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Australia New Zealand Food Authority
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08/00

INFORMATION SUMMARY

APPLICATION A401

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

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

Date received: 1 November 1999

BACKGROUND

This application seeks to include:

- MRLs for the new chemicals benzocaine, fenhexamid, tolylfluanid;
- new MRLs (extension of use) for the chemicals bentazone, bifenthrin, chlorothalonil, clomazone, beta-cyfluthrin, cypermethrin, difenoconazole, fipronil, fluazinam, fluroxypyr, imidacloprid, ioxynil, ivermectin,

methidathion, methomyl, myclobutanil, procymidone, propachlor, spinosad, tebuthiuron, trifluralin; and

- changes to existing MRLs for the chemicals benzofenap, carbendazim, chlorpyrifos, glyphosate, lincomycin, neomycin, oxyfluorfen, parathion, spinosad and tebufenozide.

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

ANTIBIOTIC MRLs

This application requests MRLs for two antibiotics, lincomycin and neomycin. These are not new antibiotics nor are the MRL amendments as a result of an extension of use. In the case of lincomycin, the Working Party on Antibiotics noted, in the course of evaluating lincomycin meat MRLs, that there was no MRL for milk despite there being a registered preparation. An MRL for lincomycin in cattle milk has been requested to address this oversight. With respect to neomycin, an MRL for milk (in the fat) already exists, however analytical data indicates that neomycin is a water soluble compound and therefore it does not make sense to set an MRL in the fat phase. A new MRL for neomycin in milk, the whole commodity, is requested in this application.

OBJECTIVE

The objective of this application is to vary Standard A14 – Maximum Residue Limits (MRLs) as outlined in **Attachment 1**, thus allowing primary producers greater flexibility with regard to the use of agricultural and veterinary chemicals whilst encouraging good agricultural practice. The chemicals listed in **Attachment 1** have already 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 on government monitoring programs.

Option 2:

- less flexibility for producers and importers;
- possibility of reducing the range and quality of commodities for consumers;
- 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 foods 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 and quality 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 application fulfils the requirements for preliminary assessment as prescribed in section 13 of the *Australian 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 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 A401** 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 <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>.

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 - A401. These will be sent to interested parties by email or by post.

CHEMICAL *Food*	**MRL** **(mg/kg)**	**JUSTIFICATION**
HERBICIDES		
Bentazone Garden pea, shelled	T*0.05	Extension of use (minor-use permit) to control weeds in processing peas. NEDI[1.] = 0.3%ADI for bentazone.
Benzofenap Rice	T*0.02 (deletion) *0.01	Residue trials have supported the establishment of an MRL at the limit of quantification (now lower). TMDI[2.] = 0.15% ADI for benzofenap
Clomazone Rice Beans (except broad beans and soya beans) Common beans (pod and / or immature seeds) Fruiting vegetables, cucurbits Poppy seed Potato	T*0.01 (deletion) *0.01 *0.01 T*0.05 *0.05 *0.05 *0.05	Extension of use to beans, cucurbits, poppy seed and potatoes for the control of broadleaf weeds and grasses. TMDI = 0.14% ADI for clomazone
Fluroxypyr Eggs Poultry, Edible offal of Poultry meat	*0.01 *0.05 *0.05	The NRA has extended the use of fluroxypyr to maize, millet, Lucerne and poppies and a changed rate of use on pastures. No change to existing MRLs for these commodities is required, however poultry MRLs are requested to account for the use of these commodities in poultry feed. TMDI = 0.9% ADI

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

CHEMICAL *Food*	MRL (mg/kg)	JUSTIFICATION
Glyphosate Barley Edible offal (mammalian) Wheat Wheat bran, unprocessed Cereal grains	 T20 (deletion) T2 (deletion) 0.5 T5 (deletion) T20 (deletion) *0.1	Deletion of temporary MRLs, established for emergency use, and re-establishment of "old" MRLs for edible offal and cereal grains. NEDI = 2% ADI for glyphosate
Ioxynil Garlic	 *0.02	Extension of use (off-label permit) as a selective post-emergence herbicide on garlic. TMDI = 0.1% ADI for ioxynil.
Oxyfluorefen Cotton seed	 T*0.05 (deletion)	Temporary MRL established for cotton has been deleted (off- label permit has expired).
Propachlor Radish Swede	 T*0.05 T*0.05	Extension of use for the control of broad leaf weeds in radish, swede and turnips. NEDI = 3% ADI for propachlor
Tebuthiuron Sugar cane	 T0.2	Extension of use (trial permit) for use in trash blanket sugarcane to control broadleaf weeds and vines. TMDI = 4% ADI for tebuthiuron.
INSECTICIDES		
Bifenthrin Avocado Stone fruit	 T0.1 T0.5	Extension of use (off-label permit) to control garden weevil on avocados and carpophilus beetle in stone fruit. NEDI = 80% ADI for bifenthrin.
Chlorpyrifos Ginger, root Ginger, root	 *0.01 (deletion) T0.05	Extension of use (minor-use, off-label permit) to control Symphyla in ginger. NEDI =82% ADI.
Beta-Cyfluthrin Rape seed	 T*0.05	Extension of use to control new insect pests in canola. TMDI = 70% ADI for beta-cyfluthrin.

CHEMICAL *Food*	**MRL** **(mg/kg)**	**JUSTIFICATION**
Alpha-Cypermethrin Asparagus Avocado Wheat Chick-pea (dry)	 T0.5 (deletion) 0.5 T0.2 *0.05 (deletion) 0.2 0.2	Extension of use (off label permit) to avocado for control of garden weevil. In addition, an extension of use for the control of redlegged earth mite, blue oat mite and native budworm in winter cereals, canola, field peas, chick-peas and faba beans has led to a change in the MRL for wheat and a new MRL for chick pea. *TMDI = 12% ADI for cypermethrin*
Fipronil Potato Peanut Peanut oil, crude Sugarcane Sweet potato Sorghum Maize Rape seed Sunflower seed Stone fruit	 T*0.01 (deletion) *0.01 T*0.01 T*0.01 T*0.01 (deletion) *0.01 T*0.01 T*0.005 (delete) T*0.01 T*0.005 T*0.01 T*0.01 T0.1	The MRLs requested for fipronil are as a result of three applications assessed by the NRA. The first is for the control of wireworm and mole crickets in potatoes and sweet potatoes and for the control of sugarcane weevil borer and white fringed weevil in peanuts. The second is for a trial permit granted for the use of fipronil to control redlegged earth mite in canola, sorghum, sunflowers and maize. Thirdly, a permit for the use of fipronil to control carpophilus beetle in stone fruit has been granted. NEDI = 81% ADI for fipronil.

CHEMICAL *Food*	MRL (mg/kg)	JUSTIFICATION
Imidacloprid Cereal grains Edible offal (mammalian) Maize Meat (mammalian) Milks Cereal grains [except maize and sorghum]	 *0.05 (deletion) 0.05 (deletion) 0.2 T*0.02 (deletion) T0.05 *0.02 (deletion) 0.05 *0.02 (deletion) 0.05 *0.05	Change in MRLs to account for an extension of use to maize, sorghum and sunflowers, applied as a seed dressing prior to sowing. TMDI = 4% ADI for imidacloprid.
Parathion Apricot Carrot Cereal grains Cotton seed Cotton seed oil, crude Edible offal (mammalian) Fruits [except apricot; peach] Meat (mammalian) Milks Peach Vegetables [except carrot]	 1 (deletion) T1 0.5 (deletion) T 0.5 0.5 (deletion) T0.5 1 (deletion) T1 0.5 (deletion) T0.5 *0.05 (deletion) T*0.05 0.5 (deletion) T0.5 *0.05 (deletion) T*0.05 *0.05 (deletion) T*0.05 1 (delete) T1 0.7 (deletion) T0.7	As an outcome of the existing chemicals review program, the NRA has cancelled all constituent approvals and product registrations for parathion. Parathion products are to be withdrawn from sale and MRLs for parathion are to be withdrawn from 30 June 2001. All existing MRLs are now considered temporary MRLs until that time.
Methidathion Coffee beans	 T0.1	Extension of use for the control of coffee scale and mealy bug in coffee. TMDI = 30% ADI for methidathion.

CHEMICAL *Food*	MRL (mg/kg)	JUSTIFICATION
Methomyl Coffee beans	 T1	Insecticide and acaracide, extended for use on coffee. TMDI = 77% ADI for methomyl.
Spinosad Brassica (cole or cabbage) vegetables Lettuce, head Lettuce, leaf Leafy vegetables Peppers Spinach Tomato	 T0.1 (deletion) 0.5 T2 (deletion) T2 (deletion) 0.2 T0.1 (deletion) 0.2 T3 (deletion) T0.1 (deletion) 0.2	The NRA has registered spinosad for use on tomato, pepper, brassica vegetables, Chinese cabbage, spinach, and lettuce (head and leaf) crops, supported by residue trial data for these crops. Existing temporary MRLs have been changed accordingly. NEDI = 3% ADI for spinosad.
Tebufenoxide Avocado	 T0.1 (deletion) T0.5	Residue trials submitted for a renewed trial permit support an increased MRL for avocado. TMDI = 16% ADI for tebufenozide.
FUNGICIDES		
Chlorothalonil Persimmons, Japanese	 T10	Extension of use (off-label permit) to control cercospora leaf spot on persimmons. TMDI = 324% ADI. However, the estimated daily intakes for chlorothalonil based on the 1996 Market Basket Survey are 0.13-0.43% ADI.
Difenoconazole Banana Avocado	 T0.5 (deletion) *0.02 0.5	Extension of use to bananas, including those interplanted with avocadoes, to control fungal diseases. TMDI = 10% of the ADI for difenoconazole.

CHEMICAL *Food*	**MRL** **(mg/kg)**	**JUSTIFICATION**
Carbendazim Broad beans (dry) Chick-pea (dry) Lentils (dry) Vegetables [except chick-pea; fruiting vegetables, cucurbits; fruiting vegetables, other than cucurbits; mushrooms] Vegetables [except broad bean (dry); chick-pea (dry); fruiting vegetables, cucurbits; fruiting vegetables, other than cucurbits; lentils (dry); mushrooms]	 T0.5 T1 (deletion) T0.5 T0.5 3 (deletion) 3	Changes to the MRLs for chick peas, broad beans and lentils have been established to support a minor-use permit for the use of carbendazim to control fungal diseases on these commodities. NEDI = 102% ADI. Further refinement of this calculation, incorporating processing factors, reduces this intake to 73.15% ADI.
Fenhexamid Strawberry	T5	New chemical (fungicide) for the control of grey mould on strawberries. ADI = 0.2 mg / kg body weight TMDI = 0.07% ADI for fenhexamid.
Fluazinam Wine-grapes	T*0.05	Extension of use (off-label permit) for the control of Phomopsis disease on wine-grapes. TMDI = 7.2% ADI for fluazinam.
Myclobutanil Strawberries	T1	Extension of use (off-label permit) for the control of powdery mildew of strawberries. TMDI = 2.3% ADI for myclobutanil.
Procymidone Spinach	T2	Extension of use (minor-use permit) for the control of *Botrytis* and *Sclerotinia* on spinach. TMDI = 17% ADI for procymidone.

CHEMICAL *Food*	**MRL** **(mg/kg)**	**JUSTIFICATION**
Tolyfluanid Strawberry	T3	New chemical (fungicide) for control of black spot and grey mould and suppression of powdery mildew on strawberries. Draft ADI = 0.1 mg/kg body weight TMDI = 0.03% ADI.
Trifluralin Prawns Shrimps	T0.001 T0.001	Extension of use (minor-use permit) to control larval mycosis in hatchery stages of prawn culture. TMDI = 6% ADI.
ANTIHELMINTHS		
Ivermectin Sheep liver Deer kidney Deer liver Deer meat	*0.01 (deletion) 0.015 *0.01 *0.01 *0.01	A change in the MRL for sheep liver to account for the control of ivermectin sensitive, gastrointestinal round worms and lungworms in sheep and an extension of use to deer. NEDI = 30% ADI
ANAESTHETIC		
Benzocaine Abalone Finfish	T*0.5 T*0.5	New chemical, for use as an anaesthetic for finfish and abalone (minor-use permit). No ADI established. The Chemicals and Non Prescription Drugs Branch (TGA) has raised no objections to the proposed use.
ANTIBIOTICS		
Lincomycin Cattle milk	*0.02	The Working Party on Antibiotics, in the course of evaluating lincomycin meat MRLs, noted there was no MRL for milk despite there being a registered preparation. TMDI = 0.1% ADI for lincomycin

CHEMICAL *Food*	MRL **(mg/kg)**	JUSTIFICATION
Neomycin Milk (in the fat) Milk	 *0.02 (deletion) 0.5	Increase in MRL to accompany change to portion of the commodity to which the MRL applies. The existing MRL, in the fat, does not correlate with the physicochemical properties of neomycin which demonstrates it is a water soluble compound. TMDI = 6% ADI for neomycin.

'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.