Commission Regulation (EU) No 1056/2012 of 12 November 2012 amending Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes with regard to transitional measures (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1056/2012

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(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 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97[(1)], and in particular Article 17(5) thereof,

Whereas:

(1) Pursuant to Article 17(2) of Regulation (EC) No 1332/2008 the deadline for submitting enzyme applications is 24 months after the date of application of the implementing measures to be laid down in accordance with Article 9(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[(2)].

(2) Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008[(3)] is applicable from 11 September 2011.

(3) The establishment of the Union list of food enzymes should take place smoothly and should not disturb the existing food enzyme market, in particular small and medium sized enterprises. If necessary, any appropriate transitional measures for the purposes of the establishment of this list may be adopted in accordance with the procedure referred to in Article 17(5) of Regulation (EC) No 1332/2008.

(4) Pursuant to Article 5(3) of Regulation (EU) No 234/2011, the applicants shall take into account latest guidance concerning the data required for risk assessment established by the European Food Safety Authority ("the Authority") that is available at the time of the submission of the application. The Authority adopted a scientific opinion on 23 July 2009 providing guidance on data requirements for the evaluation of food enzyme applications[(4)] and issued on 8 July 2011 an explanatory note for the guidance on the submission of a dossier on food enzymes[(5)]. It also adopted a scientific opinion on 25 May 2011 updating the guidance for the risk assessment of genetically modified micro-organisms and their products intended for food and feed use[(6)].

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 1056/2012. (See end of Document for details)*

(5) The detailed requirements set out in Regulation (EU) No 234/2011, by the Authority's guidance documents and explanatory note were adopted later than Regulation (EC) No 1332/2008.

(6) The experience gained in the meantime shows that the initial deadline for submitting applications is insufficient in order to allow stakeholders and in particular small and medium sized enterprises to produce all necessary data within that period. More time than originally foreseen is required for the submission of the applications to enhance the smooth transition from the present legal situation to the system established by Regulation (EC) No 1332/2008. Therefore, the 24-month period established by Regulation (EC) No 1332/2008 for submitting enzyme applications should be extended.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 17(2) of Regulation (EC) No 1332/2008, the second subparagraph is replaced by the following:

> The deadline for submitting such applications shall be 42 months after the date of application of the implementing measures laid down in accordance with Article 9(1) of Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

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, 12 November 2012.

For the Commission

The President

José Manuel BARROSO