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Safety of extended uses of UV-treated baker's yeast as a Novel Food pursuant to Regulation (EU) 2015/2283

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Abstract

In 2014, the EFSA NDA Panel concluded that UV-treated baker's yeast containing up to 3.5 Mio IU of vitamin D/100 g, is safe under the proposed conditions of use for yeast-leavened breads, rolls and fine bakery wares, and food supplements. Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on an application for an extension of the use of UV-treated baker's yeast as a novel food (NF) pursuant to Regulation (EU) 2015/2283. In this extension of use, the applicant proposed a broad range of food categories to which the NF can be added. On the basis of the proposed uses and maximum use levels, the Panel estimated the potential exposure to vitamin D from the NF and the potential combined exposure to vitamin D including also exposure from the background diet and food supplements. The Panel notes that the upper level (UL) for one age group, i.e. children aged 4–10 years, is exceeded by 4%, when summing up the highest P95 estimate for the background diet (including food supplements) and the highest P95 estimate for vitamin D from the NF under the proposed uses and maximum use levels. The Panel notes, however, the highly conservative approach for estimating the potential intake of vitamin D from the NF, given that the applicant has proposed 34 FoodEx2 level 2 food categories. Thus, the Panel considers that the UL for children aged between 4 and 10 years is highly unlikely to be exceeded. The Panel concludes that the NF is safe under the proposed conditions of use.

Keywords: Novel Foods, UV treatment, baker's yeast, vitamin D, bread, fine bakery wares, food supplements

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1. Introduction

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

On 15 May 2020, the company Lallemand Bio-Ingredients Division submitted a request to the European Commission (EC) in accordance with Article 10 of Regulation (EU) 2015/2283[1] to authorise an extension of the use of UV-treated baker's yeast (*Saccharomyces cerevisiae*) as a novel food (NF).

The application requests to extend the use of UV-treated baker's yeast (*Saccharomyces cerevisiae*) in a number of foods.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority to provide a scientific opinion on UV-treated baker's yeast as a NF.

1.2. Additional information

In 2014, EFSA published a favourable opinion on the safety of 'UV-treated baker's yeast' (EFSA NDA Panel, 2014). That application concerned baker's yeast which, due to UV radiation at a wavelength of 254 nm, contained between 1.8 and 3.5 Mio IU of vitamin D/100 g (450–875 μg/g). Following this opinion, the EC granted marketing authorisation of this NF for its use in food supplements at a use level that provides a maximum of 5 μg vitamin D2 per day and for yeast-leavened breads, rolls and fine bakery at a use level that would not exceed a maximum concentration of 5 μg vitamin D2 per 100 g of the products marketed to consumers (European Commission, 2014).

Following an assessment by the competent Authority of Denmark of an application by Lallemand in December 2016 (Denmark, 2016; unpublished), the Commission Implementing Regulation (EU) 2018/1018 changed the description/definition and specifications of the NF due to the introduction of two additional steps of the production process which included (1) an optional heating step (75°C for 10–15 minutes) resulting in an inactivation of the yeast and (2) blending with regular baker's yeast to reduce the vitamin D2 concentration to a lower level, i.e. a minimum of 800,000 IU/100 g (200 μg/g) compared to the minimum level of 1,800,000 IU/100 g (450 μg/g) in the yeast concentrate authorised in 2014 (European Commission, 2018). The application and authorisation included also an extension of use of the NF to prepacked fresh or dry yeast for home baking and a deletion of the maximum use level of the NF in food supplements.

The Panel also notes that other UV-treated NFs, i.e. UV-treated bread (EFSA NDA Panel, 2015), UV-treated milk (EFSA NDA Panel, 2016a) and powder produced from *Agaricus bisporus* mushroom exposed to UV irradiation, have been previously assessed and authorised (EFSA NDA Panel et al., 2020). Another Opinion on a UV-treated mushrooms (*Agaricus bisporus*) powder was adopted in February 2021 (EFSA NDA Panel, 2021).

2. Data and methodologies

2.1. Data

The safety assessment of this NF is based on data supplied in the application and information submitted by the applicant following an EFSA request for supplementary information.

Administrative and scientific requirements for NF applications referred to in Article 10 of Regulation (EU) 2015/2283 are listed in the Commission Implementing Regulation (EU) 2017/2469[1].

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of an NF application (EFSA NDA Panel, 2016b). As indicated in this guidance, it is the duty of the applicant to provide all of the available (proprietary, confidential and published) scientific data (including both data in favour and not in favour), that are pertinent to the safety of the NF.

2.2. Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2016b) and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of

[1] Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, pp. 64–71.

Regulation (EU) 2015/2283 and in Article 7 of the Commission Implementing Regulation (EU) 2017/2469.

This assessment concerns only the risks that might be associated with consumption of the NF under the proposed conditions of use, and is not an assessment of the efficacy of the NF with regard to any claimed benefit.

3. Assessment

3.1. Specifications

According to the Commission implementing regulation (EU) 2018/1018 (European Commission, 2018), the authorisation concerns [*citation*]: 'Baker's yeast (*Saccharomyces cerevisiae*) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D2 (ergocalciferol). Vitamin D2 content in the yeast concentrate varies between 800,000 and 3,500,000 IU vitamin D/100 g (200–875 μg/g). The yeast may be inactivated. The yeast concentrate is blended with regular baker's yeast in order not to exceed the maximum level in the pre-packed fresh or dry yeast for home baking. Tan-coloured, free-flowing granules, vitamin D2: chemical name (5Z,7E,22E)-(3S)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol, synonym: Ergocalciferol; CAS No.: 50-14-6; molecular weight: 396,65 g/mol'.

In addition, the following microbiological criteria have been set by the authorisation: Coliforms ($\leq 10^3$ cfu/g), Escherichia coli ($\leq$ 10/g), Salmonella (absence in 25 g).

3.2. Proposed uses and use levels and anticipated intake

The NF is already authorised for its use in yeast-leavened breads, rolls and fine bakery at a use level that would not exceed a maximum concentration of 5 μg vitamin D2 per 100 g of the products marketed to consumer (European Commission, 2018). In addition, it has been permitted as prepacked fresh or dry yeast for home baking with maximum use levels of 45 μg/100 g and 200 μg/100 g for fresh and dried yeast, respectively. It has also been authorised for use in food supplements without designated maximum use levels.

3.2.1. Proposed uses and use levels

In this application, the applicant seeks a number of additional uses, given in Table 1. This table includes also the currently authorised uses under the two FoodEx codes A004V (i.e. 'bread and similar products') and A009T (i.e. 'Fine bakery wares'). Regarding the authorised use of the NF for prepacked fresh or dry yeast for home baking, the Panel considers that intake estimates for the NF from yeast-leavened bread and similar products and fine bakery wares baked at home would be covered by consumption data for such products irrespective of whether they were produced industrially or baked at home.

Considering the range of the vitamin D2 content in the NF (i.e. 200–875 μg/g), the maximum use level of the NF to be added into the foods will be determined by the vitamin D content of a batch and by the proposed maximum use level for vitamin D2 from the NF when added to various foods as presented in Table 1.

Upon a question raised by EFSA, the applicant responded that the NF will be inactivated by heat treatment before it is added to the newly intended foods (see also Section 1.2).

Table 1: Proposed uses and use levels proposed by the applicant

FoodEx2 Level 1 Name	FoodEx2 Level 2 Name	FoodEx2 code	Proposed maximum levels of vitamin D2, as consumed (µg/100 g food)
Composite dishes	Dishes, incl. ready-to-eat meals (excluding soups and salads)	A03VB	3
	Fried or extruded cereal, seed or root-based products	A0EZX	5
	Soups and salads	A041K	5
Fish, seafood, amphibians, reptiles and invertebrates	Amphibians, reptiles, snails, insects	A02KP	10
Food products for young population	Infant formula (IF) and follow-on formula (FoF)	A03PY	1.2(1)
	Other food for infants and children	A03RL	0.81
	Processed cereal-based food for infants and young children	A03QX	0.81(2)
	Ready-to-eat meal for infants and young children	A03RC	0.81
Fruit and fruit products	Processed fruit products	A01ML	1.5
Grains and grain-based products	Bread and similar products(3)	A004V	5
	Breakfast cereals	A00CV	4
	Cereals and cereal primary derivatives	A000K	3
	Fine bakery wares(3)	A009T	5
	Pasta, doughs and similar products	A04QT	5
Legumes, nuts, oilseeds and spices	Spices	A016S	10
Major isolated ingredients, additives, flavours, baking and processing aids	Isolated proteins and other protein products	A0EVD	10
	Maltodextrins and similar	A0DPT	10
	Miscellaneous agents for food processing	A048P	10
Milk and dairy products	Cheese	A02QE	2
	Dairy dessert and similar	A02PT	2
	Fermented milk or cream	A02MZ	1.5
	Milk and dairy powders and concentrates	A02PD	25(4)
	Milk, whey and cream	A04NN	0. 5
Other ingredients	Vitamins	A0EVG	10
Products for non-standard diets, food imitates and food supplements	Food for particular diets	A03RR	5
	Meat and dairy imitates	A03TD	2.5
Seasoning, sauces and condiments	Condiments (including table-top formats)	A04QN	5
	Dessert sauces/toppings	A046QF	10
	Mixed and other not-listed condiments	A045J	10
	Savoury extracts and sauce ingredients	A0EQE	10
	Seasonings and extracts	A04QJ	10
Vegetables and vegetable products	Algae and prokaryotes organisms	A00VA	10
	Fungi, mosses and lichens	A00TC	10
	Processed or preserved vegetables and similar	A00ZA	2

(1): Based on the minimum use level of 1.2 µg vitamin D/100 g ready for use corresponding to 2 µg/100 kcal ready for use for IF set by Commission Delegated Regulation (EU) 2016/127 (European Commission, 2016)[2]

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0127&from=FR

(2): Based on the minimum use level of 0.81 μg vitamin D/100 g ready for use corresponding to 1 μg/100 kcal ready for use formula set by Commission Directive 2006/125/EC (European Commission, 2006) for processed cereal-based foods for infants and young children.
(3): The use of the NF in yeast-leavened breads and rolls and yeast-leavened fine bakery wares has already been authorised, at the proposed maximum levels.
(4): The proposed maximum vitamin D2 level in milk and dairy powders is 25 μg/100 g of dried powder and 2.5 μg/100 g for the reconstituted milk.

3.2.2. Anticipated intake of the NF

EFSA performed an assessment of the anticipated daily intake of vitamin D2 from the NF based on the applicant's proposed uses and maximum proposed use levels indicated in Table 1, using individual data from the EFSA Comprehensive European Food Consumption Database (EFSA, 2011). The estimated lowest and highest mean and 95th percentile daily intake of vitamin D2 from the NF among the EU dietary surveys is presented in Tables 2 and 3, expressed as μg/kg body weight (bw) per day and μg per day, respectively.

The estimated daily intake of the NF for each population group from each EU dietary survey is available in the Excel files annexed to this scientific opinion (under supporting information).

Table 2: Estimated intake of the vitamin D2 (μg/kg bw per day) from the NF based on its use as an ingredient in the intended food categories at the maximum proposed use levels

Population group	Age (years)	Mean intake[(a)] (μg/kg bw per day)		P95 intake[(b)] (μg/kg bw per day)	
		Lowest	Highest	Lowest	Highest
Infants	< 1	0.46	1.67	1.38	3.45
Young children[(c)]	1–< 3	0.75	1.42	1.11	1.69
Other children	3–< 10	0.50	1.07	0.74	1.85
Adolescents	10–< 18	0.21	0.49	0.35	0.79
Adults[(d)]	≥ 18	0.13	0.40	0.24	0.68

(a): Mean intakes are assessed for all EU dietary surveys available in the food comprehensive database on 25/03/2021. The lowest and the highest mean intake observed among all available EU surveys are reported in these columns.
(b): 95th percentile (P95) intakes are assessed for all EU dietary surveys available in the food comprehensive database on 25/3/2021. The lowest and the highest P95 intake observed among all available EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).
(c): Referred as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).
(d): Includes elderly, very elderly, pregnant and lactating women

Table 3: Estimated intake of the vitamin D2 (μg/day) from the NF based on its use as an ingredient in the intended food categories at the maximum proposed use levels

Population group	Age (years)	Mean intake (μg/day)		P95 intake (μg/day)	
		Lowest[(a)]	Highest[(a)]	Lowest[(b)]	Highest[(b)]
Infants	< 1	3.94	10.38	11.60	20.08
Young children[(c)]	1–< 3	8.69	19.45	13.07	18.98
Other children	3–< 10	9.20	23.28	13.52	36.93
Adolescents	10–< 18	11.07	20.35	17.77	38.31
Adults[(d)]	≥ 18	10.04	29.21	17.32	40.46

(a): Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 25/03/2021. The lowest and the highest averages observed among all EU surveys are reported in these columns.
(b): 95th percentile (P95) intakes are assessed for all EU dietary surveys available in the food comprehensive database on 25/03/2021. The lowest and the highest P95 observed among all available EU surveys are reported in these columns (P95 based on less than 60 individuals are not considered).
(c): Referred as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).
(d): Includes elderly, very elderly, pregnant and lactating women.

3.2.3. Combined vitamin D intake from the NF and other sources

The potential combined intake of vitamin D from the NF (vitamin D2) and other sources (vitamin D2 or D3) is estimated in Table 4 by adding up the contribution to vitamin D intake from the NF as estimated by EFSA (Table 3) and estimates for vitamin D intake from other food sources as previously reported by the EFSA NDA Panel based on a literature review (EFSA NDA Panel, 2012).

For infants aged from 4 to 12 months, data on vitamin D intake from the background diet were estimated by EFSA using composition data from the EFSA nutrient composition database and individual consumption data from national surveys from six European countries (EFSA NDA Panel, 2018). In that Opinion, the Panel noted that the P95 vitamin D intake from the diet of non-formula fed infants and excluding intake from fortified foods, ranged between 0.7 and 2.8 μg/day. The latter value (i.e. 2.8 μg/day) is considered as high vitamin D intake from the background diet of older infants in Table 4, which covers infants who consume IF. It is a conservative approach because IF-fed infants are expected to consume less vitamin D from the background diet (excluding IF) than non IF-fed infants.

The P95 exposure from the background diet alone (without food supplements) was not available for all children age groups above one year of age in the EFSA opinion from 2012, and as a substitute, the highest mean intakes across the covered surveys for each age category of children were used (Table 4). The highest mean intakes were 5.6 μg/day in young children (1–< 3 years), 2.7 μg/day in older children (3–< 10 years) and 4.0 μg/day in adolescents (10–< 17 years). The P95 intakes from the background diet plus from food supplements were, however, available for children of an age between 1 and 10 years (up to 15 μg/day) and adolescents (up to 8 μg/day) in the EFSA NDA Panel opinion from 2012 and were also used in the calculations in Table 4. The Panel considers that vitamin D2 intake from this NF when used in food supplements, would most likely come as substitute for other food supplements and therefore not increase overall vitamin D2 intake. In this 2012 Opinion, the highest P95 dietary background intake (without food supplements) across the covered surveys in adults was 16 μg vitamin D/day.

Table 4 provides an overview of the exposure to vitamin D from different sources separately and combined, and the tolerable upper intake levels (ULs) established for young children, children, adolescents and adults (EFSA NDA Panel, 2012, 2018).

Table 4: Total vitamin D intake (μg/day) resulting from combined exposure to vitamin D from the background diet and from the NF as an ingredient at the maximum use levels as proposed by the applicant

Population group	Age (years)	Intake of vitamin D from EFSA NDA Panel (2012)	Highest P95 vitamin D_2 intake from the NF taken (from Table 3)	Total intake[(f)]	UL* (μg/day) EFSA NDA Panel (2012, 2018)
Infants	< 1	2.8[(c)]	20.08	22.9	25/35[(g)]
Young children	1–< 3	5.6[(d)]	18.98	24.6	50
		15[(e)]	18.98	34.0	
Other children	3–< 10	2.7[(d)]	36.93	39.6	50
		15[(e)]	36.93	51.9	
Adolescents[(a)]	10–< 18	4[(d)]	38.31	42.3	100
		8[(e)]	38.31	46.3	
Adults[(b)]	≥ 18	16[(d)]	40.46	56.5	100

*: UL: tolerable upper intake level; NF: novel food.

(a): Food supplement for all adolescents: Intakes are assessed separately for young [10–14 years] and old adolescents [14–18 years]; the highest intake among these two sub-populations is reported here.

(b): Intakes are estimated separately for adults [18–65 years], elderly [65–75 years] and very elderly [≥ 75 years]; the highest intake estimate among these three subpopulations is reported here. The figure represents the highest P95 consumption estimate from foods excluding food supplements (EFSA NDA Panel, 2012).

(c): Highest P95 vitamin D intake from the diet of non-formula fed infants (EFSA NDA Panel, 2018, 2020).

(d): Highest mean or median intake of vitamin D from foods excluding food supplements. Data collected from different surveys/studies (EFSA NDA Panel, 2012).

(e): Estimate for combined vitamin D intake from foods and supplements; vitamin D intake from high consumers (P90 or P95 depending on surveys) in infants, children and adolescents (EFSA NDA Panel, 2012).

(f): Total intake is the estimate of vitamin D intake calculated as the sum of vitamin D intake from the background diet with or without food supplements (EFSA NDA Panel (2012), plus estimated P95 from the NF ingredient when used in foods.

(g): Upper level for vitamin D for infants up to 6 months of age (i.e. 25 μg/day) and with an age between 7 and 12 months (i.e. 35 μg/day), respectively (EFSA NDA Panel, 2018).

According to scenarios covered by Table 4, the combined high intake estimates for vitamin D from the background diet and the NF, would exceed the UL of 50 μg/day for 'other children' (aged 3–< 10 years) by 4%, when adding up the highest P95 estimate from the background diet (which included consumption of food supplements) and the highest P95 estimate for vitamin D from the NF. The scenarios of Table 4 do not consider exposure to vitamin D from food supplements by infants and adults. For adults, however, there is a margin of 43.54 μg/day to the UL of 100 μg/day. For infants up to 6 and 12 months of age, the margin to the UL is smaller, i.e. 2.12 and 12.12 μg/day, respectively.

The combined exposure estimates for vitamin D for infants and young children with an age of up to 3 years presented in Table 4, consider that the IF, FoF and processed cereal-based foods for infants and young children contained the maximum use level as proposed by the applicant in Table 1 (i.e. 1.2 μg vitamin D/100 g ready for use IF and FoF and 0.81 μg vitamin D/100 g for ready for use 'processed cereal-based food for infants and young children', respectively). The Panel notes however that according to the Commission Delegated Regulation (EU) 2019/828 (European Commission, 2019) amending Commission Delegated Regulation (EU) 2016/127 (European Commission, 2016), the maximum permitted contents of vitamin D in IF and FoF are higher than the maximum use levels proposed by the applicant for these foods. The permitted maximum contents are 2.5 and 3 μg vitamin D per 100 kcal ready for use IF and FoF, respectively, which correspond to 1.5 and 1.8 μg vitamin D per 100 g ready for use formulae, respectively. For processed cereal-based foods for infants and young children, the maximum permitted content of vitamin D is 3 μg/100 kcal ready to use food according to the Commission Directive 2006/125/EC (European Commission, 2006) corresponding to 2.43 μg vitamin D/100 g ready to use food. These foods would contribute significantly to intake in these groups, and hence, there are scenarios where vitamin D intake will approach the maximum permitted levels. These are summarised in Table 5. For the vitamin D intake coming from the background diet, the scenarios in Table 5 consider the same exposure estimates as used for the scenario in Table 4.

Table 5: Total vitamin D intake (μg/day) resulting from exposure to vitamin D from the background diet (same values as used in Table 4) and to vitamin D from the NF as an ingredient at the maximum use levels as proposed by the applicant – except regarding IF and FoF and processed cereal-based food for infants and young children (for which the higher, legal maximum use levels for vitamin D for these foods are used)

Population group	Age (years)	Intake of vitamin D, (EFSA NDA Panel (2012))	Highest P95 vitamin D_2 intake from the NF*	Total intake	UL* (μg/day) (EFSA NDA Panel, 2012, 2018)
Infants	< 1	2.8[(a)]	22.09	24.89	25/35
Young children	1–< 3	5.6[(b)]	24.61	30.21	50
		15[(c)]	24.61	39.61	

*: Instead of the maximum use levels proposed by the applicant for IF and FoF, and processed cereal based foods for infants and young children, the maximum legally permitted use levels are used in this exposure scenario.
(a): Highest P95 vitamin D intake from the diet of non-formula fed infants (EFSA NDA Panel, 2018, 2020).
(b): Highest mean or median intake of vitamin D from foods excluding food supplements. Data collected from different surveys/ studies (EFSA NDA Panel, 2012).
(c): Combined vitamin D intake from foods and supplements; vitamin D intake from high consumers (90th or 95th percentile depending on surveys) in infants, children and adolescents (EFSA NDA Panel, 2012).

Regarding the exposure to the NF itself, at an exposure of e.g. 50 μg of vitamin D2 from the NF, 5.7–25 mg of the UV-treated yeasts would be consumed.

3.2.4. Estimate of exposure to undesirable substances

In their assessment from 2014, the NDA Panel noted that 'the results of high-performance liquid chromatography (HPLC) show that, apart from the intended vitamin D2, tachysterol was the only additional sterol detected via HPLC analysis. According to the applicant, the average amounts of vitamin D and tachysterol in the vitamin D2 yeast concentrate are 750 μg/g and 140 μg/g, respectively'. The ratio between these contents of tachysterol and vitamin D and, i.e. 1/5.4, would also apply to anticipated intakes presented in Section 3.2.1. Considering the low exposure to the NF, the Panel considers that tachysterol is not of concern.

4. Discussion

The Panel notes that the UL for 'other' children (aged 3 to < 10 years) is exceeded by 4%, when adding up the highest P95 vitamin D intake estimate from the background diet (including food supplements) and the highest P95 vitamin D intake estimate from the NF under the proposed uses and maximum use levels. However, the Panel notes the conservative approach taken for estimating the potential intake of vitamin D from the NF, given that the applicant has proposed 34 FoodEx2 level 2 food categories. The intake estimates assume that whenever an individual consumes foods from these 34 food categories, each consumed food from this list contains the NF at the maximum use levels proposed by the applicant. Thus, the Panel considers that the UL for children aged between 3 and < 10 years is highly unlikely to be exceeded at the uses and maximum use levels proposed by the applicant.

The exposure scenario for 'young' children (aged 1 to < 3 years), which include also exposure from food supplements, suggest that the ULs for vitamin D would not be exceeded. This would also apply for these children, and also for infants, if they would consume IF and FoF and processed cereal foods for infants and young children containing the maximum permitted content of vitamin D set for these foods.

Table 4 includes food consumption surveys for children between 1 and 18 years of age which also covered combined consumption estimates for vitamin D from the diet including food supplements. Under the assumption that the NF when used in food supplements would rather replace than add to the intake of other vitamin D containing food supplements, the use of this NF in food supplements would not result in an increase of vitamin D intake in children between 1 and 18 years of age.

For adults, the sum of the highest P95 estimate for the potential intake of vitamin D from the NF and the highest mean intake from the diet without food supplements would result in a daily intake of 56.5 μg vitamin D, which would leave some margin to the UL for adults (i.e. 100 μg/day) regarding food supplements.

The Panel notes limitations regarding the assessment of the potential combined exposure to vitamin D from the NF and other sources. First, this exposure assessment does not consider potential exposure from other authorised NFs with vitamin D such as UV-treated bread (EFSA NDA Panel, 2015), UV-treated milk (EFSA NDA Panel, 2016a), UV-treated mushroom (EFSA NDA Panel et al., 2020). The Panel also notes uncertainty regarding the calculated combined exposures to vitamin D of the general population, given the fact that the range of foods fortified with vitamin D has increased over the years as well as the marketing of high-dose vitamin D supplements. However, the Panel considers that the applied approach for estimating the potential exposure to vitamin D from the NF is highly conservative given the large number of food categories proposed by the applicant and used for the intake estimates.

5. Conclusions

The Panel concludes that the NF is safe under the proposed conditions of use.

6. Steps taken by EFSA

1) On 29/01/2018 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of Safety of extended uses of UV-treated baker's yeast as a Novel Food pursuant to Regulation (EU) 2015/2283 Ref. Ares(2018)470279.
2) On 07/07/2020, a valid application on the safety of Safety of extended uses of UV-treated baker's yeast as a Novel Food pursuant to Regulation (EU) 2015/2283, which was submitted by name of the company, was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2020/1778) and the scientific evaluation procedure was initiated.
3) On 19/03/2021, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
4) On 15/04/2021, additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
5) During its meeting on 28/04/2021, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of Safety of extended uses of UV-treated baker's yeast as a Novel Food pursuant to Regulation (EU) 2015/2283 as a NF pursuant to Regulation (EU) 2015/2283.

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Abbreviations

AI adequate intake
bw body weight

CAS	Chemicals Abstracts Service
CFU	colony forming units
FoF	Follow-on formula
HPLC	High Performance Liquid Chromatography
IF	Infant formula
IU	International Units
NDA	Panel on Nutrition, Novel Foods and Food Allergens
NF	Novel Food
P95	95th percentile
UL	tolerable upper intake level
UV	ultraviolet

Annex A – Dietary exposure estimates to the Novel Food for each population group from each EU dietary survey

Information provided in this Annex is shown in an Excel file (downloadable at https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.6602#support-information-section).