



55 Blackall Street  
Barton ACT 2600  
Australia  
Ph: 61 2 6271 2258

PO Box 7186  
Canberra MC ACT 2610  
Australia  
Fax: 61 2 6271 2278

**22 December 1999**  
**08/00**

## **INFORMATION SUMMARY**

### **APPLICATION A398**

### **MAXIMUM RESIDUE LIMITS**

The Australia New Zealand Food Authority has received an application to amend the Australian *Food Standards Code* on the above matter. The Authority's Preliminary Assessment Report is provided below and provides further detail. The Authority now invites public submissions on any issue raised in the Report for the purposes of making a full assessment.

In accordance with the transitional arrangements for food standards between Australia and New Zealand, individual country MRLs for agricultural and veterinary chemicals continue to apply for these standards and this application proposes changes for MRLs for food sold in Australia, whether imported or domestically produced.

### **PRELIMINARY ASSESSMENT REPORT**

#### **Maximum Residue Limits – June/July/August 1999 MRLs**

**Applicant:** National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

**Date received:** 30 September 1999

#### **BACKGROUND:**

The NRA has registered or varied the registration of specific chemicals. This application seeks to include:

- MRLs for the new chemicals CGA 279202, methoxyfenozide and novaluron;
- new MRLs (extensions of use) for abamectin, carbaryl, cyfluthrin, chlorfenvinphos, chlorothalonil, chlorpyrifos, cypermethrin, cyromazine, diquat, dimethoate, dimethomorph, fluquinconazole, glufosinate-ammonium, methamidophos, methomyl, metolachlor, permethrin, phosphorous acid, propiconazole, tilmicosin and triadimefon;

- changes to existing MRLs for metolachlor, dimethoate, doramectin; and
- deletions to existing MRLs for permethrin, streptomycin and dyhydrostreptomycin;

The requested changes to Schedule 1 of Standard A14 are summarised at **Attachment 1**.

## **ANTIBIOTIC MRLS**

This application requests MRL amendments for two antibiotics, streptomycin and tilmicosin. In the case of streptomycin, the NRA proposes the deletion of MRLs for poultry and eggs as there are no longer any registered use patterns associated with these commodities. With respect to tilmicosin, the NRA has granted a trial permit for the treatment of sub-clinical bovine mastitis in non-lactating dairy cows and a temporary MRL for cattle milk is requested. The Working Party on Antibiotics has assessed this use and raised no objections to the proposed temporary MRL.

## **OBJECTIVE**

The objective of this application is to vary Standard A14 - Maximum Residue Limits (MRLs) by changing the MRL list as indicated in Attachment 1 to allow maximum flexibility for producers whilst encouraging good agricultural practice. The chemicals indicated in this Attachment have been cleared by the NRA and registered for the uses associated with the requested MRLs.

## **POSSIBLE OPTIONS**

**Option 1.** Accept the application and list the requested MRLs in Schedule 1 of Standard A14. This outcome would be based on a risk assessment, which indicated no public health and safety concerns at the predicted levels of intake.

**Option 2.** Remain with the status quo. If a possible risk to public health and safety is identified the MRLs will be referred back to the NRA for further consideration.

## **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 of agricultural produce and foods; and
- Commonwealth, State and Territory agencies involved in monitoring agricultural and veterinary chemicals in food.

## **POTENTIAL REGULATORY IMPACTS**

### **Option1:**

- greater flexibility for producers and importers;

- no additional public health risk resulting from consumption of commodities with the recommended MRLs; and
- no additional impact for government monitoring programs.

**Option 2:**

- less flexibility for producers and importers;
- possibility of reducing the range and quality of commodities for consumers; and
- discrepancy between agricultural and health legislation regarding permitted MRLs.

Clearance and registration has been granted for the chemicals listed in Attachment 1 for specified purposes. The listing of MRLs in Schedule 1 of Standard A14 will allow food containing residues up to the MRL of the listed chemicals to be traded. This has an obvious advantage to food producers. Consumers will also be advantaged by potential improvements in the variety of available food. The proposed changes to Standard A14 will complete the regulatory requirements regarding the changes to the use of these agricultural and veterinary chemicals.

**CONSIDERATION OF ISSUES UNDER SECTION 13**

- (a) This application relates to a matter that 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 application contains adequate information for independent assessment.
- (d) There are no other relevant matters

**CONCLUSIONS**

The above applications fulfil the requirements for preliminary assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*. Based on the preliminary assessment report, the Authority has determined that this application would result in a change of minor significance and complexity to the *Food Standards Code* and that no one would be adversely affected if the Authority omitted under section 36 of the *Australia New Zealand Food Authority Act 1991* to delete the second round of public comments and proceed directly to Inquiry. Should significant issues arise out of the initial public round of comments ANZFA will proceed only to the Full Assessment stage and undertake another round of comments to enable these issues to be addressed fully.

If accepted by the Authority and agreed to by the Australia New Zealand Food Standards Council, an amendment to the Code, as suggested by the applicant, would be included in Standard A14, which would allow food to be sold containing residues of the chemicals up to the limit of the MRL.

## **REGULATION IMPACT ANALYSIS**

The Authority develops food regulation suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community which includes the consumers, food industry and governments in both countries. The regulation impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, the Authority is guided by the *Australian Guide to Regulation* (Commonwealth of Australia 1997) and *New Zealand Code of Good Regulatory Practice*.

To assist in this process, comment on potential impacts or issues pertaining to these regulatory options is sought from all interested parties in order to complete the development of the regulation impact statement. Public submissions should clearly identify relevant impact(s) or issues and provide support documentation where possible.

## **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 (COAG) 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 (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification. A decision on whether to make a notification to the WTO will be made during the Authority's full assessment of this matter.

## **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. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

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 the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984*.
- **Food imported into Australia other than from New Zealand** must comply solely with the Australian *Food Standards Code*.
- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code* or the New Zealand *Food Regulations 1984*, but not a combination of both.
- **Food imported into Australia from New Zealand** must comply with the Australian *Food Standards Code*. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may be imported into Australia from New Zealand if it complies with the New Zealand *Food Regulations 1984* or *Dietary Supplements Regulations 1985*.
- **Food manufactured in Australia and sold in Australia** must comply solely with the Australian *Food Standards Code*, except for exemptions granted in Standard T1.

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 public 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 A398** 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 9855 Fax (04) 473 9855

Submissions should be received by the Authority by **9 February 2000**.

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>.

## ATTACHMENT 1

A summary of the requested MRLs for each chemical and an outline of the justification supporting the requested changes to Standard A14 are provided below. Full evaluation reports are available from the Project Manager - A398. These will be sent to interested parties by email or by post.

<b>CHEMICAL</b> <i>Food</i>	<b>MRL</b> <b>(mg/kg)</b>	<b>JUSTIFICATION</b>
<b><i>HERBICIDES</i></b>		
<b>Diquat</b> Sesame seed	T2	Extension of use. The NRA has granted an emergency permit for diquat as a pre-harvest desiccant. NEDI <sup>1</sup> = 96% ADI
<b>Glufosinate ammonium</b> Tomato	0.05*	Extension of use for the control of weeds in tomatoes. TMDI <sup>2</sup> = 18% ADI
<b>Metolachlor</b> Eggs Poultry meat Poultry, edible offal of Edible offal, mammalian	0.01* 0.01* 0.01* 0.5 (deletion) 0.05*	A formulation change to the product containing metolachlor has been made, which is registered for use to control weeds in a range of crops. A lower residue is now set for edible offal and MRLs for poultry and eggs are requested to account for feed commodities. TMDI = 0.8% ADI
<b><i>INSECTICIDES</i></b>		
<b>Abamectin</b> Blackcurrants	T0.02	An extension of use (off-label permit) to control various mites on blackcurrants. TMDI = 76% ADI
<b>Carbaryl</b> Chervil Galangal, rhizomes Herbs Rucola (rocket) Turmeric, root	T10 T5 T10 T10 T5	An extension of use (off-label minor-use) for the control of grasshoppers and beetles. TMDI = 76% ADI
<b>Chlorpyrifos</b> Sweet potato	T0.05	An extension of use for the control of African black beetle in sweet potatoes. TMDI = 114% ADI NEDI = 3% ADI

1. NEDI – National Estimated Dietary Intake
2. TMDI – Theoretical Maximum Dietary Intake

<b>CHEMICAL</b> <i>Food</i>	<b>MRL</b> <b>(mg/kg)</b>	<b>JUSTIFICATION</b>
<b>Chlorfenvinphos</b> Deer meat (in the fat)	T0.2	An extension of use for the control of ticks in deer. NEDI = 85% ADI
<b>Cypermethrin</b> Deer meat (in the fat)	T0.5	An extension of use for the control of ticks in deer. TMDI = 12% ADI
<b>Cyromazine</b> Cattle, edible offal of Cattle meat Eggs Pig, edible offal of Pig meat Poultry, edible offal of Poultry meat	0.05 0.05 0.2 0.05 0.05 0.1 0.05	An extension of use for the control of flies in animal housing and feedlots. TMDI = 3% ADI
<b>Cyfluthrin</b> Avocado	T0.05	An extension of use (trial permit) for insect control on avocados. TMDI = 55% ADI
<b>Dimethoate</b> Chervil Galangal, rhizomes Herbs Kaffir lime leaves Lemon grass Lemon verbena Mizuna Rucola (rocket) Turmeric, root Fruiting vegetables, cucurbits Fruits [except strawberry, litchi, peach and quandong] Pepper, sweet  Tomato	T2 T2 T2 T2 T2 T2 T2 T2 T2 2 (delete) 5 1 (delete) 5  1 (delete) 2 1 (delete) 2	An extension of use (off-label minor-use permit) for the control of grasshoppers and beetles in herbs and similar minor-use commodities. In addition, the NRA has re-examined residue data in relation to use patterns for cucurbits, peppers, tomatoes and fruits and found that existing MRLs should be raised to account for pre- and post-harvest uses. TMDI = 136% ADI NEDI = 0.83% ADI
<b>Fenthion</b> Tropical and sub-tropical fruits (inedible peel) Fruiting vegetables, cucurbits Fruiting vegetables, other than cucurbits	2 (delete) 5 2 (delete) 3 2 (delete) 5	The NRA has re-examined residue data in relation to use patterns for fruiting vegetables and tropical fruits and found that existing MRLs should be raised to account for pre- and post-harvest uses. TMDI = 781% ADI NEDI = 0.7% ADI

<b>CHEMICAL</b> <i>Food</i>	<b>MRL</b> <b>(mg/kg)</b>	<b>JUSTIFICATION</b>
<b>Methamidophos</b> Leafy vegetables (except lettuce head and lettuce leaf)	T1	An extension of use for the control of thrip on leafy vegetables. TMDI = 518% ADI NEDI = 11.3% ADI
<b>Methomyl</b> Guava Avocado	T0.1 T0.1	An extension of use (off-label permit) for the control of Ectropis looper on avocado and various insect pests on guava. TMDI = 74% ADI
<b>Methoxyfenozide</b> Cottonseed Tomato	T0.05* T2	A new chemical, to be used for the control of helicoverpa in cotton and tomatoes. ADI = 0.03 mg/kg bw/day TMDI = 3.2% ADI
<b>Novaluron</b> Cottonseed	T0.1	A new chemical, to be used for the control of helicoverpa in cotton. ADI = 0.001 mg/kg bw/day TMDI = 0.02% ADI
<b>Permethrin</b> Chervil Rucola (rocket) Leafy vegetables (except lettuce head and lettuce leaf)	5 (delete) 5 (delete) T5	An extension of use to control western flower thrip on leafy vegetables. TMDI = 35% ADI
<b>Phosphorous acid</b> Strawberry Chervil Galangal, rhizomes Herbs Rucola (rocket) Turmeric, root	T50 T5 T5 T5 T5 T5	An emergency use permit has been granted for the use of phosphorous acid on strawberries to control Phythophthora. In addition, an extension of use (off-label minor-use permit) to control phythophthora in herbs and other similar commodities has been given. TMDI = 20% ADI of fosetyl aluminium
<b><i>FUNGICIDES</i></b>		
<b>CGA 279202</b> Bananas Grapes Pome fruit	T0.1 T3 T0.5	A new chemical, for the control of fungal diseases on apples, pears, grapes and bananas. ADI=0.05 mg/kg bw/day TMDI = 2% ADI

<b>CHEMICAL</b> <i>Food</i>	<b>MRL</b> <b>(mg/kg)</b>	<b>JUSTIFICATION</b>
<b>Chlorothalonil</b> Pulses	T7	An extension of use for the control of <i>Ascochyta</i> spp, chocolate spot and <i>Botrytis</i> spp in pulses. TMDI = 324% ADI NEDI = 0.4% ADI
<b>Dimethomorph</b> Edible offal (mammalian) Meat (mammalian) Milks	0.01* 0.01* 0.01*	These MRLs for animal commodities are requested to account for animal feeds containing grape waste with dimethomorph residues. TMDI < 1% ADI
<b>Fluquinconazole</b> Edible offal (mammalian) Eggs Meat (mammalian)(in the fat) Milks Poultry meat (in the fat) Poultry, edible offal of Wheat	T0.2 T0.02* T0.5  T0.1 T0.02* T0.02* T0.02*	An extension of use for the control of fungal diseases in wheat. Additional MRLs for animal commodities are requested to account for animal feeds containing fluquinconazole residues. TMDI = 40% ADI
<b>Propriaconazole</b> Persimmon, American	T0.2	An extension of use (off-label minor use) for the control of leaf spot. TMDI = 3%ADI
<b>Tebuconazole</b> Broad bean (green and immature seeds) Peas Legume vegetables	0.5 (delete)  0.5 (delete) 0.5	An extension of use as a systemic fungicide for use in legumes. NEDI = 20% ADI
<b>Triadimefon</b> Mung bean (dry)	T0.1	An extension of use (emergency use permit) for the control of powdery mildew. TMDI = 15% ADI
<b>ANTIBIOTICS</b>		
<b>Streptomycin and dyhydrostreptomycin</b> Eggs Poultry, edible offal of Poultry meat	  0.2 (delete) 0.2 (delete) 0.2 (delete)	There are no registered use patterns associated with the poultry and egg MRLs presently listed in A14 and therefore these should be deleted.

<b>CHEMICAL</b> <i>Food</i>	<b>MRL</b> <b>(mg/kg)</b>	<b>JUSTIFICATION</b>
<b>Tilmicosin</b> Cattle milk	T0.025*	An extension of use (trial permit) for the treatment of sub-clinical bovine mastitis in non-lactating dairy cows. The Working Party on Antibiotics raised no objections to the proposed temporary MRL. TMDI = 15% ADI
<b><i>ANTIPARASITICS</i></b>		
<b>Doramectin</b> Sheep, edible offal of Sheep meat Sheep fat Pig meat (in the fat) Pig kidney Pig liver	0.05 0.02 0.1 0.1 0.03 0.05	An extension of use to pigs and sheep for the control of parasites. TMDI = 11% ADI

'T' indicates the MRL is subject to revision following review of additional residue data.

\*indicates the MRL is set at or about the limit of determination.