Commission Regulation (EU) No 1057/2012 of 12 November 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of dimethyl polysiloxane (E 900) as an anti-foaming agent in food supplements (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1057/2012

of 12 November 2012

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of dimethyl polysiloxane (E 900) as an anti-foaming agent in food supplements

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(1)], and in particular Article 10(3) and Article 30(5) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.

(2) That list may be amended in accordance with the procedure referred to in 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)].

(3) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application.

(4) An application for authorisation of the use of dimethyl polysiloxane (E 900) as an anti-foaming agent in food supplements was submitted and has been made available to the Member States.

(5) Food supplements in the form of effervescent tablets usually contain acids (such as citric acid) and hydrocarbonate or carbonate salts. The tablets are added to water and carbon dioxide gas is produced during the dissolution process. This gas is usually generating ascending foam overflowing the drinking glass. The ascending foam needs therefore to be partly or completely suppressed by adding an anti-foaming agent to the effervescent tablet. Dimethyl polysiloxane (E 900) can be used as a more efficient alternative to the currently authorised polysorbates and sucrose esters of fatty acids.

(6) The Report from the Commission on Dietary Food Additive Intake in the European Union[(3)] concluded that dimethyl polysiloxane (E 900) needed no further examination,

since the theoretical intake based on conservative assumptions on food consumption and additive usage did not exceed the Acceptable Daily Intake ('ADI'). The ADI value of 1,5 mg/kg bw was established on 18 May 1990 by the Scientific Committee for Food[4]. The additional intake based on the new use as anti-foaming agent in food supplements in the form of effervescent tablets is estimated to be below 10 % of the ADI. It is therefore appropriate to allow the use of dimethyl polysiloxane (E 900) in food supplements in the form of effervescent tablets.

(7) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health. Since the authorisation of use of dimethyl polysiloxane (E 900) in food supplements in the form of effervescent tablets constitutes an update of that list which is not liable to have an effect on human health, it is not necessary to seek the opinion of the European Food Safety Authority.

(8) Pursuant to the transitional provisions of Commission Regulation (EU) No 1129/2011[5] the list of food additives set out in Annex II to Regulation (EC) No 1333/2008 applies in principle from 1 June 2013. In order to allow the use of dimethyl polysiloxane (E 900) in food supplements before that date, it is necessary to specify an earlier date of application with regard to this use of that food additive.

(9) Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.

(10) 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

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 1057/2012. (See end of Document for details)*