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Updated safety evaluation of the food enzyme α-amylase from the non-genetically modified *Cellulosimicrobium funkei* strain AE-AMT

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Abstract

The food enzyme α-amylase (4-α-D-glucan glucanohydrolase; EC 3.2.1.1) is produced with the non-genetically modified *Cellulosimicrobium funkei* strain AE-AMT by Amano Enzyme Inc. In a previous opinion, a safety evaluation of this food enzyme was completed, in which EFSA concluded that this food enzyme did not give rise to safety concerns when used in starch processing for maltodextrin production. The applicant has now provided new data to extend the use of this food enzyme to six additional food manufacturing processes: baking processes, cereal-based processes, plant processing for the production of dairy analogues, processing of tea, herbal and fruit infusions, brewing processes and the production of non-wine vinegar. For its use in a total of seven food manufacturing processes, the dietary exposure to the food enzyme–total organic solids (TOS) was estimated to be up to 0.012 mg TOS/kg body weight (bw) per day in European populations. Using the toxicological data provided in the previous opinion, with a NOAEL of 230 mg TOS/kg bw per day (the highest dose tested), the Panel derived a margin of exposure of at least 19,167. Based on the revised exposure calculation and the outcome of the previous evaluation, the Panel concluded that this food enzyme does not give rise to safety concerns under the revised intended conditions of use.

Keywords: food enzyme, α-amylase, EC 3.2.1.1, 4-α-D-glucan glucanohydrolase, *Microbacterium imperial*, *Cellulosimicrobium funkei*

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1. Introduction

Article 3 of the Regulation (EC) No 1332/2008[1] provides definition for 'food enzyme' and 'food enzyme preparation'.

'Food enzyme' means a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms: (i) containing one or more enzymes capable of catalysing a specific biochemical reaction; and (ii) added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods.

'Food enzyme preparation' means a formulation consisting of one or more food enzymes in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.

Before January 2009, food enzymes other than those used as food additives were not regulated or were regulated as processing aids under the legislation of the Member States. On 20 January 2009, Regulation (EC) No 1332/2008 on food enzymes came into force. This Regulation applies to enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food, including enzymes used as processing aids. Regulation (EC) No 1331/2008[2] established the European Union (EU) procedures for the safety assessment and the authorisation procedure of food additives, food enzymes and food flavourings. The use of a food enzyme shall be authorised only if it is demonstrated that:

- it does not pose a safety concern to the health of the consumer at the level of use proposed;
- there is a reasonable technological need;
- its use does not mislead the consumer.

All food enzymes currently on the European Union market and intended to remain on that market, as well as all new food enzymes, shall be subjected to a safety evaluation by the European Food Safety Authority (EFSA) and approval via an EU Community list.

The 'Guidance on submission of a dossier on food enzymes for safety evaluation' (EFSA, 2009a) lays down the administrative, technical and toxicological data required.

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background as provided by the European Commission

Only food enzymes included in the Union list may be placed on the market as such and used in foods, in accordance with the specifications and conditions of use provided for in Article 7(2) of Regulation (EC) No 1332/2008[1] on food enzymes.

Alpha-Amylase from a non-genetically modified strain of *Microbacterium imperial* (strain AE-AMT) is a food enzyme included in the Register of food enzymes[3] to be considered for inclusion in the Union list and thus subject to a risk assessment by the European Food Safety Authority (EFSA). On 7 July 2022, EFSA concluded that this food enzyme does not give rise to safety concerns under the intended conditions of use in starch processing to produce maltodextrin.

On 24 June 2022, a new application has been introduced by the applicant "Amano Enzyme Inc" for an extension of the conditions of use for the above food enzyme in starch processing for the production of maltodextrin, baking processes, dairy analogue production, cereal-based processes, processing of tea, herbal and fruit infusions and brewing processes.

1.1.2. Terms of Reference

The European Commission requests the European Food Safety Authority to carry out the safety assessment and the assessment of possible confidentiality requests of an extension of the condition of use for the following food enzyme: Alpha-Amylase from a non-genetically modified strain of *Microbacterium imperial* (strain AE-AMT), in accordance with Regulation (EC) No 1331/2008

[1] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on Food Enzymes and Amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97. OJ L 354, 31.12.2008, pp. 7–15.

[2] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 354, 31.12.2008, pp. 1–6.

[3] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_enzymes_register.pdf

establishing a common authorization procedure for food additives, food enzymes and food flavourings.[4]

1.1.3. Interpretation of the Terms of Reference

The present scientific opinion addresses the European Commission's request to carry out the safety assessment of an extension of the conditions of use for the food enzyme α-amylase from *Microbacterium imperial* strain AE-AMT.

The production microorganism was reclassified as *Cellulosimicrobium funkei* at the species level in the previously published scientific opinion (EFSA CEP Panel, 2022). Therefore, EFSA continued to use the name *C. funkei* (instead of *M. imperial*) also in the present opinion.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier in support of the application for the authorisation of the extension of use of the food enzyme α-amylase from non-genetically modified *C. funkei* (strain AE-AMT).

Additional information was requested from the applicant during the assessment process on 13 February 2023 and received on 15 February 2023 (see 'Documentation provided to EFSA').

2.2. Methodologies

The assessment was conducted in line with the principles described in the EFSA 'Guidance on transparency in the scientific aspects of risk assessment' (EFSA, 2009b) and following the relevant existing guidance documents of EFSA Scientific Committee.

The current 'Scientific Guidance for the submission of dossiers on Food Enzymes' (EFSA CEP Panel, 2021a) has been followed for the evaluation of the application.

2.3. Public consultation

According to Article 32c(2) of Regulation (EC) No 178/2002[5] and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 16 May to 6 June 2023. No comments were received.

3. Assessment

IUBMB nomenclature	α-amylase
Systematic name	4-α-D-glucan glucanohydrolase
Synonyms	Glycogenase, endo-amylase, Taka-amylase
IUBMB No	EC 3.2.1.1
CAS No	9000-90-2
EINECS No	232–565-6

α-amylases catalyse the hydrolysis of 1,4-α-glucosidic linkages in starch (amylose and amylopectin), glycogen and related polysaccharides and oligosaccharides, resulting in the generation of soluble dextrins and other malto-oligosaccharides.

All aspects concerning the safety of this food enzyme when used in starch processing for maltodextrin production were evaluated in July 2022 (EFSA CEP Panel, 2022). Under the current assessment, EFSA evaluates this food enzyme when used in seven food manufacturing processes: starch processing for maltodextrin production, baking processes, cereal-based processes, plant processing for the production of dairy analogues, processing of tea, herbal and fruit infusions, brewing processes and production of non-wine vinegar.

[4] OJ L 354, 31.12.2008, p. 1.
[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

3.1. Source of the food enzyme

See previous evaluation (EFSA CEP Panel, 2022).

3.2. Production of the food enzyme

See previous evaluation (EFSA CEP Panel, 2022).

3.3. Characteristics of the food enzyme

See previous evaluation (EFSA CEP Panel, 2022).

3.4. Toxicological data

In the previous evaluation, the Panel identified a no observed adverse effect level (NOAEL) of 230 mg total organic solids (TOS)/kg body weight (bw) per day, the highest dose tested (EFSA CEP Panel, 2022).

3.5. Dietary exposure

3.5.1. Revised intended use of the food enzyme

The food enzyme is intended to be used in seven food manufacturing processes at the recommended use levels summarised in Table 1.

Table 1: Intended uses and recommended use levels of the food enzyme as provided by the applicant[6,7]

Food manufacturing process[(a)]	Raw material (RM)	Maximum recommended use level (mg TOS/kg RM)[(b)]
Starch processing to produce maltodextrin	Starch	109.0
Baking processes	Flour	**1.0**
Cereal-based processes	Flour, grains, cereals	**1.0**
Plant processing for the production of dairy analogues	Oat flour, almond flour, rice flour, buckwheat, pulses, legumes, oil seeds, nuts, etc.	**2.0**
Processing of tea, herbal and fruit infusions	Leaf extract	**2.0**
Brewing processes	Rice, cereals	**0.2**
Production of non-wine vinegar	Corn, wheat, rice	**2.0**

TOS: total organic solids.
(a): The name has been harmonised by EFSA according to the 'EC working document describing the food processes in which food enzymes are intended to be used' – not yet published at the time of adoption of this opinion.
(b): The numbers in bold were used for calculation.

The use of this food enzyme in starch processing to produce maltodextrin was evaluated previously. The food enzyme–TOS was considered to be removed from the maltodextrin products (EFSA CEP Panel, 2022).

In baking processes, the food enzyme is added to flour during dough preparation.[8] The activity of α-amylase reduces the viscosity of the dough and increases the volume of the final product. The food enzyme remains in the baked foods.

In cereal-based processes, the food enzyme is added to the cereal slurry.[9] The hydrolysis by α-amylase reduces the viscosity of the slurry, facilitating the downstream processing steps, such as extrusion. The food enzyme remains in the final foods, such as breakfast cereals.

[6] Technical dossier/Proposed conditions of use and, where applicable, normal and maximum use levels/p. 10.
[7] Technical dossier/Additional information February 2023.
[8] Technical dossier/Proposed conditions of use and, where applicable, normal and maximum use levels/pp. 1–2.
[9] Technical dossier/Proposed conditions of use and, where applicable, normal and maximum use levels/pp. 4–5.

In the production of dairy analogues, the food enzyme is added to a variety of plant materials together with water during saccharification.[10] α-amylase hydrolyses the gelatinised starch to reduce the viscosity of the slurry, allowing higher inclusion of plant materials in the plant-based beverages and the corresponding fermented semi-solid foods. The present α-amylase hydrolyses starch primarily to maltotriose.[11] The food enzyme remains in the final foods.

In the processing of tea, herbal and fruit infusions, the α -amylase is added to the leaf extracts from *Stevia*. The food enzyme acts on steviol glycosides in *Stevia* leaves, which alters their glycosylation pattern and thus their sensory properties.[12] The food enzyme–TOS remains in the final processed foods.

In brewing processes, the food enzyme is added to cereals at the mashing step.[13] The α-amylase, along with other saccharifying enzymes, converts the liquefied starch to fermentable sugars. The food enzyme–TOS remains in the beer.

In the production of non-wine vinegar, the food enzyme is added to milled grains or cereals during slurry mixing. The food enzyme acts on the starch present in different grains and cereals.[14] The food enzyme–TOS remains in the final processed foods.

Based on the thermostability evaluated previously (EFSA CEP Panel, 2022) and the downstream processing steps applied in the food processes, it is expected that the food enzyme is inactivated in all the relevant final foods.

3.5.2. Dietary exposure estimation

In accordance with the guidance document (EFSA CEP Panel, 2021a), dietary exposure was not calculated for starch processing to produce maltodextrin (EFSA CEP Panel, 2022), but only for the six additional food manufacturing processes, where the food enzyme–TOS remains in the final foods: baking processes, cereal-based processes, plant processing for the production of dairy analogues, processing of tea, herbal and fruit infusions, brewing processes and production of non-wine vinegar.

Chronic exposure to the food enzyme–TOS was calculated by combining the maximum recommended use level with individual consumption data (EFSA CEP Panel, 2021a). The estimation involved selection of relevant food categories and application of technical conversion factors (EFSA CEP Panel, 2021b). Exposure from all FoodEx categories was subsequently summed up, averaged over the total survey period (days) and normalised for bw. This was done for all individuals across all surveys, resulting in distributions of individual average exposure. Based on these distributions, the mean and 95th percentile exposures were calculated per survey for the total population and per age class. Surveys with only day per subject were excluded and high-level exposure/intake was calculated for only those population groups in which the sample size was sufficiently large to allow calculation of the 95th percentile (EFSA, 2011).

Table 2 provides an overview of the derived exposure estimates across all surveys. Detailed mean and 95th percentile exposure to the food enzyme–TOS per age class, country and survey, as well as contribution from each FoodEx category to the total dietary exposure are reported in Appendix A – Tables 1 and 2. For the present assessment, food consumption data were available from 43 dietary surveys (covering infants, toddlers, children, adolescents, adults and the elderly), carried out in 22 European countries (Appendix B). The highest dietary exposure was estimated to be about 0.012 mg TOS/kg bw per day in infants and toddlers at the 95th percentile.

[10] Technical dossier/Proposed conditions of use and, where applicable, normal and maximum use levels/pp. 2–3.
[11] Technical dossier/Proposed conditions of use and, where applicable, normal and maximum use levels/p. 2.
[12] Technical dossier/Proposed conditions of use and, where applicable, normal and maximum use levels/pp. 5–6.
[13] Technical dossier/Proposed conditions of use and, where applicable, normal and maximum use levels/pp. 6–7.
[14] Technical dossier/Proposed conditions of use and, where applicable, normal and maximum use levels/pp. 8–9.

Table 2: Summary of the estimated dietary exposure to the food enzyme–TOS in six population groups

Population group	Estimated exposure (mg TOS/kg body weight per day)					
	Infants	**Toddlers**	**Children**	**Adolescents**	**Adults**	**The elderly**
Age range	3–11 months	12–35 months	3–9 years	10–17 years	18–64 years	≥ 65 years
Min–max mean (number of surveys)	0.001–0.004 (12)	0.003–0.007 (15)	0.004–0.006 (19)	0.002–0.004 (21)	0.001–0.003 (22)	0.001–0.003 (23)
Min–max 95th percentile (number of surveys)	0.003–0.012 (11)	0.007–0.012 (14)	0.006–0.011 (19)	0.003–0.008 (20)	0.003–0.005 (22)	0.002–0.005 (22)

TOS: total organic solids.

3.5.3. Uncertainty analysis

In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2006), the following sources of uncertainties have been considered and are summarised in Table 3.

Table 3: Qualitative evaluation of the influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction of impact
Model input data	
Consumption data: different methodologies/representativeness/underreporting/ misreporting/no portion size standard	+/–
Use of data from food consumption surveys of a few days to estimate long-term (chronic) exposure for high percentiles (95th percentile)	+
Possible national differences in categorisation and classification of food	+/–
Model assumptions and factors	
Exposure to food enzyme–TOS was always calculated based on the recommended maximum use level	+
Selection of broad FoodEx categories for the exposure assessment	+
The consumption data covered all types of tea and herbal infusion products, not only the stevia infusion.	+
Use of recipe fractions to disaggregate FoodEx categories	+/–
Use of technical factors in the exposure model	+/–
Exclusion of one process from the exposure assessment: starch processing to produce maltodextrin	–

+: uncertainty with potential to cause overestimation of exposure.
–: uncertainty with potential to cause underestimation of exposure.

The conservative approach applied to estimate the exposure to the food enzyme–TOS, in particular assumptions made on the occurrence and use levels of this specific food enzyme, is likely to have led to overestimation of the exposure.

The exclusion of one food manufacturing process from the exposure assessment was based on > 99% of TOS removal. This is not expected to have an impact on the overall estimate derived.

3.6. Margin of exposure

A comparison of the NOAEL (230 mg TOS/kg bw per day) identified from the 90-day rat study (EFSA CEP Panel, 2022) with the derived exposure estimates of 0.001–0.007 mg TOS/kg bw per day at the mean and from 0.002–0.012 mg TOS/kg bw per day at the 95th percentile resulted in a margin of exposure (MOE) of at least 19,167.

4. Conclusion

Based on the data on the additional food manufacturing processes, and the evaluation of the data previously submitted, the Panel concludes that the food enzyme α-amylase produced with the non-genetically modified *C. funkei* strain AE-AMT does not give rise to safety concerns under the revised intended conditions of use.

5. Documentation as provided to EFSA

Application for authorisation of α-amylase from *Microbacterium imperial* AE-AMT in accordance with the Regulation (EC) No 1331/2008. June 2022. Submitted by Amano Enzymes Inc.

Additional information. February 2023. Submitted by Amano Enzymes Inc.

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EFSA (European Food Safety Authority), 2011. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. https://doi.org/10.2903/j.efsa.2011.2097

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Abbreviations

bw	body weight
CAS	Chemical Abstracts Service
CEP	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
EC	European Commission
EINECS	European Inventory of Existing Commercial Chemical Substances
EU	European Union
IUBMB	International Union of Biochemistry and Molecular Biology
MoE	margin of exposure
NOAEL	no observed adverse effect level
RM	raw material
TOS	total organic solids

Appendix A – Dietary exposure estimates to the food enzyme–TOS in details

Appendix A can be found in the online version of this output (in the 'Supporting information' section). The file contains two sheets, corresponding to two tables.

Table 1: Average and 95th percentile exposure to the food enzyme–TOS per age class, country and survey.

Table 2: Contribution of food categories to the dietary exposure to the food enzyme–TOS per age class, country and survey.

Appendix B – Population groups considered for the exposure assessment

Population	Age range	Countries with food consumption surveys covering more than day
Infants	From 12 weeks on up to and including 11 months of age	Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Portugal, Slovenia, Spain
Toddlers	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Latvia, Netherlands, Portugal, Republic of North Macedonia*, Serbia*, Slovenia, Spain
Children	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Republic of North Macedonia*, Serbia*, Spain, Sweden
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Bosnia and Herzegovina*, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Montenegro*, Netherlands, Portugal, Romania, Serbia*, Slovenia, Spain, Sweden
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Bosnia and Herzegovina*, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Montenegro*, Netherlands, Portugal, Romania, Serbia*, Slovenia, Spain, Sweden
The elderly[(a)]	From 65 years of age and older	Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Montenegro*, Netherlands, Portugal, Romania, Serbia*, Slovenia, Spain, Sweden

*: Consumption data from these pre-accession countries are not reported in Table 3 of this opinion, however, they are included in Appendix A for testing purpose.

(a): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011).