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

1-05
9 February 2005

FINAL ASSESSMENT REPORT

APPLICATION A538

MAXIMUM RESIDUE LIMITS – BENZOCAINE (LOCAL ANAESTHETIC)

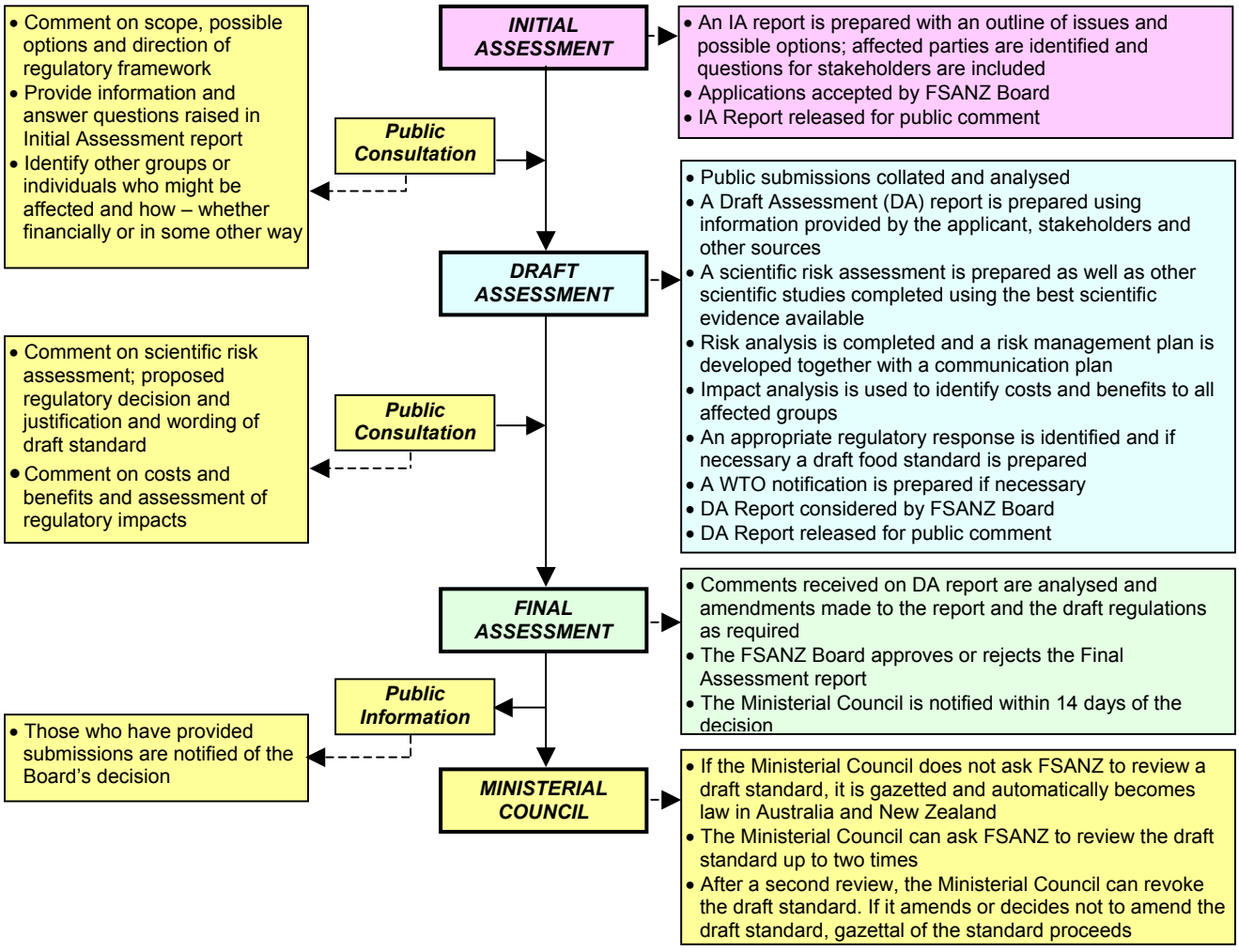
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Final Assessment Stage (s.36)

FSANZ has now completed the assessment of the Application A538 and held a single round of public consultation under section 36 of the FSANZ Act. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

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

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

Further Information

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

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

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

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

CONTENTS

Executive Summary and Statement of Reasons

This Application (A538) seeks to reduce the Maximum Residue Limits (MRLs) in the *Australia New Zealand Food Standards Code* (the Code) for the local anaesthetic benzocaine to a new lower limit of quantification (LOQ). It is an application from the Australian Pesticides and Veterinary Medicines Authority (APVMA) to update the Code in order to reflect the current registration status of this chemical's use as a local anaesthetic for abalone and finfish.

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 Office of Chemical Safety (OCS) of the Therapeutic Goods Administration (TGA) of the Australian Government Department of Health and Ageing has not set an acceptable daily intake (ADI) for benzocaine because of insufficient data. However, the OCS has concluded that from a toxicological perspective there are no objections to the proposed MRLs.

Because of the lack of an ADI, Food Standards Australia New Zealand (FSANZ) cannot compare the results of an estimated dietary exposure calculation for benzocaine to the ADI. However, as the proposed MRLs are to be established at a new lower LOQ any associated benzocaine residues should not represent an unacceptable risk to public health and safety.

FSANZ made a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

Statement of Reasons

FSANZ recommends progressing this Application for the following reasons:

- The proposed MRLs are reductions to a new, lower LOQ and the residues associated with the proposed MRLs for benzocaine should not represent an unacceptable risk to public health and safety.

- APVMA has already registered benzocaine for use as a local anaesthetic for abalone and finfish. The requested changes will benefit all stakeholders by maintaining the existing confidence in the food supply in relation to residues of this chemical and removing the discrepancy between the residues associated with the registered use of benzocaine and the MRLs in the Code.

- APVMA 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 use of benzocaine on abalone and finfish.

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

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

1. Introduction

This Application was received from APVMA on 15 April 2004 seeking amendments to Standard 1.4.2 - Maximum Residue Limits of the Code. The proposed amendments to the Standard would align MRLs in the Code for the local anaesthetic, benzocaine with the MRLs in the APVMA MRL Standard.

1.1 Summary of the proposed MRLs for benzocaine

The MRL amendments under consideration in this Application for benzocaine are as follows:

Benzocaine			
Abalone	Delete Substitute	T*0.5 *0.05	This chemical is a local anaesthetic; it used to sedate and anaesthetise fish and abalone. OCS has not set an ADI for this chemical.
Finfish	Delete Substitute	T*0.5 *0.05	However, the reduction of the MRLs to the new and lower LOQ means that no detectable residues of benzocaine should occur.

The existing 'T' MRLs of *0.5 mg/kg for benzocaine in finfish and abalone were established on the basis of an LOQ of 0.5 mg/kg for a colormetric method that was used to determine the concentration of benzocaine in finfish. This method is not specific, and detects benzocaine by reaction of its primary aromatic amine group. More specific analytical methodology is now available for the determination of benzocaine residues in fish tissues. Given the availability of this methodology, it is recommended that the 'T' MRLs be replaced with MRLs of *0.05 mg/kg.

1.2 Lack of an ADI for benzocaine

OCS reviewed the toxicology of benzocaine in 1998 and determined that there were insufficient data to allow an ADI to be established for this chemical. However, OCS concluded that, from a toxicological perspective, there were no objections to the use of this chemical in finfish and abalone as:

- the proposed MRL is at LOQ and residues of this chemical in abalone and finfish should not occur;
- the use pattern involves a withholding period of 500 days;
- benzocaine is a human therapeutic agent and is a component in a number of over the counter pharmaceutical products; and
- benzocaine is only to be supplied to aquaculture farms on veterinary prescriptions.

1.3 Limit of Quantification

The proposed MRLs in this Application are at LOQ and are indicated by an * in the above 'Summary of the proposed MRLs for benzocaine'.

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

1.4 The National Estimated Dietary Intake

Neither the TGA nor the Codex Alimentarius Commission has set an ADI for benzocaine. Because of the lack of an ADI FSANZ cannot compare the results of an estimated dietary exposure calculation for benzocaine to the ADI. However, as the proposed MRLs are to be established at a new lower LOQ any associated benzocaine residues should not represent an unacceptable risk to public health and safety.

1.5 Acute dietary exposure

Neither the TGA nor the Joint FAO/WHO Expert Committee on Food Additives, have set an acute reference dose (ARfD) for benzocaine.

2. Regulatory Problem

APVMA has approved the new lower MRLs for benzocaine as a local anaesthetic for abalone and finfish associated with the proposed MRLs in this Application, and made consequent amendments to the APVMA's MRL Standard. APVMA's approval of the lower MRLs for this chemical now means that there is a discrepancy between the residues associated with the registered use of this chemical and the MRLs in the Code. This discrepancy between agricultural and food legislation may lead to uncertainty, inefficiency and confusion in the enforcement of regulations.

3. Objective

The objective of this Application is to ensure that the residues of benzocaine 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. APVMA has already established MRLs for this chemical under the APVMA'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 FSANZ Act. These are:

3.1.1 The protection of public health and safety

Neither the OCS nor the Codex Alimentarius Commission has set an ADI for benzocaine. Because of the lack of an ADI FSANZ cannot compare the results of an estimated dietary exposure calculation for benzocaine to the ADI.

However, as the proposed MRLs are to be established at a new lower LOQ any associated benzocaine residues should 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 APVMA are based on a comprehensive examination of 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 9.1.

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.

3.1.8 Any written guidelines formulated by the Ministerial Council for the purposes of this paragraph and notified to FSANZ

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

4. Background

4.1 The use of agricultural and veterinary chemicals

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

Before registering such a product, APVMA must be satisfied that the use of the product will not result in residues that would be an undue risk to the safety of people, including people using anything containing its residues.

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

4.2 Maximum Residue Limit applications

After registering the agricultural or veterinary chemical products, based on their scientific evaluations, APVMA makes applications to FSANZ to adopt the MRLs in Standard 1.4.2 of the Code. FSANZ reviews the information provided by APVMA and validates whether the dietary exposure is within agreed safety limits.

If satisfied that the residues do not represent an unacceptable risk to public health and safety and subject to adequate resolution of any issues raised during public consultation, FSANZ will then agree to adopt the proposed MRLs into Standard 1.4.2 of the Code.

FSANZ then notifies the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) of the proposed adoption of the variation into the Code. If the Ministerial Council does not request FSANZ to review its decision, the MRLs are automatically adopted by reference under the food laws of the Australian States and Territories, after gazettal by FSANZ.

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 of older products following review.

Appropriate toxicology, residue, animal transfer, processing and metabolism studies were provided to APVMA in accordance with the *Guidelines for Registering Agricultural and Veterinary Chemicals, the Ag and Vet Requirements Series, 1997* to support the MRLs in the commodities as outlined in this Application.

Full evaluation reports for individual chemicals are available upon request from the relevant Project Coordinator at FSANZ on +61 2 6271 2222.

4.3 Maximum Residue Limits

The MRL is the highest concentration of a chemical residue that is legally permitted or accepted in a food. The MRL does not indicate the amount of chemical that is always present in a treated food but it does indicate the highest residue that could possibly result from the registered conditions of use. The concentration is expressed in milligrams of benzocaine 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. In addition, MRLs, while not direct public health limits, act to protect public health and safety by minimising residues in food consistent with the effective control of pests and diseases. FSANZ will not agree to adopt MRLs into the Code where the dietary exposure to the residues of a chemical could represent an unacceptable risk to public health and safety. In assessing this risk, APVMA and FSANZ conduct dietary exposure assessments in accordance with internationally accepted practices and procedures.

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

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

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 Code can be legally sold in New Zealand; and

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

5. Evaluation of Issues Raised in Public Comment

Submissions were received from:

- Food Technology Association of Victoria Inc.
- Sarah Jarvie.
- Queensland Health.
- Basher Ahmad Ganie.
- New South Wales Food Authority.

All submissions supported this Application.

6. Regulatory Options

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

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

6.2 Option 2– adopt the change to MRLs to delete or decrease some existing MRLs

Under this option the MRLs for benzocaine for abalone and finfish would be approved for inclusion into the Code.

7. Affected Parties

The parties affected by proposed MRL amendments include:

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

8. Impact Analysis

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

8.1 Option 1 – status quo – no change to the existing MRLs for benzocaine for abalone and finfish in the Code

8.1.1 Benefits

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of benzocaine;
- for producers of domestic and export seafood commodities, the adoption of this option would not result in any discernable benefits;
- for importers, the adoption of this option would not result in any discernable benefits; and
- for Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable benefits.

8.1.2 Costs

- for consumers there are unlikely to be any discernable costs as the unavailability of abalone and/or finfish from certain producers is likely to be seen as typical seasonal fluctuations in supply;
- for producers of domestic and exported abalone and finfish, the adoption of this option would not result in discernable costs. Primary producers do not produce abalone and/or finfish or use benzocaine to comply with MRLs. They use benzocaine to treat abalone and finfish in accordance with the prescribed label conditions, and expect that the resulting residues will be acceptable and that the legally treated foods can be legally sold;
- for importers, the adoption of this option would not result in any discernable costs; and
- for Australian Government, State and Territory agencies, the adoption of this option would create discrepancies between agricultural and food legislation thereby creating uncertainty, inefficiency and confusion in the enforcement of regulations.

8.2 Option 2– adopt the changes to MRLs decrease the existing MRLs for benzocaine for abalone and finfish

8.2.1 Benefits

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of benzocaine;
- for producers of domestic and export seafood commodities, the adoption of this option would not result in any discernable benefits;
- for importers, the adoption of this option would not result in any discernable benefits; and

- for Australian Government, State and Territory agencies, the adoption of this option would foster community confidence that regulatory authorities are maintaining the standards to minimise residues in the food supply.

8.2.2 Costs

- for consumers there are unlikely to be any discernable costs as the unavailability of abalone and/or finfish from certain importers is likely to be seen as typical seasonal fluctuations in the food supply;

- for producers of domestic and export abalone and finfish, the adoption of this option is unlikely to result in any costs, as reductions in MRLs are adopted where this is practically achievable, with little or no impact on production costs;

- for importers, the adoption of this option may result in costs, as abalone and/or finfish may not be able to be imported if these commodities contained residues consistent with the MRLs for benzocaine for abalone and finfish proposed for reduction. The reduction of these MRLs have the potential to restrict the importation of abalone and finfish and could potentially result in higher food costs and a reduced product range available to consumers, as abalone and finfish that exceed the new, lower MRLs could not be legally imported or sold to consumers. To identify any restrictions and possible trade impacts, Codex MRLs and data on imported abalone and finfish are addressed in section 9.1; and

- for Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable costs, although there would need to be an awareness of changes in the standards for residues in seafood commodities.

9. Consultation

9.1 World Trade Organization Notification

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

This Application contains variations to MRLs which are not addressed in the international Codex standard. MRLs in this Application also relate to chemicals used in the production of heavily traded agricultural commodities that may indirectly have a significant effect on trade of derivative food products between WTO members.

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

9.2 Imported Foods

Benzocaine may be used differently in countries other than in Australia because of different practices or because different products may be used. This means that residues in imported food may still be safe for human consumption, but may be different from those in domestically produced food.

The proposed reductions of MRLs for benzocaine may affect imported abalone and finfish, which may comply with existing MRLs even though these existing MRLs are no longer required for domestically produced food.

To assist in identifying possible impacts on imports FSANZ requested comments as to any possible ramifications from the proposed reduction of the benzocaine MRLs for abalone and finfish. No submissions were received addressing possible ramifications for the importation of these commodities.

10. Conclusion and Recommendation

As there is no ADI, FSANZ cannot carry out a chronic dietary exposure for the proposed MRLs for benzocaine. However, the proposed MRLs are at a new lower LOQ and residues of this chemical should not occur in abalone and finfish. FSANZ considers that the proposed MRLs for benzocaine do not represent an unacceptable risk to public health and safety. APVMA has already registered this chemical product and rejection of the MRLs would result in legally treated food not being able to be legally sold. Therefore, accepting the requested reduction will benefit all stakeholders by maintaining public health and safety while permitting the legal sale of abalone and finfish treated with benzocaine.

11. Implementation and Review

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

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

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

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

ATTACHMENTS

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

Attachment 1

Draft variation to the *Australia New Zealand Food Standards Code*

To commence: On gazettal

[1] ***Standard 1.4.2*** *of the Australia New Zealand Food Standards Code is varied by –*

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

BENZOCAINE BENZOCAINE	
ABALONE	*0.05
FINFISH	*0.05

Attachment 2

Notes on Terms

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

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

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

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

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

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 supervised trials median residue (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.

Attachment 3

Background To Dietary Exposure Assessments

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

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

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

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

Determination of the residues of a chemical in a treated food

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

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

Determination of the acceptable health standard for a chemical in food

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

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

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

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

Calculating the dietary exposure

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

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

Chronic Dietary Exposure Assessment

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

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

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

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

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

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

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

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

Attachment 4

Summary of Submissions Received

Submitter	Comments raised
Food Technology Association of Victoria	Supported the Application.
Bashir Ahmad Garnie	Supported the Application.
Sarah Jarvie	Supported the Application.
New South Wales Food Authority	Supported the Application.
Queensland Health	Supported the Application