Commission Regulation (EU) 2020/2040 of 11 December 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of pyrrolizidine alkaloids in certain foodstuffs (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/2040

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(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) On 8 November 2011, the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority ('the Authority') published a scientific opinion on the risks to public health related to the presence of pyrrolizidine alkaloids in food and feed[(3)]. The CONTAM Panel concluded that 1,2-unsaturated pyrrolizidine alkaloids may act as genotoxic carcinogens in humans. The CONTAM Panel concluded that there is a possible health concern for those toddlers and children who are high consumers of honey. In addition to honey, there are other possible sources of dietary exposure to pyrrolizidine alkaloids, which the CONTAM Panel was not able to quantify due to the lack of data. It came to the conclusion that, although no occurrence data were available, exposure to pyrrolizidine alkaloids from pollen, tea, herbal infusions and herbal dietary supplements could potentially present a risk of both acute and chronic effects in the consumer.

(3) In April 2013, the Authority published a call for proposals to investigate the concentrations of pyrrolizidine alkaloids in animal-derived food products including milk and milk products, eggs and meat and meat products, and for plant-derived food products including (herbal) teas and food supplements, across different regions in Europe. The outcome of the investigations was published on 3 August 2015[(4)].

(4) On 26 August 2016, the Authority published a scientific report on the dietary exposure assessment to pyrrolizidine alkaloids in the European population[(5)], taking into account new occurrence data. The report concluded that tea and herbal infusions are the main contributors to human exposure to pyrrolizidine alkaloids and that pollen-based supplements also contribute significantly to that exposure. It found that the exposure to

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/2040. (See end of Document for details)*

pyrrolizidine alkaloids related to the consumption of honey was lower. It also concluded that herbal food supplements can contribute significantly to the exposure but there was a lack of sufficient occurrence data.

(5) On 27 July 2017, the Authority published the statement on the risks for human health related to the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements[6]. The CONTAM Panel established a new reference point of 237 µg/kg body weight per day to assess the carcinogenic risks of pyrrolizidine alkaloids and concluded that there is a possible concern for human health related to the exposure to pyrrolizidine alkaloids, in particular for frequent and high consumers of tea and herbal infusions in the general population but, in particular, for the younger groups of the population.

(6) The presence of pyrrolizidine alkaloids in these foods can be minimised or prevented by the application of good agricultural and harvest practices. The setting of maximum levels ensures that good agricultural and harvest practices are applied in all production regions to ensure a high level of human health protection. It is therefore appropriate to set maximum levels in foodstuffs which contain significant levels of pyrrolizidine alkaloids and which therefore contribute significantly to the human exposure or which are of relevance for the exposure of vulnerable groups of the population.

(7) In certain production regions, good agricultural and harvest practices have only been recently introduced or have still to be implemented, therefore it is appropriate to provide for a reasonable period to allow all production regions to introduce such practices. Two growing seasons are necessary for a full implementation of the good agricultural and harvest practices to ensure sufficient supply for food business operators to produce foodstuffs that comply with the new requirements set out in this Regulation.

(8) Taking into account that the foodstuffs covered by this Regulation have a long shelf life of up to three years, it is appropriate to provide for a significantly long transitional period so that foodstuffs which have been lawfully placed on the market before the date of application of this Regulation can remain sufficiently long on the market. A transitional period of 18 months is appropriate to enable the selling to the final consumer of the products produced before the date of application.

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

(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

Foodstuffs listed in the Annex that were lawfully placed on the market before 1 July 2022 may remain on the market until 31 December 2023.

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 July 2022.

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

Done at Brussels, 11 December 2020.

For the Commission

The President

Ursula VON DER LEYEN