

Application for consultation to determinate the status of a novel food, pursuant to Article 4(2) of the Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods.

Recipient Member State: German Federal Office for Consumer Protection and Food Safety (BVL)

Information referred to in Article 7 of the Implementing Regulation (EU) 2018/456

1. Name and description of the food concerned

Aqueous extract from fig leaves (*Ficus carica L.*)

The product is manufactured by adding water to and heating dried and crushed leaves of *Ficus carica L.*

2. Novel food status

The product is not novel only when used as or in food supplements ("not NFS").

It is novel when used as or in food other than food supplements.

3. Food category under which it falls

The product comes under the definition in Article 3(2)(a)(iv) of Regulation (EU) 2015/2283 ("food consisting of plants or their parts").

4. Reasons

The documents submitted do not provide any evidence that the food concerned was used to a significant degree for human consumption in the Union prior to 15 May 1997 ("significant consumption").

Nor has our consultation with the senior authorities responsible for food monitoring in the German *Länder* revealed any significant consumption of the product.

The leaves of *Ficus carica L.* are included on "List 3" of Belgium's Royal Decree of 24 January 2017¹ and in the Decree of 10 August 2018 of the Italian Ministry of Health². It is therefore assumed that the leaves were being used in food supplements prior to 15 May 1997.

¹ Belgium: Royal Decree of the Kingdom of Belgium of 24 January 2017 amending the Royal Decree of 29 August 1997 on the manufacture and marketing of foods composed of or containing plants or plant preparations.

² Italian Ministry of Health: Decree of 10 August 2018 regulating the use of vegetable substances and preparations in food supplements.