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SCIENTIFIC OPINION

Safety evaluation of the food enzyme glucan 1,4-α-maltohydrolase from the genetically modified *Saccharomyces cerevisiae* strain LALL-MA+

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Abstract

The food enzyme glucan 1,4-α-maltohydrolase (4-α-D-glucan α-maltohydrolase; EC 3.2.1.133) is produced with the genetically modified *Saccharomyces cerevisiae* strain LALL-MA+ by Danstar Ferment AG. The genetic modifications do not give rise to safety concerns. The food enzyme is free from viable cells of the production organism and its DNA. It is intended to be used in the processing of cereals and other grains for production of baked products. Dietary exposure was estimated to be up to 0.014 mg TOS/kg body weight per day in European populations. Given the QPS status of the production strain and the absence of concerns resulting from the food enzyme manufacturing process, toxicity tests were considered unnecessary by the Panel. A search for the identity of the amino acid sequence of the food enzyme to known allergens was made and four matches were found, three with respiratory allergens and one with an allergen from mosquito (injected). The Panel considered that the risk of allergic reactions upon dietary exposure cannot be excluded, but the likelihood is low. Based on the data provided, the Panel concluded that this food enzyme does not give rise to safety concerns, under the intended conditions of use.

KEYWORDS

4-α-D-glucan α-maltohydrolase, EC 3.2.1.133, EFSA-Q-2023-00533, food enzyme, genetically modified microorganism, glucan 1,4-α-maltohydrolase, maltogenic α-amylase, *Saccharomyces cerevisiae*

CONTENTS

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 microorganisms or products thereof including a product obtained by a fermentation process using microorganisms: (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 EU 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.

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. On 12 June 2023, a new application has been introduced by the applicant "DANSTAR FERMENT AG" for the authorisation of the food enzyme Maltogenic α-amylase from a genetically modified *Saccharomyces cerevisiae* (strain LALL-MA+).

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 the following food enzyme: Maltogenic α-amylase from a genetically modified *Saccharomyces cerevisiae* (strain LALL-MA+) in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.[2]

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a dossier in support of the application for authorisation of the food enzyme glucan 1,4-α-maltohydrolase from a genetically modified *Saccharomyces cerevisiae* (strain LALL-MA+).

Additional information was requested from the applicant during the assessment process on 22 January 2022 and received on 20 February 2024 (see 'Documentation provided to EFSA').

[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.

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, 2009) and following the relevant guidance documents of the EFSA Scientific Committee.

The 'Scientific Guidance for the submission of dossiers on food enzymes' (EFSA CEP Panel, 2021) and the 'Food manufacturing processes and technical data used in the exposure assessment of food enzymes' (EFSA CEP Panel, 2023) have been followed for the evaluation of the application.

2.3 | Public consultation

According to Article 32c(2) of Regulation (EC) No 178/2002[3] 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 5 to 26 March 2024[4] for which no comments were received.

3 | ASSESSMENT

IUBMB nomenclature	Glucan 1,4-α-maltohydrolase
Systematic name	4-α-D-glucan α-maltohydrolase
Synonyms	Maltogenic α-amylase; 1,4-α-D-glucan α-maltohydrolase
IUBMB no	EC 3.2.1.133
CAS no	160611–47-2
EINECS no	630–523-5

Glucan-1,4-α-maltohydrolases catalyse the hydrolysis of 1,4-α-D-glucosidic linkages in starch polysaccharides releasing maltose units from the non-reducing chain ends. The food enzyme under assessment is intended to be used in the processing of cereals and other grains for production of baked products.

3.1 | Source of the food enzyme

The enzyme is produced with the genetically modified yeast *Saccharomyces cerevisiae* strain LALL-MA +, which is deposited at the German Collection of Microorganisms and Cell Cultures (DSMZ, Germany) with the deposit number DSM 34530.[5] The production strain was identified as *S. cerevisiae* by whole genome sequence (WGS) analysis using reference-based read mapping.[6]

The species *S. cerevisiae* is included in the list of organisms for which the qualified presumption of safety (QPS) may be applied, provided that the absence of resistance to antimycotics used for medical treatment of yeast infections is verified in cases where viable cells are added to the food or feed chain, and the genetic modifications do not raise concerns (EFSA, 2007; EFSA BIOHAZ Panel, 2022).[7]

3.1.1 | Characteristics of the parental microorganism

The parental strain is a *S. cerevisiae* identified by WGS and used in industrial bakery.[8]

3.1.2 | Characteristics of introduced sequences

The sequence encoding the glucan 1,4-α-maltohydrolase is a variant [redacted] compared to the wild-type gene *amyM* from *Geobacillus stearothermophilus* which has been [redacted]. The rest of the introduced sequences are from *S. cerevisiae*.

[3]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.

[4]Accessible https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000000DtMr/pc0862.

[5]Technical dossier/ Risk assessment/Source of the food enzyme/p. 1 and Annex 4.

[6]Technical dossier/ Risk assessment/Source of the food enzyme/p. 1 and Annex 1.

[7]https://zenodo.org/records/7554079.

[8]Technical dossier/ Risk assessment/Source of the food enzyme/p. 1.

An expression cassette was constructed, [redacted].[9]

Plasmid [redacted] carries [redacted] resistance [redacted] markers.[10]

3.1.3 | Description of the genetic modification process

The purpose of the genetic modification was to enable the production strain to synthesise [redacted] glucan 1,4-α-maltohydrolase from *G. stearothermophilus*.

For this purpose, the *S. cerevisiae* parental strain was co-transformed with the linear [redacted] along with the [redacted] plasmid [redacted]. The [redacted] cassette was integrated at the [redacted], leading to the deletion of [redacted]. Subsequently, the strain was cured from [redacted] resulting in the production strain *S. cerevisiae* LALL-MA+.[11]

WGS analysis confirmed the integration of [redacted] the [redacted] cassette at the [redacted].[12]

3.1.4 | Safety aspects of the genetic modification

The technical dossier contains all necessary information on the parental microorganism, the donor organism and the genetic modification process.

The production strain *S. cerevisiae* LALL-MA+ differs from the parental strain in its capacity to produce glucan 1,4-α-maltohydrolase from *G. stearothermophilus* and in its ability to grow in the presence [redacted].[13] The absence of [redacted] resistance genes [redacted] was confirmed by WGS analysis.[14]

No issues of concern arising from the genetic modifications were identified by the Panel.

3.2 | Production of the food enzyme

The food enzyme is manufactured according to the Food Hygiene Regulation (EC) No 852/2004,[15] with food safety procedures based on Hazard Analysis and Critical Control Points, and in accordance with current good manufacturing practice.

The production strain is grown as a pure culture using a typical industrial medium in a submerged, fed-batch fermentation system with conventional process controls in place. After completion of the fermentation, the enzyme is released from the yeast cells by autolysis. The solid biomass is then removed from the fermentation broth by centrifugation. The supernatant containing the enzyme is stabilised and then further purified and concentrated, including an ultrafiltration step in which enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded.[16] The applicant provided information on the identity of the substances used to control the fermentation and in the subsequent downstream processing of the food enzyme.[17]

The Panel considered that sufficient information has been provided on the manufacturing process and the quality assurance system implemented by the applicant to exclude issues of concern.

[9]Technical dossier/Risk assessment/Source of the food enzyme/p. 5.
[10]Technical dossier/Risk assessment/Source of the food enzyme/p. 6.
[11]Technical dossier/Risk assessment/Source of the food enzyme.
[12]Technical dossier/Risk assessment/Source of the food enzyme/p. 5 and Annex 1, pp. 10–17.
[13]Technical dossier/Risk assessment/Methods of analysis/Annex 22.
[14]Technical dossier/Risk assessment/Source of the food enzyme/Annex 1.
[15]Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of food additives. OJ L 226, 25.6.2004, pp. 3–21.
[16]Technical dossier/Risk assessment/Manufacturing process of the food enzyme.
[17]Technical dossier/Risk assessment/Manufacturing process of the food enzyme pp. 3–5.

3.3 | Characteristics of the food enzyme

3.3.1 | Properties of the food enzyme

The glucan 1,4-α-maltohydrolase consists of a polypeptide chain of 686 amino acids.[18] The molecular mass of the mature protein, calculated from the amino acid sequences, is 75.0 kDa. The food enzyme was analysed by sodium dodecyl sulfate-polyacrylamide gel electrophoresis.[19] A consistent protein pattern was observed across all batches. The gel showed a single major protein band corresponding to an apparent molecular mass of about 75 kDa, consistent with the expected mass of the enzyme. No other enzyme activities were reported.

The applicant's in-house determination of the glucan 1,4-α-maltohydrolase activity is based on the hydrolysis of insoluble starch linked to a blue dye (reaction conditions: pH 5.5, 60°C, 15 min) and determined by measuring the release of the soluble dye spectrophotometrically at 620 nm. The activity is expressed in Lallemand Baking JUN Plus Units (LBJPU)/g. One LBJPU is defined as the amount of enzyme that hydrolyses 0.12 µmol of glucosidic linkages per minute from starch under the conditions of the assay.[20]

The food enzyme has a temperature optimum around 80°C (pH 5.0) and a pH optimum around pH 4.5 (60°C).[9] Thermostability was tested after a pre-incubation of the food enzyme for 15 or 30 min at different temperatures (pH 5.0). Enzyme activity decreased above 85°C showing no residual activity at 95°C or 90°C after 15 or 30 min of pre-incubation, respectively.[21]

3.3.2 | Chemical parameters

Data on the chemical parameters of the food enzyme were provided for three batches used for commercialisation (Table 1).[22] The mean total organic solids (TOS) of the three batches was 3.4% and the mean enzyme activity/TOS ratio was 1507 LBJPU/mg TOS.

TABLE 1 Composition of the food enzyme.

Parameters	Unit	Batches		
		1	2	3
Glucan 1,4-α-maltohydrolase activity	LBJPU/g[a]	46,632	50,760	56,733
Protein	%	2.7	3.1	3.2
Ash	%	0.2	0.2	0.2
Water	%	96.9	96.0	96.2
Total organic solids (TOS)[b]	%	2.9	3.8	3.6
Activity/TOS ratio	LBJPU/mg TOS	1608	1336	1576

[a]LBJPU: Lallemand Baking JUN Plus Unit (see Section 3.3.1).
[b]TOS calculated as 100% – % water – % ash.

3.3.3 | Purity

The lead content in the three commercial batches was below 0.017 mg/kg[23] which complies with the specification for lead as laid down in the general specifications for enzymes used in food processing (FAO/WHO, 2006). In addition, the concentrations of arsenic, cadmium and mercury were below the limits of quantification (LoQs) of the employed methods.[24,25]

The food enzyme complies with the microbiological criteria for total coliforms, *Escherichia coli* and *Salmonella*,[26] and no antimicrobial activity was detected in any of the tested batches[27] as laid down in the general specifications for enzymes used in food processing (FAO/WHO, 2006).

The panel considered that the information provided on the purity of the food enzyme was sufficient.

[18]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme p. 1.
[19]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme/Annex 5.
[20]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme pp.1–2 and Methods of analysis/Annex 16.
[21]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme p. 2 and Annexes 6 and 6b.
[22]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme/Table 1 and Annexes 7, 8, 9 and 10, and Methods of analysis/Annexes 16, 17, 18 and 25.
[23]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme/Table 2 and Annex 13..
[24]LoQs: Pb = 0.017 mg/kg; As = 0.019 mg/kg; Cd = 0.009 mg/kg; Hg = 0.008 mg/kg.
[25]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme/Table 2 and Annex 13 and Additional information February 2024/Applicant's comments excel file.
[26]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme/Table 2 and Annex 11 and methods of analysis/Annex 20.
[27]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme/Table 2 and Annex 12 and Methods of analysis/Annex 21.

3.3.4 | Viable cells and DNA of the production strain

The absence of viable cells of the production strain in the food enzyme was demonstrated in four independent batches analysed in triplicate. Ten millilitres of product were diluted in 90 mL of sterile saline solution. Ten millilitres of product were centrifuged and most of the supernatant discarded. The pellet was then resuspended in the remaining liquid, plated on selective agar plates and incubated at 30°C for 48 h.[28] No colonies were produced. A positive control was included.[29]

The absence of recombinant DNA in the food enzyme was demonstrated by polymerase chain reaction analysis of three batches in triplicate. No DNA was detected with primers that would amplify a 660-bp fragment specific for the glucan 1,4-α-maltohydrolase gene, with a limit of detection of 0.1 ng spiked DNA/g food enzyme.[30,31]

3.4 | Toxicological data

No safety concerns arose from the genetic modification of the production strain (Section 3.1.4) and the absence of viable cells in the food enzyme was demonstrated (Section 3.3.4). Therefore, the production strain is considered to qualify for the QPS approach. In addition, no issue of concern arising from the production process of the food enzyme was identified (see Sections 3.1, 3.2 and 3.3). Consequently, the Panel considered that no toxicological studies other than the assessment of allergenicity were necessary (EFSA CEP Panel, 2021).

3.4.1 | Allergenicity

The allergenicity assessment considered only the food enzyme and not carriers or other excipients that may be used in the final formulation.

The potential allergenicity of the glucan 1,4-α-maltohydrolase produced with the *S. cerevisiae* strain LALL-MA+ was assessed by comparing its amino acid sequence with those of known allergens according to the 'Scientific opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed of the Scientific Panel on Genetically Modified Organisms' (EFSA GMO Panel, 2010). Using higher than 35% identity in a sliding window of 80 amino acids as the criterion, four matches were found.[32] The matching allergens were Asp o 21 (*Aspergillus oryzae*); Sch c 1 (glycoside hydrolase family 15 from *Schizophyllum commune* (Split Gill fungus)); Asp f 13 (partial alkaline protease from *Aspergillus fumigatus*), all known as respiratory allergens and Aed a 4 (glycosyl hydrolase from *Aedes aegypti* (yellow fever mosquito)), an injected allergen.

No information is available on oral and respiratory sensitisation or elicitation reactions of this glucan 1,4-α-maltohydrolase.

Several studies have shown that adults sensitised to respiratory allergens may ingest allergenic enzymes without acquiring clinical symptoms of food allergy (Armentia et al., 2009; Cullinan et al., 1997; Poulsen, 2004). Taking into account the wide use of α-amylase as a food enzyme, only a low number of case reports has been described in literature that focused on allergic reactions upon oral exposure to α-amylase in individuals respiratory sensitised to α-amylase (Baur & Czuppon, 1995; Kanny & Moneret-Vautrin, 1995; Losada et al., 1992; Moreno-Ancillo et al., 2004; Quirce et al., 1992). Such information has not been reported for glucoamylase. α-Glucosidase is associated with allergic reactions to insect bites, but allergic reactions after oral exposure have not been reported. In addition, no allergic reactions upon dietary exposure to any glucan 1,4-α-maltohydrolase have been reported in the literature.

Yeast, a known source of allergens, is present in the media fed to the microorganism. However, during the fermentation process, it will be degraded and utilised by the microorganism for cell growth, cell maintenance and production of enzyme protein. In addition, the microbial biomass and fermentation solids are removed. Taking into account the fermentation process and downstream processing, the Panel considered that no potentially allergenic residues from this source are present in the food enzyme.

The Panel considered that a risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but the likelihood is low.

3.5 | Dietary exposure

3.5.1 | Intended use of the food enzyme

The food enzyme is intended to be used in the processing of cereals and other grains for the production of baked products at a recommended use level of 1000–2000 LBJPU/kg flour corresponding to 0.66–1.32 mg TOS/kg flour.[33]

[28]Technical dossier/Risk assessment/Additional information February 2024/Applicant's comments excel file.

[29]Technical dossier/Risk assessment/Additional information February 2024/ Chemical composition, properties and purity of the food enzyme/Annex 14.

[30]Technical dossier/Risk assessment/Methods of analysis/Annex 23.

[31]Technical dossier/Risk assessment/Chemical composition, properties and purity of the food enzyme/Annex 15.

[32]Technical dossier/Risk assessment/Allergenicity/Annex 24.

[33]Technical dossier/Risk assesment/Intended use(s) in food and use level(s).

In the production of baked products, the food enzyme is added to flour during the preparation of the dough.[34] The glucan 1,4-α-maltohydrolase hydrolyses amylose and amylopectin and releases maltose. The conversion of starch lowers the rate of retrogradation, thereby reducing staling and improving crumb structure. The food enzyme–TOS remain in the baked foods.

Based on data provided on thermostability (see Section 3.3.1), the glucan 1,4-α-maltohydrolase may remain in its active form in baked products depending on the specific food manufacturing conditions.

3.5.2 | Dietary exposure estimation

Chronic exposure to the food enzyme–TOS was calculated by combining the maximum recommended use level with individual consumption data (EFSA CEP Panel, 2021). The estimation involved selection of relevant food categories and application of technical conversion factors (EFSA CEP Panel, 2023). Exposure from all FoodEx categories was subsequently summed up, averaged over the total survey period (days) and normalised for body weight. 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 1 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 0.014 mg TOS/kg body weight per day in children at the 95th percentile.

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

	Estimated exposure (mg TOS/kg body weight per day)					
Population group	**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)	0–0.003 (12)	0–0.007 (15)	0–0.007 (19)	0–0.004 (21)	0.001–0.002 (22)	0.001–0.002 (23)
Min–max 95th percentile (number of surveys)	0–0.009 (11)	0.001–0.013 (14)	0–0.014 (19)	0–0.008 (20)	0.002–0.006 (22)	0.002–0.004 (22)

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	
Selection of broad FoodEx categories for the exposure assessment	+
Exposure to food enzyme–TOS always calculated based on the recommended maximum use level	+
Use of recipe fractions to disaggregate FoodEx categories	+/–
Use of technical factors in the exposure model	+/–

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

[34]Technical dossier/Risk assesment/Intended use(s) in food and use level(s).

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 an overestimation of the exposure.

3.6 | Margin of exposure

Since no toxicological assessment was considered necessary by the panel, a margin of exposure was not calculated.

4 | CONCLUSIONS

Based on the data provided, the QPS status of the production strain and the absence of issues of concern arising from the enzyme production process, the Panel concluded that the food enzyme glucan 1,4-α-maltohydrolase produced with the genetically modified *Saccharomyces cerevisiae* strain LALL-MA+ does not give rise to safety concerns under the intended conditions of use.

The Panel considered the food enzyme free from viable cells and recombinant DNA of the production organism.

5 | DOCUMENTATION AS PROVIDED TO EFSA

Application for authorisation of a maltogenic α-amylase enzyme produced from the genetically modified *Saccharomyces cerevisiae* strain LALL-MA+ in accordance with Regulation (EC) No 1331/2008. June 2023. Submitted by DANSTAR FERMENT AG, an affiliate of Lallemand Inc.

Additional information. February 2024. Submitted by DANSTAR FERMENT AG, an affiliate of Lallemand Inc.

ABBREVIATIONS

EC	European Commission
EINECS	European Inventory of Existing Commercial Chemical Substances
FAO	Food and Agricultural Organisation of the United Nations
FEZ	EFSA Panel on Food Enzymes
GMO	genetically modified organism
IUBMB	International Union of Biochemistry and Molecular Biology
kDa	kiloDalton
LOQ	limit of quantification
QPS	qualified presumption of safety
TOS	total organic solids
WGS	whole genome sequencing
WHO	World Health Organization

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2023-00533

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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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 1 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, 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, Spain, Sweden
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Romania, 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, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden

[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).