Assessment of the safety of the extended uses of UV-treated Baker's yeast (S. cerevisiae) as a novel food

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Authors: Risk Assessment Unit, FSA and Risk Assessment Team FSS.
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1. Executive summary

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have undertaken an assessment of application RP1292 for the safety of the extended uses of ultraviolet (UV)-treated Baker' yeast (Saccharomyces cerevisiae) as a novel food, from Lallemand Bio-ingredients.

A novel food application has been received by Great Britain (GB) where the European Food Safety Agency (EFSA), prior to the end of the transition period, evaluated an application for the product. FSA/FSS has reviewed the EFSA opinion for this novel food (EFSA NDA Panel, 2021b) and confirmed that this is adequate for GB risk analysis. Therefore, the opinion was used to form the basis of the GB opinion.

The FSA/FSS risk assessors concluded that extended uses of UV-treated Baker's yeast, as described in the EFSA opinion (EFSA NDA Panel, 2021b), is safe based on the composition, the anticipated intake levels, and at the proposed conditions of use.

2. Background and purpose of review

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In accordance with Retained EU Regulation 2015/2283(footnote) on novel foods, the application RP1292 for the authorisation of the extension of uses of UV-treated Baker' yeast as a novel food, from Lallemand Bio-ingredients, has been submitted for authorisation in GB.

The production process of the novel food was evaluated by EFSA during the safety assessment of UV-treated baker's yeast (EFSA NDA Panel, 2014). As there were no changes to the method this has not been reviewed further.

The specification for UV-treated Baker's yeast as an authorised novel food was published in the Annex to the Union List of Novel Foods in Commission Implementing Regulation (EU) 2017/2470 (footnote) and remains unchanged for this application.

The applicant has proposed that UV-treated Baker's yeast is used as an ingredient in foods and beverages by the general population. The novel food is currently authorised for use in yeast-leavened bread, rolls and fine bakery, and pre-packed fresh or dry yeast for home baking.

The list of proposed uses from the applicant and the defined maximum proposed use level for each type of product, are shown below in Table 1. This includes the existing authorised food uses for the novel food: A004V – bread and similar products; A009T – fine bakery wares.

Table 1: Proposed use and anticipated intake levels of UV-treated Baker's yeast

FoodEx2 code	Food Category	Proposed maximum levels of vitamin D2, as consumed (µg/100 g food)
A03VB	Dishes including ready-to-eat meals (excluding soups and salads)	3
A0EZX	Fried or extruded cereal, seed or root-based products	5
A041K	Soups and salads	5
A02KP	Amphibians , reptiles, snails, insects	10
A03PY	Infant formula (IF) and follow-on formula (FoF)	1.2 (1)
A03RL	Other food for infants and children	0.81
A03QX	Processed cereal-based food for infants and young children	0.81 (2)
A03RC	Ready-to-eat meal for infants and young children	0.81
A01ML	Processed fruit products	1.5
A004V	Bread and similar products (3)	5
A00CV	Breakfast cereals	4
A000K	Cereals and cereal primary derivatives	3
A009T	Fine bakery wares (3)	5
A04QT	Pasta, doughs and similar products	5
A016S	Spices	10
A0EVD	Isolated proteins and other protein products	10
A0DPT	Maltodextrins agents for food poisoning	10
A048P	Miscellaneous agents for food processing	10
A02QE	Cheese	2
A02PT	Dairy dessert and similar	2
A02MZ	Fermented milk or cream	1.5
A02PD	Milk and dairy powders and concentrates	25 (4)
A04NN	Milk, whey and cream	0.5
A0EVG	Vitamins	10
A03RR	Food for particular diets	5
A03TD	Meat and dairy imitates	2.5
A04QN	Condiments (including table-top formats)	5
A046QF	Dessert sauces/toppings	10
A045J	Mixed and other not listed condiments	10
A0EQE	Savoury extracts and sauce ingredients	10
A04QJ	Seasonings and extracts	10
A00VA	Algae and prokaryotes organisms	10
A00TC	Fungi, mosses and lichens	10
A00ZA	Processed or preserved vegetables and similar	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): 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 novel food 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.

Whilst it was a Member State of the EU, the UK accepted the assessments of EFSA in respect of authorisations for regulated food and feed products. Since the end of the transition period, FSA/FSS has adopted equivalent technical guidance and quality assurance processes to able to undertake GB risk assessments for regulated product applications.

Where EFSA, prior to the end of the transition period, evaluated an application for a product for which an application is now made to GB, FSA/FSS has decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own opinion. Therefore, FSA/FSS risk assessors have reviewed the EFSA opinion for the application below in the context of intended GB use and have concluded that the intended uses are safe.

In reviewing the output of the EFSA risk assessment the reviewers have verified that the standard approach as outlined in the relevant guidance has been followed and the arguments made are consistent with the data summarised. Consideration has been given to the processes undertaken to ensure the outcome is robust and whether there are any aspects that would require further review such as specific issues for the countries of GB. The result of the assessment is that the EFSA scientific opinion is also adequate for GB risk analysis.

3. Details of the EFSA assessment

3.1 Methodology applied in the EFSA opinion

The assessment follows the methodology set out in the EFSA guidance on Novel Food applications (EFSA NDA Panel, 2016b) and the principles described in the relevant guidance documents from the EFSA Scientific Committee in place as of 21st January 2021 (EFSA NDA Panel, 2021a).

3.2 Source/organism

The novel food is Baker's yeast (*Saccharomyces cerevisiae*) which is treated with UV light to induce the conversion of ergosterol to vitamin D2 (ergocalciferol).

Saccharomyces cerevisiae is an organism with a long history of safe food use and has been categorised by EFSA as a micro-organism with qualified presumption of safety status (EFSA NDA Panel, 2014).

3.3 Genetic modification step

Not relevant.

3.4 Specification

The original EFSA assessment of UV-treated Baker's yeast concluded that the production process, composition, stability and the specification of the novel food did not raise any safety concerns (EFSA NDA Panel, 2014).

3.5 Exposure assessment

The novel food is currently authorised for 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 and 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.

Assessment of exposure levels to vitamin D in consumers from new food categories included current approved uses. Adults would be expected to have the highest mean and 95th percentile intake levels of 29.21 µg/day and 40.46 µg/day respectively.

Combined exposure levels from the background diet and consumption the novel food indicated that the total intake levels for vitamin D are below the upper limits proposed by EFSA for most population groups.

Other children, aged 3 to less than 10 years, who are high consumers of foods and supplements containing vitamin D, would exceed the upper limit by 4% (51.9 µg/day). For infants, the margin to the upper limits of vitamin D were smaller. For infants up to 6 months and infants aged 6 – 12 months, the intakes were 2.12 µg/day and 12.12 µg/day below the vitamin D upper limits respectively.

EFSA noted the conservative approach taken by the applicant to estimate the vitamin D intakes by assuming that each of the proposed 34 FoodEx2 level 2 food categories would be consumed at the maximum use level. The opinion considers that other children, aged 3 to less than 10 years, are highly unlikely to exceed the upper limits for vitamin D under the uses and maximum use levels proposed by the applicant.

EFSA considered that consumption of tachysterol was not of concern given the low exposure level of the novel food and the average amounts of tachysterol in the vitamin D2 yeast concentrate are 140 µg/g.

3.6 Toxicological data

The Absorption, Distribution, Metabolism and Excretion (ADME), toxicology and allergenicity of the novel food were evaluated by EFSA during the original safety assessment of UV-treated baker's yeast (EFSA NDA Panel, 2014).

4. EFSA assessment and conclusions

The EFSA Panel concludes that the extended uses of UV-treated Baker's yeast are safe under the proposed conditions of use.

5. Caveats and uncertainties

The exposure assessment does not consider the potential exposure from other authorised novel foods with vitamin D, such as UV-treated bread (EFSA NDA Panel, 2015), UV-treated milk (EFSA NDA Panel, 2016a), UV-treated mushroom powder (EFSA NDA Panel, 2020).

FSA/FSS agrees with EFSA that there is 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.

6. FSA/FSS Conclusion on applicability and reliability of the EFSA opinion for GB risk analysis

The FSA/FSS assessed the EFSA opinion for the extended uses of UV-treated Baker's yeast and confirmed that this is adequate and relevant for GB risk analysis.

FSA and FSS have access to the full dossier of information from the applicant but have used the EFSA opinion as the basis of their assessment. The FSA and FSS assessment of the EFSA opinion has confirmed the application has been assessed in line with the applicable guidance and is partially based on considerations of detailed proprietary information available to the EFSA Panel, whilst this is only briefly summarised in the EFSA opinion, this description is consistent with the conclusions.

The scientific conclusions reached by EFSA in their opinion are appropriate, and incorporate the evaluations of the ACNFP for previous UV-treated products. The conclusions of the EFSA opinion are consistent within the identified caveats and uncertainties, and would be applicable to GB.

7. Outcome of the Assessment

FSA/FSS risk assessors reviewed the EFSA opinion and considered this adequate and relevant for the GB risk analysis. Therefore, the opinion was used to form the basis of the GB opinion.

FSA/FSS had access to the full dossier of information for the application supplied by the applicant but have used the EFSA opinion as the basis of their assessment. FSA/FSS agree with the safety conclusions outlined in the EFSA opinion.

Following the principles outlined in the background for making use of the EFSA opinion, the FSA/FSS conclude that extended uses of UV treated Baker's yeast, as described in this opinion, is safe based on the composition, the anticipated intake levels, and the proposed conditions of use

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