4 November 2021
176-21

Call for submissions – Application A1212

Beta-fructofuranosidase enzyme from *Aspergillus fijiensis*

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Meiji Food Materia Co., Ltd to permit *Aspergillus fijiensis* as a microbial source for the production of the enzyme beta-fructofuranosidase as a processing aid in any food. Methods for identifying microorganisms are constantly evolving and in some cases microorganisms will be re-identified as different species. In this application, a microbial source of beta-fructofuranosidase (EC number 3.2.1.26) currently approved in the Code was originally identified as the species *A. niger,* but more advanced methods have now identified it as the species *A. fijiensis.* FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

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

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 16 December2021

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

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

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

Food Standards Australia New Zealand
PO Box 5423

Food Standards Australia New Zealand
PO Box 10559

KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

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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] https://www.foodstandards.gov.au/code/applications/Pages/a1212.aspx

Executive summary

The Australia New Zealand Food Standards Code (the Code) permits the enzyme beta-fructofuranosidase (Enzyme Commission (EC) number 3.2.1.26) derived from *Aspergillus niger* (*A. niger*) as a processing aid to perform any technological purpose in the manufacture of all foods.

Since the approval of *A. niger* as the microbial source of the enzyme in the Code, it has been re-identified as the species *Aspergillus fijiensis* (*A. fijiensis*). Meiji Food Materia Co., Ltd. has submitted an application to Food Standards Australia New Zealand (FSANZ) to permit *A. fijiensis* as a microbial source for the production of the enzyme beta-fructofuranosidase as a processing aid in any food. The request for the additional permission is to ensure regulatory certainty.

The enzyme meets international purity specifications. The enzyme is permitted for use in food production in the USA, France, Canada and Japan.

No public health and safety concerns were identified in the assessment of beta-fructofuranosidase from *A. fijiensis.* Based on the limited data available in the literature for the species *A. fijiensis* and as this is a new enzyme source, it is recommended that it is designated in the Code at the strain level, as *A. fijiensis* ATCC 20611. This strain is neither toxigenic nor pathogenic.

The no observed adverse effect level (NOAEL) in a 13-week repeated dose oral toxicity study in rats was the highest dose tested and corresponds to 920 mg/kg bw/day total organic solids (TOS). The theoretical maximum daily intake (TMDI) was calculated to be 0.52 mg/kg bw/day TOS for adults and 0.19 mg/kg bw/day for children. Comparison of the NOAEL and the calculated TMDIs gives a Margin of Exposure (MOE) of more than 1,700 for adults and 4,900 for children.

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.

The risk management conclusion is to permit the use of the enzyme beta-fructofuranosidase (EC 3.2.1.26) derived from *A. fijiensis* ATCC 20611 as a processing aid as a separate new permission consistent with the current permission for the enzyme in the Code. If approved, a reference to '*A. fijiensis* ATCC 20611' will be added into the table to subsection S18—4(5). The effect of the proposed amendment would be to permit the use of the enzyme, beta-fructofuranosidase (EC 3.2.1.26), derived from *A. fijiensis* ATCC 20611 as a processing aid to perform any technological purpose in the manufacture of any food – in accordance with the Code. The aim of the proposed amendment is to reduce confusion to industry arising from the use of different names for the same source. Reference to both names of the microbial source will also be likely to benefit international trade.

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The applicant

Meiji Food Materia Co., Ltd. is a manufacturer and marketer of speciality food ingredients including food additives and processing aids.

1.2 The application

The application seeks permission to permit *Aspergillus fijiensis* (*A. fijiensis*) as a microbial source for the production of the enzyme beta-fructofuranosidase (Enzyme Commission (EC) number 3.2.1.26) as a processing aid in any food. Methods for identifying microorganisms are constantly evolving and in some cases microorganisms will be re-identified as different species. In this application, a microbial source of beta-fructofuranosidase currently approved in the Code was originally identified as the species *A. niger,* but more advanced methods have now identified it as the species *A. fijiensis.* The request for the additional permission is to ensure regulatory certainty for the applicant.

The enzyme derived from *A. niger* was permitted in the Code as a permitted processing aid as an outcome from application A1055[2] which sought the use of fructo-oligosaccharides (FOS) as a nutritive substance. The gazettal occurred in 2013 and permitted the use of the enzyme for any technological purpose for all foods, not just for the production of FOS.

1.3 The current standard

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

1.3.1 Permitted use

Enzymes used in processing and manufacturing 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 Good Manufacturing Practice (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) or in the table to subsection S18—9(3). 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:

[2] https://www.foodstandards.gov.au/code/applications/Pages/applicationa1055shor4991.aspx

- 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; and
- present in the food at a level not greater than the maximum permitted level specified in the table.

Beta-fructofuranosidase derived from both *A. niger* and *Saccharomyces cerevisiae* are listed in the table to subsection S18—4(5) and consequentially are permitted to be used as a processing aid in the manufacture of all foods. However, beta-fructofuranosidase derived from *A. fijiensis* is not listed in the table. There are also no other permissions for beta-fructofuranosidase as a processing aid in subsection S18—9(3).

It is noted that the source microorganisms relevant to this application, being *A. niger* and *A. fijiensis* are not genetically modified (GM), so sections in the Code relevant for enzymes produced from GM microorganisms are not relevant for this assessment.

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.

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)), (in particular FAO/WHO 2006, for enzymes) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). These include specifications for enzyme preparations used in food processing.

1.3.3 Labelling requirements

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

Division 3 of Standard 1.2.3 requires certain food 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.

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.

1.3.4 International standards

In developing food regulatory measures, 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). Standards set by Codex provide a benchmark against which national food measures and regulations can be assessed. In certain situations however, FSANZ might receive an application to amend the Code for permission to use a new processing aid or food additive before an international standard exists.

There are also situations where domestic food standards will necessarily vary from international standards. This could include circumstances where:

- new data for the domestic situation that was not available at the time the international standard was set becomes available for assessment

- the domestic environment (climate and growing conditions) results in different levels of risk from contaminants, natural toxicants or nutrient levels in foods
- domestic consumption patterns result in different dietary exposures
- particular manufacturing and production processes have been adopted to meet specific domestic requirements.

Regulation (EC) No 1332/2008 (which became fully effective from January 2010) (the Regulation) harmonises for the first time the rules for food enzymes in the European Union (EU). Previous to the Regulation, food enzymes used as processing aids were not regulated at EU level.

According to the Regulation, all food enzymes currently on the EU market, as well as new food enzymes, are subject to a safety evaluation by the European Food Safety Authority (EFSA) and subsequently approved by the European Commission by means of an EU list. Currently, there is no EU list of authorised food enzymes. Until the establishment of such a list (anticipated for release in 2020- 2021), EU countries' legislation applies.

The enzyme (beta-fructofuranosidase) is permitted for use in food production in a number of other countries; being the USA, France, Canada and Japan. It has been considered Generally Recognized as safe (GRAS) in the USA. The applicant has been successful in achieving the same outcome as requested in this application by updating the permissions for the enzyme to include the microbial source of *A. fijiensis* in France and Canada. Currently an application for the same purpose is with the EFSA for its assessment which is under consideration.

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

1.4 Reasons for accepting application

The application was accepted for assessment because:

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

1.5 Procedure for assessment

The application is being assessed under the General Procedure of the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has assessed the public health and safety risks associated with the use of the enzyme beta-fructofuranosidase derived from *A. fijiensis* (as the species requested by the applicant) as a processing aid in food (see SD1). The summary of this risk assessment is provided below.

The enzyme meets international purity specifications.

No public health and safety concerns were identified in the assessment of beta-fructofuranosidase derived from *A. fijiensis* as an enzyme for food processing. The strain *A.*

fijiensis ATCC 20611 is neither toxigenic nor pathogenic (specifically for the strain ATCC 20611, see section 2.2.2 below explaining why the strain was specified).

The no observed adverse effect level (NOAEL) in a 13-week repeated dose oral toxicity study in rats was the highest dose tested and corresponds to 920 mg/kg bw/day total organic solids (TOS). The theoretical maximum daily intake (TMDI) was calculated to be 0.52 mg/kg bw/day TOS for adults and 0.19 mg/kg bw/day for children. Comparison of the NOAEL and the calculated TMDIs gives a Margin of Exposure (MOE) of more than 1,700 for adults and 4,900 for children.

A low degree of homology was found between the beta-fructofuranosidase from *A. fijiensis* and peanut agglutinin precursor from *Arachis hypogaea*. Taking into account its history of use in Australia and the lack of case reports of food allergy to beta-fructofuranosidase from *A. fijiensis*, and the low levels expected to be present in final food products, the risk of food allergy from use of the enzyme in food processing is likely to be low.

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.

2.2 Risk management

2.2.1 Regulatory approval for enzymes

The risk management options available to FSANZ, after assessment, were to either reject the application or to prepare a draft variation to amend the Code to permit the use of the enzyme beta-fructofuranosidase derived from *A.fijiensis* ATCC 20611 as a processing aid in food.

As stated above, FSANZ has concluded that beta-fructofuranosidase from *A. fijiensis* ATCC 20611 is safe for use as an enzyme for food processing. The microbiological assessment noted that it was appropriate to identify the microorganism to the strain level i.e. ATCC 20611, which is used in the proposed drafting. The risk assessment concluded that the enzyme is unlikely to pose allergenicity or toxicity concerns and further concluded that in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme.

It is noted that permission for the enzyme beta-fructofuranosidase sourced from *A. niger* is as a processing aid in the processing of all food for all technological purposes. Therefore, FSANZ prepared a draft variation to permit the use of the enzyme as a processing aid for its stated purpose, consistent with the current permission in the Code for beta-fructofuranosidase i.e. for any technological purpose in the manufacture of all foods.

2.2.2 Enzyme and source microorganism nomenclature

The discussion of the identification of the microorganism as the source of the enzyme, which is the purpose of the application is detailed within section 3.2 of SD1. In particular, this includes the history of the nomenclature. This information is summarised below.

As indicated by the applicant, the initial deposit of the strain of the microorganism was conducted in association with the filing of a patent and was classified by the American Type Culture Collection (ATCC) as *Aspergillus niger* ATCC® 20611™. In November 1997, ATCC reclassified the microorganism as the species *Aspergillus japonicus* based on its morphology. This microorganism had been re-identified as the species *Aspergillus fijiensis* in 2015 as a new species.

FSANZ's analysis of the literature identified a number of references have provided data indicating that *A. fijiensis* should not be considered a separate species but instead a

synonym of the species *A. brunneoviolaceus. A. brunneoviolaceus* (syn. *A. fijiensis*) was the confirmed species identification of the production organism. Both *A. brunneoviolaceus* and *A. fijiensis* as species have not previously been approved in the Code for enzyme production and have a modest history of use in commercial enzyme production. Although the available data for *A. brunneoviolaceus* (syn. *A. fijiensis*) suggests a low risk, this data is limited. It is recommended that the source organism be designated in the Code at the strain level rather than the species level as the identified strain, as named by ATCC as '*A. fijiensis* ATCC 20611'. This strain is neither toxigenic nor pathogenic.

As noted earlier, FSANZ added permission to use the enzyme as a processing aid in the Code in 2013 with the name beta-fructofuranosidase (Enzyme Commission (EC) number 3.2.1.26). This is also the accepted International Union of Biochemistry and Molecular Biology (IUBMB)[3] name of the enzyme. Therefore, this is the name of the enzyme which will be maintained in the draft variation.

2.2.3 Labelling requirements

The generic exemption from listing processing aids in the statement of ingredients would apply to foods produced using this processing aid (see section 1.3.3 above), unless allergens are present.

2.2.3.1 Declaration of certain substances

As noted in section 2.2.1 of SD1, residual amounts of soybean material, which is used as a fermentation nutrient, may remain in the final enzyme preparation. If soy is present in a food for sale[4], including when present as a processing aid or an ingredient or component of a processing aid, it must be declared in accordance with Division 3 of Standard 1.2.3 (Information requirements – warning statements, advisory statements and declarations). 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) of Standard 1.2.1).

2.2.4 Risk management conclusion

The risk management conclusion is to permit the use of the enzyme beta-fructofuranosidase (EC 3.2.1.26) derived from *Aspergillus fijiensis* ATCC 20611 as a processing aid as a separate new permission consistent with the current permission for the enzyme in the Code. If approved, *Aspergillus fijiensis* ATCC 20611 would be added into the table to subsection S18—4(5) as a source of the enzyme beta-fructofuranosidase (EC 3.2.1.26).

2.3 Risk communication

2.3.1 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 are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

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[3] https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC3/2/1/26.html.

[4] 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 soy when it is 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.

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

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

2.3.2 World Trade Organization (WTO)

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

There are no relevant international standards and amending the Code to permit a new microbial source of a currently permitted enzyme is unlikely to have a significant effect on international trade as Codex does not have regulations for enzymes used as processing aids. The enzyme from this source is authorised for use in the USA, France, Canada and Japan and it meets international specifications for enzymes.

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

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 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 processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as, if the draft variation is approved, the use of the processing aid would be voluntary. This standing exemption relates to food that has been determined to be safe.

FSANZ, however, has given 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 is 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 considers permitting the use of the enzyme beta-fructofuranosidase derived from *A. fijiensis* ATCC 20611 as a processing aid. FSANZ is of the view that no other realistic food regulatory measures exist, however information received during public consultation may result in FSANZ arriving at a different outcome.

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 seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme beta-fructofuranosidase (EC 3.2.1.26) derived from *A. fijiensis* ATCC 20611.

Costs and benefits of permitting A. fijiensis as an additional source microorganism for the enzyme beta-fructofuranosidase

Industry
Methods for identifying microorganisms are constantly evolving and in some cases microorganisms will be re-identified as different species. In this application, a microbial source of beta-fructofuranosidase (EC number 3.2.1.26) currently approved in the Code was originally identified as the species *A. niger,* but more advanced methods have now identified it as the species *A. fijiensis.* The effect of the draft variation, if approved, would be that both names of the same microbial source for beta-fructofuranosidase (EC number 3.2.1.26): '*A. niger*' and '*A. Fijiensis* ATCC 20611', will be listed in the table to subsection S18—4(5). The aim of the proposed amendment is to reduce confusion to industry arising from the use of different names for the same source. Reference to both names of the microbial source will also be likely to benefit international trade.

Consumers
Current and potential future consumers may benefit from the continued and potentially increased use of the enzyme from this microbial source as a processing aid for any technological purpose in all food within Australia and New Zealand with no industry confusion regarding the new identity of the source microorganism.

Government
Permitting the enzyme beta-fructofuranosidase sourced from *A. fijiensis* ATCC 20611 may result in a small and inconsequential cost to government in terms of adding the new microbial source name for the enzyme beta-fructofuranosidase to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations
FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of the enzyme beta-fructofuranosidase derived from *A. fijiensis* ATCC 20611 as a processing aid most likely outweigh the associated costs.

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded there are no public health and safety concerns with permitting the use of the enzyme beta-fructofuranosidase derived from *A. fijiensis* ATCC 20611 as a processing aid. It is recommended that the source organism be designated at the strain level (i.e. ATCC 20611) rather than the species level as scientific data is limited for the species but the strain *A. fijiensis* ATCC 20611 is neither toxigenic nor pathogenic.

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

The labelling requirements related to permitting the use of the enzyme beta-fructofuranosidase derived from *A. fijiensis* ATCC 20611 as a processing aid are discussed in section 2.2.3 above.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. FSANZ had regard to this dossier, together with other technical information including scientific literature, in assessing the application.

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

There are no Codex Alimentarius Standards for enzymes. The enzyme meets international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes. The enzyme is permitted for use in food production in a number of countries; being the USA, France, Canada and Japan. The permissions for the enzyme also includes the microbial source of *Aspergillus fijiensis* in France and Canada.

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

As mentioned above permissions for the enzyme also includes the microbial source of *Aspergillus fijiensis* in France and Canada, which is the purpose of the application. Therefore, if approved, permission to use this enzyme derived from *Aspergillus fijiensis* ATCC 20611 would bring Australia and New Zealand into line with the other countries where it is already permitted.

- **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 Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals[6] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

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

FSANZ has determined that permitting use of the enzyme beta-fructofuranosidase derived from *A. fijiensis* ATCC 20611 as a processing aid would be consistent with the specific order principles for 'Technological Function'. All other requirements of the policy guidelines would be similarly met.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

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

4 References

FAO/WHO (2006) General specifications and considerations for enzyme preparations used in food processing. Accessed 21 September 2021

IUBMB Enzyme Nomenclature EC 3.2.1.26
https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC3/2/1/26.html. Accessed 21 September 2021

The United States Pharmacopeia (2020) Food Chemicals Codex 12th Edition, United States Pharmacopeial Convention, Rockville, MD.

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

[5] Formerly the Australia and New Zealand Ministerial Forum on Food Regulation.
[6] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

Attachment A – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1212 – Beta-fructofuranosidase enzyme from *Aspergillus fijiensis*) 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 the variation.

Dated [To be completed by the delegate]

[Insert Delegate's name and position]
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 A1212 – Beta-fructofuranosidase enzyme from* Aspergillus fijiensis*) 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—4(5) (table item dealing with the enzyme β-Fructofuranosidase (EC 3.2.1.26))

Repeal the item, substitute:

β-Fructofuranosidase (EC 3.2.1.26)	*Aspergillus fijiensis* ATCC 20611 *Aspergillus niger* *Saccharomyces cerevisiae*

Attachment B – Draft Explanatory Statement

1. Authority

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

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

The Authority accepted application A1212 which seeks to permit *Aspergillus fijiensis* as a microbial source for the production of the enzyme beta-fructofuranosidase as a processing aid in any food. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The Authority has prepared a draft variation amending the table to subsection S18—4(5) of the Code to permit the use of the enzyme beta-fructofuranosidase derived from the source microorganism *A. fijiensis* ATCC 26011 as a processing aid for any technological purpose in any food. The reference to '*A. fijiensis* ATCC 26011' is a reference to the microorganism at the strain level.

The enzyme beta-fructofuranosidase derived from the microbial source *Aspergillus niger* (*A. niger*) is already permitted in the Code to be used as a processing aid in the manufacture of all food. Methods for identifying microorganisms are constantly evolving and in some cases microorganisms will be re-identified as different species. In this application, an organism previously approved in the Code was originally identified as the species *A. niger,* but more advanced methods have now identified it as the species *A. fijiensis.* Listing both names in the Code would clarify that beta-fructofuranosidase derived from '*A. niger*' or '*A. fijiensis*', is permitted to be used as a processing aid in food in accordance with the Code.

3. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate a document by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the 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) 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.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1212 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will occur for a six-week consultation

period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit additional processing aids (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting additional processing aids is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a food product to the food supply that has been determined to be safe. The use of the approved processing aid is also voluntary.

5. Statement of compatibility with human rights

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

6. Variation

Item [1] of the Schedule to the variation repeals the existing entry for the enzyme 'β-Fructofuranosidase (EC 3.2.1.26)**'** in the table to subsection S18—4(5) in Schedule 18 of the Code; and replaces it with a new entry for that enzyme.

The new entry includes a reference to '*Aspergillus fijiensis* ATCC 20611' as a source for 'β-Fructofuranosidase (EC 3.2.1.26)**'**.

If approved, the effect of the proposed amendment would be to permit the use of the enzyme, beta-fructofuranosidase (EC 3.2.1.26), derived from *A. fijiensis* ATCC 20611 as a processing aid to perform any technological purpose in the manufacture of any food – in accordance with the Code.