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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2847

of 20 December 2023

authorising the placing on the market of apple fruit cell culture biomass as a novel food and amending 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(1) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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]) has established a Union list of novel foods.

(3) On 14 April 2020, the company Mibelle Group Biochemistry ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place apple fruit cell culture biomass on the Union market as a novel food. The applicant requested for apple fruit cell culture biomass to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]).

(4) On 2 December 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of apple fruit cell culture biomass as a novel food.

(5) On 24 May 2023, the Authority adopted its scientific opinion on the 'Safety of apple fruit cell culture biomass as a novel food pursuant to Regulation (EU) 2015/2283' ([4]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(6) In its scientific opinion, the Authority concluded that the novel food apple fruit cell culture biomass, is safe under the proposed conditions of use, in food supplements for the adult population at maximum levels of 0,15 mg/day. Therefore, that scientific opinion gives sufficient grounds to establish that apple fruit cell culture biomass, when used under the proposed conditions of use fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(7) It is appropriate that the inclusion of apple fruit cell culture biomass as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283. In this regard, in line with the conditions of use of food supplements containing apple fruit cell culture biomass as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers by appropriate labelling that food supplements containing apple fruit cell culture biomass is intended for the adult population.

([1]) OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.
([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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).
([3]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51, ELI: http://data.europa.eu/eli/dir/2002/46/oj).
([4]) EFSA Journal 2023;21(7):8065

(8) Apple fruit cell culture biomass should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(9) 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

1. Apple fruit cell culture biomass is authorised to be placed on the market within the Union.

Apple fruit cell culture biomass shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with 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, 20 December 2023.

For the Commission
The President
Ursula VON DER LEYEN

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
"**Apple fruit cell culture biomass**	*Specified food category*	*Maximum levels*			
	Food supplements as defined in Directive 2002/46/EC for the adult population	0,15 mg/day	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'apple fruit cell culture biomass'. 2. The labelling of food supplements containing the novel food shall bear a statement that they should only be consumed by persons above 18 years of age."		

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification
"**Apple fruit cell culture biomass**	**Description/Definition:** The novel food is a biomass of cultivated and homogenised cells of the Swiss apple variety Uttwiler Spätlauber (Malus domestica Borkh.). The production process consists of collecting under sterile conditions specific sections of the apple, which are then placed on solid medium with the aim to induce the formation of a primary callus tissue comprised of dedifferentiated cells under sterile conditions. The callus cells are then cultivated in liquid medium and subsequently homogenised, heat treated and dried. **Characteristics/composition:** Moisture: 10,9–15,5 g/100 g Ash: 11,8–20,8 g/100 g Proteins: 14,3–20,0 g/100 g Fats: 0,6–2,5 g/100 g Non-digestible carbohydrates: 17,1–25,2 g/100 g Other carbohydrates (calculated (*)): 21,9–38,9 g/100 g Total sugars: 17,1–32,6 g/100g Fructose: 10,8–20,2 g/100 g Glucose: 3,8–7,0 g/100 g

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	Total phenols: 0,15–0,29 g/100 g Malic acid: 0,41–1,19 g/100 g Succinic acid: 0,14–0,26 g/100 g

(*) Other carbohydrates (g/100g) = 100 (Dry residue) – Ash – Protein (Nitrogen × 6,25) – Total fat – Succinic acid – L-malic acid – Dietary fibre”