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SCIENTIFIC OPINION

Safety evaluation of an extension of use of the food enzyme thermolysin from the non-genetically modified *Anoxybacillus caldiproteolyticus* strain AE-TP

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Abstract

The food enzyme thermolysin (EC. 3.4.24.27) is produced with the non-genetically modified *Anoxybacillus caldiproteolyticus* strain AE-TP by Amano Enzyme Inc. A safety evaluation of this food enzyme was made previously, in which EFSA concluded that this food enzyme did not give rise to safety concerns when used in eight food manufacturing processes. Subsequently, the applicant has requested to extend its use to one additional process, to withdraw two processes and to revise the use levels. In this assessment, EFSA updated the safety evaluation of this food enzyme for use in a total of seven food manufacturing processes. The dietary exposure to the food enzyme–total organic solids (TOS) was calculated to be up to 0.989 mg TOS/kg body weight (bw) per day in European populations. When combined with the no observed adverse effect level reported in the previous opinion (700 mg TOS/kg bw per day, the mid-dose tested), the Panel derived a revised margin of exposure of at least 708. Based on the data provided for the previous evaluation and the revised margin of exposure in the present evaluation, the Panel concluded that this food enzyme does not give rise to safety concerns under the revised intended conditions of use.

KEYWORDS

Anoxybacillus caldiproteolyticus, EC 3.4.24.27, EFSA-Q-2016-00083, EFSA-Q-2023-00003, food enzyme, thermolysin

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 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.

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.

Thermolysin (protease) from a non-genetically modified strain of *Geobacillus stearothermophilus* (strain AE-TP) 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 30 September 2022, a new application has been introduced by the applicant "Amano Enzyme Inc." for an extension of the conditions of the use of the food enzyme Thermolysin (protease) from a non-genetically modified strain of *Geobacillus stearothermophilus* (strain AE-TP).

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: Thermolysin (protease) from a non-genetically modified strain of *Geobacillus stearothermophilus* (strain AE-TP), in accordance with Regulation (EC) No 1331/2008 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 thermolysin from *Geobacillus stearothermophilus* strain AE-TP.

[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://food.ec.europa.eu/safety/food-improvement-agents/enzymes/eu-list-and-applications_en.

[4]OJ L 354, 31.12.2008, p. 1.

The production microorganism was reclassified as *Anoxybacillus caldiproteolyticus* at the species level in the scientific opinion published previously (EFSA CEP Panel, 2024). Therefore, the same species name *Anoxybacillus caldiproteolyticus* is used 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 food enzyme thermolysin from a non-genetically modified strain of *Geobacillus stearothermophilus* (AE-TP).

Additional information, requested from the applicant during the assessment process on 20 September 2023, 30 January 2024 and 13 March 2024, was received on 18 October 2023, 29 February 2024 and 18 March 2024, respectively (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, 2009) and following the relevant existing guidance documents of 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.

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 05 March to 26 March 2024.[6] No comments were received.

3 | ASSESSMENT

IUBMB nomenclature	Thermolysin
Systematic name	-
Synonyms	*Bacillus thermoproteolyticus* neutral proteinase; thermoase
IUBMB no	EC. 3.4.24.27
CAS no	37246-64-3
EINECS no	253-424-5

Thermolysins catalyse the hydrolysis of peptide bonds of proteins with broad specificity, but preferentially, between leucine and phenylalanine, releasing peptides and amino acids. All aspects concerning the safety of this food enzyme, when used in eight food manufacturing processes, were evaluated in February 2024 (EFSA CEP Panel, 2024).

Following a request to update the intended uses (withdrawing two food manufacturing processes, adding one process and revising the use levels), EFSA revises the exposure assessment and updates the safety evaluation of this food enzyme when used in seven food manufacturing processes.

3.1 | Dietary exposure

The current dietary exposure evaluation supersedes section 3.5 of the previous evaluation (EFSA CEP Panel, 2024).

[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.

[6]https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000000DtjR/pc0863.

3.1.1 | Revised intended use of the food enzyme

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

TABLE 1 Updated intended uses and use levels of the food enzyme.[7]

Food manufacturing process[a]	Raw material (RM)	Maximum recommended use level (mg TOS/kg RM)			
		Current evaluation[b]		Previous evaluation[b,c]	
Processing of dairy products					
• Production of modified milk proteins[d]	Milk proteins	**375.4**	Infant formulae	**375.4**	Infant formulae
				72.6	Other uses
Processing of cereals and other grains					
• Production of baked products	Flour	**6.3**			
Processing of meat and fish products					
• Production of modified meat and fish products[8]	Raw meat and fish	**6.3**		**1.3**	
• Production of protein hydrolysates from meat and fish proteins	Meat and fish proteins	**250.3**		**62.6**	
Processing of plant- and fungal-derived products					
• Production of plant-based analogues of milk and milk products	Plant materials	**250.3**		**0.3**	
• Production of protein hydrolysates from plants and fungi	Soybean, pea and cereal	**375.4**	Infant formulae	**375.4**	Infant formulae
		375.4	Other uses	**72.6**	Other uses
Processing of yeast and yeast products	Dried yeast	**125.1**		**1.3**	

[a]The name has been harmonised according to the 'Food manufacturing processes and technical data used in the exposure assessment of food enzymes' (EFSA CEP Panel, 2023).

[b]The numbers in bold were used for calculation.

[c]The previous evaluation is made for the food enzyme application EFSA-Q-2016-00083.

[d]This thermolysin is used only in the production of protein hydrolysates for use in infant formulae.[9]

The applicant withdrew two uses of this food enzyme (production of flavouring preparations from dairy products[10] and the processing of eggs and egg products[11]), but added one food manufacturing process (production of baked products).[12] For the production of modified milk proteins, the food enzyme is limited only to the production of infant formulae.[13]

With the objective to support the food enzyme removal in infant formulae, the applicant performed an ultrafiltration of the food enzyme solution with a membrane with a 3000 Da cut-off. The amount of food enzyme proteins before and after the ultrafiltration was measured spectrophotometrically. No proteins were detected in the fraction with a molecular mass less than 3000 Da.[14]

These data were considered by the Panel as insufficient to confirm the absence of Total Organic Solids (TOS) in the infant formulae, considering that the majority of the TOS components, that have a low molecular mass, may pass through the ultrafiltration membrane. Therefore, the Panel opted for a conservative scenario by considering that all of the food enzyme-TOS remained in infant formulae.

The Panel also noted substantial changes in the use levels recommended in the current application when compared to the previous levels. The applicant ascribes this change to the availability of more recent information on actual use levels.[15]

The additional use of the food enzyme is described below.

In the production of baked products, the food enzyme is added to the flour during the preparation of dough.[16] The proteolytic reaction of the food enzyme weakens the gluten structure in the dough, which provides desired characteristics in particular for certain baked products like biscuits, tortillas, crackers. The food enzyme–TOS remain in the final baked products.

[7]Additional information February 2024/Additional information- Intended use(s) in food and use level(s)_29 Feb 24/p. 2.

[8]Additional information February 2024/Additional infomation- Intended use(s) in food and use level(s)_29 Feb 24/Answer 1–2.

[9]Additional information October 2023; Additional information February 2024/Additional information- Intended use(s) in food and use level(s)_29 Feb 24/p. 2.

[10]Additional information February 2024/Additional information- Intended use(s) in food and use level(s)_29 Feb 24/Answer 1–3.

[11]Additional information March 2024.

[12]Additional information February 2024/Additional information- Intended use(s) in food and use level(s)_29 Feb 24/Answer 1.

[13]Additional information February 2024/Additional information- Intended use(s) in food and use level(s)_29 Feb 24/Answer 1.

[14]Technical dossier/Intended use(s) in food and use level(s) (Proposed normal and maximum use levels)/Annex 2–1 – The residual amount of enzyme in enzymatically hydrolysed milk peptides.

[15]Additional information February 2024/Additional information- Intended use(s) in food and use level(s)_29 Feb 24/p. 2.

[16]Technical dossier/Intended use(s) in food and use level(s) (Proposed normal and maximum use levels)/Annex 1-Flow chart of each application/p. 11.

Based on the thermostability evaluated previously (EFSA CEP Panel, 2024) and the thermal treatments applied during food processing, it is expected that the food enzyme is inactivated in the food manufacturing processes listed in Table 1.

3.1.2 | 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 48 dietary surveys (covering infants, toddlers, children, adolescents, adults and the elderly), carried out in 26 European countries (Appendix B). The highest dietary exposure was estimated to be 0.989 mg TOS/kg bw per day in infants at the 95th percentile.

TABLE 2 Updated dietary exposure to the 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)	0.046–0.292 (12)	0.062–0.172 (15)	0.049–0.087 (19)	0.020–0.056 (21)	0.014–0.040 (22)	0.011–0.035 (23)
Min–max 95th percentile (number of surveys)	0.110–0.989 (11)	0.142–0.452 (14)	0.092–0.250 (19)	0.040–0.141 (20)	0.030–0.113 (22)	0.026–0.098 (22)

3.1.3 | 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	
For yeast processing, although the food enzyme is not used to treat yeast cell wall, the food categories chosen for calculation cover also those containing mannoproteins resulted from the treatment of yeast cell wall	+
Exposure to food enzyme–TOS always calculated based on the recommended maximum use level	+
Selection of broad FoodEx categories for the exposure assessment	+
Use of recipe fractions to disaggregate FoodEx categories	+/–
Use of technical factors in the exposure model	+/–

Abreviations: +, 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 an overestimation of the exposure.

3.2 | Margin of exposure

In the previous evaluation, the Panel identified a no observed adverse effect level (NOAEL) of 700 mg TOS/kg body weight (bw) per day, the mid-dose tested, resulting in a margin of exposure of at least 719 (EFSA CEP Panel, 2024).

A comparison of the NOAEL with the newly derived exposure estimates of 0.011–0.292 mg TOS/kg bw per day at the mean and from 0.026 to 0.989 mg TOS/kg bw per day at the 95th percentile resulted in a revised margin of exposure of at least 708.

4 | CONCLUSION

Based on the data provided for the previous evaluation and the revised margin of exposure estimation, the Panel concluded that the food enzyme thermolysin produced with the non-genetically modified *Anoxybacillus caldiproteolyticus* strain AE-TP does not give rise to safety concerns under the revised intended conditions of use.

5 | DOCUMENTATION AS PROVIDED TO EFSA

Application for authorisation of thermolysin from *Geobacillus stearothermophilus* AE-TP in accordance with the Regulation (EC) No 1331/2008. September 2022. Submitted by Amano Enzymes Inc.

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

Additional information. February 2024. Submitted by Amano Enzymes Inc.

Additional information. March 2024. Submitted by Amano Enzymes Inc.

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

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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-2023-00003

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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, 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 2 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).