Commission Regulation (EU) No 724/2013 of 26 July 2013 amending Regulation (EU) No 231/2012 as regards specifications on several polyols (Text with EEA relevance)

COMMISSION REGULATION (EU) No 724/2013

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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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(1)], and in particular Article 14 thereof,

Having regard to 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)], and in particular Article 7(5) thereof,

Whereas:

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

(2) Those specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.

(3) On 29 November 2011 an application was submitted for the amendment of specifications concerning several polyols which was subsequently made available to the Member States.

(4) Regulation (EU) No 231/2012 lays down specifications for Mannitol (E 421(i)) and Mannitol manufactured by fermentation (E 421(ii)). In order to achieve more clarity and coherence, the currently authorised food additive ‘Mannitol (E 421(i))’ should be renamed as ‘Mannitol by hydrogenation and consequently its definition should be altered. Therefore, the specifications for that food addive should be amended.

(5) Isomalt (E 953) is manufactured in a two-stage process in which sugar is first transformed into isomaltulose and then hydrogenated. The crystalline form is obtained by a drying process afterwards. A request was made to include a different form of isomalt, aqueous solutions of isomalt, in the specifications laid down by Regulation (EU) No 231/2012. The proposed form complies with those specifications and is available for commercial use. That form of isomalt is cost-saving and time-efficient for the industry and is consequently of interest, for example, to confectionery

manufacturers. Therefore, the description of Isomalt (E 953) in the specifications should be amended.

(6) The specifications laid down by Regulation (EU) No 231/2012 provide that one of the purity criteria for polyols is the level of demineralisation or residual minerals, characterised by chlorides, sulphates and/or sulphated ashes. The same polyols are used as excipients for pharmaceutical products, and the European Pharmacopoeia have adopted conductivity as the method to evaluate the level of demineralisation of polyols. By doing so, a triple measure (of chlorides, sulphates and/or sulphated ashes) was replaced by a single one, simpler to carry out, cost-effective and more friendly to the environment. Therefore, specifications should be amended for the food additives Sorbitol (E 420 (i)), Sorbitol syrup (E 420 (ii)), Mannitol (E 421 (i)), Mannitol manufactured by fermentation (E 421 (ii)), Isomalt (E 953), Maltitol (E 965 (i)), Maltitol syrup (E 965 (ii)), Xylitol (E 967) and Erythritol (E 968) by deleting the criteria on chlorides, sulphates and sulphated ashes and replacing them with a single criterion, conductivity.

(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, except where the update in question is not liable to have an effect on human health. Since the updates concerned are not liable to have an effect on human health, it is not necessary to seek the opinion of the European Food Safety Authority.

(8) Regulation (EU) No 231/2012 should therefore be amended accordingly.

(9) 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

The Annex to Regulation (EU) No 231/2012 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 the Member States.

Done at Brussels, 26 July 2013.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 724/2013. (See end of Document for details)*

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ANNEX

The Annex to Regulation (EU) No 231/2012 is amended as follows:

(1) In the entry for food additive E 420 (i) Sorbitol, the specifications as regards purity are replaced by the following:

Purity	
Water content	Not more than 1,5 % (Karl Fischer Method)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
Reducing sugars	Not more than 0,3 % (expressed as glucose on dry weight basis)
Total sugars	Not more than 1 % (expressed as glucose on dry weight basis)
Nickel	Not more than 2 mg/kg (expressed on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

(2) In the entry for food additive E 420 (ii) Sorbitol syrup, the specifications as regards purity are replaced by the following:

Purity	
Water content	Not more than 31 % (Karl Fischer Method)
Conductivity	Not more than 10 µS/cm (on the product as such) at temperature 20 °C
Reducing sugars	Not more than 0,3 % (expressed as glucose on dry weight basis)
Nickel	Not more than 2 mg/kg (expressed on dry weight basis)
Arsenic	Not more than 3 mg/kg (expressed on dry weight basis)
Lead	Not more than 1 mg/kg (expressed on dry weight basis)

(3) The entry for food additive E 421(i) Mannitol is amended as follows:

(a) the heading is replaced by the following:
E 421 (i) MANNITOL BY HYDROGENATION

(b) the definition is replaced by the following:

Definition	Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose. The product contains min. 96 % mannitol. The part of the product which is not mannitol is mainly composed of sorbitol (2 % max), maltitol (2 % max) and isomalt (1,1 GPM (1-O-alpha-D-Glucopyranosyl-D-mannitol dehydrate): 2 % max and 1,6 GPS (6-O-alpha-D- Glucopyranosyl-D-Sorbitol): 2 % max). Unspecified impurities shall not represent more than 0,1 % of each.

(c) the specifications as regards purity are replaced by the following:

Purity	
Water content	Not more than 0,5 % (Karl Fischer Method)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
Reducing sugars	Not more than 0,3 % (expressed as glucose)
Total sugars	Not more than 1 % (expressed as glucose)
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg

(4) In the entry for food additive E 421(ii) Mannitol manufactured by fermentation the specifications as regards purity are replaced by the following:

Purity	
Arabitol	Not more than 0,3 %
Water content	Not more than 0,5 % (Karl Fischer Method)
Conductivity	Not more than 20 µS/cm (on 20 % dry solids solution) at temperature 20 °C
Reducing sugars	Not more than 0,3 % (expressed as glucose)
Total sugars	Not more than 1 % (expressed as glucose)