

APPLICATION FOR THE APPROVAL OF VITAMIN D₂ MUSHROOM POWDER AS A NOVEL FOOD INGREDIENT IN THE EUROPEAN UNION

Pursuant to

***Regulation (EU) 2015/2283 of the European
Parliament and of the Council of 25 November 2015
on Novel Foods***

NON-CONFIDENTIAL SUMMARY OF THE APPLICATION

SUBMITTED BY:

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Summary

Vitamin D₂ mushroom powder is a product of the exposure of homogenised *Agaricus bisporus* (*A. bisporus*) mushrooms to ultraviolet (UV) light, which catalyses the conversion of endogenous ergosterol within the mushrooms to vitamin D₂. The ingredient is standardised to contain a specific amount of vitamin D₂ ($\geq 1,000 \mu\text{g/g}$) and the nutritional content of vitamin D₂ mushroom powder is unchanged in comparison with conventional *A. bisporus* mushrooms, with the exception of the intended increase in vitamin D₂ content.

Cultivated and wild grown *A. bisporus* mushrooms (the source for vitamin D₂ mushroom powder) have a long history of consumption within and outside of the European Union (EU). UV-treated *A. bisporus* mushrooms also have a history of consumption in the EU (as they have been approved as a novel food ingredient since 2016) and in several non-EU countries, including the United States (U.S.), Canada and Australia. UV exposure has been applied to other approved novel foods: UV-treated baker's yeast (*Saccharomyces cerevisiae*), UV-treated bread and UV-treated milk, all of which are listed under Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods, highlighting the safety of the UV exposure process in enhancement of the vitamin D content of certain foods.

The proposed maximum use levels of vitamin D provided by vitamin D₂ mushroom powder are 2.25 $\mu\text{g}/100 \text{ g}$ for products other than beverages and 1.125 $\mu\text{g}/100 \text{ mL}$ for beverages, with no restriction of food categories. These use levels represent 15 and 7.5% (for products other than beverages and for beverages, respectively) of the most recent adequate intake (AI) for vitamin D (15 $\mu\text{g}/\text{day}$) set by the European Food Safety Authority (EFSA) in 2016. Vitamin D₂ mushroom powder is also intended for use in food supplements at 15 $\mu\text{g}/\text{day}$, which meets the AI set by EFSA. These use levels ensure that the required amount to be deemed as a "source" of vitamin D would be met and would result in intakes of vitamin D that, even for high consumers at worst-case exposure, would not exceed the tolerable upper intake levels of vitamin D established by EFSA in 2012.

Numerous preclinical and clinical safety studies have been conducted with UV-exposed vitamin D mushroom products (similar to Oakshire's vitamin D₂ mushroom powder) and the products were well tolerated in all of them. No toxicological studies have been conducted with Oakshire's vitamin D₂ mushroom powder. However, similar to EFSA's conclusions in their Scientific Opinions regarding the safety of UV-treated baker's yeast (*Saccharomyces cerevisiae*), UV-treated bread, and UV-treated milk (where it was generally concluded that no toxicological studies were required given the source, nature and intended uses of these novel foods), it is considered that the absence of toxicological studies with vitamin D₂ mushroom powder is acceptable and that vitamin D₂ mushroom powder is safe under the intended conditions of use.