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

EFSA Panel on Nutrition, Novel Foods, Food Allergens (NDA), Dominique Turck, Jacqueline Castenmiller, Stefaan De Henauw, Karen Ildico Hirsch-Ernst, John Kearney, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri, Marco Vinceti, Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Rosangela Marchelli, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk van Loveren, Wolfgang Gelbmann and Helle Katrine Knutsen

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.

© 2021 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

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

Requestor: European Commission

Question number: EFSA-Q-2020-00393

Correspondence: nda@efsa.europa.eu
Panel members: Dominique Turck, Jacqueline Castenmiller, Stefaan De Henauw, Karen Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri and Marco Vinceti.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA’s work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Suggested citation: EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods, Food Allergens), Turck D, Castenmiller J, De Henauw S, Hirsch-Ernt KI, Kearney J, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Frenzel T, Heinonen M, Marchelli R, Neuhäuser-Berthold M, Poulsen M, Maradona MP, Schlatter JR, van Loveren H, Gelbmann W and Knutsen HK, 2021. Scientific Opinion on the safety of extended uses of UV-treated baker’s yeast as a Novel Food pursuant to Regulation (EU) 2015/2283. EFSA Journal 2021;19(6):6602, 13 pp. https://doi.org/10.2903/j.efsa.2021.6602

ISSN: 1831-4732

© 2021 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.
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 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.

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 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. Tann-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 (≤ 10³ cfu/g), Escherichia coli (≤ 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 yeasted-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 |
|                      | 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 | A04QP | 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 | A04QF | 10 |
|                      | Mixed and other not-listed condiments | A04SJ | 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 | A00Z | 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
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 25/03/2021. 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(a) (μg/day) | P95 intake(b) (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 D2 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 sub-populations 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 D₂ 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 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 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 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.
References

Denmark, 2016. Initial assessment report under Article 4 of Regulation (EC) No 258/97. Extended use of UV-treated baker’s yeast (Saccharomyces cerevisiae) as a novel food ingredient. 30 June 2017/j. no. 17/01150. Unpublished.

EFSA (European Food Safety Authority), 2011. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. https://doi.org/10.2903/j.efsa.2011.2097

EFSA NDA Panel (EFSA Panel on Dietetic Products Nutrition and Allergies), 2012. Scientific Opinion on the Tolerable Upper Intake Level of vitamin D. EFSA Journal 2012;10(7):2813, 45 pp. https://doi.org/10.2903/j.efsa.2012.2813

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the safety of vitamin D-enriched UV-treated baker’s yeast. EFSA Journal 2014;12(1):3520, 19 pp. https://doi.org/10.2903/j.efsa.2014.3520

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on the safety of UV-treated bread as a novel food. EFSA Journal 2015;13(7):4148, 16 pp. https://doi.org/10.2903/j.efsa.2015.4148

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016a. Scientific opinion on the safety of UV-treated milk as a novel food pursuant to Regulation (EC) No 258/97. EFSA Journal 2016;14(1):4370, 14 pp. https://doi.org/10.2903/j.efsa.2016.4370

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016b. Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283. EFSA Journal 2016;14(11):4594, 24 pp. https://doi.org/10.2903/j.efsa.2016.4594

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D, Bresson J-L, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI, Mangelsdorf I, McArthur HJ, Naska A, nowicia G, Pentieva K, Sanz Y, Siani A, Sjödin A, Stern M, Tomé D, Loveren HV, Vinceti M, Willatts P, Fewtrell M, Lamberg-Allardt C, Pryzembel H, Arcelia D, Dumas C, Fabiani L, Martino L, Tomickova D and Neuhäuser-Berthold M, 2018. Update of the tolerable upper intake level for vitamin D for infants. EFSA Journal 2018;16:1831–4732, e05365 pp. https://doi.org/10.2903/j.efsa.2018.5365 Available online: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2018.5365

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Castenmiller J, de Henauw S, Hirsch-Ernst K-I, Kearney J, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Engel K-H, Frenzel T, Heinonen M, Marchelli R, Neuhäuser-Berthold M, Poulsen M, Sanz Y, Schlatter JR, van Loveren H, Roldan-Torres R, Steinkellner H and Knutsen HK, 2020. Scientific Opinion on the safety of vitamin D2 mushroom powder as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal 2020;18(1):5948, 23 pp. https://doi.org/10.2903/j.efsa.2020.5948

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Castenmiller J, de Henauw S, Hirsch-Ernst K-I, Kearney J, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Cubadda F, Engel K-H, Frenzel T, Heinonen M, Marchelli R, Neuhäuser-Berthold M, Poulsen M, Prieto Maradona M, Schlatter JR, van Loveren H, Roldan-Torres R, Steinkellner H and Knutsen HK, 2021. Scientific Opinion on the safety of Vitamin D2 mushroom powder (Agaricus bisporus) as a Novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal 2021;19(4):6516, 19 pp. https://doi.org/10.2903/j.efsa.2021.6516

European Commission, 2006. Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children.

European Commission, 2014. Commission implementing decision of 24 June 2014 authorising the placing on the market of UV-treated baker’s yeast (Saccharomyces cerevisiae) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (2014/396/EU).

European Commission, 2016. Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

European Commission, 2018. Commission implementing regulation (EU) 2018/1018 of 18 July 2018 authorising an extension of use of UV-treated baker’s yeast (Saccharomyces cerevisiae) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

European Commission, 2019. Commission Delegated Regulation (EU)2019/828 of 14 March 2019 amending Delegated Regulation (EU) 2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula.

Abbreviations

AI adequate intake
bw body weight
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).