COMMISSION IMPLEMENTING REGULATION (EU) 2020/443

of 25 March 2020

authorising the change of the specifications of the novel food spermidine-rich wheat germ extract (*Triticum aestivum*) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([1]), and in particular Article 12 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ([2]) establishing a Union list of authorised novel foods was adopted.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.

(4) On 6 December 2017, the company TLL The Longevity Labs GmbH ('the applicant'), informed the Commission in accordance with Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council ([3]) of its intention to place on the market spermidine-rich wheat germ extract (*Triticum aestivum*) as a novel food ingredient. Therefore, spermidine-rich wheat germ extract was included in the Union list of novel foods.

(5) On 6 August 2019, the applicant made a request to the Commission to change the specifications of spermidine-rich wheat germ extract in accordance with Article 10(1) of Regulation (EU) 2015/2283. The applicant requested to increase the level of cadaverine from the current < 0,1 μg/g to ≤ 16,0 μg/g.

(6) The applicant justifies the request by indicating that the change is necessary in order to reflect the natural levels of up to ≤ 16,0 μg/g of cadaverine that are analytically detectable in the wheat germ of the *Triticum aestivum* plant. The currently authorised level of < 0,1 μg/g cadaverine in spermidine-rich wheat germ extract represents the limit of detection with the analytical method that the applicant had erroneously included in the initial notification as the specification limit for cadaverine, and which was subsequently included in the Union list specifications of this novel food.

(7) Cadaverine is a diamine which together with histamine, tyramine, and putrescine belong to the class of the biogenic amines that are naturally formed as the result of bacterial metabolism of proteins.

(8) The health risks of biogenic amines were evaluated by the European Food Safety Authority ('the Authority') in 2011 ([4]). In the scientific opinion, the Authority noted that analytical information and food consumption data from the Member States has shown that cadaverine is present in a number of foods (alcoholic beverages, condiments, fish and fish products, meats, dairy products, vegetables and vegetable products) at mean levels up to 184 mg/kg of food with the resulting intakes reaching up to 116,1 mg of cadaverine per day.

([1]) OJ L 327, 11.12.2015, p. 1.

([2]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

([3]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p. 1.

([4]) EFSA Journal 2011;9(10):2393.

(9) Considering that the proposed maximum levels of cadaverine in the novel food and the resulting intakes on the basis of the authorised conditions of use of the novel food will be at least three orders of magnitude lower than the levels of cadaverine that are ingested from a normal diet, the Commission considers that the proposed changes in the cadaverine levels in the specifications of the spermidine-rich wheat germ extract do not alter the safety considerations that supported the authorisation of this novel food, and that a safety evaluation of the current application by the Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. Therefore, it is appropriate to amend the specifications of the novel food spermidine-rich wheat germ extract at the level for cadaverine requested by the applicant.

(10) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The entry in the Union list of authorised novel foods, as provided for in Article 6 of Regulation (EU) 2015/2283 and included in Implementing Regulation (EU) 2017/2470, referring to the novel food spermidine-rich wheat germ extract (*Triticum aestivum*), is amended as specified in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 March 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'Spermidine-rich wheat germ extract (*Triticum aestivum)*' in Table 2 (Specifications) is replaced by the following:

Authorised Novel Food	Specifications
'**Spermidine-rich wheat germ extract (*Triticum aestivum*)**	**Description/Definition:** Spermidine-rich wheat germ extract is obtained from non-fermented, non-sprouting wheat germs (*Triticum aestivum*) by the process of solid-liquid extraction targeting specifically, but not exclusively polyamines. Spermidine:(N-(3-aminopropyl)butane-1,4-diamine):0,8-2,4 mg/g Spermine: 0,4-1,2 mg/g Spermidine trichloride < 0,1 µg/g Putrescine: < 0,3 mg/g Cadaverine: ≤ 16,0 µg/g **Mycotoxins:** Aflatoxins (total): < 0,4 µg/kg **Microbiological criteria:** Total aerobic bacteria: < 10 000 CFU/g Yeast and moulds: < 100 CFU/g *Escherichia coli:* < 10 CFU/g *Salmonella:* Absence/25g *Listeria monocytogenes:* Absence/25g'