



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,  
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final

Draft

**COMMISSION REGULATION**

**of**

amending Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council

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## COMMISSION REGULATION

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**amending Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 15(4) thereof,

Having consulted the European Food Safety Authority,

Whereas:

- (1) In order to ensure that for all categories of health claims, only health claims allowed to be made on foods and compliant with the general principles and conditions set in Regulation (EC) No 1924/2006, are submitted to the Authority and therefore subject to the authorisation procedure, it is necessary to recall the conditions for an application to be considered valid and clarify the responsibility of the Member States in this respect in conformity with Article 15(2) and Article 18(3) of Regulation (EC) No 1924/2006.
- (2) Pursuant to Article 20 of Regulation (EC) No 1924/2006 the list of authorised as well as rejected claims has to be published in a register for transparency reasons. The purpose is, as explained in recital 31 of Regulation (EC) No 1924/2006, to avoid multiple applications in respect of claims which have already been assessed and subject to the authorisation procedure. Therefore, it is necessary to clarify among the modalities of presentation of a request, also the conditions applicable for the withdrawals as well as the time limits to submit a withdrawal; in particular it is foreseen that the applicant can only withdraw the application up to the moment the Authority provides its opinion pursuant to Article 16(1) or Article 18(3) of Regulation (EC) 1924/2006; this time limit is necessary in order to preserve the usefulness of the Authority's evaluation of claims and the effectiveness of the procedure for authorisation and rejection of claims and to avoid the presentation of applications on claims which have been already assessed. In this respect, only withdrawals of valid applications submitted according to the conditions set out in the present Regulation can put an end to the procedure, which otherwise will continue after the Authority has issued its opinion.

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<sup>1</sup> OJ L 404, 30.12.2006, p. 9. Regulation as corrected in OJ L 12, 18.1.2007, p. 3).

- (3) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 353/2008 is amended as follows:

- (1) The following Article 7a is added after Article 7.

*"Article 7a*

*Verification of the validity of applications by the Member States*

For applications for authorisations of health claims as referred to in Article 13(5) and Article 14(1) of Regulation (EC) No 1924/2006, the Member States shall, in accordance with Article 15(2)(a) and Article 18(3) of Regulation (EC) No 1924/2006, verify the admissibility of the applications before making them available to the Authority.

The national competent authority shall verify that:

- (i) For applications submitted under Article 15(2) of Regulation (EC) No 1924/2006 the health claim is a health claim as referred to in Article 14(1) of that Regulation.
- (ii) For applications submitted under Article 18(2) of Regulation (EC) No 1924/2006 the health claim is a health claim as referred to in Article 13(5) of that Regulation.

For (i) and (ii) the national competent authority shall verify that the applications include the data as referred to in Article 15(3) of Regulation (EC) No 1924/2006".

- (2) The following Article 7b is added after Article 7a.

*"Article 7b*

*Withdrawal of applications*

- (1) A request for the withdrawal of a valid application must be submitted to the national competent authority of a Member State, to which the application was submitted in accordance with Article 15(2) or Article 18(2) of Regulation (EC) No 1924/2006.

The national competent authority shall, without delay, inform the Authority, the Commission and the other Member States of the withdrawal.

The valid application can be withdrawn by the applicant up to the moment the Authority issues its opinion pursuant to Article 16(1) or Article 18(3) of Regulation (EC) No 1924/2006. Only the withdrawal of the application under the conditions mentioned above puts an end to the procedure.

- (2) Notwithstanding paragraph (1), in the case where the Authority seeks supplementary information from the applicant as provided for in Article 16(2) of Regulation (EC) No 1924/2006 and the applicant fails to provide the additional data within the specified time limit provided by the Authority, the application shall be deemed to be withdrawn. The

Authority shall, without delay, inform the national competent authority, the Commission and the other Member States of the withdrawal".

*Article 2*

This Regulation shall enter into force on the 20th 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*  
*Androulla VASSILIOU*  
*Member of the Commission*