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SCIENTIFIC OPINION

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Safety evaluation of the food enzyme α-galactosidase from the genetically modified *Saccharomyces cerevisiae* strain CBS 615.94

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Abstract

The food enzyme α-galactosidase (α-D-galactoside galactohydrolase; EC 3.2.1.22) is produced with the genetically modified *Saccharomyces cerevisiae* strain CBS 615.94 by Kerry Ingredients & Flavours Ltd. The production strain of the food enzyme contains multiple copies of a known antimicrobial resistance gene. However, based on the absence of viable cells and DNA from the production organism in the food enzyme, this is not considered to be a risk. As no other concerns arising from the genetically modified microbial source or from the manufacturing process have been identified, the Panel considered that toxicological tests were not needed for the assessment of this food enzyme. The food enzyme is intended to be used in guar gum processing. The dietary exposure was estimated to be up to 0.828 mg TOS/kg body weight per day in European populations. A search for the similarity of the amino acid sequence of the food enzyme to known allergens was made and no match was found. The Panel considered that a risk of allergic reactions by 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

EC 3.2.1.22, food enzyme, genetically modified microorganism, melibiase, *Saccharomyces cerevisiae*, α-D-galactoside galactohydrolase, α-galactosidase

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 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 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 on food enzymes.

Two applications have been introduced consisting of a joint dossier by the companies "DSM Food Specialties B.V and Amano Enzyme Inc." for the authorisation of the food enzyme glucose oxidase from *Aspergillus niger*, and by the company "Kerry Ingredients & Flavours" for the authorisation of the food enzyme alpha-galactosidase from a GM strain of *Saccharomyces cerevisiae* (strain CBS 615.94) carrying a gene from *Cyamopsis tetragonoloba* (guar).

Following the requirements of Article 12.1 of Regulation (EC) No 234/2011[3] implementing Regulation (EC) No 1331/2008, the Commission has verified that the two applications fall within the scope of the food enzyme Regulation and contain all the elements required under Chapter II of that Regulation.

1.1.2 | Terms of Reference

The European Commission requests the European Food Safety Authority to carry out the safety assessments on the food enzymes glucose oxidase from *Aspergillus niger* and alpha galactosidase from a genetically modified strain of *Saccharomyces cerevisiae* (strain CBS 615.94) carrying a gene from *Cyamopsis tetragonoloba* (guar) in accordance with Article 17.3 of Regulation (EC) No 1332/2008 on food enzymes.

1.2 | Interpretation of the Terms of Reference

The present scientific opinion addresses the European Commission's request to carry out the safety assessment of the food enzyme α-galactosidase from the genetically modified *S. cerevisiae* strain CBS 615.94.

[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]Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 64, 11.3.2011, pp. 15–24.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a dossier in support of the application for authorisation of the food enzyme α-galactosidase from a genetically modified *S. cerevisiae* (strain CBS 615.94). December 2013. The dossier was updated in January 2016.

Additional information was requested from the applicant during the assessment process on 20 February 2015 and 27 March 2023 and was consequently provided (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, 2009a) and following the relevant guidance documents of the EFSA Scientific Committee.

The 'Guidance on the submission of a dossier on food enzymes for safety evaluation' (EFSA, 2009b) as well as the 'Statement on characterisation of microorganisms used for the production of food enzymes' (EFSA CEP Panel, 2019) have been followed for the evaluation of the application. Additional information was requested in accordance with the updated 'Scientific Guidance for the submission of dossiers on food enzymes' (EFSA CEP Panel, 2021) and the guidance on the 'Food manufacturing processes and technical data used in the exposure assessment of food enzymes' (EFSA CEP Panel, 2023).

3 | ASSESSMENT

IUBMB nomenclature	α-Galactosidase
Systematic name	α-D-galactoside galactohydrolase
Synonyms	Melibiase; α-D-galactosidase
IUBMB no	EC 3.2.1.22
CAS no	9025-35-8
EINECS no	232–792-0

α-Galactosidases catalyse the hydrolysis of non-reducing α-D-galactose residues in α-D-galactosides, releasing D-galactose. The enzyme under assessment is intended to be used in guar gum processing.

3.1 | Source of the food enzyme

The α-galactosidase is produced with the genetically modified yeast *Saccharomyces cerevisiae* strain CBS 615.94,[4] which is deposited at the Westerdijk Fungal Biodiversity Institute Culture collection (CBS, the Netherlands) with the deposit number CBS 615.94.[5] The production strain was identified as *S. cerevisiae* by [redacted].[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 demonstrated in case where viable cells are added to the food or feed chain and, for genetically modified organisms, no concerns arise from the genetic modification (EFSA, 2007; EFSA BIOHAZ Panel, 2022).[7]

3.1.1 | Characteristics of the parental and recipient microorganisms

The parental strain is *S. cerevisiae* [redacted].[8] The recipient, *S. cerevisiae* [redacted], is a [redacted] mutant, [redacted] In the construction of the recipient strain, plasmids were used carrying genes conferring resistance [redacted].[9]

[4]Other names: 470; SU50.
[5]Technical dossier/Annex 7.
[6]Additional data June 2023/Annex 28.
[7]https://zenodo.org/records/7554079
[8]Additional data August 2017/Additional information request.
[9]Additional data August 2017/Additional information request.

3.1.2 | Characteristics of introduced sequences

The nucleotide sequence encoding for the α-galactosidase is [redacted] from *Cyamopsis tetragonoloba* (guar). It was preceded by the [redacted] signal sequence and the [redacted] promoter, both from [redacted]

Plasmid [redacted][10] [redacted] In addition to the *α-gal* expression cassette [redacted]

3.1.3 | Description of the genetic modification process

The purpose of the genetic modification was to enable the production strain to synthesise α-galactosidase from *Cyamopsis tetragonoloba*. For this purpose, plasmid [redacted], resulting in the production strain *S. cerevisiae* 470 (CBS 615.94).

As a result of genetic modification, the production strain carries [redacted] integrated into its genome. [redacted][11].

3.1.4 | Safety aspects of the genetic modification

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

The production strain *S. cerevisiae* 470 (CBS 615.94) differs from the recipient strain [redacted] in its capacity to produce the α-galactosidase from *Cyamopsis tetragonoloba* (guar) [redacted]. *S. cerevisiae* CBS 615.94 additionally contains the non-functional [redacted] gene and the [redacted] gene integrated into the chromosome.

The presence of a gene conferring antimicrobial resistance [redacted] in the production strain is considered a hazard.

3.2 | Production of the food enzyme

The food enzyme is manufactured according to the Food Hygiene Regulation (EC) No 852/2004,[12] with food safety procedures based on Hazard Analysis and Critical Control Points, and in accordance with current Good Manufacturing Practice.[13]

The production strain is grown as a pure culture using a typical industrial medium in a submerged, batch or fed-batch fermentation system with conventional process controls in place. After completion of the fermentation, the solid biomass is removed from the fermentation broth by filtration. The filtrate containing the enzyme is 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.[14] 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.[15]

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.

3.3 | Characteristics of the food enzyme

3.3.1 | Properties of the food enzyme

The α-galactosidase is a single polypeptide chain of [redacted] amino acids.[16] The molecular mass of the mature protein, calculated from the amino acid sequence, is [redacted] kDa.[17] The food enzyme was analysed by sodium dodecyl sulfate–polyacryla-

[10]Technical dossier/p. 36 and Annexes 8-9/Additional data August 2017/Additional information request.

[11]Technical dossier/Annex 6 and Additional data August 2017/Annex B.

[12]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.

[13]Technical dossier/p. 46/Annexes: 14, 15, 16.

[14]Technical dossier/pp. 46–53/Annexes: 17, 18; Additional data August 2017/Annex C.

[15]Technical dossier/p. 47/Annex 19; Additional data August 2017.

[16]Technical dossier/p. 27; Additional data August 2017/Annex G.

[17]Technical dossier/p. 27; Additional data August 2017/Annex G.

mide gel electrophoresis. 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 ■ kDa, consistent with the expected mass of the enzyme.[18] No other enzymatic activities were reported.[19]

The in-house determination of α-galactosidase activity is based on the hydrolysis of *p*-nitrophenyl-α-D-galactopyranoside (reaction conditions: pH 5.0, 40°C), measuring the release of *p*-nitrophenol spectrophotometrically at 405 nm. The enzyme activity is expressed in units/mL. One unit is defined as the quantity of enzyme which releases one µmol of *p*-nitrophenol per minute under the conditions of the assay.[20]

The food enzyme has a temperature optimum around 55°C (pH 5.0) and a pH optimum around pH 5.0 (37°C).[21] Thermostability was tested after a pre-incubation of the food enzyme for 10 min at different temperatures (pH 5). The enzyme activity decreased above 45°C, showing no residual activity above 60°C.[22]

3.3.2 | Chemical parameters

Data on the chemical parameters of the food enzyme were provided for three batches used for commercialisation (Table 1).[23] The mean total organic solids (TOS) of the three food enzyme batches was 1.1% and the mean enzyme activity/TOS ratio was 19.8 units/mg TOS.

TABLE 1 Composition of the food enzyme.

		Batches		
Parameters	**Unit**	**1**	**2**	**3**
α-Galactosidase activity	U/mL[a]	230	190	220
Protein	%	0.19	0.30	0.22
Ash	%	0.33	0.40	0.30
Water	%	98.20	98.80	98.60
Total organic solids (TOS)[b]	%	1.47	0.80	1.10
Activity/TOS ratio	U/mg TOS	15.6	23.8	20.0

[a]U: Unit/mL (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 5 mg/kg,[24,25] which complies with the specification for lead, as laid down in the general specifications for enzymes used in food processing (FAO/WHO, 2006).

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

The presence of aflatoxins (B1, B2, G1 and G2), deoxynivalenol (DON), fumonisins (B1 and B2), ochratoxin A, sterigmatocystin, T-2 toxin, zearalenone and citrinin was examined in three formulated batches and, other than DON, all were below the respective limit of detection (LOD). DON was found in all batches tested with a mean concentration of 258 µg/kg.[28,29] As the production strain is not able to produce DON, it is considered to have originated from a contamination of the carrier (wheat flour) used in the final formulation. The Panel noted that the identified levels of DON were below the maximum permitted limit of this compound in cereals products (750 µg/kg).[30] Therefore, the Panel considered these findings of no concern.

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

[18]Technical dossier/p. 26 and Additional data Jun 2023/30_Annex _NS_ SDS-PAGE.

[19]Technical dossier/p. 28.

[20]Technical dossier/p. 27 and Annex 1.

[21]Technical dossier/pp. 28–29.

[22]Additional data June 2023/Annex 31.

[23]Technical dossier/p. 25 and Annexes: 1, 24, 25; Additional data August 2017/p. 3.

[24]Technical dossier/p. 26; Additional data August 2017/Annex H.

[25]LoD: Pb = 0.005 mg/kg.

[26]Technical dossier/p. 26 and Annexes 2, 4; Additional data August 2017/Annex H.

[27]Technical dossier/p. 26 and Annex 4; Additional data August 2017/Annex H.

[28]LoDs: aflatoxins: B1, B2, G1, G2 = 1 µg/kg each; deoxynivalenol = not provided; fumonisins: B1, B2 = 5 µg/kg each; ochratoxin A = 1 µg/kg; sterigmatocystin = 1 µg/kg, T-2 toxin = 50 µg/kg, zearalenone = 5 µg/kg, citrin = 10 µg/kg.

[29]Technical dossier/Annex 3.

[30]COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006.

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 [redacted][31] [redacted].[32]

The absence of recombinant DNA in the food enzyme was demonstrated [redacted].[33]

3.4 | Toxicological data

Although all other requirements for the QPS have been met, the production strain cannot be considered suitable for the QPS approach, since it carries an acquired antimicrobial resistance gene. However, the Panel noted that no risk is expected from the presence of this antimicrobial resistance gene in the production strain, as the enzyme has been shown not to contain viable cells and recombinant DNA (Section 3.3.4). As no other concerns arising from the microbial source and its subsequent genetic modification or from the manufacturing process have been identified, the Panel considered that no toxicological studies other than assessment of allergenicity are needed for the assessment of this food enzyme.

The QPS approach to safety assessment was not considered applicable to genetically modified organisms at the time of the initial application. Consequently, the applicant submitted a battery of toxicological tests, including a bacterial gene mutation assay (Ames test), an in vitro mammalian chromosomal aberration test and a repeated dose 90-day oral toxicity study in rats. However, these studies were not considered as supporting evidence due to missing compositional data for the two batches used for toxicological studies (TOS content etc.) and the missing conversion of the concentrations/doses into TOS. It was also not clear whether the repeated dose 90-day oral toxicity study followed the OECD Test Guideline 408 and good laboratory practice (GLP).[34,35]

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 α-galactosidase produced with *S. cerevisiae* strain CBS615-94 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, no match was found.[36]

No information was available on oral and respiratory sensitisation or elicitation reactions of this α-galactosidase.

Cases of occupational allergy following exposure by inhalation of galactosidases have been reported (Stöcker et al., 2016; Bernstein et al., 1999; Muir et al., 1997).[37] However, several studies have shown that adults with occupational asthma can ingest respiratory allergens without acquiring clinical symptoms of food allergy (Brisman, 2002; Poulsen, 2004; Armentia et al., 2009).

[redacted], a known source of allergens, is present in the media fed to the microorganisms. However, during the fermentation process, this product will be degraded and utilised by the microorganisms for cell growth, cell maintenance and production of enzyme protein. In addition, the yeast 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.

[31] Additional data August 2017/Annex F.

[32] Additional data August 2017/Annex E.

[33] Additional data June 2023/Annex 29.

[34] Technical dossier/Annexes 20, 21 and 22.

[35] Background information/summary report on toxicity studies provided by contractor.

[36] Technical dossier/pp. 65–67/Annex 23.

[37] Additional data June 2023/ 32_Annex_NS_Allergencity _Literature search.

3.5 | Dietary exposure

3.5.1 | Intended use of the food enzyme

The food enzyme is intended to be used in guar gum processing at a recommended use level of 200–700 mg TOS/kg guar.[38]

In guar gum processing, the food enzyme is added to treat the guar gum/flour. The α-galactosidase hydrolyses the galactomannan to release galactose.[39] The food enzyme–TOS remains in the hydrolysed products that are intended as ingredients to a variety of foods and beverages.[40]

Partially hydrolysed guar gum obtained by physical or chemical treatment is an authorised additive (E 412) in the EU according to Annex II and Annex III to Regulation (EC) No 1333/2008 on food additives. It is used in various food products as thickener, stabiliser and emulsifier. In the framework of Regulation (EC) No 1333/2008 and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) re-evaluated guar gum used as a food additive in 2017, using actual occurrence data of guar gum (E 412) in foods made available to EFSA by industry.

Based on data provided on thermostability (see Section 3.3.1) and the downstream processing step applied in the food processes, it is expected that the enzyme is inactivated during guar gum processing.

3.5.2 | Dietary exposure estimation

Since an exposure assessment to guar gum was carried out by the EFSA ANS Panel as part of the re-evaluation programme and published in 2017, these exposure estimates were applied in this opinion and combined with the food enzyme use levels in the assessment of exposure to food enzymes used in the production of guar gum.

The ANS Panel considered a maximum level exposure assessment and a refined exposure assessment scenario. For the purpose of assessing the exposure to food enzyme–TOS, the CEP Panel decided to use the most conservative maximum level exposure scenario.

Table 2 provides an overview of the derived exposure estimates across all surveys to both guar gum used as a food additive (E 412) and subsequent exposure to the food enzyme through the consumption of guar gum.

For the assessment of guar gum (E 412) (EFSA ANS Panel, 2017), food consumption data were available from 33 different dietary surveys (covering infants, toddlers, children, adolescents, adults and the elderly), carried out in 19 European countries (Appendix B). Chronic exposure estimates were derived by multiplying guar gum (E 412) concentrations for each food category by their respective consumption amount per kg body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded because they are considered as not adequate to assess repeated exposure (EFSA ANS Panel, 2017). The so derived exposure estimates to guar gum (E 412) were combined with the maximum use level for the food enzyme provided by the applicant (see Table 2). The highest dietary exposure was estimated to be 0.828 mg TOS/kg bw per day in children at the 95th percentile.

TABLE 2 Summary of dietary exposure to guar gum (E 412) from their use as food additives in the maximum level exposure assessment scenario and subsequent exposure to the food enzyme, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw 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
Regulatory maximum level exposure scenario (mg guar gum E 412/kg body weight per day)						
Min–max mean	122.8–445.0	224.0–711.7	114.0–517.1	61.1–355.7	48.5–273.1	56.3–290.8
Min–max 95th percentile	247.1–894.2	424.2–1021.9	229.3–1182.8	106.1–741.6	96.6–542.5	110.3–586.3
Estimated exposure (mg TOS/kg body weight per day)						
Min–max mean	0.086–0.312	0.157–0.498	0.08–0.362	0.043–0.249	0.034–0.191	0.039–0.204
Min–max 95th percentile	0.173–0.626	0.297–0.715	0.161–0.828	0.743–0.519	0.068–0.38	0.077–0.41

Abbreviation: 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. Uncertainties

[38] Additional data June 2023/Reply annex.

[39] Technical dossier/Figure 7.

[40] Technical dossier/Table 7; Additional data June 2023/Table 11.

pertaining to the estimated exposure to guar gum (E 412) as conducted by the ANS Panel in 2017 are not listed and can be viewed in the Scientific Opinion on the re-evaluation of guar gum (E 412) as a food additive (EFSA ANS Panel, 2017).

The conservative approach applied to estimate the dietary 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.

TABLE 3 Qualitative evaluation of the influence of uncertainties on the dietary exposure estimate.

Sources of uncertainties	Direction of impact
Methodology used in the assessment of exposure to guar gum (E 412) (see EFSA ANS Panel, 2017)	+/–
To derive consumption data, the authorised guar gum as a food additive (E 412) was used as the proxy for the enzymatically hydrolysed guar gum	+/–
Exposure to food enzyme–TOS was always calculated based on the recommended maximum use level	+

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

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 Panel concluded that the food enzyme α-galactosidase produced with the genetically modified *S. cerevisiae* strain CBS 615.94 does not give rise to safety concerns under the intended conditions of use.

The production strain of the food enzyme contains multiple copies of a known antimicrobial resistance gene. However, based on the absence of viable cells and recombinant DNA from the production organism in the food enzyme, this is not considered to be a risk.

5 | REMARK

According to the food additive specifications set in Regulation (EU) No 231/2012, guar gum (E 412) may be partially hydrolysed only by heat treatment, or mild acid or alkaline oxidative treatment for viscosity adjustment. The Panel noted that the production of hydrolysed guar gum with the use of enzymes is not covered by the existing specifications for E 412.

6 | DOCUMENTATION AS PROVIDED TO EFSA

"α-galactosidase from a modified strain of *S. cerevisiae* CBS615-94". December 2013. Submitted by Kerry Ingredients & Flavours Ltd. The dossier was updated in January 2016.

Additional information August 2017 Submitted by Kerry Ingredients & Flavours Ltd.

Additional information June 2023 Submitted by Kerry Ingredients & Flavours Ltd.

Summary report on genotoxicity, subchronic toxicity study and allergenicity related to alpha-galactosidase from *Saccharomyces cerevisiae* (strain SU50) By Kerry Ingredients & Flavours Ltd. June 2014. Delivered by contractor FoBiG (Klarastr, Freiburg).

ABBREVIATIONS

bw	body weight
CAS	Chemical Abstracts Service
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
DON	deoxynivalenol
EINECS	European Inventory of Existing Commercial Chemical Substances
FAO	Food and Agricultural Organization of the United Nations
GLP	good laboratory practice
GMO	genetically modified organism
IUBMB	International Union of Biochemistry and Molecular Biology
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kDa	kiloDalton
LOD	limit of detection
OECD	Organisation for Economic Cooperation and Development

PCR	polymerase chain reaction
QPS	qualified presumption of safety
SDS–PAGE	sodium dodecyl sulfate–polyacrylamide gel electrophoresis
TOS	total organic solids
WGS	whole genome sequence
WHO	World Health Organization

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

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NOTE

The full opinion will be published in accordance with Article 12 of Regulation (EC) No 1331/2008 once the decision on confidentiality will be received from the European Commission.

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