

# Consultation on the determination of the status of a novel food under Article 4 (2) of Regulation (EU) 2015/2283

Information according to Article 7 of Implementing Regulation (EU) 2018/456

**Recipient Member State:** Germany

## 1. Name and description of the food in question

Cereal protein concentrate

The product has a protein content of 67-74 % in dry matter and is obtained from a cereal intermediate product from bioethanol production.

The raw material used to obtain the protein concentrate is a cereal mixture of wheat (*Triticum aestivum* L.) and triticale (genus: × *Triticosecale* Wittmack). The composition of the product essentially corresponds to commercially available cereal protein concentrate products (gluten, seitan).

## 2. Status as a novel food

The product is not a novel food.

## 3. Food category

Not applicable

## 4. Reason

The German federal states' authorities responsible for food surveillance as well as the competent authorities of the EU Member States and the European Commission were consulted.

In terms of its amino acid composition, the product in question is similar to other non-novel wheat proteins (gluten, seitan) commonly available on the market.

The protein fraction consists of 97 % cereal protein and about 3 % yeast protein, which remains in the food due to technically unavoidable residues of the yeast from the fermentation process.

The other nutritional values of the product in question are similar to that of non-novel comparative products. The absolute fat content and the fibre content are higher; carbohydrate and the protein content are lower. However, the deviations are not so extreme that a new (novel) product must be assumed here.

Insofar as this is a “production process not used for food production in the Union before 15 May 1997” (Article 3(2)(a)(vii) of Regulation (EU) 2015/2283), the question is whether the variations in the nutrient profile, and in particular the yeast protein content, is to be considered as a “significant change in the composition or structure of a food affecting its nutritional value, its metabolism or its level of undesirable substances.”

Based on the analytics provided, no significant change in the nutritional value, metabolism or undesirable substance content can be assumed. Consequently, category vii (Article 3(2)(a)(vii) of Regulation (EU) 2015/2283) is not applicable.

As no other category of novel food is relevant, the product in question is not a novel food.