Commission Regulation (EU) No 957/2014 of 10 September 2014 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the removal of montan acid esters (E 912) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 957/2014

of 10 September 2014

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the removal of montan acid esters (E 912)

(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 Articles 10(3) and 14 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) Commission Regulation (EU) No 231/2012[(2)] lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) Montan acid esters (E 912) are waxes authorised as glazing agents for surface treatment of citrus fruit, melons, papayas, mangos, avocados and pineapples in accordance with Annex II to Regulation (EC) No 1333/2008.

(4) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority ('the Authority').

(5) For that purpose, a program for the re-evaluation of food additives is laid down in the Commission Regulation (EU) No 257/2010[(3)]. Pursuant to Regulation (EU) No 257/2010 the re-evaluation of food additives other than colours and sweeteners has to be done until 31 December 2018. However, certain food additives, including montan acid esters (E 912), havehigher priority and should be evaluated earlier.

(6) Pursuant to Article 6(1) of Regulation (EU) No 257/2010, the interested business operator(s) and any other interested party shall submit the data related to the re-evaluation of a food additive within the period set by the Authority in its call for data.

(7) On 15 February 2012 the Authority launched a public call for scientific data on montan acid esters (E 912)[(4)] inviting interested parties and stakeholders to submit the requested data or to provide information by 1 June 2012.

(8) On 7 June 2013 the Authority delivered a Scientific Opinion on the re-evaluation of montan acid esters (E 912) as food additives[5]. The opinion stated that no data on toxicokinetics and reproductive and developmental toxicity of montan acid esters were available. The available data on short-term and subchronic toxicity, genotoxicity and chronic toxicity and carcinogenicity of montan acid esters were limited. No data on the usage were submitted. Based on those limitations the Authority concluded that montan acid esters as food additive could not be evaluated.

(9) Article 6(5) of Regulation (EU) No 257/2010 provides that where the information necessary for the completion of the re-evaluation of a particular food additive is not provided by the interested business operator(s) and any other interested party to the Authority within the set deadlines, the food additive may be removed from the Union list of approved food additives in accordance with the procedure laid down in Article 10(3) of Regulation (EC) No 1333/2008. Accordingly, the specifications of this food additive should also be removed from Regulation (EU) No 231/2012.

(10) Pursuant to Article 10(3) of Regulation (EC) No 1333/2008, the Union list of approved food additives shall be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council[6].

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

(12) Therefore, Annex II to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012 should be amended by removing montan acid esters (E 912) from the Union list of authorised food additives since due to the absence of recent scientific evidence its inclusion in the list can no longer be justified.

(13) 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

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

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Foods containing montan acid esters (E 912) that have been lawfully placed on the market before the entry into for of this Regulation, may continue to be marketed until stocks are exhausted.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 September 2014.

For the Commission

The President

José Manuel BARROSO