19 June 2024
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Approval report – Application A1283

2′-FL from GM *Corynebacterium glutamicum* in infant formula products

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Advanced Protein Technologies Corp. to amend the Australia New Zealand Food Standards Code to permit the use of 2′-fucosyllactose produced from genetically modified *Corynebacterium glutamicum* to be used as a nutritive substance in infant formula products.

On 23 February 2024, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 4 June 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 19 June 2024.

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

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting documents

The following documents which informed the assessment of this application are available on the FSANZ website:

SD1 Supporting document 1 – Risk and technical assessment

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Advanced Protein Technologies Corp. to amend the Australia New Zealand Food Standards Code (the Code) to permit 2′-fucosyllactose (2′-FL) produced from genetically modified (GM) *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* to be used as a nutritive substance in infant formula products.

The Code already permits 2′-FL from other GM sources to be used as a nutritive substance in infant formula products. However, the Code does not currently permit the use of 2′-FL produced from GM *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* for that purpose. The applicant also requested an exclusive use permission under the brand name 'Momstamin 2′-FL' for a period of 15 months after gazettal.

FSANZ's safety assessment concluded there are no public health and safety concerns associated with the addition of 2′-FL produced from the applicant's source organism to infant formula products at the proposed use levels. The applicant's 2′-FL is identical to the naturally occurring substance present in human milk. It is also identical to 2′-FL already assessed by FSANZ and permitted in the Code. Given this, the associated health benefits from the addition of 2′-FL to infant formula products for infants remain the same, as follows: (1) an anti-pathogenic effect; (2) immunomodulation; and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp.

Following assessment and the preparation of a draft variation, FSANZ called for submissions from 23 February 2024 to 22 March 2024. Two submissions were received, both of which supported the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved the draft variation to the Code proposed at the call for submissions. The purpose of the approved draft variation is to permit the use of 2′-FL produced from GM *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* as a nutritive substance in infant formula products in accordance with the Code.

The approved draft variation will:

- amend Schedule 26 of the Code to permit the applicant's 2′-FL to be used as a nutritive substance in infant formula products subject to certain conditions, including an exclusive use period of 15 months linked to the applicant's brand name 'Momstamin 2′-FL', and
- insert a new specification for the applicant's 2′-FL into Schedule 3 of the Code, with which the applicant's 2′-FL will have to comply when used as a nutritive substance in infant formula products (or sold for such use).

The effect of those amendments is that the applicant's 2′-FL will be permitted to be used as a nutritive substance in infant formula products in accordance with the Code.

1 Introduction

1.1 The applicant

The applicant, Advanced Protein Technologies Corp. (APTech), is a biotechnology company that specialises in fermentation and metabolic engineering for the manufacture of products related to food and biopharmaceutical industries. APTech manufactures a wide range of products, including human milk oligosaccharides, active pharmaceutical ingredients and protein materials to be used for foods, pharmaceuticals and other biotechnological purposes.

1.2 The application

On 4 September 2023, APTech applied to amend Schedule 26 of the Australia New Zealand Food Standards Code (the Code) to permit the use of 2′-fucosyllactose (2′-FL) produced from a new source organism, *Corynebacterium glutamicum* APC199 containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans,* as a nutritive substance in infant formula products.

1.3 The current Code requirements

Australian and New Zealand food laws require food for sale to comply with relevant provisions in the Code. The provisions relevant to this application are summarised below.

1.3.1 Infant formula products

The composition and labelling of infant formula products are specifically regulated in Standard 2.9.1 and Schedule 29. They set out specific compositional and labelling requirements for the following infant formula products:

- infant formula (for infants aged 0 to <12 months)
- follow-on formula (for infants aged from 6 to <12 months)
- infant formula products for special dietary use (for infants aged 0 to <12 months).

1.3.2 Permitted use

1.3.2.1 Food produced using gene technology

Paragraphs 1.1.1—10(5)(c) and (6)(g) of Standard 1.1.1 require that, unless expressly permitted, a food for sale must not be a *food produced using gene technology* or have as an ingredient or component a *food produced using gene technology*.

2′-FL produced from various sources are already permitted in the Code as *food produced using gene technology of microbiological origin* for use in infant formula products. However the Code does not currently permit the use of 2′-FL from *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans.*

The applicant's 2′-FL is a *food produced using gene technology* (section 1.1.2—2) as it is produced from an organism modified using gene technology i.e. produced from GM *C. glutamicum.* Consequently, express permission for the applicant's 2′-FL is required in accordance with paragraph 1.5.2—3(a) (i.e. to be listed in Schedule 26 and to comply with any corresponding conditions).

1.3.2.2 Nutritive substances

Paragraph 1.1.1—10(6)(b) of Standard 1.1.1 requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that was *used as a nutritive substance* (as defined in section 1.1.2—12). The applicant's 2′-FL will be *used as a nutritive substance* for the purposes of the Code because its use in infant formula products is intended to achieve specific nutritional purposes.

2′-FL is a non-digestible oligosaccharide that is a component of human milk. 2′-FL is currently permitted to be *used as a nutritive substance* in infant formula products at levels up to 96 mg/100 kJ (equivalent to 2.4 g/L) in accordance with section 2.9.1—5 (i.e. if, among other things, it is listed in the table to section S29—5 and is in a permitted form at up to the maximum amount per 100 kJ specified in that table). The table to section S29—5 lists 2′-fucosyllactose *permitted for use by Standard 1.5.2* (see section 1.3.2.1 of this report).

The applicant is not requesting any changes to the existing permissions for 2′-FL in section S29—5.

1.3.3 Identity and purity

Section 1.1.1—15 requires that a substance that is *used as a nutritive substance* must comply with any relevant identity and purity specification set out in Schedule 3. A proposed specification for the this particular 2′-FL was provided by the applicant.

1.3.4 Labelling requirements

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food.

Section 1.2.4—2 requires food products to be labelled with a statement of ingredients. Section 1.2.4—4 requires ingredients to be declared using: a name by which they are commonly known; a name that describes their true nature; or a generic ingredient name if one is specified in Schedule 10.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition content and health claims made about food. Paragraph 1.2.7—4(b) states a nutrition content claim or health claim must not be made about an infant formula product.

Section 1.5.2—4 sets out labelling requirements for foods for sale that consist of, or have as an ingredient, food that is a *genetically modified food*[2] (GM food).

Subparagraph 2.9.1—21(1)(a)(iii) of Standard 2.9.1 requires the average amount of any substance used as a nutritive substance permitted by Standard 2.9.1 to be declared in the nutrition information statement (NIS), expressed in weight/100 mL. Paragraphs 2.9.1—24(1)(ca) and (cb) prohibit the use of: the words 'human milk oligosaccharide', 'human milk identical oligosaccharide'; the abbreviations 'HMO' or 'HiMO'; or any words and abbreviations having the same or similar effect. Paragraph 2.9.1—24(1)(f) prohibits a reference to the presence of a nutrient or substance that may be used as a nutritive substance, except for a reference in: a statement relating to lactose under subsection 2.9.1—

[2] Section 1.5.2—4(5) defines ***genetically modified food*** to mean a '*food produced using gene technology that
a) contains novel DNA or novel protein; or
b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (*that being section 1.5.2—4*).

14(6); a statement of ingredients; or in the NIS.

1.4 Regulation in other countries

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards.

2′-FL produced by microbial fermentation and by chemical synthesis is permitted for use in infant formula products, equivalent products and many other foods in at least 37 countries at a range of levels. Table 1 outlines some international permissions for 2′-FL.

It is noted that internationally, the permitted levels of 2′-FL for use in infant formula range from 1.2 g/L to 2.4 g/L. FSANZ set the existing permitted maximum levels of 2′-FL in the Code after undertaking a safety, technical and health effects assessment, including estimated dietary intakes and naturally occurring levels in human milk (FSANZ 2019; FSANZ 2021).

Table 1: International permissions for use of 2′-FL in infant formula*

Country	Max. permitted amount (g/L)
Australia	2.4
New Zealand	2.4
United States	2.4
Canada[#]	1.2
Singapore	1.2
European Union (EU)	1.2
Israel	2.0
Korea	1.1
Philippines	1.2

Notes to table:
*Infant formula categories vary between countries
Permission as novel food with support for use in infant formula

Codex Alimentarius (Codex) international food standards do not currently exist for 2′-FL. However, the Codex standards for 'Infant Formula and Formulas for Special Medical Purposes Intended for Infants' (Codex Alimentarius 2020) and for 'Follow-up formula for Older Infants and Product for Young Children' (Codex Alimentarius 2023) contain provisions for 'optional ingredients' which are applicable to 2′-FL.

In the United States (US), APTech's 2′-FL produced from *C. glutamicum* APC199 (the subject of this application) has Generally Recognized as Safe (GRAS) status for use in infant formula at a level of 2.4 g/L in non-exempt formula for term infants in addition to a variety of other food uses. Notification of this conclusion was filed under GRAS Notice (GRN) 000932 and has received a letter of 'no questions' from the US Food and Drug Administration (FDA) (Advanced Protein Technologies, Corp., 2020; US FDA, 2021a).

In the European Union (EU), the applicant's 2′-FL from microbial fermentation with *C. glutamicum* APC199 received a positive scientific opinion from the European Food Safety Authority (EFSA), who concluded that this 2′-FL ingredient is safe for its intended use as a novel food (EFSA, 2022a). Formal approval for the use of APTech's 2′-FL was subsequently provided under *Commission Implementing Regulation (EU) 2023/859 of 25 April 2023 amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food 2'-Fucosyllactose (microbial source) to authorise its production by a derivative strain of Corynebacterium glutamicum ATCC 13032* (EU, 2023).

Approval for the use of the applicant's 2′-FL from *C. glutamicum* APC199 has also been issued in Korea, Thailand, Vietnam and Malaysia.

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve a draft variation amending the Code to permit the applicant's 2′-FL produced from GM *C. glutamicum* to be used as a nutritive substance in infant formula products.

The approved draft variation as proposed at assessment takes effect on gazettal and is at Attachment A.

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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on the draft variation to the Code from 23 February 2024 to 22 March 2024.

Two submissions were received, one from industry (the a2 Milk Company Limited) and one from a government agency (New Zealand Food Safety). Both submitters supported the amendment to permit the use of 2′-FL produced from this new GM source organism as a nutritive substance in infant formula products.

2.2 Risk assessment

The Code already permits 2′-FL from different source organisms to be used as nutritive substances in infant formula products. The maximum permitted amount is 96 mg/100 kJ, equivalent to 2.4 g/L. FSANZ has previously determined that there are no safety concerns associated with the addition of 2′-FL to infant formula products at concentrations up to 2.4 g/L. The applicant is not requesting a change to the maximum permitted amount. The primary purpose of the present assessment is therefore to assess the safety of 2′-FL produced by the new production strain.

The applicant's 2′-FL, produced by a microbial fermentation method of production, is identical to the naturally occurring substance present in human milk. It is also identical to 2′-FL previously assessed and permitted by FSANZ.

C. glutamicum has a long history of documented use for the production of biomolecules, including food additives, and poses negligible risks to human health. No safety concerns arising from the genetic modification were identified. Characterisation of the production strain confirmed the genetic modification is stably maintained across multiple generations.

On the basis of the data provided, no potential safety concerns were identified in the assessment of the 2′-FL production strain *C. glutamicum.* Based on previous FSANZ assessments of 2′-FL and the toxicological assessment in the present application, it was concluded that there are no public health and safety concerns associated with 2′-FL produced from the new GM source organism that is the subject of this application.

The dietary intake assessment compared the estimated dietary intake of 2′-FL from infant and follow-on formula to that of mature human milk for 3- and 9-month old infants. As there is no requested change to the current permitted amount of 2′-FL in infant formula products, no extension of use, and no data suggesting a higher concentration in human milk since the most recent FSANZ assessment, estimated dietary intakes of 2′-FL from previous FSANZ assessments were used in this current assessment. These data showed that estimated mean and 90th percentile dietary intakes of 2′-FL at the maximum permitted amount in the Code from infant formula products fall within the range of estimated dietary intakes from mature human milk.

FSANZ has previously concluded that the addition of 2′-FL to infant formula products at levels typically found in human milk does not pose a risk to normal growth of infants. Two studies provided by the applicant reported no difference in growth in infants fed formula containing lacto-N-neotetraose and 2′-FL compared to control, however were not directly relevant to the assessment because any effect (or lack of effect) on growth cannot be attributed to 2′-FL. No new relevant studies were identified for this assessment. Therefore FSANZ maintains the previous conclusion that the addition of 2′-FL to infant formula products at levels normally found in human milk is unlikely to affect growth.

Based on previous microbiological assessments, given the identical chemical structure and that the applicant has not requested any change in the maximum permitted amount of 2′-FL added to infant formula products, the associated health benefits from the use of 2′-FL as a nutritive substance in infant formula products for infants remain the same, as follows: (1) an anti-pathogenic effect; (2) immunomodulation; and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp.

Overall the safety assessment concluded there are no public health and safety concerns associated with the addition of 2′-FL produced from the new source organism to infant formula products at the maximum permitted amount in the Code.

2.3 Risk management

Breastfeeding is the recommended way to feed infants. However, a safe and nutritious substitute for human milk is needed for infants when breastfeeding is not possible. As infants are a vulnerable population group, infant formula products are regulated by prescriptive provisions for composition and labelling. Any changes to the composition of these products must be established as safe prior to being permitted.

Following assessment, FSANZ prepared a draft variation and called for submissions on the draft variation from 23 February 2024 to 22 March 2024 (the submission period).

The risk management options available to FSANZ after the submission period were to either:

- approve the draft variation proposed following assessment, or

- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

2.3.1 Regulatory approval

The draft variation prepared by FSANZ listed *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* as a source of 2′-FL in the table to subsection S26—3(7).

Application A1283 requested an amendment to the Code to provide a permission for 2′-FL produced from GM *C. glutamicum* strain APC199 containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* to be used as a nutritive substance in infant formula products. Such a permission would be specific to strain APC199 only.

The approved draft variation instead will provide a permission for 2′-FL from *C. glutamicum* containing the gene alpha-1,2-fucosyltransferase from *P. saltans* without specifying the strain of *C. glutamicum*. This approach will provide greater flexibility in terms of strain improvement and avoid the need for new applications to be lodged to provide permissions for new strains of *C. glutamicum*.

The approach is also consistent with current permissions in the Code for 2′-FL which specify the inserted gene as alpha-1,2-fucosyltransferase, and the gene donor organisms. The approved draft variation will permit the applicant's 2′-FL as a *food produced using gene technology.* Noting the applicant has not requested any changes to current permissions in the Code for 2′-FL, FSANZ considers that the applicant's 2′-FL will meet requirements under Standard 2.9.1 and Schedule 29 to be *used as a nutritive substance* with a maximum amount of 96 mg/100 kJ in infant formula products (see sections 1.3.2.1 and 1.3.2.2 of this report).

2.3.2 Specification

Section 1.1.1—15 requires substances, including those *used as a nutritive substance* to comply with any relevant specification set out in Schedule 3 when added to food in accordance with the Code, or sold for use in food. The approved draft variation will insert a new specification for the applicant's 2′-FL sourced from *C. glutamicum*, which it will have to comply with when used as a nutritive substance in infant formula products (or sold for such use).

2.3.3 Exclusivity

An applicant may request exclusive permission to use and sell a food (including a substance) for a certain period of time to recognise the investment made in developing that food, and the need to achieve return on this investment, thereby supporting innovation.

The applicant has requested an exclusive use permission for their specific brand of 2′-FL.

FSANZ has decided to grant the applicant a 15 month exclusive use permission for this 2′-FL commencing on the date of gazettal of the approved draft variation.

This means that, during that 15 month period, the permission will apply exclusively to those substances under the brand name 'Momstamin 2′-FL' in accordance with the Code.

Once the 15 month period ends, the exclusive use permission will revert to a general permission, meaning that anyone may use the permitted forms of 2′-FL in accordance with

the Code.

An exclusive use permission in the Code does not, and cannot, prevent approval of second or subsequent applications either within the exclusive use period or during the progression of an application, for the use of the same food or ingredient by other food companies, providing the application process is undertaken.

2.3.4 The five-year review for 2′-FL and LNnT in infant formula products

FSANZ is committed to reviewing any new evidence on the beneficial role of HiMOs in the normal growth and development of infants.

At the request of Food Ministers[3], FSANZ will carry out a five-year review (to be completed by March 2026) of the initial permission gazetted under Application A1155. This will review the evidence of a substantiated beneficial role of 2′-FL and Lacto-N-neotetraose (LNnT) in the normal growth and development of infants. This process will incorporate consultation with a range of stakeholders including experts, industry and government agencies, and will be independently peer reviewed.

Details on the review process, including stakeholder input, will be made available on the FSANZ website.

2.3.5 Labelling

2.3.5.1 Statement of ingredients

Standard 1.2.4 requires food for sale to be labelled with a statement of ingredients unless exempt. Should manufacturers choose to add the applicant's 2′-FL in infant formula products in accordance with the Code, then the 2′-FL must be declared as an ingredient in the statement of ingredients.

Generic ingredient labelling provisions in section 1.2.4—4 require ingredients to be identified using: a name by which they are commonly known; a name that describes its true nature; or a generic ingredient name if one is specified in Schedule 10 - Generic names of ingredients and conditions for their use. These ingredient naming requirements will apply to the applicant's 2′-FL, enabling industry to have flexibility in how they declare this ingredient (for example, using the name '2′-fucosyllactose'). However, existing prohibited representations in paragraphs 2.9.1—24(1)(ca) and (cb) will also apply to the ingredient name (refer to section 2.3.5.3 below).

2.3.5.2 Mandatory nutrition information

Section 2.9.1—21 regulates the declaration of nutrition information in a NIS on the label of infant formula products. The NIS is a single statement and may be in the form of a table, as indicated in section S29—10.

Subparagraph 2.9.1—21(1)(a)(iii) requires the average amount of any substance used as a nutritive substance permitted by Standard 2.9.1 to be declared in the NIS. Therefore, the applicant's 2′-FL will need to be declared in the NIS when it is voluntarily used in an infant formula product.

[3] Communiqué of outcomes from the Australia and New Zealand Ministerial Forum on Food Regulation meeting held on 27 November 2020

2.3.5.3 Prohibited representations

Paragraph 2.9.1—24(1)(ca) prohibits the use of the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect. In addition, paragraph 2.9.1—24(1)(cb) prohibits the use of the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect. The words and abbreviations in these provisions cannot be used anywhere on the label of a package of infant formula products. The applicant's 2′-FL will be subject to these provisions regarding prohibited representations.

2.3.5.4 Voluntary representations

Paragraph 1.2.7—4(b) states that a nutrition content or health claim must not be made about an infant formula product. Paragraph 2.9.1—24(1)(f) also prohibits a reference to the presence of a nutrient or substance that may be used as a nutritive substance, except for a reference in: a statement relating to lactose under subsection 2.9.1—14(6), a statement of ingredients, or in the NIS. These existing prohibitions for nutrition content and health claims for infant formula products will apply to the applicant's 2′-FL.

2.3.5.5 Labelling as 'genetically modified'

As discussed in section 2.3.1 of Supporting Document 1 (SD1), the applicant's 2′-FL is highly unlikely to contain novel protein or novel DNA due to the purification step used in its production. It is therefore highly unlikely that novel protein or novel DNA will be present in an infant formula product that contains this 2′-FL as an ingredient. However, where novel protein or novel DNA is present, the requirement to label the 2′-FL ingredient as 'genetically modified' will apply in accordance with section 1.5.2—4.

2.3.6 Risk management conclusion

For reasons set out in this report, FSANZ has decided to approve the draft variation to the Code proposed at the call for submissions. The purpose of the approved draft variation is to permit the use of 2′-FL from *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* as a nutritive substance in infant formula products.

The applicant's 2′-FL will be subject to relevant requirements and conditions in the Code, which include the following:

- It may be added alone, or in combination with LNnT, to infant formula products up to a maximum level of 2.4 g/L for 2′-FL, as consumed.
- The existing prohibition for the use of the words 'human milk identical oligosaccharide' or 'human milk oligosaccharide', and abbreviations 'HMO', 'HiMO' or any word or words or abbreviations having the same or similar effect, will apply to infant formula products that contain the applicant's 2′-FL.
- An exclusive use permission to use 2′-FL produced using *C. glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *P. saltans* will apply for a period of 15 months, linked to the applicant's brand name 'Momstamin 2′-FL', commencing on the date of gazettal of the approved draft variation.
- Schedule 3 of the Code will contain a specification for the applicant's 2′-FL, with which it must comply.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a routine communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

2.5 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.

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[4]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for the applications relating to nutritive substances and GM food (OIA Reference: OIA23-06224). This was because applications relating to permitting the use of nutritive substances and GM food that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29 (2)(a)).

The purpose of this consideration was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). This analysis considered the costs and benefits of permitting 2′-FL from this new GM source organism to be used as a nutritive substance in infant formula products.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the potential positives and negatives of moving away from

[4] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

the status quo by permitting the use of the applicant's 2′-FL as a nutritive substance in infant formula products.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. No information was received during the call for submissions that warranted a change to this conclusion.

Cost and benefits of permitting the nutritive substance

The food industry may benefit from this draft variation being approved. Use of the applicant's 2′-FL as a nutritive substance in infant formula products will be voluntary, and therefore industry will only use this nutritive substance where they believe a commercial net benefit exists for them. The approved draft variation will align Australia and New Zealand with the USA, the European Union, Korea, Thailand, Vietnam and Malaysia, and has the potential to enhance international trade in respect of both the import and export of infant formula products.

Producers of infant formula products in Australia and New Zealand may however face greater competition in the domestic infant formula products market from overseas-based producers that can also supply Australia and New Zealand with infant formula products containing the applicant's 2′-FL. Any such impacts to domestic producers are assumed to be outweighed by benefits to consumers from greater industry competition.

Granting an exclusive use permission will prevent other businesses from supplying 2′-FL from this additional source in the short-term. However, granting of the exclusive use permission does not preclude any other business from applying to amend the Code in relation to the same ingredient. Therefore, the market for this additional source of 2′-FL could be opened during the 15 month exclusive use period for any other business willing to make an application. At the end of the exclusive use period all businesses will experience the same benefits. See Section 2.3.3 for further information.

Significant costs for consumers are not expected. There are existing permissions in the Code for 2′-FL from other sources. Therefore, the exclusive use period is not expected to result in noticeably higher prices during the period than if exclusive use was not granted.

In the longer term, the addition of another source of 2′-FL could lead to savings for consumers if production costs are reduced and these are partly or fully passed on to them, regardless of any short-term exclusivity. Consumers may also benefit from greater availability of infant formula products containing 2′-FL, a beneficial human milk oligosaccharide.

By granting the exclusive use period requested by the applicant, FSANZ hopes to incentivise industry innovation. Consumers will benefit from these incentives where applications arise that otherwise would not have.

There are not expected to be any significant impacts for governments.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the applicant's 2′-FL to be used as a nutritive substance in infant formula products most likely outweigh the associated costs.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ completed a Risk and Technical Assessment (SD1) which is summarised in section 2.2 of this report. Previous assessments found no safety concerns associated with the addition of 2′-FL to infant formula products. New information provided did not change this conclusion.

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

Current labelling requirements discussed in section 2.3.5 will apply to the applicant's 2′-FL when used in infant formula products as a nutritive substance and will provide information to enable consumers to make informed choices.

2.5.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations described in section 2.3.5.3 which aim to prevent misleading or deceptive conduct, will apply to the applicant's 2′-FL when used in infant formula products as a nutritive substance.

2.5.3 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 used the risk analysis framework and considered the best available evidence to reach its conclusions on the safety, technical and beneficial health outcomes of the applicant's 2′-FL.

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

FSANZ considered the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. 2′-FL is permitted in infant formula and equivalent products, and several other foods across

various countries around the world.

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

The approved permission will support an internationally competitive food industry in relation to the use of 2′-FL in infant formula products as a nutritive substance and is consistent with existing permissions in the Code for 2′-FL.

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

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

As part of A1283, FSANZ has had regard to both high order and specific policy principles in the following Ministerial Policy Guidelines:

- Regulation of Infant Formula Products
- Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods.

Noting the food technology aspects, safety, associated health benefits and nutritional impact assessed in SD1 and section 2.2 of this report, FSANZ considers these policy guidelines have been met.

3 References

Codex Alimentarius (2020) Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. (CXS 72, adopted in 1981. Amendment: 1983, 1985, 1987, 2011, 2015, 2016 and 2020, Revision: 2007). Rome, Italy: Codex Alimentarius Commission. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf

Codex Alimentarius (2023) Standard for Follow-up formula for Older Infants and Product for Young Children. (CXS/156, adopted in 1987. Amendment: 1989, 2011, 2017, Revision: 2023. Rome, Italy: Codex Alimentarius Commission. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B156-1987%252FCXS_156e.pdf

FSANZ (2019) Application A1155 - 2′-FL and LNnT in infant formula and other products. Supporting Document 1 at Second Call for Submissions. Report prepared by Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1155_SD1_Risk%20assessment%20-%202nd%20CFS.pdf

FSANZ (2021) Application A1190 - 2′-FL in infant formula and other products. Supporting Document 1 at Approval. Risk and safety assessment. Report prepared by Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1190_SD1%20at%20Approval.pdf

Attachments

A. Approved draft variations to the *Australia New Zealand Food Standards Code*

B. Explanatory Statement

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

Food Standards (Application A1283 – 2′-FL from GM *Corynebacterium glutamicum* in infant formula products) 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 the Delegate]

[Insert Delegate's name and position title]
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 (Application A1283 – 2′-FL from GM* Corynebacterium glutamicum *in infant formula products) 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

Schedule 3—Identity and purity

[1] Subsection S3—2(2) (table, before the table item dealing with 2′-fucosyllactose sourced from *Escherichia coli* BL21)

Insert:

2′-fucosyllactose sourced from *Corynebacterium glutamicum*	section S3—51

[2] After section S3—50

Insert:

S3—51 Specification 2′-fucosyllactose sourced from *Corynebacterium glutamicum*

For 2′-fucosyllactose (2′-FL) sourced from *Corynebacterium glutamicum*, the specifications are the following:

(a) chemical name—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;

(b) chemical formula—$C_{18}H_{32}O_{15;}$

(c) molecular weight—488.44 g/mol;

(d) CAS number—41263-94-9;

(e) description—white to off-white/ivory powder;

(f) 2′-FL—not less than 94% (water free);

(g) D-lactose—not more than 3.0% (water free);

(h) L-fucose—not more than 3.0% (water free);

(i) 3-fucosyllactose—not more than 3.0% (water free);

(j) difucosyl-D-lactose—not more than 2.0% (water free);

(k) glucose—not more than 3.0% (water free);

(l) galactose—not more than 3.0% (water free);

(m) water—not more than 9.0%;

(n) ash, sulphated—not more than 0.5%;

(o) ethanol—not more than 1,000 mg/kg (for crystallised product from solvent only);

(p) residual proteins—not more than 0.005%;

(q) lead—not more than 0.02 mg/kg;

(r) arsenic—not more than 0.03 mg/kg;

(s) cadmium—not more than 0.01 mg/kg;

(t) mercury—not more than 0.05 mg/kg;

(u) microbiological:

(i) total plate count—not more than 500 cfu/g;

(ii) coliforms—not more than 10 cfu/g;

(iii) yeasts and moulds—not more than 100 cfu/g;

(iv) aflatoxin M1—not more than 0.025 µg/kg;

(v) residual endotoxins—not more than 10 EU/mg

Schedule 26—Food produced using gene technology

[3] Subsection S26—3(7) (table, table item 1)

Insert:

	(e) *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand Momstamin 2′-FL. 3. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1283 - 2'-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation* and ending 15 months after that date.

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1283 - 2'-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation

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.

The Authority accepted Application A1283 which sought to amend the Code to permit the use of 2′-fucosyllactose (2′-FL) produced from a new genetically modified source as a nutritive substance in infant formula products. The application also sought a 15 month exclusive use permission.The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1283 - 2'-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation* (the approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the

international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation to the Code to:

- Amend Schedule 26 of the Code to permit 2′-FL produced from a new genetically modified source i.e. *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*, to be used as a nutritive substance in infant formula products subject to certain conditions, including an exclusive use permission for a period of 15 months linked to the applicant's brand name 'Momstamin 2′-FL'.
- Insert a new specification for this 2′-FL into Schedule 3 with which this 2′-FL will have to comply when used as a nutritive substance in infant formula products (or sold for such use).

4. Documents incorporated by reference

The approved draft variation prepared by the Authority does not incorporate any documents by reference.

However, the approved draft variation varies Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3.

Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)); the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition); and the Commission Regulation (EU) No 231/2012.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1283 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 23 February 2024 for a four-week period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[5]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes the OIA advised FSANZ that a Regulatory Impact Statement was not required for the applications relating to nutritive substances OIA Reference: OIA23-06224. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

[5] Formerly known as the Office of Best Practice Regulation (OBPR)

6. 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 44 of the *Legislation Act 2003*.

7. Variation

References to 'the variation' in this section is a reference to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1283 - 2′-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation.*

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation commences on the date of gazettal of the instrument.

Schedule to the variation

Items [1] and **[2]** of the Schedule to the variation amends Schedule 3 of the Code.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code. Section 1.1.1—15 requires certain substances, e.g. substances used as nutritive substances, to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code, or sold for use in food. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

Item [1] inserts into columns 1 and 2 of the table to subsection S3—2(2), in alphabetical order, new references to '2′-fucosyllactose sourced from *Corynebacterium glutamicum* and 'section S3—51' respectively. These new references relate to the new provision inserted by **item [2]** below.

Item [2] inserts new section S3—51 which sets out the specifications relating specifically to 2′-fucosyllactose sourced from *Corynebacterium glutamicum*.

Consequently, the permission for 2′-fucosyllactose sourced from *Corynebacterium glutamicum* to be used as a nutritive substance in infant formula products (or sold for such use) is subject to the requirement in section 1.1.1—15 that the substance must comply with these specifications.

Item [3] of the Schedule to the variation amends Schedule 26 of the Code.

Schedule 26 relates to food produced using gene technology. 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* is a food produced using gene technology (as defined in subsection 1.1.2—2(3) of the Code) because it is produced from an organism modified using gene technology.

Paragraph 1.5.2—3(a) permits a food for sale to consist of, or have as an ingredient, a food produced using gene technology if the food produced using gene technology (other than a processing aid or food additive) is listed in Schedule 26 and complies with any corresponding conditions in that Schedule.

The table to subsection S26—3(7) lists food produced using gene technology of microbial origin. **Item [3]** amends item 1 of that table (2′-FL) by inserting new paragraph (e) into the column headed 'Source'. New paragraph (e) refers to:

'*Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans'*.

Associated conditions of use for 2′-FL from this new source are set out in column 3 of the table as follows:

1. the substance may only be added to infant formula products
2. during the exclusive use period, the substance may only be sold under the brand Momstamin 2′-FL and
3. for the purposes of condition 2, exclusive use period means the period commencing on the date of gazettal of the *Food Standards (A1283 - 2′-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation* and ending 15 months after that date.

Condition 2 means that 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* may only be sold under the brand 'Momstamin 2′-FL' during the exclusive use period. 'Exclusive use period' is defined in condition 3 as the period commencing on gazettal of the variation and ending 15 months after that date.

The effect of the amendment in **item [3]** is to permit the use of the substance, 2′-FL from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* as a food produced using gene technology, subject to the above conditions of use for the substance.

Once the exclusive use period ends, the permission will revert to a general permission, meaning that the proposed permission will then permit the sale and use of 2′-FL sourced from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* under any brand.

The proposed amendments made by **item [3]** do not make any substantive change to *existing* permissions and to other requirements in the Code relating to food produced using gene technology.

The effect of the amendment in **item [3]** is also to permit 2′-FL from *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans* to be used as a nutritive substance in infant formula products.

This is because subsection 2.9.1—5(1) and section S29—5 permit a '2′-fucosyllactose permitted for use by Standard 1.5.2' to be used as a nutritive substance in infant formula products at an amount no greater than 96 mg/100 kJ.