

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

Consultation request to determine the novel food status of Herbal tincture of *Pilosella officinarium* (*Hieracium pilosella* L.) (alcoholic infusion)

Recipient Member State: Czech Republic, Ministry of Agriculture, Food Safety Department

Date: 31/8/2024

Name and description of the novel food:

The application concerns of Herbal tincture of *Pilosella officinarium* (*Hieracium pilosella* L.) (alcoholic infusion).

The aerial part of the plant is collected in the wild, chopped finely (approx. 2 mm pieces) with a ceramic knife, placed in alcohol with a concentration of 60-96%. It is left to infuse for 3 weeks. The mixture of liquid and plant is then strained. The strained liquid is used in a mixed herbal tincture. The solid portion is disposed of in the normal manner. The final tincture consists of alcohol up to 15 %, water and a mixture of herbs. In this tincture *Pilosella officinarium* makes up to maximum 20 % of the total volume of all plants in the mixture.

Novel food status:

The herbal tincture up to maximum 30% of the aerial part of *Pilosella officinarium* is considered **not novel in food supplements**.

Novel food category:

Not applicable

Reason statements:

- (a) The manufacturing process used to produce the Herbal tincture up to maximum 30% of the aerial part of *Pilosella officinarium* was in common use in the EU before 15 May 1997;
- (b) Herbal tincture up to maximum 30% of the aerial parts of *Pilosella officinarium* was commonly used in dietary supplements before May 1997;

Conclusion:

For herbal tincture up to maximum 30% of the aerial part of *Pilosella officinarium* for food supplements, we have a proven history of consumption in the Czech Republic before 15 May 1997, therefore we consider it to be a **not novel food in food supplements**.