



55 Blackall Street      PO Box 7186  
Barton ACT 2600      Canberra MC ACT 2610  
Australia              Australia  
Ph: 61 2 6271 2258      Fax: 61 2 6271 2278  
[www.anzfa.gov.au](http://www.anzfa.gov.au)

**23 February 2000**  
**10/00**

## **INFORMATION SUMMARY**

### **APPLICATION A407**

#### **MAXIMUM RESIDUE LIMITS**

The Australia New Zealand Food Authority has received an application on 20 January 2000 to amend the Australian *Food Standards Code* on the above matter. The Authority's Preliminary Assessment Report is attached 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.

Food sold in Australia which is either domestically produced or imported (other than from New Zealand) must comply with the Australian MRLs (ie in the *Food Standards Code*). Food imported from New Zealand must comply with either the New Zealand MRLs (ie in the New Zealand *Food Regulations 1984*) or the Australian MRLs.

Food sold in New Zealand which is either domestically produced or imported (other than from Australia) must comply with the MRL provisions in the New Zealand *Food Regulations 1984*. Food imported from Australia must comply with either the New Zealand MRLs or the Australian MRLs.

### **PRELIMINARY ASSESSMENT REPORT**

#### **Maximum Residue Limits – January 2000 MRLs**

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

**Date received:** 20 January 2000

## **BACKGROUND:**

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

- MRLs for the **new chemicals** buprofezin, imazapyr, indoxacarb.
- new MRLs (**extensions of use**) for bitertanol, chlorothalonil, dithiocarbamate (mancozeb), doramectin, fipronil, imazapic, imidacloprid, iprodione, metalaxyl, procymidone, tebuconazole, tebufenozide.
- **changes** to existing MRLs for captan, 2,4-D, fipronil, phosphorous acid.
- **deletions** to existing MRLs for fipronil.
- **notification** of a change to the registration status for monocrotophos.

The requested changes to Schedule 1 of Standard A14 are summarised at **Attachment 1**. The evaluation reports sent to ANZFA from the NRA justifying the proposed MRL changes are available upon request (these will be emailed or posted to interested parties).

## **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 these Attachments 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.

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 fulfill 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 that 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 are 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 A407** 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  
Tel (04) 473 9942 Fax (04) 473 9855

The Authority should receive submissions by **5 April 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 <[slo@anzfa.gov.au](mailto:slo@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](mailto: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 of **A407**. These will be sent to interested parties by email or posted.

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
<b><i>HERBICIDES</i></b>		
<b>2,4-D</b> Cereal grains	0.2 to T2	<i>An increase</i> to the cereal grain MRL for use as a post-emergent herbicide.  NTMDI = 86% ADI
<b>Imazapyr</b> Edible offal (mammalian) Meat (mammalian)[in the fat] Milks Rape seed	0.05*  0.05* 0.01* 0.05*	<i>New MRLs</i> for a newly registered chemical for control of certain annual grass and broadleaf weeds.  NEDI=0.008%ADI
<b>Imazapic</b> Rape seed	0.05*	<i>An extension of use</i> to control grass, nutgrass and broadleaf weeds. Imazapic is the ISO alternatively approved name for Imazameth.(A370). NEDI=0.07%ADI
<b>Phosphorous acid</b> Fruiting vegetables, cucurbits	<del>T25 deletion</del> T100	An extension of use (off-label permit) has been granted for the control of Downy mildew cucurbits.  NEDI = 0.33% ADI
<b>Procymidone</b> Snow peas	T5	<i>An extension of use</i> for the control of fungal diseases in snow peas.  NTMDI = 18.7% ADI
<b><i>INSECTICIDES and ACARACIDES</i></b>		
<b>Buprofezin</b> Citrus fruits Edible offal (mammalian) Milks Meat	T3 T0.05* T0.01* T0.05*	<i>A new chemical</i> , to be used for the control of whitefly in citrus, cotton and vegetables, and scale insects and mealy bugs in citrus.

		ADI: 0.01 mg/kg body wt/day NTMDI = 24.7% ADI
<b>Imidacloprid</b> Brassica (cole or cabbage) vegetables	0.5	An <i>extension of use</i> to brassicas.  NTMDI = 4.1 %ADI
<b>Indoxacarb</b> Pome fruit Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Cotton seed Milk [in the fat] Meat, mammalian [in the fat] Edible offal (mammalian)	T2   T1 T3 T0.5 T0.2  T0.01*	<i>New MRLs</i> for a newly registered chemical for control of insects in pome fruit, brassica vegetables and cotton.  NTMDI=79%ADI
<b>Monocrotophos</b>  Apple Banana Beans, except broad bean and soya bean Broad beans (green pods and immature seeds) Cereal grains Cotton seed Edible offal (mammalian) Milks Pear Potato Poultry, edible offal of Poultry meat Sweet corn (corn-on-the- cob) Tomato Vegetable oils, edible	  0.5 to T0.5 0.5 to T0.5  0.2 to T0.2  0.2 to T0.2 0.02* to T0.02* 0.1 to T0.1 0.02* to T0.02* 0.002* to T.002* 0.5 to T0.5 0.1 to T0.2 0.02* to T0.02* 0.02* to T0.02*  0.01* to T0.01 0.5 to T0.5 0.05* to T0.05*	Following the outcomes of the Existing Chemicals Review Program, the NRA has cancelled all product registrations of monocrotophos. The subsequent MRLs will be withdrawn from 30 June 2002. Until this time,all existing MRLs are considered temporary.  NEDI=78%ADI
<b>Fipronil</b> Edible offal (mammalian) Eggs Meat [mammalian] [in the fat] Milks Milk [in the fat] Poultry, edible offal of Poultry meat [in the fat] Sorghum	0.02 0.02  0.05 to 0.1 0.01 <del>0.01 (deletion)</del> 0.01* 0.02	<i>An extension of use</i> and changes (increases) to specific MRLs to control insects. <i>Deletion</i> to an existing commodity MRLs to reflect current registration status. MRLs requested in animal commodities as sorghum is an animal feed commodity.



	T0.01* to 0.01	NTMDI = 78% ADI
--	----------------	-----------------

<b>Tebuconazole</b> Broad bean (green and immature seeds) Cotton seed Peas Legume vegetables	<del>T0.5 deletion</del>  T1 to 1 <del>0.5 deletion</del> 0.5	An <i>extension of use</i> for the control of fungal diseases in beans (group MRL for legume vegetables set) and establishment of permanent MRL for cotton.  NTMDI = 20% ADI
<b>Tebufenozide</b> Custard Apple Litchi Longan	T0.2 T1 T1	An <i>extension of use</i> for control of Lepidoptera.  NEDI=16%ADI
<b>FUNGICIDES</b>		
<b>Chlorothalonil</b>  Vegetables [except carrot, celery, fruiting vegetables, leafy vegetables, cucurbits, leeks, onion bulb, potato, spring onion, tomato]	       T7	An <i>extension of use</i> for an off label permit for control of white rust fungus in wasabi  NEDI = 0.43% ADI
<b>Chlorothalonil cont.</b> Vegetables [except carrot, celery, fruiting vegetables, leafy vegetables, cucurbits, leeks, onion bulb, potato, spring onion, tomato, wasabi]  Wasabi	       T7  T7	
<b>Bitertanol</b> Strawberry	T*0.1 mg/kg	An <i>extension of use</i> for the control of powdery mildew on strawberries.  NEDI = 25.8% ADI
<b>Captan</b> Stone fruits  Strawberry	<del>T20 deletion</del> 15 <del>T25 deletion</del> 10	After an evaluation of residue data, the NRA has set new (lower) residue limits for stone fruits and strawberry.  NEDI = 22.4% ADI
<b>Dithiocarbamates</b>  Herbs (except parsley)	  T5	An <i>extension of use</i> for a minor-use/off-label permit for control of Alternaria leaf spot and downy mildew.

		NEDI=58% of ADI
<b>Iprodione</b> Brussel sprouts	T0.05*	<i>An extension of use</i> for control of Damping off ( <i>Rhizoctonia</i> ). NEDI=71%ADI
<b>Metalaxyl</b> Herbs	T0.3	<i>An extension of use</i> for control of Alternaria leaf spot and downy mildew.  NEDI=6%ADI

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
<b>ANTIPARASITIC</b>		
<b>Doramectin</b>		
Pig meat (in the fat)	0.1	<i>An extension of use</i> for the control of nematodes and arthropods in pigs.  NEDI = 8.7% ADI
Pig kidney	0.03	
Pig liver	0.05	

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

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.