# Joselito® and lowering of LDL-cholesterol concentration, blood pressure, and reduction of coronary heart disease risk: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

# Joselito® and lowering of LDL-cholesterol concentration, blood pressure, and reduction of coronary heart disease risk: Evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006

**EFSA Panel on Nutrition, Novel Foods and Food allergens (NDA) | Dominique Turck | Torsten Bohn | Jacqueline Castenmiller | Stefaan De Henauw | Karen Ildico Hirsch-Ernst | Helle Katrine Knutsen | Alexandre Maciuk | Inge Mangelsdorf | Harry J. McArdle | Androniki Naska | Kristina Pentieva | Frank Thies | Sophia Tsabouri | Marco Vinceti | Jean-Louis Bresson | Thibault Fiolet | Alfonso Siani**

**Correspondence:** nda@efsa.europa.eu

**Abstract**

Following an application from Cárnicas Joselito S.A. pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Spain, the Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to '*Joselito ham increases antioxidant substances in the body, reduces blood pressure and plasma triglycerides, decreases oxidative stress and prevents effect in diseases related to the cardiovascular and intestinal systems*'. The scope of the application was proposed to fall under a health claim referring to disease risk reduction. The food constituent that is the subject of the health claim is Joselito, an Iberian ham characterised by a high content of oleic acid. The Panel considers that the food is sufficiently characterised. The Panel considers that lowering of LDL-cholesterol concentration and blood pressure is a beneficial effect by decreasing the risk of coronary heart disease. Upon a request from EFSA, the applicant identified one human intervention study as being pertinent to the claim. However, due to methodological limitations, the Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim. The Panel notes that no human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant. The Panel concludes that a cause and effect relationship has not been established between the intake of Joselito® ham and the reduction of LDL-cholesterol concentration or blood pressure.

**KEYWORDS**

ham, health claims, Iberian ham, Joselito

## CONTENTS

# 1 | INTRODUCTION

## 1.1 | Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006 harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14–17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims. According to this Regulation, an application shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

## 1.2 | Interpretation of the Terms of Reference

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to 'Joselito® ham and lowering of LDL-cholesterol concentration, blood pressure, and reduction of coronary heart disease risk'.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of Joselito® ham, a positive assessment of its safety or a decision on whether Joselito® ham is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

# 2 | DATA AND METHODOLOGIES

## 2.1 | Data

**Information provided by the applicant**

See also section Steps taken by EFSA at the end of this opinion.

**Food/constituent as stated by the applicant**

According to the applicant, the food for which the health claim is made is Joselito® ham.

**Health relationship as claimed by the applicant**

Upon a request from EFSA, the applicant clarified the claimed effect: '*the intake of Joselito® ham, rich in monounsaturated fats and antioxidant substances, reduces blood pressure and plasma triglycerides, having an effect in cardiovascular health*'.

**Mechanism by which the food/constituent could exert the claimed effect as proposed by the applicant**

The applicant claims that 'The intake of Joselito® ham has a preventive effect in diseases related to the cardiovascular system due to its nutritional composition (rich in antioxidants and monounsaturated fatty acids) and its physical-chemical properties' and '120 g of Joselito® ham produces a decrease in plasma triglycerides and blood pressure, decreases lipid peroxidation phenomena and increases the concentration of antioxidants.' The applicant states that 'The high concentration of oleic acid and antioxidant compounds in Joselito ham would be responsible for the oxidative protection of the body's cells' and that the quercetin could induce 'endothelium-mediated relaxation in the vascular smooth muscle of the rat'.

**Wording of the health claim as proposed by the applicant**

The applicant has proposed the following wording for the health claim: '*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*'.

**Specific conditions of use as proposed by the applicant**

According to the applicant, the target population for the claimed effect is 'Adult population without previous pathologies' and 'the amount of food necessary to obtain the declared effect is 120 g/day'.

**Data provided by the applicant**

The health claim application on Joselito® ham pursuant to Article 14 of Regulation (EC) No 1924/2006 was presented in a common and structured format as outlined in the Scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims (EFSA NDA Panel, 2021b).

As outlined in the General guidance for stakeholders on health claim applications (EFSA NDA Panel, 2021a), it is the responsibility of the applicant to provide the totality of the available evidence.

The application contains data claimed as confidential: nutritional composition of two batches of Joselito® and analytical methods used, manufacturing, packaging, distribution and conservation processes.

The application does not contain data claimed as proprietary.

In accordance with Art. 38 of Regulation (EC) No 178/2002[1] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[2] the non-confidential version of the dossier has been published in the OpenEFSA portal.[3]

## 2.2 | Methodologies

The general approach of the NDA Panel for the evaluation of health claim applications is outlined in the EFSA General guidance for stakeholders on health claim applications (EFSA NDA Panel, 2021a).

In assessing each specific food/health relationship, which forms the basis of a health claim, the NDA Panel considers the following key criteria:

(i) the food/constituent is defined and characterised;
(ii) the claimed effect is based on the essentiality of a nutrient; OR the claimed effect is defined and is a beneficial physiological effect for the target population and can be measured in vivo in humans;
(iii) a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Each of these three criteria needs to be assessed by the NDA Panel with a favourable outcome for a claim to be substantiated. In addition, an unfavourable outcome of the assessment of criterion (i) and/or (ii) precludes the scientific assessment of criterion (iii).

The scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health are outlined in a specific EFSA guidance (EFSA NDA Panel, 2018).

## 2.3 | Public consultation

In line with EFSA's policy on openness and transparency (EFSA NDA Panel, 2021a), and for EFSA to receive comments from the scientific community and stakeholders, the Application on 'Joselito® and lowering LDL-cholesterol concentration, blood pressure, and reduction of coronary heart disease risk' (see Section 3.2) was released for public consultation from 6/5/2024 to 27/5/2024 (PC-0930) for which no comments were received.

# 3 | ASSESSMENT

## 3.1 | Characterisation of the food/constituent

The food proposed by the applicant as the subject of the health claim is Joselito® ham.

Joselito® is a ham coming from Iberian pigs reared extensively, fed on acorns in pastures with holm oak and cork oak groves (called 'montanera fattening process'). This ham is made from the hind limb of adult pigs, cut at the level of the ischiopubic symphysis, which includes the whole osteomuscular portion.

[1]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[2]Decision https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf.

[3]https://open.efsa.europa.eu/questions/EFSA-Q-2022-00412.

A detailed summary of the manufacturing process has been provided. The main production steps included salting, washing, settling, post-salting, drying and maturing in the cellar.

The applicant provided the macronutrient composition of Joselito® ham as percentage of total weight (25.4%–29.6% protein, < 0.8% carbohydrates, 25.5–27.3% fat), and the salt content (3.7–3.9 g/100 g) of two batches of Joselito® ham. The fatty acid composition as percentage of total fat (33.6%–36.6% saturated fatty acids, 55.4%–58.0% monounsaturated fatty acids, 8.1% polyunsaturated fatty acids) was described by Bruna-García et al. (2022). No information on stability or shelf-life is provided in the application.

Following a request for clarification by EFSA, the applicant provided a comparison of the fatty acid composition of Joselito® ham with that of another Iberian cured ham as analysed in two published studies (Bruna-García et al., 2022; Fernández et al., 2020) and stated that this ham is characterised by a high content of oleic acid (54% of total fat), which would be the main food constituent responsible for the claimed effect.

The Panel considers that the food Joselito® ham, which is the subject of the health claim, is sufficiently characterised based on the manufacturing process and the nutritional composition information provided.

## 3.2 | Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is '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'. The proposed target population is the 'adult population without previous pathologies'.

Upon a request for clarification by EFSA, 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 applicant also stated that these risk factors lead to the production of reactive oxygen species, which can induce 'lipoprotein oxidation and oxidative modification of LDL, increasing their potential atherogenic properties'.

The Panel notes 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 (e.g. coronary heart disease, ischaemic stroke), depending on the part of the arterial tree affected.

As stated in the Guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA NDA Panel et al., 2018), 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. Therefore, 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.

Conversely, there is some evidence that low blood HDL-cholesterol concentration or elevated blood concentration of triglycerides are associated with an increased risk of CHD. However, changes in any of these factors alone (by dietary modification and/or drugs) have not generally been shown to reduce the risk of CHD. Therefore, human studies on how the consumption of the food/constituent prospectively modifies the risk of CHD are required for the substantiation of these claims to validate the association between these variables and the risk of disease in the context of a particular nutritional intervention (EFSA NDA Panel, 2018).

The same guidance (EFSA NDA Panel, 2018) specifies that a specific induction of antioxidant enzymes (e.g. superoxide dismutase (SOD), catalase (CAT), glutathione peroxidase (GSH-Px), haem oxygenase (HO)) or limiting the decrease in glutathione and glutathione/glutathione disulfide (GSH/GSSG) ratio are considered to be a beneficial physiological effect only if such changes provide (additional) protection of cells and molecules from oxidative damage. Such protection from oxidative damage should be demonstrated in vivo in humans. The same principle applies to non-specific changes in the overall antioxidant capacity of plasma assessed in vivo in humans using methods such as the total reactive antioxidant potential (TRAP), the ferric reducing antioxidant potential (FRAP), the Trolox-equivalent antioxidant capacity (TEAC), the oxygen radical absorbance capacity (ORAC) or the ferrous oxidation–xylenol orange (FOX) assays. In addition, the thiobarbituric acid reactive substances (TBARS) assay is not a reliable in vivo marker of lipid peroxidation. The Panel notes that none of these measures are independent risk factors for CHD or other atherosclerosis-related cardiovascular diseases (CVD).

The applicant provided one pertinent human intervention study (Mayoral et al., 2003) which investigated the effect of Joselito® ham on the blood lipid profile, on mean blood pressure and on changes in some of the aforementioned 'antioxidant measures'. Since the study did not investigate the effect of Joselito® ham on any CVD endpoint, the Panel understands that this study must be evaluated to demonstrate the effect of the Joselito® ham on the reduction of LDL-cholesterol concentration and blood pressure as risk factors for CHD.

The Panel considers that lowering of LDL-cholesterol concentration and blood pressure is a beneficial effect by reducing the risk of CHD.

### 3.3 | Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed, Google Scholar, Scopus, Web of Science, Databases of the Superior Council of Scientific Investigations in Spain. The search strings and key words used for the search have not been provided. There was no time limit, but the applicant focussed on the studies published in the last 5 years (2019–2024).

Upon a request from EFSA, the applicant identified one human intervention study (Mayoral et al., 2003) as being pertinent to the claim.

In a non-randomised, open-label, pre-post human intervention study conducted in Spain (Mayoral et al., 2003), 13 males (aged 65.8 ± 16.1 years) and 8 females (aged 81.2 ± 8.21 years) living in a residential care home were given a basal diet (BD) for 6 weeks, the same diet with 120 g of meat replaced by 120 g of Joselito® ham (Ham Diet, HD) for 6 weeks, then the basal diet for another 6 weeks. The nutritional composition (energy intake and macronutrients) was similar for the BD and the HD, except for the levels of saturated (BD: 47% vs. HD: 29%) and monounsaturated fats (BD: 39% vs. HD: 50%). The Panel notes that this was a single-arm, open label, sequential study. The Panel also notes that it is unclear how participants were recruited into the study, as no eligibility criteria were reported.

Blood pressure and blood lipid profile, among other variables, were assessed at baseline and after each dietary period. Differences between the first study period (BD) and the second study period (Joselito®) were assessed by a one-way analysis of variance (ANOVA) for normally distributed data, while non-parametric tests were used for non-normally distributed data. The Panel notes that the primary outcome of the study was not identified in the publication, that no power calculations were provided and that corrections for multiple comparisons were not considered in the statistical analyses.

Owing to the methodological limitations of the study (unclear eligibility criteria, short duration of the intervention, no control group to account for differences over time, no control for confounders, inappropriate statistical analyses), the Panel considers that no conclusions can be drawn from this study (Mayoral et al., 2003) for the scientific substantiation of the claim.

The applicant also provided one study in rats (Fernández et al., 2020), one study in yeast (Bruna-García et al., 2023) and one study on the composition of Joselito® ham (Bruna-García et al., 2022). The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

**Weight of evidence**

The Panel notes that no human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Joselito® ham and the reduction of LDL-cholesterol concentration or blood pressure.

## 4 | CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, Joselito® ham, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is reduction of '*blood pressure and plasma triglycerides, having an effect in cardiovascular health*'. The target population proposed by the applicant is the 'adult population without previous pathologies'. The Panel considers that lowering of LDL-cholesterol concentration and blood pressure is a beneficial effect by reducing the risk of coronary heart disease.
- 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.

## 5 | DOCUMENTATION AS PROVIDED TO EFSA

Health claim application on pursuant to Article 14 of Regulation (EC) No 1924/2006 (EFSA-Q-2022-00412, HC-2022-7050). Submitted by Cárnicas Joselito S.A.

## 6 | STEPS TAKEN BY EFSA

1. The application was received by EFSA on 29/07/2022.
2. The application was validated on 23/01/2024 and the scientific evaluation started.
3. EFSA sent Additional Data Request (ADR) letter to the Applicant on 05/03/2024. The clock was stopped and restarted on 24/04/2024
4. The updated application on '*Joselito® and lowering of LDL-cholesterol concentration, blood pressure, and reduction of coronary heart disease risk: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006*' was open for public consultation from 06/05/2024 to 27/05/2024 (PC-0930).

5. During its meeting on 07/06/2024, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to 'Joselito® and lowering of LDL-cholesterol concentration, blood pressure, and reduction of coronary heart disease risk: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006'.

## ABBREVIATIONS

| | |
|---|---|
| ADR | Additional Data Request |
| ANOVA | analysis of variance |
| BD | Basal Diet |
| CAT | catalase |
| CHD | coronary heart disease |
| CVD | cardiovascular disease |
| FOX | ferrous oxidation-xylenol orange |
| FRAP | ferric reducing antioxidant potential |
| GSH/GSSG | glutathione/glutathione disulfide |
| GSH-Px | Glutathione peroxidase |
| HD | Ham Diet |
| HDL | High-Density Lipoprotein |
| HO | Haem oxygenase |
| LDL | Low-Density Lipoprotein |
| NDA | Panel on Nutrition, Novel Foods and Food Allergens |
| ORAC | oxygen radical absorbance capacity |
| SBP | systolic blood pressure |
| SOD | Superoxide dismutase |
| TBARS | Thiobarbituric acid reactive substances |
| TEAC | Trolox-equivalent antioxidant capacity |
| TRAP | total reactive antioxidant potential |

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## CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

## REQUESTOR

Competent Authority of Spain following an application by Cárnicas Joselito S.A.

## QUESTION NUMBER

EFSA-Q-2022-00412



## PANEL MEMBERS

Dominique Turck, Torsten Bohn, Jacqueline Castenmiller, Stefaan De Henauw, Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri and Marco Vinceti.

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