SCIENTIFIC OPINION

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Safety of UV-treated milk as a novel food pursuant to Regulation (EC) No 258/97

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

Abstract

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on UV-treated milk as a novel food submitted pursuant to Regulation (EC) No 258/97, taking into account the comments and objections of a scientific nature raised by Member States. The novel food is cow's milk (whole, semi-skimmed or skimmed) to which a treatment with ultraviolet (UV) radiation is applied after pasteurisation in order to extend the shelf life of the milk. This treatment results in an increase in the vitamin D_3 concentrations. The Panel considers that the provided compositional data, the specifications 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 target group is the general population with the exclusion of infants (up to 1 year of age). The Panel considers that it is unlikely that tolerable upper intake levels established by EFSA for children aged 1–10 years, adolescents and adults will be exceeded. The Panel considers that the novel food is not nutritionally disadvantageous. The data provided do not give rise to concerns with regard to the microbiological quality. The Panel considers that the risk of allergic reactions to the novel food is not dissimilar to that associated with conventional milk. The Panel concludes that the novel food, UV-treated milk, is safe under the intended conditions of use as specified by the applicant.

Keywords: novel food, milk, UV treatment, safety

Requestor: European Commission, following an application by Dairy Crest Ltd.

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Summary

Following a request from the European Commission, the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on UV-treated milk as a novel food submitted pursuant to Regulation (EC) No 258/97, taking into account the comments and objections of a scientific nature raised by Member States. The assessment follows the methodology set in Commission Recommendation 97/618/EC and is based on the data supplied in the original application, the initial assessment by the competent authority of Ireland, the concerns and objections of other Member States, and the responses of the applicant.

The novel food is cow's milk (whole, semi-skimmed or skimmed) to which a treatment with ultraviolet (UV) radiation is applied after pasteurisation in order to extend the shelf life of the milk. The treatment of the milk with UV results in an increase in the vitamin D_3 concentrations by conversion of 7-dehydrocholesterol to vitamin D_3. Specifications of the novel food include the intended vitamin D_3 content (whole milk: 0.5–3.2 µg/100 g; semi-skimmed milk: 0.1–1.5 µg/100 g; skimmed milk: traces), and total viable count (< 100 colony-forming units/mL). The target group is the general population with the exclusion of infants (up to 1 year of age).

The applicant provided compositional data on macro- and micro-nutrients in milk subjected to UV treatment. The UV-treated milk contained significant amounts of vitamin D_3, whereas the contents in the control milk were below the limit of detection. Apart from vitamin D_3, there were no significant differences in the nutrient content of milks treated with UV as compared to control milk. From the data provided, the Panel considers that the formation of lipid or protein oxidation products is not of safety concern. The Panel, therefore, 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. Considering that there are no relevant changes in nutrient composition in the milks following the proposed UV treatment, the Panel considers the specified parameters as acceptable. The Panel concludes that 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 cow's milk is UV treated and contains the maximum proposed vitamin D_3 concentrations, it is unlikely that tolerable upper intake levels established by EFSA for children aged 1–10 years (50 µg/day) and adolescents and adults (100 µg/day) will be exceeded.

UV-treated milk is comparable to non-UV-treated milk, except for the vitamin D_3 content. No adverse effects regarding the contribution of milk to nutrient intakes are expected from the consumption of UV-treated milk in substitution of non-UV-treated milk. The Panel considers that the novel food is not nutritionally disadvantageous.

Information was provided on the microbiological status of the novel food. The Panel considers that the data provided do not give rise to concerns with regard to the microbiological quality of the novel food.

With regard to allergenicity, the Panel considers that the risk of allergic reactions to the novel food is not dissimilar to that associated with conventional milk.

The Panel concludes that the novel food, UV-treated milk, is safe under the intended conditions of use as specified by the applicant.

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1. Introduction

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

On 26 September 2012, the company Dairy Crest Ltd. submitted a request under Article 4 of the Novel Food Regulation (EC) N° 258/97[1] to place on the market pasteurised milk treated with ultraviolet (UV) light as a novel food.

On 10 January 2013, the competent authority of Ireland forwarded to the Commission their initial assessment report, which came to the conclusion that pasteurised milk 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 16 January 2013, the Commission forwarded the initial assessment report to the other Member States. Several of the Member States submitted comments or raised objections.

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

- Information was requested on the definite specifications of the vitamin D_3 concentrations in the UV-treated milk (including variability and upper and lower levels). The applicant was also requested to provide evidence that the process of formation of vitamin D_3 in the milk can reliably be controlled.
- Clarification was requested on the possible oxidation of lipids and proteins.
- Questions were raised on the influence of the UV treatment on light sensitive vitamins, in particular riboflavin (vitamin B_2) but also vitamins A, C and E.
- Further data were requested with regards to the inactivation of microorganisms/ microbiological specifications.
- The intake assessment of vitamin D_3 as provided by the applicant refers to the consumption of UV-treated milk only. The applicant was requested to address the possibility that the UV-treated milk is further processed to other products (such as butter, cheese, yoghurt, etc.) and the consumption of which would have an impact on the overall intake of vitamin D_3. In addition, intake from other vitamin D-enriched products already on the EU market or from vitamin D supplements should be considered.
- Further information was requested to substantiate the applicant's claim that the UV treatment would not lead to changes in the allergenic status of the milk.
- Additional information was requested on the history of use of the production process (indicated in the application as being used in South Africa).

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002,[2] the European Food Safety Authority (EFSA) is asked to carry out the additional assessment of pasteurised milk treated with UV-light as a novel food in the context of Regulation (EC) No 258/97.

EFSA is asked to carry out the additional assessment and to consider the elements of a scientific nature in the comments raised by the other Member States.

2. Data and Methodologies

2.1. Data

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 Ireland, the concerns and objections of the other Member States, the responses of the applicant and additional information submitted by

[1] 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.

[2] 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.

the applicant following EFSA requests for supplementary information (see 'Documentation provided to EFSA').

In accordance with Commission Recommendation 97/618/EC,[3] pasteurised milk treated with UV is allocated to Class 6, i.e. 'foods produced using a novel process'. The assessment of the safety of this NF is based on data supplied in the original application, the initial assessment by the competent authority of Ireland, 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 novel foods 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 from 3.1 to 3.9. The intention is to use the novel process of UV treatment of pasteurised milk to extend its shelf life from the current 12 days to 21 days and to increase vitamin D_3 concentrations. This assessment only concerns risks that might be associated with consumption of UV-treated milk, and is not an assessment of the efficacy of UV-treated milk with regard to any claimed benefit.

2.2. Methodologies

The assessment follows the methodology set in Commission Recommendation 97/618/EC 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.

3. Assessment

3.1. Specification of the novel food

The NF which is the subject of the application is UV-treated pasteurised milk.

The types of milk proposed for the UV treatment are pasteurised whole milk (≥ 3.5% fat), pasteurised semi-skimmed milk (1.5–1.8% fat) and pasteurised skimmed milk (≤ 0.5% fat) as defined by Regulation (EC) 1234/2007.[4]

The treatment of the milk with UV irradiation results in an increase in the vitamin D_3 concentrations by conversion of 7-dehydrocholesterol (a pro-vitamin present in milk) to vitamin D_3.

Specifications of the NF are provided in Table 1. They include the intended vitamin D_3 content of various UV-treated milks and microbiological specifications.

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

Parameter	Limits	Method of detection
Vitamin D_3 (µg/100 g)	Whole milk: 0.5–3.2	HPLC
	Semi-skimmed milk: 0.1–1.5	
	Skimmed milk: traces	
Total viable count (TVC) at 30°C	< 100 CFU/mL	Based on BS 4285

Nutrient analysis (e.g. protein, fat, vitamins, minerals) of three batches of control (pasteurised) milk, milk (pasteurised) UV treated once and milk (pasteurised) UV treated four times (in order to simulate a worst case scenario) was provided for the beginning of shelf life and for various later time points

[3] 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.

[4] Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation). OJ L 299, 16.11.2007, p. 1–149.

until the end of shelf life (i.e. day 14 for the control milk, day 28 for the UV-treated milk). There were no significant differences in the nutrient content of milks treated with UV as compared to control milk.

Mean values (from three batches) for the vitamin D_3 concentrations in UV-treated milk (whole milk) at the beginning of shelf life (2.8 ± 0.2 µg/100 g) and at the end of shelf life (i.e. day 28: 2.4 ± 0.2 µg/100 g) indicated stability of the vitamin D_3 in the UV-treated milk.

3.1.1. Potential lipid breakdown products

Unsaturated lipids found in milk fat and phospholipids in the milk fat globule membrane are susceptible to light-induced oxidation (van Aardt et al., 2005). Typical volatile lipid oxidation products include hexanal, 2-heptanone, n-heptanal, 1-octene-3-ol, 1-octanol and nonanol (Frankel, 1984). All of these lipid oxidation products impart off-flavours to the product (Allen and Parks, 1975; Bradley and Min, 1992).

The applicant performed a general screen for volatile organic compounds (hexanal, 2-heptanone, heptanal, 1-octen-3-ol, octanol and nonanol) by gas chromatography–mass spectrometry (GC–MS) technique. The values reported for hexanal and 2-heptanone at the beginning of shelf life for three batches of milk UV treated once and milk UV treated four times were low as compared to the high variability reported for control (pasteurised) milk. There were no significant differences after 14 days of storage of control milk as compared to the 28 days of storage of UV-treated milks. The levels of heptanal, 1-octen-3-ol, octanol and nonanol in all milks were below 10 ppb before and after storage. In addition, the applicant reported peroxide values for all three milks ranging from 0.7 to 3.3 mEq/kg fat with no significant differences shown before and after storage (although also with high variability).

Following a request from Member States about further information on the formation of (volatile) lipid oxidation products, the applicant referred to a publication by Cappozzo et al. (2015) which reported no significant differences in the effects of heat treatment (pasteurisation) and UV irradiation at a dosage of 1000 J/L on fatty acid content and free fatty acids (FFA), and inconsistent results on formation of volatile lipid oxidation products in bovine milk. The Panel notes that in this publication the UV treatment did not increase the vitamin D_3 concentrations in milk, possibly owing to a different UV treatment methodology (i.e. repeated cycles of UV irradiation instead of a continuous UV exposure). Therefore, the Panel considers that no conclusions can be drawn from this publication.

The applicant further referred to a publication by Cilliers et al. (2014) which reported no significant differences in thiobarbituric acid reactive substances (TBARS) between UV-treated milk and control milk, employing UV processing which complies with the process specifications for the NF as proposed by the applicant. No information was provided in the publication on the effect of the UV treatment on vitamin D_3 concentrations. The Panel considers that even though no information was provided on the effect of UV treatment on vitamin D_3, this publication provides evidence as the UV processing conditions are representative of the proposed UV treatment for the NF.

Following a comment from Member States on the possible formation of cholesterol oxides, the applicant provided test results on the formation of cholesterol oxide products (COPs) in milk following UV treatment. Samples drawn from three batches each of raw milk, pasteurised milk, UV-treated milks (both 1056 J/L and 2024 J/L) and UV-treated (both 1056 J/L and 2024 J/L) pasteurised milks were analysed by GC–MS for the detection, identification and quantification of COPs. There were no statistically significant differences between the control milk and UV-treated milks for 7α-hydroxycholesterol, 7β-hydroxycholesterol, 7-ketocholesterol, 5β,6β-epoxycholesterol and cholestatriol, respectively. This finding is supported by Cilliers et al. (2014) who reported low values of 7-ketocholesterol with little variance (CV 3.69%) in control milk and UV-treated milk.

Furthermore, the applicant provided an analysis of the effect of various treatments of milk on the percentage of free fatty acids (% FFA, calculated according to the AOCS titration method Ca 5a-40) at the time points day 1, 7 and 14. Overall, FFA content ranged from 0.90 to 0.94% after high-temperature short-time (HTST), 0.89 to 0.93% after UV-HTST and 0.86 to 0.91% after UV treatment at 2090 J/L. These results were not significantly different.

The Panel notes that UV treatment of milk does not lead to significant changes of lipid oxidation products including peroxides, volatile organic compounds, cholesterol oxides, thiobarbituric acid reactive substances and free fatty acids, as compared to control milk. The Panel further notes some

limitations including the high variability in the analyses of volatile oxidation products and peroxides. The Panel considers that the formation of lipid oxidation products following UV treatment of milk is not of safety concern.

3.1.2. Potential protein oxidation products

Compounds containing aromatic rings and sulfide bonds can absorb UV light. Approximately 10% of proteins contain these bonds and are susceptible to UV-light absorption. Formation of methionine sulfoxide and methionine sulfone are indicators of oxidative damage to proteins (Koivumäki et al., 2012).

The applicant was requested to provide an analysis on the formation of dityrosine and protein carbonyls in UV-treated milks. In reply, the applicant referred to the publication by Cilliers et al. (2014) which evaluated protein oxidation through methionine oxidation and dimethyl disulfide (DMS) formation. In this paper, protein oxidation results indicated the highest concentration of DMS in both raw and pasteurised milks with no significant differences in methionine sulfoxide. Methionine sulfone increased to 0.97 µg/mL and 1.09 µg/mL, respectively, for UV-treated milk and UV-treated pasteurised milk as compared to raw milk (0.58 µg/mL) and pasteurised milk (0.63 µg/mL). However, no significant difference in methionine (39.3–40.9 µg/mL) between the pasteurised and UV-treated milks was observed.

The Panel notes the increase in methionine sulfone in UV-treated milks. However, the change is small and is not reflected by unfavourable changes in other protein oxidation markers or methionine. Therefore, the Panel considers that the formation of protein oxidation products following UV treatment of milk is not of safety concern.

The Panel considers that the information provided on the composition and stability of the NF is sufficient and does not raise safety concerns.

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

3.2.1. Description of the production process

The manufacturing process involves the incorporation of a UV-source (i.e. SurePure™ turbulator) in a post-pasteurisation section of the processing line. Pasteurised milk is pumped or gravity fed through a specified number of SurePure™ units (i.e. turbulators) which irradiate the pasteurised milk with UV-C.

The process conditions of the UV treatment, i.e. energy input and range of wavelength, retention time, flow rate, and UV-dosage per area have been provided by the applicant. The dosage of UV-C irradiation amounts to 1045 J/L.

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).

The Panel considers that the production process is sufficiently described and does not raise safety concerns.

3.2.2. Effect of the production process on the composition of the novel food

The treatment of milk with UV-C light results in elevated concentrations of vitamin D_3 by conversion of 7-dehydrocholesterol present in milk to vitamin D_3.

The process conditions of the UV treatment have been provided by the applicant.

To address the effect of the UV treatment on the vitamin content other than vitamin D_3, the applicant provided analyses of riboflavin and vitamin B_{12} concentrations in control (pasteurised) milk, pasteurised milk UV treated once and pasteurised milk UV treated four times (six samples per treatment, taken from three batches of milk). There were no significant differences between the milks regarding riboflavin and vitamin B_{12} concentrations.

Data obtained from analyses of different batches of milk demonstrated that the UV treatment had no impact on the contents of macronutrients (e.g. fat and protein) and of micronutrients.

When requested to comment on the study by Guneser and Karagul Yuceer (2012) which reported on a decrease in vitamins A, B_2, C and E in cow's milk following treatment with UV-C light, the applicant indicated that the UV dosages (i.e. 12,600–88,200 J/L) reported in the paper do not apply to the proposed UV treatment which is in the range of 1000 to 2000 J/L.

The Panel considers that the data provided on the effect of the production process on the composition of the NF are sufficient and do not give rise to safety concerns.

3.2.3. Previous use of the process in the food industry

According to the applicant, the UV-light module described in this application (i.e. SurePure™) is used in South Africa for the UV treatment of liquids including milk, juices, smoothies and wine.

3.3. History of the organism used as a source of the novel food

Not applicable.

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

The target group is the general population excluding infants (up to 1 year of age). The applicant intends to use the UV treatment on whole milk, semi-skimmed and skimmed milk from cows.

In order to estimate the intake of vitamin D_3 contained at increased concentrations in the NF, the applicant used food consumption data from the UK National Diet and Nutrition Survey (NDNS) 2008/2009, for both whole milk and semi-skimmed milk, assuming that milk consumption was switched completely to UV-treated milk.

The following population subgroups were considered: young children (1.5 to 3 years), older children (4 to 10 years), adolescents (11 to 18 years) and adults (18 to 64 years).

The applicant estimated the daily vitamin D_3 intake (in µg/day and in µg/kg body weight (bw) per day) for both whole milk (Table 2) and semi-skimmed milk (not shown) for the total population (i.e. not only consumers), considering a maximum vitamin D_3 content of 3.2 µg/100 g in whole milk.

The highest daily vitamin D_3 intake was calculated for young children from 1.5 to 3 years with a daily intake of 21 µg per day at the 97.5th percentile of whole milk consumption.

Table 2: Average intake of whole milk (based on data of the UK NDNS 2008/9) for the total population and the corresponding estimated vitamin D_3 intake in µg/day, assuming a maximal vitamin D_3 content of 3.2 µg/100 g

Age range (years)	Average intake of whole milk (g/day)	Standard deviation (g/day)	P 97.5 (g/day)	Daily vitamin D_3 dose from the NF at P 97.5 (µg/day)	Daily vitamin D_3 dose from the NF at P 97.5 (µg/kg bw per day)
1.5–3	195	231	655	21.0	1.5
4–10	77	121	318	10.2	0.4
11–18	44	112	267	8.6	0.2
19–64	29	81	190	6.1	0.1

Following requests by Member States to address the possibility that UV-treated milk is further processed to other products (such as butter, cheese, yoghurt etc.) which would have an impact on the overall intake of vitamin D_3, and also to address the possible combined intake of UV-treated milk with vitamin D supplements or with other vitamin D-enriched products already on the European Union (EU) market, the applicant confirmed that the application is intended for the use of UV processing of cow's milk only (whole, semi-skimmed, skimmed).

In order to address mean and high percentile milk consumption by 'consumers only' and considering a number of other EU countries in addition to the United Kingdom, the EFSA Comprehensive European Food Consumption Database was used (Table 3). The intakes (i.e. mean, median and 95th percentile) of whole milk as indicated in Table 3 were used to estimate vitamin D_3 intake (Table 4) by considering

the maximum intended vitamin D_3 concentration (i.e. 3.2 µg/100 g) for whole milk. Vitamin D_3 intakes at the 95th percentile ranged from 9.5 to 22.0 µg/day in young children, 4.2 to 17.8 µg/day in adults and 7.0 to 24.3 µg/day in the elderly. The Panel notes that consumption of semi-skimmed milk, even though consumed at higher amounts in some population groups, results in lower vitamin D_3 intakes, owing to the lower concentration of vitamin D_3 in semi-skimmed milk.

Table 3: Daily intake (mean, median and 95th percentile) of whole milk (g/day) in 'consumers only' for young children, adults and elderly in various EU countries

	Young children			Adults			Elderly		
	Mean	**Median**	**P 95**	**Mean**	**Median**	**P 95**	**Mean**	**Median**	**P 95**
Denmark	73	36	297	37	16	130	58	26	220
Finland	122	25	557[(a)]	142	50	508	128	59	480
Germany	183	126	525	118	65	405	102	54	326
Netherlands	192	155	437[(a)]	230	142	555	139	105	512[(a)]
United Kingdom	324	332	687	124	70	411	191	165	760[(a)]

(a): High percentiles may not be statistically robust (owing to the low number of surveyed subjects/consumers) and need to be interpreted with caution

Table 4: Estimated vitamin D_3 intake in µg per day from whole milk in 'consumers only', assuming a vitamin D_3 content of 3.2 µg/100 g (i.e. maximum intended level for whole milk)

	Young children			Adults			Elderly		
	Mean	**Median**	**P 95**	**Mean**	**Median**	**P 95**	**Mean**	**Median**	**P 95**
Denmark	2.3	1.1	9.5	1.2	0.5	4.2	1.9	0.8	7.0
Finland	3.9	0.8	17.8	4.5	1.6	16.2	4.1	1.9	15.4
Germany	5.9	4.0	16.8	3.8	2.1	12.9	3.3	1.7	10.4
Netherlands	6.2	4.9	14.0	7.4	4.5	17.8	4.4	3.4	16.4
United Kingdom	10.4	10.6	22.0	4.0	2.2	13.2	6.1	5.3	24.3

Vitamin D intakes from the diet

In 2012, EFSA estimated that the mean percentile 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) whereas 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 of 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, 2–74 years) and estimated 95th percentile intakes varied from 2.4 µg/day (Spain, women, 1–64 years) to 16.0 µg/day (Finland, men, 25–74 years). For those adults who consume vitamin D also from food supplements, intakes were estimated to be 1.5-fold higher.

The Panel notes that the type of intake estimate provided by the applicant assumes that all whole milk consumed was UV-treated and contained the maximum proposed amount of 3.2 µg vitamin D_3/100 g. The Panel, therefore, considers that this estimate overestimates intakes. However, even if it is conservatively assumed that all consumed cow's milk is UV-treated and contains the maximum proposed vitamin D_3 concentrations, and also taking into account the vitamin D intake from the diet, it is 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.

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

Pasteurised bovine milk has a long history of consumption.

In the EU, vitamin D_3 and vitamin D_2 are authorised for use in food supplements[5] and addition of vitamins and minerals to foods.[6]

3.6. 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 milk subjected to the specified UV treatment, analytical comparisons of the nutrient composition, including riboflavin and vitamin B_{12}, showed no relevant reductions (Sections 3.1 and 3.2). UV-treated pasteurised milk is comparable to non-UV-treated pasteurised milk, except for the vitamin D_3 content.

Conventional pasteurised milk contains only trace amounts of vitamin D_3, whereas upon UV-C light exposure this amount increases to 0.5–3.2 µg vitamin D_3 per 100 g in whole milk and 0.1–1.5 µg vitamin D_3 per 100 g in semi-skimmed milk (according to the proposed specifications of the NF).

The Panel notes that current dietary reference values for vitamin D both for children aged 1–18 years and adults vary from 10 to 20 µg/day (SCF, 1993; IoM, 2011; NCM, 2014; D-A-CH, 2015).

Even if it is conservatively assumed that all consumed cow's milk is UV treated and contains the maximum proposed vitamin D_3 concentrations, it is 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 consumption of the NF is not nutritionally disadvantageous.

3.7. Microbiological information on the novel food

The process of UV treatment proposed by the applicant is applied to pasteurised milk in order to reduce the microbial load of the milk and thereby extend its shelf life. Pasteurisation of milk is a standard requirement in the EU (Regulation (EC) 863/2004 as amended by Regulation (EC) 2074/2005).[7] This heat treatment process eliminates non-spore forming pathogens and reduces the level of spoilage microorganisms with the purpose of enhancing food safety and establishing a stable shelf life.

The primary mechanism for UV inactivation is the damage to nucleic acid within microorganisms at wavelengths between 200–310 nm (UV-C range). The radiation dose required ranges from a few mJ/cm^2 for most bacteria to a few hundred for fungi and algae (Koutchma, 2009).

The applicant provided information on the microbial load of pasteurised milk and milk following pasteurisation plus UV treatment.

The applicant was requested to clarify whether moulds were included in the anaerobic and aerobic spore counts and, if this was not the case, to provide data on moulds in UV-treated milks. In reply, the applicant indicated that the test for anaerobic and aerobic spores count did not include any analyses on moulds but that all the samples were tested for moulds at the beginning of the shelf life, and that the results were identical in both treated and non-treated milks.

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

[5] 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.

[6] 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.

[7] Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004. OJ L 338, 22.12.2005, p. 27–59.

3.8. Toxicological information on the novel food

The applicant has not carried out any toxicological studies on the product to which the application applies.

Given the source, nature and the intended use of the NF, the Panel considers that the absence of toxicological studies with the NF is acceptable.

3.9. Allergenicity

The applicant claimed that the UV treatment would not alter the allergenic status of the milk.

Upon request by Member States, the applicant submitted results of the analyses of the major milk proteins (i.e. α-casein, β-lactoglobulin and α-lactalbumin) following irradiation with UV-C (Tammineedi et al., 2013).

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

4. Discussion

The Panel considers that the information provided on the composition, stability and the effect of the production process on the composition of the NF are sufficient and do not give rise to safety concerns.

The Panel is aware that, under certain conditions, UV treatment may result in reactions of biomolecules, such as lipids or proteins. However, the levels of potential reaction products that are formed under the employed conditions have been shown to be comparable to (untreated) control milk. The Panel considers that the formation of lipid or protein oxidation products is not of safety concern under the employed conditions for which reason no further toxicological studies are required.

The Panel notes that the applicant proposes as target group the general population with the exclusion of infants (up to 1 year of age). The Panel considers that even if it is conservatively assumed that all consumed milk is UV treated and contains the maximum proposed vitamin D_3 concentrations, it is unlikely that tolerable upper intake levels established by EFSA (EFSA NDA Panel, 2012) will be exceeded.

5. Conclusions

The Panel concludes that the novel food, UV-treated milk, is safe under the intended conditions of use as specified by the applicant.

Documentation provided to EFSA

1. Dossier on 'pasteurised milk treated with UV light' received on 23 February 2015. Submitted by Dairy Crest Ltd. on 26 September 2012.

2. Letter from the European Commission to the European Food Safety Authority with the request for an opinion on the safety of 'pasteurised milk treated with UV light as a novel food'. Ref Ares(2015)499979, dated 6 February 2015.

3. Initial assessment report carried out by the Food Safety Authority of Ireland: 'Safety Assessment of Pasteurised Milk Treated with UV Light'.

4. Member States' comments and objections.

5. Response by the applicant to the initial assessment report and the Member States' comments and objections.

6. Additional information was provided by the applicant on 17 September 2015 and on 12 November 2015.

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Abbreviations

bw	body weight
CFU	colony-forming unit
COP	cholesterol oxide product
CV	coefficient of variation
DMS	dimethyl disulphide
FFA	free fatty acids
GC	gas chromatography
HTST	high-temperature short-time
MS	mass spectrometry
TBARS	thiobarbituric acid reactive substances
TVC	total viable count
UV	ultraviolet