Consultation request for the determination of the novel food status ARTICLE 4 of Regulation (EU) 2015/2283

Consultation request to determine the status of hydroalcoholic extract of porphyra yezoensis (Ueda) stabilized in glycerin

Recipient Member State: Belgium, Federal Public Service Health, Safety of the food chain and Environment

Name and description of the novel food:

The request concerns the hydro-alcoholic extract of porphyra yezoensis (Ueda) stabilized in glycerin intended to be used in food supplements.

The ingredient is obtained by the hydro-ethanolic extraction (Ethanol/water: 70/30 v/v) of the dried thallus from the red algae Porphyra yezoensis (Ueda) M.S.Hwang & H.G.Choi, and then stabilized in glycerin. The ingredient is intended to be used in food supplements in liquid or soft capsule form intended for the general population.

The synonym of Porphyra yezoensis (common Japanese name Susab-nori, susabi-nori, amanori) is Pyropia yezoensis.

Novel food status

The ingredient is considered as novel food in food supplements and foods other than food supplements.

Novel food category

The food falls under category Article (ii) of article 3(2) of Regulation (EU) 2015/2283 *"food consisting of, isolated from or produced from microorganisms, fungi or algae"*

Justification

Despite the fact that the thallus of the algae in question is not considered as a novel food, the documentation submitted did not provide any evidence that the alcoholic extract of the algae in question was used for human consumption to a significant degree within the Union before 15 May 1997. Even though the requester indicated there is no selective enrichment during the extraction process, the concept of substantial equivalence cannot be used in the determination of the novel food status. Evidence was not available for the consumption of the extract itself.