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**5 July 2000**  
**01/01**

## **INFORMATION SUMMARY**

### **APPLICATION A414**

### **MAXIMUM RESIDUE LIMITS**

The Australia New Zealand Food Authority has received applications 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 (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999) 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 (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999. Food imported from Australia must comply with either the New Zealand MRLs or the Australian MRLs.

### **PRELIMINARY ASSESSMENT REPORT**

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

**Date received:** 1 May 2000

### **BACKGROUND**

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

- new MRLs (**extensions of use**) for bifenthrin, chlorothalonil, diafenthiuron, difenoconazole, ethephon, fluazifop-butyl, glyphosate, haloxyfop, isoxaflutole, myclobutanil, norflurazon, spinosad, tebufenozide.
- **changes** to existing MRLs for abamectin,
- **deletions** to existing MRLs for chlorpyrifos, diafenthiuron, tebufenozide.
- **notification** of a change to the registration status for imidacloprid, novaluron.

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

## **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

This application does relate to a matter that may be developed as a food regulatory measure, or warrants a variation of a food regulatory measure, and is not so similar to a previous application that it ought not be accepted.

Costs and benefits arising from any food regulatory measure, or other measures developed or varied as a result of this application, will be considered at full assessment.

There are no other relevant matters.

### CONCLUSIONS

The above application fulfils 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.

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.

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
<b>HERBICIDES</b>		
<b>Fluazifop-butyl</b> Sugar cane	T*0.1	Proposed use of fluazifop-butyl as a ripening agent in sugar cane (applied at sub-lethal rates 10 weeks before harvest)  NTDMI = 67% ADI for fluazifop-butyl
<b>Glyphosate</b> Sugar cane  Sugar cane molasses Pulses (except chick-peas, mung beans and soya beans) Adzuki bean (dry) Pulses (except chick-peas, mung beans, adzuki beans)	<del>*0.05</del> delete T0.3 T5 <del>*0.1</del> delete  T10 *0.1	Proposed use of glyphosate as a ripening agent in sugar cane (sub-lethal levels of glyphosate are applied directly onto the cane at 10 weeks before harvest). In addition, a permit has been granted for the use of glyphosate as a pre-harvest desiccant in adzuki beans.  NEDI = 1.4% ADI for glyphosate

and soya beans)		
<b>Haloxyfop</b> Sugar cane	*0.01	Proposed use of haloxyfop as a ripening agent in sugar cane (applied at lower than normal rates 10 weeks before harvest).  NEDI = 86% ADI for haloxyfop
<b>Isoxaflutole</b> Chick pea (dry)	T*0.01	Extension of use on chick peas for the control of broad leaf weeds.  NTDMI = 3% ADI
<b>Norflurazon</b> Asparagus	T0.05	Extension of use for the pre-emergent control of weeds in asparagus.  NTDMI = 2% ADI

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
<b><i>INSECTICIDES and ACARACIDES</i></b>		
<b>Abamectin</b> Cattle milk	<del>0.005</del> delete 0.02	Increase in the MRL for cattle milk to account for treatment of lactating dairy cattle for the control of internal and external parasites. NEDI = 22% ADI for abamectin
<b>Bifenthrin</b> Cotton seed  Citrus fruits Grapes	<del>0.05</del> delete 0.1 *0.05 <del>T*0.01</del> delete *0.01	Extension of use to citrus fruit; change in the registration status for grapes; increase in the MRL for cotton seed to enable a reduction in the withholding period from 7 weeks to 14 days.  NEDI = 68.6% ADI for bifenthrin
<b>Chlorpyrifos</b> Tree nuts	<del>0.2</del> delete	Deletion of MRL due to the expiry of permit.
<i>Diafenthiuron</i> Soya bean (dry)	T0.1	Emergency off- label permit issued in NSW and QLD for the control of spider mites on soya beans.  NEDI = 26% ADI for diafenthiuron
<b>Imidacloprid</b> Cotton seed	T*0.02 <del>delete</del> *0.02	Change in registration status.  NEDI = 4% ADI for imidacloprid

<b>Novaluron</b> Cotton seed  Cotton seed oil, crude	<del>T0.1</del> delete T1 T2	Amendment to an existing trial permit for the use of novaluron to control <i>Helicoverpa spp.</i> larvae in cotton.  NTMDI = 0.3% ADI for novaluron
<b>Spinosad</b> Melons, except watermelons	T0.2	Extension of use of spinosad to control cabbage moth in rockmelons and honey dew.  NEDI = 8.2% ADI for spinosad
<b>Tebufenozide</b> Kiwi fruit Oranges, Sweet, Sour	T1 <del>T1</del> delete	Extension of use to kiwi fruit for the control of light brown apple moth. Deletion of MRL for oranges.  NTMDI = 23% ADI for tebufenozide

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
<b>FUNGICIDES</b>		
<b>Difenoconazole</b> Asparagus	T*0.05	Extension of use to control <i>Stephylium</i> during the fern growth stage of asparagus production.  NTDMI = 10% ADI for difenoconazole
<i>Chlorothalonil</i> Tree tomato	T10	Extension of use for the control of fungal diseases in tree tomatoes.  NEDI = 0.43% ADI for chlorothalonil
<b>Myclobutanil</b> Asparagus	T0.02	Emergency permit issued in Queensland to control the spread of the disease <i>Puccinia asparagi</i> .  NEDI = 4.3% ADI for myclobutanil
<b>PLANT GROWTH REGULATORS</b>		
<b>Ethephon</b> Nectarine	T0.5	Extension of use to nectarines to improve fruit set and yield. NTDMI = 62.8% ADI for ethephon

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.

## 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 (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*.

- **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. 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 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 A414** at one of the following addresses:

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The Authority should receive submissions by **16 August 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>. 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>.



