Commission Regulation (EU) 2018/1555 of 17 October 2018 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/1555

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[(1)], and in particular Article 17(3) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.

(3) Following receipt of an application, the Authority is to inform without delay the other Member States and the Commission thereof, and to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Laboratoire Nurilia, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Condensyl® and decreases sperm DNA damage. High sperm DNA damage is a risk factor for male subfertility/infertility (Question No EFSA-Q-2016-00665)[(2)]. The claim proposed by the applicant was worded as follows: 'The combination of opuntia fruit dry extract standardised in quercetin and betalain, N-acetyl cysteine, zinc, vitamin B3, E, B6, B2, B9 and B12 in Condensyl® decreases sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index). High sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index) is a risk factor for male subfertility/infertility'.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2018/1555. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(6) On 5 May 2017, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented a cause and effect relationship has not been established between the consumption of Condensyl® and the reduction of sperm DNA damage in the context of reducing the risk of male infertility. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from Cargill R&D Centre Europe, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to sugar-free hard confectionery with at least 90 % erythritol and reduction of dental plaque which reduces the risk of caries (Question No EFSA-Q-2017-00002)[3]. The claim proposed by the applicant was worded as follows: 'Sugar-free hard confectionery sweetened with at least 90 % Zerose® erythritol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries'.

(8) On 21 July 2017, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented a cause and effect relationship has not been established between the consumption of sugar-free hard confectionery with at least 90 % erythritol and reduction of dental plaque which reduces the risk of dental caries. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) Following an application from Biosearch Life, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to *Lactobacillus fermentum* CECT 5716 and decreases the *Staphylococcus* load in breast milk. High *Staphylococcus* load in breast milk is a risk factor for infectious mastitis (Question No EFSA-Q-2016-00318)[4]. The claim proposed by the applicant was worded as follows: '*Lactobacillus fermentum* CECT 5716 decreases the *Staphylococcus* load in breast milk. High Staphylococcus load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis'.

(10) On 24 July 2017, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented a cause and effect relationship has not been established between the consumption of *Lactobacillus fermentum* CECT 5716 and a reduction of the *Staphylococcus* load in breast milk which reduces the risk of infectious mastitis. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) 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 health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) 2018/1555. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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, 17 October 2018.

For the Commission

The President

Jean-Claude JUNCKER