

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

UV-TREATED MUSHROOMS (*AGARICUS BISPORUS*) ENRICHED WITH VITAMIN D – DOSSIER 208**Issue**

1. The Irish competent authority has prepared comments on an application under the Novel Foods Regulation (EC) No 258/97, for the authorisation of mushrooms treated with UV light to increase Vitamin D levels. UV treated mushrooms were authorised in February 2016 by the Food Safety Authority of Ireland. However, because the treatment is a novel process companies cannot benefit from the shorter substantial equivalence process.
2. The Committee is asked whether it agrees with the initial opinion and whether it would like to make any further comments on this application. The Committee's advice will form the basis for the UK's formal response to the Commission.

Background

3. On 22 March 2017 the European Commission forwarded the Irish Competent Authority's (CA) positive Initial Opinion on an application made Walsh Mushrooms under Article 4.2 of the Regulation, for UV-treated mushrooms (*Agaricus bisporus*). Member States have until 19 May 2017 to submit any comments and/or reasoned objections to the Irish assessment.
4. The application dossier is attached as **Annex A**, the Irish Initial Assessment Report is attached as **Annex B**. Annex A and B contain commercially sensitive and confidential information.

This application

5. Mushrooms are fruiting bodies of particular fungi. The most commonly cultivated species is *A. bisporus*, which has a long history of cultivation and consumption. Edible wild Mushrooms contain high levels of dietary Vitamin D₂. Vitamin D₂ formation in fungi occurs through UV mediated photochemical conversion of ergosterol to Vitamin D₂. Exposure of the mushrooms to UV post-harvest, leads to the formation of Vitamin D₂ in the mushrooms.
6. In northern Europe adequate intakes of Vitamin D₂ in the diet may be difficult to achieve. This application seeks to increase the level of vitamin D₂ in a

particular type of mushroom by means of controlled conditions using UV irradiation to convert ergosterol to vitamin D. The applicant intends to enhance the level of Vitamin D₂ in their mushrooms to ≤10µg/100g, in line with UV-treated mushrooms previously authorised as a novel food in 2016 by a competitor. The applicant details the production process to increase Vitamin D₂ in **pg. 19-20 of Annex A**.

7. 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 discusses toxicological information on the novel food in **pg. 49-52 of Annex A** and reports that UV treatment of the novel food does not alter the composition of other vitamins, amino acids and fatty acids. The leading toxicant associated with *A. bisporus* is the Agaritine. The applicant explains that the UV treatment would only result in minimal levels of those products and so they are not of concern. Agaritine remains within the range reported in the OECD (OECD 2007) consensus document.
8. UV treated mushrooms have a history of consumption in a number of non-EU countries including USA, Canada and Australia, and have been available in the EU following authorisation in 2016.
9. The applicant has considered the anticipated intake of the novel food using the EFSA Comprehensive European Food Consumption Database and NDNS dataset (2011). As the novel food is primarily targeting the UK and Irish markets initially, the assessment largely focuses on consumption data for those Member States. Levels of consumption in the UK were found to be highest in adolescents and lowest in toddlers. Individual consumption was found to be slightly higher in Ireland than in the UK. The applicant discusses anticipated intake of the novel food in **pg. 30-39 of Annex A**.
10. The applicant states that allergenicity or other food hypersensitivities associated with *A. bisporus* are rare and there is no evidence that additional UV treatments on the novel food will affect that risk (**pg. 54-55 Annex A**).
11. The applicant explains that microbiological controls in commercial mushroom production are very established and standardised and that they have additional internal microbiological specifications in place. The applicant has demonstrated that the micro-flora of mushrooms is not affected by the UV treatment (**pg. 47-48 Annex A**).

COMMITTEE ACTION REQUIRED

12. Members are asked whether they agree with the initial opinion from the Irish Authority and whether they wish to make any comments on the application.

13. The Committee's advice will form the basis for the UK's formal response to the opinion of the Irish Competent Authority.

Secretariat
April 2017

Annexes attached:

Annex A Application for the approval of UV-treated mushrooms (*Agaricus bisporus*) enriched with vitamin D.

Annex B Initial Opinion of the Irish Competent Authority.