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

4-05
25 May 2005

INITIAL / DRAFT ASSESSMENT REPORT

APPLICATION A557

MAXIMUM RESIDUE LIMITS – LASALOCID (ANTIBIOTIC)

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 July 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

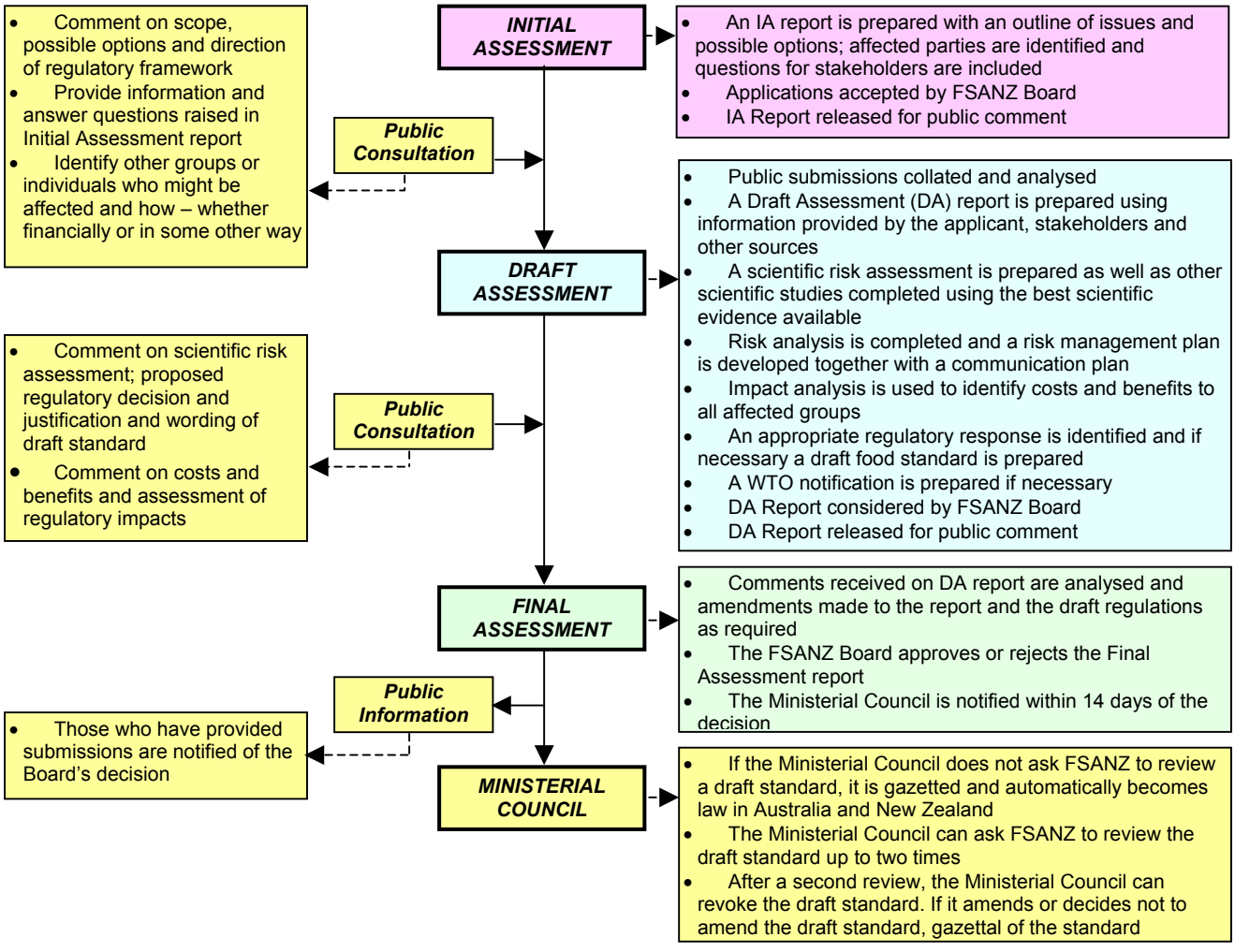
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

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

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

The process for amending the *Australia New Zealand Food Standards Code* (the 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 A557 and prepared a draft variation to the Code.

FSANZ invites public comment on 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 need to be <u>received</u> by FSANZ <u>by 6pm (Canberra time) 6 July 2005</u>.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

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 <u>Standards Development</u> tab and then through <u>Documents for Public Comment</u>.

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 (A557) seeks the establishment of Maximum Residue Limits (MRLs) for poultry commodities, for the antibiotic lasalocid into the *Australia New Zealand Food Standards Code* (the Code). It is a routine 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

This Application has been assessed against the requirement s for Initial/Draft Assessment in sections 13 and 15 of the FSANZ Act. FSANZ recommends accepting and progressing this Application for the following reasons:

- The dietary exposure assessments indicate that the residues associated with the MRLs do not represent an unacceptable risk to public health and safety. The APVMA has already registered the chemical products associated with the MRLs in this Application and the rejection of the MRLs would result in legally treated food 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 food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

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

- The 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 chemicals on commodities as outlined in this Application.

- The Office of Chemical Safety of the Therapeutic Goods Administration (OCS) of the Australian Government Department of Health and Ageing has undertaken an appropriate toxicological assessment of the chemical products and has established the relevant acceptable daily intakes (ADI).

- 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 the APVMA on 3 February 2005 seeking to amend the MRLs for lasalocid in Standard 1.4.2 of the Code. The proposed amendments to the Standard would align lasalocid MRLs for poultry commodities in the Code with the MRLs in the APVMA MRL Standard.

1.1 Summary of proposed MRLs for lasalocid

The lasalocid MRL amendments under consideration in this Application are for poultry commodities are as follows:

Lasalocid			
Eggs	Omit	T*0.05	Lasalocid is a divalent polyether ionophore antibiotic used to treat, and as a prophylactic against, coccidiosis in broilers and replacement pullets. It is a broad spectrum anticoccidial agent. It has minimal coccidial resistance and cross-resistance. It does not have a human analogue.
	Substitute	*0.05	
Poultry, edible offal of	Omit	T0.7	
	Substitute	0.4	
Poultry meat	Omit	T*0.05	
	Substitute	*0.1	
Poultry skin/fat	Omit	T1.2	NEDI = 31% of the ADI.
	Substitute	1.0	

1.2 MRLS at the limit of quantification

The proposed MRLs for lasalocid for eggs and poultry meat in this Application are at the limit of quantification (LOQ) and are indicated by an * in the 'Summary of the Requested MRLs for each Chemical…' (Attachment 2). The LOQ is the lowest concentration of an agricultural or veterinary chemical residue that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. The inclusion of the MRLs at the LOQ means that no detectable residues of the relevant chemical should occur. FSANZ incorporates MRLs at the LOQ in the Code to assist in identifying a practical benchmark for enforcement and to allow for future developments in methods of detection that could lead to a lowering of this limit.

1.3 The National Estimated Dietary Intake

The National Estimated Dietary Intake (NEDI) for lasalocid is equivalent to 31% of the ADI. This calculation is considered to be a gross overestimate of the actual consumption of lasalocid 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.

1.4 Acute dietary exposure

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

1.5 FSANZ's previous consideration of lasalocid MRLs for poultry

APVMA has previously made an Application (A521) to amend MRLs for lasalocid for poultry commodities. At the time of the Application the data before APVMA indicated that the MRLs, based on the usage of lasalocid, were inadequate. APVMA planned to undertake a full revision of the residues and MRLs associated with this chemical and requested that, until APVMA had completed its review, the MRLs for this chemical be changed to T.

FSANZ approved the draft standard relevant to Application A521 under section 18 of the FSANZ Act and then notified the Ministerial Council of its decision. The Ministerial Council did not inform FSANZ that it intended to amend or reject the approved Standard nor did the Ministerial Council request a review of the approved Standard. Therefore, the MRLs relevant to Application A521 were gazetted as part of Amendment 74 of the Code on 14 October 2004. Further details on Application A521 are available on the FSANZ website at: http://www.foodstandards.gov.au/standardsdevelopment/. APVMA now seeks to amend these MRLs to reflect current animal husbandry practices.

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.

EAGAR supported the original Application (A521) for MRLs for lasalocid on the basis that this was an ionophore and that there are no antibiotics in this class used in human medicine. They further supported the changes to MRLs in this Application on the basis that the effective control of coccidiosis by this class of compound may possibly reduce the usage of important antimicrobials (eg virginiamycin and bacitracin).

1.7 Antibiotics as allergens

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.

Lasalocid belongs to the ionophore 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. Therefore, FSANZ requests data on the occurrence of allergic reactions to residues of this chemical in poultry commodities.

2. Regulatory Problem

2.1 Current Regulations

APVMA has approved the use of lasalocid on poultry associated with the proposed MRLs in this Application, and made consequent amendments to the APVMA's MRL Standard. The approval of the use of lasalocid now means that there is a discrepancy between the residues associated with the use of lasalocid and the MRLs in the Code.

In turn, this means that where the APVMA has included MRLs for poultry 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 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 the APVMA's legislation, and now seeks by way of this Application to include the amendments to 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 10 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.

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

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

When a chemical product is registered for use or a permit for use granted, the 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 of the proposed adoption of the variation into the Code. If the 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 the 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 Manager 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 <u>not</u> 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 lasalocid 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 a 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, the 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 the 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 decrease existing MRLs for poultry, edible offal of and poultry skin/fat

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

5.3 Option 2(b) – adopt the changes to MRLs increase the MRL for poultry meat

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

5.4 Option 2(c) – adopt the change of status[1] to the MRL for eggs

Under this variation, only those variations of the status of the MRLs would be approved for inclusion of into the Code. The proposed decreases and increases of MRLs would not be approved.

Option 2 has been arranged into three Sub-options because the impacts of each sub-option are different. Splitting the option into three sub-options also allows a more detailed impact analysis. However, under the FSANZ Act, FSANZ does not have any express power to partially accept or reject an 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
- Commonwealth, State and Territory agencies involved in monitoring and regulating the use of agricultural and veterinary chemicals in food and the potential resulting residues.

[1] The status of the MRL refers to a permit as indicated by a 'T' and/or the limit of quantification as indicated by a '*'. In the case of eggs there is no proposed change to the MRL amount of 0.05 mg/kg.

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 Application 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 lasalocid in poultry commodities;

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

- for importers of poultry commodities, the adoption of this option would not result in any discernable benefits; and

- for the 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 poultry commodities from certain producers is likely to be seen as typical seasonal fluctuations in supply;

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

- for producers of domestic and export poultry commodities, the adoption of this option would result in costs resulting from not being able to legally sell food containing residues of lasalocid consistent with the increased MRL for poultry meat. Producers of poultry meat do not produce food or use chemical products to comply with MRLs. Producers use lasalocid to control *Eimeria* species in accordance with the prescribed label conditions of lasalocid, and expect that the resulting residues will be acceptable and that the legally treated poultry commodities can be legally sold. If the legal use of lasalocid results in the production of poultry commodities that cannot be legally sold under food legislation then producers of poultry commodities will incur substantial losses. Major losses for these 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 the 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 and decrease the existing MRLs for poultry, edible offal and poultry skin/fat

7.2.1 Benefits

- for consumers the major benefit would be the maintenance of the existing confidence in the supply of poultry commodities in relation to the residues of lasalocid;

- for producers of domestic and export poultry 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 the 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 poultry commodities 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 poultry commodities, the adoption of this option is unlikely to result in any costs, as reductions in lasalocid 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 poultry commodities may not be able to be imported if these commodities contained residues consistent with the MRLs proposed for reduction. Any reductions of the poultry commodity MRLs have the potential to restrict the importation of such commodities and could potentially result in higher food costs and a reduced product range available to consumers, as poultry commodities that exceed the new, lower MRLs could not be legally imported or sold to consumers. To identify any restrictions and possible trade impacts, data on imported poultry commodities are addressed in section 11.5; and

FSANZ invites comment on whether these costs are likely to be discernable by importers of food commodities.

- for the 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 for poultry commodities.

7.3 Option 2(b) – adopt the change to the MRL poultry meat and increase its existing MRL.

7.3.1 Benefits

- for consumers the major benefit would be potential flow on benefits resulting from the price and availability of poultry meat if producers can legally sell poultry meat containing residues consistent with proposed increased MRLs for poultry meat;

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

- for producers of domestic and export poultry meat, the benefits of this option would result from being able to legally sell poultry meat containing residues consistent with increased MRLs. 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 poultry meat could be legally imported if it contained residues consistent with the increased MRL; and

- for the 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 poultry meat, 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 the 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.

7.4 Option 2(c) – adopt the change of status for the MRLs for eggs

7.4.1 Benefits

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

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

- for importers of poultry commodities, the adoption of this option would not result in any discernable benefits; and

- for the Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable benefits.

7.4.2 Costs

- for consumers there are no discernable costs;

- for producers of domestic and export poultry meat, 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 the Australian Government, State and Territory agencies, the adoption of this option would not result in any discernable costs.

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

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.

8.1.1 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, but may be different from those in domestically produced food.

The proposed reductions of MRLs for poultry, edible offal and poultry skin/fat may affect imports of these commodities which 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 MRLs proposed for deletion or reduction.

FSANZ requests comment as to any possible ramifications for imports of the proposed reductions of the lasalocid MRLs for poultry, edible offal and/or poultry skin/fat

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) and 2(c) – to adopt the change to MRLs in the Code to include increase the poultry meat MRL, decrease the poultry, edible offal and poultry skin/fat MRLs and change the status of the egg MRL. 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.

10. Implementation and Review

The use of chemical products and MRLs are under constant review as part of the 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. Recommendation

This Application has been assessed against the requirement s for Initial/Draft Assessment in sections 13 and 15 of the FSANZ Act. FSANZ recommends accepting and progressing this Application for the following reasons:

- The dietary exposure assessments indicate that the residues associated with the MRLs do not represent an unacceptable risk to public health and safety. The APVMA has already registered the chemical products associated with the MRLs in this Application and the rejection of the MRLs would result in legally treated food 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 food treated with agricultural and veterinary chemicals to control pests and diseases and improve agricultural productivity.

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

- The 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 chemicals on commodities as outlined in this Application.

- The OCS has undertaken an appropriate toxicological assessment of the chemical products and has established the relevant ADIs.

- 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*, under the entries for the following chemicals, the maximum residue limit for the food, substituting –*

LASALOCID LASALOCID	
EGGS	*0.05
POULTRY, EDIBLE OFFAL OF	0.4
POULTRY MEAT	*0.1
POULTRY SKIN/FAT	1.0

Attachment 2

Notes on Terms

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

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

LOQ - Limit of Quantification - The LOQ is the lowest concentration of a 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.

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 National Nutrition Survey (NNS) and the MRL when the STMR is not available to calculate the NESTIs.

The NESTI calculation incorporates the large portion (97.5 percentile) food consumption data and can take into account such factors as the highest residue on a composite sample of an edible portion; the supervised trials median residue (STMR), representing typical residue in an edible portion resulting from the maximum permitted pesticide use pattern; processing factors which affect changes from the raw commodity to the consumed food and the variability factor.

Attachment 3

Background To Dietary Exposure Assessments

Before an agricultural or veterinary chemical is registered, the *Agricultural and Veterinary Chemicals Code, 1994* (*Ag Vet Code Act*) requires 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, 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

The APVMA assesses a range of data when considering the proposed use of a chemical product on a food. These data enable the APVMA to determine what the likely residues of a chemical will be on a treated food. 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.

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 and where applicable, the ARfD for a chemical.

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

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

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

Calculating the dietary exposure

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

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

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

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

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

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

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

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