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10/00

INFORMATION SUMMARY

APPLICATION A403

BHT RESIDUES IN FOOD

The Australia New Zealand Food Authority received an application on 12 November 1999 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.

PRELIMINARY ASSESSMENT REPORT

Applicant: Kellogg (Aust) Pty Ltd

Date received: 12 November 1999

BACKGROUND:

Kellogg (Aust) Pty Ltd has made an application to extend the current permission to use the antioxidant, butylated hydroxytoluene (BHT) (321), in the manufacture of Ready To Eat Breakfast Cereals, by increasing the permitted migration level from polyethylene (PE) film used as wrapping.

Standard A7 of the Australian *Food Standards Code* currently permits in clause 6, the use of butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) in the manufacture of polyethylene film for wrapping food. The migration of antioxidant to the food is limited to not more than 2 mg/kg of the food.

This application is to extend the limit of migration of BHT to no more than 50 mg/kg, to Ready to Eat Breakfast Cereals only.

BHT is added to PE film package liners of Ready to Eat Cereals to control rancidity, maintain fortification profiles and maintain shelf life. Although added to PE film, the antioxidant performs a technological function in the food and not the wrapping.

The applicant states that three major benefits will result from the approval of this application. These are:

- increased international harmonisation of Australian and New Zealand food standards;
- improved quality and increased shelf life of ready to eat breakfast cereals due to control of rancidity; and
- increased choice of breakfast cereals for consumers.

OBJECTIVE

A variation to standard A7 – Antioxidants in the Australian *Food Standards Code*.

POSSIBLE OPTIONS

Option 1

Maintain the status quo and do not widen the permission for antioxidants in food, as a result of migration from polyethylene film for wrapping food.

OPTION 2

Amend the Code to allow for the migration of BHT at a level of 50mg/kg only in Ready to Eat Breakfast Cereals.

Option 3

Amend the Code accordingly as BHT is already permitted to migrate from polyethylene film into foods, but apply the proposed 50mg/kg level to all foods, including the category of breakfast cereals requested.

OPTION 4

Amend the Code to allow for migration of both BHA and BHT to foods at the increased level of 50 mg/kg (in total) from packaging materials.

IDENTIFICATION OF AFFECTED PARTIES

- Manufacturers and importers/exporters of food products and packaging materials.
- Government agencies regulating the food industry in Australia and New Zealand.
- Consumers of foods and food ingredients.

POTENTIAL REGULATORY IMPACTS

Option 1 would maintain the current permission in Standard A7 of the Australian *Food Standards Code*, which is inconsistent with some international permission levels.

Option 2 would result in an inconsistent approach to the regulation of BHT when used in PE film.

Option 3 would result in increased international harmonisation of food regulation, although restricting the choice of antioxidants.

Option 4 would achieve a further increase in international harmonisation of regulations.

There are minimal perceived costs in including the requested permissions in the current standard A7 and consequentially in the joint Australia New Zealand Food Standards Code.

The information needed to make an assessment of this application will include that provided from public submissions. This preliminary assessment invites public comment on the application.

OTHER RELEVANT MATTERS

ANZFA recommended at Inquiry for review proposals, Proposal P205, *Articles and Materials in Contact with Food* and Proposal P150, *Food Additives*, that the Australia New Zealand Food Standards Council adopt joint standards for Australia and New Zealand. Neither of these proposals addressed the current permission in Standard A7 for antioxidants in PE films.

A further consideration in the assessment of this matter will be the regulation of BHT and BHA in PE film in the proposed joint FSC. The use of antioxidants in PE film may be regulated in either draft Standard 1.3.1, Food Additives or draft Standard 1.4.1 Contaminants and Restricted Substances.

CONCLUSIONS

The above application fulfils the requirements for preliminary assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

If recommended 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 extend the permission for BHT (but not BHA) migrating from polyethylene wrap to ready to eat breakfast cereals (but not other foods) from 2 mg/kg to 50 mg/kg.

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.

TOXICOLOGY

Toxicological data has been provided and this data will be comprehensively addressed during the full assessment stage of the application.

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 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 A403** 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>. 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 is provided below. Full evaluation reports are available from the Project Manager of **A405**. These will be sent to interested parties by email or posted.

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
<i>PLANT GROWTH REGULATOR/PROMOTANTS</i>		
Aminoethoxyvinylglycine Apple	T0.1	<i>New chemical (MRL)</i> to assist harvest management, reduce pre-harvest fruit drop, delay fruit maturation, maintain fruit firmness, improve quality and enhance storage potential. NEDI ¹ = 70% ADI
<i>HERBICIDES</i>		
Bromoxynil Grapes	0.01*	<i>An extension of use</i> to pastures grown as cover crops in vineyards. NTMDI ² = 21% ADI
Diflufenican Grapes	0.002*	<i>An extension of use</i> to pastures grown as cover crops in vineyards. NTMDI = 0.1% ADI
Glyphosate Pulses Chick-pea (dry) Pulses (except chick-peas)	0.1 (Deletion) T5 0.1*	<i>An extension of use</i> to control broad leaf weeds and grasses. NEDI=4%ADI
Imazamox Field pea, dry Peanut Soya bean, dry	0.05* 0.05* 0.05*	<i>New chemical</i> , to be used for post emergent control of certain annual grasses and broadleaved weeds in field peas, peanuts and soya beans. Imazamox is the active constituent in two formulations, Raptor and Raptor WG. ADI (draft) = 2.8 mg/kg/day NTMDI = 0.001% ADI

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
Imazapic Peanut	T0.1*	<i>An extension of use</i> to control grass, nutgrass and broadleaf weeds. Imazapic is the ISO alternatively approved name for imazameth.(A369). NEDI=0.05%ADI
Isoxaflutole Sugar cane Milks Meat (mammalian) Edible offal (mammalian)	T0.01* T0.05* T0.05* T0.05*	<i>New chemical (MRL)</i> for control of grasses and weeds. NEDI=3% of ADI
Metasulfuron-methyl Chick-pea (dry)	T0.05*	<i>New chemical (MRL)</i> for control of grasses and weeds. NEDI=11%ADI
Oxyfluorfen Cotton seed Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Tropical and sub-tropical fruit (inedible peel)	0.05* 0.05* 0.01*	<i>An extension of use</i> for use as a pre-emergent herbicide prior to sowing of cotton and for the control of annual broad-leaved weeds in fields of brassicas and tropical and sub-tropical fruits. NEDI=1.8%ADI
Propaquizafop Meat (mammalian) Edible offal (mammalian) Milks	0.02* 0.02* 0.01*	<i>An extension of use</i> to control grasses in pastures including lucerne, clover and vetch. Animal commodity MRLs requested as grazing may occur in these areas. NTMDI=1.7%ADI
<i>INSECTICIDES and ACARACIDES</i>		
Bifenthrin Citrus fruits Cotton seed Grapes	0.05* 0.05 to 0.1 0.01* (from temporary to a permanent MRL)	<i>An extension of use</i> to control insects on citrus fruits and grapes. An <i>increase</i> to the cotton seed MRL in order to lower the withholding period from 7 weeks to 14 days. NEDI=68%ADI

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
Cyfluthrin Beans, except broad bean and soybean Broad bean (green pods and immature seeds) Rape seed	0.5 (Deletion) 0.5 (Deletion) 0.05*	<i>An extension of use</i> to control mites on rape seed. <i>Deletions</i> to existing commodity MRLs to reflect current registration status. NTMDI = 49% ADI
Chlorpyrifos Coffee beans	T0.5	<i>An extension of use</i> for the control of pests. NEDI = 83% ADI
Clorsulon Cattle milk	1.5	<i>An extension of use</i> for the control of roundworms, lungworms, eyeworms, lice, mites and adult liver fluke. NTMDI=68%ADI
Emamectin benzoate Brassica (cole or cabbage) vegetables. Head cabbages, flowerhead brassica Cotton seed Meat, mammalian Edible offal, mammalian Milks	T0.005(deletion) 0.02 T0.005(deletion) 0.005 0.002* 0.002* 0.005*	An extension of use for the control of Diamondback Moth in brassica crops and <i>Helicoverpa</i> in cotton(temporary MRLs set as permanent and increased for brassica). MRLs have been set for animal food commodities to account for residues in animal feeds. TMDI = 1.85% ADI
Fenitrothion Apple Cabbages, head Cacao beans Cherries Fruits [except apples, cherries, grapes] Grapes Lettuce, head Lettuce, leaf Meat [mammalian] Rice, polished Soya bean (dry) Sugar Cane Tea, green, black Tomato Tree nuts	0.5 (Deletion) 0.5 (Deletion) 0.1 (Deletion) 0.5 (Deletion) 0.1 (Deletion) 0.5 (Deletion) 0.5 (Deletion) 0.5 (Deletion) 0.05 (Deletion) 0.1 (Deletion) 0.3 (Deletion) 0.02 (Deletion) 0.5 (Deletion) 0.5 (Deletion) 0.1 (Deletion)	Following the outcomes of a review on fenitrothion the NRA has recommended deletions of some MRLs and retaining of others until new data has been evaluated. The increases in MRLs for fruit and vegetables are restricted to a narrow period (late spring-summer) to control locusts. NEDI = 97% ADI

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
Fenitrothion cont. Vegetables[except cabbage, head; lettuce, head; lettuce, leaf; soya bean (dry); tomato] Fruits Meat (mammalian)[in the fat] Rice bran, unprocessed Vegetables	0.1 (Deletion) 1 T0.05* T20 0.5	
Fipronil Strawberry Peppers	T0.5 T0.1	An <i>extension of use</i> for an off-label permit for control of Western flower thrip. NEDI=67% ADI
Fluvalinate Asparagus	T0.5	A trial permit for an <i>extension of use</i> to control garden weevil in asparagus. NTMDI=6%ADI
Imidacloprid Edible offal (mammalian) Meat (mammalian) Milks Maize Sweet corn (corn-on-the-cob)	0.05 to 0.2 0.02 to 0.05 0.02 to 0.05 T0.02 to 0.05 0.02*	An <i>increase</i> in the previously requested MRLs and an <i>extension of use</i> to control insects. NTMDI=4%ADI
Ivermectin Cattle milk	0.02 to 0.05	An <i>increase</i> to the MRL following re-evaluation of trial residue data for the control of roundworms, lungworms, eyeworms, lice, mites and adult liver fluke. NTMDI=70%ADI
Oxydemeton-methyl Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead cabbages	0.5	New <i>chemical (MRL)</i> for control of aphids. NEDI=47%ADI

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
Oxydemeton-methyl cont. Cotton seed Cotton seed oil, crude Eggs Edible offal (mammalian) Lupins (dry) Meat (mammalian) Milks Poultry, edible offal of Poultry meat	 0.01* 0.01* 0.01* 0.01* 0.01* 0.01* 0.01* 0.01* 0.01**	
Pymetrozine Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Potato	 T0.1 to T0.02* T0.02 to 0.02*	Changed MRLs following re- evaluation of residue trial data. NEDI=3%ADI
Tebufenozide Coffee beans	T0.05	An <i>extension of use</i> for control of leaf rollers and looper in coffee. NEDI=16%ADI
FUNGICIDES		
Azoxystrobin Grapes Dried grapes Edible offal (mammalian) Meat (mammalian) Milks Fruit vegetables, cucurbits Tomatoes Potatoes	 2 5 0.01 0.01* 0.005 1 0.5 0.01*	<i>New chemical (MRL)</i> for control of downey and powdery mildew and blight. Animal commodity MRLs are requested since grazing may occur in these areas and/or resulting grapes may be fed to animals in feed. NEDI ¹ = 0.67% ADI
Imazalil Citrus fruits	T10 10	A new product containing imazalil for post-harvest treatment of citrus and pome fruit has been registered. No change to existing MRLs is needed, however the temporary MRL for citrus fruit is changed to permanent.

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
Fluquinconazole Meat (mammalian)[in the fat] Edible offal of [mammalian] Milks Wheat Eggs Poultry meat in the fat] Poultry, edible offal of	T0.5 to 0.5 T0.2 to 0.2 T0.1 to 0.1 T0.05 to 0.02 T0.2 to 0.02 T0.5 to 0.02 T0.2 to 0.02	<i>A decrease</i> to some of the temporary MRLs requested in A 398 (September 1999) as a result of re-evaluation of residue trial data. NEDI=40%ADI
Iprodione Macadamia nuts Almonds	T0.2 to 0.01* 0.02*	<i>An extension of use and a decrease</i> to control fungal diseases in nuts. NEDI=70%ADI
Kresoxim-methyl Apples Meat (mammalian)[in the fat] Edible offal (mammalian) Milks	0.1 0.01* 0.01* 0.001*	<i>New chemical (MRL)</i> for control of fungus. NEDI=0.03%ADI
Phosphorous acid Pistachio nut	T500	<i>An extension of use</i> for an off-label permit for the control of sooty cankers and dieback of trees. <i>No ADI.</i> NEDI=0.28% of PTWI (ANZFA set a Provisional Tolerable Weekly Intake of 70 mg/kg bw/week on the sum of phosphates and phosphonates.).
Procymidone Broccoli	T5	<i>An extension of use</i> as a fungicide. NEDI=20%ADI
ANTIBIOTICS		
Flavophospholipol Cattle fat Cattle kidney Cattle liver Cattle meat Cattle milk	0.01* 0.01* 0.01* 0.01* T0.01*	<i>A new antibiotic (MRL)</i> to improve milk production in lactating dairy cattle. There has been no ADI established, however, overseas residue trials indicated that residues were undetectable in cattle tissues and milk under the proposed use pattern.

CHEMICAL Food	MRL (mg/kg)	JUSTIFICATION
Flavophospholipol cont.		The Working Party on Antibiotics raised no objections to the proposed MRLs. The WPA concluded that flavophospholipol did not appear to have a human analogue and that the proposed uses do not seem to have the capacity to expose humans to dietary intake of the drug.
Lasalocid Cattle milk	0.01*	<i>An extension of use</i> for the treatment of coccidiosis in cattle. The Working Party on Antibiotics raised no objections to the proposed MRLs NTMDI=27%ADI
Neomycin Poultry meat Poultry liver Poultry kidney Eggs	T0.5 T0.5 T10 T0.5	<i>An extension of use</i> for the treatment of bacterial enteritis (scours). The Working Party on Antibiotics raised no objections to the proposed temporary MRLs recommended by the Joint Expert Committee on Food Additives (JECFA) until a special review of neomycin is conducted. NEDI 12%ADI
ANTIPARASITICS		
Abamectin Pig kidney Pig liver Pig meat [in the fat] Cattle milk	0.01 0.02 0.02 0.005 to 0.02	<i>An extension of use and change</i> for control of internal and external parasites. NEDI=21%ADI

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.