12 May 2021
155-21

Approval report – Application A1206

Subtilisin from GM *Bacillus licheniformis* as a processing aid (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to permit the use of subtilisin from a genetically modified strain of *Bacillus licheniformis* containing the subtilisin gene from *Pyrococcus furiosus*, as a processing aid in the production of potable alcohol.

On 3 December 2020, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 28 April 2021. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 12 May 2021.

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

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

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Supporting document

The following document, which informed the assessment of this Application, is are available on the FSANZ website:

SD1 Risk and technical assessment report – Application A1206 – Subtilisin from GM *Bacillus licheniformis* as a processing aid (enzyme)

Executive summary

Novozymes Australia Pty Ltd (Novozymes) applied to Food Standards Australia New Zealand (FSANZ) to amend Schedule 18 – Processing Aids of the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme subtilisin (EC 3.4.21.62) from a genetically modified (GM) strain of *Bacillus licheniformis* (*B. licheniformis*) containing the subtilisin gene from *Pyrococcus furiosus*, as a processing aid in the production of potable alcohol. Subtilisin would be used at the minimum levels necessary to achieve the desired effect and according to requirements for normal production following Good Manufacturing Practice (GMP).

Enzymes used to produce and manufacture food are considered processing aids and are regulated by the Code.

FSANZ has undertaken an assessment to determine whether the enzyme achieves its technological function in the quantity and form proposed to be used and to evaluate public health and safety concerns that may arise from the use of this enzyme.

FSANZ concludes that the proposed use of this subtilisin as an enzyme processing aid in potable alcohol production is consistent with its typical function of hydrolysing proteins. Subtilisin performs its technological purpose during production of potable alcohol and is not performing a technological function in the final food, therefore functioning as a processing aid as defined in the Code. There are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code which would have to be complied with.

After undertaking a risk assessment, FSANZ concluded that the use of the enzyme under the proposed conditions is safe. *B. licheniformis* has a long history of safe use as a source microorganism of enzyme processing aids, including several that are already permitted in the Code. In the absence of any identifiable hazard, an Acceptable Daily Intake of 'not specified' has been assessed as being appropriate for this enzyme.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 3 December 2020 to 27 January 2021. Four submissions were received in response. Three submitters were supportive of the draft variation and one submitter did not support it but provided no reasoning.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to subsection S18—9(3) of the Code to permit the enzyme subtilisin (EC 3.4.21.62) from a genetically modified strain of *B. licheniformis* containing the subtilisin gene from *Pyrococcus furiosus*, as a processing aid in the production of potable alcohol. This is subject to the condition that the amount of enzyme used must be consistent with GMP.

1 Introduction

1.1 The Applicant

The applicant is Novozymes Australia Pty Ltd (Novozymes), a biotechnology company that manufactures industrial and food enzymes.

1.2 The Application

Novozymes applied to Food Standards Australia New Zealand (FSANZ) for permission to use the enzyme subtilisin (EC 3.4.21.62) from a genetically modified (GM) strain of *Bacillus licheniformis* (*B. licheniformis*) containing the subtilisin gene from *Pyrococcus furiosus* as a processing aid in the production of potable alcohol. Subtilisin would be used at minimum levels necessary to achieve the desired effect and according to requirements for normal production following Good Manufacturing Practice (GMP).

1.3 The current Standard

Australian and New Zealand food laws require that food for sale must comply with the Australia New Zealand Food Standards Code (the Code). The requirements in the Code relevant to this application are summarised below.

1.3.1 Permitted use

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

Paragraph 1.1.1—10(6)(c) provides that 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 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions: it is used to perform a technological purpose during the course of processing; it does not perform a technological purpose in the food for sale; and it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

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

- permitted to be used as processing aids for *specific* technological purposes in relation to:
  - if a food is specified—that food; or
  - if no food is specified—any food;
- present in the food at a level not greater than the maximum permitted level specified in the table.

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

Serine proteinases of microbial origin (*Aspergillus oryzae, Bacillus amyloliquefaciens, Bacillus halodurans, Bacillus licheniformis,* and *Bacillus subtilis*) are currently permitted enzymes in the Code (S18—4(5)). They are generally permitted as serine proteinases with the number EC 3.4.21.14. This would include subtilisin with *B. licheniformis* as the source, but not containing the gene for subtilisin from *Pyrococcus furiosus* as requested in this application. The enzymes currently permitted may be used to perform any technological function including, but not limited to, producing potable alcohol as requested in this application.

1.3.2 Identity and purity requirements

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

Subsection S3—2(1) incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 20 (2017)), and the United States Pharmacopeial Convention (2018) Food chemicals codex (11th 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.

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

Section 1.5.2—4 requires processing aids that are, or have as ingredients, food 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 subsections 1.2.1—8(1) and 1.2.1—9(3), 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 Food Standards Australia New Zealand Act 1991* (the FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General procedure in the FSANZ Act.

1.6 Decision

For reasons set out in this report, FSANZ decided to approve a draft variation permitting the use of this enzyme as a processing aid in the production of potable alcohol, as requested by the applicant.

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 3 December 2020 to 27 January 2021. Four submissions were received, two from government agencies, one from an industry body and one from an individual. The government agencies and industry body supported the application and draft variation. The individual submitter did not support it but did not provide any further detail or reasoning.

Table 1: Summary of issues

Submitter	Comments
New Zealand Food and Grocery Council	Supports the draft variation proposed.
New Zealand Food Safety (Ministry for Primary Industries)	Supports the draft variation proposed.
Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	Supports the progression of the application.
Individual submitter	Does not support.

2.2 Risk assessment

The safety assessment concluded that the use of the enzyme under the proposed conditions is safe. *B. licheniformis* has a long history of safe use as a source microorganism of enzyme processing aids, including several that are already permitted in the Code. The bacterium is neither toxigenic nor pathogenic. Characterisation of the GM production strain confirmed both presence and stable inheritance of the inserted subtilisin gene.

The applicant provided a 13-week toxicity study in rats and *in vitro* genotoxicity studies with an α-amylase produced by a closely related predecessor strain of the subtilisin production strain. This α-amylase was chosen as most appropriate for assessment of subtilisin, because the recipient strain of the α-amylase production strain is identical to the one for the subtilisin production strain, and the method used to insert the DNA is identical to the one described for the construction of the subtilisin production strain. The α-amylase was not genotoxic *in vitro* and caused no adverse effects in a 13-week toxicity study in rats. The no observed adverse effect level (NOAEL) was 796 mg/kg body weight (bw)/day total organic solids (TOS), the highest dose tested.

A comparison of the NOAEL of the closely related α-amylase with the estimated theoretical maximum daily intake (TMDI) (0.03 mg/kg bw/day TOS) indicates that the Margin of Exposure between the NOAEL and TMDI is more than 26,500.

A degree of amino acid sequence homology with a food allergen from melon was identified, but the enzyme is considered unlikely to pose an allergenicity concern because a study with another subtilisin from *B. licheniformis* found no evidence of food allergenicity, exposure is expected to be very low and there is a long history of safe use of subtilisin enzymes from other sources with no reports of food allergy identified.

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

2.3 Risk management

2.3.1 Regulatory approval for processing aids

As outlined above, FSANZ has concluded from the risk assessment undertaken that there are no safety concerns relating to the use of the subtilisin preparation as a processing aid in the production of potable alcohol.

From the food technology assessment, FSANZ concluded that the proposed use of this subtilisin as an enzyme in potable alcohol production is consistent with its typical function of hydrolysing proteins. Subtilisin performs its technological purpose during production of potable alcohol and is not performing a technological function in the final food, therefore functioning as a processing aid as defined in the Code.

FSANZ therefore considers it is appropriate to permit the use of the enzyme subtilisin from a GM strain of *B. licheniformis* containing the subtilisin gene from *Pyrococcus furiosus* as a processing aid in the production of potable alcohol. The maximum level at which the enzyme may be present in food is an amount consistent with GMP. A draft variation to the Code has been prepared to permit the use of this enzyme as requested by the applicant (Attachment A). There are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code which would have to be complied with.

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

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'subtilisin' for the enzyme with the number EC 3.4.21.62 (IUBMB 2020). This is the name that is used in the approved draft variation to the Code.

2.3.2 Labelling

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 of this report).

A food for retail sale or sold to a caterer that contains the enzyme subtilisin sourced from the GM strain *B. licheniformis* as an ingredient would be required to be labelled 'genetically modified' in conjunction with the name of the GM food, if novel DNA or novel protein from the GM strain of *B. licheniformis* remains in that food for sale (see paragraph 1.5.2—4(1)(b) of

the Code). The proposed use of this enzyme is as a processing aid in the production of potable alcohol. It is unlikely that potable alcohol produced using this enzyme will contain novel DNA or novel protein.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions 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 standards' development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

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

The draft variation was considered for approval by FSANZ having regard to all submissions made during the call for submissions period.

2.5 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has 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 (RIS) for permitting genetically modified foods and the voluntary addition of processing aids to foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods and new enzyme processing aids is deregulatory as their use will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration 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 (where the status quo is rejecting the application). This analysis considers permitting the use the enzyme subtilisin from a genetically modified strain of *B. licheniformis* containing the subtilisin gene from *Pyrococcus furiosus* as a processing aid in the production of potable alcohol.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of subtilisin from a genetically modified strain of *B. licheniformis* containing the subtilisin gene from *Pyrococcus furiosus,* as a processing aid in the production of potable alcohol.

Due to the voluntary nature of the permission, manufacturers would only use this subtilisin preparation as a processing aid (enzyme) in the production of potable alcohol, where they believe a net benefit exists for them. Part of any cost savings to industry may be passed onto consumers. There may be small and likely inconsequential costs of monitoring an extra GM food ingredient for regulators to ensure compliance with labelling requirements.

FSANZ's assessment at the call for submissions was that the direct and indirect benefits that would arise from permitting the use of subtilisin (EC 3.4.21.62) from a genetically modified strain of *B. licheniformis* containing the subtilisin gene from *Pyrococcus furiosus,* as a processing aid in the production of potable alcohol, most likely outweigh the associated costs.

No further information was received during the consultation process that changed the findings from the analysis of costs and benefits in the call for submissions.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

The Standards in the Code which are relevant to the permitted use of the enzyme processing aid in question apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 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 subtilisin (EC 3.4.21.62) from a genetically modified strain of *B. licheniformis* containing the subtilisin gene from *Pyrococcus furiosus*, as a processing aid in the production of potable alcohol.

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

Existing labelling requirements in the Code relevant to subtilisin are discussed in section 2.3.2 of the report above. FSANZ considers those requirements would enable consumers to make informed choices.

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

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

In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex Alimentarius 'general standard' for enzymes. However, Novozymes provided evidence that their subtilisin enzyme preparation complies with the purity criteria for Enzyme Preparations in Food in Food Chemicals Codex (FCC 2018) and conforms to the JECFA specification for enzyme preparations (JECFA 2006).

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

Permission to use this enzyme will help foster continued innovation and improvements in food manufacturing techniques and processes. It is appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme as an alternative to those currently permitted.

Its approval will also allow for Australia and New Zealand to be competitive with other international markets where this enzyme is used. FSANZ understands that the use of enzymes in foods is not restricted or specifically regulated in a number of countries.

Regulation (EC) No 1332/2008 (the Regulation) harmonises the rules for food enzymes in the European Union (EU) (EC 2008). 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 subsequent approval 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 2021), EU Member States' legislation applies.

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

3 References

EC (2008) Regulation (EC) No 1332/2008 of 16 December 2008 on food enzymes. Accessed 10 February 2021.

FCC (2018) Enzyme preparations. In: *Food Chemicals Codex*, 11th edition. Rockville (MD): United States Pharmacopeial Convention

International Union Of Biochemistry And Molecular Biology (IUBMB) 2020, https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC34/3421a.html#2162. Accessed 10 February 2021

JECFA (2006) General Specifications and Considerations for Enzyme Preparations. In: *Combined Compendium of Food Additive Specifications [Online Edition].* World Health Organization, Geneva, Switz. Available at: http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/. Accessed 10 February 2021

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 draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1206 – Subtilisin from GM *Bacillus licheniformis* as a processing aid (enzyme)) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert name and title of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 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 A1206 – Subtilisin from GM* 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 into the table to subsection S18—9(3), in alphabetical order

Subtilisin (EC 3.4.21.62) sourced from *Bacillus licheniformis* containing the gene for subtilisin from *Pyrococcus furiosus*	For use in the production of potable alcohol.	GMP

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 A1206 which seeks to permit the use of subtilisin (EC 3.4.21.62) from a genetically modified strain of *Bacillus licheniformis* (*B. licheniformis*) containing the subtilisin gene from *Pyrococcus furiosus*, as a processing aid in the production of potable alcohol. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting,[3] 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 draft variation amending the table to subsection S18—9(3) of the Code to permit the use of the enzyme subtilisin (EC 3.4.21.62) sourced from *B. licheniformis* containing the gene for subtilisin from *Pyrococcus furiosus,* as a processing aid in the production of potable alcohol.

3. Documents incorporated by reference

The variation in this instrument does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1206 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 3 December 2020 for an eight-week consultation period.

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

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

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] inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry consists of the enzyme subtilisin (EC 3.4.21.62) sourced from *Bacillus licheniformis* containing the gene for subtilisin from *Pyrococcus furiosus*, as a processing aid in food for a specific technological purpose.

The technological purpose is for use in the production of potable alcohol.

The permission is subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with good manufacturing practice.