SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 30 September 2021

doi: 10.2903/j.efsa.2021.6884

Re-evaluation of thaumatin (E 957) as food additive

EFSA Panel on Food Additives and Flavourings (FAF),
Maged Younes, Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Paul Fowler, Maria Jose Frutos Fernandez, Peter Fürst, Rainer Gürtler, Ursula Gundert-Remy, Trine Husøy, Melania Manco, Wim Mennes, Sabina Passamonti, Peter Moldeus, Romina Shah, Ine Waalkens-Berendsen, Detlef Wölfle, Matthew Wright, Monika Batke, Polly Boon, Ellen Bruzell, James Chipman, Riccardo Crebelli, Rex Fitzgerald, Cristina Fortes, Thorhallur Halldorsson, Jean-Charles LeBlanc, Oliver Lindtner, Alicja Mortensen, Evangelia Ntzani, Heather Wallace, Consuelo Civitella, Zsuzsanna Horvath, Federica Lodi, Alexandra Tard and Giorgia Vianello

Abstract

The present opinion deals with the re-evaluation of thaumatin (E 957) when used as a food additive. Thaumatin is a natural plant protein, consisting of thaumatin I and thaumatin II proteins together with minor amounts of plant constituents, obtained by acidic aqueous extraction of the arils of the fruit of *Thaumatococcus daniellii* plant. The Panel followed the conceptual framework for the risk assessment of certain food additives and considered that thaumatin is a digestible protein; adequate exposure estimates were available; there was no concern with respect to the genotoxicity; no conclusion on oral allergenicity could be drawn from the available human data; no adverse effects were observed in sub-chronic toxicity studies in rats and dogs at the highest dose tested of up 5,200 and 1,476 mg/kg bodyweight (bw) per day, respectively, and in a prenatal developmental toxicity study up to 2,000 mg/kg bw per day; moderate confidence in the body of evidence supported the absence of association between exposure to thaumatin and adverse health outcomes. Therefore, the Panel concluded that there is no need for a numerical acceptable daily intake (ADI) for thaumatin (E 957) and, based on a margin of safety (MOS) of 5,417, considered to be an underestimate and derived using the highest 95th percentile (P95) exposure of 0.48 mg/kg bw per day in consumers only, there is no safety concern for thaumatin (E 957) at the regulatory maximum level exposure assessment scenario, which was considered the most appropriate. The Panel recommended that European Commission considers introducing in the EU specifications for thaumatin (E 957) a new specification limit for the minimum combined content of thaumatin I and II proteins in E 957, a specification limit for yeast, mould counts and *Salmonella* spp and lowering the existing maximum limit for arsenic along with the inclusion of maximum limits for mercury and cadmium.

Keywords: thaumatin, E 957, food additive, sweetener

Requestor: European Commission

Question number: EFSA-Q-2011-00725

Correspondence: fip@efsa.europa.eu

Panel members: Maged Younes, Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Paul Fowler, Maria Jose Frutos Fernandez, Peter Fürst, Ursula Gundert-Remy, Rainer Gürtler, Trine Husøy, Melania Manco, Wim Mennes, Peter Moldeus, Sabina Passamonti, Romina Shah, Ine Waalkens-Berendsen, Detlef Wölfle and Matthew Wright.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgements: The Panel wishes to thank the following for the support provided to this scientific output: Antonio Rivas Cornejo and the members of the FAF WG Specifications of Food Additives.

Suggested citation: EFSA FAF Panel (EFSA Panel on Food Additives and Flavouring), Younes M, Aquilina G, Castle L, Engel K-H, Fowler P, Frutos Fernandez MJ, Fürst P, Gürtler R, Gundert-Remy U, Husøy T, Manco M, Mennes W, Passamonti S, Moldeus P, Shah R, Waalkens-Berendsen I, Wölfle D, Wright M, Batke M, Boon P, Bruzell E, Chipman J, Crebelli R, Fitzgerald R, Fortes C, Halldorsson T, LeBlanc J-C, Lindtner O, Mortensen A, Ntzani E, Wallace H, Civitella C, Horvath Z, Lodi F, Tard A and Vianello G, 2021. Scientific Opinion on the re-evaluation of thaumatin (E 957) as food additive. EFSA Journal 2021;19(11):6884, 72 pp. https://doi.org/10.2903/j.efsa.2021.6884

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Summary

The present opinion deals with the re-evaluation of thaumatin (E 957) when used as a food additive.

Thaumatin (E 957) is authorised as a food additive in the European Union (EU) in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives and its specifications are defined in the Commission Regulation (EU) No 231/2012.

Thaumatin was previously assessed by both the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1986 (JECFA, 1986) and the Scientific Committee on Food (SCF) (1985, 1989). Following these evaluations, thaumatin (E 957) was considered acceptable for use and the acceptable daily intake (ADI) was established as 'not specified'. A more recent opinion on the safety of thaumatin for use as a feed additive concluded that there were no concerns for consumer safety from the use of thaumatin in feed and water for drinking for all species, as 'thaumatin is a highly digestible protein and no residues in edible tissues/products are expected' (EFSA FEEDAP Panel, 2011). In 2015, the former EFSA ANS Panel issued a scientific opinion on a proposed extension of use of thaumatin (E 957) concluding that, based on the existing toxicological evaluations, the proposed extension of uses and changes to use levels would not represent a safety concern (EFSA ANS Panel, 2015).

The current risk assessment was carried out based on structured protocols (EFSA, 2020a,b) on hazard identification and characterisation (EFSA, 2020a) and on exposure assessment (EFSA, 2020b). The protocols defined the strategy to be applied for collecting and selecting data, appraising the relevant evidence and analysing and integrating the evidence.

According to Commission Regulation No 231/2012, thaumatin (E 957) is obtained by acidic aqueous extraction of the arils of the fruit of *Thaumatococcus daniellii* (Benth) plant. This food additive is a natural plant protein material: it consists essentially of the proteins thaumatin I and thaumatin II, together with minor amounts of plant constituents, such as arabinogalactan and arabinoglucuronoxylan polysaccharides, derived from the source material. Based on the data provided by interested business operators (electrophoretic analysis), it was shown that thaumatin (E 957) does not only contain the two thaumatin proteins but also other proteins and/or peptides.

The Panel took note that the current EU specification for the minimum purity assay reflects the total protein content in E 957, i.e. not less than 93% (established using Kjeldahl method with nitrogen conversion factor (NCF) of 6.2), whereas the actual content of thaumatin I and II proteins may be only four-fifths of this total, as indicated by one interested business operator. Therefore, the Panel considered that a new specification limit for the minimum combined content of thaumatin I and II proteins in E 957, determined by a validated analytical methodology for quantifying the thaumatin proteins, e.g. high-performance liquid chromatography (HPLC), should be introduced in the EU specifications for E 957.

Based on the analytical data provided by the interested business operators and the dietary exposure estimation to the food additive, the Panel calculated the potential exposure to the toxic elements from the use of E 957 (Appendix E). The Panel considered appropriate to lower the existing EU maximum limit for arsenic and to add maximum limits for mercury and cadmium to the EU specifications for thaumatin (E 957).

Because of its botanical origin, thaumatin (E 957) may be prone to microbiological contamination. The Panel noted that in addition to the already included EU specification limits for total aerobic microbial count and *E. coli*, further microbiological specifications for yeasts, moulds and *Salmonella* spp should be introduced. In addition to microbiological contamination, mycotoxins and pesticides residues may be possible contaminants in E 957. Based on the data and information provided, the Panel considered that there is no concern with respect to contamination by mycotoxins in E 957 and thus no need to introduce limit values for mycotoxins in the EU specifications of this food additive. Regarding pesticides, no residues were detected in one batch of thaumatin (E 957); therefore, the Panel considered that limit values for pesticides in the EU specifications of E 957 are not needed, as long as it is assured that arils are collected from plants that are not commercially cultivated.

Only data on thaumatin digestibility (*in vitro* and *in vivo*) were received from the interested business operators and no new data were identified in the literature. No other data on absorption, distribution, metabolism and excretion (ADME) were available. Based on the available studies, the Panel considered that thaumatin is a readily digestible protein. Acute toxicity studies in mice and rats showed no adverse effects up to 20 and 21 g/kg body weight (bw).

Thaumatin (E 957) did not show a genotoxic potential in a limited bacterial mutation assay and in a dominant lethal test in mice. The Panel noted that the available data set is not aligned with current

requirements for genotoxic hazard identification. However, based on the nature of E 957, the Panel overall concluded that there is no concern with respect to genotoxicity. The toxicology data set consisted of studies, assessed as relevant and reliable based on the criteria established in the draft protocol on hazard identification and characterisation of sweeteners (EFSA, 2020a), on short-term and sub-chronic toxicity in rats and dogs, prenatal developmental toxicity in rats and sensitisation in different experimental animal species. Human data were also available and consisted of three limited human oral intervention studies and two observational studies (exposure to thaumatin via inhalation). No reproductive, chronic toxicity or carcinogenicity studies were available. In the sub-chronic toxicity studies in rats, no effects were observed on testis, uterus or ovaries.

Overall, the repeated dose toxicity studies and a prenatal developmental toxicity study in animals did not identify any adverse effects. Allergenicity via oral exposure was considered unlikely based on animal studies, but was possible via inhalation based on two observational studies in humans. However, indications of allergenicity of thaumatin (E 957) via inhalation in occupational settings are not considered relevant for dietary exposure.

Thaumatin (E 957) is authorised in the EU in 15 food categories with maximum permitted levels (MPLs) ranging from 0.5 to 400 mg/kg and at *quantum satis* (QS) in the three food categories (FCs) of table-top sweeteners. Thaumatin (E 957) is not authorised according to Annex III of Regulation (EC) No 1333/2008. An interested business operator provided EFSA with one use level only (100 mg/kg) in foods belonging to FC 11.4.3 table-top sweeteners in tablets.

Dietary exposure to the food additive was estimated according to different exposure scenarios based on consumers only. The highest mean and 95th percentile (P95) exposure among consumers of one or more food categories containing thaumatin (E 957) was found in adolescents (0.08 and 0.33 mg/kg bw per day), while among consumers of individual food categories the highest mean and P95 exposure was found in consumers only of FC 05.1 chocolate and chocolate products in children with 0.17 and 0.48 mg/kg bw per day, respectively. The Panel considered that the exposure to thaumatin (E 957) from its use as a food additive was overestimated in the regulatory maximum level exposure assessment scenario, given that exposure calculations based on the MPLs/maximum reported use levels were considered applicable to all foods within each food category, while the percentage of the foods in a subcategory labelled with thaumatin (E 957) in Mintel's Global New Products Database (GNPD) was maximally 3.2%.

In the refined brand-loyal scenario, the highest mean exposure was found in children and adolescents (0.01 mg/kg bw per day) while the highest P95 was 0.02 mg/kg bw per day in adults. Infants and toddlers exposure was not presented for this scenario due to no reported consumption of table-top sweeteners and because of only few consumers (less than 6) found per survey, respectively. For this scenario, the Panel considered that the exposure to thaumatin (E 957) was underestimated due to the overall uncertainties and in particular that use levels were only available for table-top sweeteners, whereas thaumatin (E 957) is labelled on other foods such as flavoured drinks (especially in energy drinks), food supplements as well as in a small number of other subcategories in GNPD.

Based on a rat 13-week no observed adverse effect level (NOAEL) of 5,200 mg/kg bw per day, the highest dose tested in males, including a factor of 2 for extrapolation from sub-chronic to chronic exposure (EFSA Scientific Committee, 2012a), a margin of safety (MOS) of 5,417 was derived using the highest P95 exposure in consumers only (0.48 mg/kg bw per day based on the regulatory maximum level exposure assessment scenario). The Panel considered that the MOS is an underestimation since the exposure data are based on a regulatory maximum level exposure assessment scenario.

According to the conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010 (EFSA ANS Panel, 2014) and given that:

- thaumatin is a digestible protein;
- adequate exposure estimates were available;
- there was no concern with respect to the genotoxicity;
- no conclusion on oral allergenicity could be drawn from the available human data;
- no adverse effects were observed in sub-chronic toxicity studies in rats and dogs at the highest dose tested (5,200 mg/kg bw per day and 1,476 mg/kg bw per day, respectively) and in a prenatal developmental toxicity study (2,000 mg/kg bw per day);
- moderate confidence in the body of evidence supported the absence of association between exposure to thaumatin and adverse health outcomes

the Panel concluded that there is no need for a numerical ADI for thaumatin (E 957). Based on a calculated MOS of 5417, considered to be an underestimate, the Panel concluded that there is no

safety concern for thaumatin (E 957) at the regulatory maximum level exposure assessment scenario, which was considered the most appropriate.

The Panel recommends the European Commission to consider:

- introducing the CAS number 53850-34-3 in the EU specifications for E 957
- introducing a new specification limit for the minimum combined content of thaumatin I and II proteins in E 957, determined by using a validated analytical methodology for quantifying specifically the thaumatin proteins, e.g. HPLC;
- lowering the existing EU maximum limit for arsenic and adding maximum limits for mercury and cadmium to the EU specifications for E 957;
- introducing a specification limit for yeast and mould counts and *Salmonella* spp in the EU specifications for E 957, based on the information provided by the interested business operators and Panel considerations.

Table of contents