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Safety evaluation of the food enzyme peroxidase obtained from soybean (*Glycine max*) hulls

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Abstract

The food enzyme considered in this opinion is a peroxidase (hydrogen-peroxide oxidoreductase; EC 1.11.1.7) obtained from hulls of soybeans (*Glycine max*) by the company Kerry Ingredients & Flavours. The compositional data provided were considered sufficient. The manufacturing process did not raise safety concerns. The enzyme is intended to be used in baking processes. Based on the maximum recommended use level, dietary exposure to the food enzyme total organic solids (TOS) was estimated on the basis of individual data from the EFSA Comprehensive European Food Consumption Database. This exposure estimate is lower than the exposure to the fraction of soybean comparable to the food enzyme TOS resulting from the consumption of whole soybean-derived foods by roughly an order of magnitude. As the food enzyme is derived from edible parts of soybean, in line with the requirements of the guidance document on food enzyme assessment, the Panel concluded that the provision of toxicological data was unnecessary. The potential allergenicity was evaluated by searching for similarity between the amino acid sequence of soybean peroxidase retrieved from the database Uniprot and the sequences of known food allergens; no match was found. Peroxidase from soybean hulls is not listed as an allergen in allergen databases. However, several soybean- and soybean hull proteins are known to be respiratory or food allergens. Based on the origin of the food enzyme from edible parts of soybean, the enzyme manufacturing process, the compositional and biochemical data provided, and the dietary exposure assessment, the Panel concluded that this food enzyme does not give rise to safety concerns under the intended conditions of use. However, the Panel noted that this food enzyme may contain allergenic soybean proteins, thus, adverse reactions in susceptible soybean-allergic individuals cannot be ruled out.

Keywords: food enzyme, peroxidase, hydrogen-peroxide oxidoreductase, EC 1.11.1.7, *Glycine max*, soybean hull

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Table of contents

1. Introduction

Article 3 of the Regulation (EC) No 1332/2008[1] provides definitions 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, and
- 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.

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

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

1.1.1. Background as provided by the European Commission

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

Three applications have been introduced by the companies DSM Food Specialities B.V, Novozymes A/S and Kerry Ingredients & Flavours for authorisation of the food enzymes asparaginase from a genetically modified strain of *Aspergillus niger* (strain DS 53180), glucoamylase from a genetically modified strain of *Aspergillus niger* (strain NZYM-BE) and peroxidase obtained from soy bean hulls respectively.

Following the requirements of Article 12.1 of Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008, the Commission has verified that the three application fall within the scope of the food enzyme Regulation and contains 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 asparaginase from a genetically modified strain of *Aspergillus niger* (strain DS 53180), glucoamylase from a genetically modified strain of *Aspergillus niger* (strain NZYM-BE) and peroxidase obtained from soy bean hulls in accordance with Article 17.3 of Regulation (EC) No 1332/2008 on food enzymes.

[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, p. 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, p. 1–6.

1.2. Interpretation of the Terms of Reference

The present scientific opinion addresses the request from the European Commission to carry out a safety assessment of the food enzyme peroxidase obtained from soybean (*Glycine max*) hulls.

1.3. Information on existing authorisation and evaluations

According to the applicant, no similar food enzyme has been evaluated.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier in support of the application for authorisation of the food enzyme peroxidase obtained from soybean (*G. max*) hulls.[3] The food enzyme is intended to be used in baking processes.[4]

2.2. Methodologies

The assessment was conducted in line with the principles described in 'Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA' (EFSA, 2009a) and following the relevant existing guidelines from the EFSA Scientific Committee.

The current 'Guidance on the submission of a dossier for safety evaluation of a food enzyme' (EFSA, 2009b) has been followed for the evaluation of the application with the exception of the exposure assessment, which was carried out in accordance with the methodology described in the 'CEF Panel statement on the exposure assessment of food enzymes' (EFSA CEF Panel, 2016).

3. Assessment

3.1. Technical Data

3.1.1. Identity of the food enzyme

IUBMB nomenclature:	Peroxidase
Systematic name:	Phenolic donor: hydrogen-peroxide oxidoreductase
Synonyms:	Lactoperoxidase, guaiacol peroxidase, plant peroxidase, soybean peroxidase
IUBMB No:	EC 1.11.1.7
CAS No:	9003-99-0
EINECS No:	232-668-6

The food enzyme is obtained via aqueous extraction from soybean hulls.

3.1.2. Chemical parameters

The amino acid sequence of the peroxidase obtained from the hulls of soybeans (*G. max*) has not been provided by the applicant. Using sodium dodecyl sulfate-polyacrylamide gel electrophoresis (SDS–PAGE) analysis, the applicant compared the protein profile of the food enzyme with pure horseradish and soybean peroxidases, used for diagnostic and research purposes, and indicated a band migrating between 36.5 and 48.5 kDa to be the soybean peroxidase.

The protein profiles of three food enzyme batches, determined using SDS–PAGE analysis, were comparable. Apart from the band assigned to the peroxidase by the applicant, the gels showed several additional bands. The observed complexity of the protein profiles reflects the fact that the food enzyme is extracted from soybean hulls without further protein fractionation.

Data on chemical parameters were provided for three commercial food enzyme batches. The average total organic solids (TOS) content was 3.49% (w/w); the values ranged from 2.90% to 3.88% (Table 1). The TOS content is a calculated value: 100% food enzyme minus % water content minus % ash.

[3] http://registerofquestions.efsa.euopa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00897

[4] This is an EC working document describing the food processes in which food enzymes are intended to be used. Not yet published at the time of adoption of this opinion.

The average enzyme activity/TOS ratio of the three commercial food enzyme batches was 5.63 units/mg TOS; the values ranged from 5.43 to 5.93 units/mg TOS (Table 1). Considering the low variability of the enzyme activity/TOS ratio in the three food enzyme batches for commercialisation, the average activity/TOS ratio of 5.63 units/mg TOS was used for subsequent calculations.

No analytical data on side activities of the food enzyme were provided. Taking into account that the food enzyme is obtained from an edible part of a plant, the Panel considered this acceptable.

Table 1: Compositional data provided for three batches of the food enzyme after the extraction and separation from solids

Parameter	Unit	Batches		
		1	2	3
Peroxidase activity	Units/g batch	200	230	160
Protein	%	0.24	0.28	0.23
Ash	%	0.22	0.32	0.30
Water	%	96.1	95.8	96.8
Total organic solids (TOS)[(a)]	%	3.68	3.88	2.90
Peroxidase activity/mg TOS	Units/mg TOS	5.43	5.93	5.52

(a): TOS, total organic solids. TOS calculated as 100% - % water - % ash.

The lead content in these three commercial batches was $\leq$ 1 mg/kg, which complies with the specification for lead (not more than 5 mg/kg), as laid down in the general specifications and considerations for enzymes used in food processing (FAO/WHO, 2006).

The food enzyme complies with the microbiological criteria as laid down in the general specifications and considerations for enzymes used in food processing (FAO/WHO, 2006), which stipulate that *Escherichia coli* and *Salmonella* species are absent in 25 g of sample and total coliforms are not more than 30 CFU (colony forming units) per gram.

In addition to the data presented in Table 1, the applicant provided data on three other batches of the food enzyme, demonstrating that the amounts of several mycotoxins (aflatoxins B1, B2, G1 and G2; deoxynivalenol; ochratoxin A; sterigmatocystin; T-2 toxin; zearalenone) were below the respective limits of quantification.[5]

The Panel considered the compositional data provided for the food enzyme as sufficient.

3.1.3. Properties of the food enzyme

The peroxidase catalyses the reductive cleavage of hydrogen peroxide by two phenolic donors, resulting in two phenoxyl radicals of the donors and water. The resulting free radicals react non-enzymatically with other compounds.

The peroxidase activity is quantified based on the oxidation of 2,2′-azino-bis (3-ethylbenz-thiazole-6-sulfonic acid) (ABTS). The analytical principle is based on the spectrophotometric detection (405 nm) of the resonance-stabilised radical cation $ABTS^{\bullet+}$ formed in the presence of excess substrate and hydrogen peroxide (reaction conditions: pH 5.0–6.0, temperature 40°C). The activity is expressed in units/mg where one unit produces one micromole of $ABTS^{\bullet+}$ per minute under the assay conditions.

The peroxidase has been characterised regarding its activity depending on temperature and pH. The temperature profile has been measured from 20°C up to 60°C (with an optimum of 45–55°C at pH 5) and within a pH range of 2–9 (with an optimum of 5–6 at 40°C). The thermostability of the food enzyme was tested over the range of 20–100°C after pre-incubation at 20°C to 90°C at pH 5 for 20 min and at 100°C for 10 min. The activity was measured under standard conditions. The food enzyme shows about 100% activity at 30°C and approximately 70% residual activity at 80°C after 20 min incubation; at 100°C no enzyme activity was detected after 10 min.

[5] The following limits of quantification were reported by the applicant. Aflatoxins (B1, B2, G1, G2): 1 μg/kg food enzyme, deoxynivalenol: 100 μg/kg food enzyme, ochratoxin A: 1 μg/kg food enzyme, sterigmatocystin: 1 μg/kg food enzyme, T2-toxin: 50 μg/kg food enzyme, zearalenone: 100 μg/kg food enzyme.

3.1.4. Information on the source material

The food enzyme is obtained from the hulls of genetically non-modified soybeans (*G. max*). The applicant states that the quality of the raw materials is regularly controlled on, for example, heavy metals, mycotoxins and pesticides through testing and the supplier assurance program. The applicant provided a certificate of analysis to a batch of the soybean hulls.

Soybean hulls are consumed as parts of foods that are prepared using whole soybeans. For example, Natto, a traditional Japanese food, consists of fermented cooked whole soybeans that have not been hulled.

3.1.5. Manufacturing process

A comprehensive data set related to the manufacturing process including a flow diagram was provided. The food enzyme is manufactured in accordance with Regulation (EC) No 852/2004[6], with food safety procedures based on the principles of hazard analysis and critical control points (HACCP principles), and in accordance with current good manufacturing practice (GMP). The manufacturing site is certified in accordance with ISO 9001 and ISO 14001 standards.

The food enzyme is obtained by repeated extraction of the hulls with an aqueous solution of calcium chloride and sodium benzoate. In the primary liquid/solid separation, the solids are removed using decanters and by low force centrifugation. The liquid containing the enzyme is then concentrated by ultrafiltration, spray dried and formulated into a food enzyme preparation by mixing with wheat flour as a carrier. Ash and moisture contents were determined in each step; TOS and the peroxidase activity/mg TOS ratio were calculated.

According to the applicant, 71 kg of the food enzyme preparation (including maltodextrin and wheat flour) are produced from 1,000 kg soybean hulls. This enzyme preparation is employed to add 35 mg TOS/kg flour. This yield factor of 7.1% (w/w) will be used in the subsequent calculation of dietary exposure.

Microbial contamination is prevented by the hygienic design of the equipment, cleaning and sterilisation of the process area and equipment, and use of a sterile filtration step. It is controlled by plate counts or microscopy at regular steps during the process.

The Panel considered the information provided on the raw materials and the manufacturing process to be sufficient.

3.1.6. Reaction and fate in foods

Ferulic acid is a minor component of arabinoxylans, bound to arabinose residues as an ester. The peroxidase catalyses the formation of diferulic acid linkages, creating inter-chain bonds between arabinoxylans.

According to the applicant, the peroxidase is not known to catalyse other reactions than those resulting in phenoxyl radicals, and finally diferulic acid linkages. These reaction products are naturally present in arabinoxylan-containing foods. There are no indications for unintended products resulting from the peroxidase or side activities.

The data and information provided on the enzyme stability indicate that the peroxidase is inactivated during processing under the intended conditions of use.

3.1.7. Case of need and intended conditions of use

The food enzyme is intended to be used in baking processes[7] up to a maximum recommended dose of 35 mg TOS/kg flour. The dosage applied in practice by a food manufacturer depends on the particular process. The peroxidase is added during the dough preparation in order to improve the handling properties and the baking performance of the dough, mainly by forming diferulic acid linkages. Such linkages create interchain bonds between the arabinoxylans, resulting in an entangled network that makes the dough stronger.

[6] Regulation (EC) No 852/2004 of the European Parliament of the Council of 29 April 2004 on the hygiene of food additives. OJ L 226 25.6.2004, p. 3–21.

[7] The description provided by the applicant has been harmonised by EFSA in accordance with the 'EC working document describing the food processes in which food enzymes are intended to be used'. Not yet published at the time of adoption of this opinion.

3.2. Dietary exposure

Following the EFSA Guidance Document on food enzymes (EFSA, 2009b), a comparison was made between:

- dietary exposure to the food enzyme–TOS, resulting from the intended use as proposed by the applicant (herein referred to as 'FE–TOS'); and
- dietary exposure to a fraction of whole soybean comparable to the FE–TOS, resulting from the consumption of whole soybean-derived foods (herein referred to as source material TOS equivalent, 'SMT–Equivalent').

In both cases, food consumption data from the EFSA Comprehensive European Food Consumption Database (hereafter the EFSA Comprehensive Database[8]) were used.

Exposure estimates were calculated using the methodology described in the CEF Panel statement on the exposure assessment of food enzymes (EFSA CEF Panel, 2016). The assessment of the food processes covered in this opinion involved the selection of relevant food groups and the application of process and technical conversion factors (Appendix B), as appropriate (Section 3.2.3). These input data were subject to a stakeholder consultation through open calls,[9] and adjusted in accordance with feedback received.

3.2.1. EFSA Comprehensive European Food Consumption Database

Since 2010, the Comprehensive Database has been populated with detailed national data on food consumption. Competent authorities in European countries provide EFSA with data regarding the level of food consumption by individual consumers, as taken from the most recent national dietary survey in their country (EFSA, 2011a).

The food consumption data gathered by EFSA were collected using different methodologies and thus direct country-to-country comparisons should be made with caution. Depending on the food category and the level of detail used in exposure calculations, uncertainties might be introduced owing to subjects possibly underreporting and/or misreporting consumption amounts. Nevertheless, the EFSA Comprehensive Database is the best available source of food consumption data across Europe.

Food consumption data from the population groups' infants, toddlers, children, adolescents, adults and the elderly were used for the exposure assessment. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Appendix A).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b).

3.2.2. Exposure assessment methodology

Chronic exposure was calculated based on individual consumption, averaged over the total survey period, excluding surveys with only one day per subject. 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, 2011a).

Exposure to the FE–TOS was calculated for each individual in the database by multiplying the values reported in Appendix B for each food category by their respective consumption amount per kilogram of body weight (kg bw).

The dietary exposure to the SMT–Equivalent was calculated by first estimating the intake of whole soybean seeds from all dietary sources (applying the recipe and conversion fractions reported in Appendix C). Second, the so-derived intake of whole soybean was converted into a soybean fraction comparable to the FE–TOS via the application of a factor provided by the applicant to take into account the yield of the FE–TOS from the whole soybean source (Section 3.1.5).

In both cases, the exposure per FoodEx category (Appendices B and C) was subsequently added to derive an individual total exposure per day. Finally, these exposure estimates were averaged over the number of survey days and normalised for individual body weight (bw), resulting in an individual average exposure/day per kg bw for the survey period. This was done for all individuals in the survey and per age group, resulting in distributions of individual average exposure per survey and population group. Based on these distributions, the mean and 95th percentile exposures were calculated per survey for the total population and per population group.

[8] Available from: http://www.efsa.europa.eu/en/food-consumption/comprehensive-database
[9] http://www.efsa.europa.eu/en/data/call/161110

3.2.3. Exposure to food enzyme–TOS according to the intended use proposed by the applicant

Exposure to the FE–TOS was estimated based on intended uses and the recommended maximum use levels of the FE–TOS provided by the applicant (Section 3.1.7). Relevant food groups and/or individual foods were selected from the Comprehensive Database and were assumed to always contain the FE–TOS at the maximum recommended use level.

To facilitate matching of the reported use levels for baking processes with foods identified in the Comprehensive Database, the selected foods were disaggregated to ingredient level as appropriate, and converted into the corresponding raw material, i.e. flour, via the application of conversion factors (Appendix B). For example, consumption of 100 g of bread was converted into an intake of 70 g flour (recipe fraction of 0.7) and then multiplied by 35 mg TOS/kg flour, as provided by the applicant, to arrive at an exposure of 2.45 mg TOS/100 g bread.

Exposure to the FE–TOS was calculated by multiplying the values reported for each food category by their respective consumption amount per kilogram of body weight (kg bw) separately for each individual in the database. Table 2 provides an overview of the derived exposure estimates. Average and 95th percentile exposure to the FE-TOS per age class, country and survey are reported in Appendix E Table 1. The contribution of the FE–TOS from each FoodEx category to the total dietary exposure is indicated in Appendix E Table 2.

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

Population group	Estimated exposure (mg/kg bw per day)					
	Infants	**Toddlers**	**Children**	**Adolescents**	**Adults**	**The elderly**
Age range	**3–11 months**	**12–35 months**	**3–9 years**	**10–17 years**	**18–64 years**	**≥ 65 years**
Min–max mean (number of surveys)	0.02–0.11 (6)	0.09–0.22 (10)	0.10–0.21 (18)	0.06–0.14 (17)	0.04–0.08 (17)	0.04–0.07 (14)
Min–max 95th percentile (number of surveys)	0.14–0.30 (5)	0.21–0.37 (7)	0.18–0.39 (18)	0.10–0.28 (17)	0.08–0.17 (17)	0.08–0.13 (14)

bw: body weight.

3.2.4. Dietary exposure to SMT–Equivalent resulting from the consumption of whole soybean-derived foods

The FoodEx categories likely to contain whole soybeans (i.e. unhulled) or produced from whole soybeans were selected from the EFSA Comprehensive Database (Appendix C), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b). The process was aided by qualitative information from the Mintel's Global New Products Database.[10]

Soybeans are separated into different fractions for food and feed uses and hulling of soybeans generally occurs at an early stage in soybean processing (OECD, 2012), therefore, foods such as soybean flour, textured soy protein, soybean oil and lecithin, which are obtained at a later stage of soybean processing (Verhoeckx et al., 2015) were not suitable to estimate intake of soybean hulls.

Historically soybean hulls were mainly used in feed production; however, due its high fibre content, it is nowadays also used in food production. Soybean hull is added directly to some foods targeting vegetarian or vegan consumers, however due the fact that these foods only became available on the European market after 2011, and due to lack of detail on consumption in the Comprehensive Database, these categories could not be taken into account in the exposure assessment (Appendix D). Therefore, consumption of soybean hulls was estimated through selection of foods containing whole soybean. In Europe, whole soybeans are typically consumed as such in the form of edamame, or in coagulated form in the shape of tofu. Other foods which can be made using whole soybean include soy drinks, cheese, yoghurt and ice cream. The Panel therefore decided to estimate exposure based on these foods and used a brand-loyal model, whereby it is assumed that a consumer always chooses the same brand.

[10] Accessible at http://www.mintel.com/global-new-products-database

The selected FoodEx categories (Appendix C) were converted from food as consumed (including ingredients in composite foods) to the respective exposure to a fraction of unhulled soybean that is comparable to the FE–TOS (i.e. the SMT-Equivalent) via application of the technical conversion factors described in Appendix C. For example, soya drink contains about 5.8% soybean.[11] The consumption of 100 mL soya drink was converted into an intake of 5.8 g whole soybean; then by applying a factor of 8% (w/w), 5.8 g of whole soybean was converted to 0.46 g of soybean hull. The seed coat, removed during the hulling, constitutes 7–10% of the weight of unprocessed soybean seeds (O'Bryan et al., 2014). Finally, the 0.46 g intake of soybean hull was converted into 33 mg of SMT–Equivalent after application of the enzyme yield factor of 7.1% (w/w). The figure of 7.1% came from Section 3.1.5, and is used to ensure that the intake of SMT–Equivalent is calculated on the same basis (i.e. based on the same enzyme preparation) as was used to calculate the use level of 35 mg TOS/kg flour.

As whole soybean is a very infrequently consumed food in Europe, and is hence not well reflected by a 'total population' estimate, the SMT–Equivalent was estimated for consumers only (Table 3).

Table 3 provides an overview of the estimated exposure to the SMT–Equivalent in consumers. Average and 95th percentile exposure to the SMT–Equivalent per age class, country and survey are reported in Appendix E Table 3. The contribution of the SMT–Equivalent from each FoodEx category to the total dietary exposure is indicated in Appendix E Table 4.

Table 3: Summary of estimated dietary exposure to the SMT-Equivalent, resulting from the consumption of whole soybean-derived foods, in six consumer groups (consumers only)

Population group	Estimated exposure (mg/kg bw per day)					
	Infants	**Toddlers**	**Children**	**Adolescents**	**Adults**	**The elderly**
Age range	**3–11 months**	**12–35 months**	**3–9 years**	**10–17 years**	**18–64 years**	**≥ 65 years**
Min–max mean (number of surveys)	0.04–7.75 (5)	0.62–8.59 (8)	0.29–4.93 (14)	0.19–3.63 (13)	0.30–4.49 (16)	0.21–1.28 (12)
Min–max 95th percentile (number of surveys)	not estimated[(a)]	13.52 (1)	0.73–4.17 (2)	not estimated[(a)]	1.14–4.85 (6)	not estimated[(a)]

bw: body weight.
(a): less than 60 consumers.

3.2.5. Comparison of the exposure estimates

Exposure to the FE–TOS (Table 2) is lower than that to the SMT–Equivalent in consumers (Table 3) by roughly an order of magnitude.

3.2.6. 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 4.

[11] As typically used by EFSA in data conversion.

Table 4: Qualitative evaluation of the influence of uncertainties on the dietary exposure estimate

Sources of uncertainty	Direction of impact	
	Exposure to FE–TOS	Exposure to SMT–Equivalent
Model input data		
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard.	+/–	+/–
Use of data from food consumption survey 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		
FoodEx categories included in the exposure assessment were assumed to always contain the FE–TOS.	+	NA
Exposure to FE–TOS was always calculated based on the maximum recommended use level.	+	NA
Selection of broad FoodEx categories for the exposure assessment.	+	NA
Selection of FoodEx categories likely to contain unhulled soybean for the intake assessment of SMT-equivalent, based on the national food descriptors, recipe databases and the Mintel Global New Products Database.	NA	+/–
Use of technical factors in the exposure model.	+/–	+/–
The applied yield factor was based on the food enzyme preparation with 29.1 units/mg TOS.	NA	+/–
Use of recipe fractions in disaggregation of FoodEx categories likely to contain unhulled soybean and/or food likely to contain the food enzyme.	+/–	+/–

+: uncertainty with potential to cause overestimation of exposure; –: uncertainty with potential to cause underestimation of exposure; NA: not applicable.

Both the FE–TOS estimate and the SMT–Equivalent estimate are derived using the same food consumption data and exposure model, and hence share a number of uncertainties. The conservative approach applied to the exposure estimate for FE–TOS, in particular, assumptions made on the occurrence and use levels of this specific food enzyme, is likely to have led to a considerable overestimation of the exposure. For the estimation of intake of the SMT–Equivalent, uncertainties taken into account do not indicate either over- or underestimation of intake.

Overall, the Panel noted that actual exposure to the FE–TOS is likely to be considerably lower than the estimated one, and consequently the margin between the estimate of exposure to the FE–TOS and the SMT–Equivalent is likely to be higher than estimated.

3.3. Toxicological data

According to Commission Implementing Regulation (EU) No 562/2012[12], an application for the safety evaluation of a food enzyme does not need to include toxicological data if the food enzyme is obtained from edible parts of a plant intended or reasonably expected to be ingested by humans.

According to the EFSA Guidance on the submission of a dossier on food enzymes for safety evaluation, the justification for not supplying toxicological data may include a documented history on the safety of the source of the food enzyme, the composition and the properties of the food enzyme, as well as its use in foods, demonstrating no adverse effects on human health when consumed in a comparable way (EFSA, 2009b).

The Panel considers these requirements as being fulfilled because:

i) whole soybean and derived products are routinely eaten in many parts of the world (reviewed by Erdman and Fordyce, 1989).

[12] Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes. OJ L 168, 28.6.2012, p. 21–23.

ii) soybean hulls used for the production of the food enzyme comply with the legal requirements regarding limits of potential contaminants and residues. The manufacturing process of the food enzyme is not considered to introduce substances that could raise safety concerns.
iii) the compositional data provided on the food enzyme are considered sufficient.
iv) exposure to the food enzyme, calculated on the basis of FE–TOS, is lower than the exposure to a soybean fraction comparable to the FE–TOS, resulting from the consumption of whole soybean-derived foods.

3.4. Allergenicity

The potential allergenicity of peroxidase from soybean hulls was assessed by comparing the amino acid sequence with those of known allergens according to the EFSA '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). The amino acid sequence of the peroxidase from soybean hulls was not provided by the applicant, but retrieved from the database Uniprot.[13] Using higher than 35% identity in a sliding window of 80 amino acids as the criterion, no matches were found.

The food enzyme peroxidase from the hulls of soybean is not listed as an allergen in either the IUIS allergen data base of the WHO/International Union of Immunological Societies or in the AllergenOnline database of the FARRP (Food Allergy Research and Resource Program). However, soybeans and products thereof are listed as products causing allergies (Regulation (EU) No 1169/2011). Several soybean and soybean hull proteins are known to be respiratory or food allergens (reviewed by Batista et al., 2007; Verhoeckx et al., 2015). The enzyme peroxidase might contain soybean allergens, as the supplied SDS–PAGE analysis showed several other protein bands in addition to the food enzyme peroxidase.

The Panel noted that wheat is used as a carrier of the food enzyme preparation. Wheat contains substances and products causing allergies (respiratory and food allergies) and intolerances (gluten intolerance) (Regulation (EU) No 1169/2011).[14] The food enzyme preparation might contain traces of wheat allergens and gluten, which may give rise to safety concerns in wheat-allergic and gluten-intolerant consumers.

Conclusions

Based on the manufacturing process and the compositional and biochemical data provided, and taking into account the comparative dietary intake assessment, the Panel considers that the food enzyme peroxidase obtained from soybean hulls by the company Kerry Ingredients & Flavours does not give rise to safety concerns under the intended conditions of use.

The Panel noted that the food enzyme may contain allergenic soybean proteins, thus, adverse reactions in susceptible soybean allergic individuals cannot be ruled out.

Documentation provided to EFSA

1) Dossier 'Application for authorisation of peroxidase (*Glycine max*)'. August 2013. Submitted by Kerry Ingredients and Flavours.
2) Changes to the Dossier in section 'Chemical composition'. March 2014. Provided by Kerry Ingredients and Flavours.
3) Summary report on technical data and dietary exposure related to peroxidase from soybean (*Glycine max*) hulls. March 2015. Delivered by Hylobates Consulting (Rome, Italy) and BiCT (Lodi, Italy).
4) Summary report on genotoxicity, subchronic toxicity study and allergenicity related to peroxidase extracted from soybean (*Glycine max*) hulls. August 2014. Delivered by FoBiG GmbH (Freiburg, Germany).
5) Correction of the units/g TOS figure. May 2016. Provided by Kerry Ingredients and Flavours.

[13] http://www.uniprot.org/uniprot/O22443
[14] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

6) Correction to the Dossier in sections 'Chemical composition' and 'Manufacturing process'. October 2016. Provided by Kerry Ingredients and Flavours.
7) Additional information on the yield factor on the food enzyme, contaminant screening of the raw materials and a SDS-PAGE of the food enzyme; correction of the enzyme activity unit. March 2017. Provided by Kerry Ingredients and Flavours.
8) Additional information on the yield factor and further clarification to different values about the enzymatic activity (unit/mg TOS) presented on various occasions. July 2017. Provided by Kerry Ingredients and Flavours.

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Abbreviations

ABTS	2,2′-azino-bis (3-ethylbenz-thiazole-6-sulfonic acid)
bw	body weight
CAS	Chemical Abstracts Service
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
EINECS	European Inventory of Existing Commercial Chemical Substances
FAO	Food and Agricultural Organization of the United Nations
FARRP	Food Allergy Research and Resource Program

FE	food enzyme
FE–TOS	food enzyme–total organic solids
GMP	good manufacturing practice
GNPD	Global New Products Database
HACCP	hazard analysis and critical control points
IUBMB	International Union of Biochemistry and Molecular Biology
IUIS	International Union of Immunological Societies
OECD	Organisation for Economic Co-operation and Development
SDS–PAGE	sodium dodecyl sulfate–polyacrylamide gel electrophoresis
SMT–Equivalent	source material tos–equivalent
TOS	total organic solids
WHO	World Health Organization

Appendix A – Population groups considered for the exposure assessment

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

(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, 2011a).

Appendix B – FoodEx categories used to derive exposure estimates for the food enzyme–TOS and the respective conversion factors

FoodEx code	FoodEx category	Conversion factor from FoodEx food group to raw material[a]	Recipe fraction[b]	mg TOS/kg flour
A.01	Grains and grain-based products (unspecified)	0.8	1	35
A.01.03	Grain milling products (unspecified)	1	1	35
A.01.03.001	Wheat milling products (unspecified)	1	1	35
A.01.03.001.001	Wheat flour, brown	1	1	35
A.01.03.001.002	Wheat flour, Durum	1	1	35
A.01.03.001.003	Wheat flour, white	1	1	35
A.01.03.001.004	Wheat flour, wholemeal	1	1	35
A.01.03.001.005	Graham flour	1	1	35
A.01.03.001.006	Wheat flour, gluten free	1	1	35
A.01.03.001.014	Wheat starch	1.2	1	35
A.01.03.002	Rye milling products (unspecified)	1	1	35
A.01.03.002.001	Rye flour, gluten free	1	1	35
A.01.03.002.002	Rye flour, light	1	1	35
A.01.03.002.003	Rye flour, medium	1	1	35
A.01.03.002.004	Rye flour, wholemeal	1	1	35
A.01.03.003	Buckwheat milling products (unspecified)	1	1	35
A.01.03.003.001	Buckwheat flour	1	1	35
A.01.03.004	Corn milling products (unspecified)	1	1	35
A.01.03.004.001	Corn flour	1	1	35
A.01.03.004.003	Corn starch	1.3	1	35
A.01.03.005	Oat milling products (unspecified)	1	1	35
A.01.03.005.002	Oat flour	1	1	35
A.01.03.005.004	Oat starch	1.2	1	35
A.01.03.006	Rice milling products (unspecified)	1	1	35
A.01.03.006.001	Rice flour	1	1	35
A.01.03.006.002	Rice flour white	1	1	35
A.01.03.006.003	Rice flour, instant	1	1	35
A.01.03.006.004	Rice starch	1.2	1	35
A.01.03.007	Spelt milling products	1	1	35
A.01.03.008	Other milling products (unspecified)	1	1	35
A.01.03.008.001	Amaranth flour	1	1	35
A.01.03.008.002	Barley flour	1	1	35
A.01.03.008.003	Chapatti flour	1	1	35
A.01.03.008.004	Flour mix, wheat/rye/barley/oats	1	1	35
A.01.03.008.005	Millet flour	1	1	35
A.01.03.008.007	Sorghum flour	1	1	35
A.01.04	Bread and rolls (unspecified)	1	0.7	35
A.01.04.001	Wheat bread and rolls	1	0.7	35
A.01.04.002	Rye bread and rolls	1	0.7	35
A.01.04.003	Mixed wheat and rye bread and rolls	1	0.7	35
A.01.04.004	Multigrain bread and rolls	1	0.7	35
A.01.04.005	Unleavened bread, crisp bread and rusk (unspecified)	1	0.8	35
A.01.04.005.001	Crisp bread, rye wholemeal	1	0.9	35

FoodEx code	FoodEx category	Conversion factor from FoodEx food group to raw material[a]	Recipe fraction[b]	mg TOS/kg flour
A.01.04.005.002	Crisp bread, rye, light	1	0.9	35
A.01.04.005.003	Crisp bread, wheat, wholemeal	1	0.9	35
A.01.04.005.004	Crisp bread, wheat, light	1	0.9	35
A.01.04.005.005	Rusk, light	1	0.9	35
A.01.04.005.006	Rusk, wholemeal	1	0.9	35
A.01.04.005.007	Pita bread	1	0.7	35
A.01.04.005.008	Matzo	1	0.9	35
A.01.04.005.009	Tortilla	1	0.7	35
A.01.04.006	Other bread	1	0.7	35
A.01.04.007	Bread products	1	0.7	35
A.01.07	Fine bakery wares (unspecified)	1	0.5	35
A.01.07.001	Pastries and cakes (unspecified)	1	0.5	35
A.01.07.001.001	Beignets	1	0.15	35
A.01.07.001.002	Buns	1	0.7	35
A.01.07.001.003	Cake from batter	1	0.25	35
A.01.07.001.004	Cheese cream cake	1	0.24	35
A.01.07.001.005	Cheese cream sponge cake	1	0.24	35
A.01.07.001.006	Chocolate cake	1	0.24	35
A.01.07.001.007	Chocolate cake with fruits	1	0.24	35
A.01.07.001.008	Cream cake	1	0.24	35
A.01.07.001.009	Cream cheese cake	1	0.24	35
A.01.07.001.010	Cream custard cake	1	0.24	35
A.01.07.001.011	Cream custard sponge cake	1	0.24	35
A.01.07.001.012	Croissant	1	0.5	35
A.01.07.001.013	Croissant, filled with chocolate	1	0.5	35
A.01.07.001.014	Croissant, filled with cream	1	0.5	35
A.01.07.001.015	Croissant, filled with jam	1	0.5	35
A.01.07.001.016	Croquembouche	1	0.15	35
A.01.07.001.017	Doughnuts	1	0.24	35
A.01.07.001.018	Clair	1	0.15	35
A.01.07.001.019	Flan	1	0.5	35
A.01.07.001.020	Fruit cake	1	0.6	35
A.01.07.001.021	Fruit pie	1	0.15	35
A.01.07.001.022	Cheese pie	1	0.15	35
A.01.07.001.023	Fruit tart	1	0.15	35
A.01.07.001.024	Gingerbread	1	0.6	35
A.01.07.001.025	Gougere	1	0.15	35
A.01.07.001.026	Kringles	1	0.25	35
A.01.07.001.027	Nut cream cake	1	0.24	35
A.01.07.001.028	Pancakes	1	0.25	35
A.01.07.001.029	Profiterole	1	0.15	35
A.01.07.001.030	Pyramid cake	1	0.25	35
A.01.07.001.031	Rhubarb flan	1	0.15	35
A.01.07.001.032	Scone	1	0.5	35
A.01.07.001.033	Sponge dough	1	0.25	35
A.01.07.001.034	Sponge cake	1	0.25	35
A.01.07.001.035	Sponge cake roll	1	0.25	35

FoodEx code	FoodEx category	Conversion factor from FoodEx food group to raw material[a]	Recipe fraction[b]	mg TOS/kg flour
A.01.07.001.036	Muffins	1	0.25	35
A.01.07.001.037	Waffles	1	0.25	35
A.01.07.001.038	Apple strudel	1	0.15	35
A.01.07.001.039	Cream-cheese strudel	1	0.24	35
A.01.07.001.040	Cheese pastry goods from puff pastry	1	0.15	35
A.01.07.001.041	Croissant from puff pastry	1	0.6	35
A.01.07.001.042	Brioche	1	0.5	35
A.01.07.001.044	Lebkuchen	1	0.6	35
A.01.07.001.045	Dumpling	1	0.5	35
A.01.07.001.046	Cake marbled, with chocolate	1	0.5	35
A.01.07.001.047	Marzipan pie	1	0.25	35
A.01.07.001.048	Baklava	1	0.15	35
A.01.07.002	Biscuits (cookies)	1	0.9	35
A.01.07.002.001	Biscuits, sweet, plain	1	0.9	35
A.01.07.002.002	Biscuits, chocolate filling	1	0.81	35
A.01.07.002.003	Biscuits, cream filling	1	0.81	35
A.01.07.002.004	Biscuits, fruit filling	1	0.81	35
A.01.07.002.005	Biscuits, vanilla filling	1	0.81	35
A.01.07.002.006	Butter biscuits	1	0.81	35
A.01.07.002.007	Biscuit, iced	1	0.81	35
A.01.07.002.008	Speculaas	1	0.9	35
A.01.07.002.009	Biscuits, sweet, wheat wholemeal	1	0.9	35
A.01.07.002.010	Biscuits, oat meal	1	0.9	35
A.01.07.002.011	Biscuits, spelt meal	1	0.9	35
A.01.07.002.012	Biscuits, salty	1	0.9	35
A.01.07.002.013	Biscuits, salty, with cheese	1	0.81	35
A.01.07.002.014	Sticks, salty	1	0.81	35
A.17.03.003	Biscuits, rusks and cookies for children	1	0.9	35
A.18.04.001	Find bakery products for diabetics	1	0.5	35
A.19.01.001	Sandwich and sandwich-like meal	1	0.32	35
A.19.01.002	Pizza and pizza-like pies	1	0.3	35

TOS: total organic solids.
(a): Available at see http://www.fao.org/fileadmin/templates/ess/documents/methodology/tcf.pdf
(b): Derived from publically available recipe information, and/or food label information (such as Mintel's Global New Products Database http://www.mintel.com/global-new-products-database).

Appendix C – FoodEx categories used to derive intake estimates for the whole soybean and the respective conversion factors

FoodEx code	FoodEx category	Conversion factor from FoodEx food group to whole soybean[(a)]	Proportion of whole soybean used as ingredient or in the production of foods (%)	Source
A.04.02.012	Soya beans (*Glycine max*)	1	100	
A.08.09.007	Soya cheese	1	48	Ingredient list on food label (GNPD)
A.08.09.008	Soya drink	0.058	100	Typically used by EFSA in data conversion
A.08.09.009	Soya yoghurt	1	7.8	Ingredient list on food label (GNPD)
A.08.09.011	Tofu	0.29	100	FAO Food composition tables for international use
A.20.02.002	Ice cream, not milk-based	1	4.96	Ingredient list on food label (GNPD)

(a): Available at see http://www.fao.org/fileadmin/templates/ess/documents/methodology/tcf.pdf

Appendix D – Food groups excluded from the intake assessment of soybean hull foods

search date: 7/11/2017				
where Region matches Europe				
and Full text search matches soy/soya				
and Super-Category matches one or more of Food, Drink				
and Ingredient Search matches all of (Soybean Fibre and all child ingredients, Soybean Fibre) together as the Ingredients				
Sub-Category (Top 5)	**Country**	**Company (Top 5)**	**Brand (Top 5)**	**#**
Meat Substitutes	France	Nutrition & Santé	Céréal Grill Végétal	4
			Céréal Grill Vegetal	2
		Triballat Noyal	Sojasun	1
	Belgium	Colruyt	Boni Selection Veggie	1
	Denmark	I Am Foods	Funky Fields	1
	Germany	Triballat Noyal	Sojade	1
	Netherlands	SoFine Foods	So Fine	1
	UK	Cauldron Foods	Cauldron	1
Sweet Biscuits/ Cookies	Austria	Mondelez	Milka Cookies Sensations	1
			Milka Sensations	1
	Switzerland	Mondelez	Milka Cookies Sensations	2
	Belgium	Mondelez	Milka Sensations	1
	Portugal	Mondelez	Milka Cookies Sensations	1
Dry Soup	Finland	Orkla Health	Get Started by Nutrilett	2
			Nutrilett	1
		Collett Pharma	Nutrilett	1
	Poland	Axellus	DietaLight	1
Prepared Meals	France	Sojasun	Sojasun	1
		Triballat Noyal	Sojasun Mon Plat Végétal	1
		Viviers de France	Côté Phare Exotique	1
	Germany	Eat Happy Togo	Wakame	1
Snack/Cereal/ Energy Bars	Italy	Valsoia	Valsoia	1
	Netherlands	The Natural Brands Company	Wallaby Superbar	1
Other	Poland	Polgrunt	Orico	1
		Valsoia	Valsoia Bonta'e Salute	1
		Zaklad Przetworstwa Miesnego JBB	JBB Baldyga Grill Dobry	1
	Austria	Sojasun	Sojasun	1
	Finland	Orkla Health	Get Started by Nutrilett	1
	Germany	Valsoia	Valsoia	1
	Netherlands	Tazaki Foods	Yutaka	1
	Spain	Sojasun	Sojasun	1
	UK	Nature's Path Foods	Nature's Path Organic Optimum	1
	Slovakia	Koro	Koro	1
Total				39

Appendix E – Dietary exposure estimates to the food enzyme–TOS and the SMT–Equivalent in details

Information provided in this appendix is shown in an excel file (downloadable at http://onlinelibrary.wiley.com/wol1/doi/10.2903/j.efsa.2017.5119/suppinfo).

The file contains four sheets, corresponding to four 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

Table 3: Average and 95th percentile exposure to the SMT–Equivalent per age class, country and survey

Table 4: Contribution of food categories to the dietary exposure of the SMT–Equivalent per age class, country and survey