Commission Regulation (EU) No 594/2012 of 5 July 2012 amending Regulation (EC) 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non dioxin-like PCBs and melamine in foodstuffs (Text with EEA relevance)

COMMISSION REGULATION (EU) No 594/2012

of 5 July 2012

amending Regulation (EC) 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non dioxin-like PCBs and melamine in foodstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[(1)], and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006[(2)] sets maximum levels for certain contaminants in foodstuffs.

(2) Commission Regulation (EU) No 1259/2011[(3)], amending Regulation (EC) No 1881/2006, established new maximum levels for non dioxin-like PCBs applicable as from 1 January 2012. It is appropriate to provide that those maximum levels are not applicable to foodstuffs which were lawfully placed on the market before that date.

(3) Commission Regulation (EU) No 105/2010[(4)], amending Regulation (EC) No 1881/2006, established a final lower maximum level for Ochratoxin A in spices, which is supposed to be achievable by applying good practices. To enable the spices producing countries to put prevention measures in place and in order to avoid disruptions of trade to an unacceptable extent, that Regulation furthermore provided for a higher maximum level to be applied for a limited period of time. The Regulation furthermore provided that an assessment should be performed of the achievability of the lower levels for ochratoxin A by applying good practices in the different producing regions in the world. This assessment had to be done before the lower maximum level of Ochratoxin A would become applicable. Although a significant improvement in the application of good practices in the different producing regions in the world has been noticed, the projected lower maximum level for Ochratoxin A is not yet achieavable in *Capsicum* species on a consistent basis. It is therefore appropriate to postpone the application of the lower maximum level for *Capsicum* spp.

(4) Wheat gluten is produced as a co-product of the starch production. Evidence has been provided that the current maximum level of Ochratoxin A in wheat gluten is no longer achievable, in particular at the end of the storage season, even with the strict application of good practices as regards storage, possibly due to the changing climate conditions.

It is therefore appropriate to modify the current maximum level to a level which is achievable by applying good practices and which still provides a high level of human health protection.

(5) The Scientific Panel on Contaminants in the Food Chain of the European Food Safety Authority (EFSA) has, on a request from the Commission, adopted on 4 April 2006 an updated scientific opinion relating to ochratoxin A in food[(5)], taking into account new scientific information and derived a tolerable weekly intake (TWI) of 120 ng/kg b.w. In accordance with the conclusions of the opinion adopted by EFSA, the envisaged changes as regards Ochratoxin A in this Regulation continue to provide a high level of human health protection.

(6) The EFSA has, on a request from the Commission, on 18 March 2010, adopted a scientific opinion related to the melamine in feed and food[(6)]. Its findings show that exposure to melamine can result in the formation of crystals in the urinary tract. Those crystals cause proximal tubular damage and have been observed in animals and children as a result of incidents involving adulteration of feed and infant formula with melamine, leading to fatalities in some instances. The Codex Alimentarius Commission has established maximum levels for melamine in feed and food[(7)]. It is appropriate to include those maximum levels in Regulation (EC) No 1881/2006 to protect public health as those levels are in accordance with the conclusions of the EFSA's opinion.

(7) Therefore, Regulation (EC) No 1881/2006 should be amended accordingly.

(8) 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 have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Amending provisions

Regulation (EC) No 1881/2006 is amended as follows:

(1) In Article 11, the first paragraph is amended as follows:

(a) the introductory sentence is replaced by the following:

> This Regulation shall not apply to products that were placed on the market before the dates referred to in points (a) to (f) in conformity with the provisions applicable at the respective date:

(b) the following points (e) and (f) are added:

(e) 01 January 2012 as regards the maximum levels for non dioxin-like PCBs laid down in section 5 of the Annex;

(f) 01 January 2015 as regards the maximum level for Ochratoxin A in *Capsicum* spp. laid down in point 2.2.11. of the Annex.

(2) The Annex is amended in accordance with the Annex to this Regulation.

Article 2

Entry into force

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

It shall apply from the date of entry into force with the exception of the provisions laid down in point 2.2.11 of the Annex which shall apply from 1 July 2012.

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

Done at Brussels, 5 July 2012.

For the Commission

The President

José Manuel BARROSO