An Alpha-glucosidase Enzyme
from a Recombinant Strain of *Trichoderma reesei*

APPLICATION TO EXTEND THE USE OF A CURRENTLY PERMITTED PROCESSING AID

Food Standards Australia
New Zealand

Applicant: DANISCO NEW ZEALAND LTD

6th October 2021

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APPENDIX A: Technical information

APPENDIX A1 & A2: International Approvals – CONFIDENTIAL ATTACHMENT

EXECUTIVE SUMMARY:

Danisco New Zealand Ltd (IFF) is seeking approval for a "an alpha-glucosidase (EC 3.2.1.20)" enzyme for use as processing aid in brewing application. The enzyme designated as "an α-glucosidase" or "Alpha-glucosidase" throughout the dossier is already approved for use in other food applications by FSANZ.

In October 2019, following an evaluation of DuPont's Application A1169, FSANZ recommended to the Ministerial Forum on Food Regulation this enzyme be approved for use in the manufacture and/or processing of potable alcohol, lysine, organic acids, monosodium glutamate and other biochemicals, and isomalt-oligosaccharides (IMO) and other sweeteners. The Ministerial Forum granted approval in these food applications, and this was subsequently Gazetted to the Joint Australia New Zealand Food Standards Code in January 2020.

The enzyme in this application is the identical to the α-glucosidase in A1169, derived from the same selected non-pathogenic, non-toxigenic strain of *Trichoderma reesei* which has been genetically modified to overexpress the Alpha-glucosidase gene from *Aspergillus niger.*

The enzyme as it is presented in this application is intended for use in brewed beverages. In brewing, Alpha-glucosidase is used by adding it to the mash, to will create IMOs and reduce the share of fermentable sugars in wort. Further to this, by adding Alpha-glucosidase to fermentation, it will eventually break down IMOs and limit dextrins during the fermentation, and this way increase the conversion from starch to alcohol.

In brewing, Alpha-glucosidase is used as a processing aid where the enzyme is either not present in the final beverage or present in insignificant quantities having no function or technical effect in the final beverage.

To assess the safety of the Alpha-glucosidase for use in this application, IFF H&B vigorously applied the criteria identified in the guidelines as laid down by Food Standards Australia New Zealand (FSANZ) utilising enzyme toxicology/safety data, the safe history of use of enzyme preparations from *T. reesei* and of other Alpha-glucosidase enzymes in food, the history of safe use of the *T. reesei* production organism for the production of enzymes used in food, an allergenicity evaluation, and a comprehensive survey of the scientific literature.

In A1169 different endpoints of toxicity were investigated, and the results are evaluated and assessed in this document. In genotoxicity studies, Alpha-glucosidase is not mutagenic, clastogenic or aneugenic.

Based on a worst-case scenario that a person is consuming Alpha-glucosidase from beer products, the calculated Theoretical Maximum Daily Intake (TMDI) will be 0.255 mg TOS/kg body weight/day. This submission describes that this TMDI still offers a 110.6-fold margin of safety.

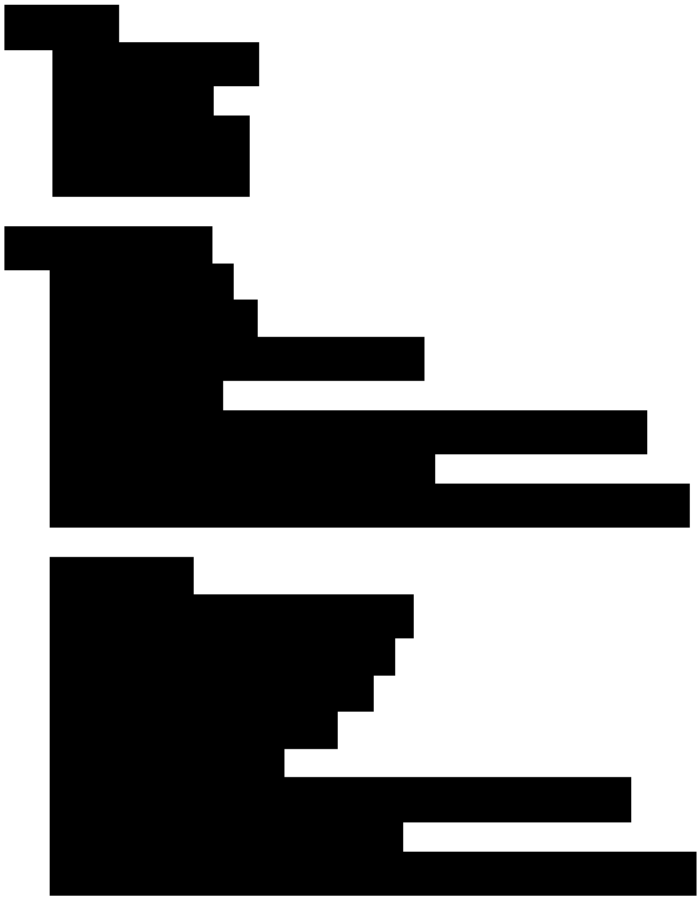
Based on the results of safety studies and other evidence, Alpha-glucosidase has been demonstrated as safe for its intended applications, including brewing and at the proposed usage levels. Approval of this application would provide manufacturers and/or consumers with benefits of facilitating the brewing process and providing differentiated brewed beer products.

General information

1.1 Applicant details

Applicant:

Danisco New Zealand Ltd



Email Address:

See above

Nature of Applicants Business:

Danisco New Zealand Ltd – A subsidiary of International Flavors and Fragrances Inc (IFF), manufacturer/marketer of specialty food ingredients, food additives and food processing aids.

Details of Other Individuals etc.:

No other individuals, companies or organisations are associated with this application.

1.2 Purpose of the application

This application seeks to modify Schedule 18 to Standard 1.3.3 Processing Aids to permit the use of an approved *Processing Aid*, subject of this application. The intended use of the processing aid is brewing.

This application is made solely on behalf of IFF, the manufacturer/marketer of the *Processing Aid*. When approved, the *Processing Aid* would be available for use by any brewed beverage manufacturer in Australia and New Zealand.

Alpha-glucosidase, the subject of this application, is intended for use in brewing, to produce beer products.

Currently, no Alpha-glucosidase from *T. reesei* expressed in *A. niger* is permitted as a Processing Aid, for use in brewing. However, it is permitted for use in the manufacture and/or processing of potable alcohol, lysine, organic acids, monosodium glutamate and other biochemicals, and isomalt-oligosaccharides and other sweeteners. The is also an approval for α-glucosidase from *A. niger* and also *A. oryzae* for general use as processing aids under Schedule 18 to Standard 1.3.3 Processing Aids.

Approval of this application would provide food processors with a new enzyme preparation offering the benefits and advantages discussed in Section 2 and Appendix A.

1.3 Justification for the application

1.3.1. Regulatory Impact Information

A. Costs and Benefits of the application

Alpha-glucosidase is an enzyme produced by submerged fermentation of *T. reesei* carrying the gene encoding the α-glucosidase gene from *A. niger.* alpha-D-glucoside glucohydrolase (EC 3.2.1.20, CAS 9001-42-7). Comprehensive evidence was provided in A1169 to support the safety of the production organism and the enzyme for use the manufacture and/or processing of potable alcohol, lysine, organic acids, monosodium glutamate and other biochemicals, and isomalt-oligosaccharides and other sweeteners.

The enzyme is intended for use in brewing to produce low alcohol or low carbohydrate beer products. Depending on the final product in brewing, Alpha-glucosidase performs its technological function either during mashing, to reduce fermentability and produce low alcohol beer or, during fermentation, to increase fermentability and a produce low calorie/low carb beer product.

More information on the benefits of this enzyme in brewing can be found in Section 2 and Appendix A.

Enzyme preparations are widely used as processing aids in the manufacture of food products. Currently no α-glucosidase from *A. niger* expressed in *T. reesei* is permitted as a processing aid in brewing application. Approval of this application would provide food processors with a new enzyme preparation offering the benefits and advantages as discussed previously.

B. Impact on international trade

An extension to the current approval of α-glucosidase from *A. niger* expressed in *T. reesei* for use of this enzyme in brewing application in the Australia New Zealand Food Standards Code may promote international trade for products produced with this enzyme product and reduce technical barriers to trade.

1.4. Support for the application

No marketing or promotional activities have been undertaken for α-glucosidase from *A. niger* expressed in *T. reesei* in the Australia/New Zealand market. Hence at this stage, no requests from food manufacturers are provided in support of this application. However, the need and justification for use of the processing aid are discussed in Section 1.3, and it is anticipated that support from the food processing industry will be submitted during the period for public comment on the application Draft Regulatory Measure/Assessment Report.

1.5. Assessment Procedure

This application seeks to modify Schedule 18 to Standard 1.3.3 Processing Aids to permit and extension to the use of a Processing aid that is currently permitted. Based on guidance in the Application Handbook, IFF considers General Procedure Level 1 (up to 350 hours) to be the appropriate procedure for assessment of the application.

1.6. Confidential Commercial Information (CCI)

Certain (identified) information included in Appendix A are labelled with Confidential Commercial information is regarded by the applicant as **Confidential Commercial Information** and is provided in the application strictly on this basis. This information is the result of a significant research and development effort and investment by the applicant; it is not in the public domain and is considered as either proprietary or commercially sensitive. It would be disadvantageous to the applicant if this information were released into the public domain.

1.7. Exclusive Commercial Capturable Benefit (ECCB)

According to Section 8 of the FSANZ Act, this application is not expected to confer Exclusive Capturable Commercial Benefit (ECCB).

1.8. International and other National Standards

A detailed overview of the CODEX status, and International and National Standards, that have approved Alpha-glucosidase from A. niger expressed in T. reesei for use in food applications was provided in FSANZ Application A1169 Appendix D, in 2018.

In the time since DuPont Australia Pty Ltd submitted A1169, the approvals for this enzyme in have been issued in other countries. Please refer to Appendix A1 and A2 (**Commercial in Confidence**) for further details.

1.9. Statutory Declaration

I, Caroline Elizabeth Gray,

of 7 Te Kare Rd, Wai O Taiki Bay, Auckland 1072, New Zealand, Regulatory Affairs Manager/Director

make the following declaration under the Oaths and Declaration Act 1959:

1. the information provided in this application fully sets out the matters required; and
2. the information is true to the best of my knowledge and belief; and
3. no information has been withheld which might prejudice this application to the best of my knowledge and belief.

I understand that a person who intentionally makes a f0alse statement in a statutory declaration is guilty of an offence under section 11 of the Statutory Declarations Act 1959, and I believe that the statements in this declaration are true in every particular.

Signature _____

Declared at Auckland on 7th of October 2021

Before me, Laurene Catherine Holley of Auckland, Barrister + Solicitor

_____

Signature

Laurene Holley
Barrister
PO Box 25939 St Helliers
AKLD 1740 Ph: 0274578468

1.10. Checklist

	Mandatory Requirements	Check	Page Number	Remarks
General requirements for applications	A. Form of the application	✓	N.A.	
	Table of contents	✓	1	
	Executive summary	✓	2	
	B. Applicant details	✓	3	Section 1.1
	C. Purpose of application	✓	4	Section 1.2
	D. Justification for the application	✓	4	Section 1.3
	D.1 Regulatory impact information	✓	4	Section 1.3.1
	D.1.1 Costs and benefits of the application	✓	4	Section 1.3.1
	D.1.2 Impact on international trade	✓	5	Section 1.3.1
	E Information to support the application	✓	5	Section 1.4
	E.1 Data requirements	✓	N.A.	
	F. Assessment procedure	✓	5	Section 1.5
	G. Confidential commercial information (CCI)	✓	5	Section 1.6
	H. Other confidential information	✓		
	I. Exclusive capturable commercial benefit (ECCB)	✓	5	Section 1.7
	J. International and other national standards	✓	5	Section 1.8
	J.1 International Standards	✓	5	Section 1.8
	J.2 Other national standards or regulations	✓	5	Section 1.8
	K. Statutory declaration	✓	6	Section 1.9
	L. Checklist	✓	7	Section 1.10
3.3.2. Processing aids	A. Technical information on the processing aid	✓	9	Section 2
	A.1 Information on the type of processing aid	✓	9	Section 2.1
	A.2 Information on the identity of the processing aid	✓	9	Section 2.2
	A.3 Information on the chemical and physical properties of the processing aid	✓	9	Section 2.3
	A.4 Manufacturing process	✓	11	Section 2.4
	A.5 Specification for identity and purity	✓	11	Section 2.5
	A.6 Analytical method for detection	×		Not applicable for enzymes used as processing aids
	B. Information related to the safety of a chemical processing aid	×		Not applicable for enzymes used as processing aids as they are not chemicals
	C. Information related to the safety of an enzyme processing aid	✓	13	Section 3
	C.1 General information on the use of the	✓	13	Section 3

	enzyme as a food processing aid in other countries			
	C.2 Information on the potential toxicity of the enzyme processing aid	✓	13	Section 3
	C.3 Information on the potential allergenicity of the enzyme processing aid	✓	13	Section 3
	C.4 Safety assessment reports prepared by international agencies or other national government agencies, if available	✓	13	Section 3
	D. Additional information related to the safety of an enzyme processing aid derived from a microorganism		13	Section 3
	D.1 Information on the source microorganism	✓	13	Section 3
	D.2 Information on the pathogenicity and toxicity of the source microorganism	✓	13	Section 3
	D.3 Information on the genetic stability of the source organism	✓	13	Section 3
	E. Additional information related to the safety of an enzyme processing aid derived from a genetically-modified microorganism		13	Section 3
	E.1 Information on the methods used in the genetic modification of the source organism	✓	13	Section 3
	F Information related to the dietary exposure to the processing aid		13	Section 4
	F.1. A list of foods or food groups likely to contain the processing aid or its metabolites	✓	13	Section 4.1
	F.2 The levels of residues of the processing aid or its metabolites for each food or food group	✓	13	Section 4.2-4.3
	F.3 For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption	✓	15	Section 4.4
	F.4 The percentage of the food group in which the processing aid is likely to be found or the percentage of the market likely to use the processing aid	✓	16	Section 4.5
	F.5 Information relating to the levels of residues in foods in other countries	✓	16	Section 4.6
	F.6 For foods where consumption has changed in recent years, information on likely current food consumption	✓	16	Section 4.7

2. Technical information

2.1. Type of processing aid

The Alpha-glucosidase enzyme is produced by submerged fermentation of *T. reesei*, carrying the alpha-glucosidase gene from *A. niger*.

This Processing Aid falls into the category "Enzymes of microbial origin" from the Food Standard Code section 1.3.3-6 Enzymes.

2.2. Identity

2.2.1 Chemical/Common Name:

The systematic name of the principle enzyme activity is alpha-D-glucoside glucohydrolase. Other names used are acid maltase, glucoinvertase, glucosidosucrase, lysosomal alpha-glucosidase, maltease, myltase-glucoamylase.

- EC number: 3.2.1.20
- CAS number: 9001-42-7

The enzyme described in this dossier was also identified historically as Transglucosidase (EC 2.4.1.24), with synonyms oligoglucan-branching glycosyltransferase; 1,4-alpha-D-glucan 6-alpha-D-glucosyltransferase; T-enzyme; D-glucosyltransferase; and 1,4-alpha-D-glucan:1,4-alpha-D-glucan (D-glucose) 6-alpha-D-glucosyltransferase.

Biological source: The Alpha-glucosidase enzyme is an enzyme produced by submerged fermentation of *Trichoderma reesei*, carrying the alpha-glucosidase gene from *Aspergillus niger*.

2.2.2 Marketing Name of the Processing Aid:

The marketing name of this enzyme preparation will depend on the application. An example marketing name of the Alpha-glucosidase DIAZYME TGO®.

2.2.3 Molecular and Structural Formula:

The enzyme Alpha-glucosidase is a protein. The amino acid sequence is known refer to A1169 Appendix E4 (**Confidential Commercial Information**) for details.

2.3. Chemical and physical properties

As detailed in A1169, the primary function of Alpha-glucosidase is to produce isomalto-oligosaccharides (IMOs), by splitting maltose, releasing a glucose, and adding to other glucose moity to another sugar with an α-1,6 -link to form IMO. It has also been found that, in the absence of maltose, the trans-glucosidase break down IMOs and other saccharides to glucose. Both of these functions have potential application in brewing.

When added to the mash earlier in the brewing process, under controlled conditions Alpha -glucosidase will act to produce IMOs, resulting in a low alcohol beer product. When added later

in the process, during fermentaion after the malotse has been used up, Alpha-glucosidase will convert the IMO's to glucose and other saccharides resulting in a low carbohydrate beer product.

Depending on the application and conditions of use, α-glucosidase can have the following benefits in brewing:

- Production of a low carbohydrate beer, thus a lower calorie product.
- Lower alcohol content as required in the 'light' beer category.
- Improved processes - better, quicker and more stable process.

For further details on the efficicacy and benefits for the use of Alpha-glucosidase in brewing please refer to Appendix A, Section 1.

Appearance:

Brown liquid.

Substrate specificity:

In the synthetic or transfer reaction, Alpha-glucosidase hydrolyses and transfers an alpha-Dglucosyl units of oligosaccharides and convert 1,4 glucosidic linkage to 1,6 glucosidic linkages. Transfer occurs most frequently to HO-6 (the hydroxy group at the 6-position), producing isomaltose from D-glucose, and panose from maltose.

When the enzyme is present in a solution, where no or little terminal, nonreducing (1->4)-linked alpha-D-glucose residues are present, the enzyme' reaction is to decompose IMO and limit dextrins to glucose, by hydrolysing the 1,6 glucosidic linkages as well as the 1,4 glucosidic linkages.

Activity:

In the decomposition or hydrolysis reaction, the activity of the Alpha-glucosidase is defined in U (units) /g. This activity is measured based on the ability of alpha-glucosidase enzyme to catalyse the hydrolysis of p-nitrophenyl-alpha-D-glucopyranoside (PNPG) to glucose and p-nitrophenol. At an alkaline pH, the nitrophenol forms a yellow color that is proportional to alpha-glucosidase activity and is monitored at 420nm via the use of an enzyme standard.

In the synthetic or transfer reaction, the activity of the Alpha-glucosidase is defined in TGU (Transglucosidase Unit). TGU is defined as the amount of enzyme which will produce one micromole of trisaccharide per minute under assay conditions.

Temperature optimum:

Approximately 58-70°C, with activity observed from 30°C until 90°C.

Thermal stability:

The enzyme is relatively stable for 30 minutes at 60°C, while it is inactivated after 30 minutes of incubation at 71°C.

pH optimum:

Approximately below pH 5.6.

pH stability:

The enzyme exhibits activity at pH <8.3.

Please refer to A1169, Appendix A, Section 2, for additional details relevant to the chemical and physical specifications for Alpha-glucosidase including enzyme activity, temperature optimum, thermal stablity, pH optimum and pH stablity.

Interaction of the enzyme with different foods:

The Alpha-glucosidase enzyme preparation will be used as a processing aid where the enzyme is not present or active in the final food or present in negligible amounts with no technical function in the final food.

Nutritional implication:

Alpha-glucosidase is a protein and any residual amounts remaining in food consumed would accordingly have the same nutritional value. However, the use levels of Alpha-glucosidase are very low, and as with other enzymes that are currently approved and used as Processing Aids, use of this preparation in foods would not have any nutritional significance.

2.4. Manufacturing process

The enzyme is produced by a submerged fermentation process using appropriate substrate and nutrients. When fermentation is complete, the biomass is removed by centrifugation/filtration. The remaining fermentation broth containing the enzyme is filtered and concentrated. The concentrated enzyme solution is then standardised and stabilised with diluents. Finally, a polish filtration is applied.

Full details on the manufacturing process including the raw materials used were provided in the Appendix A (section 4) and Appendix E5 (**Confidential Commercial Information)** of Application A1169. The manufacturing process and materials, as detailed in A1169, have not changed in the time since the initial application was lodged.

The production of Alpha-glucosidase is monitored and controlled by analytical and quality assurance procedures that ensure that the finished preparation complies with the specifications and is of the appropriate quality for use as a processing aid in food processing applications.

2.5. Specification for identity and purity

Impurity profile:

Appropriate GMP controls and processes are used in the manufacture of Alpha-glucosidase to ensure that the finished preparation does not contain any impurities of a hazardous or toxic nature. The specification for impurities and microbial limits is as follows:

Metals:	
Lead	less than 5 mg/kg
Microbiological:	
Total viable count	less than 10,000 CFU/g
Total coliforms	less than 30 CFU/g
E. coli	absent in 25g
Salmonella	absent in 25g

Antibiotic activity	Negative by test
Production strain	Negative by test
Physical properties:	
Appearance	brown liquid

Standard for identity:

Alpha-glucosidase meets the specifications laid down by the Joint FAO/WHO Expert Committee on Food Additives and the Food Chemicals Codex.

3. Safety

The safety of Alpha-glucosidase derived from a selected non-pathogenic, non-toxigenic strain of *Trichoderma reesei,* which is genetically modified to overexpress the alpha-glucosidase gene from *Aspergillus niger,* was established in A1169. IFF refers the FSANZ to Section 3 of the submitted A1169 dossier which addresses the following requirements of Section C, Section D, and Section E of Part 3.3.2 of Chapter 3.3 of the Food Standards Australia New Zealand Application Handbook, including:

- Information related to the safety of an enzyme processing aid
- Additional information related to the safety of an enzyme processing aid derived from a microorganism
- Additional information related to the safety of an enzyme processing aid derived from a genetically-modified microorganism
- Additional information related to the safety of an enzyme processing aid derived from a genetically-modified microorganism

4. Dietary Exposure

4.1. List of food or food groups likely to contain the enzyme or its metabolites

According to the food group classification system used in Standard 1.3.1 Food Additives Schedule 15 (15-5), aside from those applications currently listed as approved under S18-9, Schedule 18 to Standard 1.3.3 Processing Aids, Alpha-glucosidase will additionally be used in:

- 14.2.1 Beer and related products

4.2. Levels of residues in food

The proposed application rate of Alpha-glucosidase in its intended application is listed below.

Application	Raw material (RM)	Recommended use levels (mg TOS/kg RM)	Maximal recommended use levels (mg TOS/kg RM)
Brewing	Cereals	40-60	60

As outlined in previous sections, in beer making, Alpha-glucosidase performs its technological function at either the mashing step or in the fermentation. IFF expects the Alpha-glucosidase to be inactivated or removed during the subsequent production and refining processes for all applications.

Brewing processes adds to the category liquid foods.

Raw materials used in brewing processes are various kinds of cereals (e.g. malt, barley, wheat, sorghum and maize). Yields will vary dependent on the type of cereal, process used, and the type of drink produced.

Beer production has a range of raw material to final food (RM/FF) from 14-28 kg of grist per 100L of beer, with 80-90 % of all beers produced at a RM/FF ratio of 14-20 kg of grist per 100 L of beer.

The assumption used for calculation of dietary exposure is a yield of 100L of drink per 17 kg of cereal corresponding to a RM/FF ratio of 0.17 kg grist per L of beer.

The most appropriate way to estimate the human consumption in the case of food enzymes is using the Budget Method (Hansen, 1966; Douglass *et al.*, 1997). This method enables one to calculate a Theoretical Maximum Daily Intake (TMDI) based on conservative assumptions regarding physiological requirements for energy from food and the energy density of food rather than on food consumption survey data.

The Budget Method was originally developed for determining food additive use limits and is known to result in conservative estimations of the daily intake.

The Budget Method is based on the following assumed consumption of important foodstuffs and beverages (for less important foodstuffs, e.g., snacks, lower consumption levels are assumed):

Average consumption over the course of a lifetime/kg body weight/day	**Total solid food (kg)**	**Total non-milk beverages (l)**	**Processed food (50% of total solid food) (kg)**	**Soft drinks (25% of total beverages) (l)**
	0.025	0.1	**0.0125**	**0.025**

In addition to the assumptions from the Budget Method, it is assumed that beer is consumed in the same amount as soft drinks (25% of total liquid intake).

4.3. Exposure Assessment

The recommended use levels of the enzyme Alpha-glucosidase are given (Section 4.2), based on the raw materials used in the various food processes. For the calculation of the Theoretical Maximium Daily Intake (TMDI), the maximum use levels are chosen. Furthermore, the calculation considers how much food or beverage is obtained per kg raw material, and it is assumed that all the TOS will end up in the final product.

Application		**Raw material (RM)**	**Maximal recommended use level (mg TOS/kg RM)**	**Example Final food (FF)**	**Ratio RM/FF**	**Maximal level in FF (mg TOS/kg food)**
Beverages	Brewing processes	wort	60	Beer	0.17	**10.2**

The Total TMDI can be calculated on basis of the maximal values found in food and beverages multiplied by the average consumption of food and beverages pr kg body weight/day, which in this case is bread and soft drinks. Consequently, the Total TMDI will be:

TMDI in food (mg TOS/kg body weight/day)	TMDI in beverage (mg TOS/kg body weight/day)	Total TMDI (mg TOS/kg body weight/day)
0	10.2 x 0.025=0.255	**0.255**

From previous calculations of Alpha-glucosidase use in A1169 estimation of the TMDI for liquid foods was 0.168 mg TOS /kg BW/day and for solid foods it was 0.275 mg TOS/kg BW/day.

TMDI Total:

TMDI – Liquid Foods + TMDI – Solid Foods = 0.443 mg/TOS kg bw

0.443 mg/TOS kg bw + 0.255 mg/TOS kg bw (from beer) = 0.698 mg/TOS kg bw

Determination of the Margin of Safety

The margin of safety is calculated by dividing the NOAEL obtained from the 13-weeks oral (gavage) study in rats by the human exposure (worst case scenario). If the margin of safety is greater than 100, it suggests that the available toxicology data support the proposed uses and application rates.

As described in Application A1169, in the 18-week oral (gavage) study in rats for from Aspergillus niger, a NOAEL was established at 63.64 mg total protein/kg bw/day equivalent to 77.2 mg TOS kg bw/day.

NOAEL: 63.64 mg TP/kg bw/day = 77.2 mg TOS/kg bw/day

$$\text{Margin of Safety} = \frac{NOAEL\ ((mg/kg\ bw)/day)}{Human\ Exposure\ ((mg/kg\ bw)/day)}$$

$$\text{Margin of Safety} = \frac{77.2\ mg\ TOS/kg\ bw/day}{0.698\ mgTOS\ /kg\ bw/day}$$

Margin of Safety = 110.6

Based on a margin of safety of 110.6, the proposed uses of Alpha-glucosidase in brewing are not a human health concern and are supported by existing toxicology data.

4.4. Likely level of consumption of foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs)

Not applicable. Alpha-glucosidase is not expected to be used in production of any foods or food groups that are currently not listed in NNSs. If such usage arises, an application would be made to inform FSANZ.

4.5. Percentage of the food group in which the processing aid is likely to be found or the percentage of the market likely to use the processing aid

The enzyme would be used as a processing aid in about:

- 5% of the tonnage of brewed products sold in Australia and New Zealand

4.6. Levels of residues in food in other countries

Applications and levels of use of the Alpha-glucosidase preparation in other countries is the same as presented in section 4.2.

4.7. Likely current food consumption for foods where consumption has changed in recent years

Not applicable. Consumption of beer products produced with Alpha-glucosidase is not expected to have a significant change.

5. References

Douglass JS, Barraj LM, Tennant DR, Long WR, Chaisson CF (1997). Evaluation of the Budget Method for screening food additive intakes. Food Additives and Contaminants, 14, 791-802

Hansen, S.C. (1996). Acceptable daily intake of food additives and ceiling on levels of use. Food Cosmet. Toxicol., 4, 427-432.