Commission Regulation (EU) 2016/239 of 19 February 2016 amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane alkaloids in certain cereal-based foods for infants and young children (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/239

of 19 February 2016

amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane alkaloids in certain cereal-based foods for infants and young children

(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) The Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority (EFSA) adopted an opinion on tropane alkaloids in food and feed[(3)].

(3) Tropane alkaloids are secondary metabolites which naturally occur in plants of several families including *Brassicaceae*, *Solanaceae* and *Erythroxylaceae*. More than 200 TAs have been identified so far. The most studied tropane alkaloids are (-)-hyoscyamine and (-)-scopolamine. Atropine is the racemic mixture of (-)-hyoscyamine and (+)-hyoscyamine of which only the (-)-hyoscyamine enantiomer exhibits anticholinergic activity.

(4) The presence of tropane alkaloids in genus *Datura* is well known. *Datura stramonium* is widely distributed in temperate and tropical regions and for this reason seeds of *Datura stramonium* have been found as impurities in linseed, soybean, sorghum, millet, sunflower and buckwheat and products thereof. The *Datura stramonium* seeds cannot be easily removed from sorghum, millet and buckwheat by sorting and cleaning and therefore sorghum, millet and buckwheat and their derived products and cereal based foods containing these are found to be contaminated with tropane alkaloids.

(5) The CONTAM Panel established a group Acute Reference Dose ('ARfD') of 0,016 μg/kg body weight ('b.w.') expressed as the sum of (-)-hyoscyamine and (-)-scopolamine, assuming equivalent potency. The CONTAM Panel concluded that, based on the limited information available, the dietary exposure of toddlers could exceed significantly the group ARfD.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/239. (See end of Document for details)*

(6) It is therefore appropriate to establish a maximum level for (-)-hyoscyamine and (-)-scopolamine in cereal-based foods for infants and young children containing millet, sorghum, buckwheat or their derived products. However, as for analytical reason it is not always possible to distinguish between the enantiomers of hyoscyamine, it is appropriate to establish the maximum level for atropine and scopolamine. As the synthesis of tropane alkaloids in plants leads to (-)-hyoscyamine and (-)-scopolamine and not to (+)-hyoscyamine, analytical results on atropine in food of plant origin reflects the occurrence of (-)-hyoscyamine.

(7) It is appropriate to establish the sampling rules to be applied for the control of compliance with the maximum levels.

(8) Regulation (EC) No 1881/2006 should therefore be amended accordingly.

(9) 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:

Article 1

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

Article 2

The sampling for the control of compliance with the maximum levels shall be performed in accordance with the rules set out in Part J of Annex I to Commission Regulation (EC) No 401/2006[(4)].

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*.

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

Done at Brussels, 19 February 2016.

For the Commission

The President

Jean-Claude JUNCKER