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COMMISSION

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

**of **XXX****

**authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health, and amending Regulation (EU) No 432/2012**

*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 IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health, and amending Regulation (EU) No 432/2012**

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(4) thereof,

Whereas:

- (1) Regulation (EC) No 1924/2006 provides that health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in the list of permitted health claims.
- (2) Pursuant to Article 13(3) of Regulation (EC) No 1924/2006, Commission Regulation (EU) No 432/2012<sup>2</sup> established a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.
- (3) 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.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority, any relevant provisions of Union law and other legitimate factors relevant to the matter under consideration.
- (5) In order to stimulate innovation, health claims which are based on newly developed scientific evidence and/or which include a request for the protection of proprietary data shall undergo an accelerated type of authorisation.
- (6) Following an application from Zespri International Limited, 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 green kiwifruit (*Actinidia deliciosa* "Hayward") and the maintenance of normal defecation (Question No EFSA- Q-2020-000562).

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<sup>1</sup> OJ L 404, 30.12.2006, p. 9, ELI: <http://data.europa.eu/eli/reg/2006/1924/oj>.

<sup>2</sup> Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136, 25.5.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/432/oj>).

- (7) The claim initially proposed by the applicant was worded as follows: ‘Regular consumption of green kiwifruit contributes to gastrointestinal comfort’ or ‘regular consumption of green kiwifruit reduces gastrointestinal discomfort’. Taking into account the proposed health relationship, and in agreement with the applicant, the Authority changed the wording of the assessed claim to: ‘Regular consumption of green kiwifruit maintains normal defecation’.
- (8) On 11 June 2021, the Authority published its scientific opinion on that claim<sup>3</sup>, which concluded that on the basis of the data presented, a cause-and-effect relationship had been established between the consumption of green kiwifruit (*Actinidia deliciosa* “Hayward”) and maintenance of normal defecation. The target population is the general population. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and should be included in the Union list of permitted health claims, established by Regulation (EU) No 432/2012.
- (9) Following a request by the applicant to the Commission for a more consumer-friendly wording, the Authority confirmed that the wording ‘Consumption of green kiwifruit contributes to normal bowel function by increasing stool frequency’ reflects the scientific evidence.
- (10) The Panel noted in its scientific opinion that no conclusions could be drawn for the scientific substantiation of the claim from the studies performed with foods other than fresh green kiwifruits.
- (11) Article 13(3) of Regulation (EC) No 1924/2006 provides that permitted health claims must be accompanied with all necessary conditions (including restrictions) for their use. Accordingly, the list of permitted health claims should include the wording of the claims and their specific conditions of use, and where applicable, conditions or restrictions of use and/or an additional statement or warning, in accordance with Regulation (EC) No 1924/2006 and in line with the opinions of the Authority.
- (12) In accordance with Article 20 of Regulation (EC) No 1924/2006, the Register of nutrition and health claims containing all authorised health claims should be updated.
- (13) Regulation (EU) No 432/2012 should therefore be amended accordingly.
- (14) The Member States have been consulted.

HAS ADOPTED THIS REGULATION:

#### *Article 1*

The health claim set out in the Annex to this Regulation shall be included in the Union list of permitted health claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

#### *Article 2*

The Annex to Regulation (EU) No 432/2012 is amended in accordance with the Annex to this Regulation.

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<sup>3</sup> EFSA Journal 2021;19(6):6641

*Article 3*

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*  
*Ursula VON DER LEYEN*

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