COMMISSION IMPLEMENTING REGULATION (EU) 2023/943

of 11 May 2023

authorising the placing on the market of cellobiose 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 28 May 2020, the company SAVANNA Ingredients GmbH ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place cellobiose on the Union market as a novel food. The applicant requested for cellobiose to be used in a number of foods intended for the general population, including food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]) intended for the general population, excluding infants and young children.

(4) On 28 May 2020, the applicant also made a request to the Commission for the protection of proprietary data for data on the identity ([4]), production process ([5]), composition ([6]), genotoxicity ([7]), subchronic toxicity ([8]) and human studies ([9]).

([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]) 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).

([4]) 2.2 Identity Cellobiose UPDATED 07122021.pdf; 2.2.1 ID_NMR_Cellobiose.pdf; 2.2.2 ID_NMR_Cellobiose_Amendment.pdf; 2.2.6 Cellobiose_NMR-Data_UPDATED_07052021.pdf; 2.2.7 Cellobiose_HRMS-Data_UPDATED_07122021.pdf; 2.2.10_Cellobiose NMR HMBC COS UPDATED 07122021.pdf

([5]) 2.3.15 PCR Enzyme_1_UPDATED_07052021.pdf; 2.3.16 PCR Enzyme_2_UPDATED_07052021.pdf

([6]) 2.4.3.2 Stab cellob applications.pdf; 2.4.01 Comp Anal. L1018025.pdf; 2.4.02 Comp Anal. L1018031.pdf; 2.4.03 Comp Anal. L1018205.pdf; 2.4.04 Comp Anal. L1018231.pdf; 2.4.05 Comp Anal. L1017514.pdf; 2.4.06 DNA_Cellobiose.pdf; 2.4.07 Stability analysis L1018025_UPDATED_07122021.pdf; 2.4.08 Stability analysis L1018031_UPDATED_07122021.pdf; 2.4.09 Stability analysis L1018205_UPDATED_07122021.pdf; 2.4.10 Stability analysis L1018231_UPDATED_07122021.pdf; 2.4.11 Stability analysis L1017514_UPDATED_07122021.pdf; 2.4.12_Summary stability UPDATED 07122021.xlsx; 2.4.13 Cellobiose applications food; 2.4.14 VA CRO Val.pdf; 2.4.29_LoD protein-content_NEW 06122021.pdf

([7]) 2.10.2.1 Genotoxicity.pdf; 2.10.2.1.1 OECD 471 Cellobiose.pdf; 2.10.2.1.2 OECD 487 Cellobiose.pdf

([8]) 2.10.2.3 Subchronic oral toxicity UPDATED_07052021.pdf; 2.10.2.3.1 Dose_Range_Cellobiose.pdf; 2.10.2.3.2 OECD 408 Cellobiose.pdf; 2.10.2.3.3._32942_Suppl_2021-05-03.pdf

([9]) 2.10.3 Human data.pdf; 2.10.3.3.1 Tolerance Cellobiose final.pdf; 2.10.3.3.2 Study protocol.pdf; 2.10.3.3.3 Study protocol Signatures.pdf; 2.10.3.3.4 Statist analysis plan signed.pdf; 2.10.3.3.5 Statistical analysis.pdf; 2.10.3.3.6 Data listing.pdf; Moré, Postrach, Bothe, Heinritz and Uebelhack (2019). A Dose-Escalation Study Demonstrates the Safety and Tolerability of Cellobiose in Healthy Subjects. *Nutrients* 12(1): 64, https://www.mdpi.com/2072-6643/12/1/64.

(5) On 23 September 2020, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of cellobiose as a novel food.

(6) On 28 September 2022, the Authority adopted its scientific opinion on the 'Safety of cellobiose as a novel food pursuant to regulation (EU) 2015/2283' ([10]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that cellobiose is safe under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that cellobiose, when used in a number of foods intended for the general population, including food supplements as defined in Directive 2002/46/EC intended for the general population, excluding infants and young children, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on data on the identity, production process, composition, genotoxicity, subchronic toxicity and human studies without which it could not have assessed the novel food and reached its conclusion.

(9) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those data and studies and to clarify its claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.

(10) The applicant declared that it held proprietary and exclusive rights of reference to the data on the identity, production process and composition, and genotoxicity, subchronic toxicity and human studies at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.

(11) The Commission assessed all the information provided by the applicant and considered that it has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, data on the identity, production process, composition, genotoxicity, subchronic toxicity and human studies should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place cellobiose on the market within the Union during a period of five years from the entry into force of this Regulation.

(12) However, restricting the authorisation of cellobiose and the reference to the data contained in the applicant's file for its sole use does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.

(13) It is appropriate that the inclusion of cellobiose 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 cellobiose as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers through the use of an appropriate label that food supplements containing cellobiose should not be consumed by infants and young children.

(14) Cellobiose 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.

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

([10]) *EFSA Journal* 2022;20(11):7596.

HAS ADOPTED THIS REGULATION:

Article 1

1. Cellobiose is authorised to be placed on the market within the Union.

Cellobiose 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

Only the company SAVANNA Ingredients GmbH ([11]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from 1 June 2023, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of SAVANNA Ingredients GmbH.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of SAVANNA Ingredients GmbH.

Article 4

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, 11 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

([11]) Dürener Straße 67, 50189 Elsdorf, Germany.

ANNEX

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
'**Cellobiose**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'cellobiose'. 2. The labelling of food supplements containing cellobiose shall bear a statement that those food supplements should not be consumed by infants and young children.		Authorised on 1 June 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: SAVANNA Ingredients GmbH, Dürener Straße 67, 50189 Elsdorf, Germany. During the period of data protection, the novel food cellobiose is authorised for placing on the market within the Union only by SAVANNA Ingredients GmbH, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of SAVANNA Ingredients GmbH. End date of the data protection: 1 June 2028.'
	Food supplements as defined in Directive 2002/46/EC for the general population, excluding infants and young children	3 g/day			
	Dried, canned-tinned, raw cured (or seasoned), cooked cured (or seasoned) meat	2 g/100 g			
	Fresh raw, preserved or partly preserved sausages	2 g/100 g			
	Meat based spreadable-textured specialties	2 g/100 g			
	Liver based spreadable-textured specialties	2 g/100 g			
	Savoury sauce dry preparation	40 g/100 g			
	Table-top sweeteners in powder form	60 g/100 g			
	Table-top sweeteners in tablets	60 g/100 g			

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

Authorised Novel Food	Specification
'**Cellobiose**	**Description/Definition:** Cellobiose is a disaccharide with two glucose monomers linked by a β-(1–4) glucosidic bond, that is produced from sucrose and glucose in a two-step enzymatic reaction, followed by a series of purification steps. **Characteristics/composition:** Cellobiose DM (%): ≥ 99 Moisture (%): < 1 Other identified sugars (%): ≤ 1 Optical rotation $[\alpha]_D$ (c 10, water): +33–36 Ash (g/100 g): < 0,1 Protein content (g/100 g): < 0,01 **Heavy metals:** Arsenic: < 0,1 mg/kg **Microbiological criteria:** Total aerobic count (cfu/g): ≤ 1 000 Yeast and moulds (cfu/g): ≤ 100 Salmonella (in 25 g): n.d. Coliforms (cfu/g): ≤ 10 *E. coli* (in 10 g): n.d. cfu: colony forming units n.d.: not detected'