



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

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12/00

INFORMATION SUMMARY

APPLICATION A409

MAXIMUM RESIDUE LIMITS

The Australia New Zealand Food Authority has received an application on 14 March and 16 April 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 Standards 1999 and 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 – March and April 2000 MRLs

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

Date received: 14 March and 6 April 2000

BACKGROUND:

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

- MRLs for a **new** chemical carfentrazone-ethyl.
- New MRLs (**extensions of use**) for carbendazim, chlorothalonil, chlorpyrifos, dimethomorph, emamectin benzoate, fipronil, fluazifop-butyl, fludioxonil, glyphosate, glufosinate-ammonium, lufenuron, mancozeb (dithiocarbamates) iprodione, oryzalin, oxyfluorfen, parathion-methyl, propiconazole, pymetrozine and metalaxyl.
- **Changes** to MRLs for fludioxinil, iprodione, lufenuron, mancozeb, spinosad and trichlorfon.
- **Deletions** to MRLs for mancozeb (dithiocarbamates),
- **Deletions** following expiry of permits for cyanamide, diofenolan, fluvalinate, phosphorous acid.
- **Notification** of a change to the registration status and consequent commodity MRLs for parathion-methyl as a result of the existing chemical review program by the NRA.

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

Option 1:-

- 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 can be developed as a food regulatory measure.
- (b) This application is not so similar to a previous application that it ought not be accepted.
- (c) There are no other measures that would be more cost effective than a food regulatory measure.
- (d) The costs that would arise from a food regulatory measure developed as a result of the application would outweigh the direct and indirect benefits that would arise from the measure.

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 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. It is considered that this application may constitute a potential Sanitary Phytosanitary (SPS) matter and needs to be notified to the WTO.

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 A409** 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 July 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 of **A 409**.

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
<i>HERBICIDES</i>		
Carfentrazone-ethyl Cereal grains Edible offal (mammalian) Eggs Meat (mammalian) Milks Poultry meat Poultry edible offal of	0.05* 0.05* 0.05* 0.05* 0.025* 0.05* 0.05*	<i>A new MRL</i> for post-emergence control of broadleaf weeds in winter cereals. Animal commodity MRLs requested to accommodate feeding of the treated grain to animals. NEDI=1.5% ADI
Fluazifop butyl Coffee beans	T1.0 (Sunset date 1 June 2002)	<i>An extension of use</i> for control of annual and perennial grasses in coffee crops. NTMDI=63% ADI
Glufosinate ammonium Coffee beans	T0.05* (Sunset date 1 June 2002)	<i>An extension of use</i> for control of annual and perennial broad-leaved weeds and grasses in coffee crops. NTMDI=18% ADI

<p>Glyphosate Coffee beans</p> <p>Pulses (except chick-peas and soybeans; requested in A405)</p> <p>Mung beans (dry)</p> <p>Pulses (except chick-peas, mung beans and soybeans)</p>	<p>T0.2 (Sunset date 1 June 2002)</p> <p>0.1* (Deletion)</p> <p>T10 (Sunset date 31 December 2000) 0.1*</p>	<p><i>An extension of use</i> for control of broad leaf weeds and grasses in coffee crops, and an <i>increase</i> in the MRL for mung beans.</p> <p>NEDI=1.4% ADI</p>
<p>Oryzalin Coffee beans</p>	<p>T0.1 (Sunset date 1 June 2002)</p>	<p><i>An extension of use</i> for control of broad leaf weeds and grasses in coffee crops.</p> <p>NTMDI=0.4% ADI</p>
<p>Oxyfluorfen Coffee beans</p> <p>Cotton seed</p> <p>Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicae</p> <p>Tropical and sub-tropical fruit (inedible peel)</p>	<p>T0.05 (Sunset date 1 June 2002)</p> <p>0.05*</p> <p>0.05*</p> <p>0.01*</p>	<p><i>An extension of use</i> for control of broad leaf weeds and grasses in coffee crops.</p> <p><i>An extension of use</i> as a pre-emergent herbicide prior to sowing.</p> <p><i>An extension of use</i> for control of broad leaf weeds and grasses in a variety of tropical and sub-tropical crops</p> <p>NTMDI=1.8% ADI (DIAMOND model) NTMDI=1.4% (NRA calculation)</p>

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
<i>INSECTICIDES and ACARACIDES</i>		
<p>Chlorpyrifos</p> <p>Vegetables [except asparagus; brassica vegetables; cassava; celery; potato; tomato]</p> <p>Vegetables [except asparagus; brassica vegetables; cassava; celery; leek; potato; tomato]</p> <p>Leek</p>	<p>0.01* (deletion)</p> <p>0.01*</p> <p>T5 (Sunset date 1 November 2002)</p>	<p><i>An extension of use</i> for a minor-use, off-label permit for control of cutworm and wingless grasshopper in leeks.</p> <p>NEDI=83%ADI 1996 ATDS=3% of ADI (for highest consumers on a per kg bodyweight basis)</p>
<p>Emamectin benzoate</p> <p>Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicae</p> <p>Cotton seed</p> <p>Brassica (cole or cabbage) vegetables, head cabbages, flowerhead</p> <p>Cotton seed</p> <p>Meat (mammalian) Edible offal, mammalian Milks</p>	<p>T0.005 (Deletion)</p> <p>T0.005 (Deletion)</p> <p>0.02</p> <p>T0.005 (Sunset date 31 October 2001)</p> <p>0.002* 0.002* 0.005*</p>	<p><i>An increase in the MRL</i> for control of insects in Brassica. Animal MRLs are requested to cover the feeding of treated crops to animals from use of the chemical.</p> <p>NEDI=2.6% ADI</p>

Fipronil Wine-grapes	T0.01*(Sunset date 30 June 2000)	<i>An extension of use</i> for an efficacy trial for control of insects on wine grapes. NEDI=65% ADI
Lufenuron Cotton seed Cotton seed oil, crude Milks Meat (mammalian), in the fat Edible offal (mammalian) Eggs Poultry, edible offal of Poultry meat [in the fat]	T0.02 to T0.2 T0.5 T0.2 T1 T0.01* T0.05 T0.01* T1 (Sunset dates for temporary MRLs 1 July 2002)	<i>An increase</i> for cotton seed and <i>an extension of use</i> for control of insects on crops. Animal MRLs are requested to cover the feeding of treated crops to animals from use of the chemical. NEDI=21% ADI
Parathion-methyl Cotton seed Cotton seed oil, crude Edible offal (mammalian) Fruits Meat [mammalian] Milks Vegetables Brassica vegetables Carrot Celery Cotton seed Citrus fruit Edible offal (mammalian) Fruiting vegetables, cucurbits Fruiting vegetables, other than cucurbits (except sweet corn) Grapes Legume vegetables Meat [mammalian] Milks Pome fruits Potato Pulses Stone fruits	1 (Deletion) 0.05 (Deletion) 0.05 (Deletion) 1 (Deletion) 0.05 (Deletion) 0.05 (Deletion) 1 (Deletion) T0.1 T0.5 T3 T1 T1 T0.05* T1 T0.2 T0.5 T0.5 T0.05* T0.05* T0.5 0.05* T0.2 T0.2	Following a review of parathion-methyl under the NRA's Existing Chemical Review Program, the NRA have requested deletions to a number of commodities and have requested MRLs in a range of other commodities. The temporary MRLs expire in 3 years after this review is finalised or as determined by the NRA. Maintenance of the temporary MRL is dependent of the registrant or person or group wishing to retain the MRL formally undertaking to generate the requested residue data within the allocated time frame. NEDI=87%ADI

Sweet corn	0.1*	
Pymetrozine Melons, except watermelons	T0.02	<i>An extension of use</i> for control of plant-sucking insects, such as aphids and whitefly.
Watermelon	T0.02 (Sunset date 31 December 2000)	NEDI=2% ADI
Spinosad Sweet corn (kernels) Sweet corn (corn on the cob)	T0.1 (Deletion) 0.02	<i>A decrease in the MRL and a change in commodity</i> for control of caterpillar pests on corn. NEDI=7% ADI
Trichlorfon Vegetables [except beetroot, brussel sprouts, cauliflower, celery, kale, pulses, sweet corn (corn-on-the-cob)]	0.1 (Deletion)	<i>A change in the MRL</i> for control of fruit-fly on peppers.
Vegetables [except beetroot, brussel sprouts, cauliflower, celery, kale, peppers, pulses, sweet corn (corn-on-the-cob)]	0.1 T0.5 (Sunset date 5 May 2001)	NEDI=97% ADI
Peppers		

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
FUNGICIDES		
Carbendazim Custard apple	T1 (Sunset date 31 December 2002)	<i>An extension of use</i> for a minor use permit for control of fungal diseases on custard apples. NEDI=73%ADI
Chlorothalonil Sunflower seeds	T0.01*	<i>An extension of use</i> for an emergency use permit for control of Head rot. 1996 ATDS = 0.4% ADI
Dimethomorph Poppy seed	0.02*	<i>An extension of use</i> for control of downy mildew on oilseed poppies. NTMDI=3% of ADI
Fludioxinil		<i>A decrease in the MRL</i> as a result of re-

Potato	T0.05 to 0.02	evaluation of residue trial data. NEDI=0.03% ADI
Iprodione Sunflower seeds Macadamia nuts Almonds	T0.05* T0.2 to 0.01* 0.02*	<i>An extension of use</i> for an emergency use permit for control of Head rot. <i>A decrease to the MRL</i> for macadamia nuts as a result of re-evaluation of residue trial data, and establishment of an MRL in almonds. NEDI=71% ADI 1996 ATDS=3% ADI
Mancozeb (dithiocarbamates) Poppy seed Pulses Fruiting Vegetables (other than cucurbits) Beans (dry) Broad bean (dry)[faba bean] Chick-pea (dry) Peas (dry) Egg plant [Aubergine] Okra Sweet corn (corn-on-the-cob) Tomato	 0.2* 0.53 0.5 (Deletion) 0.5 (Deletion) T0.5 (Deletion) T0.5 (Deletion) 3 (Deletion) 3 (Deletion) 0.5 (Deletion) 3 (Deletion)	<i>An extension of use</i> for downy mildew on oilseed poppies and target spot in capsicum. <i>Maintenance</i> of the temporary MRL in grapes, and <i>changes</i> for various fruiting vegetables and pulses. 1994 ATDS=46% of ADI (in highest consumers on a per/kg bodyweight basis). Not analysed in 1996 ATDS. More refined dietary calculations will be pursued by the NRA and ANZFA following completion of the review of dithiocarbamates under the NRA's Existing Chemical Review Program.

Metalaxyl Edible offal (mammalian)	0.5	Animal MRLs are requested to cover the feeding of treated crops to animals from use of the chemical to control fungi on grapes and macadamias. NEDI=6%ADI
Meat [mammalian][in the fat]	0.05*	
Propiconazole Mushrooms	0.05*	<i>An extension of use</i> for control of fungus on timber trays used in mushroom production. NEDI=5% ADI

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
DELETIONS OF MRLS FOR PERMITS		
Cyanamide Blueberries	T0.05*	Deletion of MRLs following expiry of permits and use no longer required.
Diufenolan Sheep, edible offal of Sheep meat [in the fat]	T0.2 T5	Deletion of MRLs following expiry of permits and use no longer required.
Fluvalinate Asparagus	T0.5	Requested in A405 (withdrew from drafting of A405)
Phosphorous acid Plums	T100	Deletion of MRLs following expiry of permits and use no longer required.

1. NEDI – National Estimated Dietary Intake
2. NTMDI – National Theoretical Maximum Dietary Intake
3. ATDS-Australian Total Diet Survey

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.

