



**EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to “complex carbohydrates” and “contribute to satiety” pursuant to Article 14 of Regulation (EC) No 1924/2006**

**EFSA Publication; Tetens, Inge**

*Link to article, DOI:*  
[10.2903/j.efsa.2014.3652](https://doi.org/10.2903/j.efsa.2014.3652)

*Publication date:*  
2014

*Document Version*  
Publisher's PDF, also known as Version of record

[Link back to DTU Orbit](#)

*Citation (APA):*  
EFSA Publication (2014). EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to “complex carbohydrates” and “contribute to satiety” pursuant to Article 14 of Regulation (EC) No 1924/2006. Parma, Italy: European Food Safety Authority. The EFSA Journal, No. 3652, Vol.. 12(5), DOI: 10.2903/j.efsa.2014.3652

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## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to “complex carbohydrates” and “contribute to satiety” pursuant to Article 14 of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to “complex carbohydrates” and “contribute to satiety”. The claimed effect proposed by the applicant is “contribute to satiety” and the proposed target population is infants and young children from birth to three years of age. The Panel considers that the information provided by the applicant does not establish that an increase in satiety is a beneficial physiological effect for infants and young children. The Panel concludes that a cause and effect relationship has not been established between the consumption of “complex carbohydrates” and a beneficial physiological effect for infants and young children in the context of this application.

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#### KEY WORDS

complex carbohydrates, satiety, infants, children, health claims

<sup>1</sup> On request from the Competent Authority of France following an application by Specialised Nutrition Europe (formerly IDACE), Question No EFSA-Q-2008-131, adopted on 9 April 2014.

<sup>2</sup> Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Hendrik Van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

Suggested citation: EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to “complex carbohydrates” and “contribute to satiety” pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2014;12(5):3652, 7 pp. doi:10.2903/j.efsa.2014.3652

Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

## SUMMARY

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to “complex carbohydrates” and “contribute to satiety”.

The scope of the application was proposed to fall under a health claim referring to children’s development and health.

The claimed effect proposed by the applicant is “contribute to satiety”. The target population proposed by the applicant is infants and young children from birth to three years of age.

The Panel considers that the information provided by the applicant does not establish that an increase in satiety is a beneficial physiological effect for infants and young children.

The Panel concludes that a cause and effect relationship has not been established between the consumption of “complex carbohydrates” and a beneficial physiological effect for infants and young children in the context of this application.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> 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 to 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 Article 15 of this Regulation, an application for authorisation 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).

## STEPS TAKEN BY EFSA

- The application was received on 14/02/2008.
- The scope of the application was proposed to fall under a health claim referring to children’s development and health.
- On 26/03/2008, during the validation process of the application, EFSA sent a request to the applicant asking it to provide missing information.
- On 08/08/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 10/10/2013.
- On 21/11/2013, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 29/11/2013. On 24/01/2014, EFSA received the requested information and the clock was restarted, in compliance with Article 16(1) of Regulation (EC) No 1924/2006.
- During its meeting on 09/04/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to “complex carbohydrates” and “contribute to satiety”.

## TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 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: “complex carbohydrates” and “contribute to satiety”.

## EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of “complex carbohydrates”, a positive assessment of its safety, nor a decision on whether “complex carbohydrates” 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.

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<sup>4</sup> 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. OJ L 404, 30.12.2006, p. 9–25.

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 17 of Regulation (EC) No 1924/2006.

## INFORMATION PROVIDED BY THE APPLICANT

**Applicant’s name and address:** Specialised Nutrition Europe (formerly IDACE), 9-31, Avenue des Nerviens, 1040, Brussels, Belgium.

### Food/constituent as stated by the applicant

According to the applicant, the food constituent for which the claim is made is complex carbohydrates. Complex carbohydrates are a group of carbohydrates consisting of available complex carbohydrates (slowly and rapidly digestible starch) and unavailable complex carbohydrates (resistant starch, oligosaccharides and non-starch polysaccharides).

### Health relationship as claimed by the applicant

According to the applicant, all types of available complex carbohydrates have an effect on satiety, owing to the release of energy after digestion, either short term (for rapidly digestible starch) or in the longer-term (for slowly digestible starch).

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

The applicant has proposed the following wording for the health claim: “complex carbohydrates contribute to satiety”.

As equivalent alternative wordings, the applicant has also proposed: “Complex carbohydrates/non-digestible oligosaccharides/starch/dietary fibre/are/provide/promotes/contributes/important/a feeling/satisfying/for satiety/of satisfaction/to satiety”.

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

The target population proposed by the applicant is infants (from birth onwards) and young children (up to three years of age) as defined in Directive 89/398/EEC on foodstuffs intended for particular nutritional uses.

The applicant has proposed that the content of complex carbohydrates in final products should be within the range set in Directive 2006/141/EC on follow-on formulae and Directive 2006/125/EC on processed cereal-based foods. The applicant has proposed that the quantity of complex carbohydrates (starch) in follow-on formulae, “growing up milk”, and cereals for obtaining the health effect is: 0.8-1.8 g/100 mL, 0.8-1.8 g/100 mL and 0.71-1.57 g/100 g respectively.

## ASSESSMENT

The approach used in the evaluation of Article 14 health claims is explained in the general guidance for stakeholders<sup>5</sup>.

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

1. the food/constituent is defined and characterised;
2. the claimed effect is defined and is a beneficial physiological effect;

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<sup>5</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect.

Substantiation of the claim is dependent on a favourable outcome of the assessment of 1, 2 and 3 above. Thus, a cause and effect relationship is considered not to be established if the outcome of any one of these assessments is unfavourable.

### **1. Relevance of the claimed effect to human health**

The claimed effect proposed by the applicant is “contribute to satiety”. The target population proposed by the applicant is infants and young children from birth to three years of age.

During the evaluation process, the applicant was requested to clarify under what circumstances an increase in satiety may be a beneficial physiological effect for infants and young children. In reply, the applicant indicated that an increase in satiety may help a child to sleep longer hours, with fewer interruptions during the nights, and that early development of sleeping through the night is associated with the subsequent weight of the child. The applicant did not provide scientific evidence which could support a beneficial physiological effect of increasing satiety for infants and young children.

The Panel considers that the information provided does not establish that an increase in satiety is a beneficial physiological effect for infants and young children (from birth to three years of age).

The Panel concludes that a cause and effect relationship has not been established between the consumption of “complex carbohydrates” and a beneficial physiological effect for infants and young children in the context of this application.

## **CONCLUSIONS**

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

- The claimed effect proposed by the applicant is “contribute to satiety”. The target population proposed by the applicant is infants and young children from birth to three years of age. The information provided does not establish that an increase in satiety is a beneficial physiological effect for infants and young children.
- A cause and effect relationship has not been established between the consumption of “complex carbohydrates” and a beneficial physiological effect for infants and young children in the context of this application.

## **DOCUMENTATION PROVIDED TO EFSA**

Health claim application on “complex carbohydrates” and “contribute to satiety” pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0051\_FR). February 2008. Submitted by Specialised Nutrition Europe (formerly IDACE).