16 February 2016
[04–16]

Call for submissions – Application A1120

Agarose Ion Exchange Resin as a Processing Aid for Lactoferrin Production

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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, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 29 March 2016

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
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Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
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Supporting document

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 resin under consideration 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 by Schedule 18 of the revised Code. Permission is specifically sought for this processing aid to be included in the table to subsection S18—9(3) *Permitted processing aids—various technological purposes*, and for a specification for this resin to be added to Schedule 3 – Identity and purity in the revised Code.

The resin 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. Pre-treated skim milk or whey is passed through the resin, which is contained within a fixed-bed ion exchange column. A brine solution is passed through the resin to wash out the purified lactoferrin. The column is reused after rinsing and regeneration.

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, provide confirmation that potential impurity levels are of no toxicological concern.

It is concluded that that the proposed use of the resin as a processing aid for lactoferrin production, in its prescribed form and usage, is technologically justified and presents no identifiable public health and safety concerns.

FSANZ has therefore prepared a draft variation to permit the agarose ion exchange resin as a processing aid in the production of lactoferrin from milk and milk-related products.

1 Introduction

1.1 The Applicant

The Applicant is 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 purpose of the Application is 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 nutraceutical.

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.

The Applicant reports 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. As such, it has been used in other countries since lactoferrin was first produced commercially in 1986. Guidelines for the main process steps have been provided in the Application.

1.3 The current Standard

All references to the *Australia New Zealand Food Standards Code* (the Code) in this assessment summary and related SD are to the revised Code which takes effect and replaces the current Code on 1 March 2016. This is because the gazettal of any draft variation will not occur until after this date and therefore it is unnecessary to amend the current Code.

Ion exchange resins used in processing and manufacturing food are considered processing aids. Only those processing aids listed in Schedule 18 are permitted to be used in producing food sold in Australia and New Zealand. Permission is sought for this processing aid to be included in the table to subsection S18—9(3) *Permitted processing aids—various technological purposes*.

All permitted processing aids are also required to have a specification for identity and purity in Schedule 3. If permitted, a new specification will therefore be included in this Schedule.

1.3.1 International Standards

Codex Alimentarius (Codex) does not have Standards for processing aids. However, this processing aid does conform 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 October 2004 (US FDA 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'. The process conditions include pH 3–14 and temperatures 5–60°C. This approval is effective only for the listed manufacturer and its customers.

GRAS Notices were published for the manufacturing process for lactoferrin using this agarose ion exchange 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.

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.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

The evidence presented to support the proposed use of this agarose ion exchange resin provided adequate assurance that, in its prescribed form and usage, the resin is technologically justified and effective in achieving its stated purpose.

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, provide confirmation that potential impurity levels are of no toxicological concern.

Therefore, it is concluded that the proposed use of the resin as a processing aid for lactoferrin production presents no identifiable public health and safety concerns.

For further details on the risk assessment, refer to the Risk and Technical Assessment Report (SD1).

2.2 Risk management

The risk assessment conclusions provide evidence that there are likely to be no safety risks from the use of this agarose ion exchange resin as a processing aid. As processing aids require permissions in the Code, the only risk management options available to FSANZ are to approve or reject the request to amend the Code. The regulatory options analysed in section 2.4.1.1 take account of the safety of the resin.

2.2.1 Permissions for agarose ion exchange resin

If permitted, 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. The resin under consideration is similar with respect to the matrix. However, the resins differ in that the new resin is derivatised with sulphonate groups, whilst the already permitted resin is derivatised with tertiary amine groups.

To clearly differentiate between the two resins in Schedule 18, they will be listed according to their composition. That is, the already permitted resin will be re-named as an *amine* agarose ion exchange resin. The new resin will be listed as a *sulphonate* agarose ion exchange resin.

Schedule 18 also includes a definition for agarose ion exchange resin (subsection S18—9(2)). If the new resin is permitted, the existing definition for agarose ion exchange resin will be replaced with two separate definitions: one for the sulphonate resin, the other for the amine resin.

2.2.2 Specification

Permissions for processing aids are linked to their specification for identity and purity, provided in Schedule 3 of the revised Code. The resin permitted for the production of beer has an individual specification referenced in subsection S3—6. If permitted, an individual specification will be included in Schedule 3 for the new resin as a *sulphonate* agarose ion exchange resin. The existing specification will be re-named so as to be applicable to the *amine* agarose ion exchange resin.

The existing specification for the amine resin includes provisions around the limitations of use and processing conditions (paragraph 2 of the specification). The new specification for the sulphonate resin will differ, in that it will not include such provisions. Upon review, these provisions are not relevant for a specification on identity and purity. There are a number of other specifications for permitted resins that currently contain such provisions around the limitations of use and processing conditions. These will all be reviewed via an appropriate mechanism (e.g. through a Code maintenance proposal) to ensure consistency across the specifications for resins in Schedule 3.

2.2.3 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 the production of lactoferrin would not be declared on the label of the food.

2.2.4 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 indicate that there are likely to be no public health and safety risks associated with its use. A limited analysis of costs and benefits (see section 2.4.1.1) indicates that the direct and indirect benefits that would arise from developing or varying a food regulatory measure would outweigh any costs to the community, Government or industry of such a measure. Based on this information, the preferred risk management option is to prepare a draft variation to Schedule 18 and Schedule 3 of the revised Code.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ has developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the Food Standards 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 are called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

This Application requested a permission in the Code for the use of the agarose ion exchange resin as a processing aid in the production of lactoferrin. Codex does not regulate processing aids and there are no other relevant international standards.

As the resin is a processing aid, there is no requirement to include it on product labels. Amending the Code to approve the resin as a processing aid in food product manufacturing is unlikely to have a significant effect on trade between member nations.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement is not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

FSANZ was required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application.

The benefits and costs associated with the proposed amendments to the Code were analysed using regulatory impact principles. The level of analysis was commensurate with the nature of the Application and significance of the impacts.

Two regulatory options were considered:

(1) prepare a draft variation amending Schedule 18 to permit the use of the agarose ion exchange resin for the production of lactoferrin as a processing aid, and amending Schedule 3 to include a new specification for the resin.

(2) reject the Application.

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. However, FSANZ undertook a limited impact analysis.

A consideration of the costs and benefits of the regulatory options was not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that were considered cannot be assigned a dollar value.

Rather, the assessment sought to highlight the qualitative effects of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

Option 1 – Prepare a draft variation to Schedule 18 and Schedule 3 of the revised Code

Sector	Costs or benefits to sector
Consumers	The Applicant claims that this processing aid is the only viable commercial method currently available for lactoferrin production. Therefore, the approval of this processing aid could potentially benefit consumers by providing for the greater availability of this high value bioactive ingredient in food products, in particular, dairy-based special purpose type foods. The types of foods that would include lactoferrin as a premium ingredient would not replace existing basic food products and limit consumer choice. Rather, consumer choice could be expected to be enhanced through a range of dairy-based special purpose type foods containing this premium ingredient entering the market.
Industry	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. Approval of this processing aid would also 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 and permit importers of food products containing lactoferrin to import such products (subject to regulatory requirements).

Sector	Costs or benefits to sector
Governments	There are no costs or benefits to governments associated with this option. Schedule 18 of the revised Code already permits the use of an agarose ion exchange resin as a processing aid for the production of beer.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no benefits to consumers of this option. The range of food products containing lactoferrin as a premium ingredient would likely remain limited.
Industry	There are no benefits to industry from this option. The Applicant claims that the resin is the only viable commercial method currently available for lactoferrin production. It has already been permitted for use as a food contact substance by the US FDA, and it meets the requirements for food contact as given in Regulation (EC) No. 1935/2004. If this application was rejected, a potential cost to the Australian and New Zealand dairy industry might relate to their inability to remain competitive in the growing domestic and international market for lactoferrin and to be innovative in the development of value-adding new products and ingredients.
Governments	There are no benefits or costs to governments for this option.

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 or industry that would arise from the development or variation of the food regulatory measure.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

Schedules 18 and 3 apply in New Zealand and there are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

See below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

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

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

The labelling requirements for processing aids are discussed in Section 2.2.3 – Labelling considerations. No issues have been identified.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the risk analysis which is provided in SD1. 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 meets the requirements as given in Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food. In addition, it has been approved as a food contact substance by the USFDA.

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

As mentioned above, the agarose ion exchange resin is the only viable commercial method currently available for lactoferrin production and, as such, has been the method used in other countries since lactoferrin was first produced commercially in 1986. The Applicant anticipates 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 Ministerial Council**[1]

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 has 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'.

3 Draft variation

The draft variation to the revised Code is at Attachment A and is intended to take effect on gazettal. Note that the new section relevant to this Application is numbered S3—34 to take account of other variations due to other Applications which will insert sections S3—31 to S3—33 into Schedule 3.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments (FRLI).

4 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).

[1] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)
[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. Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)
B. Draft Explanatory Statement

Attachment A – Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)

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

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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

"

[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

Attachment B – Draft 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 revised Code.

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 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 revised 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 will include 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) will occur 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 other variations which will insert sections S3—31 to 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 or “GMP”.