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Scientific Opinion on the safety of UV-treated bread as a novel food**

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SCIENTIFIC OPINION

Scientific Opinion on the safety of UV-treated bread as a novel food¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) was asked to carry out the additional assessment for UV-treated bread as a novel food (NF) in the context of Regulation (EC) No 258/97, taking into account the comments and objections of a scientific nature raised by Member States. The NF is bread to which a treatment with UV radiation is applied after baking in order to convert ergosterol, which is present in bread as a result of yeast fermentation, to vitamin D₂. The provided compositional data, the specifications (i.e. vitamin D₂ content of 0.75–3 µg/100 g in the UV-treated bread, 1–5 g/100 g of yeast in the dough) and the data from batch testing do not give rise to safety concerns. The data provided on the production process are sufficient and do not give rise to safety concerns. The Panel considers that even if it is conservatively assumed that all consumed breads are UV-treated and contain the maximum proposed amount of 3 µg vitamin D₂/100 g, it is highly unlikely that tolerable upper intake levels for vitamin D, established by EFSA for various age groups, will be exceeded. The NF is not nutritionally disadvantageous. Under certain conditions, UV treatment may result in reactions of biomolecules. However, the levels of potential reaction products that may be formed under the employed conditions are low compared with the reactions induced by the baking process. Therefore, the Panel considers that it is not necessary to perform additional analyses and that the absence of toxicological studies with the novel food is acceptable. The risk of allergic reactions to the NF is not dissimilar to that associated with conventional bread. The Panel considers that bread enriched with vitamin D₂ through UV treatment is safe under the conditions of use as specified by the applicant.

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KEY WORDS

novel food, bread, UV treatment, vitamin D

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SUMMARY

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) was asked to carry out the additional assessment for UV-treated bread as a novel food (NF) in the context of Regulation (EC) No 258/97, taking into account the comments and objections of a scientific nature raised by Member States.

The NF is bread to which a treatment with UV radiation is applied after baking in order to convert ergosterol, which is present in bread as a result of yeast fermentation, to vitamin D₂ (ergocalciferol). Specifications of the NF include the intended vitamin D₂ content (0.75–3 µg/100 g) in the UV-treated bread and the amount of yeast (1–5 g/100 g) required in the dough in order to achieve the amount of vitamin D₂.

The applicant provided compositional data on macro- and micronutrients in various types of bread subjected to the UV treatment at pilot and commercial scale. The UV-treated breads contained significant amounts of vitamin D₂, while the contents in the control breads were below the limit of detection. The contents of water, protein, fat, carbohydrate, fibre, different groups of fatty acids, vitamin E and B vitamins in the UV-treated breads were comparable to those in the control breads. The UV treatment results in the formation of vitamin D₂ in only a thin outer layer (i.e. crust, 2–3 mm) of the bread. Peroxide values and folate contents in crust and crumb following UV treatment were comparable to those determined in the control. The Panel considers that the provided compositional data, the specifications and the data from batch testing do not give rise to safety concerns.

The process conditions of the UV treatment have been provided by the applicant. The parameters of the process have to be adjusted on a case-by-case basis to achieve the target level of vitamin D₂. Considering that there are no relevant changes in nutrient composition in the breads following the proposed UV treatment, the Panel considers the specified parameters, including the range of wavelength for the UV treatment, as acceptable. The Panel concludes that the data provided on the production process are sufficient and do not give rise to safety concerns.

Based on available data from the EFSA Comprehensive European Food Consumption Database, the applicant provided intake estimates (mean and 95th percentile) of vitamin D₂ from UV-treated bread under the assumption that all bread consumed was treated and contained the maximum proposed amount of vitamin D₂ of 3 µg/100 g. The mean and 95th percentile vitamin D₂ intake estimates range from 2.6 to 4.8 µg/day and 5.6 to 10.5 µg/day, respectively, for adults and the elderly, from 2.3 to 4.3 µg/day and 3.6 to 8.8 µg/day, respectively, in adolescents and from 1.4 to 4.2 µg/day and 3.6 to 7.2 µg/day, respectively, for children. The Panel considers that even if it is conservatively assumed that all consumed breads are UV-treated and contain the maximum proposed amount of 3 µg vitamin D₂/100 g, it is highly unlikely that tolerable upper intake levels for vitamin D established by EFSA for children aged 1–10 years (50 µg/day) and adolescents and adults (100 µg/day) will be exceeded.

Both *Saccharomyces cerevisiae* and vitamin D₂ have a long history of food use. *Saccharomyces cerevisiae* has an extensive history of food use in the baking and brewing industries and has been categorised by EFSA as a microorganism that has Qualified Presumption of Safety (QPS) status. In the European Union (EU), vitamin D₃ and vitamin D₂ are authorised for use in food supplements and addition of vitamins and minerals to foods.

UV-treated breads are comparable to untreated breads, except for the vitamin D₂ content. No adverse effects regarding the contribution of bread to nutrient intakes are expected from the consumption of UV-treated bread in substitution of traditional bread. The Panel considers that the NF is not nutritionally disadvantageous.

The microbiological status of the bread is mainly determined by the thermal treatment in the course of the baking processing. The Panel considers that the data provided do not give rise to concerns with regard to the microbiological quality of the NF.

The applicant has not carried out toxicological studies on the NF. The Panel is aware that, under certain conditions, UV treatment may result in reactions of biomolecules, such as lipids or proteins. However, the reactions potentially induced by the UV treatment have to be considered in the light of the preceding baking process. The levels of potential reaction products that may be formed under the employed conditions from UV-induced oxidative reactions are low compared with the reactions induced by the baking process. Therefore, the Panel considers that it is not necessary to perform additional analyses and that the absence of toxicological studies with the NF is acceptable.

With regards to allergenicity, the Panel considers that the risk of allergic reactions to the NF is not dissimilar to that associated with conventional bread.

The Panel considers that bread enriched with vitamin D₂ through UV treatment is safe under the conditions of use as specified by the applicant.

TABLE OF CONTENTS

Abstract	1
Summary	2
Background as provided by the European Commission.....	5
Terms of reference as provided by the European Commission.....	5
Assessment	6
1. Specification of the novel food.....	6
2. Effect of the production process applied to the novel food	8
3. History of the organism used as a source	9
4. Anticipated intake/extent of the use of the novel food	9
5. Information from previous exposure to the novel food or its source.....	12
6. Nutritional information on the novel food.....	12
7. Microbiological information on the novel food.....	13
8. Toxicological information on the novel food	13
8.1. Vitamin D ₂ content.....	13
8.2. Effect of the UV treatment on bread constituents and potential toxicity thereof.....	13
9. Allergenicity	14
Discussion	14
Conclusions	15
Documentation provided to EFSA	15
References	15

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

On 12 February 2014, the company Viasolde AB submitted a request in accordance with Article 4 of the novel food Regulation (EC) No 258/97⁴ to place on the market bread treated with UV light as a novel food ingredient.

On 14 March 2014, the competent authority of Finland forwarded to the Commission its initial assessment report, which came to the conclusion that bread treated with UV light meets the criteria for acceptance of a novel food defined in Article (3)1 of Regulation (EC) No 258/97.

On 19 March 2014, the Commission forwarded the initial assessment report to the other Member States. Several Member States submitted comments or raised objections.

In consequence, a decision is now required by the Commission under Article 7(1) of Regulation (EC) No 258/97.

The concerns of a scientific nature raised by the Member States can be summarised as follows:

- There appears to be a lack of standardisation of the process. The uniformity of vitamin D content that would be obtained in commercial batches and compliance with the specifications in various batches of different breads throughout the life cycle of the product needs to be confirmed. Different levels of vitamin D may be formed depending on the characteristics of the bread.
- There is no information on the peroxide value at the end of the shelf life of the bread.
- Further information on the possibility of UV treatment to give rise to oxidation products or treatment-induced aggregates is requested. The potential cross-linking of proteins due to UV treatment, which could have specific allergic properties, is not addressed. The presence of degradation products of proteins, such as oligopeptides, amino acids or their UV-light oxidative transformation substances that may be of safety concern, is not addressed.
- The potential formation of oxidation products of sterols, such as oxysterols, which show toxic characteristics, is not addressed.
- The scientific literature describes the formation of mutagenic substances caused by UV irradiation, e.g. from the substance maltol, which is present in bread and baked goods. The applicant should be requested to provide an assessment of UV irradiation of bread, taking into account the effects of UV light on substances present in the bread crust, as described in the literature.
- Sterilisation typically involves a wavelength of 254 nm, further justification for the broader wavelength range proposed (230–315 nm) and consideration on whether it raises safety concern are requested.
- Information on whether the data relating to Nordic breads can be translated to other types of breads and whether UV treatment has any effects on the composition of these breads.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002,⁵ the European Commission asks the European Food Safety Authority to provide a scientific opinion by carrying out the additional

⁴ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p. 1–6.

⁵ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

assessment for bread treated with UV light as a novel food ingredient in the context of Regulation (EC) No 258/97.

ASSESSMENT

In accordance with Commission Recommendation 97/618/EC,⁶ bread enriched with vitamin D₂ through treatment with ultraviolet (UV) radiation (thereafter called UV-treated bread) is allocated to Class 6, i.e. “foods produced using a novel process”. The assessment of the safety of this novel food (NF) is based on data supplied in the original application, the initial assessment by the competent authority of Finland, the concerns and objections of the other Member States and the responses of the applicant. The data are required to comply with the information required for NFs of Class 6, i.e. structured schemes I, II, III, IX, X, XI, XII and XIII of Commission Recommendation 97/618/EC. In the text these structured schemes are listed 1 to 8. The intention is to market UV-treated bread for use as a source of vitamin D. This assessment only concerns risks that might be associated with consumption, and is not an assessment of the efficacy of UV-treated bread with regard to any claimed benefit.

1. Specification of the novel food

The NF is bread to which a treatment with UV radiation is applied after baking in order to convert ergosterol, which is present in bread as a result of yeast fermentation, to vitamin D₂ (ergocalciferol). Specifications of the NF are provided in Table 1. They include the intended vitamin D₂ content of the UV-treated bread and the amount of yeast required in the dough in order to achieve the amount of vitamin D₂.

Table 1: Specifications of the UV-treated bread as proposed by the applicant

Parameter	Value	Method
Vitamin D ₂ (µg/100 g)	0.75–3	EN 12821, 2009 ^(a)
Yeast in dough (g/100 g)	1–5	Recipe calculation

(a): European Standard

Based on the performed tests the applicant proposed that the following bread types are subject to the UV treatment process: white bread (mainly from wheat flour), dark bread (wholly or partially with rye flour), wholemeal bread (wholly or partially with wholemeal flour), crisp bread, flatbread, sourdough bread as well as buns and bread rolls.

The applicant provided compositional data on macro- and micronutrients in representative types of bread commonly eaten in Scandinavia that had been subjected to the UV treatment. Table 2 shows analytical results (based on single measurements per bread) for two white wheat breads, dark wholemeal bread with rye and wheat flatbread treated with UV using pilot scale equipment. The UV-treated breads contained significant amounts of vitamin D₂, while the contents in the control breads were below the limit of detection of 0.5 µg/100 g. The contents of water, protein, fat, carbohydrate, fibre, different groups of fatty acids, vitamin E and B-vitamins in the UV-treated breads were comparable to those in the control breads. The Panel notes the apparent variability in the folate content across the breads.

⁶ Commission Recommendation 97/618/EC: Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L 253, 16.9.1997, p. 1–36.

Table 2: Compositional data of different types of bread treated with UV (values per 100 g)

Analyte	White 1		White 2		Wholemeal		Flat bread	
	control	UV ^(a)	control	UV ^(a)	control	UV ^(a)	control	UV ^(a)
Vitamin D ₂ (µg)	< 0.5	2.5	< 0.5	2.7	< 0.5	0.9	< 0.5	5.3
Water (g)	32.8	32.2	35.5	35.1	31.8	35.6	32.4	31.8
Protein (N × 6.25)	9.1	8.9	8.8	8.9	6.6	6.5	8.4	8.4
Fat (g)	2.0	2.0	4.3	4.3	6.1	5.9	3.2	3.3
SFA (%) ^(b)	15.0	15.0	10.1	10.3	11.4	11.2	13.7	13.5
MUFA (%) ^(b)	37.0	37.1	52.9	52.9	32.5	28.2	46.5	46.5
PUFA (%) ^(b)	46.9	47.1	36.4	36.2	55.4	59.2	38.9	39.0
Carbohydrates (g) ^(c)	50.2	51.5	45.6	46.1	39.4	39.8	52.0	52.6
Fibre (g)	4.4	3.9	4.3	4.1	9.5	9.9	2.9	2.8
Vitamin E (mg)	0.364	0.366	0.911	0.871	3.92	4.65	0.841	0.886
Thiamine (mg)	0.088	0.088	0.087	0.082	0.168	0.168	0.133	0.130
Riboflavin (mg)	0.040	0.040	0.030	0.020	0.040	0.040	0.020	0.020
Niacin (mg)	2.82	2.81	2.78	2.80	3.29	2.96	2.90	2.83
Pyridoxine (mg)	0.119	0.109	0.074	0.081	0.157	0.161	0.077	0.097
Folate (µg)	60.9	49.7	32.6	33.2	26.3	27.6	28.2	34.1

Methods: moisture, NMKL (Nordic Committee on Food Analysis) 23; crude protein (Kjeldahl), NMKL 6; fat, SLV VF 1980; SFA, AOCS (American Oil Chemists` Society) Cd 1c-85; MUFA, AOCS Cd 1c-85, PUFA, AOCS CD 1c-85; fibre, AOAC 985.29 2003; vitamin E, EN 12822 2000; vitamin D₂, EN 12581:2009-08; thiamine, EN 14122-2001 mod.; riboflavin, EN 14152 mod.; niacin, AOAC 944.13/45.2.04 (1990); pyridoxine, EN 14164:2008; folate, AOAC 944.12/45.2.03 (1990).

SFA, saturated fatty acids; MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids.

(a): Energy inputs: white wheat breads (9 mJ/cm²), dark wholemeal bread with rye (18 mJ/cm²), wheat flatbread (4 mJ/cm²).

(b): Expressed as % of total fatty acids.

(c): Calculated from other analyses.

The applicant also presented compositional data on three batches of wheat flatbread treated with UV at commercial production scale (Table 3). Except for one batch, the target content of vitamin D₂ (1 µg/100 g bread) was reproducibly achieved by the UV treatment. No consistent effects of the treatment were observed for the contents of thiamine, riboflavin, niacin and pyridoxine. For folate, the contents were also comparable to the control in two batches (B, C); the Panel notes the apparent variability in the folate content in samples from one of the batches (A).

Table 3: Compositional data of wheat flatbread treated with UV at commercial production scale (values per 100 g)

Batch	Thiamine (mg)	Riboflavin (mg)	Niacin (mg)	Pyridoxine (mg)	Folate (µg)	Vitamin D ₂ (µg)
A						
Control A	0.133	0.030	0.878	0.0557	31.3	< 0.25 ^(a)
1A	0.148	0.020	0.738	0.0458	19.4	1.09
2A	0.151	0.030	0.738	0.0521	17.2	0.90
3A	1.135	0.020	0.789	0.0506	18.5	0.98
Average	0.145	0.023	0.770	0.0495	18.4	0.99
B						
Control B	0.147	0.020	0.972	0.0554	27.1	< 0.25
1B	1.134	0.030	0.884	0.0479	28.7	0.96
2B	0.148	0.030	0.799	0.0526	20.9	0.94
3B	0.150	0.025	0.888	0.0564	27.4	1.03
Average	0.144	0.028	0.857	0.0523	25.7	0.97
C						
Control C	0.145	0.020	1.03	0.0527	23.2	< 0.25
1C	1.133	0.020	0.949	0.0559	28.2	1.04
2C	0.144	0.020	1.02	0.0472	25.7	0.69
3C	0.135	0.020	1.06	0.0498	25.6	0.81
Average	0.137	0.020	1.01	0.0510	26.5	0.85

Conditions of treatment: 3 x 300 kg of dough resulting in 7 500 individual pieces of bread; UV-treated area (each piece): 115x105x11 mm; energy input: 4.0 mJ/cm²; time of UV exposure: six seconds.

Methods: vitamin D₂, EN 12851:2009-08; thiamine, EN 14122:2001 mod.; riboflavin, EN 14152:2006, mod.; niacin, AOAC 944.13 / 45.2.04 (1990); pyridoxine, EN 14164:2008; folate, AOAC 45.2.09 (2004).

(a): limit of detection.

The applicant provided analytical data on UV-treated hotdog buns demonstrating that the UV treatment results in the formation of vitamin D₂ in only a thin outer layer (i.e. crust, 2-3 mm) of the bread surface. The content of vitamin D₂ in the crust of the UV-treated hotdog buns amounted to 37 µg/100 g whereas it was not detectable (< 0.5 µg/kg) in the crumb. Peroxide values and folate contents in crust and crumb of the UV-treated buns were comparable to those determined in the control. According to the applicant, peroxide values were determined three days after bread production and UV treatment; this is considered acceptable by the Panel.

No specific data on the stability of the NF have been provided.

The Panel considers that the provided compositional data, the specifications and the data from batch testing do not give rise to safety concerns.

2. Effect of the production process applied to the novel food

Bread is treated with UV after the baking process. Ergosterol, the pro-vitamin D₂ generated by the yeast, is converted into vitamin D₂ (ergocalciferol). The process conditions of the UV treatment, i.e. the time required, the distance of the UV source to the bread, the energy input and the range of wavelength, have been provided by the applicant.

The parameters of the process have to be adjusted on a case-by-case basis to achieve the target level of vitamin D₂. They depend on different factors, such as composition of the raw material, water content and size and shape of the type of bread.

Considering that there are no relevant changes in nutrient composition in the breads following the proposed UV treatment, the Panel considers the specified parameters, including the range of wavelength for the UV treatment, as acceptable.

According to the applicant, the equipment used for UV irradiation can be adjusted so that the production of a specified level of vitamin D₂ can be achieved with a maximum tolerance of $\pm 10\%$. However, the applicant also emphasized that the process has to be set up and specifically standardised depending on the characteristics of the bread and proposed that adequate testing at a commercial bakery should be performed each time the process is applied for commercial scale operation. The applicant also stated that the vitamin D₂ content of the final product will be analysed in each batch.

Compositional data from batches obtained at commercial production scale demonstrated that the target amount of vitamin D₂ can be reproducibly achieved (Table 3). The transformation of ergosterol to vitamin D₂ occurs solely in a thin outer layer (2–3 mm) of the bread surface.

Data obtained from analyses of different types of bread produced at pilot and commercial scale demonstrated that the UV treatment had no impact on the contents of macroconstituents (protein, fat, carbohydrates) and of microconstituents (vitamin E and B vitamins) (Tables 2 and 3).

The applicant selected folate as the particular indicator for potential oxidative deteriorations induced by the UV treatment. Despite some analytical uncertainties, the data provided showed that there are no relevant changes in the content of this vitamin as a result of UV treatment (Tables 2 and 3).

UV radiation in the range of 240–280 nm is lethal to most microorganisms. The maximum germicidal effect is achieved at 254 nm. Practical applications are the inhibition of microorganisms on surfaces, the inactivation of microorganisms in air and the sterilisation of liquids (Bintsis et al., 2000; Guerrero-Beltrán and Barbosa-Cánovas, 2004; Koutchma, 2008).

According to the United States Food and Drug Administration, UV radiation for the processing and treatment of food may be safely used for the following purposes: surface microorganism control in high fat-content food irradiated in vacuum or in an inert atmosphere; sterilization of water used in food production; reduction of human pathogens and other microorganisms in juice products (FDA, 2000).

The Panel concludes that the data provided on the production process are sufficient and do not give rise to safety concerns.

3. History of the organism used as a source

Not applicable

4. Anticipated intake/extent of the use of the novel food

The applicant provided bread consumption data (mean and 95th percentile) from 13 European Union countries, for adults, the elderly, adolescents and children, from the EFSA Comprehensive European Food Consumption Database (FoodEx Level 2). High bread consumption was reported in Denmark, Germany, Ireland, the Netherlands and Eastern European countries (mean 138–160 g/day and 95th percentile 281–350 g/day in adults). The lowest bread consumption was reported in Spain (mean 88 g/day and 95th percentile 192 g/day). The applicant also provided data separated by sex, based on published national consumption survey reports. Bread consumption was higher in males than in females for all age groups.

Based on available data from the EFSA Comprehensive European Food Consumption Database, the applicant provided intake estimates of vitamin D₂ from UV-treated bread under the assumption that all bread consumed was treated and contained the maximum proposed amount of 3 µg/100 g (Table 3).

The mean and 95th percentile vitamin D₂ intake estimates from the UV treated bread range from 2.6 to 4.8 µg/day and 5.6 to 10.5 µg/day, respectively, for adults and the elderly, from 2.3 to 4.3 µg/day and 3.6 to 8.8 µg/day, respectively, in adolescents and from 1.4 to 4.2 µg/day and 3.6 to 7.2 µg/day, respectively, for children.

The applicant also provided estimates by sex based on data from published national consumption survey reports, which were in the same order of magnitude.

The Panel notes that the type of intake estimate provided by the applicant assumes that all bread consumed was UV-treated and contained the maximum proposed amount of 3 µg vitamin D₂/100 g. The Panel therefore considers that this estimate significantly overestimates intakes. However, even if it is conservatively assumed that all consumed breads are UV-treated and contain 3 µg vitamin D₂/100 g, it is highly unlikely that tolerable upper intake levels established by EFSA (EFSA NDA Panel, 2012) for children aged 1–10 years (50 µg/day) and adolescents and adults (100 µg/day) will be exceeded.

Table 4: Estimated intake of vitamin D from UV-treated bread, based on data from the EFSA Comprehensive European Food Consumption Database

Country	Adults				The elderly				Adolescents				Children			
	Bread intake (g/day)		Vitamin D intake (µg/day)		Bread intake (g/day)		Vitamin D intake (µg/day)		Bread intake (g/day)		Vitamin D intake (µg/day)		Bread intake (g/day)		Vitamin D intake (µg/day)	
	Mean	P95	Mean	P95	Mean	P95	Mean	P95	Mean	P95	Mean	P95	Mean	P95	Mean	P95
Belgium	126	285	3.8	8.6	121	240	3.6	7.2	118	250	3.5	7.5	78	137	2.3	4.1
The Czech Republic	159	341	4.8	10.2	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Denmark	160	281	4.8	8.4	156	266	4.7	8.0	142	259	4.3	7.8	140	239	4.2	7.2
France	109	252	3.3	7.6	138	297	4.1	8.9	78	192	2.3	3.6	48	120	1.4	3.6
Germany	135	287	4.1	8.6	143	269	4.3	8.1	134	292	4.0	8.8	94	175	2.9	5.3
Hungary	153	297	3.1	8.9	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Ireland	138	281	3.1	8.4	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Italy	114	350	3.1	10.5	124	260	3.7	7.8	111	241	3.3	7.2	81	185	2.4	5.6
Latvia	144	350	4.3	10.5	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Spain	88	192	2.6	5.8	n.a.	n.a.	n.a.	n.a.	135	260	4.1	7.8	97	183	2.9	5.5
Sweden	102	187	3.1	5.6	n.a.	n.a.	n.a.	n.a.	76	149	2.3	4.5	62	128	1.9	3.8
The Netherlands	153	300	4.6	9.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	62	128	1.9	3.8
The United Kingdom	111	222	3.3	6.7	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a., not available

5. Information from previous exposure to the novel food or its source

Both *Saccharomyces cerevisiae* (*S. cerevisiae*) and vitamin D₂ have a long history of food use.

S. cerevisiae has an extensive history of food use in the baking and brewing industries. EFSA has categorised *S. cerevisiae* as a microorganism that has Qualified Presumption of Safety (QPS) status (EFSA BIOHAZ Panel, 2014).

In Canada, the addition of vitamin D₂-yeast to yeast-leavened bakery products has been permitted at a level up to 90 IU (International Unit) (2.25 µg) per 100 g of product (Health Canada, 2011). In the USA, the food additive regulations allow for the use of vitamin D₂ baker's yeast in yeast-leavened baked products at levels not to exceed 400 IU (10 µg) of vitamin D₂ per 100 g of the finished food (FDA, 2012). In the EU, UV-treated baker's yeast may be placed on the market as a novel food ingredient in yeast-leavened breads and rolls and in yeast-leavened fine bakery wares at maximum use levels of 5 µg of vitamin D₂/100 g final product and in food supplements at a maximum use level of 5 µg of vitamin D₂/day (EU, 2014).

In the EU, vitamin D₃ and vitamin D₂ are authorised for use in food supplements⁷ and addition of vitamins and minerals to foods.⁸

6. Nutritional information on the novel food

UV treatment for the purpose of reducing microorganisms has been reported to reduce vitamin contents in foods such as milk (Guneser and Karagul Yuceer, 2012) or juices (Tran and Farid, 2004; Bhat et al., 2011). For breads subjected to the specified UV treatment, analytical comparisons of the nutrient compositions, including B vitamins and folate, no relevant reductions were observed (Section 2.2). UV-treated breads are comparable to untreated breads, except for the vitamin D₂ content. No adverse effects regarding the contribution of bread to nutrient intakes are expected from the consumption of UV-treated bread in substitution of traditional bread.

The Panel notes that current dietary reference values for children aged 1–18 years and for adults vary from 5 to 15 µg/day and from 10 to 20 µg/day, respectively (SCF, 1993; IoM, 2011; DACH, 2013; NNR, 2013).

In 2012, EFSA estimated that the mean intake of vitamin D from foods among young children varies from 1.7 µg/day (Denmark, boys, 1–3 years) to 5.6 µg/day (Greece, 1–5 years) while the high percentile intake estimates vary from 2.4 µg/day (Denmark, 95th percentile, boys, 1–3 years) to 11.9 µg/day (Greece, 90th percentile, 1–5 years) (EFSA NDA Panel, 2012).

In adolescents, mean intake from foods varies from 1.6 µg/day (Spain, 11–17 years) to 4.0 µg/day (Belgium, boys, 13–18 years). Intakes at the 95th percentile were between 3.0 µg/day (Spain, 11–17 years) and 7.7 µg/day (Italy, boys, 10 to < 18 years, including fortified food). Mean or median intakes from foods and supplements and for the 95th percentile of consumption are within these ranges.

For adults, estimates on mean intake of vitamin D from foods varied from 1.1 µg/day (Spain, women, 18–64 years) to 8.2 µg/day (Finland, men, 25–74 years) and estimated 95th percentile intakes varied from 2.4 µg/day (Spain, women, 18–64 years) to 16.0 µg/day (Finland, men, 25–74 years). For those adults who also consume vitamin D from food supplements, intakes were estimated to be 1.5-fold higher.

⁷ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.07.2002, p. 51–57.

⁸ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.

Even if it is conservatively assumed that all consumed breads are UV treated and contain 3 µg vitamin D₂/100 g, it is highly unlikely that tolerable upper intake levels established by EFSA (EFSA NDA Panel, 2012) for children aged 1–10 years (50 µg/day) and adolescents and adults (100 µg/day) will be exceeded.

The Panel considers that the NF is not nutritionally disadvantageous.

7. Microbiological information on the novel food

The microbiological status of the bread is mainly determined by the thermal treatment in the course of the baking processing. The application of the UV treatment after baking is not expected to introduce any additional microbiological contamination. Rather, it is expected to reduce potential contaminations, e.g. mould spores from the air, which may occur during the cooling phase of the process.

The Panel considers that the data provided do not give rise to concerns with regard to the microbiological quality of the NF.

8. Toxicological information on the novel food

The applicant has not carried out toxicological studies on the NF.

8.1. Vitamin D₂ content

Tolerable upper intake levels for vitamin D have been set as 25 µg/day for infants (up to one year of age), 50 µg/day for children from 1 to 10 years of age, 100 µg/day for adolescents from 11 to 17 years of age and 100 µg/day for adults (EFSA NDA Panel, 2012). Based on the estimated intake scenarios (Section 4), the applicant calculated that vitamin D₂ intake from UV-treated bread would represent up to 10 to 15 % of the tolerable upper intake levels, depending on the age group (Section 6).

8.2. Effect of the UV treatment on bread constituents and potential toxicity thereof

It is known that UV treatment can induce oxidation reactions of macromolecules, such as fat or proteins. UVB exposure could induce radical formation of aromatic amino acids (e.g. tryptophan, tyrosine and phenylalanine) triggering redox processes with reactive residues and subsequently the formation of cross-links.

Oxidative species have been shown to be generated from fructose upon UV treatment (Elsinghorst and Tikekar, 2014). The formation of furan, one of the final photolysis products, was induced by UV treatment of apple cider. In freshly prepared apple cider, no furan was formed at a UVC dose of 1.8 J/cm²; at a dose of 8.8 J/cm² the concentration of furan amounted to about 60 µg/l (Fan and Geveke, 2007). The formation of furan was also demonstrated in UV-treated simulated fruit juices sweetened with high-fructose corn syrup (Bule et al., 2010). According to analytical data provided by the applicant, the contents of fructose in types of bread intended for UV treatment ranged from 0.8 to 5.2 g/100 g. Upon request by EFSA, the applicant provided data demonstrating that in two UV-treated breads containing 0.46 µg vitamin D₂/100 g and 6.8 µg vitamin D₂/100 g, respectively, furan was not detectable (< 5.0 µg/kg).

One Member State raised concerns with respect to the mutagenicity observed *in vitro* for UV-treated maltol, a compound present in bread crust (Watanabe-Akanuma et al., 2007). In this study, untreated maltol was not mutagenic up to 5 mg/plate in the Ames test. When maltol was treated with either UVA (320–400 nm, 230 µW/cm²) for 5–30 minutes or UVC (610 µW/cm²) for three minutes in sodium phosphate buffer (pH 7.4) prior to the exposure of bacterial cells, it was found to be mutagenic to *Salmonella typhimurium* strains TA100, TA104 and TA97. Taking the mutagenicity observed after UVA treatment in 100 mM sodium-phosphate buffer (pH 7.4) as reference, higher relative mutagenicity was observed under neutral and alkaline conditions (pH 6.5–8.9), while lower relative mutagenicity was observed under acidic conditions (pH 5.5–6.0). Maltol treated with UVC in 100 nM

sodium chloride (NaCl) was found to be mutagenic, whereas no mutagenicity was observed when maltol was treated with UVA in 100 mM NaCl solution (pH 6.0) or water. Addition of thiol compounds (cysteine or glutathione, 200 µg/well, dissolved in sodium phosphate buffer, pH 7.4) to the UVA-irradiated maltol diminished the mutagenicity by 80 %. The Panel notes that the mutagenic effect for UV-treated maltol observed *in vitro* was highly dependent on the experimental conditions, i.e. UV wavelength, radiation time and dose, liquid matrix, pH, absence of thiol compounds. These conditions do not occur when applying the intended UV treatment to bread. Therefore, the Panel does not consider this observation relevant for the NF.

The UV-induced conversion of ergosterol to vitamin D₂ is accompanied by isomerisations resulting in tachysterol and lumisterol (Havinga et al., 1960). The formation of these by-products has also been observed following UV treatment of mushrooms (Kalaras et al., 2012; Keegan et al., 2013). After UV treatment of baker's yeast the average amounts of vitamin D₂ and tachysterol in the resulting yeast concentrate were 750 µg/g and 140 µg/g, respectively (EFSA NDA Panel, 2014). Assuming similar proportions of these substances upon UV treatment of bread, the applicant calculated that the intended maximum level of vitamin D₂ (3 µg/100 g bread) would result in 0.6 µg tachysterol/100 g bread. This is lower than 0.93 µg/100 g bread expected from the use of vitamin D₂-enriched UV-treated baker's yeast, which did not give rise to safety concerns (EFSA NDA Panel, 2014).

For vegetable oils, the UV-induced formation of β-sitosterol oxidation products has been described (Zhang et al., 2006). After an exposure time of 21 hours (light intensity 765 W/m²; 300–800 nm), between 5 % (sunflower oil) and 12 % (rapeseed oil) of β-sitosterol had been oxidized. Respective data for solid foods, such as bread, are lacking.

The contents of total phytosterols reported in bread range from 40.5 mg/100 g dry weight (white bread) to 80.3 mg/100 g dry weight (rye bread made from rye and wheat flour) and 90.2 mg/100 g dry weight (rye bread made only from rye flour) (Piironen et al., 2002). Assuming that the maximum oxidation rate for phytosterols upon UV treatment is in the same order of magnitude as the maximum oxidation rate (1 %) reported for phytosterols following thermal processing (Scholz et al., 2015), phytosterol oxidation products expected in bread as a result of the UV treatment would amount to, approximately, 0.4–0.9 mg/100 g dry weight. Taking into account the short time of the UV treatment and the fact that UV-induced oxidations would occur in only the outer layer of the bread, the formation of phytosterol oxidation products is not considered to be of relevance.

The Panel considers that the available data on potential effects of UV treatment on several compounds present in bread do not give rise to safety concerns.

9. Allergenicity

The Panel considers that the risk of allergic reactions to the NF is not dissimilar to that associated with conventional bread.

DISCUSSION

According to the compositional data provided, specified levels of vitamin D₂ can be reproducibly achieved by UV treatment of bread. However, the applicant emphasized that the process has to be set up and specifically standardised depending on the characteristics of the bread. Adequate testing should be performed each time the process is applied for commercial scale operation.

The Panel is aware that, under certain conditions, UV treatment may result in reactions of biomolecules, such as lipids or proteins. However, the reactions potentially induced by the UV treatment have to be considered in the light of the preceding baking process. The levels of potential reaction products that may be formed under the employed conditions from UV-induced oxidative reactions are low compared with the reactions induced by the baking process. Therefore, the Panel considers that it is not necessary to perform additional analyses and that the absence of toxicological studies with the novel food is acceptable.

Even if it is conservatively assumed that all consumed breads are UV treated and contain 3 µg vitamin D₂/100 g, it is highly unlikely that tolerable upper intake levels established by EFSA (EFSA NDA Panel, 2012) will be exceeded.

CONCLUSIONS

The Panel considers that bread enriched with vitamin D₂ through UV treatment is safe under the conditions of use as specified by the applicant.

DOCUMENTATION PROVIDED TO EFSA

1. Application for the approval of bread enriched with vitamin D through treatment with ultra violet light as a novel food. 22 August 2012, revised on 10 December 2013. Submitted by Viasolde AB.
2. Initial assessment report carried out by the Food Safety Authority of Finland: “Bread enriched with vitamin D through treatment with ultraviolet light”. 28 February 2014.
3. Member States’ comments and objections.
4. Response by the applicant to the initial assessment report and the Member States’ comments and objections.
5. Letter from the European Commission to the European Food Safety Authority with the request for a scientific opinion on bread treated with UV light as a novel food ingredient. SANCO/E6/SH/ks ref. Ares(2014)3759522, dated 12 November 2014.
6. Applicant’s reply to an EFSA request for additional information. 21 April 2015.

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