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

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FINAL ASSESSMENT REPORT

APPLICATION A608

MAXIMUM RESIDUE LIMITS – OXYTETRACYCLINE (ANTIBIOTIC)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

Oxytetracycline (OTC) is an antibiotic. It is temporarily registered under a permit, by the Australian Pesticides and Veterinary Medicines Authority (APVMA), for use in the treatment and control of bacterial infections in farmed fish.

Application A608 seeks to omit the temporary (denoted by the 'T') Maximum Residue Limit (MRL) for OTC in salmonids of T*0.2 mg/kg and replace it with a more general temporary MRL of T0.2 mg/kg for fish in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* (the Code). The temporary designation is retained as this denotes that the MRL has been established to cover the residues arising from the temporary use of OTC in farmed fish under the APVMA permit.

It is also recommended that the '*' symbol indicating that the MRL is at the limit of quantification (LOQ) be removed as analytical methods can now measure OTC residues in fish at levels significantly lower than 0.2 mg/kg.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety by ensuring that any potential residues in food are within appropriate safety limits. The dietary exposure assessment indicates that in relation to the current health reference standard, setting the MRL as proposed does not present any public health and safety concerns.

The *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty), excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

The Applicant initially sought to include an MRL for fish muscle, which is consistent with draft international commodity names that are being introduced for MRLs for veterinary medicines. The Code currently incorporates commodity names which have been established primarily for agricultural chemicals, and whole commodities as generally traded. Because fish may be traded as a whole commodity, with heads and bones, an MRL that is limited to only the muscle tissue may prevent a whole commodity with detectable levels of OTC in the heads and bones to be able to move in trade. This was not the intent of the APVMA Application. The APVMA amended its Application to request the MRL be for fish, not fish muscle.

Food Standards Australia New Zealand (FSANZ) recognises that there is an international movement toward different MRL setting processes and commodity names for veterinary medicines and agricultural chemicals. FSANZ notes this new direction and will work closely with the APVMA and jurisdictions to develop a uniform approach regarding how future MRL notifications for veterinary medicines could be incorporated into the Code.

In their submission, the Queensland Government suggested that a method for analysis and sampling of fish for OTC be developed. FSANZ considered this and determined that prescribing a method of analysis is outside the scope of this Application and would also warrant a national discussion on the appropriateness of this prescriptive measure.

Additionally, it is likely that this would delay the process of setting an MRL to allow fish currently being legally treated with OTC to be sold.

The MRL variation for OTC in fish, which has been amended from that proposed in the Initial/Draft Assessment Report, has been agreed to by the Applicant and the jurisdiction that raised the issue in their submission.

FSANZ made a Sanitary and Phytosanitary notification to the World Trade Organization (WTO). No comments were received from WTO members.

FSANZ decided, pursuant to section 36 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), as in force before 1 July 2007, to omit to invite public submissions in relation to the Application prior to making a Draft Assessment. In making this decision, FSANZ was satisfied that the Application raised issues of minor significance or complexity only. FSANZ considered submissions on the Draft Assessment Report in making the Final Assessment.

Purpose

The purpose of this Application is to remove the current OTC MRL for salmonids and replace it with a general MRL for fish in the Code in line with permitted use of OTC in aquaculture in Australia. This will permit the sale of farmed fish with residues up to the MRL and protect public health and safety by minimising residues in foods consistent with the effective treatment of OTC sensitive infections.

Decision

FSANZ has made an assessment and recommends approving the draft variation to Standard 1.4.2 – Maximum Residue Limits to include a temporary MRL of T0.2 mg/kg for oxytetracycline in fish.

Reasons for decision

FSANZ recommends approving the draft variation to Standard 1.4.2 for the following reasons:

- MRLs serve to allow residues of agriculture and veterinary chemicals to be present in food.

- MRLs serve to protect public health and safety by setting a maximum limit for residues that are used for the control of pests and diseases in food.

- The Dietary Exposure Assessment indicates that setting the MRL as proposed does not present any public health and safety concerns.

- OTC is not considered to present a significant risk in the development of antimicrobial resistance in the treatment of infections in humans.

- The variation will benefit stakeholders by maintaining public health and safety while permitting the legal sale of fish treated with OTC, with residues up to the MRL, to control OTC sensitive infections.

- The variation will also benefit importers by allowing the import of fish with residues of OTC up to the MRL.

- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of OTC in farmed fish and established a MRL for fish as outlined in this Application.

- The Office of Chemical Safety (OCS), part of the Therapeutic Goods Administration (TGA), has undertaken an appropriate toxicological assessment of OTC and has established an acceptable daily intake (ADI).

- FSANZ has undertaken a regulation impact assessment and concluded that the draft variation is necessary, cost-effective and will benefit producers and consumers.

- The variation will remove a discrepancy between agricultural and food legislation and provide certainty and consistency for producers of domestic and export fish and fish products, importers of fish and fish products and Australian, State and Territory enforcement agencies.

- The amendment is consistent with the FSANZ Act section 18 objectives.

Consultation

FSANZ has completed the assessment of Application A608 and held one round of public consultation, between 8 August 2007 and 19 September 2007, under section 36 of the FSANZ Act, as in force before 1 July 2007. Public comment was specifically sought on the cost/benefit impacts and public health and safety considerations associated with the proposed MRL.

This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

If the Ministerial Council does not request FSANZ review the draft amendment 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.

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INTRODUCTION

This Application was received from the Australian Pesticides and Veterinary Medicines Authority (APVMA) on 7 June 2007 seeking a variation to Standard 1.4.2 – Maximum Residue Limits (Australia only). The draft variation to the standard extends the current oxytetracycline (OTC) Maximum Residue Limit (MRL) of T*0.2 mg/kg in salmonids to a temporary MRL of T0.2 mg/kg for fish. This brings the Code in line with permits for use of OTC in aquaculture in Australia.

The Applicant initially sought a variation to Standard 1.4.2 to include an MRL for fish muscle, which is consistent with the Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA) draft food commodity classification system. Fish muscle is not a commodity name currently used in the Code and because fish may be sold as a whole commodity, with heads and bones, an MRL that is limited to only the muscle tissue may prevent a whole commodity with detectable levels of OTC in the heads and bones to be able to move in trade. This limitation was not the intent of the APVMA Application and on 6 December 2007, the APVMA amended its Application to request the MRL be for fish. FSANZ accepted this amendment.

FSANZ recognises that there may be an international movement toward different MRL-setting processes and commodity names for veterinary medicines and agricultural chemicals. FSANZ notes this new direction and will work closely with the APVMA and jurisdictions to develop a uniform approach regarding how future MRLs for veterinary medicines could be incorporated into the Code.

FSANZ's role in the regulation of agricultural and veterinary chemicals is to protect public health and safety. This is achieved by setting maximum limits for potential residues that may be present in food, within appropriate safety limits.

The MRL is the highest concentration of a chemical residue, expressed in milligrams per kilogram (mg/kg), that is legally permitted or accepted in food for sale. 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 for that chemical.

FSANZ will not agree to adopt an MRL into the Code where dietary exposure to potential residues of a chemical presents a 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.

MRLs assist in determining whether a veterinary or agriculture product has been used according to its registered use. If the MRL is exceeded it would indicate that the chemical has been misused.

FSANZ does not issue permits or grant permission for the temporary use of agricultural and veterinary chemicals. This role is undertaken by the APVMA. Further information on permits for the use of agricultural and veterinary chemicals can be found on the APVMA website at www.apvma.gov.au or by contacting APVMA on +61 2 6210 4700.

1. Background

1.1 Current Standard

Standard 1.4.2 currently lists MRLs for oxytetracycline in: kidney of cattle, goats, pigs and sheep; liver of cattle, goats, pigs and sheep; meat (mammalian); milks; poultry, edible offal of; and poultry meat and temporary MRLs for honey and salmonids.

The APVMA recently approved the use of OTC to treat infections caused by OTC-sensitive organisms in farmed fish and made amendments to the APVMA MRL Standard accordingly. Consequently there is a discrepancy between the potential residues associated with the use of OTC and the temporary MRLs in Standard 1.4.2.

In its Application, the APVMA recommended that the temporary status of the APVMA MRL be retained and that the '*' symbol indicating that the MRL is at the limit of analytical quantification (LOQ) be removed as analytical methods can now measure OTC residues in fish at levels significantly lower than 0.2 mg/kg.

1.2 Use of Agricultural and Veterinary Chemicals

In Australia, the APVMA is responsible for assessing and registering agricultural and veterinary chemical products, and regulating them up to the point of sale. Following the sale of such products, the use of these chemicals is regulated by State and Territory 'control of use' legislation.

Before registering a chemical product, the APVMA independently evaluates its safety and performance, making sure that the health and safety of people, animals and the environment are protected.

When a chemical product is registered for use or a permit for use granted, the APVMA includes MRLs in the APVMA 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.

Whilst there are no currently registered chemical products containing antibiotics for use against bacterial infections in farmed fish in Australia, the APVMA has temporarily approved the use of OTC under permit to treat infections caused by susceptible organisms. Additionally, OTC is registered and legally used in other countries. The absence of an MRL in Australia for such antimicrobial agents for use in aquaculture systems has been identified as a significant risk to the sustainability of this industry. Significant outbreaks of bacterial disease have already occurred in finfish in aquaculture in Australia, including *Streptococcus iniae*, *Vibrio* spp., *Aeromonas* spp. and rickettsia-like organisms.

1.3 Maximum Residue Limit Applications

After registering agricultural or veterinary chemical products based on scientific evaluations, the APVMA makes applications to FSANZ to adopt the MRLs into Standard 1.4.2. FSANZ reviews information provided by APVMA and validates whether dietary exposure is within appropriate safety limits, such as the Acceptable Daily Intake (ADI) or other recognised reference health standard.

If satisfied that the residues are within safety limits and subject to adequate resolution of any issues raised during public consultation, FSANZ will agree to incorporate the proposed MRLs in Standard 1.4.2.

Appropriate toxicology, residue, animal transfer, processing and metabolism studies are provided to the APVMA in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the application for an OTC MRL for fish as outlined in this Application.

FSANZ notifies the Ministerial Council when variations to the Code are approved. If the Ministerial Council does not request a review of the draft variation to Standard 1.4.2, the MRL is automatically adopted by reference into the food laws of the Australian States and Territories.

A report on oxytetracycline is available on request from the relevant Project Coordinator at FSANZ on +61 2 6271 2222.

1.4 Variation to Standard 1.4.2 Maximum Residue Limits

The draft variation is to omit the MRL for the antibiotic oxytetracycline in salmonids of T*0.2 mg/kg and insert an MRL of T0.2 mg/kg for fish in the Code. The variation would mean extending the current permission to include all fish (excluding crustacea) and allow the sale of fish and fish products with OTC residues up to the MRL. The requested MRL and dietary exposure estimate are outlined in the table below.

A guide to the table with notes on terms used and a list of acronyms appearing in MRL application reports are provided in **Attachment 2**.

In considering issues associated with MRLs, it should be noted that MRLs and variations to MRLs in the Code do not permit or prohibit the use of agricultural and veterinary chemicals. Other Australian Government, State and Territory legislation regulates use of agricultural and veterinary chemicals.

Since the Draft Assessment Report was released, the Applicant communicated that they would like to make an amendment to the proposed commodity that the MRL would apply. The Applicant amended the commodity name from 'fish muscle' to 'fish'. This change is necessary because the trade of fish may be as the whole commodity, including head and bones, and a commodity limited to 'fish muscle' may prevent a whole fish with detectable levels of OTC in the head or bones to move in trade. This request seems reasonable as the MRL needs to be practical for commercial use.

The draft variation to Standard 1.4.2 of the Code is at **Attachment 1**.

Requested MRLs			Dietary Exposure Estimates
Oxytetracycline Oxytetracycline belongs to the tetracycline class of antibiotics. This class has human analogues. In Australia OTC is only used in veterinary situations. The APVMA has advised that the registered use relates to permits to treat bacterial infections in farmed fish intended for human consumption. OTC is incorporated into feed that is administered to fish to treat infections caused by OTC sensitive organisms. Tetracyclines affect antimicrobial activity by binding to the 30S ribosomal subunit of susceptible organisms. This interferes with the binding of aminoacyl *t*RNA to the messenger RNA/ribosome complex, which interferes with bacterial protein synthesis in growing or multiplying organisms.			National Estimated Daily Intake (NEDI) = 4% of ADI
Salmonids	Omit	T*0.2	
Fish	Insert	T0.2	

1.5 Acute Dietary Exposure

FSANZ and the APVMA use dietary exposure assessments (dietary modelling) to estimate the public health impact of chemical residues in food. National acute dietary exposure is assessed against an acute reference dose (ARfD). In Australia, ARfDs are set by the Office of Chemical Safety (OCS), internationally, they are set by the Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA). Neither the OCS nor JECFA have established an ARfD for OTC, therefore no estimate of the national acute dietary exposure (National Estimated Short Term Intake or NESTI) has been conducted. The dietary exposure assessment and the terms are further explained in the risk assessment section of this report (Section 5) and in **Attachment 2**.

1.6 Antimicrobial Resistance

The National Health and Medical Research Council (NHMRC) established the Expert Advisory Group on Antimicrobial Resistance (EAGAR) to provide advice to government and regulatory agencies on antimicrobial resistance and measures to reduce the risks of antimicrobial resistance. EAGAR's interest in the development of antimicrobial resistance focuses on antimicrobials of high and medium importance in the treatment of human infections.

OTC belongs to the tetracycline group of antibiotics. Other antibiotics in this group such as demeclocycline, doxycycline, minocycline and tetracycline are used in human therapeutics and are classed as antibiotics of low importance in the EAGAR Importance Ratings and Summary of Antibiotic Uses in Humans in Australia.

As part of its Application to vary the OTC MRL for salmonids in the Code, the APVMA provided information on the use of OTC in aquaculture systems to EAGAR. As OTC is part of the tetracycline group of antibiotics that is of low importance in the treatment of human infections and is only used in veterinary situations in Australia, EAGAR considers its endorsement of the recommended MRL is not required.

Based on the above, and taking into consideration the results of the dietary exposure assessment, FSANZ concludes that there are no anticipated antimicrobial resistance concerns arising from this Application. The draft variation poses no adverse consequences to human health.

1.7 Australia and New Zealand Joint Food Standards

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

The Trans Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand commenced on 1 May 1998. The following provisions apply under the TTMRA.

- Food produced or imported into Australia that complies with Standard 1.4.2 can be legally sold in New Zealand.

- Food produced or imported into New Zealand that complies with the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Food Standards, 2007* can be legally sold in Australia.

New Zealand MRLs are further discussed in section 10.4 of this Report.

2. The Problem and Issues

2.1 The Problem

Including MRLs in the Code allows commodities legally treated, and where any residues do not exceed MRLs, to be sold legally. Changes to Australian MRLs reflect the changing availability of agricultural and veterinary chemicals to primary producers including aquaculturalists. These changes include both the development of new products and crop or animal uses, and the withdrawal of older products following review.

Currently, the Code allows OTC to be present only in salmonids. Salmonids refers to members of the fish family 'Salmonidae', this includes salmon, trout and chars. There are other fish that are not members of the salmonid family.

This Application emerged as a result of the APVMA issuing an emergency permit for the temporary use of OTC as a constituent of a medicated feed for use in non-salmonid farmed fish (aquaculture). These fish are unable to be sold legally in Australia with any residues of OTC.

2.2 The Issues

Whilst it is likely that the use of OTC in Australia would be limited to the treatment of farmed finfish, the draft variation does not limit the MRL to 'finfish'.

The APVMA's initial recommendation for the MRL entry for OTC in fish muscle is consistent with the JECFA draft food commodity classification system and the limit is consistent with the international Codex Standard.

However, 'fish muscle' is not a commodity name currently used in the Code and because fish may be sold as a whole commodity, with heads and bones, etc, an MRL that is limited to only the muscle may prevent a whole commodity with detectable levels of OTC in the heads and bones to be able to move in trade.

FSANZ recognises that 'fish muscle' is a JECFA commodity name and as such, the commodity name does not currently appear in the Code. This issue was raised during the public consultation period and is addressed further in Section 10.1.

Standard 2.2.3 in the Code has a general definition for 'fish', which includes crustaceans. However, Standard 1.4.2 has specific commodities and portions to which the MRLs apply. Schedule 4, within Standard 1.4.2, separates fish from crustaceans. This indicates that, for the purpose of the APVMA Application, the MRL proposed for fish would not apply to crustaceans.

3. Objectives

In assessing this Application, FSANZ aims to ensure that the proposed MRL does not present a risk to public health and safety and that the sale of legally treated food is permitted. The APVMA has allowed the use of OTC under permit in accordance with its legislation, and now seeks to have the relevant MRL amendment included in Standard 1.4.2 of the Code.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The Ministerial Council has endorsed a Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food[1], which has been provided to FSANZ.

[1] http://www.foodstandards.gov.au/standardsdevelopment/ministerialcouncilpo1603.cfm accessed 27 September 2007.

In consultation with stakeholders, FSANZ is exploring alternative options for regulating chemical residues in food. To ensure appropriate consultation, this process will take some time to complete.

The draft variation to Standard 1.4.2 is consistent with the section 18 objectives, including the Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food.

4. Key Assessment Questions

The primary role of FSANZ in developing food regulatory measures for agricultural and veterinary chemicals is to ensure that the potential residues in treated food do not present public health and safety concerns.

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

In assessing the public health and safety implications of chemical residues, FSANZ considers dietary exposure to chemical residues from potentially treated foods in the diet by comparing dietary exposure with the relevant health standard. FSANZ will not approve MRLs for inclusion in the Code where the dietary exposure to residues of a chemical could represent a risk to public health and safety. In assessing this risk, FSANZ reviews dietary exposure assessments in accordance with internationally accepted practices and procedures.

RISK ASSESSMENT

5. Risk Assessment Process

5.1 Determination of the Residues of a Chemical in a Treated Food

The APVMA assesses a range of data when considering the proposed use of a chemical product on a food. These data assist the APVMA to determine what the likely residues of a chemical will be in a treated food. The APVMA also use these data to determine the maximum amount of residues that would be likely to be in a food if the chemical product is used as proposed. The APVMA then establishes an MRL. For OTC, the APVMA established a temporary 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 a risk to public health and safety.

5.2 Determining the Acceptable Reference Health Standard for a Chemical in Food

The APVMA and FSANZ use reference health standards in dietary exposure assessments. Reference health standards indicate the amount of the food chemical that can be ingested from the diet every day over a lifetime without any appreciable risk to health.

In setting a reference standard, the OCS assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI and where applicable, the ARfD for chemicals. The Australian ADI for OTC was adopted from the figure established by JECFA. Neither the OCS nor JECFA have established an ARfD for OTC, and as such a NESTI has not been calculated.

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.

5.3 Dietary Exposure Assessment

Dietary modelling combines food consumption data with food chemical concentration data to estimate dietary exposure (intake) to food chemicals. In a dietary exposure assessment, estimated dietary exposure to a food chemical is compared to an established reference health standard.

In assessing the public health and safety implications of chemical residues, FSANZ considers the APVMA dietary exposure assessment and provides an independent assessment of the dietary exposure to chemical residues from potentially treated foods in the diet by comparing the dietary exposure with the relevant health standard. FSANZ will <u>not</u> approve MRLs for inclusion in the Code where the dietary exposure to the residues of a chemical could represent a risk to public health and safety. Dietary exposure assessments are conducted in accordance with internationally accepted practices and procedures.

The main steps undertaken in conducting a dietary exposure assessment are:

- determination of the chemical residue and its likely concentration in a treated food;
- validation of the acceptable reference health standard/s for a chemical in food (i.e. the ADI and/or the ARfD);
- calculating the dietary exposure to a chemical from relevant foods, using food consumption data from national nutrition surveys; and
- comparing the estimated dietary exposure to the acceptable reference health standard.

5.4 Calculating Dietary Exposure (chronic and acute)

The APVMA and FSANZ undertake chronic dietary exposure assessments for all agricultural and veterinary chemicals and undertake acute dietary exposure assessments where OCS or the Joint Food and Agriculture Organization / World Health Organization Meeting on Pesticide Residues (JMPR) or JECFA (in the case of antibiotics) have established an ARfD. The dietary exposure assessments are based on food consumption data for raw commodities, derived from individual dietary records from the latest National Nutrition Survey (NNS).

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

5.4.1 Chronic Dietary Exposure Assessment

The National Estimated Daily Intake (NEDI) represents an estimate of chronic dietary exposure. Chemical residue data, as opposed to the MRL, are the preferred concentration data to use if they are available, as they provide a more realistic estimate of dietary exposure. The NEDI calculation may incorporate more specific data including food consumption data for particular 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 agricultural or veterinary chemical residue levels. Monitoring and surveillance data or data from such as the Australian Total Diet Surveys (ATDS) may also be used.

In conducting chronic dietary exposure assessments, the APVMA and FSANZ consider the residues that could result from the permitted uses of a chemical product on foods. Where data are 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 commodity is treated with an agricultural or veterinary chemical; 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 compound over the lifetime of consumers.

The residues that are likely to occur in all foods are multiplied by the mean daily consumption of these foods derived from individual dietary records from the latest 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 or bread. The estimated exposure for each food is added together to provide the total mean dietary exposure to a chemical from all foods with MRLs.

The estimated mean dietary exposure 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 mean 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 mean dietary 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 commodities 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 agriculture 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.

5.4.2 Acute Dietary Exposure Assessment

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 for 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.

The NESTI is calculated in a similar way to the chronic dietary exposure. The residues of a chemical in a specific food are multiplied by the 97.5^{th} percentile food consumption of that food, a variability factor is applied if appropriate, the exposure divided by a mean body weight for the population group being assessed and this result is compared to the ARfD. NESTIs are calculated from ARfDs set by OCS, JMPR or JECFA, the consumption data from the 1995 NNS and the MRL when the data on the actual residues in foods are not available. FSANZ considers that the acute dietary exposure to the residues of a chemical is acceptable where the best estimate of acute dietary exposure does not exceed the ARfD.

6. Risk Assessment Summary

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

For this Application, the APVMA has assessed appropriate toxicology, residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005.* The outcomes of this assessment supported the use of OTC in farmed fish and recommended an MRL for fish of T0.2 mg/kg. The APVMA advised that the proposed T0.2 mg/kg would be appropriate for all fish.

The OCS has undertaken an appropriate toxicological assessment of the chemical products and has established an ADI of 0.03 mg/kg bw/day for OTC. The Australian ADI was adopted from the figure established by JECFA. As neither OCS nor JECFA have established an ARfD for OTC, a NESTI has not been calculated.

FSANZ reviewed the dietary exposure assessment submitted by the APVMA as part of its Application and concluded that the residues associated with the proposed MRL for fish do not present any public health and safety concerns. This was determined by comparing estimates of dietary exposure to OTC (calculated using national food consumption data and MRLs for all foods for which its use is permitted during production), with the ADI. The NEDI for OTC is 4% of the ADI.

The additional safety factors inherent in calculation of the ADI mean that there is negligible risk to public health and safety when estimated exposures are well below this reference health standard.

The NEDI calculation is a conservative overestimate of dietary exposure to potential residues in food. In reality, only a portion of fish for which use of OTC is permitted would be treated with it during production. Also, most treated commodities contain residues well below the MRL before they appear on the market; and residues are usually reduced during storage, washing, preparation, commercial processing and cooking. It is also unlikely that every food for which an MRL is proposed or permitted will have been treated with the same pesticide during production and eaten over the lifetime of consumers.

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.

RISK MANAGEMENT

7. Options

7.1 Option 1 – no change to the existing oxytetracycline temporary MRL for salmonids

Under this option, the *status quo* would be maintained and there would be no change to the existing OTC MRL of T*0.2 mg/kg in salmonids in the Code.

7.2 Option 2 – vary Schedule 1 of Standard 1.4.2 in the Code to extend the existing permission to fish as proposed

Under this option, the oxytetracycline MRL of T*0.2 mg/kg in salmonids would be omitted and the proposed MRL of T0.2 mg/kg in fish would be approved for inclusion in the Code.

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 affected parties, any alternative options consistent with the objective of the proposed changes, and the potential impacts of any regulatory or non-regulatory provisions. Information from public submissions is needed to make a final assessment of the proposed changes.

8.1 Affected Parties

The parties affected by the proposed MRL amendment include:

- domestic and international consumers;
- producers and processors of domestic and export fish and fish products;
- importers of fish and fish products; and
- Australian Government, State and Territory agencies involved in monitoring and regulating the use of agricultural and veterinary chemicals in food and the potential resulting residues.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – no change to the existing oxytetracycline temporary MRL for salmonids

8.2.1.1 Benefits

- for consumers there are unlikely to be any discernable benefits;
- for producers and processors of domestic and export fish commodities this option would not result in any discernable benefits;
- for importers this option would not result in any discernable benefits; and
- for Australian Government, State and Territory agencies this option would not result in any discernable benefits.

8.2.1.2 Costs

- for consumers there are unlikely to be any discernable costs as the unavailability of some fish or fish products from certain suppliers is likely to be seen as typical fluctuation in the food supply;

- for producers and processors of domestic and export fish and fish products the absence of an MRL may give rise to the concern that legal use of chemical products may result in the production of fish and fish products that may not be legally sold under food legislation. Primary producers do not produce food or use antibiotics to comply with MRLs. They use antibiotics to treat and control disease in accordance with the prescribed label conditions, and expect that the resulting residues will be acceptable and that legally treated food can be legally sold;

- for importers this option would not result in any discernable costs; and

- for Australian Government, State and Territory agencies, this option would give rise to uncertainty, inefficiency and confusion in the enforcement of regulations.

8.2.2 Option 2 – vary the Code in Schedule 1 of Standard 1.4.2 to extend the existing permission to fish as proposed

8.2.2.1 Benefits

- maintaining consumer confidence in the food supply in relation to residues of veterinary chemicals in foods and potential flow on benefits resulting from the price and availability of fish and fish products if producers and processors can legally sell food containing residues consistent with the proposed extended permission;

- producers and processors would legally be able to sell fish and fish products containing residues up to the proposed MRL;

- fish and fish products with residues consistent with the proposed MRL could be legally imported and sold; and

- for Australian Government, State and Territory agencies, an MRL in line with the permitted use would create certainty and allow efficient enforcement of regulations.

8.2.2.2 Costs

- for consumers there are unlikely to be any discernable costs;

- for producers and processors of domestic and export fish and fish products, this option is unlikely to result in any discernable costs because the proper use of OTC will result in compliance with the proposed MRL;

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

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

- there are unlikely to be any discernable costs to industry or government by varying the MRL to extend the permission to fish. This is reflected in the Business Cost Calculator Report, in accordance with the Office of Best Practice Regulation (OBPR) guidelines which is found at **Attachment 4**.

8.3 Comparison of Options

In assessing applications, FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community, including consumers, food industries and governments in Australia. For Application A608, there are no options other than a variation to Standard 1.4.2.

FSANZ's preferred approach is to adopt option 2 – to vary the Code in Schedule 1 of Standard 1.4.2 to extend the existing permission for OTC residues in salmonids to permit a temporary MRL of 0.2 mg/kg of this antibiotic in fish for the following reasons:

- There are no public health and safety concerns associated with the proposed MRL amendment (this benefit also applies to option 1).

- The change would minimise potential costs to producers and processors of fish and fish products and rural and regional communities in terms of confidence in legally being able to sell legally treated fish and fish products.

- The change would minimise residues consistent with the effective use of veterinary medicine to treat diseases.

- An MRL in line with the permitted use of OTC in aquaculture would assist enforcement.

Option 1 is an undesirable option.

- The costs to producers and processors of fish and fish products would result from an inability to sell legally treated food. These costs may impact negatively on their viability and in turn the viability of the rural and regional communities that depend upon the sale of fish commodities.

- A discrepancy between permitted use of the antibiotic and food legislation could have negative impacts on compliance costs for producers and processors of fish and fish products, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

Applications by the APVMA to amend MRLs in the Code do not normally generate public interest. FSANZ adopts a basic communication strategy, with a focus on alerting the community that a change to the Code is being contemplated.

FSANZ publishes the details of the Application and subsequent assessment reports on its website, notifies the community to the period of public consultation through newspaper advertisements, and issues media releases drawing attention to proposed Code amendments. Once the Code has been amended, FSANZ incorporates the changes in the website version of the Code and, through its email and telephone advice service, responds to industry enquiries.

Should the media show an interest in the antibiotic being assessed, FSANZ or the APVMA can provide background information and other advice as required.

10. Consultation

To assist FSANZ in making its Final Assessment, FSANZ, under section 36 of the FSANZ Act, as in force before 1 July 2007, invited one round of public comment, between 8 August 2007 and 19 September 2007. Public comment was specifically sought on the cost/benefit impacts and public health and safety considerations associated with the proposed MRL. Six submissions were received during this period, and are summarised in **Attachment 4.**

Submissions were received from: one member of the public; the Food Technology Association of Australia (FTAA); the Queensland Health Environmental Health Unit; the New South Wales Food Authority (NSWFA); the Australian Food and Grocery Council (AFGC); and the Food and Beverage Importers' Association (FBIA).

The issues raised by Queensland Health (commodity description), the FBIA (inclusion of prawns), the AFGC (cost to exporters and compliance with the European Union (EU) limit), and the member of the public (antimicrobial resistance) are addressed below.

10.1 Issues raised in submissions

10.1.2 Queensland Health

Queensland Health supported the proposed MRL subject to a number of issues being addressed in the Final Assessment Report.

Queensland Health noted that in the Draft Assessment Report, the APVMA approval for OTC was for farmed finfish and the proposed variation to the OTC MRL was to extend the limit from salmonids to fish muscle and that the proposed MRL would apply to <u>all</u> fish. Queensland Health implied that there was inconsistency in the terms used in the Draft Assessment Report.

<u>10.1.2.1 FSANZ response</u>

FSANZ acknowledges that at Draft Assessment the proposed MRL would apply to <u>all</u> fish muscle. However, the amended Application means that the proposed MRL would apply to fish as per Schedule 4 Foods and classes of foods in Standard 1.4.2. Currently, Schedule 4 indicates that fish includes diadromous, marine and freshwater fish. Schedule 4 separates fish and crustaceans and as such crustaceans would be excluded from the MRL for OTC.

In its submission, the Queensland Government suggested that a method for analysis and sampling of fish for OTC be developed.

FSANZ considered this and determined that prescribing a method of analysis is outside the scope of this Application and could result in a delay to the inclusion of an MRL in the Code for OTC. This would delay fish that are currently able to be legally treated with OTC to be sold. Further, FSANZ held communications with the relevant Queensland agencies, which supported FSANZ's approach to not unnecessarily delay the completion of this MRL Application.

Based on the data provided by the APVMA and FSANZ's own assessment of the scientific literature, FSANZ is satisfied that the MRL applies to all fish.

10.1.3 Food and Beverage Importers Association (FBIA)

The FBIA requested that prawns be specifically included in the MRL or that an editorial note be considered to indicate that 'fish' includes prawns (as per the definition in Standard 2.2.3 – Fish and Fish Products). The FBIA also provided documentation from Thailand and Codex to support the consideration of including prawns in the proposed MRL.

10.1.3.1 FSANZ response

The original intent of the APVMA Application was to allow farmed fish, such as Barramundi, legally treated with OTC to be legally sold in Australia. The intent was not to include crustacea.

FSANZ discussed the inclusion of crustaceans, in particular prawns, with the Applicant. The APVMA advised that it did not establish the proposed MRL with any potential use levels in crustacea or provide a dietary exposure assessment of crustacea to determine any public health and safety issues. The APVMA proposed the MRL for fish and did not intend to include prawns, therefore the draft variation is limited to fish. FSANZ has noted the FBIA submission to include a MRL for OTC in crustaceans and will consider this issue in any future OTC proposal with a view to further align the Australian MRL with international standards.

10.1.4 Australian Food and Grocery Council (AFGC)

The AFGC raised the issue that the EU currently permits OTC residues of up to 0.1 mg/kg in all food producing animals, therefore there may be a cost to producers exporting to the EU market in ensuring that their products are compliant with the EU limit. Additionally, the AFGC queried the difference between the EU limit and the proposed Australian MRL.

10.1.4.1 FSANZ response

The APVMA has proposed an MRL of T0.2 mg/kg and a withholding period for fish treated with OTC that, if used in accordance with the directions, will result in residue levels that are not detectable. A not detectable level could be considered best practice. Fish harvested within this holding period, could potentially have residue levels that exceed the proposed MRL or an international limit. Producers wanting to harvest fish prior to the end of the withholding period and export to the EU would need to analyse fish to ensure the residue limit is not exceeded. However, complying with the recommended withholding period would ensure that residue levels are below the required limit and there would be no discernable cost to exporters.

10.1.5 Antimicrobial resistance

A member of the public opposed the approval of all antibiotics due to the possibility that they may lead to antibiotic resistance in pathogens.

10.1.5.1 FSANZ response

Although OTC belongs to the tetracycline group of antibiotics that are used in human therapeutics, OTC is only used in animals in Australia. This group of antibiotics are classed as antibiotics of low importance in the EAGAR Importance Ratings and Summary of Antibiotic Uses in Humans in Australia. Therefore, there are no issues in regard to anti microbial resistance from residues of OTC in fish. This is further discussed in Section 1.7 – Antimicrobial resistance.

10.2 World Trade Organization (WTO)

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

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

Agricultural and veterinary chemicals are used differently in different countries around the world as pests, diseases and environmental factors differ and because permissions for products differ. This means that residues in imported foods may be different from those in domestically produced foods.

Application A608 requests deleting the existing MRL for OTC residues in salmonids and incorporating a more general MRL of T0.2 mg/kg in fish in the Code. In the EU, the European Agency for the Evaluation of Medicinal Products currently permits OTC residues of 100 µg/kg (0.1 mg/kg) in muscle of all food producing species. Oxytetracycline is approved for use in aquaculture in the United States and a tolerance of 2 ppm (2 mg/kg) for residues of OTC in finfish and lobster muscle has been codified. The APVMA has advised that Japan has established an MRL of 0.2 mg/kg for fish. The variation indicates that OTC residues in fish may have an effect on trade of fish and derivative food products between WTO members.

This Application was notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures, as 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 comments were received from WTO members.

10.3 Codex Alimentarius Commission MRLs

Codex standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The following table lists the MRL proposed in Application A608 and its corresponding MRL in the international Codex standard.

Chemical Food	**Proposed MRL** **mg/kg**	**Codex MRL** **mg/kg**
Oxytetracycline Fish	T0.2	fish muscle 0.2

10.4 New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2007

All imported and domestically produced food sold in New Zealand (except for food imported from Australia) must comply with the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Food Standards 2007* (the New Zealand MRL Standards).

Under the New Zealand MRL Standards, agricultural chemical residues, which includes veterinary medicines, in food must comply with the specific MRLs listed in the Standards. The New Zealand Standards also include a provision for residues of up to 0.1 mg/kg for agricultural chemical / commodity combinations not specifically listed or, if the food is imported, it may comply with Codex MRLs. Further information about the New Zealand MRL Standards is available on the New Zealand Food Safety Authority website at: http://www.nzfsa.govt.nz/acvm/registers-lists/nz-mrl/index.htm

MRLs in the Code and in the New Zealand MRL Standards may vary for a number of legitimate reasons including differing use patterns for chemical products as a result of varying pest and disease pressures and varying climatic conditions.

The following table lists the proposed variation to the MRL in Application A608 and includes the corresponding MRL that has been established in the New Zealand MRL Standards. Notwithstanding the provision for residues of up to 0.1 mg/kg in the New Zealand MRL Standards, New Zealand has established an MRL of 0.1 mg/kg for oxytetracycline in fish meat.

Chemical Food	**Proposed MRL** **mg/kg**	**NZ MRL** **mg/kg**
Oxytetracycline Fish	T0.2	Fish meat 0.1

CONCLUSION

11. Conclusion and Preferred Approach

This Application has been assessed against the requirements of the FSANZ Act. FSANZ recommends approving the draft variation to Standard 1.4.2 – Maximum Residue Limits.

The preferred approach is to adopt option 2 to vary the oxytetracycline MRL in Schedule 1 of Standard 1.4.2 as proposed.

Preferred Approach

FSANZ has made an assessment and recommends approving the draft variation to Standard 1.4.2 – Maximum Residue Limits to include a temporary MRL of T0.2 mg/kg for oxytetracycline in fish.

11.1 Reasons for Preferred Approach

FSANZ recommends approving the draft variation to Standard 1.4.2 for the following reasons:

- MRLs serve to allow residues of agriculture and veterinary chemicals to be present in food.
- MRLs serve to protect public health and safety by setting a maximum limit for residues that are used for the control of pests and diseases in food.
- The Dietary Exposure Assessment indicates that setting the MRL as proposed does not present any public health and safety concerns.
- Oxytetracycline is not considered to present a significant risk in the development of antimicrobial resistance in the treatment of infections in humans.
- The variation will benefit stakeholders by maintaining public health and safety while permitting the legal sale of fish treated with OTC, with residues in the fish up to the MRL, to control OTC sensitive infections.
- The variation will also benefit importers by allowing the import of fish with residues of OTC up to the MRL.
- The APVMA has assessed appropriate residue, animal transfer, processing and metabolism studies, in accordance with *The Manual of Requirements and Guidelines – MORAG – for Agricultural and Veterinary Chemicals 1 July 2005* to support the use of OTC in farmed fish and established a MRL for fish as outlined in this Application.
- The Office of Chemical Safety (OCS), part of the Therapeutic Goods Administration (TGA), has undertaken an appropriate toxicological assessment of OTC and has established an acceptable daily intake (ADI).
- FSANZ has undertaken a regulation impact assessment and concluded that the draft variation is necessary, cost-effective and will benefit producers and consumers.
- The variation will remove a discrepancy between agricultural and food legislation and provide certainty and consistency for producers of domestic and export fish and fish products, importers of fish and fish products and Australian, State and Territory enforcement agencies.

- The amendment is consistent with the FSANZ Act section 18 objectives.

11.2 Implementation and Review

The use of chemical products and MRLs are under constant review as part of the APVMA Existing Chemical Review Program. In addition, regulatory agencies continue to monitor health, agricultural and environmental issues associated with chemical product use. 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 studies such as the Australian Total Diet Study.

These monitoring programs and the continual review of the use of agricultural and veterinary chemicals mean that there is considerable scope to review chemical residues in food.

The MRL amendment in this Application will take effect on gazettal. The MRL will be subject to existing monitoring arrangements.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. A Guide to the Table Outlining the Requested Variation to Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* and Estimated Dietary Exposure to the Relevant Chemical
3. Summary of issues raised in public submissions
4. Business cost calculator report

Attachment 1

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

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunsetting.

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 *the food and associated MRL for the following chemical –*

OXYTETRACYCLINE INHIBITORY SUBSTANCE, IDENTIFIED AS OXYTETRACYCLINE	
SALMONIDS	T*0.2

[1.2] *inserting in alphabetical order in* Schedule 1*, the food and associated MRL for the following chemical –*

OXYTETRACYCLINE INHIBITORY SUBSTANCE, IDENTIFIED AS OXYTETRACYCLINE	
FISH	T0.2

Attachment 2

A Guide to Dietary Exposure Assessment, the Terms Used in the Table and Risk Assessment

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

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

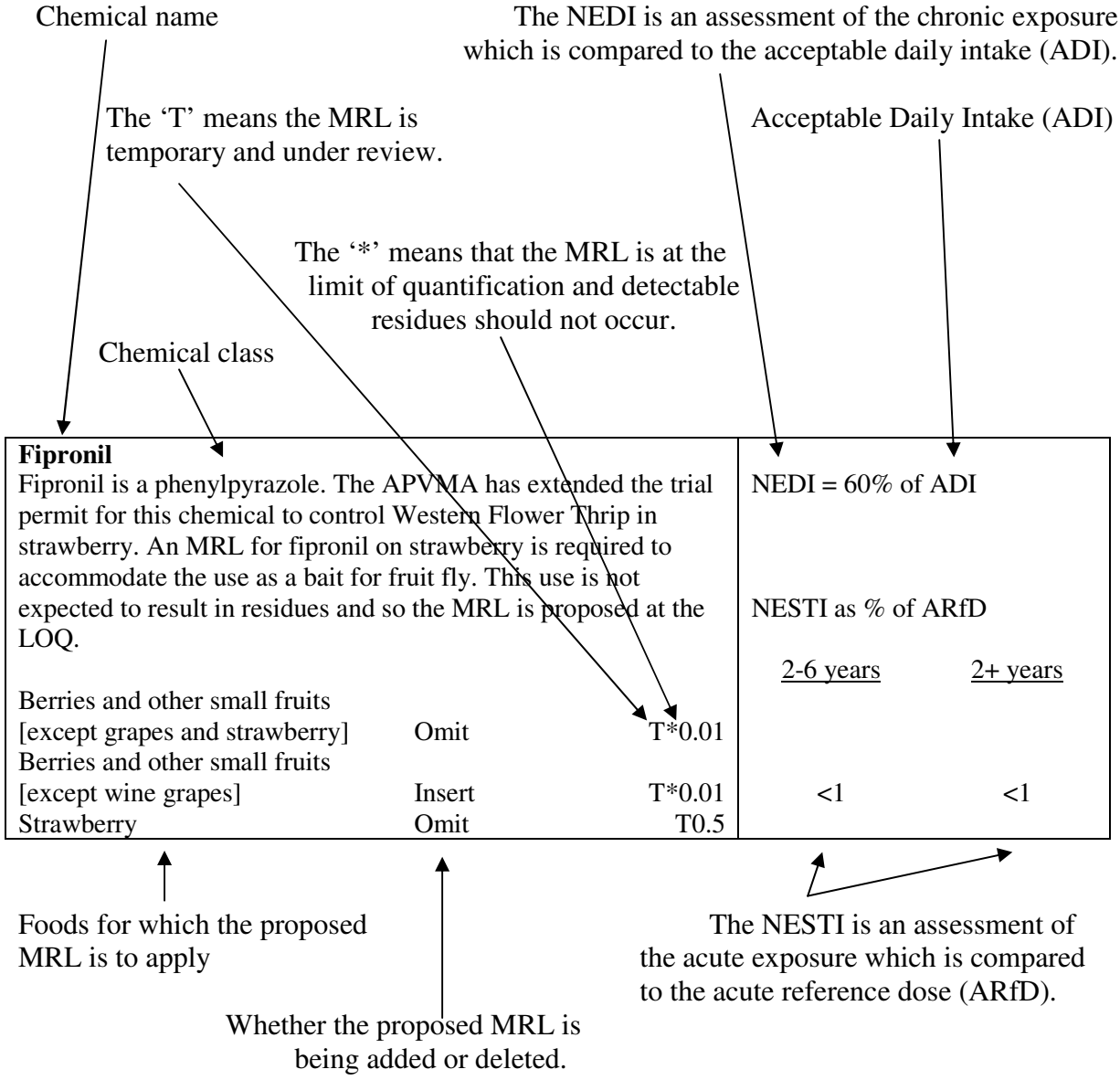
LOQ - Limit of Quantification - The LOQ is the lowest concentration of a pesticide residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

NEDI - National Estimated Daily Intake – Although an estimate of daily intake, the NEDI represents a realistic estimate of chronic dietary exposure and is the preferred calculation. It may incorporate more specific food consumption data including that for particular 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 more specific residue data are often not available and in these cases the MRL is used.

NESTI - National Estimated Short Term Intake - The NESTI is used to estimate acute dietary exposure. Acute (short term) dietary exposure assessments are undertaken when an ARfD has been determined for a chemical. Acute dietary exposures are normally only estimated based on consumption of raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis. FSANZ has used ARfDs set by the TGA and Joint FAO/WHO Meeting on Pesticide Residues, the consumption data from the 1995 NNS and the MRL when the supervised trials median 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 where appropriate.

The following are examples of entries and the proposed MRLs listed are not part of this Application.



There is more information on the NEDI, NESTI ADI and ARfD above and in the Risk Assessment section of this report. 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. And that the acute dietary exposure to the residues of a chemical is acceptable where the best estimate of acute dietary exposure does not exceed the ARfD.

Information about the use of the chemical is provided so consumers can see the reason why the residues may occur in food.

Data from the 19th and 20th Australian Total Diet Surveys (ATDS) are provided when available because they provide an indication of the typical exposure to chemicals in table ready foods. The ATDS results are more realistic because analysed concentrations of the chemical in foods as consumed are used; the NEDI and NESTI calculations are theoretical calculations that conservatively overestimate exposure.

Chlorpyrifos

Chlorpyrifos is an acaricide, nematicide and insecticide. The APVMA has approved an extension of use for the control of pests in coffee crops.

NEDI = 83% of ADI

20th ATDS = <1% of ADI for all population groups assessed

19th ATDS = 3% of ADI for toddlers 2 years, 1% of ADI for boys 12 years and <1% of ADI for other population groups assessed

NESTI as % of ARfD

			2-6 years	2+ years
Coffee beans	Insert	T0.5	8	<1

Small variations may be noted in the exposure assessment between different ATDSs. These variations are minor and typically result because of the different range of foods in the individual studies.

Acronyms:

1.	**ADI**	Acceptable Daily Intake
2.	**APVMA**	Australian Pesticides and Veterinary Medicines Authority
3.	**ARfD**	Acute Reference Dose
4.	**ATDS**	Australian Total Diet Survey (from 2005, this is now called the Australian Total Diet Study)
5.	**the Code**	*Australia New Zealand Food Standards Code*
6.	**DIAMOND**	Dietary Modelling of Nutritional Data
7.	**FSANZ**	Food Standards Australia New Zealand
8.	**JECFA**	Joint FAO/WHO Expert Committee on Food Additives
9.	**JMPR**	Joint FAO/WHO Meeting on Pesticide Residues
10.	**LOQ**	Limit of Analytical Quantification
11.	**MRL**	Maximum Residue Limit
12.	**NEDI**	National Estimated Daily Intake
13.	**NESTI**	National Estimated Short Term Intake
14.	**NNS**	National Nutrition Survey of Australia 1995
15.	**OCS**	Office of Chemical Safety
16.	**TMRL**	Temporary MRL
17.	**TGA**	Therapeutic Goods Administration

Attachment 3

Summary of Submissions

The following submissions were received by FSANZ.

Submitter Organisation	Name
Food Technology Association of Australia	David Gill Paul Elwell-Sutton
Australian Food and Grocery Council	Kim Leighton
Queensland Health	Gary Bielby
New South Wales Food Authority	David Cusack
Food and Beverage Importers Association	Tony Beaver

Submitter	Position	Comments
Food Technology Association of Australia	Supports option 2	The FTAA endorsed the extension of OTC to include fish muscle.
Paul Elwell-Sutton	Does not support the application.	Believes there should be no residues of any antibiotic in food due to the potential for residues to promote antibiotic resistance in pathogens.
Australian Food and Grocery Council	Supports option 2	AFGC notes that the EU limit is 0.1mg/kg and that the APVMA proposal is for T0.2 mg/kg. The AFGC also noted that there may be some cost to exporters to ensure that their products are compliant with the EU limit.
Queensland Health	Supports option 2	Queensland Health would like to see the following issues addressed in the FAR: The use of OTC for all fish and not just farmed fish; Testing as per schedule 4 is difficult as fish are generally traded as whole but the MRL is proposed to only apply to muscle; and The term 'fish muscle' is consistent with JECFA.
New South Wales Food Authority	Supports option 2	The Authority has consulted with NSW Health and NSW DPI prior to the submission.
Food and Beverage Importers Association	Supports option 2	The FBIA would like to have prawns specifically included in the MRL or there be an editorial note that indicates the term 'fish' includes 'prawns'.

Attachment 4

Business Cost Calculator Report

A 608 – Maximum Residue Limits – Oxytetracycline (Antibiotic) in Fish

Problem: Currently, the Code allows oxytetracycline (OTC) to be present only in salmonids. Salmonids refers to members of the fish family 'Salmonidae', this includes salmon, trout and chars. There are other fish that are not members of the salmonid family. This application emerged as a result of the APVMA issuing an emergency permit for the temporary use of OTC as a constituent of a medicated feed for use in non-salmonid farmed fish. These fish are unable to be sold legally in Australia with any residues of OTC.

Objective: To ensure that the proposed MRL does not present a risk to public health and safety and that the sale of legally treated food is permitted.

Policy Options

Option Name	Quickscan Result
• No change to the existing oxytetracycline TMRL for salmonids	FALSE
• Vary the Code in Schedule 1 of Standard 1.4.2 - Maximum Residue Limits to extend the existing permission to fish as proposed	FALSE

Compliance Cost Summary

Option Name: No change to the existing oxytetracycline TMRL for salmonids

Businesses Affected: N/A

Type	Cost per Business	Total Cost of Regulation
N/A	N/A	N/A

Option Name: Vary the Code in Schedule 1 of Standard 1.4.2 - Maximum Residue Limits to extend the existing permission to fish as proposed

Businesses Affected: N/A

Type	Cost per Business	Total Cost of Regulation
N/A	N/A	N/A

Caution should be used comparing options and interpreting results over time. The Business Cost Calculator does not estimate the future values of ongoing costs. Refer to the User Guidelines for further information.

This report contains summaries of compliance costs only. An assessment on the compliance cost in itself does not provide an answer to which policy option is the most effective and efficient one. Rather, it provides information which needs to be considered alongside other relevant factors and issues when deciding between alternative policy options.