

Summary of the application: Vitamin D2 mushroom powder (*Agaricus bisporus*)

Applicant: MBio, Monaghan Mushrooms, Tullygony, Tyholland, Co. Monaghan, Ireland

MBio, a business unit of Monaghan Mushrooms Ireland Unlimited Company, requests approval for “vitamin D2 mushroom (*Agaricus bisporus*) powders” at 587.5 µg/g of the powder by the means of controlled UV-light.

MBio has developed a process to achieve enhanced vitamin D2 levels in mushroom powders (587.5 µg/g) by the use of UV light, under mild conditions to preserve its nutrient rich content. MBio has confirmed that vitamin D2 mushroom powders consist of the same compositional and nutritional properties as dried traditional common button mushrooms (*Agaricus bisporus*) with the exception of enhanced vitamin D2 levels and are, therefore, safe. This process of drying, milling and UV treatment does not affect the levels of any primary or secondary metabolites in the mushroom powders, except for the conversion of ergosterol to ergocalciferol (vitamin D2). The mild drying process does not impact the nutritional status of the powders, other than a concentration effect from the removal of water. The fresh mushrooms used to generate vitamin D2 mushroom powder are sustainably sourced, fully traceable and vegan.

Monaghan Mushrooms successfully obtained approval for UV treated fresh mushrooms with vitamin D2 (10 µg/100g) levels under the novel food regulation (EC) No. 258/97, in 2016. Additionally, the enhancement of vitamin D in mushrooms by pulses of UV light has been investigated since the 1990s and such mushrooms are currently on the market in the EU as well as in non-EU countries such as Australia, the USA and New Zealand. Mushrooms and numerous ingredients are considered safe for consumption in foods and supplements within the EU (as elsewhere in the world).

No toxicological studies have been conducted for MBio’s vitamin D2 mushroom powder, however, the levels of potential toxicological compounds generated during production of the powder confirmed no potential risk in the product and therefore, are safe for human consumption. Additionally, EFSA’s conclusions regarding the safety of Vitamin D2 mushroom powder, UV-treated baker’s yeast (*Saccharomyces cerevisiae*), UV-treated bread, and UV-treated milk indicated that no toxicological studies were required given the source, nature and intended uses of these novel foods. The proposed food categories and intended use levels for the novel food is the same as specified in commission implementing regulation (EU) 2020/1163, of 6 August 2020.

MBio, the food business operator, provides data in addition to that addressed in Commission implementing regulation (EU) 2020/1163, of 6 August 2020, demonstrating that its vitamin D2 mushroom powders (vitamin D2, 587.5 µg/g), is safe for consumption. Hence, MBio is seeking approval for vitamin D2 mushroom powder as a novel food for their use as a food ingredient and food supplement in Europe, under Regulation (EU) 2015/2283 of the European Parliament and of the Council, under class 6 of article 1 (2), foods consisting of, isolated from or produced from microorganisms, fungi or algae.