17 August 2026
409-26

Approval report – Application A1345

Dextransucrase from *Bacillus subtilis* (gene donor: *Streptococcus salivarius*) for use as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Danisco Australia Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the enzyme dextransucrase (EC 2.4.1.5) for use as a processing aid in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in foods containing sucrose.

On 21 April 2026, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 2 submissions.

FSANZ approved the draft variation on 5 August 2026. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 17 August 2026.

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

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

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Supporting document

The following document, which informed the assessment of this application, is available on the A1345 webpage, on the FSANZ website[2]:

Supporting Document – Risk and technical assessment report

The published submissions from the call for submissions can be found on the A1345 Consultation Hub page.

[2] A1345 webpage – https://www.foodstandards.gov.au/food-standards-code/applications/a1345-dextransucrase-bacillus-subtilis-processing-aid

Executive summary

Danisco Australia Pty Ltd has applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the enzyme dextransucrase (EC 2.4.1.5) for use as a processing aid in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in foods containing sucrose. The enzyme is produced by *Bacillus subtilis* containing the gene for dextransucrase from *Streptococcus salivarius*.

FSANZ determined that the enzyme is used in a way that is technologically justified. It does not perform a technological function in the final food and therefore functions as a processing aid for the purposes of the Code. There are existing identity and purity specifications in the Code that the enzyme must meet when used in food or sold for use in food.

FSANZ's assessment concluded there are no safety concerns with the use of dextransucrase produced by *B. subtilis* under the proposed conditions of use.

Following assessment, FSANZ prepared a draft variation to the Code and called for submissions on 21 April 2026. Two submissions were received in the 6-week consultation period. FSANZ has had regard to these submissions.

Based on this information and other relevant considerations outlined in this report, FSANZ has approved the draft variation proposed at the call for submissions.

The approved draft variation will list Dextransucrase (EC 2.4.1.5), sourced from *B. subtilis* containing the gene for dextransucrase from *S. salivarius*, and its associated technological purpose in the table to subsection S18—9(3) of the Code. This table lists substances (including enzymes) permitted to be used as processing aids for specific technological purposes. The enzyme will have to be used at a level in accordance with Good Manufacturing Practice.

The effect of this amendment will be to permit the use of this enzyme as a processing aid in accordance with the Code.

1 Introduction

1.1 The applicant

The applicant is Danisco Australia Pty Ltd – a subsidiary of International Flavors and Fragrances Inc.

1.2 The application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the enzyme dextransucrase (EC 2.4.1.5) for use as a processing aid in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in foods containing sucrose.

The enzyme is produced by *Bacillus subtilis* containing the gene for dextransucrase from *Streptococcus salivarius*.

The applicant has indicated the enzyme is to be used in accordance with Good Manufacturing Practice (GMP).[3]

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

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 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)

[3] GMP is defined in section 1.1.2—2 of the Code as follows: ***GMP*** *or* ***Good Manufacturing Practice****, with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:*
(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and
(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:
*(i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging; and*
(ii) is not intended to accomplish any physical or other technical effect in the food itself;
(c) preparing and handling the substance in the same way as a food ingredient.

or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified.

An enzyme of microbial origin listed in the table to subsection S18—4(5) is 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.

Dextransucrase from *B. subtilis* containing the gene for dextransucrase from *S. salivarius* is not listed in the table to subsection S18—4(5) nor the table to subsection S18—9(3) and therefore is not currently a permitted processing aid for use in food processing.

1.3.2 Identity and purity requirements

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

Subsection S3—2(1) 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 26 (2021)), and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

1.3.3 Labelling requirements

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

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

Division 3 of Standard 1.2.3 requires declarations of certain foods (e.g. allergens) on the label of food for sale, unless an exemption applies. If the declaration relates to a processing aid, it must be made in the statement of ingredients and must include the required name[4] for the food which is to be declared in conjunction with the words ‘processing aid’.

If the requirement for a statement of ingredients does not apply, the required name must be declared on the label of the food for sale. If a food for retail sale is not required to bear a label, the required name must be displayed in connection with the display of the food or provided to the purchaser on request. If food sold to a caterer is not required to bear a label, the required name must be provided to the caterer with the food.

[4] ***Required name*** of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3 (see subsection 1.1.2—2(3)).

1.4 International standards

1.4.1 International

In developing food regulatory measures, Food Standards Australia New Zealand (FSANZ) must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). There is no Codex 'general standard' for processing aids. However, as noted in section 1.3.2 of this report, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

Additionally, there is a Codex guideline—*Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010)—which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under GMP conditions.

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 accordance with the FSANZ Act.

1.7 Decision

Following assessment, FSANZ drafted a variation amending the Code to permit the use of the enzyme as a processing aid in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in foods containing sucrose.

For the reasons outlined in this report and after consideration of submissions received during the consultation period, FSANZ approved the draft variation without change.

The approved draft variation 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 a proposed draft variation on 21 April 2026. The consultation period was 6 weeks.

Two submissions were received, which are publicly available on the A1345 Consultation Hub page.

One submission from New Zealand Food Safety supported the proposed draft variation and did not raise any issues. The other submission from a private individual did not support the draft variation and raised 2 issues.

Responses to the issues raised are provided in Table 1.

Table 1: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
Animal (vivisection) testing cannot be reliably applied to humans and the testing done is not sufficiently reliable.	Private individual – WSL	FSANZ would like to thank this submitter for their comments concerning the use of animals for toxicological testing. Toxicological data requirements for assessing the safety of substances added to, or present in, food are informed by internationally recognised risk assessment principles, including those established by the Food and Agriculture Organization of the United Nations and the World Health Organization. Consistent with these principles, FSANZ considers relevant laboratory animal data as part of the scientific weight-of-evidence used to characterise potential food-related health risks. FSANZ scientists are experienced in evaluating the relevance and limitations of such data for human health risk assessment, including the appropriateness of extrapolating findings from laboratory animal studies to humans. While no experimental model is a perfect substitute for humans, laboratory animal studies remain an internationally accepted and scientifically useful method for identifying and characterising the potential toxicity of substances in food. Such studies can provide information on possible effects across mammalian organs, tissues, physiological systems and metabolic processes, and are considered alongside other relevant evidence. Importantly, Australia and New Zealand recognise the 3Rs (Replacement, Reduction and Refinement) as critical components of the ethical, humane and responsible care and use of animals for scientific purposes. For this application, FSANZ considered the available toxicological and other relevant evidence and concluded there are no safety concerns associated with the proposed use of this dextransucrase under the stated conditions of use.

A justification is required for the need for the processing aid.	Private individual – WSL	FSANZ's assessment concluded the proposed use of this dextransucrase is both technologically justified and safe (see sections 2.2 and 2.3 of this report and the SD). Due to the voluntary nature of the permission, industry will make business decisions on whether to use the enzyme taking into account the costs and benefits of that use (see section 2.6.1 of this report).

2.2 Food technology assessment

The proposed use of dextransucrase as a processing aid to produce glucose oligosaccharides and polysaccharides in the manufacture of sucrose-containing foods is consistent with the typical function of the enzyme. The stated benefits include improved food product texture and sucrose reduction. The evidence presented to support its proposed use provides adequate assurance that the use of the enzyme, in the quantity and form proposed to be used (which must be consistent with GMP), is technologically justified.

Dextransucrase fulfils its primary function during the manufacture of food products and does not perform a technological purpose in the final food. It therefore functions as a processing aid for the purposes of the Code.

There are relevant identity and purity specifications for the enzyme in the Code with which the enzyme would have to comply whenever it is added to food for sale in accordance with the Code or sold for such use.

2.3 Risk assessment

No public health or safety concerns were identified with the use of the production organism, which is neither pathogenic nor toxigenic. Analysis of the modified production strain confirmed the presence and stability of the inserted DNA. No significant sequence homology between the enzyme and any known toxins or allergens was identified.

Glucose derived from wheat is used in the fermentation process to produce dextransucrase and therefore wheat may be present in the final enzyme preparation.

There was no evidence of genotoxicity *in vitro*. The no observed adverse effect level (NOAEL) in a 90-day oral gavage study in rats was 1000 mg total organic solids (TOS)/kg bw/day.

The theoretical maximum daily intake (TMDI) of this dextransucrase was calculated to be 3.58 mg TOS/kg bw/day. A comparison of the NOAEL and the TMDI results in a margin of exposure (MOE) of approximately 300.

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 there are no safety concerns from the use of this dextransucrase from *B. subtilis* in the quantity and form required to perform its typical function in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in foods containing sucrose, which must be consistent with GMP.

2.4 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation during a period of 6 weeks.

The risk management options available to FSANZ after the call for submissions were to:

- approve the draft variation proposed at the call for submissions, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

The risk and technical assessment concluded the proposed use of dextransucrase as a processing aid is technologically justified and there are no public health and safety concerns.

Having regard to the submissions received and, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment (Attachment A).

Risk management considerations for this application relating to the regulatory approval, nomenclature, specifications and labelling are discussed below.

2.4.1 Regulatory approval for processing aids

As stated above, FSANZ has approved a draft variation to permit the use of the enzyme as a processing aid in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in sucrose-containing foods. The express permission also provides permission for the enzyme's potential presence in the food for sale (Attachment A).

2.4.2 Enzyme nomenclature, source microorganism nomenclature and specifications

FSANZ notes the International Union of Biochemistry and Molecular Biology (IUBMB) lists the accepted name 'dextransucrase' for the enzyme EC 2.4.1.5 (see section 2.1 of the SD). This is the name used in the approved draft variation.

Nomenclature for the host and gene donor organisms – *Bacillus subtilis* and *Streptococcus salivarius*, respectively – is in accordance with accepted international norms for bacterial taxonomy.

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 of the Code for enzyme preparations used in food processing (refer to section 1.3.2 above). As stated above, this enzyme will have to comply with those specifications whenever it is added to food in accordance with the Code or sold for such use

2.4.3 Labelling

The labelling provisions in the Code will apply to foods for sale that are manufactured using this processing aid. See section 1.3.3 of this report (above).

Section 2.4 of SD states that glucose derived from wheat is used in the fermentation process to produce dextransucrase and therefore wheat may be present in the final enzyme preparation. Declaration requirements for wheat will apply if it is present in a food for sale that is manufactured using this processing aid.

2.4.4 Risk management conclusion

The risk management conclusion is to permit the enzyme dextransucrase produced by *B. subtilis* containing the gene for dextransucrase from *S. salivarius* to be used as a processing aid in the production of oligosaccharides and polysaccharides to reduce sucrose

content and improve texture in foods containing sucrose in accordance with the Code.

The enzyme and its associated technological purpose will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for specific technological purposes. The maximum permitted level of the enzyme that may be present in the food would have to be an amount consistent with GMP.

2.5 Risk communication

2.5.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ applied a standard communication strategy to this application. The call for submissions was notified via the Food Standards Notification Circular 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.

2.6 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:

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

FSANZ assessed that a Regulation Impact Statement is not required for this application. This is because applications relating to permitting processing aids are determined to be safe and considered to be minor in impact or deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved.

However, FSANZ had 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 (as per paragraph 29(2)(a) of the FSANZ Act).

The consideration of the costs and benefits in this section is 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 the status quo by permitting the proposed use of this dextransucrase from *B. subtilis* (EC 2.4.1.5) as a processing aid.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

Costs and benefits of permitting the proposed use of the enzyme dextransucrase from B. subtilis (EC 2.4.1.5) as a processing aid.

Industry might benefit from several improvements and efficiencies from the proposed use of

this enzyme. Due to the voluntary nature of the permission, industry would only use this enzyme as proposed where they believe a net benefit exists for them.

If industry experiences cost savings because of using this enzyme as a new processing aid, industry might pass on some of the cost savings to consumers.

Permitting the proposed use of this enzyme might result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids that are already monitored for compliance.

Conclusion of costs and benefits

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of this enzyme as a processing aid are likely to outweigh the associated costs.

2.6.1.2 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.

2.6.1.3 Any relevant New Zealand standards

The relevant standards in the Code apply in Australia and New Zealand. There are no relevant New Zealand only Standards.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

FSANZ undertook a risk and technical assessment and concluded there were no public health and safety concerns associated with the proposed use of this enzyme (see section 2.2 of this report and the SD).

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

The labelling requirements for this enzyme are discussed in sections 1.3.3 and 2.4.3 of this report.

2.6.2.3 The prevention of misleading or deceptive conduct

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

2.6.3 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 best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of their application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in the SD.

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

In terms of food safety, the relevant international standard setting body is Codex. There is no Codex 'general standard' for processing aids. However, as noted in section 1.3.2 of this report, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which this enzyme would have to comply when added to food in accordance with the Code or sold for use in food.

There is also a Codex guideline—Guidelines on Substances used as Processing Aids (CAC/GL 75-2010)—which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP (see section 1.4.1 of this report).

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

Australia and New Zealand will remain competitive with international markets where approval for the use of this enzyme is granted. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk and technical assessment is that there are no public health and safety concerns associated with the proposed use of this enzyme as a processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme for the applications proposed by the applicant. Ultimately, the 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 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**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[5] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function

[5] https://www.foodregulation.gov.au/resources/publications/policy-guideline-addition-substances-other-vitamins-and-minerals

- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the proposed use of this enzyme as a processing aid would be consistent with these specific order policy principles for ‘technological function’. All other relevant requirements of the policy guideline would be similarly met.

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 A1345 – Dextransucrase from *Bacillus subtilis* (gene donor: *Streptococcus salivarius*) for use as a processing aid) 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]

[To be signed by the 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 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 A1345 – Dextransucrase from* Bacillus subtilis *(gene donor:* Streptococcus salivarius*) for use as a processing aid) 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:

Dextransucrase (EC 2.4.1.5) sourced from *Bacillus subtilis* containing the gene for dextransucrase from *Streptococcus salivarius*	For use in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in foods containing sucrose	GMP

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1345 – Dextransucrase from* Bacillus subtilis *(gene donor:* Streptococcus salivarius*) for use as a processing aid) 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 A1345, which sought to amend the Code to permit the use of the enzyme dextransucrase (EC 2.4.1.5) from *Bacillus subtilis* containing the gene for dextransucrase from *Streptococcus salivarius* as a processing aid in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in foods containing sucrose.

The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards* (*Application A1345 – Dextransucrase from* Bacillus subtilis *(gene donor:* Streptococcus salivarius*) for use as a processing aid*) *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 amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme dextransucrase (EC 2.4.1.5) sourced from *Bacillus subtilis* containing the gene for dextransucrase from *Streptococcus salivarius* as a processing aid in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in foods containing sucrose. This permission is subject to the condition that the maximum permitted level or amount of the enzyme that may be present 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 would prescribe identity and purity specifications for the processing aid 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 when added to food in accordance with the Code or sold for use in food.

Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2021) and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). These include general specifications for the identity and purity parameters of 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 A1345 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 21 April 2026 for a 6-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

A regulation impact statement (RIS) was not prepared. FSANZ's assessment is that a RIS is not required for this application. This is on the basis that the application is minor and deregulatory in nature. It sought to permit the use of a processing aid found to be safe and that use is voluntary. This position is consistent with earlier advice from the Office of Impact Analysis (OIA23-06225)[6].

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

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 'variation' in this section are references to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1345 – Dextransucrase from* Bacillus subtilis *(gene donor:* Streptococcus salivarius*) for use as a processing aid) 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 will commence on the date of gazettal of the instrument.

Schedule to the variation

Item [1] of the Schedule to the variation inserts a new entry, in alphabetical order, into the table to subsection S18**—**9(3) of the Code.

The new entry consists of the following enzyme in column 1 of the table:

- 'Dextransucrase (EC 2.4.1.5) sourced from *Bacillus subtilis* containing the gene for dextransucrase from *Streptococcus salivarius*'

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. for use in the production of oligosaccharides and polysaccharides to reduce sucrose content and improve texture in foods containing sucrose.

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

The approved draft variation permits the use of the enzyme dextransucrase (EC 2.4.1.5) from *Bacillus subtilis* containing the gene for dextransucrase from *Streptococcus salivarius* as a processing aid in accordance with the Code.