EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10642/2021
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[…](2021) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) …/…

of XXX

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(Text with EEA relevance)

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 18(5) 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 (''the Authority''), for a scientific assessment, as well as to the Commission and the Member States for information.

(3) The Authority is 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 DuPont Nutrition Biosciences ApS, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related *Bifidobacterium animalis* subsp. *lactis* Bi-07 (Bi-07) and the contribution to increasing lactose digestion (Question No EFSA-Q-2020-00024). The claim proposed by the applicant was worded as follows: '*Bifidobacterium animalis* subsp. *lactis* Bi-07 contributes to the improvement of lactose digestion in individuals who have difficulty digesting lactose'.

(6) The Commission, the Member States and the applicant received the scientific opinion[2] on that claim 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 *Bifidobacterium animalis* subsp. *lactis* Bi-07 and a beneficial physiological effect (i.e. the improvement of symptoms of lactose maldigestion) in individuals with lactose maldigestion. Accordingly, as the health claim does not

[1] OJ L 404, 30.12.2006, p. 9.
[2] EFSA Journal 2020;18(7):6198.

comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted claims, it should not be authorised.

(7) Following an application from Tchibo GmbH, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to Coffee C21 and the protection of DNA from strand breaks (Question No EFSA-Q-2019-00423). The claim proposed by the applicant was worded as follows: 'regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body'.

(8) The Commission, the Member States and the applicant received the scientific opinion[3] on that claim 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 Coffee C21 and the protection of DNA from strand breaks. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted claims, it should not be authorised.

(9) Following an application from NattoPharma ASA, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to MenaQ7® and the maintenance of the elastic properties of the arteries (Question No EFSA-Q-2019-00229). The claim proposed by the applicant was worded as follows: 'MenaQ7®, vitamin K2 as menaquinone-7, improves arterial stiffness'.

(10) The Commission, the Member States and the applicant received the scientific opinion[4] on that claim 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 MenaQ7® and the maintenance of the elastic properties of the arteries. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted claims, it should not be authorised.

(11) The comments from DuPont Nutrition Biosciences ApS and Tchibo GmbH received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006, have been considered when adopting this Regulation.

(12) 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 13(3) of Regulation (EC) No 1924/2006.

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*.

[3] EFSA Journal 2020;18(3):6055.
[4] EFSA Journal 2020;18(1):5949.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN