Assessment of the safety of Vitamin D2 Mushroom (Agaricus bisporus) powder as a novel food ingredient

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1. Executive summary

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have undertaken an assessment of application RP1158 for the safety of Vitamin D2 Mushroom Powder (Agaricus bisporus) as a novel food, from MBio.

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 Vitamin D2 Mushroom Powder, 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 1) on novel foods, the application RP1158 for the authorisation as a novel food of Vitamin D2 Mushroom Powder as a novel food, from MBio, has been submitted for authorisation in GB.

The novel food (see Table 1 below for specification) is 100% mushroom powder derived from the fruiting body of mushrooms, specifically, Agaricus bisporus. After cultivation and harvesting, the mushrooms are dried, milled to a powder, and then exposed to ultraviolet (UV) light under controlled conditions. This UV irradiation step increases the vitamin D2 levels in the mushroom powder.

Table 1: Specification for the novel food ingredient

Parameter	Specification Limit
Ash	? 13.5%
Water Activity	< 0.5%
Moisture content	? 7.5%
Carbohydrate	? 35%
Total Dietary Fibre	? 15%
Crude Protein (N x 6.25)	? 22%
Fat	? 4.5%
Vitamin D_2	580 – 595 µg/g
Lead	< 0.5 mg/kg
Cadmium	< 0.5 mg/kg
Mercury	< 0.1 mg/kg
Arsenic	< 0.3 mg/kg
Aflatoxin B1	? 0.10 µg/kg
Aflatoxins B1 + B2 + G1 + G2	< 4 µg/kg
TVC	1×10^4 cfu/g
TYMC	< 100 cfu/g
E.coli	< 10 cfu/g
Salmonella spp.	Not detected in 25g
Listeria spp.	Not detected in 25g
Enterobacteriaceae	< 10 cfu/g

TVC: Total viable count

TYMC: Total yeast and mould count

CFU: Colony forming units

The applicant has proposed that Vitamin D2 Mushroom Powder is used as an ingredient in foods and beverages by the general population. The list of proposed uses and the defined maximum proposed use level for each type of product, are shown below in Table 2.

Table 2: Proposed use and maximum use levels for Vitamin D2 Mushroom powder

FoodEx2 Code	Food Category	Maximum use level (mg novel food/100g)	Corresponding levels of vitamin D2 (µg/100g or 100ml) (a)
A00CV	Breakfast cereals	3.58	2.1
A0BY0	Leavened bread or similar	3.58	2.1
A00BK	Yeast leavened pastry	3.58	2.1
A000K	Cereals and cereal primary derivatives	3.58	2.1
A007D	Pasta and similar products	3.58	2.1
A040M	Pasta and rice based dishes	3.58	2.1
A0BX9	Fruit/vegetable juices or nectars	1.79	1.1
A03BM	Concentrated or dehydrated fruit/vegetable juices	12.52 (b)	7.4
A02LR	Milk and dairy products	3.58	2.1
A02MZ	Fermented milk or cream	3.58	2.1
A02NA	Sour cream products	3.58	2.1
A02NE	Yoghurt	3.58	2.1
A02NQ	Yoghurt drinks	1.79	1.1
A02NR	Probiotic milk-like drinks	1.79	1.1
A0C69	Fermented milk products	3.58	2.1

FoodEx2 Code	Food Category	Maximum use level (mg novel food/100g)	Corresponding levels of vitamin D2 (µg/100g or 100ml) (a)
A02NT	Traditional sour milk products	3.58	2.1
A02NV	Kefir	1.79	1.1
A02NY	Traditional Nordic fermented milks	1.79	1.1
A02PC	Flavoured traditional sour milk products	3.58	2.1
A02PD	Milk and dairy powders and concentrates	3.58	2.1
A02PE	Milk and dairy concentrate	3.58	2.1
A02PH	Milk and dairy powders	35.78 (c)	21.3
A02PJ	Milk powders	35.78 (c)	21.3
A02PM	Cream powders	146.68 (d)	87.3
A02PN	Whey powder	35.78 (c)	21.3
A02MP	Flavoured milks	1.79	1.1
A02MK	Cream and cream products	3.58	2.1
A0EZB	Whey	3.58	2.1
A02MV	Buttermilk	3.58	2.1
A02PT	Dairy dessert and similar	3.58	2.1
A02QE	Cheese	3.58	2.1
A02QF	Fresh uncured cheese	3.58	2.1
A02QH	Mascarpone	3.58	2.1
A02QJ	Mozzarella	3.58	2.1
A02QK	Quark	3.58	2.1
A04NV	Miscellaneous fresh uncured cheeses	3.58	2.1
A0CRN	Cheese curd	3.58	2.1
A02RA	Brined cheese (Feta type and similar)	3.58	2.1
A02RB	Soft brined cheese (feta type)	3.58	2.1
A02RG	Ripened cheese	3.58	2.1
A02RH	Soft ripened cheese	3.58	2.1
A031A	Processed cheese and spreads	3.58	2.1
A03RS	Food for weight reduction	3.58	2.1
A03RV	Single meal replacement for weight reduction	3.58	2.1
A03TH	Milk imitates	1.78	1.1
A03TQ	Dairy imitates other than milks	3.58	2.1
A0BXC	Dairy imitates	3.58	2.1
A03TE	Meat imitates	3.58	2.1
A0B9J	Soups, dry mixture, uncooked	32.2 (e)	19.2
A041L	Soups, ready-to-eat	3.58	2.1
A0EQV	Puffs/curls-type extruded snack	3.58	2.1
A011L	Potato crisps or sticks	3.58	2.1

(a): The maximum specification for vitamin D content in vitamin D2 mushroom powder of 595 lg vitamin D2/gram of mushroom powder is used.
(b): Adjusted for being present in concentrated or dehydrated form; reconstitution factor of 7.
(c): Adjusted for being present in powder form; reconstitution factor of 10.
(d): Adjusted for being present in powder form – assumed to be used as coffee whitener; reconstitution factor of 41.
(e): Adjusted for being present in powder form; reconstitution factor of 9.

Foods for specific medical purposes (FSMP) and food supplements are intended for consumers above the age of 1 year old and limited to 15 µg/g day.

Whilst it was a Member State of the EU, 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, 2016) 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 a whole fruiting body mushroom powder containing vitamin D2 (ergocalciferol) induced by UV treatment.

The source of the novel food is the fungus Agaricus bisporus as listed in the Index fungorum (http://www.indexfungorum.org/names/names.asp). Various common synonyms for this mushroom are white button mushroom, champignon de Paris, cremini, chestnut mushrooms and, when fully developed, Portobello mushroom.

3.3 Genetic modification step

Not relevant.

3.4 Specification

Information on the production process, composition, stability and the specification of the novel food does not raise safety concerns.

3.5 Exposure assessment

The novel food is proposed to be used as an ingredient in food products corresponding to 2.1µg of vitamin D2/100 g for products other than beverages and 1.1µg of vitamin D2/100 ml for beverages, as well as in food supplements and foods for medical special purposes, at a maximum dose of 15µg of vitamin D2/day.

Estimated intakes of the novel food show that other children would be expected to have the highest mean intake of 17.60 mg/day, whereas adolescents and adults would have the highest

95th percentile intake levels of 34.45 mg/day.

Based on the highest estimated daily intakes of the novel food and using a maximum content of 595µg vitamin D2/g, the highest (95th percentile) daily intake of vitamin D2 would be 20.50 µg/day for adolescents and adults.

Combined exposure levels from the background diet and consumption of the novel food indicates that the total intake levels for vitamin D are below the upper limits proposed by the EFSA NDA Panel for all population groups.

There is no concern with respect to the exposure to undesirable substances from the consumption of novel food at the proposed uses.

3.6 Toxicological data

No Absorption, Distribution, Metabolism and Excretion (ADME) studies were provided, but published human studies indicate that vitamin D2 from powdered UV-irradiated mushrooms is bioavailable, and consumption of these mushrooms resulted in dose-related increases in the serum concentrations of 25(OH)D2.

The Panel reviewed publicly available studies on a similar material to the novel food (powder of UV-radiated Agaricus bisporus) alongside the source, nature and the intended use of the novel food. Based on this information, the Panel considered that no toxicological studies were required.

The novel food has the same composition as non-UV treated button mushrooms, the only difference is the increased levels of vitamin D2. Consumers are not expected to have an increased risk of allergenicity from exposure to the novel food because UV treatment of the mushrooms does not alter this risk.

4. EFSA assessment and conclusions

The EFSA Panel concludes that the novel food, Vitamin D2 Mushroom Powder, containing vitamin D2 in the ranges of 580 – 595 µg/g, is safe under the proposed conditions of use.

5. Caveats and unertainties

FSA/FFS 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.

FSA/FSS could not have completed the assessment of the product without the data claimed as proprietary by the applicant.

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

The FSA/FSS assessed the EFSA opinion for Vitamin D2 mushroom powder 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.

The FSA/FSS conclude that Vitamin D2 Mushroom Powder, as described in this opinion, is safe based on the composition, the anticipated intake levels, and the proposed conditions of use.

8. References

- EFSA NDA Panel (EFSA Panel on Nutrition, Novel Food and Food Allergens), 2016. Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Gra?yna Nowicka, Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé, Dominique Turck, Hendrik Van Loveren, Marco Vinceti and Peter Willatts, 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 2016;14(11):4594, 24 pp https://doi.org/10.2903/j.efsa.2016.4594
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- EFSA NDA Panel (EFSA Panel on Nutrition, Novel Food and Food Allergens), 2021b. 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, 2021. Safety of Vitamin D mushroom powder (Agaricus bisporus) as a Novel food pursuant to Regulation (EU) 2015/2283, EFSA Journal 2021b;19(4):6516, 19 pp https://doi.org/10.2903/j.efsa.2021.6516

1. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001