Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs (Text with EEA relevance)

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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 Panel) of the European Food Safety Authority (EFSA) adopted an opinion on arsenic in food[(3)] on 12 October 2009. In this opinion, CONTAM Panel concluded that the provisional tolerable weekly intake (PTWI) of 15 μg/kg body weight established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is no longer appropriate as data had shown that inorganic arsenic causes cancer of the lung and urinary bladder in addition to skin, and that a range of adverse effects had been reported at exposures lower than those reviewed by the JECFA.

(3) CONTAM Panel identified a range of benchmark dose lower confidence limit ($BMDL_{01}$) values between 0,3 and 8 μg/kg b.w. per day for cancers of the lung, skin and bladder, as well as skin lesions. The scientific opinion concluded that the estimated dietary exposures to inorganic arsenic for average and high level consumers in Europe are within the range of the $BMDL_{01}$ values identified, and that therefore there is little or no margin of exposure and the possibility of a risk to some consumers cannot be excluded.

(4) The scientific opinion identified high consumers of rice in Europe, such as certain ethnic groups, and children under three years of age as the most exposed to inorganic arsenic dietary exposure. Dietary exposure to inorganic arsenic for children under three years old, including from rice-based foods, is in general estimated to be about 2 to 3-fold that of adults.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/1006. (See end of Document for details)*

(5) Since the analysis of inorganic arsenic is reliable for rice and rice based products, maximum levels for inorganic arsenic should be set for rice and rice based products. Differentiated maximum levels should be proposed in view of the arsenic content.

(6) The scientific information on the need for a specific maximum level for parboiled milled rice is very recent. Therefore, Member States should collect additional data before 1 January 2018 on the inorganic arsenic content of this commodity in order to confirm the need for a specific maximum level for this commodity and to reassess the maximum limit.

(7) The occurrence data demonstrate that rice waffles, rice wafers, rice crackers and rice cakes can contain high levels of inorganic arsenic and these commodities can make an important contribution to the dietary exposure of infants and young children. Therefore, a specific maximum level for these commodities should be envisaged.

(8) Rice is an important ingredient in a broad variety of food for infants and young children. Therefore, a specific maximum level should be established for this commodity when used as an ingredient for the production of such food.

(9) Member States and food business operators should be allowed time to adapt to the new maximum levels established by this Regulation. The date of application of the maximum levels of arsenic should therefore be deferred.

(10) 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 maximum levels of arsenic in subsection 3.5 (Arsenic (inorganic)) of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, shall apply from 1 January 2016.

Foodstuffs not complying with these maximum levels which are lawfully placed on the market prior to the date of application may continue to be marketed after that date until their date of minimum durability or use-by-date.

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, 25 June 2015.

For the Commission

The President

Jean-Claude JUNCKER