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Scientific Opinion on the safety of the extension of use of thaumatin (E 957)

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)

Abstract

Following a request from the European Commission, an exposure assessment was carried out based on the maximum permitted levels (MPLs) authorised in Annex II of Regulation (EC) No 1333/2008 for thaumatin (E 957) and the proposed increase in its use level in flavoured drinks and proposed extension of use in several food categories at the levels proposed by the applicant. The safety of thaumatin as a food additive was previously evaluated by the EU Scientific Committee on Food (SCF) in 1984 and 1988 and by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1989. Following these assessments, thaumatin was considered acceptable for use, and the ADI was established as 'not specified'. In these evaluations it was, moreover, noted that thaumatin, being a protein, undergoes digestion to normal food components. In providing a scientific opinion on the safety of the proposed extensions of use and use levels, the ANS Panel has decided that a comparison of the exposure resulting from the current uses and use levels with the exposure resulting from these additional proposed uses would be sufficient to address the safety of thaumatin. The Panel calculated that a maximum daily intake of 1.03 mg/kg bw/day of thaumatin, resulting from the exposure assessment at the current proposed uses, or 1.10 mg/kg bw/day, at the proposed new Maximum Permitted Levels (MPLs), would represent 0.12 % or 0.13 %, respectively, of the total daily protein intake for an adult. These percentages would be even lower for children of all ages. The Panel concluded, based on the existing toxicological evaluations, that the proposed extension of uses and changes to use levels would result in a margin of safety of approximately 1 300 which would not represent a safety concern.

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Keywords: food additive, sweetener, thaumatin, E 957, extension of use

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Summary

Thaumatin is an aqueous extract obtained from the arils of the katemfe fruit (*Thaumatococcus daniellii* Benth) and is composed primarily of two proteins (thaumatin I and II). Thaumatins occur in nature, albeit with a narrow distribution, among plant species. Impurities in thaumatin consist of minor amounts of plant constituents, such as arabinogalactan and arabinoglucuronoxylan polysaccharides, derived from the source material. Those are normal constituents of plant gums and mucilages.

Thaumatin (E 957) is currently an authorised food additive in the European Union under Annex II of Regulation (EC) No 1333/2008. It may be used in several food categories, either as a sweetener (thaumatin is approximately 2 000 to 3 000 times sweeter than sucrose) or as a flavour enhancer.

Thaumatin was previously assessed for food safety for consumers by both the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Scientific Committee on Food (SCF) between 1986 and 1989. Following these assessments, thaumatin was considered acceptable for use, and the Acceptable Daily Intake (ADI) was established as 'not specified'.

Following a request from the European Commission to take into account the extension of use of thaumatin (E 957) in several food categories at different permitted levels, the increase in the currently approved maximum use level (from 0.5 mg/L to 5 mg/L) in food category 14.1.4, Flavoured drinks, and the use as a food additive in food flavourings under Annex III, part 4, of Regulation (EC) No 1333/2008, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) has provided a scientific opinion on the safety of the proposed extension of uses.

In order to address the safety of this proposed extension of use, the Panel has decided that a comparison of the exposure estimate from the currently authorised uses and from the proposed new uses and use levels would be an adequate approach. The safety of thaumatin (E 957) as a food additive will be considered by the ANS Panel under the re-evaluation programme for food additives already permitted in the EU before 20 January 2009, as envisaged by Commission Regulation (EU) No 257/2010. Meanwhile, the Panel considered that the available toxicological assessments of thaumatin previously performed by the SCF and JECFA would remain valid and, in principle, there would be no need to reconsider this to address the Terms of Reference.

In the present opinion, an anticipated exposure to thaumatin (E 957) as a food additive at the Maximum Permitted Levels (MPLs) was undertaken by the applicant using the FAIM (Food Additives Intake Model) tool, taking into consideration the current authorised uses and the proposed extension of uses and changes to use levels as provided by the applicant.

The Panel noted that the mean dietary exposure to thaumatin (E 957) in the total population from currently approved uses and use levels, as reported by the applicant, ranged from 0.003 to 0.02 mg/kg body weight (bw)/day in the elderly up to 0.04 to 0.13 mg/kg bw/day in children. High-level exposure ranged from 0.07 to 0.22 mg/kg bw/day in adolescents up to 0.04 to 1.03 mg/kg bw/day in adults.

Estimated exposure at both the currently authorised and at the changed use and proposed extended uses and use levels resulted in mean intakes ranging from 0.03 to 0.10 mg/kg bw/day in the elderly up to 0.13 to 0.34 mg/kg bw/day in children. High-level exposure ranged from 0.13 to 0.32 mg/kg bw/day in adolescents up to 0.09 to 1.10 mg/kg bw/day in adults.

The EFSA ANS Panel noted that the current exposure estimates appear higher than the estimated human exposure of 2 mg/person/day (equivalent to 0.03 mg/kg bw/day for a 70-kg adult) considered by JECFA and the SCF in their evaluations. The basis for the estimated exposure of 2 mg/person/day was not stated in the SCF or JECFA conclusions, however the Panel understands that at the time the SCF and JECFA estimated mean exposure for adults only. A comparison of the upper range of the mean exposure for adults in the current estimate is similar to the SCF and JECFA estimates (0.03 mg/kg bw/day for a 70-kg adult).

Neither JECFA nor the SCF allocated a numerical ADI for thaumatin owing to its lack of toxicity in the available studies, combined with its being readily digested to normal food components. The amino acid sequence of the protein was known and there was no indication of the presence of unusual

amino acid side-chains, or atypical peptide linkages or end-groups. Thaumatin, *in vitro*, was broken down to the same extent as ovalbumin, and the *in vivo* nitrogen digestibility of both compounds appeared comparable. No antibodies to thaumatin were detected in either rats or man after prolonged oral administration. In addition, the Panel noted that in 1986 the SCF had specifically requested additional data on the possible formation of neuroendocrine or hormonally active peptides, which had been provided for its later evaluation in 1989. Taken along with structural and conformational considerations, these data led the SCF to conclude that following digestion thaumatin was unlikely to give rise to neuroendocrine or hormonally active peptides.

The ANS Panel noted that the lowest no observed adverse effect levels (NOAELs) identified in previous evaluations were 1 400 mg/kg bw/day from a study in dogs and 2 700 mg/kg bw/day in rats, both corresponding to the highest doses tested in these studies (3.0 % in the diet). The Panel noted that the highest estimated exposure of 1.10 mg/kg bw/day would still result in a margin of safety of approximately 1 300 from the lowest NOAEL.

In the JECFA opinion it was indicated that the only dietary effect of thaumatin was an insignificant contribution to the normal protein intake. The ANS Panel considered appropriate to calculate the contribution of thaumatin to the normal protein intake based on the most recent information. The ANS Panel noted that the Population Reference Intake (PRI) for protein was recently set by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) at 0.83 g protein/kg bw/day for adults, applicable both to high-quality protein and to protein in mixed diets, and that the PRI for children ranged from 0.83 (in adolescents) to 1.03 g protein/kg bw/day (in toddlers). Hence a maximum daily intake of 1.03 mg/kg bw/day of thaumatin at the current proposed uses or 1.10 mg/kg bw/day at the proposed new MPLs would represent 0.12 % or 0.13 %, respectively, of the total daily protein intake for an adult. The Panel noted that, as exposure estimates for thaumatin in children were lower than for adults and the PRI for children was higher than for adults, this would represent a lower percentage of the total daily protein intake for children of all ages.

The Panel concluded, based on the existing toxicological evaluations, that the proposed extension of uses and changes to use levels would result in a margin of safety of approximately 1 300 which would not represent a safety concern.

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1. Introduction

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008[1] on food additives. Only food additives that are included in the Union list, in particular in Annex II to that regulation, may be placed on the market and used in foods under the conditions of use specified therein.

Thaumatin (E 957) is currently an authorised food additive in the European Union under Annex II of Regulation (EC) No 1333/2008. It may be used in several food categories, either as a sweetener (is approximately 2 000 to 3 000 times sweeter than sucrose) or as flavour enhancer.

Thaumatin is an aqueous extract obtained from the arils of the katemfe fruit of the *Thaumatococcus daniellii* Benth plant and is composed primarily of two proteins (thaumatin I and II). Thaumatins occur in nature, albeit with a narrow distribution, amongst plant species. Impurities in thaumatin consist of minor amounts of plant constituents, such as arabinogalactan and arabinoglucuronoxylan polysaccharides, derived from the source material. Those are normal constituents of plant gums and mucilages.

Thaumatin has been previously assessed for food safety for consumers by both JECFA (1986) and the Scientific Committee for Food (1985 and 1989), neither body proposing an ADI.

The Commission received a request vis-à-vis an amendment of Annexes II and III to Regulation (EC) No. 1333/2008, specifically on the use of Thaumatin (E 957) as a food additive, namely:

1) Extension of use in several food categories at different maximum permitted levels;
2) Increase of the currently approved maximum use-level (from 0.5 mg/L to 5 mg/L) in food category 14.1.4 Flavoured drinks, and;
3) Use as a food additive in food flavourings under Annex III part 4 of Regulation (EC) No 1333/2008 [it would be added *quantum satis* to the flavour premix, with the maximum limit in the final food (as carry over) compliant with provisions as per Annex II of Regulation].

1.1.2. Terms of Reference

The European Commission asks the European Food Safety Authority to provide a scientific opinion on the safety of the proposed extension of use of Thaumatin (E 957) as a food additive in several food categories, in accordance with Regulation (EC) No 1331/2008[2] establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

1.2. Interpretation of the Terms of Reference

In order to address the safety of this proposed extension of use, the Panel has decided that a comparison of the exposure estimate from the currently authorised uses and from the proposed new uses and use levels would be an adequate approach.

The safety of thaumatin (E 957) as a food additive[3] will be considered under the re-evaluation programme for food additives already permitted in the EU before 20 January 2009, as envisaged by Commission Regulation (EU) No 257/2010[4]. Meanwhile, the Panel considered that the available

[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

[2] Regulation (EU) 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

[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00725

[4] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up the program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.

toxicological assessments of thaumatin (SCF, 1985, 1989; JECFA, 1986) would remain valid and in principle there would be no need to reconsider this to address the Terms of Reference.

1.3. Additional information

The applicant has provided information on existing uses, authorisations and evaluations in the European Union.

1.3.1. Evaluations in the European Union

Evaluation by the European Scientific Committee on Food (SCF)

The SCF assessed the safety of thaumatin in its initial review of sweeteners in 1984 (SCF, 1985). Data on the history of use of the source material, *Thaumatococcus daniellii*; the properties of the two main active ingredients, the proteins thaumatin I and thaumatin II; the levels of use and estimated intake of thaumatin; and the allergenicity, digestibility, mutagenicity and subchronic toxicity of thaumatin were examined by the committee. Following its review, the committee had outstanding questions regarding the potential for receptor binding and possible endocrine activity, and thus it did not establish an Acceptable Daily Intake (ADI) but considered thaumatin to be 'temporarily acceptable' until further information could be evaluated.

The safety of thaumatin was re-addressed 3 years after the initial evaluation (SCF, 1989). The committee reviewed data on relative organ weights and the histopathology of various endocrine organs in rats and dogs, the analysis of structure/receptor relationships, the results of a 90-day study in humans, and the results of a 4-week study to investigate thyroid function in rats. Thaumatin was considered acceptable from a toxicological point of view based on the lack of consistent treatment-related effects on relative organ weights and the histopathology of various endocrine organs in two rat studies and a single dog study; no treatment-related changes in three serum parameters in humans exposed to large doses of thaumatin (280 mg/day) for 12 weeks; the structural and conformational considerations that thaumatin is unlikely to give rise on digestion to neuroendocrine or hormonally active peptides; and the small exposure to thaumatin, arising from a few food commodities and estimated to be 1–2 mg/person/day from use at levels up to about 30 ppm. Thaumatin was considered acceptable for use, and the ADI was established as 'not specified'.

Safety evaluation by the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

EFSA's FEEDAP Panel evaluated the safety of thaumatin for use in all animal species (EFSA FEEDAP Panel, 2011). Safety for the target species was based on the lowest no observed adverse effect (NOAEL) identified by JECFA (1986), which was 10 g/kg body weight/day in dogs (the highest dose tested). From this NOAEL, the FEEDAP Panel calculated the maximum safe feed concentrations for the target species (range 1 667 to 5 000 mg/kg feed) and concluded that the proposed use levels of 1 to 5 mg thaumatin/kg feed were safe for all animal species and included a 'considerable margin of safety'. Owing to this large margin of safety, it was concluded that thaumatin could be simultaneously administered in feed and water for drinking. The FEEDAP Panel also 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'.

1.3.2. Authorisations and evaluations by international organisations

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Thaumatin (E 957) was initially reviewed by JECFA at its 27th meeting; however, neither an appropriate long-term animal study nor adequate studies in humans were available, so no ADI was allocated (JECFA, 1983). At its 29th meeting, JECFA reviewed a comprehensive data set for thaumatin that included digestibility, mutagenicity, teratogenicity, allergenicity, acute and short-term animal toxicity, and human studies (JECFA, 1986). Based on the results of these studies, JECFA noted that the digestion of thaumatin would not be different from that of other dietary proteins; hormonally active polypeptides would not be likely to result from the digestion of thaumatin; there was no evidence of mutagenic, teratogenic or allergenic effects; that no effect levels of 30 and 10 g/kg body

weight/day were observed in 90-day studies in rats and dogs, respectively and no treatment-related changes were observed following the consumption of 280 mg thaumatin/day for 13 weeks by human volunteers. JECFA established that the ADI was 'not specified', based on an anticipated maximum daily intake of 2 mg/person/day, and 'in view of the fact that thaumatin makes an insignificant contribution to the normal protein diet and is metabolized into normal body constituents' (JECFA, 1986).

According to the applicant the NOAELs stated above are assumed to be errors in transcription since from the description of the studies in the JECFA opinion also reported in the current dossier, the NOAEL appeared to be 3.0 % in the diet for both animal species, corresponding to a daily dose of approximately 2 700 mg/kg bw/day in rats (2 394-2 500 in male rats, 2 822-2 925 in female rats), and approximately 1 400 mg/kg bw/day in dogs (range 1 101-1 600 mg/kg bw/day in male dogs; 1 249 to 1 791 mg/kg bw/day in female dogs). The dose conversion was provided by the applicant on the basis of the original study reports considered by JECFA.

Thaumatin is approved for use in the USA, Canada, Australia and New Zealand, Switzerland, Israel, China, Japan, Hong Kong, Korea, Singapore, Mexico, Brazil and South Africa.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier in support of its application for the extension of the approved uses of thaumatin (E 957) in the EU and the changes in the maximum permitted levels of use in category 14.1.4.

2.2. Methodologies

The current 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012) has been followed by the ANS Panel for the evaluation of the proposed extension of the authorisation of the already authorised food additive thaumatin (E 957).

Exposure to thaumatin (E 957) from its use as a food additive was calculated by the applicant using the FAIM tool with MPLs, and including the proposed changes of use and extension of uses and levels of use as provided by the applicant as listed in Table 2.

3. Assessment

3.1. Technical data

The applicant has provided evidence that the food additive thaumatin (E 957) to be used for the proposed extension of uses complies with the current specifications laid down in Commission Regulation (EU) No 231/2012[5].

The applicant submitted data on the potential presence of pesticide residues included in the United States Pharmacopeia pesticide screen; no such residues were detected.

3.1.1. Manufacturing process

The applicant has submitted detailed information on the manufacturing process used to produce thaumatin by water extraction from the arils of the fruit of the West African plant *Thaumatococcus. daniellii*, including information on the raw materials and the processing aids used.

3.1.2. Methods of analysis in food

The applicant has submitted information on the methods used for the determination of thaumatin in food.

[5] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.03.2012, p. 1–295.

According to both EU specifications and JECFA (2006), thaumatin is assayed by the Kjeldahl method.

The applicant has submitted information on analytical methods for the determination of thaumatin in beverage and powder extracts using high-performance liquid chromatography (HPLC) and in food and botanical extracts using HPLC/tandem mass spectrometry.

3.1.3. Reaction and fate in food

The applicant has submitted data on the stability of the food additive during long-term storage at room temperature, and on its stability when used in soft drink formulations (liquid and powdered) and in jellied sweets.

After 3 years of storage of the additive at room temperature, the total bacterial count was decreased compared to the analysis conducted following production. Total bacterial count at 3 years was greater than a reference batch that was recently produced. Another study was conducted in the dark with the additive to detect protein degradation, as hydrolysis of thaumatin would result in a release of amino acids and small molecular weight proteins. During the period tested (36 months) no change in its appearance was observed, and no degradation of the thaumatin was detected. The results were the same in accelerated conditions (dark at 40 ± 1 ºC for 6 months).

The stability of thaumatin in soft drinks (lemonade, cola and whole orange squash) was tested (visual examination and tasting) under refrigerated and room temperature conditions (5 and 20 ºC).

Another stability study on the evolution of thaumatin stored for 8 months in a soft drink at pH 3 and in a powdered beverage at room temperature in the dark or light or under elevated temperature conditions (40 ºC) in the dark was performed. The thaumatin content did not change during the 8 months of storage for the samples at ambient temperature.

In jellied sweets stored at ambient temperature (dark and light) and at 40 ºC in the dark, it was observed that thaumatin was degraded after 1 month in the elevated temperature study at 40 ºC, whereas, at ambient temperature, thaumatin was not detected after 3 months of storage in dark or light. Therefore gelatin might account for the instability of thaumatin.

The thermostability of thaumatin was studied by Kaneko and Kitabatake (2001), over a pH range from 2 to 10 at 80 ºC for 7 and 15 minutes, and they found that the hydrolysis of peptide bonds and other reactions take place more slowly under acidic conditions, indicating that the mechanism of inactivation and the thermostability of thaumatin depended on the pH.

3.2. Authorised uses and use levels

Maximum Permitted Levels (MPLs) of use for thaumatin (E 957) have been defined in Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing the Union list of food additives, as amended.

Currently, thaumatin (E 957) is an authorised sweetener in the EU with MPLs ranging from 0.5 to 400 mg/kg in foods and it is authorised at *quantum satis* levels in table-top sweeteners.

Table 1 summarises foods that are permitted to contain thaumatin (E 957) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008 as amended.

Table 1: MPLs of thaumatin (E 957) in foods according to Annex II to Regulation (EC) No 1333/2008

FCS category number	Food categories	Current MPL (mg/L or mg/kg as appropriate)	Restrictions/exception
01.4	Flavoured fermented milk products including heat-treated products	5	Only as a flavour enhancer
03	Edible ices	50	Only energy reduced or with no added sugar
05.1	Cocoa and chocolate products as covered by Directive 2000/36/EC	50	Only energy reduced or with no added sugar
05.2	Other confectionery including breath refreshening microsweets	50	Only cocoa or dried fruit based, energy reduced or with no added sugar
05.2	Other confectionery including breath refreshening microsweets	50	Only confectionery with no added sugar
05.3	Chewing gum	10	Only with added sugar or polyols, as flavour enhancer(a)
05.3	Chewing gum	50	Only with no added sugar
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	50	Only confectionery with no added sugar
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	50	Only cocoa or dried fruit based, energy reduced or with no added sugar
11.4.1	Table-top sweeteners in liquid form	*Quantum satis*	
11.4.2	Table-top sweeteners in powder form	*Quantum satis*	
11.4.3	Table-top sweeteners in tablet form	*Quantum satis*	
14.1.4	Flavoured drinks	0.5	Only water-based flavoured non-alcoholic drinks. As flavour enhancer only
16	Desserts excluding products covered in categories 1, 3 and 4	5	As flavour enhancer only
17.3	Food supplements supplied in a syrup-type or chewable form	400	

FCS: Food Categorisation System.
(a): If E 950, E 951, E 957, E 959 and E 961 are used in combination in chewing gum, the maximum level for each is reduced proportionally.

3.3. Exposure data

3.3.1. Data on the proposed changes to the authorised uses and use levels

The applicant has submitted an application to use thaumatin in non-alcoholic beverages at a higher use level than that currently permitted (from 0.5 mg/L to 5 mg/L in food category 14.1.4, flavoured drinks) and to enhance the flavour and sweetness profile in a variety of products (alcoholic beverages, fine bakery wares, etc.) and the mouth-feel of beverages.

In addition, taking into account the fact that thaumatin is often incorporated into the flavour premix used in the manufacturing of foodstuffs, the applicant has submitted a further application to add thaumatin as a flavour carrier under Annex III of Regulation (EC) No 1333/2008, which establishes a list of approved food additives and their conditions of use. The use would be under part 4 of Annex III as an additive in flavours. The applicant has proposed that a reference to carry-over conditions is included so that it is clear that the use of flavour premixes containing thaumatin may be used only in applications in which thaumatin is a permitted additive.

The proposal from the applicant for the extension of use and use levels of thaumatin (E 957) is presented in Table 2 together with the currently authorised MPLs.

Table 2: Currently authorised MPLs and proposed extension of uses and use levels for thaumatin (E 957)

FCS category number	Food categories	Currently authorised MPL (mg/L or mg/kg as appropriate)	Currently authorised and change of use levels and proposed extension of use (mg/L or mg/kg as appropriate)	Restrictions/ exception
1.4	Flavoured fermented milk products including heat-treated products	5	5	Only as a flavour enhancer
3	Edible ices	50	50	Only energy reduced or with no added sugar
4.2.5	Jams, jellies and marmalades and similar products		5	Energy reduced or with no added sugar
5.1	Cocoa and chocolate products as covered by Directive 2000/36/EC	50	50	Only energy reduced or with no added sugar
5.2	Other confectionery including breath refreshening microsweets	50	50	Only cocoa or dried fruit based, energy reduced or with no added sugar
5.2	Other confectionery including breath refreshening microsweets	50	50	Only confectionery with no added sugar
5.3	Chewing gum	10	10	Only with added sugar or polyols, as flavour enhancer
5.3	Chewing gum	50	50	Only with no added sugar
5.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	50	50	Only confectionery with no added sugar
5.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	50	50	Only cocoa or dried fruit-based, energy-reduced or with no added sugar
6.3	Breakfast cereals		10	Energy reduced or with no added sugar
7.2	Fine bakery wares		30	
11.4.1	Table-top sweeteners in liquid form	*Quantum satis*[a]	*Quantum satis*[a]	
11.4.2	Table-top sweeteners in powder form	*Quantum satis*[a]	*Quantum satis*[a]	
11.4.3	Table-top sweeteners in tablets form	*Quantum satis*[a]	*Quantum satis*[a]	
12.1.2	Salt substitutes		15	
12.5	Soups and broths		15	
12.6	Sauces		15	
14.1.4	Flavoured drinks	0.5	5	Only water-based flavoured non-alcoholic drinks. As flavour enhancer only
14.2.1	Beer and malt beverages		5	
14.2.2	Wine and other products defined by Regulation (EEC) No 1234/2007 and alcohol-free counterparts		5	
14.2.4	Fruit wine and made wine		5	
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008		5	
14.2.7	Aromatised wine-based products as defined by Regulation (EEC) No 1601/91		5	
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol		5	
15.1	Potato-, cereal-, flour- or starch-based snacks		10	
16	Desserts excluding products covered in category 1, 3 and 4	5	5	As flavour enhancer only
17.1	Food supplements supplied in a solid form, including capsules and tablets and similar forms excluding chewable forms		400	

FCS category number	Food categories	Currently authorised MPL (mg/L or mg/kg as appropriate)	Currently authorised and change of use levels and proposed extension of use (mg/L or mg/kg as appropriate)	Restrictions/ exception
17.2	Food supplements supplied in a liquid form		400	
17.3	Food supplements supplied in a syrup-type or chewable form	400	400	
18	Processed foods not covered by categories 1 to 17, excluding foods for infants and young children		10	Ready meals (chilled, frozen, dried) only

FCS: Food Categorisation System.
(a): Although permitted at *quantum satis* levels, a level of use of 10 mg/kg in table-top sweeteners (liquid, powder and tablet form) is considered an appropriate current level of use by the applicant and was used in the intake assessment.

Additionally, the applicant has requested the inclusion of thaumatin in Part 4 of Annex III to Regulation (EC) No 1333/2008 for use at *quantum satis* in all food flavourings provided that carry-over is limited to the conditions of use in the final foodstuffs at the maximum limit permitted under Annex II.

3.3.2. Food consumption data used for the exposure assessment

EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with data on national food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons should be interpreted with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database represents the best available source of food consumption data across Europe at present.

Food consumption data from the following population groups: toddlers, children, adolescents, adults and the elderly were used for the exposure assessment. Thus, for the present assessment, food consumption data were available from 26 different dietary surveys carried out in 17 European countries, as listed in Table 3.

Table 3: Population groups considered for the exposure estimates of thaumatin (E 957) from the FAIM tool

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

(a): The terms 'children' and 'the elderly' correspond respectively to 'other children' and the merging of the categories 'elderly' and 'very elderly' in the EFSA guidance 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011c). Nomenclature from the FoodEx classification system has been linked to the Food Classification System (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, FoodEx food codes were matched to the FCS food categories.

The UK National Diet and Nutrition Survey (NDNS) rolling programme 2008–2011

The applicant has provided information on the UK NDNS rolling programme 2008–2011, which was used to calculate an exposure estimate.

The Panel, however, decided to use only the data-derived FAIM (Food Additives Intake Model) template, as recommended in 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012) noting that the UK NDNS rolling programme data are already included in the EFSA Comprehensive Database (EFSA, 2011a).

3.4. Exposure assessment

The exposure to thaumatin (E 957) was calculated using the current MPLs and the changes in use and proposed extension of use provided by the applicant as listed in Table 2 for each food group combined with their respective consumption per kg body weight (bw) for each survey and for the five population groups described in Table 3.

Exposure was estimated using the food additives intake model (FAIM), available on the EFSA website[6]. This template allows calculation of chronic exposure based on consumption data over the total survey period excluding surveys with only one day per subject, which were not considered adequate to assess repeated dietary exposure, as suggested by the EFSA Working Group on Food Consumption and Exposure (EFSA, 2011a). High-level exposure was calculated for only those population groups whose sample size was sufficiently large to allow calculation of the 95th percentile (EFSA, 2011a). The Panel estimated chronic exposure for the following population groups: toddlers, children, adolescents, adults, and the elderly. Calculations were performed using individual body weights.

High-level exposure (typically 95th percentile of consumers only) was calculated by adding the 95th percentile of exposure from one food group (i.e. the one having the highest value) to the mean exposure resulting from the consumption of all other food groups. This is based on the assumption that an individual might be a high-level consumer of one food category and would be an average consumer of the others. This approach has been tested several times by the Panel in re-evaluation of food colours and has shown reasonable correlation with high-level total intakes when using the raw food individual consumption data. Therefore, as recommended by the Panel in its current 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012), this approach was followed using the FAIM tool for the calculations based on the MPLs and the change in use and proposed extension of use levels in order to avoid excessively conservative estimates.

The Panel noted that these exposure estimates should be considered to be conservative, as it is assumed that all processed foods contain thaumatin (E 957) at the MPLs or at the proposed use levels in all food categories.

Food codes representative of each proposed food use described in part D of Annex II to Regulation (EC) No 1333/2008 were chosen from the food code list associated with the food consumption survey available in the FAIM template. Although the approved use for categories 03 Edible ices, and 05, Confectionery, are restricted to the use in foods that are energy reduced or with no added sugar only, all foods within these categories were considered in the intake assessment, thus providing a conservative estimate of intake for these food categories in particular. Furthermore, it is proposed that thaumatin is used in only energy-reduced or no-added-sugar varieties of category 04.2.5, Jams, jellies and marmalades, and category 06.3, Breakfast cereals; however, all foods in these categories are included in the assessment.

Furthermore, the applicant wishes to add the use of thaumatin as a flavour under Annex III of Regulation (EC) No 1333/2008, which establishes a list of approved food additives and their conditions

[6] http://www.efsa.europa.eu/en/topics/topic/additives.htm

of use. The use would be under part 4 of Annex III as an additive in flavours with a carry-over limited to the conditions of use in the final foodstuffs at the maximum limit permitted under Annex II. It is assumed that the intake of thaumatin through this use would already be accounted for through its current approved and proposed estimates of use provided in this section of the report and that therefore an additional estimate of use as an additive in flavours would not be required.

3.4.1. Thaumatin (E 957) from its currently authorised uses and from the proposed changes of uses and use levels

The estimated exposure to thaumatin (E 957) from its use as a food additive for all five population groups (min–max across the dietary surveys) is reported in Table 4. The following scenarios were considered:

1) at the current MPLs;
2) at the current MPLs and at the proposed changes of uses and use levels provided by the applicant.

Detailed results by age class and survey are presented in Appendix A.

Table 4: Estimated exposure to thaumatin (E 957) from its use as a food additive: at the current MPLs and at the changed use and proposed extended uses and use levels.

Estimated exposure (mg/kg bw/day)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Current MPLs					
Mean	0.02–0.12	0.04–0.13	0.02–0.05	0.01–0.03	0.003–0.02
High level	0.17–0.44	0.13–0.42	0.07–0.22	0.04–1.03	0.04–0.63
Current MPLs and proposed changes of uses and use levels					
Mean	0.09–0.27	0.13–0.34	0.07–0.16	0.03–0.12	0.03–0.10
High level	0.25–0.51	0.21–0.64	0.13–0.32	0.09–1.10	0.09–0.71

The mean dietary exposure to thaumatin (E 957) in the total population from currently approved uses and levels of use, as reported by the applicant using the FAIM tool (see Table 4), ranged from 0.003 to 0.02 mg/kg bw/day in the elderly up to 0.04 to 0.13 mg/kg bw/day in children. High-level intakes ranged from 0.07 to 0.22 mg/kg bw/day in adolescents up to 0.04 to 1.03 mg/kg bw/day in adults.

Estimated exposure at both the currently authorised and the proposed extended uses and use levels resulted in mean intakes ranging from 0.03 to 0.10 mg/kg bw/day in the elderly up to 0.13 to 0.34 mg/kg bw/day in children. High-level intakes ranged from 0.13 to 0.32 mg/kg bw/day in adolescents up to 0.09 to 1.10 mg/kg bw/day in adults.

3.4.2. Main food categories contributing to exposure to thaumatin (E 957)

The main food categories contributing to exposure to thaumatin (E 957) using MPLs (> 5 % of the total mean exposure) and the number of surveys in which each food category contributes are shown in Table 5.

Table 5: Main food categories contributing to exposure to thaumatin (E 957) using MPLs from currently approved uses (% min–max) and the number of surveys ≥ 5 % contribution (n) in which each food category contributes

FCS category number	FCS food category	Toddlers[a]	Children[a]	Adolescents[a]	Adults[a]	The elderly[a]
		Range of % contribution to the total exposure (number of surveys)[a]				
01.4	Flavoured fermented milk products including heat-treated products	11–59 (4)	6–29 (13)	7–16 (6)	6–21 (12)	9–13 (7)
03	Edible ices	19–68 (4)	22–66 (15)	26–63 (12)	14–60 (15)	12–56 (7)

FCS category number	FCS food category	Toddlers[a]	Children[a]	Adolescents[a]	Adults[a]	The elderly[a]
		Range of % contribution to the total exposure (number of surveys)[a]				
05.1	Cocoa and chocolate products as covered by Directive 2000/36/EC	9–34 (4)	14–54 (15)	26–58 (12)	16–60 (15)	10–54 (7)
14.1.4.1	Flavoured drinks with sugar	–	5 (2)	6–9 (5)	6–14 (5)	21–21 (1)
14.1.4.2	Flavoured drinks with sweeteners	–	–	6 (1)	10 (1)	–
16	Desserts excluding products covered in categories 1, 3 and 4	6–12 (2)	5–10 (5)	6(1)	7–8 (3)	7–13 (2)
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	–	6–15 (2)	–	6–33 (7)	23–63 (2)

–: no information available; TBC: to be confirmed.
(a): Total number of surveys in FAIM per population group: toddlers = 4; children = 15; adolescents = 12; adults = 15; elderly = 7.

The main food categories contributing to exposure to thaumatin (E 957) using MPLs (> 5 % of the total mean exposure) for the currently authorised uses and the proposed extension of use and use levels and the number of surveys in which each food category contributes are shown in Table 6.

Table 6: Main food categories contributing to exposure to thaumatin (E 957) using MPLs from currently approved uses and the proposed extension of uses and use levels (% min–max) and number of surveys ≥ 5 % contribution (n) in which each food category contributes

FCS category number	FCS food category	Toddlers[a]	Children[a]	Adolescents[a]	Adults[a]	The elderly[a]
		Range of % contribution to the total exposure (number of surveys)[a]				
01.4	Flavoured fermented milk products including heat-treated products	6–24 (3)	5–13 (7)	–	9–9 (1)	5–5 (1)
03	Edible ices	7–38 (4)	9–36 (15)	6–26 (12)	5–18 (13)	6–14 (6)
04.2	Processed fruit and vegetables	7–46 (4)	5–18 (13)	7–14 (10)	7–19 (12)	11–23 (7)
05.1	Cocoa and chocolate products as covered by Directive 2000/36/EC	6–15 (3)	5–20 (15)	8–17 (12)	5–12 (13)	5–9 (4)
06.3	Breakfast cereals	–	7 (1)	–	6 (1)	8 (1)
07.2	Fine bakery wares	20–66 (3)	5–55 (15)	6–44 (12)	7–40 (14)	8–37 (6)
12.1	Salt and salt substitutes	–		–	6 (1)	7 (1)
12.5	Soups and broths	6 (1)	7–28 (5)	7–27 (4)	10–34 (4)	15–32 (2)
12.6	Sauces		6–7 (2)	6–9 (4)	5–8 (6)	6 (2)
14.1.4.1	Flavoured drinks with sugar	6–9 (3)	6–25 (12)	7–35 (10)	5–29 (10)	5–22 (2)
14.1.4.2	Flavoured drinks with sweeteners	–	–	10–15 (2)	8–21 (2)	–
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	–	–	–	5–34 (15)	10–41 (7)
16	Desserts excluding products covered in category 1, 3 and 4	5 (1)	–	–		–
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	–	–	–	5–16 (2)	6–32 (2)

FCS category number	FCS food category	Toddlers[a]	Children[a]	Adolescents[a]	Adults[a]	The elderly[a]
		Range of % contribution to the total exposure (number of surveys)[a]				
18	Processed foods not covered by categories 1 to 17	–	11 (1)	6–11 (2)		

(a): Total number of surveys in FAIM per population group: toddlers = 4; children = 15; adolescents = 12; adults = 15; elderly = 7.

Using current MPLs and the proposed extension of use and use levels, category 07.2, Fine bakery wares, was one of the main contributors to the intake of thaumatin for all population groups. Category 03, Edible ices, was an important food group for toddlers, children and adolescents, whereas category 14.2, Alcoholic beverages, was an important contributor among adults and the elderly.

The major food categories that contributed to the total intakes were determined to be edible ices and cocoa and chocolate products, for all population groups, based on the currently approved uses of thaumatin (E 957). Although the approved use for categories Edible ices (FCS 03) and Cocoa and chocolate products (FCS 05.1), permit the use of thaumatin, this use is specific only to foods that are energy reduced or with no added sugar. As it was not possible to separate these food categories in the FAIM tool further, all foods within these categories were considered in the intake assessment. In addition, for category Processed fruit and vegetables (FCS 04.2), although thaumatin is proposed only for use in jams, jellies and marmalades (FCS 04.2.5), the entire category was considered in the current assessment. Furthermore, it is proposed that thaumatin is used only in energy-reduced or no-added-sugar varieties of jams, jellies and marmalades and breakfast cereals (FCS 06.3); however, all foods in these categories are included in the assessment. The limitations in the food categorisation used in the FAIM tool result in a conservative estimate of intake for these food categories. When new uses proposed by the applicant were also considered, Fine bakery wares (FCS 07.2) were noted to be one of the main contributors for all groups. The proposed uses of thaumatin in salt and salt substitutes, sauces, ready-to-eat snacks and processed foods were smaller contributors to total intakes.

3.4.3. Uncertainty analysis

The uncertainties in the exposure assessment of thaumatin (E 957) are discussed above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2006), the sources of uncertainty considered are summarised in Table 7.

Table 7: Qualitative evaluation of the influence of uncertainties on the dietary exposure estimate to thaumatin (E 957)

Sources of uncertainties	Direction
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Use of data from food consumption survey of few days to estimate long-term (chronic) exposure for high percentiles (95th percentile)	+
Use of the FAIM tool nomenclature (FoodEx level 2) for food categories	+
Food categories selected for the exposure assessment: exclusion of food categories owing to missing FoodEx linkage (Only for the food category 05.4. Decorations, coatings and fillings)	–
Food categories selected for the exposure assessment: inclusion of food categories without considering the restriction/exception	+
Occurrence data: MPLs considered applicable for all items within entire food category	+
Proposed extension of use in Part 4 of Annex III to Regulation (EC) No 1333/2008 not considered	–

+: uncertainty with potential to cause over-estimation of exposure; -: uncertainty with potential to cause under-estimation of exposure

The Panel considered the impact of the uncertainties in the exposure assessment and concluded that, overall, uncertainty could lead to an overestimation of the calculated exposure estimates.

3.5. Discussion

Thaumatin was previously assessed for food safety for consumers by both JECFA (1986) and the SCF (1985, 1989). Following these assessments, thaumatin was considered acceptable for use, and the ADI was established as 'not specified'.

The European Commission asked EFSA to provide a scientific opinion on the safety of the proposed extension of use of thaumatin (E 957) as a food additive in several food categories, in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

In order to address the safety of this proposed extension of use, the Panel decided that a comparison of the exposure estimate from the currently authorised uses with that for the proposed new uses and use levels would be an adequate approach. The safety of thaumatin (E 957) as a food additive will be considered by the ANS Panel under the re-evaluation programme for food additives already permitted in the EU before 20 January 2009, as envisaged by the Commission Regulation (EU) No 257/2010. Meanwhile, the Panel considered that the available toxicological assessments of thaumatin (SCF, 1985, 1989; JECFA, 1986) would remain valid, and in principle there would be no need to reconsider this to address the Terms of Reference.

In the present opinion, an anticipated exposure with MPLs to thaumatin (E957) as a food additive has been undertaken by the applicant using the FAIM tool, taking into consideration the current authorised uses and the proposed extension of uses and changes to use levels as provided by the applicant.

The Panel noted that the mean dietary exposure to thaumatin (E 957) in the total population from currently approved uses and use levels, as reported by the applicant, ranged from 0.003 to 0.02 mg/kg bw/day in the elderly up to 0.04 to 0.13 mg/kg bw/day in children. High-level exposure ranged from 0.07 to 0.22 mg/kg bw/day in adolescents up to 0.04 to 1.03 mg/kg bw/day in adults.

Estimated exposure at both the currently authorised and at the changed use and proposed extended uses and use levels resulted in mean intakes ranging from 0.03 to 0.10 mg/kg bw/day in the elderly up to 0.13 to 0.34 mg/kg bw/day in children. High-level exposure ranged from 0.13 to 0.32 mg/kg bw/day in adolescents up to 0.09 to 1.10 mg/kg bw/day in adults.

The EFSA ANS Panel noted that the current exposure estimates appear higher than the estimated human exposure of 2 mg/person/day (equivalent to 0.03 mg/kg bw/day for a 70-kg adult) considered by JECFA and the SCF in their evaluations (SCF, 1985; JECFA, 1986). The basis for the estimated exposure of 2 mg/person/day was not stated in the SCF or JECFA conclusions, however the Panel understands that at the time the SCF and JECFA estimated mean exposure for adults only. A comparison of the upper range of the mean exposure for adults in the current estimate is similar to the SCF and JECFA estimates (0.03 mg/kg bw/day for a 70-kg adult).

Neither JECFA nor the SCF allocated a numerical ADI for thaumatin owing to its lack of toxicity in the available studies, combined with its being readily digested to normal food components. The amino acid sequence of the protein was known and there was no indication of the presence of unusual amino acid side-chains, or atypical peptide linkages or end-groups. Thaumatin, *in vitro*, was broken down to the same extent as ovo-albumin, and the *in vivo* nitrogen digestibility of both compounds appeared comparable. No antibodies to thaumatin were detected in either rats or humans after prolonged oral administration (JECFA, 1986). In addition, the Panel noted that in 1986 the SCF had specifically requested additional data on the possible formation of neuroendocrine or hormonally active peptides, which had been provided for the 1989 SCF evaluation. Taken along with structural and conformational considerations, these data led the SCF to conclude that, following digestion, thaumatin was unlikely to give rise to neuroendocrine or hormonally active peptides.

The ANS Panel noted that the lowest NOAELs identified in previous evaluations (JECFA, 1986) both corresponding to the highest dose tested of 3.0 % in the diet, equivalent to approximately 1 400 mg/kg bw/day from a study in dogs and 2 700 mg/kg bw/day in rats. The Panel noted that the highest estimated exposure of 1.10 mg/kg bw/day in humans would still result in a margin of safety of approximately 1 300 from the lowest NOAEL from these two studies.

In the JECFA opinion it was indicated that the only dietary effect of thaumatin was an insignificant contribution to the normal protein intake (JECFA, 1986). The ANS Panel considered appropriate to calculate the contribution of thaumatin to the normal protein intake based on the most recent information. The ANS Panel noted that the Population Reference Intake (PRI) for protein was recently set by the EFSA NDA Panel at 0.83 g protein/kg bw/day for adults, applicable to both high-quality protein and protein in mixed diets. The Panel noted that the PRI for children ranged from 0.83 (in adolescents) to 1.03 g protein/kg bw/day (in toddlers) (EFSA NDA Panel, 2012). Therefore a maximum daily intake of 1.03 mg/kg bw/day of thaumatin at the current proposed uses or 1.10 mg/kg bw/day at the proposed new MPLs would represent 0.12 % or 0.13 %, respectively, of the total daily protein intake for an adult. The Panel noted that, as exposure estimates for thaumatin in children were lower than those for adults and the PRI for children was higher than that for adults, this would represent a lower percentage of the total daily protein intake for children of all ages.

4. Conclusions

The Panel concluded, based on the existing toxicological evaluations, that the proposed extension of uses and changes to use levels would result in a margin of safety of approximately 1300 which would not represent a safety concern.

Documentation provided to EFSA

1. Application to .amend Annex II and III of Regulation (EC) No 1333/2008 for the extension of use of thaumatin (E 957). August 2014. Submitted by Naturex.

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Abbreviations

ADI	Acceptable Daily Intake
ANS Panel	EFSA Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
FAIM	Food Additives Intake Model
FAO	Food and Agriculture Organization of the United Nations
FCS	Food Categorisation System
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MPL	Maximum Permitted Level
NDNS	NDNS (UK) National Diet and Nutrition Survey
NOAEL	no observed adverse effect level
PRI	Population Reference Intake
SCF	Scientific Committee on Food
WHO	World Health Organization

Appendix A – Summary of the total estimated exposure of thaumatin (E 957) using MPLs and change of use and levels proposed for the extension of use per age class and survey: mean and high level (mg/kg bw/day)

	MPL		MPLs and change of use and levels proposed for the extension of use	
	Mean	High level	Mean	High level
Toddlers				
Bulgaria (Nutrichild)	0.02	0.17	0.14	0.31
Finland (DIPP)	0.04	0.19	0.09	0.25
Germany (Donald 2006_2008)	0.09	0.44	0.15	0.51
The Netherlands (VCP_Kids)	0.12	0.33	0.27	0.48
Children				
Belgium (Regional_Flanders)	0.13	0.42	0.34	0.64
Bulgaria (Nutrichild)	0.05	0.33	0.19	0.47
Czech Republic (SISP04)	0.11	0.34	0.22	0.45
Denmark (Danish Dietary Survey)	0.07	0.14	0.13	0.21
Finland (DIPP)	0.09	0.25	0.15	0.31
Finland (STRIP)	0.09	0.20	0.29	0.39
France (INCA 2)	0.07	0.18	0.22	0.33
Germany (Donald 2006_2008)	0.13	0.38	0.22	0.48
Greece (Regional_Crete)	0.05	0.25	0.20	0.40
Italy (INRAN_SCAI_2005_06)	0.06	0.13	0.13	0.23
Latvia (EFSA_TEST)	0.04	0.17	0.22	0.34
The Netherlands (VCP_Kids)	0.11	0.32	0.25	0.46
Spain (enKid)	0.08	0.20	0.18	0.31
Spain (Nut_Ink05)	0.06	0.32	0.17	0.43
Sweden (NFA)	0.10	0.24	0.28	0.42
Adolescents				
Belgium (Diet_National_2004)	0.04	0.12	0.15	0.27
Cyprus (Childhealth)	0.02	0.10	0.07	0.15
Czech Republic (SISP04)	0.05	0.22	0.14	0.32
Denmark (Danish Dietary Survey)	0.03	0.08	0.09	0.14
France (INCA 2)	0.03	0.10	0.11	0.19
Germany (National_Nutrition_Survey_II)	0.03	0.20	0.10	0.28
Italy (INRAN_SCAI_2005_06)	0.03	0.16	0.08	0.21
Latvia (EFSA_TEST)	0.03	0.16	0.15	0.28
Spain (AESAN_FIAB)	0.02	0.07	0.07	0.13
Spain (enKid)	0.05	0.14	0.12	0.20
Spain (Nut_Ink05)	0.03	0.17	0.10	0.24
Sweden (NFA)	0.05	0.14	0.16	0.25

	MPL		MPLs and change of use and levels proposed for the extension of use	
	Mean	**High level**	**Mean**	**High level**
Adults				
Belgium (Diet_National_2004)	0.02	0.08	0.11	0.20
Czech Republic (SISP04)	0.01	0.77	0.08	0.83
Denmark (Danish_Dietary_Survey)	0.01	0.04	0.06	0.11
Finland (FINDIET_2007)	0.02	0.10	0.05	0.14
France (INCA2)	0.02	0.06	0.07	0.12
Germany (National_Nutrition_Survey_II)	0.02	1.03	0.09	1.10
Hungary (National_Repr_Surv)	0.01	0.06	0.03	0.09
Ireland (NSIFCS)	0.02	0.07	0.10	0.19
Italy (INRAN_SCAI_2005_06)	0.01	0.17	0.04	0.20
Latvia (EFSA_TEST)	0.01	0.08	0.08	0.15
The Netherlands (DNFCS_2003)	0.03	0.12	0.12	0.27
Spain (AESAN)	0.02	0.21	0.06	0.25
Spain (AESAN_FIAB)	0.02	0.44	0.05	0.48
Sweden (Riksmaten_1997_98)	0.02	0.05	0.10	0.14
United Kingdom (NDNS)	0.02	0.07	0.09	0.16
The elderly				
Belgium (Diet_National_2004)	0.01	0.63	0.10	0.71
Denmark (Danish_Dietary_Survey)	0.01	0.04	0.05	0.09
Finland (FINDIET_2007)	0.02	0.08	0.03	0.09
France (INCA2)	0.01	0.04	0.05	0.10
Germany (National_Nutrition_Survey_II)	0.01	0.29	0.08	0.36
Hungary (National_Repr_Surv)	0.003	0.05	0.03	0.09
Italy (INRAN_SCAI_2005_06)	0.01	0.10	0.03	0.12