21 March 2019
[75-19]

Approval report – Application A1165

Lysophospholipase from *Trichoderma reesei* as a processing aid (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by AB Enzymes GmbH to permit the use of the enzyme lysophospholipase from a genetically modified strain of *Trichoderma reesei* as a processing aid in starch processing, including the production of syrups.

On 13 November 2018, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 6 March 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 21 March 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 Risk and Technical Assessment Report (unrevised at approval)

[1] http://www.foodstandards.gov.au/code/applications/Pages/A1165.aspx

Executive summary

AB Enzymes GmbH submitted an application to Food Standards Australia New Zealand (FSANZ) to use the enzyme lysophospholipase (EC 3.1.1.5) from a genetically modified strain of *Trichoderma reesei* (a fungus) as a processing aid in starch processing, including the production of syrups.

Lysophospholipase breaks down lysophospholipids in starch. These lysophospholipids would otherwise affect the filtration rate and clarity of the starch hydrolysates (syrups). The enzyme can be used to produce a variety of syrups and sweeteners derived from starch, which in turn may be used as ingredients in foods such as confectionery and baked products, amongst others.

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). If approved, this enzyme would be listed in the table to subsection S18—9(3), which includes enzymes permitted for use for a specific technological purpose.

The enzyme is derived from a genetically modified strain of *T. reesei* (strain RF7206), expressing a lysophospholipase gene from *Aspergillus nishimurae*. The lysophospholipase derived from this genetically modified organism has a higher activity compared to other enzyme products on the market. As a result, less of the enzyme is used and less excipients (substances added to stabilise the enzyme) are added when the enzyme preparation is being applied.

FSANZ's risk assessment concluded that there were no public health and safety issues associated with using this lysophopholipase. 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 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 the enzyme lysophospholipase derived from a genetically modified strain of *T. reesei,* as a processing aid in starch processing, including the production of syrups. The amount of enzyme used must be consistent with good manufacturing practice (GMP).

1 Introduction

1.1 The applicant

AB Enzymes GmbH is an industrial biotechnology company that develops, manufactures and supplies enzyme preparations for industrial applications worldwide.

1.2 The application

The application was received on 4 June 2018.

The application sought to change the Australia New Zealand Food Standards Code (the Code) to permit use of the enzyme lysophospholipase (EC 3.1.1.5) from a genetically modified strain of *Trichoderma reesei* as a processing aid in starch processing, including the production of syrups. The starch sources are mainly wheat and maize/corn.

Lysophospholipase catalyses the hydrolysis of lysophospholipids present in starch, which would otherwise have a negative impact on the filtration rate and clarity of the starch hydrolysates (syrups).

During starch processing, the enzyme is inactivated by heating the syrup to 85°C and it has no function in the final food. Subsequent purification steps will remove the majority of the inactivated enzyme.

The enzyme is sourced from a genetically modified strain of *T. reesei* (strain RF7206), expressing a lysophospholipase gene from *Aspergillus nishimurae.* The lysophospholipase from AB Enzymes has been found to have a higher activity compared to other enzyme products on the market. As a result, enzyme use level is lower and less excipients are added when the enzyme preparation is being applied during starch processing. Although sourced from a genetically modified organism, the enzyme itself is not protein engineered.

The lysophospholipase is produced by submerged fermentation. After a number of processing steps involving filtering and concentrating the liquid containing the enzyme, the resulting concentrated enzyme solution is free of the production organism and insoluble substances, ready for the final preparation. The enzyme is sold mainly as a liquid enzyme preparation.

1.3 The current standard

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

Permitted use

Enzymes used to process and manufacture food are considered processing aids. Paragraph 1.1.1—10(6) 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’, or a ‘food produced using gene technology’, 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 perform a technological function 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.

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.

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 safety assessment concluded that the enzyme meets its stated purpose to process starch, including the production of syrups. The risk assessment concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. In addition, ingestion of any residual lysophospholipase in food products is unlikely to pose an allergenicity concern (for further details, refer to the Risk and technical assessment report (SD1)). Therefore, FSANZ permits the use of the enzyme as a processing aid for its stated purpose.

The draft variation as proposed following assessment was approved without change after the consideration of submissions. The approved draft variation 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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 13 November 2018. Three submissions were received: two from government agencies and one from the food industry. All three submissions supported the application and proposed draft variation to the Code (Table 1). Both the Victorian Department of Health and Human Services and the Victorian Department of Economic Development, Jobs, Transport and Resources, and New Zealand Ministry for Primary Industries supported FSANZ's assessment of the application and raised no issues.

Table 1: Summary of issues raised by submissions

Raised by	Issue	FSANZ response
New Zealand Food and Grocery Council	The submitter notes that the enzyme sold as an ingredient in syrups or sweeteners may contain traces of wheat. If wheat is present, even in a processing aid, then the wheat presence triggers a mandatory labelling requirement. The submitter is of the view that testing of the final product may remove this need although a cautionary approach could be the inclusion of a 'may contain' statement.	The enzyme is typically used in starch processing, i.e. the production of syrups derived from wheat as well as corn/maize starches. Section 2.3.2.2 of this report notes that if wheat is present in the food for sale, including when present as a component of a processing aid, it must be declared. FSANZ notes it is up to individual food manufacturers to make their own decisions regarding whether or not to analyse the food for sale and, depending on the results, make a determination regarding the appropriate declarations or statements.
New Zealand Food and Grocery Council	The submitter believes the addition of 'and sweeteners' to the inclusions for starch processing in Schedule 18 would assist in removing uncertainty about use of the enzyme beyond syrups i.e. the technological purpose should be amended to read 'For use in starch processing, including in the production of syrups and sweeteners'.	FSANZ has prepared a draft variation to Schedule 18 granting permission for use of the enzyme to reflect what was sought in the application. The draft variation has been worded so that it does not preclude manufacturers from using the enzyme for other purposes, such as in the production of sweeteners. The distinction between the two enzyme products is minor and FSANZ's view is that a specific reference to sweeteners is not necessary for regulatory certainty.

2.2 Risk assessment

No public health and safety concerns associated with the use of lysophospholipase from genetically modified *T. reesei* were identified as a result of the hazard assessment.

Molecular evidence confirmed the taxonomy of the recipient strain of the lysophospholipase gene as *T. reesei*. This fungus is not toxigenic or pathogenic and has a long history of safe use in the production of a number of enzyme processing aids that are already permitted in the Code. No extraneous genetic material is carried across from the donor organism (*A. nishimurae*) as part of the genetic modification. The genetic modification has been shown to be phenotypically stable.

The enzyme was not genotoxic in a bacterial reverse mutation assay (Ames test) or a chromosomal aberration test in Chinese hamster lung fibroblast V79 cells. No adverse effects were observed in a 90-day oral gavage study in rats at doses up to 1000 mg/kg bw/day, equivalent to 995 mg/kg bw/day when expressed as total organic solids (TOS). The

Theoretical Maximal Daily Intake (TMDI) in humans under the proposed conditions of use is TOS equal to 0.006 mg/kg bw/day. Consequently, the Margin of Safety (MoS) between the human TMDI and the NOAEL in rats is 159,167.

Bioinformatic searches did not identify any significant homology of the amino acid sequence of the enzyme with those of known toxins or allergens. The enzyme may contain traces of wheat. As wheat is a major food allergen, risk management measures are indicated to protect wheat-allergic individuals.

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 lysophospholipase from the genetically modified strain of *T. reesei* as a food processing aid in starch processing, including the production of syrups. 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.

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'. 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 for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

2.3.1 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 'lysophospholipase' for the enzyme with an EC number of EC 3.1.1.5 (IUBMB 2017). This is the name that is used in the proposed draft variation to the Code for this enzyme.

The source microorganism is *T. reesei* containing the gene for lysophospholipase isolated from *Aspergillus nishimurae.*

2.3.2 Labelling considerations

Paragraph 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. Standard 1.2.4 of the Code generally requires food products to be labelled with a statement of ingredients. Sections 1.2.3—3(2)(d) and (e) of that Standard exempt processing aids from the requirement to be declared in the statement of ingredients.

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.

2.3.2.1 Labelling requirements for food produced using gene technology

Standard 1.5.2 outlines provisions for labelling of foods produced using gene technology. The enzyme is a food produced using gene technology for Code purposes. Section 1.5.2—4 indicates that labelling requirements apply for processing aids that are foods produced using gene technology, where novel DNA or novel protein from the processing aid remains present in the food for sale.

Section 1.5.2—4 requires certain foods for sale that consist of or have as an ingredient, food that is a genetically modified food to be labelled as 'genetically modified'. FSANZ also notes that the Code's labelling requirements – including those 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. The requirements for labelling as 'genetically modified' differ depending on whether the genetically modified 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 enzyme lysophospholipase 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 genetically modified strain of *T. reesei* (that is the source microorganism, not the enzyme) remains in that food for sale.

FSANZ however, also notes that the enzyme is used as a processing aid to manufacture foods such as syrups. If that food, e.g. the syrup, is not a food for sale itself but is used as an ingredient in a food for retail sale or 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 genetically modified food (section 1.5.2—4(1)).

2.3.2.2 Declaration of certain substances

The enzyme preparation may contain traces of wheat. If wheat is present in a food for retail sale or food sold to a caterer, 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).

2.3.3 Risk management conclusion

The risk management conclusion is to add the permission for the new enzyme lysophospholipase derived from the genetically modified strain of *T. reesei*, expressing a

lysophospholipase gene from *A. nishimurae,* 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 starch processing, including the production of syrups. The maximum permitted level is an amount consistent with GMP.

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 the use of processing aids (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting processing aids is machinery in nature and the use of the processing aid is voluntary once the application has been successfully approved. This standing exemption relates to the introduction of a processing aid 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 lysophospholipase from the genetically modified strain of *T. reesei* as a processing aid in starch processing, including the production of syrups.

Costs and benefits permitting the use of lysophospholipase from a genetically modified strain of T. reesei *as a processing aid in starch processing, including the production of syrups*

The enzyme prevents the formation of lysophospholipid micelles which will improve the filtration rate of syrups and prevent the syrups from becoming cloudy. Improving the filtration rate of syrups enhances production efficiency. The cloudiness of syrups affects the aesthetics and consumer acceptability; reducing this may lead to less food wastage. Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists. There are other enzymes available to industry that perform similar functions and it is of benefit to industry to have additional choice, especially where the enzyme is more effective or cheaper.

The enzyme is permitted in France and the US (US FDA 2016) and is currently under consideration in the EU. 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 these countries into the domestic market.

There may be benefits to the consumer where cost savings from using the enzyme are passed on.

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 lysophospholipase (EC 3.1.1.5) from a genetically modified strain of *T. reesei* 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 safety assessment (SD1) and concluded there were no public health and safety issues associated with the use of the enzyme lysophospholipase, sourced from a genetically modified strain of *T. reesei*, as a food processing aid for use in starch processing, including the production of syrups.

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 2.3.2.

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 i.e. the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2016) and the Food Chemicals Codex specifications for enzymes (Food Chemicals Codex 10th edition (2016)).

- **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. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The outcome of the risk assessment indicated that there are no public health and safety concerns associated with the production microorganism *T. reesei* or with using lysophospholipase as a food processing aid in starch processing. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme with enhanced functionality.

The applicant has indicated that the enzyme has shown great potential in food manufacturing, and a letter of support from a leading agribusiness states that, based on first results presented to it, the use of this new enzyme in the starch industry (glucose filtration)

looks quite promising. However, 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 businesss.

- **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[2] 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 lysophospholipase, sourced from *T. reesei*, as a processing aid in starch processing, is consistent with these specific order policy principles for 'Technological Function'.

3 References

FAO/WHO (2016) General specifications and considerations for enzyme preparations used in food processing. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

IUBMB (2017) EC 3.1.1.5. http://www.sbcs.qmul.ac.uk/iubmb/enzyme/EC3/0101a.html#05

The United States Pharmacopeia (2016) Food Chemicals Codex 10th Edition, United States Pharmacopeial Convention, Rockville, MD. http://publications.usp.org/

US Food and Drug Administration (2016) GRAS notices – GRN000653. https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=653&sort=GRN_No&order=DESC&startrow=1&type=basic&search=653

Attachments

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

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

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

Food Standards (Application A1165 – Lysophospholipase from *Trichoderma reesei* 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 the variation.

Dated [To be completed by the Delegate]

Insert Delegate Title
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Application A1165 – Lysophospholipase from* Trichoderma reesei *as a Processing Aid (Enzyme)) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] **Schedule 18** is varied by inserting in the table to section S18—9(3), after the entry for '*Listeria* phage P100'

Lysophospholipase (EC 3.1.1.5) sourced from *Trichoderma reesei* containing the gene for lysophospholipase isolated from *Aspergillus nishimurae*	For use in starch processing, including the production of syrups	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 A1165 which seeks permission to use the enzyme lysophospholipase (EC 3.1.1.5) from a genetically modified strain of *Trichoderma reesei* as a processing aid for use in starch processing, including the production of syrups. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft Standard.

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.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a variation to amend the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme lysophospholipase (EC 3.1.1.5) from a genetically modified strain of *Trichoderma reesei* as a processing aid for use in starch processing, including the production of syrups.

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 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 2016) and the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th 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 A1165 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 13 November for a five-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 “Lysophospholipase (EC 3.1.1.5) sourced from *Trichoderma reesei* containing the gene for lysophospholipase isolated from *Aspergillus nishimurae*” into column 1, and “For use in starch processing, including the production of syrups” into column 2, and “GMP” into column 3.

The new entry will, in effect, permit the enzyme lysophospholipase (EC number 3.1.1.5), derived from the genetically modified strain of *T. reesei*, to be used as a processing aid in food for the technological purpose of starch processing, including the production of syrups, with the condition that the amount used must be consistent with good manufacturing practice (GMP).