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3 March 1999
9/99

INFORMATION SUMMARY

APPLICATION A367

CELLULOSE-BASED ION EXCHANGE RESINS

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 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.

REGULATORY 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 regulatory 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 regulatory 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.

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*, as gazetted in New Zealand, 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 **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must for most products comply solely with the *Australian Food Standards Code*.

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 A369** 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 **14 April 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.

PRELIMINARY ASSESSMENT REPORT

**SUBJECT: APPLICATION A367
CELLULOSE-BASED ION EXCHANGE RESINS**

Applicant: Life Technologies Limited

Date received: 10 November 1998

PROBLEM/BACKGROUND:

Currently, in Australia, the *Food Standards Code* (AFSC) lists ion exchange resins in Group VII - Ion Exchange Resins, of Table II - Processing Aids Restricted by Function and Residue Level, in the schedule to Standard A16 - Processing Aids.

There is no comparable standard for processing aids in the New Zealand Food Regulations 1984. Processing aids are either regulated as food additives or are not specifically regulated in New Zealand.

Group VII of Standard A16 lists specific substances which may be used as ion exchange resins in the manufacture of food or food ingredients. Cellulose-based ion exchange resins are currently not listed in this table. However, 'regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide' is currently listed in Table VI - Processing Aids Used In Packaged Water and In Water Used As An Ingredient In Other Foods, of Standard A16.

The cellulose-based ion exchange resins which are the subject of this application may be considered to be derivatives of the regenerated cellulose currently permitted by Table VI of Standard A16. However, the resins in question are considered to be sufficiently different so as to warrant a separate application.

The applicant states that cellulose based ion exchange resins are used for isolating proteins from production liquors or waste streams. Exactly which ion exchange resin is used depends on the properties of the target proteins and the liquid stream from which it is to be isolated.

Other separation technologies (for example, membrane filtration technology) may be used for the separation of proteins. However, the applicant claims that the use of ion exchange resins for protein separation results in proteins with a higher degree of purity, which significantly improves their functional properties.

OBJECTIVE:

This application seeks approval of four cellulose-based ion exchange resins for the production of proteins for use as food ingredients. There are four main variations on a common base matrix:

Sulphopropyl cellulose;
Carboxymethyl cellulose;
Diethyl aminoethyl cellulose; and

Quaternary amine cellulose.

The base matrix is crosslinked hydroxypropylated regenerated cellulose.

POSSIBLE OPTIONS (including alternatives)

1. Amend Standard A16 to permit the use of cellulose-based ion exchange resins as processing aids.
2. Maintain the *status quo* and do not permit the use of cellulose-based ion exchange resins as processing aids.

Alternatives to regulation are not considered appropriate to regulate the use of ion exchange resins. Currently processing aids used in Australia are listed in Standard A16. New entries in the schedule to Standard A16 are required to undergo an evaluation to ensure there are no health and safety concerns with permitting their use. The standard is intended to reflect current use and prohibit inappropriate use of processing aids.

IDENTIFICATION OF AFFECTED PARTIES AND POTENTIAL REGULATORY IMPACTS

Manufacturers are likely to be most affected by the permission to use cellulose ion exchange resins. Proteins obtained using this technology are used by manufacturers for food production. Manufacturers will benefit by the availability of protein types and purity which would otherwise not be available.

Consumers may be indirectly affected as the availability to manufacturers of a range of proteins with specific nutritional or functional properties may enable manufacturers to provide a greater range or better quality of foods to consumers.

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.

OTHER RELEVANT MATTERS

Confidential commercial information

The applicant has requested that information relating to the manufacturing processes and conditions for the resins be treated as 'confidential commercial information'. The Authority has accepted this request.

International regulations

Codex does not regulate the use of processing aids.

The USA Code of Federal Regulations (CFR), Title 21, part 173.25 (a)(20), in force as at 1 April 1998 currently includes the use of -

regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then sulfonated whereby the amount of epichlorohydrin plus propylene oxide employed does not exceed **250 percent** by weight of the starting quantity of cellulose.

Specifications

Standard A11 - Specifications for Identity and Purity of Food Additives, Processing Aids, Vitamins, Minerals and Other Added Nutrients, cites the specification for regenerated cellulose listed in A16 as 'USA CFR, Title 21, part 173.25 (a)(20), in force as at 1 April **1994**'. This differs from the current CFR, in force as at 1 April 1998 (quoted above) in that "the amount of epichlorohydrin plus propylene oxide employed does not exceed **60 percent** by weight of the starting quantity of cellulose". This is significantly lower than the figure listed in the current CFR.

Review of the *Food Standards Code*

A review of Standard A16 is required during development of a joint Australia New Zealand Food Standards Code, in particular to identify and meet New Zealand requirements. A proposal document, P188 - Review of Processing Aids - Standard A16, was released for public comment on 28 October 1998.

The specific ion exchange resins under consideration in this application have not been included in the review of Standard A16 as they have not previously undergone a safety evaluation or approval process in Australia or New Zealand.

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 Authority and agreed to by the Australia New Zealand Food Standards Council, an amendment to the Code, as suggested by the applicant, would permit the use of cellulose-based ion exchange resins as processing aids.