REGULATED PRODUCTS SAFETY ASSESSMENT

Safety Assessment on the Change of Conditions of Use for the Novel Food, UV-treated Baker's Yeast (RP1908)

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FSA Research and Evidence

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) received an application from Lallemand Bio-ingredients, Canada ("the applicant") for a change in the intended conditions of use of UV-treated Baker's yeast (*Saccharomyces cerevisiae*) as a novel food in February 2023.

The novel food is UV-treated Baker's yeast which is intended to be used as a food ingredient. The novel food is manufactured by treating Baker's yeast with ultraviolet light to induce the conversion of ergosterol to vitamin D_2 (ergocalciferol).

UV-treated Baker's yeast is currently authorised as a novel food in the UK and EU under assimilated Commission Regulation (EU) 2017/2470. This new application is a change in the conditions of use seeking to extend the intended use of UV-treated Baker's yeast within the food category: water-based beverages.

The FSA and FSS in their evaluation of the application reviewed the safety dossier and supplementary information provided by the applicant. The FSA and FSS did not consider any potential health benefits or claims arising from consuming the food, as the focus of the novel food assessment is to ensure the change in the conditions of use to extend the food is safe, and not putting consumers at a nutritional disadvantage.

The FSA and FSS concluded that the applicant had provided sufficient information to assure that the change in the conditions of use for UV-treated Baker's yeast to include the food category water-based beverages, was safe under the intended conditions of use. The anticipated intake levels and the intended use in foods was not considered to be nutritionally disadvantageous.

The safety assessment represents the opinion of the FSA and FSS.

1. Introduction

UV-treated Baker's yeast is an authorised novel food in the UK. It was originally authorised as an application from Lallemand Bio-ingredients, Canada, in June 2014, for use in yeast-leavened bread and rolls, yeast leavened fine bakery wares and food supplements (added to the list of authorised novel foods in assimilated Commission Regulation (EU) 2017/2470).

In July 2018, an extension of use for the novel food was authorised for pre-packed fresh and dry yeast for home baking, and food supplements, without indication of maximum permitted levels (added to the list of authorised novel foods in assimilated Commission Regulation (EU) 2017/2470).

In February 2022, an extension of use for the novel food was authorised for a number of different food categories in the EU – Commission Implementing Regulation (EU) 2022/196. This same extension of use application has also been authorised in Great Britain under the Food Additives, Food Flavourings and Novel foods (Authorisations)(England) Regulations 2023/334 (assimilated Commission Regulation (EU) 2017/2470 was updated accordingly).

In February 2023, Lallemand Bio-ingredients, Canada ("the applicant") submitted an application to the FSA and FSS to change the conditions of use of UV-treated Baker's yeast to extend the use to water-based beverages. The novel food is manufactured by treating Baker's yeast (*S. cerevisiae*) with ultraviolet light to induce the conversion of ergosterol to vitamin D_2 (ergocalciferol).

The FSA and FSS have undertaken the safety assessment of the intended extension of the authorised uses for UV-treated Baker's yeast to additional food categories under the novel foods legislation, assimilated Regulation (EU) 2015/2283.

Under Article 3(4) of assimilated Commission Implementing Regulation (EU) 2017/2469, it may not be necessary for the applicant to provide all the data required under Article 5 of this Regulation when a novel food application seeks to modify the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised novel food. Verifiable justification explaining that the intended changes do not affect the results of the existing safety assessment is provided by the applicant. Given that the novel food is identical to the one reviewed in the previous assessment, this new safety assessment has focused on the impact of the intended changes of use for UV-treated Baker's yeast.

The evaluation by the FSA and FSS assessed the food safety risks of the novel food and its production, in line with Article 11 of assimilated Regulation (EU) 2015/2283 and Article 7 of assimilated Commission Implementing Regulation (EU) 2017/2469. The basis and structure of the assessment was conducted in accordance with the relevant technical guidance put in place by the European Food Safety Agency (EFSA) for full novel food applications (EFSA NDA Panel, 2016) which the FSA and FSS considers is relevant and should be applied to this novel food application owing to similarities in the regulatory regimes.

This assessment outlines the conclusions of the FSA and FSS on the change in the conditions of use for UV-treated Baker's yeast as a novel food to include the food category: water-based beverages.

2. Assessment

2.1. Overview

Prior to leaving the EU in December 2020, the UK accepted the assessments of EFSA in respect of authorisations for regulated food and feed products whilst it was a Member State of the EU.

In 2014, EFSA conducted the original safety assessment for UV-treated Baker's yeast (EFSA NDA Panel, 2014) and concluded the novel food was safe under the intended conditions of use. UV-treated Baker's yeast was subsequently authorised as a novel food in the UK and EU under assimilated Commission Regulation (EU) 2017/2470.

The information set out in this FSA-FSS opinion concerning the identity of the novel food, the production process, the compositional information, stability, specification, Absorption, Distribution, Metabolism and Excretion (ADME), nutritional information, toxicological information and allergenicity was provided by the applicant in the original novel food application.

The information in these specific sections of the original novel food application have not been updated and remain the same in this submission.

The FSA and FSS have assessed the relevant information in these sections of the original novel food application and agree that the conclusions of the original assessment by EFSA remain accurate and reliable in the context of the intended extension to the conditions of use to water-based beverages and applicable in the UK. As such the previous assessment has been used as a starting point and the focus of this review has been the impact of the changes to the conditions of use requested.

2.1.1. Identity of the Novel Food

The novel food is UV-treated Baker's yeast (*S. cerevisiae*) which is a tan-coloured granular powder containing vitamin D_2 (ergocalciferol). The content of vitamin D_2 is specified at 1,800,000 – 3,500,000 IU vitamin D/100 g (450 – 875 µg/g).

Vitamin D_2 (Figure 1) is classified by the following information:

- Chemical name: (3S,5Z,7E,22E)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol
- Chemical Formula: $C_{28}H_{44}O$
- CAS number: 50-14-6
- Molecular weight: 396,65 g/mol

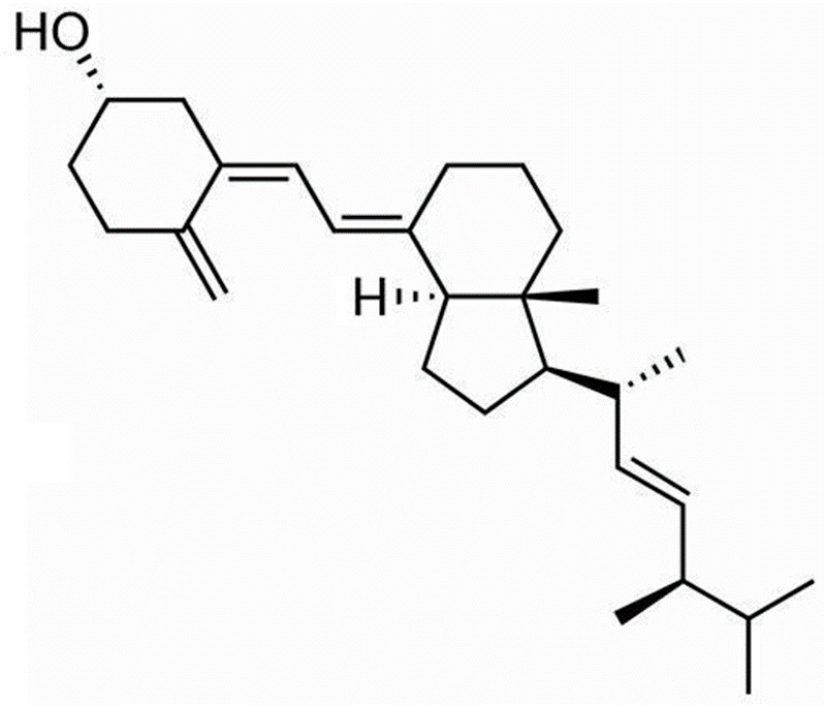

Figure 1. The structural formula of vitamin D_2 (ergocalciferol)

There is no change to the identity of the novel food in this application, which is currently defined in the List of Novel Foods (assimilated Commission Implementing Regulation (EU) 2017/2470).

2.1.2. Production Process

The novel food is manufactured by treating Baker's yeast with ultraviolet (UV) light to induce the conversion of the ergosterol present in the yeast to vitamin D_2 (ergocalciferol).

In the original assessment, EFSA concluded that the data provided on the production process was sufficient and did not give rise to any safety concerns (EFSA NDA Panel, 2014). Upon review, the FSA and FSS agree with this decision and the changes to the conditions of use sought do not change this opinion.

The production process for UV-treated Baker's yeast remains unchanged in this application.

2.1.3. Compositional Information

The composition of the novel food was assessed by EFSA in the original authorisation (EFSA NDA Panel, 2014) and no concerns were raised. Upon review, the FSA and FSS agree with this decision and the changes to the conditions of use sought do not change this opinion.

No further compositional data was provided for assessment because there are no changes to the production process or the specification of the novel food in this application.

2.1.4. Stability

The stability of the novel food was assessed by EFSA in the original authorisation (EFSA NDA Panel, 2014) and no concerns were raised. Upon review, the FSA and FSS agree with this decision and the changes to the conditions of use sought do not change this opinion.

No further stability data was provided for assessment because there are no changes to the production process or the specification of the novel food in this application.

2.1.5. Specification

The specification for the novel food (Table 1) is currently defined in the List of Novel Foods (assimilated Commission Implementing Regulation (EU) 2017/2470).

Table 1. Specification for the novel food reproduced from the List of Novel Foods (assimilated Commission Implementing Regulation (EU) 2017/2470)

Parameter	Specification	Method
Vitamin D_2	1,800,000 – 3,500,000 IU vitamin D/100 g	AOAC 982.29 (modified)
Coliforms	< 1,000/g	FDA-BAM
Escherichia coli	< 10/g	FDA-BAM
Salmonella	Absent in 25g	FDA-BAM

AOAC = Association of Official Analytical Chemists; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual

Upon review, the FSA and FSS agree with this decision and the changes to the conditions of use sought do not change this opinion.

The specification of UV-treated Baker's yeast remains unchanged in this application.

2.1.6. History of Use

UV-treated Baker's yeast is currently authorised as a novel food in the UK (assimilated Commission Implementing Regulation (EU) 2017/2470). The current authorised uses and maximum use levels for UV-treated Baker's yeast are listed in Table 2.

Table 2. Current authorised uses and maximum use levels of the novel food reproduced from the List of Novel Foods (assimilated Commission Implementing Regulation (EU) 2017/2470)

Specified Food Category	Maximum Use Levels (per 100g)
Yeast-leavened breads and rolls	5 µg
Yeast-leavened fine bakery wares	5 µg
Food supplements *	In accordance with the Regulations *
Pre-packed fresh or dry yeast for home baking	45 µg for fresh yeast 200 µg for dried yeast
Dishes, including ready-to-eat meals (excluding soups and salads)	3 µg
Soups and salads	5 µg
Fried or extruded cereal, seed or root-based products	5 µg
Infant formula and follow-on formula as defined by assimilated Regulation (EU) No 609/2013	1.2 µg **
Other foods for infants and children	0.81 µg
Processed cereal-based food as defined by assimilated Regulation (EU) No 609/2013	0.81 µg ***
Ready-to-eat meal for infants and young children	0.81 µg
Processed fruit products	1.5 µg
Processed vegetables	2 µg
Breakfast cereals	4 µg
Pasta, doughs and similar products	5 µg
Other cereal based products	3 µg
Spices	10 µg
Isolated protein and other protein products	10 µg
Maltodextrins and similar	10 µg
Miscellaneous agents for food processing	10 µg
Cheese	2 µg
Dairy dessert and similar products	2 µg
Fermented milk or cream	1.5 µg
Milk and dairy powders and concentrates	25 µg
Milk, whey and cream	0.5 µg

Specified Food Category	Maximum Use Levels (per 100g)
Meat and dairy analogues	2.5 µg
Total diet replacement for weight control as defined by assimilated Regulation (EU) No 609/2013	5 µg
Meal replacements for weight control	5 µg
Foods for special medical purposes as defined in assimilated Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended

* Food Supplements as defined in the Food Supplements (England) Regulations 2003/1387, the Food Supplements (Wales) Regulations 2003/1719 and the Food Supplements (Scotland) Regulations 2003/278.
** Based on the minimum use level of 1.2 µg vitamin D per 100 g ready for use corresponding to 2 µg per 100 kcal ready for use for infant formula set by assimilated Commission Delegated Regulation (EU) 2016/127.
*** Based on the minimum use level of 0.81 µg vitamin D per 100 g ready for use corresponding to 1 µg per 100 kcal ready for use formula set by assimilated Commission Directive 2006/125/EC for processed cereal-based foods for infants and young children.

2.1.7. Intended Use and Maximum Use Levels

The general population are identified as the target population for the novel food.

The intended use and maximum use level for the novel food in the additional food category is shown in Table 3.

Table 3. Intended use and maximum use level for the extension of use of the novel food

Intended Food Category	Maximum Levels of Vitamin D (per 100g)
Water-based beverages	1.5 µg

The combined estimated intake of vitamin D from consumption of the intended and current authorised uses novel food is shown in Table 4. This is based on the previous exposure assessment (EFSA NDA, 2021) and assuming that all populations are high-level consumers of the novel food in water-based beverages at the maximum level of 1.5 µg of vitamin D per 100g.

Table 4. Estimated total intake of vitamin D_2 from consumption of the additional intended food use, existing authorised food uses of UV treated Baker's yeast, and the background diet.

Population Group	Background Dietary Vitamin D intake (µg) *	P95 intake levels for authorised NF uses (µg/day)	P95 intake level for new NF use (µg/day)	Total vitamin D intake (µg/day)
Infants	2.8 **	22.09 ***	1.01	25.9
Young children	2.56 – 9.1	24.61 ***	3.59	30.76 – 37.3
Other children	2.12 – 10.1 2.39 – 7.97	13.52 – 36.93	6.1	21.74 – 53.13 22.01 – 51
Adolescents	3.19 – 9.46 4.02 – 11.9	17.77 – 38.31	14.31	35.27 – 62.08 36.1 – 64.52

Population Group	Background Dietary Vitamin D intake (µg) *	P95 intake levels for authorised NF uses (µg/day)	P95 intake level for new NF use (µg/day)	Total vitamin D intake (µg/ day)
Adults	4.57 – 13.4	17.32 – 40.46	11.71	56.74 – 65.57

Infants 0 to 6 months and 7 to < 12 months; young children 12 – 35 months; other children 3 to < 7 years and 7 to < 10 years; adolescents 10 to < 14 years and 14 to < 18 years; adults 18 years and above.
* Background vitamin D dietary intake for all sub-populations, except infants, taken from Annex B of Scientific opinion on the tolerable upper intake level for vitamin D, including the derivation of a conversion factor for Calcidiol monohydrate (EFSA NDA Panel, 2023).
** Highest P95 vitamin D intake from the diet of non-formula fed infants (EFSA NDA Panel, 2018).
*** instead of the maximum use levels intended by the applicant for IF and FoF and processed cereal based foods for infants and young children, EFSA used the maximum legally permitted use levels in the exposure scenario (EFSA NDA Panel , 2021).

For the young children, adolescent and adult sub-populations, the combined estimated vitamin D intake is expected to be below the tolerable upper intake level of 50 µg/day for young children, and 100 µg/day for adolescents and adults.

For other children, aged 3 to < 7 years and 7 to < 10 years, the combined estimated intake for vitamin D ranges from 21.74 – 53.13 µg/day and 22.01 and 51 µg/day, respectively. The highest values reported for the combined estimated intakes exceed the tolerable upper intake level for vitamin D of 50 µg/day by 6.3 % (other children aged 3 to < 7 years) and 2.0% (other children aged 7 to < 10 years).

In infants, the combined estimated intake of vitamin D is reported as 25.9 µg/day. For children aged 0 to 6 months, this is 3.6% higher than the upper tolerable upper intake level for vitamin D (25 µg/day); however, for children aged from 7 to up to 12 months, this is below the tolerable upper intake level of 35 µg/day.

2.1.8. Absorption, Distribution, Metabolism and Excretion (ADME)

Information concerning the ADME of the novel food was assessed by EFSA in the original assessment. An animal feeding study and a human trial demonstrated that vitamin D_2 from UV-treated Baker's yeast prepared in baked bread was bioavailable.

No concerns were raised by EFSA concerning the ADME of the novel food (EFSA NDA Panel, 2014). Upon review, the FSA and FSS agree with this decision and the changes to the conditions of use sought do not change this opinion.

No studies on the bioavailability of vitamin D_2 from the novel food in water–based beverages were provided in this application.

2.1.9. Nutritional Information

Information concerning the nutritional profile of the novel food was assessed by EFSA in the original assessment. EFSA concluded that UV-treated Baker's yeast was not nutritionally disadvantageous for consumers (EFSA NDA Panel, 2014). Upon review, the FSA and FSS agree with this decision and the changes to the conditions of use sought do not change this opinion.

No further nutritional information was provided for assessment because there no change to the production process or the specification of the novel food in this application.

2.1.10. Toxicological Information

No toxicological information for UV-treated Baker's yeast was provided in the original application. EFSA concluded that this was acceptable given the source, nature and intended uses of the novel food (EFSA NDA Panel, 2014). Upon review, the FSA and FSS agree with this decision and the changes to the conditions of use sought do not change this opinion.

No further toxicological information was provided for assessment because there are no changes to the production process or the specification of the novel food.

2.1.11. Allergenicity

In the original assessment of the allergenicity of the novel food, EFSA considered that the risk of allergenic reactions to UV-treated Baker's yeast was no greater than for other foods containing *S. cerevisiae* (EFSA NDA Panel, 2014). Upon review, the FSA and FSS agree with this decision and the changes to the conditions of use sought do not change this opinion.

No further allergenicity information was provided for assessment because there are no changes to the production process and the specification of the novel food.

3. Discussion

This application seeks to change the conditions of use for UV-treated Baker's yeast as a novel food to include the food category: water-based beverages. No other changes to the production process, composition, stability or the specification are made.

The combined estimated highest 95th percentile intakes from the background diet, existing and intended uses of UV-treated Baker's yeast indicate that the tolerable upper intake level for vitamin D is not expected to be exceeded in the young children, adolescent and adult population groups.

In infants, the combined estimated intake for vitamin D is reported as 25.9 µg/day. This exceeds the tolerable upper intake level for vitamin D of 25 µg/day by 3.6% for children aged 0 to 6 months, but not the tolerable upper intake level of 35 µg/day for children aged 7 to < 12 months.

The combined estimated intakes for vitamin D for other children, aged 3 to < 7 years and 7 to < 10 years, range from 21.74 – 53.13 µg/day and 22.01 – 51 µg/day, respectively. The estimated highest vitamin D intake levels in these age groups exceed tolerable upper intake level for vitamin D of 50 µg/day by 6.3 % (other children aged 3 to < 7 years) and 2.0% (other children aged 7 to < 10 years).

The most significant contribution for vitamin D intake from consumption of the novel food in infant and other children sub-populations comes from the current authorised uses of UV-treated Baker's yeast.

For infants, ten out of eleven EU national dietary surveys report that the estimated 95th percentile vitamin D intakes from the current authorised uses of the novel food range from 11.60 – 15.89 µg/day. Using these figures, the combined estimated intakes for vitamin D are below the tolerable upper intake level of 25 µg/day for children aged 0 – 6 months.

In one out of eleven EU national dietary surveys (Latvia – EFSA NDA, 2021), the estimated 95th percentile vitamin D intake from the current authorised uses of the novel food is 22.09 µg/day. Only when this value is used to determine the combined estimated intake of vitamin D_2 is the tolerable upper intake level of 25 µg/day for vitamin D in children aged 0 – 6 months exceeded.

For the other children sub-population, seventeen out of eighteen EU national dietary surveys report that the estimated 95th percentile vitamin D intakes for the current authorised uses of the novel food range from 13.52 – 30.24 µg/day. The combined estimated vitamin D intakes using these figures are below the tolerable upper intake level of 50 µg/day for other children.

In one out of eighteen EU national dietary surveys (Greece – EFSA NDA, 2021), the estimated 95th percentile vitamin D intake from the current authorised uses of the novel food is 36.93 µg/day. Only when this value is used to determine the combined estimated intake of vitamin D_2 is the tolerable upper intake level of 50 µg/day for vitamin D in other children exceeded.

The FSA and FSS do not consider the consumption of UV-treated Baker's yeast from water-based beverages by infants and other children to be a concern for the following reasons

i. the wide range of estimated vitamin D intake levels from current

authorised uses of the novel food

ii. the intake assessment assumes that an individual consumes foods from all current and intended food categories (> 20 food categories) and these foods contain the novel food at the maximum use level

iii. the estimated vitamin D intake levels from water-based beverages containing the novel food have been calculated on the basis that individuals are high-level consumers.

As such it is unlikely that individual consumers would exceed the tolerable upper intake level given the conservative nature of the intake assessment.

4. Conclusions

The FSA and FSS have undertaken the assessment of the extension of use of UV-treated Baker's yeast and concluded that the composition of the novel food is safe under the intended conditions of use and does not pose a safety risk to human health. The anticipated intake levels and the intended uses in food was not considered to be nutritionally disadvantageous.

These conclusions were based on the information in the novel food dossier and the supplementary information submitted by the applicant.

Abbreviations

ACNFP	Advisory Committee on Novel Foods and Processes
ADME	Absorption, Distribution, Metabolism and Excretion
AOAC	Association of Official Analytical Chemists
BAM	Bacteriological Analytical Manual
CAS	Chemical Abstracts Service
EFSA	European Food Safety Agency
EU	European Union
FDA	Food and Drug Administration
FoF	Follow-on Formula
FSA	Food Standards Agency
FSS	Food Standards Scotland
IF	Infant Formula
UV	Ultraviolet

References

EFSA NDA Panel (EFSA Panel on Nutrition and Novel Foods). (2016). 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*, *14*(11), 4594. https://doi.org/10.2903/j.efsa.2016.4594

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

EFSA NDA Panel (Panel on Dietetic Products, Nutrition and Allergies). (2018). Update of the tolerable upper intake level for vitamin D for infants. *EFSA Journal*, *16*, e05365. https://doi.org/10.2903/j.efsa.2018.5365

EFSA NDA Panel (Panel on Dietetic Products, Nutrition and Allergies). (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*, *19*(6), 6602. https://doi.org/10.2903/j.efsa.2021.6602

EFSA NDA Panel (Panel on Dietetic Products, Nutrition and Allergies). (2023). Scientific opinion on the tolerable upper intake level for vitamin D, including the derivation of a conversion factor for calcidiol monohydrate. *EFSA Journal*, *21*(8). https://doi.org/10.2903/j.efsa.2023.8145