Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1023

of 23 July 2018

correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods

(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 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 8 thereof,

Whereas:

(1) Pursuant to Article 8 of Regulation (EU) 2015/2283, the Commission is 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) Pursuant to Article 36 of Regulation (EU) 2015/2283, the new novel food Regulation applies from 1 January 2018. A number of products were authorised or notified under Regulation (EC) No 258/97 during the period between the Standing Committee vote on the Union list on 6 December 2017 and the date of application of Regulation (EU) 2015/2283 on 1 January 2018. These products should therefore be included in the Union list established through Implementing Regulation (EU) 2017/2470.

(4) On 19 December 2017, the company Demethra Biotech S.r.l. notified the Commission that it placed the novel food '*Echinacea purpurea* extract from cell cultures' on the Union market pursuant to Article 5 of Regulation (EC) No 258/97. This novel food was not included in the Union list. Therefore, a new entry should be added to Tables 1 and 2 of the Annex to Implementing Regulation (EU) 2017/2470.

(5) On 21 and 22 December 2017, two companies, DuPont Nutrition & Biosciences ApS and FrieslandCampina Nederland BV, notified the Commission that they placed the novel food '2'-Fucosyllactose (microbial source)' on the Union market pursuant to Article 5 of Regulation (EC) No 258/97. '2'-Fucosyllactose (microbial source)' was already included in the Annex to Implementing Regulation (EU) 2017/2470. Those new notifications modify the numerical values of several parameters listed in the

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specifications of this novel food and therefore, the entry '2'-Fucosyllactose (microbial source)' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 should be corrected accordingly.

(6) On 20 December 2017, the company c-LEcta GmbH notified the Commission that it placed the novel food 'Trehalose' on the Union market pursuant to Article 5 of Regulation (EC) No 258/97. 'Trehalose' was included in the Annex to Implementing Regulation (EU) 2017/2470. That new notification concerns a new source of trehalose, sucrose. Therefore, the specifications of the entry 'Trehalose' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 should be corrected accordingly.

(7) After the publication of Implementing Regulation (EU) 2017/2470, a number of errors or omissions were noted concerning the specifications or the conditions of use of a number of authorised novel foods. Therefore, the Union list established in the Annex to Implementing Regulation (EU) 2017/2470 should be corrected.

(8) The novel food 'L-Alanyl-L-Glutamine' was authorised under certain conditions of use pursuant to Article 5 of Regulation (EC) No 258/97. The category 'Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen' was erroneously omitted. Therefore, a correction adding 'Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen' as allowed food category in the entry 'L-Alanyl-L-Glutamine' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(9) The novel food 'Glucosamine HCl' was authorised under certain conditions of use pursuant to Article 5 of Regulation (EC) No 258/97. The food category 'Milk-based drinks and similar products intended for young children' was added erroneously and should be deleted from this entry. A correction in the entry 'Glucosamine HCl' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is therefore necessary.

(10) The novel food 'Lacto-*N*-neotetraose' was authorised under certain conditions of use and maximum levels by Commission Implementing Decision (EU) 2016/375[(4)]. The wording 'at concentrations up to 1,2 g/l' was added erroneously and should be removed from the food category 'Milk-based drinks and similar products intended for young children' for this novel food. Therefore, a correction of the entry 'Lacto-*N*-neotetraose' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(11) The novel food 'Spermidine-rich wheat germ extract (*Triticum aestivum*)' was authorised under certain conditions of use for 'adult population excluding pregnant and lactating women' pursuant to Article 5 of Regulation (EC) No 258/97. However, the exclusion of pregnant and lactating women erroneously did not feature in the Union list. In consequence, the correction of the entry 'Spermidine-rich wheat germ extract (*Triticum aestivum*)' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(12) The novel food 'Antarctic Krill oil from *Euphausia superba*' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 erroneously omitted the following requirement, which should be added: 'Oxidative stability: all food products containing Antarctic Krill oil from *Euphausia superba* should demonstrate oxidative stability

by appropriate and recognised national/international test methodology (e.g. AOAC)'. Therefore, a correction of this entry in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(13) The novel food 'Antarctic Krill oil rich in phospholipids from *Euphausia superba*' was authorised under certain conditions of use by the Finnish competent authorities[(5)]. The specifications erroneously added the following requirement: 'Oxidative stability: all food products containing Antarctic Krill oil rich in phospholipids from *Euphausia superba* should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC)'. This requirement should be removed. Therefore, a correction of the entry 'Antarctic Krill oil rich in phospholipids from *Euphausia superba*' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(14) The novel food 'Chia seeds (*Salvia hispanica*)' was initially authorised under certain conditions of use by Commission Decision 2009/827/EC[(6)]. The specifications erroneously added the following requirement: '(EU: carbohydrates are available = sugar + starch)'. This requirement should be removed. Therefore, a correction of the entry 'Chia seeds (*Salvia hispanica*)' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(15) The novel food 'Chitosan extract from fungi (*Agaricus bisporus*; *Aspergillus niger*)' was initially authorised under certain conditions of use pursuant to Article 5 of Regulation (EC) No 258/97. The specifications erroneously added the following requirement: 'Fat binding capacity 800 x 9 w/wet weight): pass'. This requirement should be replaced by 'Fat binding capacity 800 x (w/w wet weight): pass'. Therefore, a correction of the entry 'Chitosan extract from fungi (*Agaricus bisporus*; *Aspergillus niger*)' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(16) The novel food 'Citicoline' was authorised under certain conditions of use by Commission Implementing Decision 2014/423/EU[(7)]. In Table 2 of the Annex to Implementing Regulation (EU) 2017/2470, the specifications of the novel food 'Citicoline' refer to citicoline produced via either a synthetic or a microbial process. After the publication of that Regulation, it became clear that microbial process for the production of citicoline, also involved synthetic process. Thus, the specifications concerning 'Citicoline' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 should be corrected to include only the microbial production process.

(17) The novel food '*Echinacea angustifolia* extract from cell cultures' was initially authorised under certain conditions of use pursuant to Article 5 of Regulation (EC) No 258/97. The specifications erroneously omitted the wording 'description/definition'. Therefore, a correction of the entry '*Echinacea angustifolia* extract from cell cultures' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(18) The novel food 'Galacto-oligosaccharide' is included in the Union list established by Implementing Regulation (EU) 2017/2470. The following microbial sources *Pichia pastoris*, *Kluyveromyces lactis*, *Sporobolomyces singularis* and *Papiliotrema terrestris* of the enzyme 'β-galactosidase' were erroneously omitted in the specifications.

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Therefore, these sources of β-galactosidase should be added to the entry 'Galacto-oligosaccharide' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470.

(19) The novel food 'Vitamin K_2 (menaquinone)' was initially authorised under certain conditions of use by Commission Decision 2009/345/EC[8]. The chemical definition of Vitamin K_2 was added to 'specifications of microbiologically produced vitamin K_2 (menaquinone-7)' but erroneously not added to 'specifications of synthetic vitamin K_2 (menaquinone-7)'. Therefore, a correction of the entry 'Vitamin K_2 (menaquinone)' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(20) The novel food 'Yeast beta-glucans' was authorised under certain conditions of use by Commission Implementing Decision 2011/762/EU[9]. In the specifications, 'Microbiological data' and 'heavy metals' erroneously refer to the three forms of Yeast beta-glucans instead of to the form 'Insoluble in water but dispersible in many liquid matrices'. Therefore, a correction of the entry 'Yeast beta-glucans' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(21) The novel food 'Phytosterols/phytostanols' was authorised under certain conditions of use by Commission Decision 2004/333/EC[10]. On 14 April 2016, the company BASF SE Human Nutrition, ENS/HR notified the Commission that it placed the novel food 'Phytosterols/phytostanols' on the Union market in the category 'Food supplement' pursuant to Article 5 of Regulation (EC) No 258/97. The category 'Food supplement' was erroneously omitted. Therefore, a correction adding 'Food supplement' as allowed food category in the entry 'Phytosterols/phytostanols' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(22) The novel food 'Arachidonic acid-rich oil from the fungus *Mortierella alpina*' was authorised under certain conditions of use by Commission Decision 2008/968/EC[11]. The following non-genetically modified strain 'CBS 210.32' of the fungus *Mortierella alpina* was erroneously not included in the specifications. Therefore, this strain should be added to the entry 'Arachidonic acid-rich oil from the fungus *Mortierella alpina*' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470.

(23) The novel food 'Epigallocatechin gallate as a purified extract from green tea leaves (*Camellia sinensis*)' was initially authorised under certain conditions of use pursuant to Article 5 of Regulation (EC) No 258/97. The food category 'Foods fortified in accordance with Regulation (EC) No 1925/2006' was added erroneously and should be deleted from this entry. Furthermore, a correction adding 'Foods' to 'food supplements as defined in Directive 2002/46/EC' as the allowed food category in the entry 'Epigallocatechin gallate as a purified extract from green tea leaves (*Camellia sinensis*)' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(24) The novel food 'Lycopene from tomatoes' was authorised under certain conditions of use pursuant to Article 5 of Regulation (EC) No 258/97. The food category 'Food supplement' was omitted erroneously and should be added to this entry. Therefore, a correction adding 'Food supplement' as allowed food category in the entry 'Lycopene from tomatoes' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

(25) In addition, after the publication of Implementing Regulation (EU) 2017/2470, several typographical errors have been identified in the Annex. While such typographic errors are usually corrected by a corrigendum, for the sake of clarity for economic operators and enforcement authorities, the correction of those typographical errors should be included in this correcting act.

(26) Given the number of corrections, it is appropriate to replace the whole Annex to Implementing Regulation (EU) 2017/2470.

(27) 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 replaced by 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, 23 July 2018.

For the Commission

The President

Jean-Claude JUNCKER