*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for consultation and discussion.*

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EC) 1881/2006 as regards maximum levels of pyrrolizidine alkaloids in certain foods

(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]](#footnote-1), and in particular Article 2(3) thereof,

Whereas:

1. Commission Regulation (EC) No 1881/2006[[2]](#footnote-2) sets maximum levels for certain contaminants in foodstuffs.
2. In October 2011, the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (the Authority) adopted a scientific opinion on the risks to public health related to the presence of pyrrolizidine alkaloids in food and feed[[3]](#footnote-3).The CONTAM Panel concluded that 1,2-unsaturated PAs 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. It was furthermore concluded 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 have been published in 2015[[4]](#footnote-4). Pyrrolizidine alkaloids were detected in only 2 % of the samples of the animal derived foods and in case of detection, the levels were low. In contrast, pyrrolizidine alkaloids were found in 91 % of the samples of all types of (herbal teas) and in 60 % of the samples of food supplements, with highly variable levels.
4. In July 2016, the Authority approved a scientific report on the dietary exposure assessment to pyrrolizidine alkaloids in the European population[[5]](#footnote-5), following a request from the Commission for a dietary exposure assessment to pyrrolizidine alkaloids in honey, tea, herbal infusions (herbs) and food supplements, taking into account new occurrence data.
5. Following initial discussions on appropriate risk management measures to ensure a high level of human health protection, the Commission requested the Authority to assess the health risks related to the estimated exposures to pyrrolizidine alkaloids from honey, tea, herbal infusions and food supplements. In June 2017, the Authority approved the statement on the risks for human health related to the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements[[6]](#footnote-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.
6. It is therefore appropriate to set maximum levels in foodstuffs which contain significant levels of pyrrolizidine alkaloids and which contribute significantly to the human exposure or which are of relevance for the exposure of vulnerable groups of the population.
7. A reasonable period should be provided to allow the food business operators to adapt to the new requirements set out in this Regulation.
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

Foodstuffs listed in the Annex to this Regulation that were lawfully placed on the market before the date of application of this Regulation may remain on the market until (6 months after the entry into application).

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,

 For the Commission

 The President

1. OJ L 37, 13.2.1993, p. 1. [↑](#footnote-ref-1)
2. Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5). [↑](#footnote-ref-2)
3. EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Pyrrolizidine alkaloids in food and feed. EFSA Journal 2011; 9(11):2406. [134 pp.] doi:10.2903/j.efsa. 2011.2406. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal) [↑](#footnote-ref-3)
4. Mulder PPJ, López Sánchez P, These A, Preiss-Weigert A and Castellari M, 2015. Occurrence of Pyrrolizidine Alkaloids in food. EFSA supporting publication 2015:EN-859, 116 pp. Available online: [www.efsa.europa.eu/publications](http://www.efsa.europa.eu/publications) [↑](#footnote-ref-4)
5. EFSA (European Food Safety Authority), 2016. Dietary exposure assessment to pyrrolizidine alkaloids in the European population. EFSA Journal 2016;14(8):4572, 50 pp. doi:10.2903/j.efsa.2016.4572 [↑](#footnote-ref-5)
6. EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2017. Statement on the risks for human health related to the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements. EFSA Journal 2017;15(7):4908, 34 pp. <https://doi.org/10.2903/j.efsa.2017.4908> [↑](#footnote-ref-6)