TRANSLATION

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

Consultation on the determination of the status of a novel food under Article 4 (2) of the abovementioned Regulation

Recipient Member State: Germany

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

1. Name and description of the food in question

Biomass of *Propionibacterium freudenreichii* (heat-killed) with higher content of cobalamin

The biomass is produced by fermentation in bioreactors in the presence of cobalt salts after which the growth medium is removed from the biomass by centrifugation or filtration followed by washing, heat-killing and drying.

The product is supposed to be consumed both as such and as an ingredient in food including food supplements.

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.

Propionibacterium freudenreichii (*PF*) biomass has been widely consumed in the EU as part of certain cheeses that are ripened by fermentation with that microorganism (e.g. Comté, Samsoe, Maasdam and others). According to information from Denmark *PF* microbial culture is approved under Danish national rules for use in dairy products, desserts and dietary supplements. The *PF* culture is widely used for industrial production of fermented foods. The pure culture of *PF* is also marketed as such to final consumers for home-production of foods in at least one Member State.

As a result, a human consumption of *PF* biomass to a significant degree within the Union before 15 May 1997 is established.

During the production process of the *PF* biomass in question a higher concentration of cobalt salts is added in order to raise the amount of naturally occurring cobalamin (vitamin B12) in the bacterium.

In so far as this might be “a production process not used for food production within the Union before 15 May 1997” (Article 3(2)(a)(vii) of Regulation (EU) 2015/2283), the question is whether the increased concentration of cobalamin is to be considered as a “significant change in the composition or structure of a food affecting its nutritional value, its metabolism or level of undesirable substances.”
As the metabolism of the PF microorganism is depending on the production of cobalamin, cobalt is an essential growth factor. Thus, cobalamin (in lower amounts) is always present in PF biomass, also in commonly produced one.
The applied production process with higher amount of cobalt salts present does not introduce a new component to the PF biomass but rather aims at increasing the naturally present amount of cobalamin. Considering that there is no tolerable upper intake level (UL) set for cobalamin because no clearly defined adverse effects could be found, vitamin B12 can be considered safe even in higher amounts.

In the opinion of the Recipient Member State, no significant change affecting its nutritional value, its metabolism or level of undesirable substances is assumed, leading to the conclusion that category vii (Article 3(2)(a)(vii) of Regulation (EU) 2015/2283) is not applicable.