30 September 2019
[96-19]

Approval report – Application A1164

Pullulanase from *Bacillus licheniformis* as a processing aid (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by DuPont Australia Pty Ltd to permit the use of the enzyme pullulanase from a genetically modified strain of *Bacillus licheniformis* as a processing aid in brewing and starch processing.

On 6 June 2019, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 11 September 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 25 September 2019.

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

Table of contents

Supporting document

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

SD1 Amended Risk and Technical Assessment Report

[1] http://www.foodstandards.gov.au/code/applications/Pages/A1164.aspx

Executive summary

DuPont Australia Pty Ltd sought permission to use the enzyme pullulanase (EC 3.2.1.41) from a genetically modified (GM) strain of *Bacillus licheniformis* as a processing aid in brewing and starch processing.

Pullulanase breaks down polysaccharides like pullulan and amylopectin, to release oligosaccharides and glucose. In brewing applications, pullulanase facilitates the brewing process by increasing the amount of smaller fermentable sugars. In starch processing, pullulanase facilitates the production of syrups (e.g. glucose syrup) from starch. In turn, the syrups may be used as ingredients in a range of foods and beverages.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Standards 1.1.1, 1.1.2, 1.3.3 and Schedule 18 of the Australia New Zealand Food Standards Code (the Code). The table to subsection S18—9(3) lists enzymes permitted for use for a specific technological purpose.

B. licheniformis has a long history of safe use in producing enzyme processing aids, including several that are already permitted in the Code. The pullulanase that is the subject of this application is derived from a GM strain of *B. licheniformis* (strain BMP139), expressing a pullulanase gene from *Bacillus deramificans*. This pullulanase will provide food processors with an alternative enzyme preparation for degrading polysaccharides in brewing and in the production of syrups.

FSANZ's risk assessment concluded that there are no public health and safety issues associated with using this pullulanase. In the absence of any identifiable hazard, FSANZ concluded that an acceptable daily intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The enzyme product may contain traces of soy and wheat protein from the culture medium used to grow the production organism, however, risk management measures through labelling exist to protect wheat-allergic or soy-allergic individuals.

The stated technological purpose of this enzyme is clearly articulated in the application. The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications.

A total of three submissions were received on FSANZ's assessment report, all of which were supportive of the application and proposed draft variation to the Code.

The FSANZ Board has approved a draft variation to the Code, which permits this pullulanase as a processing aid in brewing and starch processing. The amount of enzyme used must be consistent with good manufacturing practice (GMP).

1 Introduction

1.1 The applicant

DuPont Australia Pty Ltd is a subsidiary of E I du Pont de Nemours and Company. It manufactures specialty food ingredients, food additives and food processing aids for industrial applications.

1.2 The application

The application was received on 29 May 2018.

The application sought to change the the Code to permit use of the enzyme pullulanase (EC 3.2.1.41) from a genetically modified (GM) strain of *B. licheniformis* as a processing aid in brewing and starch processing.

Pullulanase acts on pullulan[2] and amylopectin in starch-containing raw materials, to break them down to oligosaccharides and glucose. This results in improved properties of the raw materials during starch processing, better and/or more consistent product characteristics, and more effective production processes. For example, in brewing, the enzyme increases the amount of fermentable carbohydrates and the fermentation rate. In starch processing, the enzyme facilitates a higher glucose yield and less isomaltose formation.

The enzyme preparation will be used as a processing aid and has no technological purpose in the final food. No residual enzyme activity remains after incubation for 30 minutes at temperatures above 67°C.

The enzyme is sourced from a GM strain of *B. licheniformis* (strain BMP139), expressing a pullulanase gene from *B. deramificans.* This proprietary strain from DuPont will provide food processors with an alternative enzyme preparation for degrading polysaccharides in brewing and the production of syrups.

The pullulanase is produced in a three part process comprising submerged fermentation (growth of the organism and production of the enzyme); recovery (separation of the enzyme from the fermentation medium, purification and concentration); and formulation.

1.3 The current standards

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

Permitted use

Enzymes used to process and manufacture food are considered processing aids. Paragraph 1.1.1—10(6)(c) of the Code provides that a food for sale must not have, as an ingredient or a component, a substance that is ‘used as a processing aid’, unless expressly permitted.

Section 1.1.2—13 of the Code defines the expression ‘used as a processing aid’. That definition imposes certain conditions on substances permitted by Standard 1.3.3 and Schedule 18 to be used as a processing aid, such that it does not have a technological

[2] A polysaccharide made up of maltotriose units.

purpose in the final food for sale.

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.

Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Section 1.5.2—3 of Standard 1.5.2 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).

Identity and purity requirements

Paragraph 1.1.1—15(1)(b) 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.

Labelling requirements

Subsection 1.1.1—10(8) of the Code provides that 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 and substances to be declared when present in a food for sale. Subsection 1.2.3—4(2) states the food or substance may be present as a substance or food used as a processing aid, or an ingredient or component of such a substance or food.

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 prevail.

Section 1.5.2—4 requires processing aids that are 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. 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 subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act; and
- it related to a matter that might be developed as a food regulatory measure.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The food technology aspect of the Risk and Technical Assessment Report concluded that the enzyme meets its stated purpose in brewing and starch processing. The risk assessment

concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. Labelling requirements exist to protect wheat-allergic or soy-allergic individuals from any traces of soy and wheat that may be present in the enzyme product (see section 2.3.3 below). Therefore, FSANZ has approved the use of the enzyme as a processing aid for its stated purpose.

The draft variation as proposed following assessment was approved with one minor amendment. The text of the proposed permission was changed from wording '*containing the gene for pullulanase isolated from* Bacillus deramificans*'* to *'containing the pullunase gene from* Bacillus deramificans*'.* This change was made to ensure consistency with other enzyme permissions in the Code and in draft variations currently under consideration. The approved draft variation, as varied after consideration of submissions, is at Attachment A. The approved variation takes effect on gazettal.

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.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 6 June 2019. Three submissions were received: two from government agencies and one from the food industry. All three submissions supported the application and the proposed draft variation to the Code (Table 1) and did not raise any issues.

Table 1: Summary of issues raised by submissions

Raised by	Issue	FSANZ response
Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	Supportive	No response required
New Zealand Food Safety (Ministry for Primary Industries)	Supportive	No response required
New Zealand Food and Grocery Council	Supportive	No response required

2.2 Risk assessment

No public health and safety concerns associated with the use of this pullulanase were identified as a result of the hazard assessment.

B. licheniformis is non-pathogenic and has a long history of safe use to produce enzyme processing aids, including several that are already permitted in the Code.

Pullulanase from *B. licheniformis* was not genotoxic *in vitro* or *in vivo*, and did not cause adverse effects in short-term toxicity studies in rats. The no observed adverse effect level (NOAEL) in a 13-week repeated dose oral toxicity study in rats was the highest dose tested,

2500 mg/kg bw/day or 246 mg/kg bw/day on a total organic solids (TOS) basis. The applicant's estimated theoretical maximal daily intake (TMDI) based on the proposed uses is 0.049 mg/kg bw/day TOS. Therefore the Margin of Exposure (MOE) between the NOAEL and TMDI is more than 5000.

Bioinformatic analysis indicated that this pullulanase had no homology to known protein allergens or toxins and is unlikely to pose an allergenicity or toxicity concern.

The enzyme product may contain traces of soy and wheat protein and these may be carried over into the final enzyme preparation. As wheat and soy are major food allergens, labelling requirements already exist to protect wheat-allergic or soy-allergic individuals. These involve the declaration of these substances on product labels (see section 2.3.3.2).

Based on the reviewed toxicological data, it is concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) of 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme, in the form and prescribed amounts is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications.

For further details on the risk assessment, refer to the Risk and technical assessment report (SD1).

2.3 Risk management

The risk assessment concluded that there are no safety concerns from the use of this pullulanase as a food processing aid in brewing and starch processing. As processing aids require permissions in the Code, the main risk management option available to FSANZ was to approve or reject the request to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management issues considered for this application were related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.5.1.1 take account of the safety of the enzyme.

2.3.1 Regulatory approval for enzymes

The express permission for the enzyme's use as a processing aid will also provide the permission for the potential presence of the enzyme 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'.

2.3.2 Enzyme and source microorganism nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'pullulanase' for the enzyme with an EC number of EC 3.2.1.41 (IUBMB 2017). This is the name that is used in the proposed draft variation to the Code for this enzyme.

The nomenclature of the gene donor and production microorganisms were checked and confirmed as being appropriate as listed in the application (see section 3.1 of SD1). The source organism *B. licheniformis* is already permitted as a production microorganism for several enzymes within Schedule 18.

2.3.3 Labelling considerations

The risk assessment concluded that the use of the enzyme preparation poses no concern to public health and safety and that it performs its technological purpose as a processing aid. Therefore, the generic exemption from declaration of processing aids in the statement of ingredients will apply to foods containing this processing aid and no new labelling requirements are proposed.

2.3.3.1 Labelling requirements for food produced using gene technology

Section 2.1.3 of SD1 states the enzyme is denatured during the lautering and boiling steps in brewing, and denatured as a consequence of the saccharification step in starch processing. Denaturation of the enzyme protein does not alter the status of the food as being GM.

The requirements for labelling as 'genetically modified' differ depending on whether the GM food is an ingredient of the food for sale or not, as follows. If a food for retail sale or sold to a caterer contains the denatured enzyme pullulanase as an ingredient, that food would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid, if novel DNA or novel protein from the GM strain of *B. licheniformis* (that is the source microorganism, not the enzyme) remains in that food for sale.

FSANZ however, also notes the enzyme is used for starch processing to manufacture syrups. If the syrup is not a food for sale itself but is used as an ingredient in a food for retail sale or in food sold to a caterer, the enzyme would not be an ingredient in the food for sale containing the syrup. The requirement to label as 'genetically modified' would not apply to that food for sale because the labelling requirements only apply to food that consists of, or has as an ingredient, a GM food (section 1.5.2—4(1)).

2.3.3.2 Declaration of certain substances

Section 3.3.5 of SD1 states the enzyme preparation may contain traces of wheat or soy from the culture medium used to grow the production organism. If wheat or soy is present, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared in accordance with section 1.2.3—4 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 (section 1.2.1—9 of Standard 1.2.1).

Certain products are exempt from the requirement to declare wheat. In the case where the enzyme is used in the manufacture of glucose syrups made from wheat starch, the glucose syrups would be exempt from declaring wheat if they have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable, and they have a gluten protein content that does not exceed 20 mg/kg (subparagraph 1.2.3—4(1)(b)(i)(B)). Beer is also exempt from declaring wheat (and any other cereals containing gluten).

Certain products are exempt from the requirement to declare soy, but these exemptions do not apply to soy protein, which is the specific nutrient for the production organism used during the production of this enzyme.

2.3.4 Risk management conclusion

The risk management conclusion is to add the permission for pullulanase derived from a GM strain of *B. licheniformis*, expressing a pullulanase gene from *B. deramificans,* as a

processing aid into the table to S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose is for use in brewing and starch processing. The maximum permitted level is an amount consistent with GMP. Labelling requirements exist to protect wheat-allergic or soy-allergic individuals from the potential presence of soy and wheat proteins in the final enzyme preparation. These involve the declaration of these substances, where appropriate.

2.4 Risk communication

2.4.1 Consultation

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

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

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

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 permitting new processing aids (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting processing aids is machinery in nature as they are part of implementing a regulatory framework where the use of new aids is voluntary once an application has been 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 would arise from this 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 (S.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 either approving or rejecting the application (retain the status quo). A consideration of costs and benefits was included in the call for submissions (CFS) report based on the information and data held at that time. No further information has been received during the consultation process to date that influenced

the findings from the analysis of costs and benefits in the CFS.

The consideration of the costs and benefits outlined in this section is not intended to be an exhaustive, quantitative economic analysis of the measure and, 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 pullulanase from the GM strain of *B. licheniformis* as a processing aid in brewing and starch processing.

Costs and benefits permitting the use of pullulanase from a GM strain of B. licheniformis *as a processing aid*

The enzyme would facilitate the degradation of polysaccharides in brewing and starch processing, and may have other uses. The syrups produced through this enzyme may be used as ingredients in a range of foods and beverages. This may reduce costs and improve purity/quality of certain ingredients. Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists.

The enzyme is permitted in France, Denmark, Japan, and USA. The international permissions of this enzyme may be a business opportunity for Australian and New Zealand industries, although there may also be competing imports from the other countries (mentioned) into the domestic market.

There may be benefits to the consumer where cost savings from using the enzyme are passed on, and/or purity or quality of products are improved.

Permitting the enzyme may result in a small cost to government in terms of adding the enzyme to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment was that the direct and indirect benefits that would arise from permitting the use of this pullulanase as a processing aid outweigh the associated costs.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

Standards 1.1.1, 1.1.2 and 1.3.3 and Schedule 18 apply in both Australia and New Zealand and there are no other 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 Risk and Technical Assessment (SD1) and concluded there are no public health and safety issues associated with the use of this pullulanase.

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

The labelling considerations for the enzyme processing aid are discussed in section 2.3.3.

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 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 which is provided in SD1 – Risk and Technical Assessment Report. The applicant submitted a dossier of scientific studies as part of their application. Other technical information sourced by FSANZ, including scientific literature, was also used in assessing the application.

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

There are no Codex Alimentarius Standards for processing aids or enzymes. However, the enzyme has been permitted for use in several countries overseas (see section 2.5.1.1). In addition, it meets international specifications for enzyme preparations – a new specification for pullulanase from a GM *B. licheniformis* was published in FAO JECFA Monographs 11 (2011), and it meets the other general specifications for enzymes set out in the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes.

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

As mentioned above, this enzyme is already permitted in several countries. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets.

The conclusion of the risk assessment is there are no public health and safety concerns associated with the production microorganism *B. licheniformis* or with using pullulanase as a food processing aid in brewing and starch processing. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from this alternative enzyme preparation for degrading polysaccharides in brewing and the production of syrups.

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**

FSANZ identified no issues relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals[3] 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 determined that permitting the use of this pullulanase as a processing aid in brewing and starch processing is consistent with these specific order policy principles for 'Technological Function'.

3 References

FAO/WHO (2011) Compendium of food additive specifications (FAO JECFA Monograph 11) 74th meeting. www.fao.org/docrep/014/i2358e/i2358e00.pdf

FAO/WHO (2017) General specifications and considerations for enzyme preparations used in food processing. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

IUBMB (2017) EC 3.2.1.41. https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC3/2/1/41.html

Ministry of Health Labour and Welfare (MHLW) Japan (2001) Foods and food additives produced by recombinant DNA techniques. https://www.mhlw.go.jp/english/topics/food/

The United States Pharmacopeia (2018) Food Chemicals Codex 11th Edition, United States Pharmacopeial Convention, Rockville, MD. http://publications.usp.org/

US Food and Drug Administration (2016) GRAS notices – GRN000072. https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=72&sort=GRN_No&order=DESC&startrow=1&type=basic&search=pullulanase

Attachments

A. Approved variation to the Australia New Zealand Food Standards Code
B. Explanatory Statement
C. Draft variation to the Australia New Zealand Food Standards Code (call for

[3] http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

submissions)

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

Food Standards (Application A1164 – Pullulanase from *Bacillus licheniformis* as a processing aid (Enzyme)) Variation

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 details 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 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 A1164 – Pullulanase from* Bacillus licheniformis *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

[1] Schedule 18 is varied by inserting in the table to subsection S18—9(3), in alphabetical order

Pullulanase (EC 3.2.1.41) sourced from *Bacillus licheniformis* containing the pullulanase gene from *Bacillus deramificans.*	For use in brewing and in starch processing.	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 A1164 which seeks permission to use the enzyme pullulanase (EC 3.2.1.41) from a genetically modified (GM) strain of *Bacillus licheniformis* as a processing aid in brewing and starch processing. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

2. Purpose

The Authority has approved an amendment to the table to section S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme pullulanase (EC 3.2.1.41) from a GM strain of *B. licheniformis* as a processing aid in brewing and starch processing.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

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 2017) and the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th 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 A1164 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 6 June 2019 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ 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 variation inserts in the table to subsection S18—9(3) in Schedule 18 in alphabetical order, a new entry for “Pullulanase (EC 3.2.1.41) sourced from *Bacillus licheniformis* containing the pullulanase gene from *Bacillus deramificans*” into column 1, and “For use in brewing and in starch processing” into column 2, and “GMP” into column 3.

The new entry will, in effect, permit pullulanase (EC number 3.2.1.41), derived from the GM strain of *B. licheniformis*, to be used as a processing aid in food, with a technological purpose of brewing and starch processing, with the condition that the amount used must be consistent with good manufacturing practice (GMP).

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

1 Name

This instrument is the *Food Standards (Application A1164 – Pullulanase from* Bacillus licheniformis *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

[1] **Schedule 18** is varied by inserting in the table to subsection S18—9(3), in alphabetical order

Pullulanase (EC 3.2.1.41) sourced from *Bacillus licheniformis*, containing the gene for pullulanase isolated from *Bacillus deramificans.*	For use in brewing and in starch processing.	GMP