15 August 2022
212-22

Approval report – Application A1244

Chymosin from GM *Trichoderma reesei* as a processing aid (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Danisco New Zealand Ltd to amend the Australia New Zealand Food Standards Code to permit the use of a chymosin (EC 3.4.23.4), sourced from a genetically modified (GM) strain of *Trichoderma reesei*, as a processing aid in the manufacture of cheese, cheese products and fermented and rennetted milk products.

On 4 April 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 3 August 2022 The Food Minister's Meeting[1] was notified of FSANZ's decision on 15 August 2022.

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

[1] Formerly the Australia and New Zealand Ministerial Forum on Food Regulation.

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Supporting document

The following document[1] which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report

[1] A1244 - Chymosin from GM Trichoderma reesei as a processing aid (enzyme) (foodstandards.gov.au)

Executive summary

Danisco New Zealand Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of chymosin (EC 3.4.23.4), sourced from a genetically modified (GM) strain of *Trichoderma reesei* (*T. reesei*), as a new processing aid in the manufacture of cheese, cheese products and fermented and rennetted milk products.

There are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code with which the enzyme must comply. The safety assessment included consideration of bioinformatics, toxicity and dietary exposure and identified no public health and safety concerns.

After undertaking its risk and technical assessment, FSANZ concluded that there were no public health and safety concerns with the use of chymosin produced from a GM strain of *T. reesei,* expressing a chymosin gene from the domestic cow, *Bos Taurus,* under the proposed use conditions.

As chymosin performs its technological function during food processing, not in the food for sale, it would function as a processing aid for the purposes of the Code.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 4 April 2022 to 12 May 2022. FSANZ received two submissions from government agencies which both supported the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to the table to subsection S18—9(3) of the Code to permit the use of the enzyme, chymosin (EC 3.4.23.4), sourced from *T. reesei* containing the chymosin gene from *Bos taurus*, as a processing aid in the manufacture of cheese, cheese products and fermented and rennetted milk products. This permission will be subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with Good Manufacturing Practice (GMP). The effect of the approved draft variation is to permit the proposed use of this enzyme as a processing aid in accordance with the Code.

1 Introduction

1.1 The applicant

Danisco New Zealand Ltd is a subsidiary of International Flavors and Fragrances Inc (IFF) and a manufacturer/marketer of specialty food ingredients, food additives and food processing aids based in New Zealand.

1.2 The application

The purpose of the application is to amend the Code to permit the use of chymosin (EC 3.4.23.4), sourced from a genetically modified (GM) strain of *Trichoderma reesei* (*T. reesei*), containing the chymosin gene from the domestic cow, *Bos taurus*, as a processing aid in the manufacture of cheese, cheese products and fermented and rennetted milk products. The applicant is requesting the approval of this chymosin to perform the technological function of clotting milk by the highly specific cleavage of a single bond in the κ-chain molecule. Once the reaction has occurred and the kappa casein becomes unstable, the micelles clot. This clot is the formation of cheese and the separation of whey from the curds (Belenkaya et al, 2020).

There is already an established history of use for chymosin in the manufacture of certain dairy foods (Garg and Johri 1995) and three other sources of chymosin are approved for use in the Code. Danisco has highlighted that approval would provide manufacturers with an additional choice of enzyme to facilitate the coagulation of casein, support effective production processes and reduce the use of raw materials.

1.3 The current standard

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

1.3.1 Permitted use

Enzymes used to process and manufacture food are considered processing aids. Although they may be present in the final food, they no longer provide a technological purpose in the final food.

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a processing aid’ unless that substance’s use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance ‘used as a processing aid’ in relation to a food is a substance used during the course of processing that meets all of the following conditions: it is used to perform a technological purpose during the course of processing; it does not perform a technological purpose in the food for sale; and it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform *any* technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from

particular sources, that are permitted to be used as processing aids for *specific* technological purposes in relation to:

- if a food is specified—that food; or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

Paragraph 1.1.1—10(6)(g) requires that the presence of a food produced using gene technology as an ingredient or component in a food for sale must be expressly permitted by the Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

There is currently a permission for chymosin (EC 3.4.23.4) derived from different sources in the table to subsection S18—4(5), to be used in the manufacture of any foods. However, chymosin from the particular microbial source requested in this application is not currently permitted.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23, 2019) and the United States Pharmacopeial Convention Food Chemicals Codex (12th edition, 2020). Certain earlier publications from these primary sources include the relevant specifications for enzyme preparations used in food processing (JECFA (2006) and FCC (2008), respectively).

1.3.3 Labelling requirements

Paragraph 1.1.1—10(8) of the Code provides that a food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Subsection 1.2.3—4(1) requires certain foods (foods listed in the table to section S9—3 or their derivatives e.g., cereals containing gluten, and sulphites added at a certain concentration level) to be declared when present in a food for sale. Paragraph 1.2.3—4(5)(c) states the food may be present as a substance used as a processing aid, or an ingredient or component of such a substance. Where the food to be declared is a substance used as a processing aid or an ingredient or component of such a substance, subsection 1.2.3—6(2) requires a declaration for the purposes of paragraph 1.2.1—8(1)(d) or subparagraph 1.2.4—5(6)(b)(i) to be made by (among other things) listing in the statement of ingredients of the food for sale the required name of the food to be declared and the words ‘processing aid’ in conjunction with that required name[2]. If the food is not required to bear a label, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (subsections 1.2.1—9(6) and (7)).

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be

[2] On 25 February 2021 the Code was amended to introduce new requirements for the labelling of allergens in food, including requirements for how to declare allergens when they are present in a food for sale. Suppliers have until 25 February 2024 to change over to these new requirements. If a food was packaged and labelled before 25 February 2024 and it complied with the previous allergen labelling requirements, then that food can remain on sale for another two years as long as it complies with the rest of the Code.

declared in the statement of ingredients, unless other requirements apply.

Section 1.5.2—4 requires processing aids that are, or have as ingredients, foods produced using gene technology to be labelled 'genetically modified', where novel DNA and/or novel protein from the processing aid remains present in the final food. The requirement applies to foods for sale that consist of, or have as an ingredient, food that is a *genetically modified food*[3] (GM food). The requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer under subsections 1.2.1—8(1) and 1.2.1—9(3), and section 1.2.1—15, respectively.

1.4 International standards

The Codex Alimentarius does not establish standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes established by JECFA and Food Chemicals Codex, as outlined in Section 1.3.2 above.

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 in the FSANZ Act.

1.7 Decision

For reasons set out in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of this enzyme as a processing aid in the manufacture of cheese, cheese products and fermented and rennetted milk products.

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation 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 a draft variation to the Code from 4 April 2022 to 12 May 2022. Two submissions were received, both from government agencies, and both supported the application and draft variation (see Table 1).

[3] 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*).

Table 1: Summary of submitters comments

Submitter	Comments
New Zealand Food Safety	Supports amending the Code to permit use of the enzyme.
Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions	Supports progression of the application.

2.2 Risk assessment

FSANZ assessed the public health and safety risks associated with the use of chymosin (EC 3.4.23.4), sourced from a GM strain of *T. reesei,* as a processing aid in the manufacture of cheese, cheese products and fermented and rennetted milk products (see SD1). A summary of this risk assessment is provided below.

No public health and safety concerns were identified in the assessment of this chymosin sourced from a GM strain of *T. reesei* containing the chymosin gene from *Bos taurus* under the proposed use conditions. The host organism (*T. reesei)* is neither pathogenic nor toxigenic and has a long history of safe use in food. The gene donor organism (*Bos taurus)* has a history of safe use for food enzymes and raises no safety concerns. Analysis of the GM production strain (*T. reesei* t-AWL31) confirmed the presence and stability of the introduced DNA.

Chymosin produced by alternate GM hosts are already permitted in the Code. The results of bioinformatics searches showed no homology with known toxins or food allergens. The scientific literature includes cases of respiratory allergy to bovine rennet or chymosin, but no cases of allergic reactions in response to oral exposure. There is a substantial body of evidence that people can safely consume proteins to which they have a respiratory allergy. Wheat is used as a source of glucose for fermentation during production of the enzyme and will be labelled as required (see section 1.3.3 for more information).

No toxicology studies in animals have been conducted with this particular chymosin. Toxicity studies conducted on enzymes produced by related strains of *T. reesei* include a number of studies in rodents, as well as genotoxicity assays. No adverse effects or evidence of pathogenicity were identified in any of the rodent studies, and no evidence of mutagenicity or clastogenicity was identified in any of the genotoxicity assays. The most closely related strain is one producing catalase, and for that enzyme, a no observed adverse effect level (NOAEL) of 700 mg total organic solids (TOS)/kg bw/day was identified in a 90-day oral toxicity study in rats. This value has been used for the calculation of a Margin of Exposure (MOE) for chymosin, on the basis of Safe Strain Lineage. The theoretical maximum daily intake (TMDI) of this chymosin was calculated by FSANZ to be 0.125 mg TOS/kg bw. A comparison of the NOAEL and the TMDI results in a large MOE of approximately 5600.

Based on the reviewed data it is concluded that in the absence of any identifiable hazard an Acceptable Daily Intake (ADI) ‘not specified’ is appropriate. FSANZ concludes that there are no public health and safety concerns.

2.3 Risk management

2.3.1 Regulatory approval for processing aids

After assessing an application, FSANZ must either prepare a written draft measure or reject the application.

As outlined above, FSANZ's assessment concluded that there are no public health and safety concerns relating to the proposed use of this chymosin (EC 3.4.23.4) sourced from a GM strain of *T. reesei* as a processing aid.

Based on the food technology assessment, FSANZ concluded that use of this enzyme in the manufacture of cheese, cheese products and fermented and rennetted milk products is consistent with its typical function of hydrolysis of the kappa casein bond to produce milk curd. Analysis of the evidence provided adequate assurance that the enzyme's use in the quantity and form proposed, which must be consistent with GMP controls and processes, is technologically justified. There are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code with which the enzyme must comply.

As chymosin performs its technological function during food processing, not in the food for sale, it would function as a processing aid for the purposes of the Code.

FSANZ therefore considered it appropriate to prepare a draft variation amending the Code to permit the proposed use of this enzyme (Attachment A); and called for submissions on the draft variation.

Following the call for submissions and having regard to all submissions received, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change.

The express permission for the enzyme to be used as a processing aid would also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code).[4]

2.3.2 Enzyme nomenclature

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'chymosin' for the enzyme with an EC number of EC 3.4.23.4. FSANZ decided to use this name to remain consistent with how chymosin from permitted sources is referenced in the Code.

2.3.3 Labelling requirements

Subject to subsections 2.2.3.1 and 2.2.3.2 below, the generic exemption from listing processing aids in the statement of ingredients would apply to foods manufactured using this enzyme processing aid (see Section 1.3.3 above).

2.3.3.1 Labelling requirements for food produced using gene technology

Standard 1.5.2 in effect provides that a substance used as a processing aid that contains novel DNA or novel protein is a GM food. In contrast to the generic exemption for listing processing aids, subsection 1.5.2—4(2) states that the information relating to foods produced using gene technology must include the statement 'genetically modified' in conjunction with the name of the GM food. Subsection 1.5.2—4(3) states that if the GM food is used as a processing aid, the information may be included in the statement of ingredients. A food for

[4] 'Food produced using gene technology' is defined in subsection 1.1.2—2(3) as meaning 'a food which has been derived or developed from an organism which has been modified by gene technology'.

retail sale or sold to a caterer that contains the enzyme chymosin sourced from this GM *T. reesei* strain as an ingredient (e.g. the enzyme is used in the manufacture of cheese) will be required to be labelled 'genetically modified' in conjunction with the name of the enzyme.

2.4 Risk communication

2.4.1 Consultation

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

The process by which FSANZ considers standards 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.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. All comments are valued and contribute to the rigour of our assessment.

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

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting processing aids and genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods and new processing aids is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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 (i.e. rejecting the application). This analysis considered permitting the use of chymosin derived from a new source, i.e., from GM *T. reesei* containing the chymosin gene from *Bos Taurus* (the enzyme), as a processing aid in the manufacture of cheese, cheese products and fermented and rennetted milk 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. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme.

Costs and benefits of permitting the use of enzyme chymosin (EC 3.4.23.4) sourced from a GM strain of T. reesei as a processing aid (the new enzyme source)

Using the enzyme preparation from a GM strain of *T. reesei* may benefit industry by having additional choice of inputs to their manufacturing process especially if it proves cheaper, is more effective than what is presently available or results in additional competition among suppliers. Due to the voluntary nature of the permission, manufacturers would only use it where they believe a net benefit exists for them. Part of savings to the manufacturing industry may be passed on to consumers.

Permitting the enzyme to be used as a processing aid may result in a small cost to government in terms of adding this new substance to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions was that the direct and indirect benefits that would arise from permitting the proposed use of the new enzyme source in question most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

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 Standards in the Code which are relevant to the permitted use of the enzyme processing aid in question 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 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 undertook a safety assessment (SD1) and concluded that there were no public health and safety concerns relating to the use of the enzyme.

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

Existing labelling requirements in the Code related to this enzyme are discussed in Section 2.3.2 of the report above.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 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. The risk assessment is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. This dossier, together with other technical information including scientific literature, was considered by FSANZ in assessing the application.

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

There are no Codex Alimentarius Standards for processing aids or enzymes. However, there are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code with which the enzyme must comply.

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

The use of this enzyme is already permitted in the USA, Denmark, France and Mexico. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with the other countries where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment was there are no public health and safety concerns associated with the production microorganism or with using the enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from this alternative enzyme for the various applications proposed by the applicant.

Ultimately, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

- **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[5]**

The Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[6], formulated by the Food Ministers' Meeting, 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:

[5] Formerly known as the Forum on Food Regulation.
[6] Available on the Food regulation website (accessed 18 January 2022).

- 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 this enzyme as a processing aid is consistent with the specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 References

Belenkaya SV, Shcherbakov DN, Balabova DV, Belov AN, Koval AD, Elchaninov (2020) Production of Maral (*Cervus elaphus sibiricus* Servertzov) Recombinant Chymosin in the Prokaryotic Expression System and the Study of the Aggregate of Its Biochemical Properties Relevant for the Cheese-Making Industry. Applied Biochemistry and Microbiology 56(6):647-656

FAO/WHO (2006) Combined compendium of food additive specifications, Food and Agriculture Organization of the United Nations, Rome. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

IUBMB (2021) EC 3.4.23.4. https://iubmb.qmul.ac.uk/enzyme/EC3/4/23/4.html

The United States Pharmacopeia (2020) Food Chemicals Codex 12th Edition, United States Pharmacopeial Convention, Rockville, MD. http://publications.usp.org/

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 (Application A1244 – Chymosin from GM *Trichoderma reesei* as a processing aid (enzyme)) 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 Delegate]

[Insert name and title of delegate]
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 2022. 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 A1244 – Chymosin from GM* Trichoderma reesei *as a processing aid (enzyme)) Variation.*

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 18—Processing aids

[1] Subsection S18—9(3) (table)

Insert:

Chymosin (EC 3.4.23.4) sourced from *Trichoderma reesei* containing the chymosin gene from *Bos taurus*	For use in the manufacture of cheese, cheese products, fermented milk products and rennetted milk products.	GMP

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.

The Authority accepted Application A1244 which sought to amend the Code to permit the use of the enzyme chymosin (EC 3.4.23.4) sourced from a genetically modified strain of *Trichoderma reesei* (*T.reesei*), expressing a chymosin gene from *Bos taurus*, as a processing aid in the manufacture of cheese, cheese products and fermented and rennetted milk products. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting (FMM)[7], 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 sunsetting under the *Legislation Act 2003*.

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

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

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 amending the table to section S18—9(3) of the Code to permit the use of the enzyme, chymosin (EC 3.4.23.4) sourced from a genetically modified strain of *T. reesei* expressing a chymosin gene from *Bos taurus*, as a processing aid in the manufacture of cheese, cheese products and fermented and rennetted milk products. This permission is subject to the condition that the maximum permitted level or amount of this enzyme that may be used in the food must be consistent with good manufacturing practice (GMP).

4. Documents incorporated by reference

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

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO/WHO 2019) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). These include specifications for enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1244 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 4 April 2022 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement (RIS) for applications relating to permitting new processing aids and genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and genetically modified foods is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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

Item [1] of the Schedule to the variation inserts, in alphabetical order, a new entry into the table to subsection S18—9(3). The new entry consists of the following enzyme:

"Chymosin (EC 3.4.23.4) sourced from *Trichoderma reesei* containing the chymosin gene

from *Bos taurus*" (column 1 of the table).

The permitted technological purpose for this enzyme is use as a processing aid in the manufacture of cheese, cheese products, fermented milk products and rennetted milk products (column 2 of the table).

The permission would be subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP (column 3 of the table).

The variation permits the proposed use of the enzyme, chymosin (EC number 3.4.23.4), sourced from *T. reesei* containing the chymosin gene from *B. taurus*, as a processing aid in accordance with the Code.