10 November 1999
07/99

EXPLANATORY NOTES

APPLICATION A367

CELLULOSE-BASED ION EXCHANGE RESIN

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

Approval was requested for four main variations of ion exchange resin using a common base matrix:

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

The base matrix is crosslinked hydroxypropylated regenerated cellulose.

- 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.
- Permission to use the resins should be included in Group VII of Table II in Standard A16 – Processing Aids, and should not be restricted to specific applications.
- Specifications for the resins should be included as an addendum to Standard A11– Specifications for Identity and Purity of Food Additives, Processing Aids, Vitamins, Minerals, and Other Added Nutrients, until such time as specifications are included in the source specification document, the US Code of Federal Regulations (US CFR).
- A consequential amendment should be made to draft Standard 1.3.4 – Identity and Purity, of the proposed joint *Food Standards Code*, to include the US CFR as a secondary source of specifications.

PROPOSED DRAFT VARIATION TO THE AUSTRALIAN *FOOD STANDARDS CODE*

See attached

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.*

Consideration of the Regulatory Impact for this proposal concludes that the benefits to industry and consumers of providing permission for the use of cellulose-based ion exchange resins outweighs any slight costs to enforcement agencies as a result of implementing and administering new requirements.

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 are notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification.

This matter does not need to be notified to the WTO as a SPS notification or a TBT notification because, 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.

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.

- **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

The Authority has completed a full assessment of the application, prepared draft variations to the Australian *Food Standards Code* and will now conduct an inquiry to consider the draft variations and its regulatory impact.

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 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.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A367** 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
Email <info@anzfa.gov.au>

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942 Fax (04) 473 9855
Email <nz.reception@anzfa.gov.au>

Submissions should be received by the Authority by **22 December 1999.**

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 addresses.

Attached:

Draft variation to the *Food Standards Code*

DRAFT VARIATION TO THE AUSTRALIAN 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 1999"

[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

"Quaternary amine cellulose" immediately after "Pyridoxine hydrochloride" in Column 1 of the Schedule and "Addendum 7" immediately opposite in Column 2 of the Schedule

insert

"Diethyl aminoethyl cellulose" immediately before "Dimethyl dicarbonate" in Column 1 of the Schedule and "Addendum 8" immediately opposite in Column 2 of the Schedule

insert

"Carboxymethyl cellulose" immediately after "Carbon dioxide" in Column 1 of the Schedule and "Addendum 9" immediately opposite in Column 2 of the Schedule

[4] Standard A11, after Note 1 to Addendum 6 (Specification for Oxidised Polyethylene)

ADDENDUM 7

SPECIFICATION FOR QUATERNARY AMINE CELLULOSE

(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 8

SPECIFICATION FOR DIETHYL AMINOETHYL CELLULOSE

(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 250% 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.

ADDENDUM 9

SPECIFICATION FOR CARBOXYMETHYL CELLULOSE

(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 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 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.

[5] Standard A16

omit

Group VII (Ion-Exchange resins) in Table II (Processing Aids Restricted by Function and Residue Level) in 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 250% by eight 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 250% by eight of the starting quantity of cellulose	NS
Sulphonated copolymer of styrene and divinylbenzene	NS

[6] Standard A16, Table VI

omit

"Regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide" in Column 1 of the Table and "NS" immediately opposite in Column 2 of the Table

1. , London, pp 4888-4896.