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

6-04
4 August 2004

INITIAL / DRAFT ASSESSMENT REPORT

APPLICATION A535

MAXIMUM RESIDUE LIMITS – NEOMYCIN (ANTIBIOTIC)

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
15 September 2004
(See 'Invitation for Public Submissions' for details)

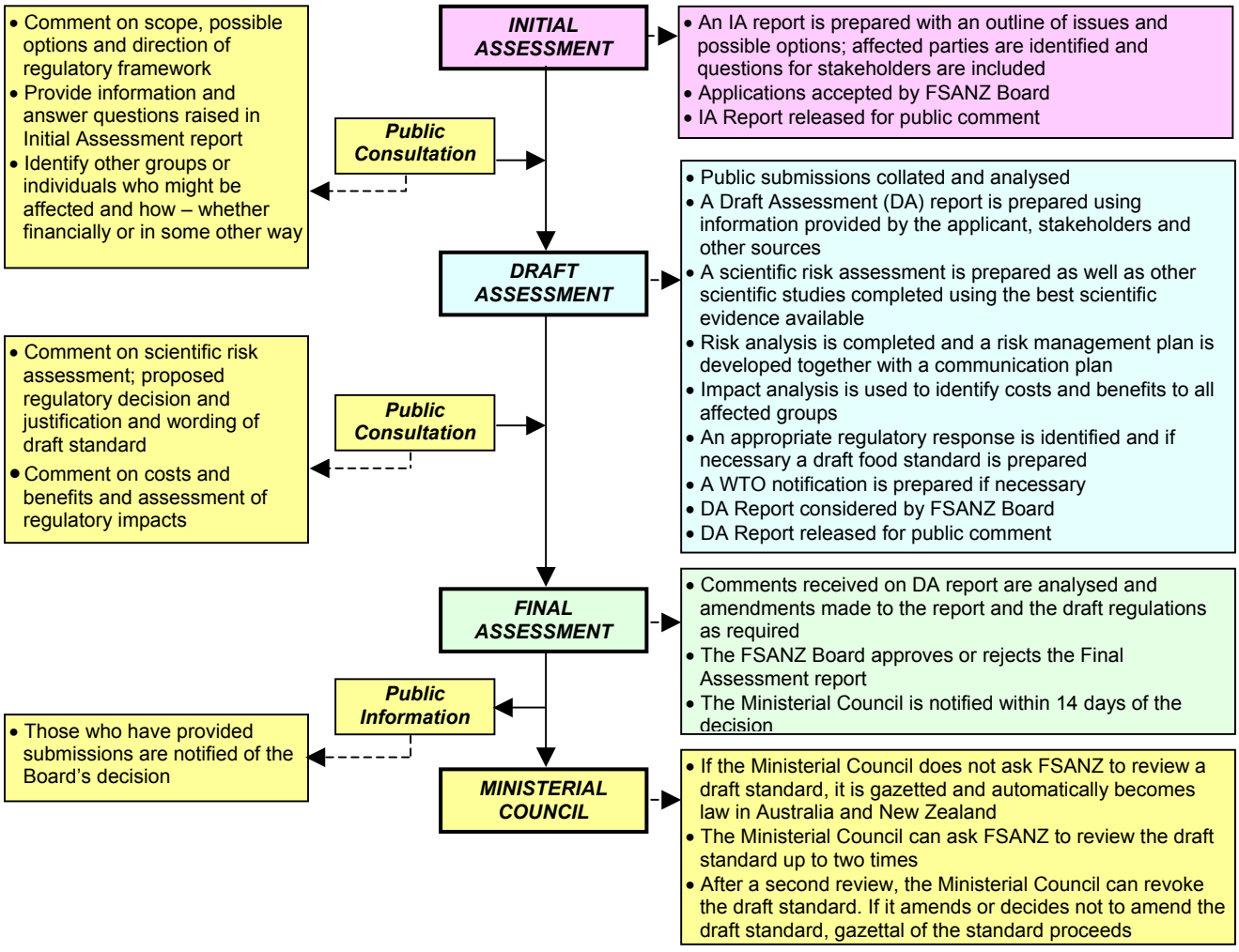
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

The process for amending the *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.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial / Draft Assessment Report of Application A535, which includes the identification and discussion of the key issues and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Initial / Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

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

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

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

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

Submissions should be received by FSANZ **by 15 September 2004**.

Submissions received after this date may not be considered, unless the Project Coordinator has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary and Statement Of Reasons

This Application (A535) seeks the establishment of Maximum Residue Limits (MRLs) for meat commodities, for the antibiotic neomycin into the *Australia New Zealand Food Standards Code* (the Code). 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 agricultural and veterinary chemicals in use in Australia.

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

The dietary exposure assessment indicates that the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety.

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

Statement of Reasons

FSANZ recommends progressing this Application for the following reasons:

- The dietary exposure assessment indicates that the residues associated with the proposed MRLs for neomycin do not represent an unacceptable risk to public health and safety.

- APVMA has already registered neomycin and the rejection of the proposed MRLs would result in legally treated products not being able to be legally sold. Therefore, the requested changes will benefit all stakeholders by maintaining public health and safety while permitting the legal sale of meat commodities treated with neomycin to treat diseases and improve agricultural productivity.

- 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 the veterinary chemical product.

- The Office of Chemical Safety (OCS) of the Therapeutic Goods Administration (TGA) has undertaken an appropriate toxicological assessment of neomycin.

- OCS has not yet set an acceptable daily intake for neomycin. However, they support the internationally recognised ADI set by the Joint Expert Committee for Food Additives (JECFA) and this has been used in estimated dietary exposure calculations.

- The Expert Advisory Group on Antimicrobial Resistance (EAGAR) has evaluated the impact of the potential residues of neomycin in the food supply and has supported the proposed MRLs in this Application.

- FSANZ has undertaken a preliminary 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 30 March 2004 seeking amendments to Standard 1.4.2 of the Code. The proposed amendments to the Standard would align MRLs in the Code for the antibiotic neomycin with the MRLs in APVMA's MRL Standard.

1.1 Summary of the proposed MRLs for neomycin

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

Chemical Food	**MRL (mg/kg)**	
Neomycin		
Edible offal (mammalian)	Delete	*0.5
Fats mammalian [except milk fats]	Delete	*0.02
	Substitute	T0.5
Kidney of cattle, goats, pigs and sheep	Add	T10
Liver of cattle, goats, pigs and sheep	Add	T0.5
Meat (mammalian)	Delete	*0.5
	Substitute	T0.5
Milk	Delete	0.5
Milks	Add	T1.5

Neomycin is an amino glycoside antibiotic; it is used is to treat bacterial enteritis (scours) in cattle and pigs. Amino glycosides are mostly bactericidal antibiotics with activity limited to aerobic bacteria and mycoplasma. This chemical has limited use in human medicine. The data before APVMA indicates that the present MRLs, based on the usage of neomycin, should be reviewed due to concerns about residues in kidney exceeding the current MRL. Both the New South Wales and Victorian Departments of Agriculture have indicated an on-going problem with violations on neomycin residues in kidney resulting from the therapeutic use on culled cows and also on calves. There were no concerns about food safety or dietary risk. Some of the above cases were the result of parenteral use. However, none of the residues found by the States in kidney exceeded the Codex MRL of 10 mg/kg.

There is no change to the dose rates, methods of use for neomycin or the withholding period. The current method of uses include:

- Cattle – injection, orally and topically;
- Pigs – injection or orally; and
- Sheep – injection only.

1.2 The ADI for neomycin

The OCS has not yet set an acceptable daily intake for neomycin. As part of its application, APVMA has supplied a letter from TGA in which TGA states that it supports the ADI set by JECFA of 0.06 mg/kg BW/Day.

This ADI has been used in the chronic estimated dietary exposure calculations for this application.

1.3 MRLs for Permits

The proposed MRLs in this Application that are temporary are indicated by a 'T' in the above 'Summary of proposed MRLs for Neomycin'. These MRLs may include uses associated with:

- the minor use program;
- off-label permits for minor and emergency uses; or
- trial permits for research.

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

1.4 The National Estimated Dietary Intake

The National Estimated Dietary Intake (NEDI) for neomycin is equivalent to 25% of the ADI. This calculation is considered to be a gross overestimate of the actual consumption of neomycin as it assumes all slaughtered animals were treated and contain residues at the MRL. This calculation used summary food consumption figures derived from the National Nutrition Survey 1995 data. It is concluded that the chronic dietary exposure is less than the ADI and the risk is acceptable.

1.5 Acute dietary exposure

Neither the OCS nor JECFA, have set an acute reference dose for neomycin.

1.6 Expert Advisory Group on Antimicrobial Resistance

The National Health and Medical Research Council established EAGAR to provide advice to government and regulatory agencies on antibiotic resistance and especially measures to reduce the risks of antibiotic resistance.

As part of its application, APVMA has supplied a letter from EAGAR in which EAGAR state that they support the proposed MRLs as a temporary measure only, until the APVMA's review of this chemical is completed.

1.7 Antibiotics as allergens

APVMA assesses the potential allergenicity of antibiotic residues in food commodities. While evidence for residues of antibiotics in foods causing allergic reactions is sparse, there is some evidence for rare occurrences of allergic reactions to the β-lactam antibiotics. For this reason β-lactam antibiotics are only used as therapeutic treatments for individual animals and not as a mass medication.

Neomycin belongs to the amino glycoside group of antibiotics and not to the β-lactam group of antibiotics. Therefore, allergic reactions to the residues of this chemical in food are not expected to occur. However, FSANZ recognises that the proposed MRLs for this chemical may be of concern to some of our stakeholders.

FSANZ requests data on the occurrence of allergic reactions to residues of this chemical in mammalian commodities.

2. Regulatory Problem

2.1 Current Regulations

APVMA has approved the use of neomycin on animals associated with the proposed MRLs in this Application, and made consequent amendments to the APVMA's MRL Standard. The approval of the use of neomycin now means that there is a discrepancy between the residues associated with the use of neomycin and the MRLs in the Code. In turn, this means that where APVMA has included MRLs for meat commodities for this chemical that are not included in the Code, those commodities cannot be legally sold under food legislation if it contains any detectable residues of this chemical.

3. Objective

The objective of this Application is to ensure that the residues of neomycin 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 under APVMA's legislation, and now seeks, by way of this Application to include the amendments in the Code.

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 an agricultural or veterinary chemical product is registered for use or a permit for use granted, APVMA includes MRLs in its 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.

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

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

FSANZ will not 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. Options

5.1 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 to the Code.

5.2 Option 2(a) – adopt the change to MRLs to delete or decrease some existing MRLs.

Under this option, only those variations that were reductions and deletions would be approved for inclusion into the Code. The proposed increases and inclusions of new MRLs would not be approved.

5.3 Option 2(b) – adopt the changes to MRLs to include new or increase some existing MRLs.

Under this option, only those variations that were increases and additions of MRLs would be approved for inclusion into the Code. The proposed decreases and deletions of MRLs would not be approved.

Option 2 has been arranged into two sub-options because the impacts of each sub-option are different. Splitting the option into two sub-options also allows a more detailed impact analysis. However, FSANZ cannot legally separate these two sub-options and may only accept or reject the Application.

6. 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.

7. 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 proposal, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make a final assessment of this proposal will include information from public submissions.

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

7.1.1 Benefits

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of neomycin;

- for producers of domestic and export meat 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.

7.1.2 Costs

- for consumers there are unlikely to be any discernable costs as the unavailability of some meat commodities from certain producers is likely to be seen as typical seasonal fluctuations in the food supply;

FSANZ invites comment on whether these costs are likely to be discernable by consumers

- for producers of domestic and export meat commodities, the adoption of this option would result in costs resulting from not being able to legally sell food containing residues consistent with increased MRLs or MRL additions for neomycin. Primary producers do not produce meat commodities or use neomycin to comply with MRLs. They use neomycin to treat diseases in accordance with the prescribed label conditions, and expect that the resulting residues will be acceptable and that the legally treated meat commodities can be legally sold. If the legal use of neomycin results in the production of meat commodities that cannot be legally sold under food legislation then primary producers will incur substantial losses. Major losses for primary producers would in turn impact negatively upon rural and regional communities;

- 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.

7.2 Option 2(a) – adopt the changes to MRLs to delete and decrease some existing MRLs

7.2.1 Benefits

- for consumers the major benefit would be the maintenance of the existing confidence in the food supply in relation to residues of neomycin;

- for producers of domestic and export meat 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.

7.2.2 Costs

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

FSANZ invites comment on whether these costs are likely to be discernable by consumers

- for producers of domestic and export meat commodities, 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 meat commodities may not be able to be imported if these commodities contained residues consistent with the MRLs for neomycin proposed for deletion or reduction. Any MRL deletions or reductions have the potential to restrict the importation of meat commodities and could potentially result in higher food costs and a reduced product range available to consumers, as meat commodities 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 are addressed in section 11.5.3 and data on imported foods are addressed in section 11.5.4; and

FSANZ invites comments from importers on the impacts of the deletions or reduction of MRLs

- 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 meat commodities.

7.3 Option 2(b) – adopt the changes to MRLs to include new and increase some existing MRLs

7.3.1 Benefits

- for consumers, the major benefit would be potential flow on benefits resulting from the price and availability of meat commodities if growers can legally sell food containing residues consistent with increased MRLs or MRL additions;

FSANZ invites comment as to whether this benefit is likely to be discernable

- for producers of domestic and export meat commodities, the benefits of this option would result from being able to legally sell meat commodities containing residues consistent with increased MRLs or MRL additions.

Other benefits include the consistency between agricultural and food legislation thereby minimising compliance costs to primary producers;

- for importers, the adoption of this option would result in the benefit that meat commodities could be legally imported if it contained residues consistent with increased MRLs or MRL additions; and

- for Australian Government, State and Territory agencies, the benefits of this option would include the removal of discrepancies between agricultural and food legislation thereby creating certainty and allowing efficient enforcement of regulations.

7.3.2 Costs

- for consumers there are no discernable costs;

- for producers of domestic and export meat commodities, the adoption of this option would not result in any discernable costs;

- 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 not result in any discernable costs, although there may be minimal impacts associated with slight changes to residue monitoring programs.

8. Consultation

FSANZ has decided, pursuant to section 36 of the FSANZ Act, to omit to invite public submissions in relation to the application prior to making a Draft Assessment. However, FSANZ now invites written submissions for the purpose of the Final Assessment under s.17(3)(c) of the FSANZ Act and will have regard to any submissions received. FSANZ was satisfied that omitting to invite public submissions prior to making a draft assessment was warranted as the application raises matters of minor significance or complexity. Furthermore, FSANZ considered that omitting to invite public submissions prior to making a Draft Assessment would not significantly adversely affect the interests of any person or body.

Section 63 of the FSANZ Act provides that subject to the *Administrative Appeals Act 1975*, application may be made to the Administrative Appeals Tribunal for review of a decision of FSANZ under section 36 of the FSANZ Act not to do something.

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

8.1 World Trade Organization Notification

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

MRLs prescribed in the Code constitute a mandatory requirement applying to all food products of a particular class whether produced domestically or imported. Food products exceeding their relevant MRL set out in the Code cannot legally be supplied in Australia. In administrative terms and consistent with international practice, MRLs assist in regulating the use of agricultural and veterinary chemical products. MRLs indicate whether agricultural and veterinary chemical products have been used in accordance with the registered conditions of use.

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

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

This Application will be notified as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO SPS agreement because the primary objective of the measure is to support the regulation of the use of agricultural and veterinary chemical products to protect human, animal and plant health and the environment.

9. Conclusion

Option 1 is a viable option but its adoption would result in:

- potential substantial costs to primary producers that may have a negative impact on their viability and in turn the viability of the rural and regional communities that depend upon the sale of the agricultural produce; and

- discrepancies between agricultural and food legislation which could have negative impacts on the compliance costs of primary producers, perception problems in export markets and undermine the efficient enforcement of standards for chemical residues.

FSANZ's preferred approach is adopt Options 2(a) and 2(b) – to adopt the change to MRLs in the Code to include new or increase some existing MRLs and to delete or decrease some existing MRLs. FSANZ prefers this approach because:

- the residues associated with the MRL amendments would not result in an unacceptable risk to public health and safety (this benefit also applies to Option 1);

- the changes would minimise the potential costs to primary producers and rural and regional communities in terms of legally being able to sell legally treated food;

- the changes would minimise residues consistent with the effective use of agricultural and veterinary chemicals to control pests and diseases; and

- the changes would remove discrepancies between agricultural and food legislation and assist enforcement.

Adopting option 2(a) may result in compliance costs for importers and industry where there are decreases or deletions of MRLs. Industry is invited to submit specific details of these costs.

10. 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;
- Commonwealth programs such as the National Residue Survey; and
- dietary exposure surveys such as the Australian Total Diet Survey.

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

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.

11. Consideration of Issues under section 13 of the *Food Standards Australia New Zealand Act 1991*

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

11.1 Paragraph 13(2)(a)

This Application relates to a matter that may warrant a variation to a food regulatory measure.

11.2 Paragraph 13(2)(b)

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

11.3 Paragraph 13(2)(c)

This Application does not suggest that the proposed amendment would present any further costs that would outweigh the direct and indirect benefits to the community, Government or industry.

11.4 Paragraph 13(2)(d)

The nature of this Application is such that only an amendment to a standard (i.e. a food regulatory measure) can achieve what it is that the Applicant seeks. No other measures appear to be available, or as cost-effective.

11.5 Paragraph 13(2)(e)

Other relevant matters for consideration by FSANZ are as follows:

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

Regulation 12(a)

This is not relevant to this Application.

Regulation 12(b)

This is not relevant to this Application.

11.5.2 World Trade Organization Notification

This is addressed in section 8.1.

11.5.3 Codex MRLs

The standards of the Codex Alimentarius Commission are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. The Codex Alimentarius Commission has recently adopted the following MRLs for neomycin:

Neomycin Food	**Codex MRL (mg/kg)**
Fat (all species)	0.5
Kidney (all species)	10
Liver (all species)	0.5
Milk (cattle)	0.5
Muscle (all species)	0.5

Further, the recent recommendation by JECFA of an MRL for 1.5 mg/kg for milk is under consideration by Codex.

11.5.4 Imported Foods

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

The proposed deletions of the MRLs for mammalian edible offal, affects all mammalian offal other than the kidney and liver of cattle, goats, pigs and sheep. The proposed kidney and liver MRLs are equal to or greater than the MRL proposed for deletion. However, the proposed deletion of the mammalian edible offal MRL may affect imported food containing offal other than kidney and liver of cattle, goats, pigs and sheep.

These imported products may be complying with existing MRLs even though these existing MRLs are no longer required for domestically produced food. This is because imported food that may contain residues consistent with the MRL proposed for deletion.

To assist in identifying possible impacts where imported food may be affected, FSANZ has compiled the following table that states the imported quantity of mammalian edible offal for the years 2001 and 2002.

Food	2001 Tonnes	2002 Tonnes
Edible offal (mammalian)	5127	5088

FSANZ requests comment as to any possible ramifications for imports of the proposed deletion of the mammalian edible offal MRLs in this Application.

12. Consideration of Issues under section 15(3) of the *Food Standards Australia New Zealand Act 1991*

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

12.1 Paragraph 15(3)(a)

This is not relevant to this Application.

12.2 Paragraph 15(3)(b)

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

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

OCS has not established an ADI for neomycin. As part of its application, APVMA has supplied a letter from TGA in which TGA state that they support the ADI for this chemical set by JECFA of 0.06 mg/kg. This ADI has been used in the chronic estimated dietary exposure calculations for this application. APVMA and FSANZ have carried out an estimate of the chronic dietary exposure to neomycin and compared it to its TGA standard. Based on this chronic dietary exposure assessment, the residues associated with the proposed MRLs do not represent an unacceptable risk to public health and safety. EAGAR has evaluated the impact of the potential residues of neomycin in the food supply and has supported the proposed MRLs in this application.

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

The MRLs are listed in Standard 1.4.2 of the Code. Consumers may access that material to ascertain information as to the potential of residues of agricultural and veterinary chemicals to occur in foods.

12.2.3 Paragraph 10(1)(c) the prevention of misleading or deceptive conduct

This is not relevant for this Application.

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

12.2.4 Paragraph 10(2)(a) 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 up to date detailed scientific information. That includes a rigorous toxicological assessment and dietary exposure assessments undertaken in accordance with international protocols.

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

This is addressed in section 11.5.

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

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

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

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

12.2.8 Paragraph 10(2)(e) any written policy 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.

12.3 Paragraph 15(3)(c)

FSANZ has undertaken a preliminary regulation impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the Code did not produce costs to bodies or persons that outweighed the benefits to the public.

12.4 Paragraph 15(3)(d)

The nature of this Application is such that only an amendment to a standard (i.e. a food regulatory measure) can achieve what it is that the Applicant seeks. No other measures appear to be available, or as cost-effective.

12.5 Paragraph 15(3)(e)

This is addressed in section 11.5.

13. Recommendation

FSANZ recommends progressing this Application for the following reasons:

- The dietary exposure assessment indicates that the residues associated with the proposed MRLs for neomycin do not represent an unacceptable risk to public health and safety. APVMA has already registered the veterinary chemical product in this Application and the rejection of the MRLs would result in products of legally treated animals not being able to be legally sold. Therefore, the requested changes will benefit all stakeholders by maintaining public health and safety while permitting the legal sale of products treated with neomycin to treat diseases and improve agricultural productivity.

- 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 the veterinary chemical product.

- OCS has not set an acceptable daily intake for neomycin. However, there is an internationally recognised ADI set by JECFA and this has been used in estimated dietary exposure calculations.

- EAGAR has evaluated the impact of the potential residues of neomycin in the food supply and has supported the proposed MRLs in this application.

- FSANZ has undertaken a preliminary 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.

ATTACHMENTS

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

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

NEOMYCIN INHIBITORY SUBSTANCE, IDENTIFIED AS NEOMYCIN	
EDIBLE OFFAL (MAMMALIAN)	*0.5
MILK	0.5

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

NEOMYCIN INHIBITORY SUBSTANCE, IDENTIFIED AS NEOMYCIN	
KIDNEY OF CATTLE, GOATS, PIGS AND SHEEP	T10
LIVER OF CATTLE, GOATS, PIGS AND SHEEP	T0.5
MILKS	T1.5

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

NEOMYCIN INHIBITORY SUBSTANCE, IDENTIFIED AS NEOMYCIN	
FATS MAMMALIAN [EXCEPT MILK FATS]	T0.5
MEAT (MAMMALIAN)	T0.5

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.

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 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.

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 an agricultural or veterinary 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

The Office of Chemical Safety of the TGA assesses the toxicology of agricultural and veterinary chemicals and establishes the ADI 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.

Calculating the dietary exposure

APVMA and FSANZ undertake chronic dietary exposure assessments for all agricultural and veterinary chemicals 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 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 an agricultural or veterinary chemical product on <u>all</u> 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.