

20 May 2016
[12–16]

Approval report – Application A1120

Agarose Ion Exchange Resin as a Processing Aid for Lactoferrin Production

Food Standards Australia New Zealand (FSANZ) has assessed an Application made by Fonterra Co-operative Group Limited to permit the use of an agarose ion exchange resin as a processing aid in the production of high purity lactoferrin from bovine milk and milk-related products.

On 16 February 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received five submissions.

FSANZ approved the draft variation on 4 May 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 17 May 2016.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting documents

The following document which informed the assessment of this Application is available on the FSANZ website at

<http://www.foodstandards.gov.au/code/applications/Pages/A1120AgaroseIonExchangeResinPA.aspx>

SD1 Risk and Technical Assessment Report

Executive summary

Fonterra Co-operative Group Limited submitted an Application seeking permission to use an agarose ion exchange resin as a processing aid in the production of high purity lactoferrin from bovine milk and milk-related products. Lactoferrin, present in milk at very low levels, has a range of physiological functions and the Application indicated that there is increasing interest in its use as a nutraceutical.

The agarose ion exchange resin under consideration consists of porous, spherical beads with a diameter of between 100-300 µm. It has strong cation exchange functionality, with the capacity to bind and extract large proteins like lactoferrin from dairy streams such as skim milk and whey, at high flow rates. The Applicant claimed it is the only resin with all of the specific characteristics that make it suitable for the commercial extraction of lactoferrin with a high yield and purity.

Processing aids are regulated under Schedule 18 in the *Australia New Zealand Food Standards Code*. The agarose ion exchange resin is appropriate for listing in the table to subsection S18—9(3), and requires a new specification in Schedule 3.

FSANZ's risk assessment concluded that there were no public health and safety concerns associated with the proposed use of the agarose ion exchange resin and, in its prescribed form and usage, is technologically justified. Therefore, the assessment considered that the resin should be permitted for use as a processing aid.

The FSANZ Board has approved a draft variation to the table to subsection S18—9(3) and a new section to Schedule 3 (S3—34), which sets out a specification for the agarose ion exchange resin. This will permit the use of the resin as a processing aid in the production of lactoferrin from milk and milk-related products.

FSANZ received five submissions on the draft variation following the call for submissions, with all submitters supporting the draft variation.

1 Introduction

1.1 The Applicant

The Applicant was Fonterra Co-operative Group Limited, a New Zealand-based global dairy company that processes and exports a range of dairy products and ingredients internationally.

1.2 The Application

The Application was received on 23 September 2015.

The purpose of the Application was to seek permission to use an agarose ion exchange resin as a processing aid in the production of high purity lactoferrin from bovine milk and milk-related products. The resin achieves this by binding and extracting lactoferrin from dairy streams such as skim milk and whey.

Lactoferrin, present in milk at very low levels, has a range of physiological functions and the Application indicated that there is increasing interest in its use as a nutraceutical¹.

The agarose ion exchange resin consists of porous, spherical beads with a diameter of between 100–300 µm. It comprises an agarose backbone cross-linked with epichlorohydrin and reacted with allyl glycidyl ether (or alternatively propylene oxide), and then derivatised with sulphonate groups to provide cation exchange functionality, which allows for effective binding and extraction of lactoferrin.

In typical use, the agarose ion exchange resin is packed into a fixed-bed ion exchange column, washed, rinsed and equilibrated. A pre-treated dairy stream (whey or skim milk) is passed through the column. Between 60-100% of lactoferrin may be adsorbed (bound) to the charged functional groups of the resin. Lactoferrin is desorbed (detached) from the resin using a buffer. It then undergoes a process of ultrafiltration and drying to produce the finished product powder.

The Applicant reported that the resin has been fully evaluated for safety for the intended purpose and is approved by the United States Food and Drug Administration (USFDA) as a food contact substance. Although other techniques have been studied, the resin is the only viable commercial method currently available to efficiently produce lactoferrin with a high yield and purity. As such, it has been used in other countries since lactoferrin was first produced commercially in 1986. Guidelines for the main process steps were provided in the Application.

1.3 The current Standard

Ion exchange resins used in processing and manufacturing food are considered processing aids. Only those processing aids listed in Schedule 18 in the *Australia New Zealand Food Standards Code* (the Code) are permitted to be used in producing food sold in Australia and New Zealand.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that might be developed as a food regulatory measure.

¹ A substance derived from food that is thought to have certain health benefits beyond its basic nutritional value.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for public comment on a draft variation to the Code between 16 February 2016 and 29 March 2016 after assessing the Application. Five submissions on the draft variation were received – two from government departments (one Australian; one New Zealand) and three from the food industry. The draft variation to Schedules 18 and 3 was supported by all submitters and no issues were raised.

Submitters noted that the agarose ion exchange resin has been evaluated for safety for the intended purpose and approved for use in other countries. Approval for its use in Australia and New Zealand would further develop commercial opportunities for the Australian and New Zealand dairy sector. Submitters were satisfied that the use of the agarose ion exchange resin is technologically justified and presents no public health and safety concerns.

2.2 Risk assessment

FSANZ's risk assessment concluded that the proposed use of the agarose ion exchange resin as a processing aid for lactoferrin production presents no public health and safety concerns.

For each lactoferrin isolation cycle, the resin is subjected to cleaning/rinsing procedures that result in negligible impurity levels in the resin. This minimises the potential for resin impurities to be present in the isolated lactoferrin and in the flow-through milk/whey stream.

Theoretical estimates of dietary exposure to resin impurities, calculated using conservative assumptions, provided confirmation that potential impurity levels are of no toxicological concern.

The evidence presented to support the proposed uses provided adequate assurance that the resin, in its prescribed form and usage, was technologically justified and was demonstrated to be effective in achieving its stated purpose.

For further details on the risk assessment, refer to the Risk and Technical Assessment Report (SD1), which remains unchanged from the call for submissions.

2.3 Risk management

The risk assessment conclusions provided evidence that there were no safety risks from the use of the agarose ion exchange resin as a processing aid. As processing aids require permissions in the Code, the only risk management options available to FSANZ were to approve or reject the draft variation to the Code.

Additionally, as discussed below, the risk management evaluation considered international standards, permissions for processing aids – which are linked to their specification for identity and purity, the applicability of the labelling provisions in the Code, and an analysis of benefits and costs.

2.3.1 International standards

Codex Alimentarius (Codex) does not have Standards for processing aids. However, the agarose ion exchange resin conforms to the definition of food processing aids as described in the *Procedural Manual of the Codex Alimentarius Commission* (24th edition, 2015) and the *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010).

There is no process in place whereby this processing aid can be specifically approved in the EU. However, it meets the requirements as given in Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food.

The agarose ion exchange resin has been approved as a food contact substance by the USFDA (FCN 000443) effective 29 September 2004. It is approved for intended use as 'an ion exchange resin' and for 'repeated use in extracting individual proteins or substances present in similar low concentrations from liquid, water-based food materials, such as milk, whey, fruit juice, beer and wine' (US FDA 2004). In addition, GRAS Notices were published for the manufacturing process for lactoferrin using the resin in 2014 (GRAS GRN Nos. 464, 465) (US FDA, 2014a; US FDA 2014b).

The Application contained copies of the relevant approvals and associated documents.

2.3.2 Permissions for agarose ion exchange resin

The agarose ion exchange resin for lactoferrin production will be included in the table to subsection S18—9(3).

Schedule 18 already permits the use of an agarose ion exchange resin for the removal of specific proteins and polyphenols from beer. However, the two resins differ in that the one permitted for beer production is derivatised with tertiary amine groups, whilst the other intended for lactoferrin production is derivatised with sulphonate groups. To clearly differentiate between the two resins in Schedule 18, they are to be listed in the table to subsection S18—9(3) (in alphabetical order) as an *amine* agarose ion exchange resin and a *sulphonate* agarose ion exchange resin, respectively.

Schedule 18 also includes a definition for agarose ion exchange resin (subsection S18—9(2)). This definition will be replaced with two separate definitions (in alphabetical order): one for the amine resin, the other for the sulphonate resin.

2.3.3 Specification

Permissions for processing aids are linked to their specification for identity and purity, provided in Schedule 3 of the Code. An individual specification is to be included in Schedule 3 for the *sulphonate* agarose ion exchange resin. This is in addition to the existing specification, which will be clearly identified as an *amine* agarose ion exchange resin, referenced in subsection S3—6.

2.3.4 Labelling considerations

As a general rule, processing aids are exempt from the requirement to be declared in the statement of ingredients in accordance with paragraphs 1.2.4—3(2)(d) and (e) in Standard 1.2.4. Therefore, the use of the agarose ion exchange resin as a processing aid for lactoferrin production would not have to be declared on the label of the food.

2.3.5 Cost benefit analysis

FSANZ undertook a basic cost benefit analysis for this Application and concluded that permitting the use of the agarose ion exchange resin as a food processing aid for lactoferrin production had benefits to the food industry, especially the dairy industry. In particular, approval of this processing aid would provide the dairy industry with the opportunity to recover lactoferrin from low value dairy streams for supply to, and use in, domestic and international markets. The cost to the industry to use the processing aid (noting that use is entirely voluntary) would be offset by the value of lactoferrin as a premium ingredient.

In addition, approval of the processing aid would provide the dairy industry in Australia and New Zealand with the opportunity for innovation in the development of value-added new products and ingredients for both the domestic and export markets.

Consumers might also benefit from the approval of this processing aid, through a possible increase in the availability of this high value bioactive ingredient in various food products, in particular, dairy-based special purpose type foods.

No costs to consumers, Governments or other stakeholders were identified that would override these benefits. There were no benefits in rejecting the Application.

Therefore, FSANZ concluded that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the costs to the community, Government and industry that would arise from the development or variation of such a food regulatory measure.

2.3.6 Risk management conclusion

The proposed use of the agarose ion exchange resin as a processing aid for lactoferrin production, in its prescribed form and usage, is technologically justified. The risk assessment conclusions indicated that there were no public health and safety concerns associated with its use. The resin has already been assessed as safe and permitted for use in other major jurisdictions. The basic cost benefit analysis indicated that the benefits accrued from permitting the use of the processing aid would outweigh any costs. Based on this information, the preferred risk management option was to approve a draft variation to Schedules 18 and 3.

3 Decision

The FSANZ Board has approved a draft variation (as proposed at the call for submissions) to the table to subsection S18—9(3) to permit the use of the agarose ion exchange resin as a processing aid for lactoferrin production.

All permitted processing aids are also required to have a specification for identity and purity in Schedule 3. The FSANZ Board has approved a new specification for the agarose ion exchange resin for inclusion in this Schedule.

The draft variation was approved without change following assessment and is at Attachment A. The variation takes effect on gazettal.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

4 Risk communication

4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on an application or proposal was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

The FSANZ Board considered the draft variation taking into account comments received from the call for submissions.

The Applicant, individuals and organisations that made submissions on this Application were notified at each stage of the assessment. Subscribers and interested parties were also notified via email about the availability of reports for public comment.

The FSANZ Board's decision has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review by Ministers, the Applicant and stakeholders will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

5 FSANZ Act assessment requirements

5.1 Section 29

5.1.1 Cost benefit analysis

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for Applications relating to processing aids as they are machinery in nature and their use is voluntary. Notwithstanding this, FSANZ conducted a basic cost benefit analysis, which is described in Section 2.3.5 above.

5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

5.1.3 Any relevant New Zealand standards

Schedule 18 and Schedule 3 apply to New Zealand and there are no relevant New Zealand only Standards.

5.1.4 Any other relevant matters

Other relevant matters are considered below.

5.2 Subsection 18(1)

FSANZ also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

5.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concluded there were no public health and safety concerns relating to permitting the agarose ion exchange resin as a processing aid for the production of lactoferrin.

5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The labelling approach for the processing aid is discussed in Section 2.3.4 above. The existing provisions in the Code are considered to be appropriate for the permitted use of the processing aid.

5.2.3 The prevention of misleading or deceptive conduct

There were no issues identified with this Application relevant to this objective.

5.3 Subsection 18(2) considerations

FSANZ also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis which is provided in SD1 – the Risk and Technical Assessment Report. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information including scientific literature was also used in assessing the Application.

- **the promotion of consistency between domestic and international food standards**

There are no Codex Alimentarius Standards for processing aids. However, the agarose ion exchange resin conforms with the Codex definition of a food processing aid, and the Codex *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010). In addition, it meets EU requirements for materials and articles intended to come into contact with food (Regulation (EC) No. 1935/2004).

The resin has been approved as a food contact substance in the United States, and GRAS Notices were published for the manufacturing process for lactoferrin using the resin in 2014.

- **the desirability of an efficient and internationally competitive food industry**

The agarose ion exchange resin is the only viable commercial method currently available for lactoferrin production. As such, it has been the method used in other countries since lactoferrin was first produced commercially in 1986.

The Applicant anticipates that the approval of its use would be supported by the food industry and that it will benefit all dairy food processing companies. However, the food industry will make their own economic decisions, taking account of costs and benefits of using the new resin as a processing aid, to determine if it is of benefit to their business.

- **the promotion of fair trading in food**

The agarose ion exchange resin has been assessed as safe and permitted for use in other countries. Permitting its use in Australia and New Zealand would support fair trading for both domestic and international food manufacturers and retailers.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*² includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the use of the agarose ion exchange resin as a processing aid for the production of lactoferrin is consistent with the specific order policy principles for 'Technological Function'.

6 References

Codex Alimentarius Commission (2010) Guidelines on substances used as processing aids, CAC/GL 75-2010 <http://www.codexalimentarius.org/standards/list-of-standards/>. Accessed on 23 December 2015.

Codex Alimentarius Commission (2015) Procedural Manual, 24th edition <http://www.fao.org/fao-who-codexalimentarius/procedures-strategies/procedural-manual/en/>. Accessed on 23 December 2015.

European Commission (2004) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. Official Journal of the European Union 47(L338):4-17 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2004.338.01.0004.01.ENG&toc=OJ:L:2004:338:TOC. Accessed on 23 December 2015.

US FDA (2004) Inventory of Effective Food Contact Substance (FCS) Notifications. Food Contact Notification No. 443. Amersham Biosciences. Food Contact Substance: Agarose, polymer with (chloromethyl)oxirane, 2-hydroxy-3(3-sulfopropoxy)propyl ethers, sodium salts (CAS Reg. No. 676618-71-6).

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

US FDA (2014a) GRAS Notice No GRN 464 [Cow's milk-derived lactoferrin]. Submitted by Morinaga Milk Industry Co., Ltd, Tokyo, Japan to the U.S. Food and Drug Administration (US FDA), on 22 March 2013. Releasable dossier and Agency Response Letter available at this link <http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=464>. Accessed on 23 December 2015.

US FDA (2014b) GRAS Notice No GRN 465 [Cow's milk-derived lactoferrin]. Submitted by Morinaga Milk Industry Co., Ltd, Tokyo, Japan to the U.S. Food and Drug Administration (US FDA), on 22 March 2013. Releasable dossier and Agency Response Letter available at this link <http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=465>. Accessed on 23 December 2015.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (A1120 – Agarose Ion Exchange Resin as a Processing Aid for Lactoferrin Production) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (A1120 – Agarose Ion Exchange Resin as a Processing Aid for Lactoferrin Production) Variation*.

2 Variation to standards in the Australia New Zealand Food Standards Code

The Schedule varies standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 3 is varied by

[1.1] omitting the words “agarose ion exchange resin” from the table to subsection S3—2(2), substituting “amine agarose ion exchange resin”

[1.2] inserting in the table to subsection S3—2(2) in alphabetical order

sulphonate agarose ion exchange resin	section S3—34
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[1.3] omitting the words “agarose ion exchange resin” from the heading to section S3—6, substituting “amine agarose ion exchange resin”

[1.4] inserting after section S3—33

S3—34 Specification for sulphonate agarose ion exchange resin

(1) This specification relates to agarose, cross-linked with epichlorohydrin and reacted with allyl glycidyl ether or propylene oxide, then derivatised with sulphonate groups whereby the amount of epichlorohydrin plus allyl glycidyl ether or propylene oxide does not exceed 250% by weight of the starting quantity of agarose.

(2) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

[2] Schedule 18 is varied by

[2.1] omitting the definition of “agarose ion exchange resin” in subsection S18—9(2)

[2.2] inserting in subsection S18—9(2) in alphabetical order

amine agarose ion exchange resin means agarose cross-linked 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 amount of agarose.

sulphonate agarose ion exchange resin means agarose cross-linked with epichlorohydrin and reacted with allyl glycidyl ether or propylene oxide, then derivatised with sulphonate groups whereby the amount of epichlorohydrin plus allyl glycidyl ether or propylene oxide does not exceed 250% by weight of the starting quantity of agarose.

[2.3] omitting the words “Agarose ion exchange resin” in the table to subsection S18—9(3), substituting “Amine agarose ion exchange resin”

[2.4] inserting in the table to subsection S18—9(3) in alphabetical order

Sulphonate agarose ion exchange resin	Production of lactoferrin from bovine milk and milk-related products	GMP
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Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1120 which seeks to permit an agarose ion exchange resin as a processing aid. The resin will be used in the production of high purity lactoferrin from bovine milk and milk-related products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

Ion exchange resins used in processing and manufacturing food are considered to be processing aids. Only those processing aids listed in Schedule 18 of the Code are permitted to be used in producing food sold in Australia and New Zealand. The Authority has proposed that the agarose ion exchange resin is permitted as a processing aid for lactoferrin production by adding this resin to the table to subsection S18—9(3) in Schedule 18.

Permissions for processing aids are also linked to their specification for identity and purity, provided in Schedule 3 of the Code. Since there are no specifications for the agarose ion exchange resin for lactoferrin production in any of the monographs in Schedule 3 (subsections S3—2 and S3—3), a new specification will be written into Schedule 3.

3. Documents incorporated by reference

The approved draft variation incorporates a specification by reference to a specific document in force or existing at the commencement of the variation.

The incorporated specification is an extraction regime described in the 2014 compilation of the United States Code of Federal Regulation. The latter is referred to in order to provide technical detail required to support the provisions of the Code. This reference by incorporation is consistent with the current practice in the Code, particularly Schedule 3 which itself already incorporates the same document by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1120 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (including the draft variation) occurred for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 and Schedule 3 is likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

6.1 Variation to Schedule 3

Item [1] varies Schedule 3.

Subitem [1.1] omits the words 'agarose ion exchange resin' from the table to subsection S3—2(2), and substitutes those words with 'amine agarose ion exchange resin'.

Subitem [1.2] inserts a reference to 'sulphonate agarose ion exchange resin' into the table to subsection S3—2(2) in alphabetical order, together with a reference to the provision that sets a specification for that substance ('section S3—34').

Subitem [1.3] omits the words 'agarose ion exchange resin' from the heading to section S3—6, and substitutes those words with 'amine agarose ion exchange resin'.

Subitem [1.4] inserts new section S3—34, which sets a specification for a sulphonate agarose ion exchange resin. The new section is numbered S3—34 to take account of another variation which will insert section S3—33 into Schedule 3.

6.2 Variation to Schedule 18

Item [2] varies Schedule 18.

Subitem [2.1] omits the definition of 'agarose ion exchange resin' in subsection S18—9(2).

Subitem [2.2] inserts in subsection S18—9(2), in alphabetical order, definitions for the following terms used in section S18—9:

- 'amine agarose ion exchange resin'; and
- 'sulphonate agarose ion exchange resin'.

Subitem [2.3] omits the words 'Agarose ion exchange resin' from the table to subsection S18—9(3), and substitutes those words with 'Amine agarose ion exchange resin'.

Subitem [2.4] inserts in the table to subsection S18—9(3), in alphabetical order, a new entry for 'Sulphonate agarose ion exchange resin'. The effect of this amendment is that sulphonate agarose ion exchange resin is permitted as a processing aid where:

- its technological purpose is the production of lactoferrin from bovine milk and milk-related products; and
- its maximum levels are consistent with good manufacturing practice (GMP).