

# 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 extract of LMZ (Lutein, Meso-zeaxanthin, Zeaxanthin) 15 % in oil suspension**

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

**Date:** 15/09/2022

## **Name and description of the novel food:**

*Lutein*, *Zeaxanthin* and *Meso-zeaxanthin* derived from the flowers of the marigold (*Tagetes erecta* L.) are ingredients of the food supplement. The *Lutein* / *Meso-zeaxanthin* / *Zeaxanthin* are made from oleoresin of dried petals of *Tagetes erecta* L. which are extracted by a dissolvent and purified by saponification and crystallization.

Specification of the extract: *Lutein* 7-10%, *Meso-zeaxanthin* 7-10%, *Zeaxanthin* 1-5%, sunflower oil 75-85%, DI-  $\alpha$ -tocopherol 0,1-1%.

## **Novel food status**

Extract of LMZ (*Lutein*, *Meso-zeaxanthin*, *Zeaxanthin*) 15 % in oil suspension is considered as **not novel in food supplements**.

## **Novel food category**

Not applicable

## **Reason statement:**

- (a) the manufacturing process used for the production of LMZ extract was commonly used before 15 May 1997 in the EU;
- (b) *lutein*, *zeaxanthin* and *meso-zeaxanthin* are members of a large group of natural carotenoids classified more closely as xanthophylls widely distributed in the diet as a constituent of plant foods;
- (c) natural *lutein* is not a novel food according to the EU Novel Food Catalogue;
- (d) *zeaxanthin* is an isomer of *lutein*, *lutein* and *zeaxanthin* often occur together - *lutein* can be converted to *zeaxanthin* in the blood serum;
- (e) aerial parts of *Tagetes erecta* L. used for isolation of the extract of *lutein*, *meso-zeaxanthin* and *zeaxanthin* are not considered as a novel in food supplements in any EU Member State;
- (f) *Tagetes erecta* L. (aerial part of the plant) is included in the Belgian Belfrit list of plants authorised for use as a food supplement;
- (g) according to the available data, the flowers of the *Tagetes erecta* L. are used as a source of the abovementioned food and feed xanthophylls since the 1960s (ERNA Fact sheets, Brussels 2004);

- (h) Denmark authorises the addition of *lutein* to food supplements at a daily dose of 20 mg by means of an implementing decree under no: BEK nr 1281 af 29/11/2017;
- (i) Italian competent authority has confirmed the history of consumption of *lutein*, *meso-zeaxanthin* and *zeaxanthin* for food supplements;
- (j) *lutein*, *meso-zeaxanthin* and *zeaxanthin* are included in the list of approved substances of the Italian Ministry of Health.

**Conclusion:**

Based on the data received, the production process of LMZ extract was commonly used before 15 May 1997 in the EU and there is no concentration of individual ingredients. *Lutein*, *Zeaxanthin* and *Meso-zeaxanthin* – and the source material – the marigold flower *Tagetes Erecta L.* – are listed in one or more of the official lists permitted for use in food supplements. The consumption history of *lutein*, *meso-zeaxanthin* and *zeaxanthin* for food supplements was confirmed. The extract of LMZ (*Lutein*, *Meso-zeaxanthin*, *Zeaxanthin*) 15 % in oil suspension does not fall under the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods.