

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods

Consultation request for a determination of novel food status pursuant to Article 4(2) of the above Regulation

Recipient Member State: National Food Chain Safety Office, Hungary

Name of the food: Fermented wheat germ extract

Description of the food:

The product is derived from wheat (*Triticum aestivum*) germ fermented with *Saccharomyces cerevisiae* baker's yeast. The fermentation medium is extracted with ethyl acetate and -after removal of the solvent- formulated into capsules with excipients.

The product is intended to be used as foods for special medical purposes and as food supplement by the applicant.

Status: Novel food

Novel food category:

(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

— traditional propagating practices which have been used for food production within the Union before 15 May 1997, or

—non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

Statement of reasons:

A history of consumption to a significant degree within the EU prior to 15 May 1997 is not demonstrated for fermented wheat germ extract. No evidence was provided in the dossier and no Member States and the Commission had knowledge of a significant consumption before 15 May 1997.

The novel food status of other ingredients and any other food safety issue in the dossier has not been evaluated.