

8 November 2000
09/01

STATEMENT OF REASONS

APPLICATION A367

CELLULOSE BASED ION EXCHANGE RESINS

The Australia New Zealand Food Authority (ANZFA) has before it an application received on 10 November 1998 from Life Technologies Limited to amend the *Food Standards Code* to permit the use of four cellulose-based ion exchange resins, namely:

- Sulphopropyl cellulose (SP) resin;
- Carboxymethyl cellulose (CM) resin;
- Diethyl aminoethyl cellulose (DEAE) resin; and
- Quaternary amine cellulose (QAE) resin.

STATEMENT OF REASONS

The Authority has recommended to the Australia New Zealand Food Standards Council that it adopt the draft variations to the *Food Standards Code*, as amended, for the following reasons:

- There are no significant toxicological concerns raised in relation to the application.
- Use of the four cellulose-based ion exchange resins is technologically justified for isolating specific proteins from production liquors or waste streams, which can then be used as food ingredients with highly specific functional characteristics.

The drafting prepared after Full Assessment is amended for the following reasons:

- consistently name the resins;
- update the specification for the SP resin to the current (2000) United States Code of Federal Regulations;
- modify the specifications to the CM and DEAE resins, making them slightly more stringent; and
- continue the existing permission for the SP resin to be used as a processing aid in packaged water and water used as and ingredient in other foods.

The commencement date of the amended draft variation is from the date of gazettal.

REGULATION IMPACT

ANZFA has undertaken a regulation impact assessment process, which also fulfils the requirement in New Zealand for an assessment of compliance costs. That process concluded that the amendment to the Code is necessary, cost effective and of benefit to both producers and consumers.

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).

This Application may be a potential SPS matter. However, while there is no international standard for the regulation of processing aids, or specifically ion exchange resins, the matter is not expected to have a significant trade effect and therefore was not notified to the WTO.

VARIATIONS TO THE *FOOD STANDARDS CODE*

A367 – CELLULOSE-BASED ION EXCHANGE RESINS

To commence: On gazettal

[1] *Standard A11, subclause (1)(k)*

omit

1 April 1994

substitute

1 April 2000

[2] *Standard A11, column 1 of the Schedule*

omit

Regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide

substitute

Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then sulphonated whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting quantity of cellulose

[3] *Standard A11, Schedule*

insert

Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with carboxymethyl groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 70% by weight of the starting quantity of cellulose

immediately after

Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then sulphonated whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting quantity of cellulose *in Column 1 of the Schedule*

and

Addendum 8 *immediately opposite in Column 2 of the Schedule*

insert

Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with quaternary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting quantity of cellulose

immediately after

Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with carboxymethyl groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 70% by weight of the starting quantity of cellulose *in Column 1 of the Schedule*

and

Addendum 9 *immediately opposite in Column 2 of the Schedule*

insert

Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with tertiary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 70% by weight of the starting quantity of cellulose

immediately after

Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with quaternary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting quantity of cellulose *in Column 1 of the Schedule*

and

Addendum 10 *immediately opposite in Column 2 of the Schedule*

[4] Standard A11, immediately after Addendum 7

insert

ADDENDUM 8

- (a) This specification relates to regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with carboxymethyl groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 70% by weight of the starting quantity of cellulose.
- (b) The resins are limited to use in aqueous process streams for the isolation and purification of protein concentrates and isolates. The pH range for the resins shall be no less than 2 and no more than 10, and the temperatures of water and food passing through the resin bed shall not exceed 40°C.
- (c) When subjected to the extraction regime listed in the CFR part 21, 173.25(c)(4), but using dilute hydrochloric acid at pH2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25ppm of organic extractives.

ADDENDUM 9

- (a) This specification relates to regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with quaternary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting quantity of cellulose.
- (b) The resins are limited to use in aqueous process streams for the isolation and purification of protein concentrates and isolates. The pH range for the resins shall be no less than 2 and no more than 10, and the temperatures of water and food passing through the resin bed shall not exceed 50°C.
- (c) When subjected to the extraction regime listed in the CFR, part 21, 173.25(c)(4), but using dilute hydrochloric acid at pH2 in place of 5% acetic acid, the ion exchange resins result in no more than 25ppm of organic extractives.

ADDENDUM 10

- (a) This specification relates to:
 - (i) Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with tertiary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 70% by weight of the starting quantity of cellulose; and
 - (ii) Regenerated cellulose, crosslinked and alkylated with epichlorohydrin then derivatised with tertiary amine groups whereby the amount of epichlorohydrin does not exceed 10% by weight of the starting quantity of cellulose.

- (b) The resins are limited to use in aqueous process streams for the isolation and purification of protein concentrates and isolates. The pH range for the resins shall be no less than 2 and no more than 10, and the temperatures of water and food passing through the resin bed shall not exceed 50°C.
- (c) When subjected to the extraction regime listed in the CFR part 21, 173.25(c)(4), but using dilute hydrochloric acid at pH2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25ppm of organic extractives.

[5] Standard A16, Group VII of Table II of the Schedule

substitute

Group VII - Ion-Exchange Resins

Column 1 Substance	Column 2 Maximum permitted residue (mg/kg)
Cross-linked phenol-formaldehyde activated with one or both of the following: triethylene tetramine and tetraethylenepentamine	NS
Cross-linked polystyrene, chloromethylated, then aminated with trimethylamine, dimethylamine, diethylenetriamine, or dimethylethanolamine	NS
Divinylbenzene copolymer	NS
Epichlorohydrin cross-linked with ammonia and then quaternised with methyl chloride to contain not more than 18% strong base capacity by weight of total exchange capacity	NS
Hydrolysed copolymer of methyl acrylate and divinylbenzene	NS
Methyl acrylate-divinylbenzene-diethylene glycol divinyl ether terpolymer containing not less than 7% divinylbenzene and not more than 2.3% diethylene glycol divinyl ether, aminolysed with dimethaminopropylamine and quaternised with methyl chloride	NS
Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with carboxymethyl groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 70% by weight of the starting quantity of cellulose	NS

Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with quaternary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting quantity of cellulose	NS
Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then sulphonated whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting quantity of cellulose	NS
Regenerated cellulose, crosslinked and alkylated with epichlorohydrin and propylene oxide, then derivatised with tertiary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 70% by weight of the starting quantity of cellulose	NS
Sulphonated copolymer of styrene and divinylbenzene	NS

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 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 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*.

Any person or organisation may apply to the Authority to have the *Australian Food Standards Code* amended. In addition, the Authority may develop proposals to amend the *Australian Food Standards Code*. The Authority can provide advice on the requirements for applications to amend the *Australian Food Standards Code*.

FURTHER INFORMATION

Submissions: No submissions on this matter are sought as the Authority has completed its assessment and the matter is now with the Australia New Zealand Food Standards Council for consideration.

Further information on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the following addresses:

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Requests for copies of other information papers should be addressed to the Authority's Information Officer at the above address, or Email info@anzfa.gov.au