

3 June 2014
[10–14]

Call for submissions – Application A1091

Enzyme Nomenclature Change – Carboxyl Proteinase to Aspergillopepsin I & II

FSANZ has assessed an Application made by the Australian Wine Research Institute to amend the processing aid Standard to update the current entry for the enzyme carboxyl proteinase, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 15 July 2014

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

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

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Executive summary

FSANZ has 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 has assessed this Application from two perspectives: to determine the reason behind the IUBMB nomenclature change for carboxyl proteinase, and to ascertain if the scope of the enzymes proposed by the Applicant matches that of the current permissions in the Code.

The likely reason for the IUBMB's nomenclature change is that IUBMB reviewed 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. Replacing the carboxyl proteinase permission with permissions for these two new enzyme groups, using these source microorganisms, is therefore consistent with IUBMB recommendations. FSANZ notes that an existing entry for the mucorpepsin source microorganism in the Table to clause 17 of Standard 1.3.3 can provide the remaining microbiological source permission (for *Rhizomucor miehei*) that is currently listed in the carboxyl proteinase entry.

FSANZ has therefore concluded that the carboxyl proteinase entry in the Table to clause 17 of Standard 1.3.3 should be replaced with two new entries, Aspergillopepsin I and Aspergillopepsin II. The microbiological sources for these two enzyme names are proposed 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 is 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 3.4.23.6) be split into twelve new 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)
- Pycnoporoepsin (EC 3.4.23.30)

The Applicant has 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 The current Standard and details of proposed changes

1.3.1 History of enzyme processing aid regulations

Standard A16 – Processing Aids was introduced into the Australian *Food Standards Code* in 1996, following consideration by FSANZ under Proposal P86 – Development of a Standard to Regulate Processing Aids. During P86, FSANZ adopted the principle of naming and classifying enzyme processing aids according to 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).

During all of these reviews, FSANZ reaffirmed the use of IUBMB nomenclature as the basis of naming and classifying enzyme processing aids. During Proposal P276, FSANZ proposed to use the 1992 IUBMB recommendations to update the nomenclature for several enzymes (including carboxyl proteinase). However, industry submitter feedback at the time stated that this was unnecessary, and that the preference was to maintain existing nomenclature arrangements in Standard 1.3.3.

1.3.2 Current Standard

Clause 17 of Standard 1.3.3 provides permissions for enzymes of microbial origin that may be used as processing aids in the manufacture of food. The Table to clause 17 lists these enzymes and their permitted microbiological sources, and the current entry for carboxyl proteinase as follows:

Enzyme	Source
Carboxyl proteinase EC 3.4.23.6	<i>Aspergillus melleus</i> <i>Aspergillus niger</i> <i>Aspergillus oryzae</i> <i>Rhizomucor miehei</i>

1.3.3 Proposed changes to Standard 1.3.3

The Applicant has 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	<i>Aspergillus melleus</i> <i>Aspergillus niger</i> <i>Aspergillus oryzae</i> <i>Rhizomucor miehei</i>
Aspergillopepsin II EC 3.4.23.19	<i>Aspergillus niger</i>

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 new 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.

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
- related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

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 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 has not provided 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 split was made to ensure that the enzymes were named to better reflect their microbiological source.

2.1.2 Scope of the carboxyl proteinase category

Carboxyl proteinase was first introduced as the EC¹ 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 (*Aspergillus melleus*, *A. niger*, *A. oryzae*, *Rhizomucor miehei*).

As discussed, the 1992 IUBMB recommendations (IUBMB, 1992) have split carboxyl proteinase into twelve separate new 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.

¹ EC stands for Enzyme Commission number

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	<i>A. melleus</i>	✘→			Not recognised by the IUBMB as a source of these enzymes
	<i>A. niger</i>	→	Aspergillopepsin I and II	<i>A. niger</i>	Recognised by IUBMB as a source of EC 3.4.23.18 and EC 3.4.23.19
	<i>A. oryzae</i>	→	Aspergillopepsin I	<i>A. oryzae</i>	Recognised by IUBMB as a source of EC 3.4.23.18 (but not EC 3.4.23.19)
	<i>R. miehei</i>	- ↘	Mucorpepsin (already in Standard 1.3.3, so no change due to changes to carboxyl proteinase)	<i>R. miehei</i>	Mucorpepsin is one of the twelve enzymes that replace carboxyl proteinase. <i>R. miehei</i> is recognised by IUBMB as a source of Mucorpepsin but not Aspergillopepsin I or II.
Mucorpepsin	<i>R. miehei</i>	↓ →	Mucorpepsin (no change to entry in Standard 1.3.3)	<i>R. miehei</i>	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 (provided *A. melleus* and *R. miehei* are removed as microbiological sources). 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.

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 Risk communication

2.3.1 Consultation

FSANZ has developed and applied a standard communication strategy to this Application. All calls for submissions are notified via the FSANZ 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. 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 Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the COAG Legislative and Governance Forum on Food Regulation (the Forum). 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.

2.3.2 World Trade Organization (WTO)

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

There are no relevant international standards that will be affected, and the proposed variation to the Code will have no effect on imported foods that have used these processing aids, as the current range of enzymes that are permitted for use as processing aids in Standard 1.3.3 will remain unchanged. As such, the proposed variation is unlikely to have a significant effect on international trade, and FSANZ considers a notification to the WTO (under Australia's and New Zealand's obligations to the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement) to be unnecessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

Two regulatory options were considered for Application A1091:

1. prepare a 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 Application.

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 have been analysed using regulatory impact principles.

The level of analysis is commensurate to the nature of the Application and significance of the impacts.

FSANZ has informed the Office of Best Practice Regulation (OBPR) of this Application and the details of the proposed variations. OBPR has informed FSANZ (OBPR, pers. com.)² that this Application is likely to have a minor regulatory impact on business and, as such, a Council of Australian Governments (COAG) Regulation Impact Statement does not need to be prepared. However, FSANZ has prepared a limited impact analysis so that potential costs and benefits are known and accommodated. This analysis is provided in the tables below.

Our consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that are considered cannot be assigned a dollar value.

Option 1 – Prepare a draft variation to Standard 1.3.3

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	<p>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.</p> <p>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. Under this option, a change in the nomenclature to Aspergillopepsin I and II will allow the industry to be confident that they are permitted to use these enzymes in their manufacturing practices.</p> <p>Industry will also have certainty that where overseas food regulations permit enzymes referred to as either Aspergillopepsin I or II, that the Code also permits these enzymes. This consistency will assist industry in accessing overseas markets.</p>
Governments	Government enforcement authorities will benefit from additional clarity in Standard 1.3.3 as to the enzymes that are permitted for use as processing aids (improved clarity on the correct names and classification of enzymes). There are no costs to governments from this Application.

Option 2 – Reject the Application

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.

² OBPR (2014) *personal communication* 14 March 2014. OBPR ID 16758.

Brief analysis indicates the preferred option is to prepare a draft variation to Standards 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.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards, as the changes are to joint Australia and New Zealand standards.

2.4.1.4 Any other relevant matters

There are no other relevant matters.

2.5.1 Subsection 18(1)

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

2.5.1.1 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 permitted under the carboxyl proteinase entry.

2.5.1.2 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.

2.5.1.3 The prevention of misleading or deceptive conduct

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

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 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 promotion of fair trading in food**

The proposed amendments will provide all sectors of the food industry with greater regulatory clarity and certainty in the use of processing aids. These changes will therefore minimise any barriers to the competitiveness of local manufacturing that may exist in respect to the use of enzyme processing aids.

- **any written policy guidelines formulated by the Ministerial Council³.**

There are no written policy guidelines from the COAG Legislative and Governance Forum on Food Regulation that apply to this Application.

3 Conclusion

The conclusion of this report is that the carboxyl proteinase enzyme entry in the Table to Clause 17 of Standard 1.3.3 should be replaced with two new enzymes: Aspergillopepsin I and Aspergillopepsin II. The microbiological sources for these two enzymes are proposed to be *Aspergillus niger* and *Aspergillus oryzae*; and *Aspergillus niger* respectively. A draft variation with these changes has been provided at Attachment A for comment by submitters. The draft variation is intended to take effect on the date of gazettal.

4 Draft variation

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

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

4.2 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

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 will be released in the near future.

³ Now known as the COAG Legislative and Governance Forum on Food Regulation

⁴ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

The FSANZ Board is expected to consider Proposal 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 need to be amended to incorporate any outstanding changes made to the current Code, including the draft variations at Attachment A.

5 References

IUBMB (1979). Enzyme Nomenclature: Recommendations (1978) of the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology. Academic Press Ltd, New York.

IUBMB (1992). Enzyme Nomenclature: Recommendations (1992) of the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology. Academic Press Ltd, California.

Attachments

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

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



Food Standards (A1091 – Enzyme Nomenclature Change – Carboxyl Proteinase to Aspergillopepsin I & II) 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 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	<i>Aspergillus melleus</i> <i>Aspergillus niger</i> <i>Aspergillus oryzae</i> <i>Rhizomucor miehei</i>
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”

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

“

Aspergillopepsin I EC 3.4.23.18	<i>Aspergillus niger</i> <i>Aspergillus oryzae</i>
Aspergillopepsin II EC 3.4.23.19	<i>Aspergillus niger</i>

”

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 (FSANZ) 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 FSANZ 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.

FSANZ has received Application A1091 which seeks 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 FSANZ has considered the Application in accordance with Division 1 of Part 3 of the FSANZ Act and has prepared a draft variation to Standard 1.3.3.

2. Purpose

The draft variation will 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.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, FSANZ's consideration of Application A1091 will include 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) will occur for a six-week consultation period.

A Regulation Impact Statement (RIS) has not been prepared because the proposed variation to Standard 1.3.3 is likely to have a minor impact on business and individuals. FSANZ has consulted with the Office of Best Practice Regulation to confirm that a RIS is 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 carboxyl proteinase (EC 3.4.23.6) entry in the Table to clause 17 of Standard 1.3.3 with Aspergillopepsin I (EC 3.4.23.18) and Aspergillopepsin II (EC 3.4.23.19).