Therefore the requested changes (Option 1) will benefit all stakeholders by maintaining public health and safety while addressing the potential bioresmethrin residues in animal commodities that may occur following the feeding of treated cereal grains.

ATTACHMENTS

1. Draft Variation to the *Food Standards Code*.
2. Statement of Reasons.
3. Summary of Public Submissions Received at Initial Assessment.

ATTACHMENT 1

DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

APPLICATION A448 - MAXIMUM RESIDUE LIMITS - BIORESMETHRIN

The *Food Standards Code* is varied by -

[1] *Inserting in columns 1 and 2 respectively of Schedule 1 in Standard A14 in Volume 1, in relation to each chemical shown in bold type below, the food and the maximum residue limit for that food listed below -*

Chemical Food	**MRL**
Bioresmethrin	
Edible offal, mammalian	0.01
Eggs	0.05
Meat (Mammalian) (in the fat)	T0.5
Milks	0.05
Poultry, edible offal of	0.01
Poultry meat (in the fat)	0.5

Explanatory Note: These are MRLs for an existing chemical but are for foods that are not currently listed.

[2] *Inserting in columns 1 and 2 respectively of Schedule 1 in Standard 1.4.2 in Volume 2, in relation to each chemical shown in bold type below, the food and the maximum residue limit for that food listed below -*

BIORESMETHRIN BIORESMETHRIN	
EDIBLE OFFAL (MAMMALIAN)	T*0.01
EGGS	T0.05
MEAT (MAMMALIAN) (IN THE FAT)	T0.5
MILKS	T0.05
POULTRY, EDIBLE OFFAL OF	T*0.01
POULTRY MEAT (IN THE FAT)	T0.5

Explanatory Note: These are new MRLs for an existing chemical but are for foods that are not currently listed.

ATTACHMENT 2

STATEMENT OF REASONS

APPLICATION A448 - MAXIMUM RESIDUE LIMITS - BIORESMETHRIN

FOR RECOMMENDING A VARIATION TO STANDARD A14 AND STANDARD 1.4.2 - MAXIMUM RESIDUE LIMITS.

On 24 November 2000, the Australia New Zealand Food Standards Council (ANZFSC) adopted the *Australia New Zealand Food Standards Code* (known as Volume *2 of* the *Food Standards Code*). Subsequently all applications to amend Maximum Residue Limits (MRLs) apply equally to Volume 1 and Volume 2 of the *Food Standards Code* (Standard A14 and Standard 1.4.2 respectively). Consequently all references throughout this document to the *Food Standards Code* are references to Volume 1 and Volume 2.

The Australia New Zealand Food Authority (ANZFA) has before it Application **A448** (received 8 August 2001), from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) to amend the current MRLs in the *Food Standards Code*.

ANZFA has completed a Draft Assessment (Full Assessment - s.15) of the Application, and prepared draft variations to Standard A14 of Volume 1 and Standard 1.4.2 of Volume 2 of the *Food Standards Code*.

ANZFA recommends progressing the application for the following reasons:

- The current Application (**A448**) is a routine application from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), to update the *Food Standards Code* in order to reflect the current registration status of bioresmethrin use in Australia.

- ANZFA is satisfied from the dietary modelling performed that the changes to the *Food Standards Code* for potential residues of bioresmethrin in this application will not result in an unacceptable risk to public health and safety.

- None of ANZFA's section 10 objectives of food regulatory measures are compromised by the proposed changes. The requested variation to the *Food Standards Code* should commence on gazettal.

- ANZFA has made a Sanitary and Phytosanitary notification to the World Trade Organization and it is not necessary to make another.

SUMMARY OF PROPOSED MRLS FOR A448

The Summary of Proposed MRLs – Explanatory Notes and Diagrams

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

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

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

Glossary:

ADI	Acceptable Daily Intake.
LOQ	Limit of Analytical Quantification.
NEDI	National Estimated Daily Intake.
*****	MRL set at or about the limit of quantification.
T	Temporary MRL

Chemical Food	**MRL** (gm/kg)		**Information**
Bioresmethrin			
Edible offal, mammalian	Add	T*0.01	Bioresmethrin is used to control
Eggs	Add	T0.05	insect pests in grain, which in turn
Meat (Mammalian) (in the fat)	Add	T0.5	may be fed to animals. In the 19th
Milks	Add	T0.05	(1998) Australian Total Diet
Poultry, edible offal of	Add	T*0.01	Survey bioresmethrin was not
Poultry meat (in the fat)	Add	T0.5	detected in any foods NEDI = 47% of ADI

REGULATORY IMPACT

ANZFA has undertaken a regulatory impact assessment, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the *Food Standards Code* is necessary, cost effective and of benefit to both producers and consumers.

CODEX ALIMENTARIUS COMMISSION MRLS

The Codex Alimentarius Commission has not set any MRLs for bioresmethrin in meat, dairy and poultry products.

IMPORTED FOODS

The inclusion of MRLs for bioresmethrin is not restrictive to imported food commodities.

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, and it is primarily the registered conditions of use that act to protect human, animal and plant health and the environment. This application contains proposed MRLs for bioresmethrin, which is used in the production of heavily, traded agricultural commodities, which may indirectly have a significant effect on trade of derivative food products between WTO members.

ANZFA has made a Sanitary and Phytosanitary (SPS) notification in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures as the primary objective of the measure is to support regulating 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 and a further notification is unnecessary.

The Draft variations are at Attachment 1 to the Draft Assessment Report.

ATTACHMENT 3

SUMMARY OF PUBLIC SUBMISSIONS RECEIVED AT INITIAL ASSESSMENT (PRELIMINARY ASSESSMENT S.15)

Submitter	Comments raised
Food Technology Association of Victoria	Accepts the application.
W J Murray Consulting Services	Supports the application.
National Council of Women of Australia	Did not comment about the application. However they did comment on the process of making submissions.
New Zealand Ministry of Health	Had no concerns about the application. Questioned the inclusion of current MRLs in the NEDI.
Safemeat	Supports the application.
Consumers' Association of South Australia	Supports the submission made by National Council of Women of Australia.