COMMISSION IMPLEMENTING REGULATION (EU) 2019/1272

of 29 July 2019

correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods and Implementing Decision (EU) 2017/2078 authorising an extension of use of yeast beta-glucans as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(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 Articles 8 and 12 thereof,

Whereas:

(1) Pursuant to Article 8 of Regulation (EU) 2015/2283, the Commission was to establish, by 1 January 2018, the Union list of novel foods authorised or notified under Regulation (EC) No 258/97 of the European Parliament and of the Council ([2]).

(2) The Union list of novel foods authorised or notified under Regulation (EC) No 258/97 was established by Commission Implementing Regulation (EU) 2017/2470 ([3]).

(3) Commission Implementing Regulation (EU) 2018/1023 ([4]) corrected Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods in order to include a number of authorised or notified novel foods not included in the initial Union list.

(4) After the publication of Implementing Regulation (EU) 2017/2470 and Implementing Regulation (EU) 2018/1023, the Commission identified additional errors in the Annex to Implementing Regulation (EU) 2017/2470.

(5) Corrections are needed in order to provide clarity and legal certainty to food business operators and to Member States' competent authorities, thus providing for the proper implementation and use of the Union list of novel foods.

(6) On 22 November 2018, the competent authority of Italy made a request to the Commission for the correction in the Union list relating to the designation and the specific labelling requirement of the novel food *Echinacea purpurea* extract from cell cultures. This novel food was authorised through notification procedure pursuant to Article 5 of Regulation (EC) No 258/97. The competent authority of Italy has made an error by notifying the wrong name for the cell cultures and therefore, the request asks to replace the name of the cell cultures HTN®Vb with the name EchiPure-PC™ in the designation of the novel food as listed in the Union list and in the specific labelling requirement of foods containing it, as well as in the specifications of the novel food.

(7) A correction of the designation and of the specific labelling requirement in Table 1 and a correction of the specifications in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 of the novel food *Echinacea purpurea* extract from cell cultures are therefore necessary.

([1]) OJ L 327, 11.12.2015, p. 1.
([2]) 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).
([3]) 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).
([4]) Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (OJ L 187, 24.7.2018, p. 1).

(8) The novel foods yeast beta-glucans were authorised under certain conditions of use by Commission Implementing Decision 2011/762/EU ([5]). Use of yeast beta-glucans in additional food categories was later authorised by Commission Implementing Decision (EU) 2017/2078 ([6]). In the specifications of yeast beta-glucans in Implementing Decision (EU) 2017/2078, the measurement units for heavy metals are wrongly expressed in mg/g instead of mg/kg. This error was transferred in the Union list established by Implementing Regulation (EU) 2017/2470. Therefore, the specifications of the yeast beta-glucans relating to heavy metals in Annex I to Implementing Decision (EU) 2017/2078 and in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 should be corrected accordingly.

(9) Implementing Regulation (EU) 2017/2470 and Implementing Decision (EU) 2017/2078 should be corrected accordingly.

(10) 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 Annex to Implementing Regulation (EU) 2017/2470 is corrected in accordance with the Annex to this Regulation.

Article 2

Annex I to Implementing Decision (EU) 2017/2078 is corrected in accordance with the Annex to this Regulation.

Article 3

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, 29 July 2019.

For the Commission
The President
Jean-Claude JUNCKER

([5]) Commission Implementing Decision 2011/762/EU of 24 November 2011 authorising the placing on the market of yeast beta-glucans as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 313, 26.11.2011, p. 41).
([6]) Commission Implementing Decision (EU) 2017/2078 of 10 November 2017 authorising an extension of use of yeast beta-glucans as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 295, 14.11.2017, p. 77).

ANNEX

(1) The Annex to Implementing Regulation (EU) 2017/2470 is corrected as follows:

(a) the entry for *Echinacea purpurea* extract from cell cultures in Table 1 (Authorised novel foods) is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'*Echinacea purpurea* extract from cell cultures	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'dried extract of *Echinacea purpurea* from cell cultures EchiPure-PC™"	
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract from florets within the flower head of *Echinacea purpurea*		

(b) the entry for *Echinacea purpurea* extract from cell cultures in Table 2 (Specifications) is replaced by the following:

Authorised novel food	Specification
'*Echinacea purpurea* extract from cell cultures	**Description/Definition:** Dried extract of *Echinacea purpurea* from cell cultures EchiPure-PC™'

(c) the entries for Yeast beta-glucans in Table 2 (Specifications) under the heading *Heavy metals for insoluble in water, but dispersible in many liquid matrices* are replaced by the following:

	'Lead: < 0,2 mg/kg Arsenic: < 0,2 mg/kg Mercury: < 0,1 mg/kg Cadmium: < 0,1 mg/kg'

(2) Annex I to Implementing Decision (EU) 2017/2078 is corrected as follows:

The entries for Lead, Arsenic, Mercury and Cadmium in the Table Specifications of Yeast *(Saccharomyces cerevisiae)* beta-glucans are replaced by the following:

'Lead	< 0,2 mg/kg
Arsenic	< 0,2 mg/kg
Mercury	< 0,1 mg/kg
Cadmium	< 0,1 mg/kg'