COMMISSION IMPLEMENTING REGULATION (EU) 2021/2129

of 2 December 2021

authorising the placing on the market of calcium fructoborate as a novel food 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) On 25 March 2019, the company VDF FutureCeuticals, Inc. ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 to place calcium fructoborate on the Union market as a novel food. The applicant requested calcium fructoborate to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]), for the adult population, excluding pregnant and lactating women.

(4) The applicant also submitted a request to the Commission for the protection of proprietary data for a number of data submitted in support of the application, namely, detailed description of the production process ([4]); methods of analysis ([5]); certificates of analysis ([6]); stability report ([7]); dietary boron intake assessment ([8]); toxicokinetic study ([9]); bacterial reverse mutation test ([10]); in vitro mammalian micronucleus assay ([11]); 90-day toxicity study in rats ([12]);

([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]) Section 2.b.1/VDF Calcium Fructoborate - Production Process.pdf.
([5]) Methods of analysis, excluding Thermogravimetric Analysis (TGA) - Annex C - Methods of Analysis - CONF.pdf.
([6]) Annex D - Certificates of Analysis -CONF.pdf.
([7]) Annex E - Stability - CONF.pdf.
([8]) Annex F - Boron Intake Report – CONF.pdf.
([9]) Annex G - Nemzer, 2018 - CONF&PROP.pdf (Unpublished Study report 2018).
([10]) Annex G - Schreib et al., 2015 - CONF&PROP.pdf (Unpublished Study report 2015a).
([11]) Annex G - Donath et al., 2015 - CONF&PROP.pdf (Unpublished Study report 2015b).
([12]) Annex G - Bauter et al 2015 1 CONF&PROP.pdf; Annex G - Bauter et al 2015 2 CONF&PROP.pdf (Unpublished Study report 2015c).

particle size analysis ([13]); particle size method of analysis ([14]); fructose analysis ([15]); amino acid analysis ([16]); microorganisms analysis ([17]); physiochemical stability ([18]); stability of fructose in the novel food ([19]); background dietary boron intakes ([20]); boron dissociation under varying pH ([21]).

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 10 July 2019, requesting it to provide a scientific opinion by carrying out a safety assessment of calcium fructoborate as a novel food.

(6) On 25 May 2021, the Authority adopted its scientific opinion on the 'Safety of calcium fructoborate as a novel food pursuant to Regulation (EU) 2015/2283' ([22]). This opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(7) In that opinion, the Authority concluded that the novel food, calcium fructoborate, is safe for the adult population, excluding pregnant and lactating women, at intake levels up to 220 mg/day (3,14 mg/kg bw per day). Therefore, the opinion of the Authority gives sufficient grounds to establish that calcium fructoborate under the specific conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.

(8) Since few data are available regarding the safety of calcium fructoborate in the population under 18 years of age and by pregnant and lactating women, a labelling should be provided in order to properly inform the consumers that the food supplements containing calcium fructoborate should not be consumed by those population groups.

(9) In its opinion, the Authority considered that all the data for which the applicant requested data protection, except for the dietary boron intake assessment and background dietary boron intakes, served as a basis to establish the safety of the novel food. On this basis, the Commission considers that the conclusions on the safety of calcium fructoborate could not have been reached without the data from the reports of those studies.

(10) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those data and to clarify their claim to an exclusive right of reference to those data, as required under Article 26(2)(b) of Regulation (EU) 2015/2283.

(11) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive rights of reference to those data under national law, and that therefore third parties cannot lawfully access or use those data or refer to those data.

(12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, detailed description of the production process; methods of analysis; certificates of analysis; stability report; toxicokinetic study; bacterial reverse mutation test; in vitro mammalian micronucleus assay; 90-day toxicity study in rats; particle size analysis; particle size method of analysis; fructose analysis; amino acid analysis; microorganisms analysis; physiochemical stability; stability of fructose in the novel food; boron dissociation under varying pH contained in the applicant's file, on which the Authority based its conclusion on the safety of the novel food and without which it could not have assessed the novel food, should not be used by the Authority for the benefit of any subsequent applicant for a period of 5 years from the date of entry into force of this Regulation. Accordingly, only the applicant should be authorised to place calcium fructoborate on the market within the Union during that period.

([13]) Calcium Fructoborate - Particle Size COAs.pdf.
([14]) Calcium Fructoborate - Particle Size MOA.pdf.
([15]) Attachment - Response 3 – Fructoborate Analysis.pdf.
([16]) Attachment - Response 5 - Amino Acid Analysis.pdf.
([17]) Attachment - Response 6 - Micro Analysis.pdf.
([18]) Attachment - Response 7 - Physiochem Stability.pdf.
([19]) Attachment_Clarification_Resp_Q8_Fructose_Stability_CONF.pdf.
([20]) Ca Fructoborate_Response EFSA Q9-11_17 Jul 2020.pdf.
([21]) Ca Fructoborate_Response EFSA Q_ADME_06 Apr 2021.pdf.
([22]) EFSA Journal 2021;19(6):6661.

(13) However, restricting the authorisation of calcium fructoborate and of the reference to the data contained in the applicant's file for the sole use of the applicant, does not prevent other 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 authorisation under Regulation (EU) 2015/2283.

(14) 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,

HAS ADOPTED THIS REGULATION:

Article 1

1. Calcium fructoborate as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of 5 years from 23 December 2021 only the initial applicant,

Company: VDF FutureCeuticals, Inc.,

Address: 300 West 6th Street Momence, Illinois 60954, the United States,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for that novel food without reference to the data protected pursuant to Article 2 or with the agreement of VDF FutureCeuticals, Inc.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

The data contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of 5 years from 23 December 2021 without the agreement of VDF FutureCeuticals, Inc.

Article 3

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

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, 2 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

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
	Specified food category	Maximum levels	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'calcium fructoborate'. 2. The labelling of food supplements containing calcium fructoborate shall bear a statement that those food supplements should not be consumed by population under 18 years of age and by pregnant and lactating women.		Authorised on 23 December 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: VDF FutureCeuticals, Inc., 300 West 6th Street Momence, Illinois 60954, the United States. During the period of data protection, the novel food calcium fructoborate is authorised for placing on the market within the Union only by VDF FutureCeuticals, Inc., 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 VDF FutureCeuticals, Inc. End date of the date protection: 23 December 2026'
Calcium fructoborate	Food supplements as defined in Directive 2002/46/EC for the adult population, excluding food supplements for pregnant and lactating women	220 mg/day			

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

'Authorised Novel Food	Specifications
Calcium fructoborate	*Description/Definition* The novel food is calcium fructoborate, a calcium salt tetrahydrate of a bis(fructose) ester of boric acid in the form of a powder, represented by Ca[(C6H10O6)2B]2•4H2O, with a molecular mass of 846 Da. The novel food is produced by chemical synthesis whereby fructose is combined with boric acid in water to produce a bis(fructose) ester of boric acid through various heating and mixing processes. Calcium carbonate is then added to produce a solution containing the calcium salt of fructoborate (tetrahydrate). The solution is freeze-dried, ground to produce the final powdered product, and then packaged and stored under representative storage conditions (22 ± 1°C RH 55-60 %). *Characteristics/composition* Free moisture: < 5,0 % Calcium: 4,5-5 % Boron: 2,5-2,9 % Fructose: 80-85 % Ash: 15-16 % *Heavy metals* Arsenic: ≤ 1 mg/kg *Microbiological criteria* Total plate count: ≤ 1 000 CFU/g [(a)] Yeast and mould: < 100 CFU/g Coliforms: ≤ 10 CFU/g *Escherichia coli*: < 10 CFU/g *Salmonella* spp.: Absence in 25 g Coagulase-positive staphylococci: Absence in 1 g

(a) CFU: colony forming units'