Commission Regulation (EU) 2018/681 of 4 May 2018 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for Polyvinyl alcohol-polyethylene glycol graft-co-polymer (E 1209) (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/681

of 4 May 2018

amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for Polyvinyl alcohol-polyethylene glycol graft-co-polymer (E 1209)

(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) In accordance with Annex II to Regulation (EC) No 1333/2008, polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209) is authorised as a food additive in the food category 17.1 ‘food supplements supplied in a solid form including capsules and tablets, excluding chewable forms’. According to the current EU specifications, the maximum permissible amount of ethylene glycol and diethylene glycol, which are present as impurities in the food additive polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209), is 50 mg/kg for each of them.

(4) On 26 June 2015 an application was submitted for the amendment of the specifications regarding the limits for ethylene glycol and diethylene glycol in polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209). The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/681. (See end of Document for details)*

(5) The applicant requested to increase the maximum individual limits for those two impurities in the specifications of polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209) to an overall limit of 'Not more than 620 mg/kg for ethylene glycol individually or in combination with diethylene glycol'. The applicant claimed that this specification was included in the original application that was assessed by the European Food Safety Authority ('the Authority') in 2013[(4)] and that the proposed limit (620 mg/kg for ethylene glycol individually or in combination with diethylene glycol) was identical to the limit for ethylene glycol in pharmaceutical products.

(6) In its opinion of 18 May 2017[(5)] the Authority concluded that the applicant's request would result in total exposure from food additive uses below the group tolerable daily intake (TDI) of 0,5 mg/kg body weight/day allocated by the Scientific Committee on Food (SCF) and that the amendment to the specifications as regards the level of the impurities ethylene glycol and diethylene glycol in polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209) proposed by the applicant is not of a safety concern. However, the Authority noted that the analytical results provided were consistently and considerably lower (up to 360 mg/kg) than the proposed level of 620 mg/kg for ethylene glycol individually or in combination with diethylene glycol in the EU specifications for E 1209.

(7) It followed from the discussions with Member States at the Working Party of Governmental Experts on Food Additives that the maximum limit for ethylene glycol and diethylene glycol should be kept as low as can reasonably be achieved as demonstrated by the analytical data to limit their contribution to the TDI.

(8) When updating specifications laid down in Regulation (EU) No 231/2012, it is necessary to take into account the specifications and analytical techniques for food additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

(9) JECFA's specifications for polyvinyl alcohol-polyethylene glycol graft-co-polymer (INS 1209) were prepared at the 80th JECFA's meeting[(6)] and published in the FAO JECFA Monographs 17[(7)] in 2015. The level for ethylene glycol and diethylene glycol set therein is of 'Not more than 400 mg/kg (singly or in combination)'.

(10) Consequently, it is appropriate to amend the levels of the impurities ethylene glycol and diethylene glycol in the food additive polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209) to 'not more than 400 mg/kg for ethylene glycol individually or in combination with diethylene glycol'.

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

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2018/681. (See end of Document for details)*

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 all Members States.

Done at Brussels, 4 May 2018.

For the Commission

The President

Jean-Claude JUNCKER