Commission Regulation (EC) No 1169/2009 of 30 November 2009 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 (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1169/2009

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(Text with EEA relevance)

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[(1)], 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 made on foods, only health claims compliant with the general principles and the conditions set out in Regulation (EC) No 1924/2006 are submitted to the European Food Safety Authority (EFSA), hereinafter referred to as the Authority, and therefore subject to the authorisation procedure, it is necessary to lay down the conditions under which applications for authorisation of health claims may 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 an application, also the rules on withdrawals of applications as well as the time limits to submit a request for withdrawal.

(3) The applicant should only be allowed to withdraw an application up to the moment the Authority adopts its opinion pursuant to Article 16(1) or Article 18(3) of Regulation (EC) No 1924/2006. Such 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 submission of applications

on claims which have already been assessed. In this respect, only withdrawals of applications submitted according to the conditions set out in the present Regulation can put an end to the authorisation procedure, which otherwise will continue after the Authority has issued its opinion.

(4) 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

Commission Regulation (EC) No 353/2008[(2)] is amended as follows:

1. the following Article 7a is inserted after Article 7:

Article 7a

Verification of the validity of applications by the Member States

1 In accordance with Article 15(2)(a) and Article 18(3) of Regulation (EC) No 1924/2006, Member States shall verify the validity of applications before making them available to the Authority.

2 For the purposes of paragraph 1, the national competent authority shall verify that applications submitted under Article 15 or 18 of Regulation (EC) No 1924/2006 include the data as referred to in Article 15(3) of that Regulation.

3 The national competent authority shall also verify that:

(i) for applications submitted under Article 15 of Regulation (EC) No 1924/2006 the health claim is a health claim concerning the reduction of disease risk claims or referring to children's development and health;

(ii) for applications submitted under Article 18 of Regulation (EC) No 1924/2006 the health claim is any health claim as referred to in Article 13(5) of that Regulation with the exception of health claims referring to children's development and health.;

2. the following Article 7b is inserted after Article 7a:

Article 7b

Withdrawal of applications

1 An application submitted under Article 15 or 18 of Regulation (EC) No 1924/2006 may be withdrawn by the applicant up to the moment the Authority adopts its opinion pursuant to Article 16(1) or Article 18(3) of Regulation (EC) No 1924/2006.

2 A request for withdrawal of an 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.