7 October 2014
[20–14]

Approval Report – Application A1091

Enzyme Nomenclature Change – Carboxyl Proteinase to Aspergillopepsin I & II

Food Standards Australia New Zealand (FSANZ) has assessed an application made by the Australian Wine Research Institute to amend Standard 1.3.3 - Processing Aids. The amendments update the current entry for the enzyme carboxyl proteinase to reflect a change to the naming and classification of carboxyl proteinase enzymes made by the International Union of Biochemistry and Molecular Biology.

On 3 June 2014, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 18 September 2014. The Australia and New Zealand Ministerial Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 3 October 2014.

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

[1] convening as the Australia and New Zealand Food Regulation Ministerial Council

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Executive summary

FSANZ received an Application to amend Standard 1.3.3 – Processing Aids in the *Australia New Zealand Food Standards Code* (the Code) from the Australian Wine Research Institute.

The purpose of the Application is to update the Table to clause 17 of Standard 1.3.3 to reflect a change to the naming and classification of carboxyl proteinase enzymes that was made by the International Union of Biochemistry and Molecular Biology (IUBMB). The Application requests that the enzyme carboxyl proteinase is updated and replaced with Aspergillopepsin I and Aspergillopepsin II. The justification for the changes is to align them with current international enzyme nomenclature recommendations (IUBMB, 1992).

FSANZ understands that the IUBMB's change in nomenclature was the result of an IUBMB review of its rules for naming and classifying enzymes. Enzyme names that end in '-ase' can no longer refer to groups of enzymes (as was the case with carboxyl proteinase); such names can only apply to single catalytic entities. Also, the IUBMB recommendations no longer use 'proteinase', as it has determined that 'peptidase' is a term that more accurately reflects the catalytic activity of these enzymes. IUBMB has updated the carboxyl proteinase category in accordance with these rules by splitting the category into smaller groups of enzymes with names that reflect their microbiological source.

The current permissions for carboxyl proteinase in Standard 1.3.3 permit enzymes from four microbiological sources only: *Aspergillus melleus, A. niger, A. oryzae* and *Rhizomucor miehei*. Aspergillopepsin I and II enzymes are the only IUBMB replacements for carboxyl proteinase that have *A. niger* and *A. oryzae* listed as their source microorganisms. *A. melleus* is not listed as a source for any of the twelve new enzymes (including the two enzymes requested by the Applicant) or as a source for any other functionally related enzyme. FSANZ also notes that an existing entry for the mucorpepsin in the Table to clause 17 of Standard 1.3.3 can provide the source permission for *Rhizomucor miehei* that is currently listed in the carboxyl proteinase entry. Therefore, replacing the carboxyl proteinase permission with permissions for Aspergillopepsin I and II enzymes, using *A. niger* and *A. oryzae* source microorganisms, is consistent with IUBMB recommendations and will reflect the current range of permitted enzymes.

Submitters to the Call for Submissions report supported the proposed changes to the Code, and did not raise any other matters for consideration. Therefore, FSANZ has approved the variations to the Code without any further modifications from the previous version of the drafting. This means that the carboxyl proteinase entry in the Table to clause 17 of Standard 1.3.3 can be replaced with two new entries for Aspergillopepsin I and Aspergillopepsin II. The microbiological sources for the Aspergillopepsin I and II entries are to be *Aspergillus niger and Aspergillus oryzae, and Aspergillus niger* respectively.

1 Introduction

1.1 The Applicant

The Australian Wine Research Institute Ltd (AWRI) is an organisation that supports Australian grape and wine producers with new innovations, tools and practices for their businesses.

1.2 The Application

The Application was received by FSANZ on 19 September 2013. The purpose of the Application was to update the Table to clause 17 of Standard 1.3.3 – Processing Aids to reflect a change to the naming and classification of carboxyl proteinase enzymes that was made by the International Union of Biochemistry and Molecular Biology (IUBMB). The IUBMB is a not-for-profit organisation that promotes research and education in biochemistry and molecular biology throughout the world and is viewed internationally as the authority for enzyme nomenclature. Previous IUBMB nomenclature recommendations have formed the basis for the names of enzymes that are currently listed in Standard 1.3.3.

The IUBMB currently recommends (IUBMB, 1992) that carboxyl proteinase enzymes (EC[2] 3.4.23.6) be split into twelve enzyme categories:

- Aspergillopepsin I (EC 3.4.23.18)
- Aspergillopepsin II (EC 3.4.23.19)
- Penicillopepsin (EC.4.23.20)
- Rhizopepsin (EC 3.4.23.21)
- Endothiapepsin (EC 3.4.23.22)
- Mucorpepsin (EC 3.4.23.23)
- Candidapepsin (EC 3.4.23.24)
- Saccharopepsin (EC 3.4.23.25)
- Rhodotorulapepsin (EC 3.4.23.26)
- Physaropepsin (EC 3.4.23.27)
- Acrocylindroopepsin (EC 3.4.23.28)
- Pycnoporopepsin (EC 3.4.23.30)

The Applicant stated that because the current enzyme nomenclature for carboxyl proteinase enzymes is out-of-date, the entry in Standard 1.3.3 should be updated to provide regulatory certainty for the permission to use these enzymes.

1.3 Reasons for accepting the application

The Application was accepted for assessment because it:

- complied with the procedural requirements under subsection 22(2)
- related to a matter that warranted the variation of a food regulatory measure.

1.4 Procedure for assessment

The Application was assessed under the General Procedure.

[2] EC stands for Enzyme Commission number

1.5 The current Standard and details of proposed changes

1.5.1 History of enzyme processing aid regulations

Standard A16 – Processing Aids was introduced into the Australian *Food Standards Code* in 1996, following consideration by the National Food Authority (now FSANZ) under Proposal P86 – Development of a Standard to Regulate Processing Aids. During the consideration of Proposal P86, the National Food Authority adopted the principle of naming and classifying enzyme processing aids according to 1972 IUBMB nomenclature recommendations. This principle was supported by submitters during several rounds of public consultation.

Australia and New Zealand moved to a joint food regulatory system in 2002. As part of this process, FSANZ replaced Standard A16 with Standard 1.3.3 following a review of how processing aids were regulated in both countries. The enzyme processing aid requirements in Standard 1.3.3 were further reviewed in 2008 under Proposal P276 – Review of Processing Aids (Enzymes).

1.5.2 Proposed changes to Standard 1.3.3

Standard 1.3.3 provides permissions to use processing aids in Australian and New Zealand foods. Clause 17 of Standard 1.3.3 specifically relates to enzymes of microbial origin. Clause 17 permits processing aids listed in the Table to clause 17 to be used as enzymes in the manufacture of food, provided that the enzyme derives from the corresponding source(s) specified in the Table. The current entry for carboxyl proteinase in the Table to clause 17 is as follows:

Enzyme	**Source**
Carboxyl proteinase EC 3.4.23.6	*Aspergillus melleus* *Aspergillus niger* *Aspergillus oryzae* *Rhizomucor miehei*

In the original application to FSANZ, the Applicant requested that the carboxyl proteinase entry be deleted and replaced with the following two new entries that reflect IUBMB nomenclature changes:

Enzyme	**Source**
Aspergillopepsin I EC 3.4.23.18	*Aspergillus melleus* *Aspergillus niger* *Aspergillus oryzae* *Rhizomucor miehei*
Aspergillopepsin II EC 3.4.23.19	*Aspergillus niger*

The Applicant stated that the Australian wine industry had recently developed a mixture of Aspergillopepsin I and II enzymes for use in wine processing. AWRI had therefore made the Application to FSANZ to ensure that wine manufacturers have regulatory certainty over the permissions to use this new mixture of enzymes.

Although the IUBMB has reclassified the carboxyl proteinase enzymes into twelve enzyme groups, the Applicant has only requested the inclusion of Aspergillopepsin I and II in the Table to clause 17. The intent is not to add new source organism permissions into the table, but to only update the names for the existing permissions.

2 Summary of the findings

2.1 Risk assessment

FSANZ's approach to date has been to base the name of the enzyme categories in Standard 1.3.3 on those recommended by the IUBMB. As such, it is imperative for FSANZ to ensure that any change to the name of an enzyme category does not change its original functionality or scope of the original permission.

2.1.1 Rationale for the nomenclature change

The IUBMB did not provide a direct rationale for why carboxyl proteinase has been split and renamed into twelve separate enzyme categories. However, it is likely that the IUBMB has removed the carboxyl proteinase enzyme category so that there is no longer any reference to 'proteinase'. IUBMB revised the general principles for naming enzymes in 1992 (IUBMB, 1992), and some of these principles conflict with the name 'carboxyl proteinase':

1. Names purporting to be the names of enzymes, especially those ending in '–ase', should only be used for single enzymes (single catalytic entities), and should not be used for more than one enzyme (carboxyl proteinase was one such name that applied to a group of enzymes).

2. Enzymes are to be principally classified according to the reaction that they catalyse. The IUBMB acknowledged that this principle was difficult to apply to enzymes that begin with the number 3.4, which have now been named as 'peptidases' to reflect their catalytic activity. The difficulty lies with the historical use of 'peptidase' as a category name for only some of the 3.4 enzymes (3.4.11-19), with 'proteinase' used for other 3.4 enzymes (3.4.21-99). To resolve this problem, the IUBMB decided that both 3.4.11-19 and 3.4.21-99 enzyme subcategory groups would be referred to as peptidases by using the names 'exopeptidases' and 'endopeptidases' respectively, and that 'proteinase' would no longer be used.

Although the name 'carboxyl proteinase' is no longer used, it is unclear to FSANZ why the enzymes in this category were split into twelve smaller groups. However, the likely reason is that the enzymes names better reflect their microbiological source.

2.1.2 Scope of the carboxyl proteinase category

Carboxyl proteinase was first introduced as the EC 3.4.23.6 enzyme category by the IUBMB in its 1972 set of nomenclature recommendations (IUBMB, 1979). At this time, the category was named 'microbial carboxyl proteinases' and referred to 20 microbial sources for this enzyme category. However, while the current permissions for carboxyl proteinase in Standard 1.3.3 are based on the 1972 recommendations, they do not permit enzymes from all of the listed sources, with only four sources permitted (*A. melleus, A. niger, A. oryzae, R. miehei*).

As discussed, the 1992 IUBMB recommendations (IUBMB, 1992) have split carboxyl proteinase into twelve separate enzyme groups, each with its own microbiological sources. FSANZ has reviewed the IUBMB specifications for these new enzymes, and has determined that the Applicant's selection of names and sources does not completely accord with these requirements. A summary of FSANZ's review is provided in Table 1 below.

Table 1: Revision to the scope of amendments to Standard 1.3.3

Current permissions in Standard 1.3.3			FSANZ's revised amendments		Reason for revision
Enzyme	**Permitted Source**		**Enzyme**	**Permitted Source**	
Carboxyl proteinase	*A. melleus*	→			Not recognised by the IUBMB as a source of these enzymes, and therefore cannot be used as a source of carboxyl proteinase
	A. niger	→	Aspergillopepsin I and II	*A. niger*	Recognised by IUBMB as a source of EC 3.4.23.18 and EC 3.4.23.19
	A. oryzae	→	Aspergillopepsin I	*A. oryzae*	Recognised by IUBMB as a source of EC 3.4.23.18 (but not EC 3.4.23.19)
	R. miehei	⇢	Mucorpepsin (already in Standard 1.3.3, so no change resulting from changes to carboxyl proteinase)	*R. miehei*	Mucorpepsin is one of the twelve enzymes that replace carboxyl proteinase. *R. miehei* is recognised by IUBMB as a source of Mucorpepsin but not Aspergillopepsin I or II.
Mucorpepsin	*R. miehei*	⇢	Mucorpepsin (no change to entry in Standard 1.3.3)	*R. miehei*	No change, as this permission already exists in Standard 1.3.3.

IUBMB does not list either *A. melleus* or *R. miehei* as microbiological sources of Aspergillopepsin I. *A. melleus* is not listed as a source for any of the twelve new enzymes (including the two enzymes requested by the Applicant) or as a source for any other functionally related enzyme. IUBMB lists *A. melleus* as a source for oryzin – EC 3.4.21.63 only. However one of the new enzymes – mucorpepsin (EC 3.4.23.23) – does have *R. miehei* listed as a source microorganism.

Aspergillopepsin I and II categories (EC 3.4.23.18 and 3.4.23.19) are the only new enzymes that have *A. niger* and *A. oryzae* as their source microorganisms. Replacing carboxyl proteinase with these two new enzyme groups, using these source microorganisms only, is therefore consistent with IUBMB recommendations. Mucorpepsin is already listed in the Table to clause 17 of Standard 1.3.3 and so the table does not need to be updated to provide permission to use the currently permitted enzymes that are derived from *R. miehei*.

2.2 Risk management

The risk assessment shows that the description of the enzymes and source organisms proposed by the Application are equivalent to the original carboxyl proteinase enzymes, and that *A. melleus* and *R. miehei* do not have to be listed as microbiological sources. At the Call for Submissions on Application A1091, FSANZ's draft variation reflected these findings by adding the Applicant's proposed Aspergillopepsin I and II entries to the Table to clause 17 of Standard 1.3.3, but without listing *A. melleus* or *R. miehei* as source microorganisms. The Applicant was informed of the modification to their original application, and agreed to the revised variation. It should be noted that the removal of *A. melleus* as a source of these enzymes will not adversely affect industry manufacturing practices, as carboxyl proteinase enzymes could not be previously sourced from this organism. As stated in Section 2.1.2 above, the mucorpepsin entry provides for enzyme processing aids derived from *R. miehei*.

Because the proposed changes do not alter the range of permitted enzyme processing aids, they do not need to be accompanied by any further risk management strategies to manage public health and safety risks. Additionally, processing aids do not have to be labelled in the ingredient list of foods, since they do not have a technological function in the final product. The change in enzyme naming and categorisation will therefore have no impact on labelling requirements within the Code.

Therefore, this Application does not require the implementation of any new specific risk management measures or alteration to existing strategies.

2.3 Cost benefit analysis

Following the receipt of submissions, all of which supported the variation, the following regulatory options were considered for Application A1091:

1. approve the draft variation to Standard 1.3.3 to replace the carboxyl proteinase entry in the Table to clause 17 with entries for Aspergillopepsin I and II
2. reject the draft variation.

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the Code are analysed using regulatory impact principles. This level of analysis is commensurate to the nature of the Application and significance of the impacts.

FSANZ informed the Office of Best Practice Regulation (OBPR) of this Application and the details of the proposed variation. The OBPR informed FSANZ on 14 March 2014 (OBPR ID 16758) that this Application was likely to have a minor regulatory impact on business and, as such, a Council of Australian Governments (COAG) Regulation Impact Statement did not need to be prepared. However, FSANZ has prepared a limited impact analysis as detailed in the tables below. Our consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative analysis of the options and, in fact, most of the effects that are considered cannot be assigned a dollar value.

Option 1 – Approve the draft variation

Sector	Costs or benefits to sector
Consumers	There should be no measurable impact on consumers, as existing food processing techniques will remain unchanged, and will continue to have the same cost profile.
Industry	There are specific benefits to the wine industry with this option, as they use Aspergillopepsin I and II enzymes as part of wine processing methods. The benefits to industry will not be financial in nature, but will instead be related to certainty over the regulatory status with the use of Aspergillopepsin I and II enzymes. Currently, the Code permits the use of these enzymes, but refers to them by different names. The proposed nomenclature change will allow the industry to be confident that they are permitted to use the enzymes in their manufacturing practices. Industry will also have certainty that where overseas food regulations permit Aspergillopepsin I or II, that the Code also permits these enzymes. This consistency will assist industry in accessing overseas markets.
Governments	Enforcement authorities will benefit from additional clarity in Standard 1.3.3 as to the enzymes that are permitted for use as processing aids (clarity on the correct names and classification of enzymes). There are no costs to governments from this draft variation.

Option 2 – Reject the draft variation

Sector	Costs or benefits to sector
Consumers	There are no benefits or costs to consumers of this option.
Industry	There are no benefits to industry with this option. However, having the out-of-date 'carboxyl proteinase' enzyme name and category means that uncertainty will remain for industry as to whether this permission applies to Aspergillopepsin I and II enzymes or not, given that the name and category is no longer recommended for use.
Governments	There are no benefits or costs to governments for this option.

The brief analysis indicates the preferred option is to approve the draft variation to Standard 1.3.3 to replace the carboxyl proteinase entry in the table to clause 17 with entries for Aspergillopepsin I and II. There are no costs linked to updating the nomenclature to the 1992 IUBMB recommendations for Aspergillopepsin I and II or removing the reference to *A. melleus*, while there are benefits to governments and the food industry (especially the wine industry) from improved regulatory clarity associated with the use of these enzymes.

2.4 Summary of submissions

FSANZ received comments from three submitters:

- Food Technology Association of Australia
- New Zealand Ministry for Primary Industries
- Victorian Departments of Environment and Primary Industries and Health

All three submitters expressed support for the proposed variation. No other issues were raised in their submissions.

2.5 Decision

The draft variation as proposed following assessment was approved without change. This means that the carboxyl proteinase entry in the Table to clause 17 of Standard 1.3.3 can be replaced with two new entries for Aspergillopepsin I and Aspergillopepsin II. The microbiological sources for the Aspergillopepsin I and II entries are to be *Aspergillus niger and Aspergillus oryzae, and Aspergillus niger* respectively. The variation takes effect on the date of gazettal.

The approved draft variation is at Attachment A. The explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

2.6 Risk communication

Consultation is a key part of FSANZ's standards development process. Stakeholders are notified of matters relating to applications via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

The process by which FSANZ considers standard 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. Every submission on an application or proposal is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

The submitters to this Application will be informed of the approval decision. Subscribers and interested parties will also be informed via email about the availability of the Approval report.

FSANZ's decision has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review, the Applicant and stakeholders including the public will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.6 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:

2.6.1 Section 29

2.6.1.1 Cost-benefit analysis

FSANZ has undertaken a cost-benefit analysis for Application A1091 as detailed above in Section 2.3.

2.6.1.2 Other measures

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

2.6.1.3 Any relevant New Zealand standards

The draft variation will amend Standard 1.3.3, which is a joint Australia and New Zealand Standard.

2.6.1.4 Any other relevant matters

The Australian Food and Grocery Council provided late comments after the closing date for receipt of submissions. However, FSANZ notes that the AFGC comments accord with those made in other submissions.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

FSANZ is of the view that this Application poses no risk to public health and safety. The assessment of the scope mentioned in Section 2.1.2 demonstrates that the source organisms for Aspergillopepsin I and II, and therefore the types of enzymes that will be permitted, are equivalent to those that were previously available under the carboxyl proteinase entry.

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

FSANZ does not propose any new risk management strategies relating to the provision of information to consumers, because existing strategies provide sufficient risk management. Therefore, the Application has no impact on the provision of information relating to food to enable consumers to make informed choices.

2.6.2.3 The prevention of misleading or deceptive conduct

There will be no changes to food manufacturing as a result of this Application. Therefore, the Application does not increase the potential for misleading or deceptive conduct.

2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the risk assessment which is provided in Section 2.1 of this report.

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

There are no Codex Alimentarius Standards for enzymes. However, Aspergillopepsin I has been provided with a Generally Recognised as Safe (GRAS) status in the United States of America (GRN 000333), although the permitted source organisms differ from those proposed under this Application.

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

The proposed amendments will reflect the terminology being used internationally for carboxyl proteinase enzymes, and so will provide clarity for the food industry when dealing with overseas markets.

- **the promotion of fair trading in food**

The proposed amendments will provide the food industry with greater regulatory clarity and certainty in the use of processing aids. The changes will minimise any barriers to the competitiveness of local manufacturing from the use of enzyme processing aids.

- **any written policy guidelines formulated by the Ministerial Council[3].**

There are no written policy guidelines from the Forum that apply to this Application.

3 Transitional arrangements for Code Revision

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – details of which are on the FSANZ website[4].

[3] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)
[4] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions was released in July 2014.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then be amended to incorporate any outstanding changes made to the current Code. The amendment to the new Code resulting from Application A1091 is provided at Attachment C.

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025

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

Food Standards (A1091 – Enzyme Nomenclature Change – Carboxyl Proteinase to Aspergillopepsin I & II) 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 Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
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 (A1091 – Enzyme Nomenclature Change – Carboxyl Proteinase to Aspergillopepsin I & II) 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] Standard 1.3.3 is varied by

[1.1] omitting from the Table to clause 17

“

Carboxyl proteinase EC 3.4.23.6	*Aspergillus melleus* *Aspergillus niger* *Aspergillus oryzae* *Rhizomucor miehei*

”

[1.2] inserting in the Table to clause 17, in alphabetical order

“

Aspergillopepsin I EC 3.4.23.18	*Aspergillus niger* *Aspergillus oryzae*
Aspergillopepsin II EC 3.4.23.19	*Aspergillus niger*

”

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 A1091 which sought to update the Table to clause 17 of Standard 1.3.3 – Processing Aids to reflect the current naming and classification of carboxyl proteinase enzymes. The Authority has considered the Application in accordance with Division 1 of Part 3 of the FSANZ Act and prepared a draft variation to Standard 1.3.3.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation[5], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft 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 *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved a draft variation to replace the carboxyl proteinase (EC 3.4.23.6) entry in the Table to clause 17 of Standard 1.3.3 with two new entries: Aspergillopepsin I (EC 3.4.23.18) and Aspergillopepsin II (EC 3.4.23.19). This variation updates the naming and classification for the enzymes previously permitted by carboxyl proteinase, so that they are consistent with the current recommendations of the International Union of Biochemistry and Molecular Biology.

The draft variation, along with an existing entry in the Table to clause 17 for mucorpepsin (EC 3.4.23.23), provides equivalent permissions for the use of enzyme processing aids as currently provided by carboxyl proteinase. The draft variation will place *Aspergillus niger* and *A. oryzae* into the microbiological sources column of Aspergillopepsin I, and *A. niger* into the microbiological sources column of Aspergillopepsin II, to ensure that the equivalent range of enzyme processing aids is permitted for use.

3. Documents incorporated by reference

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

[5] convening as the Australia and New Zealand Food Regulation Ministerial Council

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1091 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. A call for submissions (including the draft variation) took place over a six-week consultation period (3 June – 15 July 2014).

A Regulation Impact Statement (RIS) was not prepared because the proposed variation to Standard 1.3.3 is likely to have a minor impact on business and individuals. FSANZ consulted with the Office of Best Practice Regulation to confirm that a RIS was not required.

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

The variation replaces the entry for carboxyl proteinase (EC 3.4.23.6) in the Table to clause 17 of Standard 1.3.3 with entries for Aspergillopepsin I (EC 3.4.23.18) and for Aspergillopepsin II (EC 3.4.23.19).

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025

Background

FSANZ is reviewing the Australian New Zealand Food Standards Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, such as the variations proposed by A1091. This is the rationale for the draft variation below. It is provided for background only. Its content and structure may change as P1025 progresses.

Draft instrument

Food Standards Code—Variation

Made under the *Food Standards Australia New Zealand Act 1991*

1 Name of instrument

This instrument is the *Food Standards Australia New Zealand Code — Revocation and Transitional Variation 2015 (No. 2).*

2 Commencement

This instrument commences on the day after it is registered.

3 Variation of Schedule 18

Schedule 1 varies the Australia New Zealand Food Standards Code – Schedule 18 – Processing aids.

Schedule 1 Variation of Schedule 18

(section 4)

[1] Omit from the table to subsection 18—4(5)

Carboxyl proteinase EC 3.4.23.6	*Aspergillus melleus* *Aspergillus niger* *Aspergillus oryzae* *Rhizomucor miehei*

[2] Insert into the table to subsection 18—4(5), in alphabetical order

Aspergillopepsin I EC 3.4.23.18	*Aspergillus niger* *Aspergillus oryzae*
Aspergillopepsin II EC 3.4.23.19	*Aspergillus niger*