**Initial assessment of UV-treated mushrooms (*Agaricus bisporus*) with increased vitamin D content**

Regulation (EC) No 258/97

**Applicant:** Monaghan Mushrooms, Ireland

**Contact person:** Juan Valverde

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

## Introduction

An application for the authorisation of mushrooms (*Agaricus bisporus*) treated with UV light to increase vitamin D content was submitted to the Food Safety Authority of Ireland (FSAI) by Monaghan Mushrooms of Ireland in accordance with *Article 4* of the novel food Regulation (EC) No 258/97. The application was accepted by the FSAI on February 4th, 2015.

Vitamin D refers to a group of fat soluble secosteroids responsible for enhancing the intestinal absorption of certain minerals. Humans can derive vitamin D from the diet or through the interaction of sunlight with the skin. The dermal synthesis route in some EU Member States is limited by natural limitations in sunlight exposure and skin pigmentation which makes access to dietary vitamin D more important. Very few foods naturally contain vitamin D (e.g. oily fish), though foodstuffs fortified with vitamin D and food supplements containing vitamin D are available on the EU market. The production of vitamin D in mushrooms subjected to UV light treatment has been investigated since the 1990s. However, significant if unpredictable levels of vitamin D can already be found in wild mushrooms and conventionally grown mushrooms that are exposed to sunlight in outdoor markets.

The applicant proposes exposing commercially grown *A. bisporus* mushrooms to a defined level of pulsed UV light for the purpose of increasing the Vitamin D content. Ergosterol (biological precursor of vitamin D) is naturally present in mushrooms and is converted to ergocalciferol (vitamin $D_2$) upon exposure to UV light. Other than raising the vitamin D content, the applicant demonstrates that the overall composition of the mushrooms is not altered significantly by the UV treatment.

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 UV-treated mushrooms are placed in Class 6 of Commission Recommendation 97/618/EC: "Foods produced using a novel process".

## I. Specification of the novel food

The commercial cultivation of *Agaricus bisporus* mushrooms is long established worldwide with the key nutrients, anti-nutrients and toxicants set out in the OECD Consensus Document on Compositional Considerations for New Varieties of the Cultivated Mushrooms *Agaricus bisporus* 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 demonstrated that the levels of macro- and micro-nutrients (with the exception of vitamin D) are not significantly affected by the post-harvest exposure of *A. bisporus* to UV light. The applicant has also demonstrated that the only change to the production process is the post-harvest UV treatment which is optimised to ensure a vitamin D content of 5-10µg (average 6.97µg)/100g fresh weight (FW) at the expiration of shelf life.

## II. Production process

Production of the novel food is based on the standard commercial production of *A. bisporus* mushrooms to which is added a step involving post-harvest exposure to pulsed UV light. The UV treatment is capable of increasing the vitamin D level to between 5µg and 40µg/100g FW of mushrooms with a precision of approximately 12%. The applicant has optimised the UV treatment to result in mushrooms with average vitamin D levels of 6.97µg/100g FW. Briefly, mushrooms of a specific dimension and density are placed in an open top container which is then passed under a UV-light source before packaging. The UV treatment is carried out in a controlled environment that results in each punnet of mushrooms being exposed to a defined number of pulses at a set distance from the light source that reproducibly delivers approximately 50 $J/m^2$.

## III. History of the source organism

*Agaricus bisporus* has a long history of cultivation and is the most consumed mushroom in the EU. Seven EU Member States are in the top ten worldwide for cultivation of this mushroom which 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 used 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 vitamin D mushrooms have an average vitamin D content of 6.97µg/100g FW and the applicant estimates that an 80g serving (average serving size) could provide 5.58µg of vitamin D, just over the EFSA recommended daily allowance (RDA) of 5µg. EFSA also concluded that the tolerable upper limit (UL) of vitamin D for adults and adolescents is 100µg/day. The applicant presents mushroom

consumption data for six countries (UK, USA, Canada, Germany, France and Ireland) which shows that Ireland consumes most, with an average of 2.99kg/person/year. Using the worst case scenario, the applicant estimates that to reach the vitamin D tolerable upper limit of 100µg/day, an Irish consumer would need to consume 1.43kg of the novel mushrooms in one day, which is approximately half the amount consumed by an Irish individual in one year. Therefore, while the RDA for vitamin D can be achieved by consuming a portion of the novel mushrooms, it is unlikely that the UL would be reached or exceeded. UV-treated mushrooms will be marketed as an alternative source of vitamin D and will be labelled accordingly so that it will be difficult for consumers to accidentally exceed the RDA or UL when consuming them, for example in combination with fortified food or vitamin D supplements.

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

*A. bisporus* mushrooms have a long history of cultivation and consumption in the EU, while dietary vitamin D is naturally available in some foods and readily available in fortified food and in dietary supplements. The applicant emphasises that commercial and wild mushrooms exposed to natural sunlight contain significant though unpredictable amounts of vitamin D and that UV-treated mushrooms are already commercially available in the USA, Canada and Australia.

## XI. Nutritional information on the novel food

The applicant demonstrates that the nutritional content of mushrooms exposed to UV light is unchanged and remains within the ranges published in the OECD Consensus Document. The vitamin D levels in UV-treated mushrooms are relatively stable throughout their shelf life and cooking does not significantly impact on those levels. The average vitamin D level of the novel mushrooms to be placed on the market is 6.97µg/100g FW, or 5.6µg/80g FW (average serving size). This represents approximately 112% of the vitamin D RDA which is not a concern as the levels will likely be reduced somewhat during the shelf life and by cooking. The level of vitamin D in the UV-treated mushrooms is relatively moderate and consistent compared to that found in wild mushrooms or conventionally grown mushrooms sold in outdoor markets.

## XII. Microbiological information on the novel food

Microbiological controls in commercial mushroom production are standardised and will not be affected by the additional UV treatment.

## XIII. Toxicological information on the novel food

The primary recognised toxicant associated with *A. bisporus* mushrooms is the phenylhydrazine derivative agaritine which can be present at 80-1,730mg/kg FW, though more usually at 200mg - 500mg/kg FW. Of importance for this novel food application is whether the UV treatment alters the level of endogenous agaritine in the mushroom. The applicant analysed untreated and UV-treated mushrooms for the

presence of agaritine by HPLC, using a published method, and concluded that UV exposure of *A. bisporous* mushrooms does not significantly affect the level of agaritine which remains within the range reported in the OECD consensus document.

***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 with a number of Member States among the top ten global producers. By adding a single and controllable UV-exposure step to the production process, the applicant demonstrates that consumers can achieve their recommended daily allowance for vitamin D via an alternative food source. The applicant emphasises that wild mushrooms as well as commercially cultivated mushrooms sold in outdoor markets already contain significant if unpredictable levels of vitamin D. In addition, UV-treated mushrooms are already commercially available on the US, Canadian and Australian markets 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 that cooking does not significantly reduce levels. The concentration of the primary toxicant (agaritine) in *A. bisporus* mushrooms is not impacted by the UV exposure process.

**Recommendation**

On the basis of the information provided by the applicant, along with subsequent clarifications, the Food Safety Authority of Ireland has not identified any safety concerns with the consumption of commercially cultivated mushrooms (*A. bisporous*) 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 Monaghan Mushrooms of Ireland meet the criteria for novel food set out in *Article 3.1.* of the novel food Regulation (EC) No 258/97.