



**30 May 2001
15/01**

PRELIMINARY ASSESSMENT REPORT

APPLICATION A422

MAXIMUM RESIDUE LIMITS - ANTIBIOTICS

Applicant: National Registration Authority for Agricultural and Veterinary Chemicals.

Date received: 6 September 2000.

BACKGROUND:

The Maximum Residue Limit (MRL) is the highest concentration of a chemical residue that is legally permitted or accepted in a food. The MRL does not indicate the amount of chemical that is always present in a treated food but it does indicate the highest residue that could result from the registered conditions of use. The concentration is expressed in milligrams per kilogram (mg/kg) of the food. MRLs are indicators of whether an agricultural or veterinary chemical product has been used according to its registered use and if the MRL is exceeded then this indicates a likely misuse of the chemical product. However, MRLs are not established for specific commodities if the residues resulting from the use of the chemical product could represent an unacceptable risk to public health and safety.

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

1.1 Food Standards Setting in Australia and New Zealand

1.1.1 Treaty between the Commonwealth of Australia and New Zealand

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

1.1.2 Trans Tasman Mutual Recognition Arrangement

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

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

1.2 Anomalies between the NRA MRL Standard and the MRL Standard in the *Food Standards Code*

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has informed the Australia New Zealand Food Authority (ANZFA) of anomalies between the NRA MRL Standard and the *Food Standards Code* for the antibiotics benzyl G penicillin, erythromycin, and procaine penicillin. This application includes proposed amendments to correct these anomalies.

1.3 Role of the NRA

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

As a result of the NRA registrations, variations of registration and adjustments to correct anomalies between the NRA MRL Standard and the *Food Standards Code*, the NRA has advised ANZFA of the following MRL amendments.

MRLS for new chemical

- avilamycin.

Changes to existing MRLs

- benzyl G penicillin, erythromycin, oxytetracycline and procaine penicillin.

2. OBJECTIVE:

The objective of this application is to vary the *Food Standards Code* in accordance with the amendments in Attachment 1 to allow maximum flexibility for producers whilst encouraging good agricultural practice. The NRA has cleared the chemicals indicated in the attachment and products have been registered for the uses associated with the requested MRLs.

3. POSSIBLE OPTIONS (including alternatives)

Option 1.

Amend Schedule 1 of Standard A14 and Schedule 1 of Standard 1.4.2 to include the proposed MRLs in the *Food Standards Code*. The effect of this option would be that legally treated food could be legally sold and imported if it contained residues consistent with the MRLs in this application.

Option 2.

Remain with the status quo and not include the MRLs in Schedule 1 of Standard A14 and Schedule 1 of Standard 1.4.2. The effect of this option would be that food could not be legally sold and imported if it contained residues greater than those currently stipulated in the *Food Standards Code*.

4 IDENTIFICATION OF AFFECTED PARTIES

The parties affected by this application include:

- growers and producers of domestic and export food commodities;
- consumers, including domestic and overseas customers;
- importers and exporters of agricultural produce and foods; and
- Commonwealth, State and Territory agencies involved in monitoring agricultural and veterinary chemicals in food.

5 CONSIDERATION OF ISSUES UNDER SECTION 13

- (a) this application relates to matters that may be developed as a food regulatory measure or may require a variation to a standard;
- (b) this application is not so similar to a previous application that it ought not be accepted;
- (c) the benefits of the food regulatory measure in this application outweigh the direct and indirect costs to the community, Government and industry (see Option 1 in the Potential Regulatory Impacts below);
- (d) other measures (available to the Authority or not) would not be more cost effective than a food regulatory measure developed or varied as a result of the application; and
- (e) there are no other relevant matters.

6 POTENTIAL REGULATORY IMPACTS

In considering the regulatory impact of the options listed below, it needs to be noted that registration has been granted for the chemicals listed in Attachment 1 for specific purposes. The listing of MRLs in Schedule 1 of Standard A14 and Schedule 1 of Standard 1.4.2 would

only allow the treated food to be legally sold if it contained chemical residues not exceeding the MRL for the specified chemical(s). The inclusion of an MRL does not on its own permit or prohibit a particular product from being used. This is regulated by other legislation.

The inclusion of MRLs in the *Food Standards Code* allows food producers to trade food that has been legally treated with registered agricultural and veterinary products. The use of agricultural and veterinary products provides effective pest and disease control. This potentially leads to improved productivity for producers, better quality food for consumers and more competitive primary industries.

Any MRL deletions or reductions have the potential to restrict the importation of foods and could potentially result in higher food costs and a reduced product range available to consumers, as foods that exceed the MRLs could not be legally sold to consumers. To identify any restrictions and possible trade impacts, Codex MRLs and data on imported foods have been considered in assessing the reductions and deletions within this application.

Option 1: To Include the Proposed MRLs in the *Food Standards Code*

Will:

- permit greater flexibility for producers and importers of food that contain residues up to the MRL permitted for that food;
- result in a slight impact on government monitoring programs, as more comprehensive monitoring may be required; and
- potentially permit more variety and more competitively priced food for consumers.

Option 2: Do Not Include the Proposed MRLs in the *Food Standards Code*

Will result in:

- a discrepancy between agricultural and health legislation; in that the agricultural legislation will permit the use of agricultural and veterinary products but the health legislation will prohibit the sale of the legally treated food;
- potentially less flexibility for producers and importers; and
- the possibility of reducing the range and quality of foods for consumers.

7 WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may

have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

Matters relating to public health and safety may be notified as a Sanitary or Phytosanitary notification, and other matters as a Technical Barrier to Trade (TBT) notification. It is considered that this application may constitute a potential TBT matter and needs to be notified to the WTO.

8 CODEX MRLs

There are no Codex MRLs for the chemical/commodities in this Application.

9 IMPORTED FOODS

Australia has imported the following quantity of foods for 1999 and 2000.

Food	1999	2000	Custom Tariff Code
Honey	10kt	18kt	0409
Poultry Eggs	67kt	35kt	0407 & 0408
Poultry meat	14kt	14kt	160231 & 160232

ANZFA recognises that changes to MRLs have implications for the importation of food, particularly where MRLs are deleted and therefore no detectable residue is permitted. ANZFA requests comment on the significance of the changes to MRLs for imported foods.

10 CONCLUSION

The above application fulfils the requirements for preliminary assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act, 1991*.

11 FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination

thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand (*Maximum Residue Limits of Agricultural Compounds*) *Mandatory Food Standard 1999*.

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.
- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.

In addition to the above, all food sold in New Zealand must comply with the *New Zealand Fair Trading Act 1986* and all food sold in Australia must comply with the *Australian Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the *Australian Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority 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.

Following its full assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry, which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager – Application A422** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Fax (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by: **11 July 2001**.

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <sl@anzfa.gov.au>. Submissions should not be sent by email, as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.

**A SUMMARY OF THE REQUESTED MRLS FOR EACH CHEMICAL AND AN
OUTLINE OF THE INFORMATION SUPPORTING THE REQUESTED CHANGES
TO THE *FOOD STANDARDS CODE* IS PROVIDED BELOW.**

**The Full Evaluation Reports for additions of and changes to chemicals / MRLs are
available upon request from the Project Manager at ANZFA.**

National Estimated Dietary Intake

The National Estimated Dietary Intake (NEDI) represents an estimate of dietary exposure. It may incorporate 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 as the above data is often not available and in these cases the MRL is used.

Glossary of Acronyms:

1. ADI Acceptable Daily Intake
2. LOQ Limit of Quantitation.
3. NEDI National Estimated Dietary Intake.
4. * MRL is set at or about the limit of quantitation, and therefore no detectable residues should be in the food.
5. T indicates the MRL is temporary for a period of time and subject to revision following review of additional data.

CHEMICAL Food	MRL (gm/kg)	INFORMATION
A1. Deletions and reductions		
Benzyl G Penicillin Eggs Poultry, edible offal of Poultry meat	Delete 0.018 Delete 0.06 Delete 0.06	As these are deletions no NEDI has been calculated
Erythromycin Eggs	Delete 0.3	As this is a deletion no NEDI has been calculated
Procaine Penicillin Eggs Poultry, edible offal of Poultry meat	Delete 0.03 Delete 0.1 Delete 0.1	As these are deletions no NEDI has been calculated

A5. Antibiotics used for therapeutic use but with human analogue		
Oxytetracycline Honey	Add T0.3	Temporary MRL to facilitate additional research and field trials to support the current registered use for the control of European Foul Brood in honey bees. NEDI = 38.3% of the ADI
A6. Growth Promotants with no human analogue.		
Avilamycin Poultry meat Poultry, Edible offal of	Add *0.05 Add *0.05	NRA has advised that this is a new active ingredient in poultry feed premix to improve feed efficiency by modifying gut microflora populations. Detectable levels are below LOQ. NEDI = 0.003% of ADI.