



Council of the  
European Union

Brussels, 27 March 2017  
(OR. en)

7683/17

DENLEG 24  
AGRI 161  
SAN 119

**COVER NOTE**

---

From:	European Commission
date of receipt:	24 March 2017
To:	General Secretariat of the Council
No. Cion doc.:	D049412/01
Subject:	COMMISSION REGULATION (EU) .../... of XXX refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health

---

Delegations will find attached document D049412/01.

---

Encl.: D049412/01



Brussels, **XXX**  
SANTE/10220/2016  
(POOL/E1/2016/10220/10220-EN.doc)  
D049412/01  
[...](2017) **XXX** draft

**COMMISSION REGULATION (EU) .../...**

**of **XXX****

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

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

**refusing to authorise a health claim 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<sup>1</sup>, 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 (EFSA), hereinafter referred to as '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 Beghin-Meiji and Tereos Syral, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to short-chain fructooligosaccharides from sucrose and maintenance of normal defecation (Question No EFSA-Q-2015-00377<sup>2</sup>). The applicant has proposed the following wording for the health claim: “maintain normal intestinal regularity” or “maintain intestinal regularity by increasing the

---

<sup>1</sup> OJ L 404, 30.12.2006, p. 9.

<sup>2</sup> EFSA Journal 2016;14(1):4366.

frequency of bowel movements" or "contributes to normal intestinal regularity or normal bowel function."

- (6) On 8 January 2016, 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 had not been established between the consumption of short-chain fructooligosaccharides from sucrose and maintenance of normal defecation under the conditions of use proposed by the applicant. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (7) The comments from the applicant received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.
- (8) 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 claim 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*.

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

Done at Brussels,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*