

## SAFETY ASSESSMENT

### UV-treated mushrooms (*Agaricus bisporus*) with increased vitamin D content

**Applicant:** Walsh Mushrooms, UK

**Contact:** Mr Padraic O'Leary

**Novel Food Classification:** *Article 1.2(f)*

#### Introduction

An application for the authorisation of mushrooms (*Agaricus bisporus*) treated with UV light to increase the vitamin D content was submitted to the Food Safety Authority of Ireland (FSAI) by Walsh Mushrooms of the UK in accordance with *Article 4* of the novel food Regulation (EC) No 258/97. The application was accepted by the FSAI on December 21<sup>st</sup> of 2016.

Vitamin D refers to a group of fat soluble secosteroids involved with enhancing the intestinal absorption of certain minerals. Humans can derive vitamin D from the diet or through the interaction of sunlight with the skin. Access to dietary sources of vitamin D is more important for some EU Member States because the dermal synthesis route is restricted by natural phenomena including reduced sunlight levels and issues related to skin pigmentation. Very few foods naturally contain vitamin D (e.g. oily fish), though foodstuffs fortified with vitamin D and food supplements containing vitamin D are widely available on the EU market. Commercially cultivated mushrooms do not normally contain vitamin D at levels of any dietary significance. However, significant but unpredictable levels of vitamin D can be found in wild-grown mushrooms and commercially grown mushrooms that are exposed to sunlight, for example in outdoor markets.

The applicant proposes to expose commercially grown post-harvest *A. bisporus* mushrooms to a defined level of pulsed UV light for the purpose of increasing the Vitamin D<sub>2</sub> content. 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 like Australia, the USA and New Zealand. Ergosterol (biological precursor of vitamin D) is naturally present in mushrooms and is converted to ergocalciferol (vitamin D<sub>2</sub>) upon exposure to UV light. The applicant intends to enhance the level of vitamin D in their mushrooms to ≤10mg/100g, in line with UV-treated mushrooms authorised as a novel food in 2016 to a competitor. The applicant relies on peer-reviewed publications rather than analytical data to demonstrate that UV-treated and non-treated mushrooms are compositionally and nutritionally equivalent and therefore safe. The applicant intends

to make a nutrition claim in respect of the vitamin D content but that is not addressed in this assessment.

The applicant classifies the novel food in line with *Article 1.2(f)* of the novel food Regulation (EC) No 258/97: “*foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances*”. For the purposes of the safety assessment, the applicant has chosen Class 2 of Commission Recommendation 97/618/EC: “Complex NF from non-GM sources”. However, the correct classification is 6, “Foods produced using a novel process”, but as the information required in both classifications is almost identical, this is not of any material significance to the safety assessment.

## **I. Specification of the novel food**

The commercial cultivation of *Agaricus bisporus* mushrooms is a long established process in the EU and worldwide. Cultivated *Agaricus bisporus* mushrooms are classified as “closed cap” or “large flat” depending on size, and “chestnut” or portobello” mushrooms depending on colour. The key nutrients, anti-nutrients and toxicants have been established and are set out in an OECD Consensus Document on Compositional Considerations for New Varieties of the Cultivated Mushrooms *Agaricus bisporus* which was published by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology in 2007 (<http://www.oecd.org/env/ehs/biotrack/46815276.pdf>). The applicant has not provided any analytical data that could be used to determine whether the UV treatment has any effect on compositional or nutritional specifications of the UV-treated mushrooms. However, they cite a 2011 peer-reviewed publication which concludes that the compositional impact of UV light treatment on *Agaricus bisporus* mushrooms is limited to the vitamin D content. Mushrooms packed in punnets are currently dispatched with a maximum 7 day shelf-life under refrigerated (4-8°C) conditions. The applicant has demonstrated through trials that the applied UV treatment will reproducibly result in a vitamin D<sub>2</sub> content of no greater than 10g/100g fresh weight.

## **II. Production process**

Production of the novel food is based on the standard commercial production of *A. bisporus* mushrooms which are subjected to a post-harvest exposure to pulsed UV light. The applicant has conducted trials to optimise the UV-treatment process that will ensure a consistent level of vitamin D ( $\leq 10\mu\text{g}/100\text{g}$ ), taking into consideration variables such as the different types of mushroom and punnet sizes. The UV-treatment is achieved by a commercial UV light source emitting light in the range of 200-800nm at 505 joules/pulse placed at a fixed distance above a conveyor belt. The process is not considered by the applicant as a critical control point in the company

HACCP plan. However, risk management measures are in place to mitigate any potential problems.

### **III. History of the source organism**

*Agaricus bisporus* has a long history of cultivation worldwide and is the type of mushroom most consumed in the EU. This mushroom is well characterised in terms of its key nutrients, anti-nutrients and toxicants as set out in the relevant OECD Consensus Document.

### **IV. – VIII. GM aspects**

The *Agaricus bisporus* mushroom produced by the applicant is not derived using genetic modification and therefore these sections are not applicable.

### **IX. Anticipated intake/extent of use of the novel food**

The novel mushrooms have a vitamin D content of  $\leq 10\mu\text{g}/100\text{g}$  fresh weight. Using the EFSA Comprehensive European Food Consumption Database the applicant assigned Level 3 FoodEx name ‘*Cultivated mushroom (syn. Button mushroom) (Agaric)*’ to the novel food. As the novel food is primarily targeting the UK and Irish markets initially, consumption data for those Member States were considered first. Levels of consumption in the UK were found to be highest in adolescents and lowest in toddlers while in Ireland individual consumption was slightly higher than in the UK.

### **X. Information from previous human exposure to the novel food or its source**

Cultivated and wild grown *A. bisporus* mushrooms have a long history of consumption within and outside of the EU. UV treated mushrooms have a history of consumption in a number of non-EU countries including USA, Canada and Australia, and since 2016 have been authorised for the EU market.

### **XI. Nutritional information on the novel food**

The applicant is satisfied from a review of the literature that the nutritional content of mushrooms exposed to UV light is unchanged, with the exception of the intended increase in vitamin D. The vitamin D levels in UV-treated mushrooms are relatively stable and remain at more than 30% of the reference intake value (Annex XIII of Regulation (EU) 1169/2011) per serving (100g) for at least two days beyond their shelf life. The applicant considers it unlikely, even for high intake mushroom consumers, that the dietary vitamin D levels would exceed the tolerable upper limit for any of the consumer age groups.

Dietary vitamin D is naturally available in a few foods and readily available in fortified food and in dietary supplements. A daily reference intake value for vitamin D of  $5\mu\text{g}$  is set out in Annex XIII of Regulation (EU) No 1169/2011, while EFSA has set a dietary reference value of  $15\mu\text{g}/\text{day}$  for adults. Simultaneous consumption of

vitamin D from a number of sources (UV-treated mushrooms, wild mushrooms, vitamin D fortified foods and vitamin D supplements) could potentially result in excessive vitamin D consumption. However, the risk of UV-treated mushrooms causing excessive vitamin D intake can be mitigated by product labelling to indicate the presence of vitamin D in the novel mushrooms. In addition, a further assessment provided by the applicant concluded that consumption of UV treated mushrooms by any age group also consuming vitamin D from other sources should not result in the EFSA-derived tolerable upper intake level for vitamin D being exceeded.

## **XII. Microbiological information on the novel food**

Microbiological controls in commercial mushroom production are standardised and the applicant has internal microbiological specifications in place. The applicant has demonstrated that the micro-flora of mushrooms is not affected by the proposed UV treatment process.

## **XIII. Toxicological information on the novel food**

The applicant cites a 2011 publication which reports that, with the exception of vitamin D levels, UV treatment of *A. bisporous* mushrooms does not alter their composition in terms of vitamin C, folate, vitamins B6, vitamin B5, riboflavin, niacin, amino acids, fatty acids, ergosterol, or agaritine. The primary recognised toxicant associated with *A. bisporus* mushrooms is agaritine, a phenylhydrazine derivative. Agaritine is synthesised in the hyphae at the point of contact with the compost and subsequently trans-located to the mushroom proper. UV treatment of the mushrooms would not be expected to promote significant synthesis of this compound since it is carried out post-harvest when the lower part of the hyphae has been removed. In addition, agaritine and its metabolites are thermally unstable, diminishing during cooking and processing and so not generally considered a significant safety threat for mushroom consumers. The formation of by-products in the mushrooms during the conversion of previtamin D<sub>2</sub> to vitamin D<sub>2</sub> (tachysterol-2 and luminosterol-2) is a function of the UV dose. However, the applicant asserts that the UV-treatment dose of their mushrooms would only result in minimal levels of those products and so they are not of concern.

### ***Allergenicity***

Allergenicity or other food hypersensitivities associated with *A. bisporus* are rare and there is no reason to believe that the additional UV treatment will alter that risk.

### **Conclusions**

For people who rely on a dietary source of vitamin D, the current options include foods such as oily fish that contain appreciable amounts of vitamin D, along with fortified foods and food supplements. The consumption of *Agaricus bisporous* mushrooms in the EU is well established. Wild mushrooms as well as commercially cultivated mushrooms sold in outdoor markets already contain significant, though

unpredictable levels of vitamin D. In addition, UV-treated mushrooms are already commercially available on the US, Canadian and Australian markets, and more recently on the EU market with no adverse effects reported to date.

The applicant shows that vitamin D is relatively stable in the mushrooms for the duration of the shelf life and somewhat beyond. The level of agaritine in *A. bisporus* mushrooms is not considered a significant risk in untreated mushrooms and is not impacted by the UV exposure process.

### **Recommendation**

On the basis of the information provided by the applicant, the Food Safety Authority of Ireland has not identified any safety concerns associated with the consumption of commercially cultivated mushrooms (*A. bisporus*) subjected to controlled exposure to UV light. To help consumers make an informed choice and avoid exceeding the RDA, advice should be provided regarding the vitamin D content of these mushrooms.

Therefore, the FSAI considers that UV-treated *Agaricus bisporus* mushrooms produced by Walsh Mushrooms of the UK meet the criteria for novel food set out in *Article 3.1.* of the novel food Regulation (EC) No 258/97.