Commission Regulation (EU) 2019/1901 of 7 November 2019 amending Regulation (EC) No 1881/2006 as regards maximum levels of citrinin in food supplements based on rice fermented with red yeast Monascus purpureus (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/1901

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amending Regulation (EC) No 1881/2006 as regards maximum levels of citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus*

(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 citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus*.

(2) Following a request from the Commission to deliver a scientific opinion on the health risks from citrinin in food and feed, on 2 March 2012, the Scientific Panel on Contaminants in the Food Chain of the European Food Safety Authority ('the Authority') adopted an opinion on the risks for public and animal health related to the presence of citrinin in food and feed[(3)]. The Scientific Panel on Contaminants concluded that based on the available data, a concern for genotoxicity and carcinogenicity could not be excluded as regards citrinin at the level of no concern for nephrotoxicity.

(3) Data available on the presence of citrinin in certain red yeast rice preparations revealed high levels of citrinin in those preparations. Therefore, a maximum level for citrinin in red yeast rice preparations was established in Regulation (EC) No 1881/2006. Given the gaps in knowledge as regards the presence of citrinin in red yeast rice preparations and in other foodstuffs and the remaining uncertainties as regards its carcinogenicity and genotoxicity, a review of the maximum level was considered to be appropriate.

(4) In 2015, the Authority published a call for proposals to investigate the concentrations of citrinin in food samples with special focus on grains and grain-based products from different geographic regions in Europe. The report describing the outcome of these investigations 'Occurrence of citrinin in food'[(4)] was published in 2017. Representative data on the occurrence of citrinin in food in Europe were obtained, mainly in cereals and cereal products and food supplements based on rice fermented with red yeast.

(5) The new occurrence data on citrinin indicate that there is no need to establish the maximum levels of citrinin in food other than red yeast rice supplements. However, for citrinin in food supplements containing red yeast *Monascus purpureus* the obtained

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2019/1901. (See end of Document for details)*

representative occurrence data provide evidence that the maximum level should be lowered. No new toxicity data on citrinin, requiring an update of the Authority's assessment of the risks of citrinin for public health, have become available. Therefore, the uncertainties as regards the genotoxicity and carcinogenicity of citrinin remain. It is therefore necessary for the protection of public health that the levels of citrinin in food are as low as reasonable achievable. This is particularly relevant for food supplements based on rice fermented with red yeast as data provide evidence that very high levels of citrinin can be found in certain samples of these products, resulting in a high exposure to citrinin for consumers of these products. At the same time, according to the available data, it follows that by applying good manufacturing processes low levels of citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus* can be achieved. Given the remaining uncertainties as regards the toxicity of citrinin and the feasibility to achieve low levels of citrinin by applying good manufacturing practices, it is appropriate to lower the maximum level for citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus* to ensure a high level of human health protection.

(6) A reasonable period should be provided to allow the Member States and food business operators to adapt to the new requirements set out in this Regulation. Regulation (EC) No 1881/2006 should therefore be amended accordingly.

(7) 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

Food supplements based on rice fermented with red yeast *Monascus purpureus* that were lawfully placed on the market before the entry into force of this Regulation may remain on the market 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.*

It shall apply from 1 April 2020.

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

Done at Brussels, 7 November 2019.

For the Commission

The President

Jean-Claude JUNCKER