Commission Implementing Regulation (EU) 2016/862 of 31 May 2016 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 IMPLEMENTING REGULATION (EU) 2016/862

of 31 May 2016

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[(1)], and in particular Article 18(4) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on food 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 Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority. In some cases, the scientific risk assessment alone cannot provide all the information on which a risk management decision should be based and therefore other legitimate factors relevant to the matter under consideration should also be taken into account.

(4) Following an application from Oy Karl Fazer AB, 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 high-fibre sourdough rye bread and a reduction of post-prandial glycaemic responses (Question No EFSA-Q-2014-00012[(2)]). The claim proposed by the applicant was worded as follows: 'Consumption of high-fibre sourdough rye bread contributes to a reduction of glycaemic response accompanied with a decreased insulin response after a meal'. Upon request of the Authority, the applicant specified that as regards the claimed effect high-fibre sourdough rye bread should be compared with glucose.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/862. 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*

(5) On 8 October 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded on the basis of the data presented that a cause and effect relationship had been established between the consumption of almost any food and a reduction of post-prandial blood glucose responses as compared with glucose.

(6) Pursuant to Articles 6(1) and 13(1) of Regulation (EC) No 1924/2006 health claims need to be based on generally accepted scientific evidence. Authorisation may be legitimately withheld if health claims do not comply with other general and specific requirements of Regulation (EC) No 1924/2006, even in the case of a favourable scientific assessment by the Authority. The Authority noted in its scientific opinion that, when comparable amounts of available carbohydrates from different carbohydrate-containing foods are tested, almost any carbohydrate-containing food would induce a reduction of post-prandial blood glucose responses compared with the blood glucose responses elicited by the consumption of glucose. In addition, it noted that foods containing low amounts of carbohydrates or no available carbohydrates would also induce lower post-prandial blood glucose responses when compared with glucose.

(7) Regulation (EC) No 1924/2006 defines ‘claim’ as any message or representation which states, suggests or implies that a food has particular characteristics. A claim on high-fibre sourdough rye bread and post-prandial glycaemic responses would suggest that high-fibre sourdough rye bread has particular characteristics in relation to the reduction of post-prandial glycaemic responses when compared with glucose, while in fact almost all foods have that effect. Point (a) of the second paragraph of Article 3 of Regulation (EC) No 1924/2006 provides that the use of health claims shall not be misleading. A claim suggesting that a particular food possesses certain beneficial properties when in fact almost all foods possess such properties would be misleading.

(8) In the light of the above, the claim on the consumption of high-fibre sourdough rye bread and the reduction of post-prandial glycaemic responses does not comply with the requirements of Regulation (EC) No 1924/2006 and should therefore not be included in the list of permitted health claims.

(9) 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.

(10) The Member States have been consulted,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim set out 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*.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/862. 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*

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

Done at Brussels, 31 May 2016.

For the Commission

The President

Jean-Claude JUNCKER