Council of the European Union

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	18 July 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D(2025) 105920
Subject:	COMMISSION REGULATION (EU) .../... of XXX refusing to authorise a health claim made on foods and referring to the reduction of disease risk

Delegations will find attached document D(2025) 105920.

Encl.: D(2025) 105920

EUROPEAN
COMMISSION

Brussels, XXX
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[…](2025) XXX draft

[…]

COMMISSION REGULATION (EU) …/…

of XXX

refusing to authorise a health claim made on foods and referring to the reduction of disease risk

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

refusing to authorise a health claim made on foods and referring to the reduction of disease risk

(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 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 the Union list of permitted health claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for the authorisation 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.

(3) Following the 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 the health claim 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, in line with Article 17(1) of Regulation (EC) No 1924/2006.

(5) Following an application from Cárnicas Joselito S.A. ('the applicant'), submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to 'Joselito® ham and the increase in antioxidant substances in the body, the reduction of blood pressure and plasma triglycerides, the decrease in oxidative stress and a preventive effect in diseases related to the cardiovascular and intestinal systems' (Question No EFSA-Q-2022-00412). The claim proposed by the applicant was worded as follows: 'The intake of Joselito ham produces a health benefit by causing an increase in antioxidant substances in the body, reducing blood pressure and plasma triglycerides, producing a decrease in oxidative stress and a preventive effect in diseases related to the cardiovascular and intestinal systems'.

[1] OJ L 404, 30.12.2006, p. 9. (data.europa.eu/eli/reg/2006/1924/oj)

(6) Upon a request for clarification by the Authority of 5 March 2024, the applicant specified that the disease is 'cardiovascular disease, specifically atherosclerosis', and identified four risk factors, namely 'elevated blood LDL-cholesterol concentrations', 'low blood HDL cholesterol concentrations', 'increased blood pressure (hypertension)' and 'excessive fat accumulation (obesity)'. The Authority noted that the term 'cardiovascular diseases' covers a wide range of conditions, some of which are related to atherosclerosis, and that atherosclerosis can lead to different disease endpoints, including coronary heart disease (CHD). The Authority referred in its opinion to the Guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA NDA Panel et al., 2018[2]), which states that elevated blood LDL-cholesterol concentration and elevated arterial systolic blood pressure (SBP) are independently associated with an increased risk of coronary heart disease (CHD) and lowering LDL-cholesterol concentration and SBP would generally reduce the risk of CHD. It therefore clarified that the scientific substantiation of claims relating to a reduced risk of CHD can be based on evidence of a reduction in either blood LDL-cholesterol concentration or arterial SBP, and evidence of a reduction in the incidence of CHD is not required. Based on the above and on the pertinent human intervention study[3] provided by the applicant on the effect of the Joselito® ham on the reduction of LDL-cholesterol concentration and blood pressure as risk factors for CHD, from which however no conclusions could be drawn for the scientific substantiation of the claim, the Authority assessed the relationship between the consumption of Joselito® ham and the reduction of blood LDL-cholesterol concentration or blood pressure.

(7) The Authority considered that lowering of LDL-cholesterol concentration and blood pressure is a beneficial effect by reducing the risk of coronary heart disease.

(8) On 4 July 2024, the Authority published a scientific opinion[4] on Joselito® ham and lowering of blood LDL-cholesterol concentration or blood pressure and reduction of coronary heart disease risk.

(9) In its scientific opinion the Authority concluded that, on the basis of the data presented, a cause-and-effect relationship has not been established between the consumption of Joselito® ham and the reduction of blood LDL-cholesterol concentration or blood pressure. 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 health claims, it should not be authorised.

(10) The Authority forwarded its scientific opinion to the Commission, the applicant and the Member States. Upon publication of that opinion, the Commission did not receive any comments from the applicant or members of the public pursuant to Article 16(6) of Regulation (EC) No 1924/2006.

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2 EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food allergens), Turck, D., Bresson, J. L., Burlingame, B., Dean, T., Fairweather-Tait, S.,Heinonen, M., Hirsch-Ernst, K. I., Mangelsdorf, I., McArdle, H. J., Naska, A., Neuhäuser-Berthold, M., Nowicka, G., Pentieva, K., Sanz, Y., Sjödin, A.,Stern, M., Tomé, D., Van Loveren, H., Siani, A. (2018). Guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health: (revision 1). EFSA Journal, 16(1), e05136. https://doi.org/10. 2903/j.efsa.2018. 5136

3 Mayoral, P., Martinez-Salgado, C. S., Santiago, J. M., Rodriguez-Hernandez, M. V., García-Gomez, M. L., Morales, A., López-Novoa, J. M., & Macías-Nuñez,J. F. (2003). Effect of ham protein substitution on oxidative stress in older adults. The Journal of Nutrition, Health & Aging, 7, 84–89

4 EFSA Journal. 2024;22(7):e8862

(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 claim set out in the Annex to this Regulation shall not be included in the Union list of permitted health claims as provided for in Article 14(1) 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
Ursula VON DER LEYEN