

II

(Non-legislative acts)

REGULATIONS

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)

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⁾.

⁽¹⁾ OJ L 37, 13.2.1993, p. 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).

⁽³⁾ EFSA CONTAM Panel, 2011. Scientific Opinion on Pyrrolizidine alkaloids in food and feed. *EFSA Journal* 2011; 9(11):2406. [134 pp.], doi:10.2903/j.efsa.2011.2406.

⁽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. <http://www.efsa.europa.eu/en/supporting/pub/en-859>

- (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 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.

⁽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.

⁽⁶⁾ EFSA CONTAM Panel, 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>

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

ANNEX

In Section 8 of the Annex to Regulation (EC) No 1881/2006, the following entries are added:

	"Foodstuffs" (1)	Maximum level (*) (µg/kg)
8.4.	Pyrrolizidine alkaloids	
8.4.1.	Herbal infusions (dried product) (**) (***) with the exception of the herbal infusions referred to in 8.4.2. and 8.4.4.	200
8.4.2.	Herbal infusions of rooibos, anise (<i>Pimpinella anisum</i>), lemon balm, chamomile, thyme, peppermint, lemon verbena (dried product) and mixtures exclusively composed of these dried herbs (**) (***) with the exception of the herbal infusions referred to in 8.4.4.	400
8.4.3.	Tea (<i>Camellia sinensis</i>) and flavoured tea (****)(<i>Camellia sinensis</i>) (dried product) (***) with the exception of the tea and flavoured tea referred to in 8.4.4.	150
8.4.4.	Tea (<i>Camellia sinensis</i>), flavoured tea (****)(<i>Camellia sinensis</i>) and herbal infusions for infants and young children (dried product)	75
8.4.5.	Tea (<i>Camellia sinensis</i>), flavoured tea (****)(<i>Camellia sinensis</i>) and herbal infusions for infants and young children (liquid)	1,0
8.4.6.	Food supplements containing herbal ingredients including extracts (**) with the exception of the food supplements referred to in 8.4.7.	400
8.4.7.	Pollen based food supplements (39) Pollen and pollen products	500
8.4.8.	Borage leaves (fresh, frozen) placed on the market for the final consumer (**)	750
8.4.9.	Dried herbs with the exception of the dried herbs referred to in 8.4.10. (**)	400
8.4.10.	Borage, lovage, marjoram and oregano (dried) and mixtures exclusively composed of these dried herbs (**)	1 000
8.4.11.	Cumin seeds (seed spice)	400

(*) The maximum level refers to the lowerbound sum of the following 21 pyrrolizidine alkaloids:

- intermedine/lycopsamine, intermedine-N-oxide/lycopsamine-N-oxide,
- senecionine/senecivernine, senecionine-N-oxide/senecivernine-N-oxide,
- seneciphylline, seneciphylline-N-oxide,
- retrorsine, retrorsine-N-oxide,
- echimidine, echimidine-N-oxide,
- lasiocarpine, lasiocarpine-N-oxide,
- senkirkine,
- europine, europine-N-oxide,
- heliotrine and heliotrine-N-oxide

and the following additional 14 pyrrolizidine alkaloids known to co-elute with one or more of the above identified 21 pyrrolizidine alkaloids, making use of certain currently used analytical methods:

- indicine, echinatine, rinderine (possible co-elution with lycopsamine/intermedine)
- indicine-N-oxide, echinatine-N-oxide, rinderine-N-oxide (possible co-elution with lycopsamine-N-oxide/intermedine-N-oxide)
- integerrimine (possible co-elution with senecivernine/senecionine)
- integerrimine-N-oxide (possible co-elution with senecivernine-N-oxide/senecionine-N-oxide)
- heliosupine (possible co-elution with echimidine)
- heliosupine-N-oxide (possible co-elution with echimidine-N-oxide)
- spartiodine (possible co-elution with seneciphylline)
- spartiodine-N-oxide (possible co-elution with seneciphylline-N-oxide)
- usaramine (possible co-elution with retrorsine)
- usaramine N-oxide (possible co-elution with retrorsine N-oxide)

Pyrrolizidine alkaloids, which can be individually and separately identified with the used method of analysis, shall be quantified and included in the sum.

(**) Without prejudice to more restrictive national rules in certain Member States on the placing of the market of pyrrolizidine alkaloid containing plants.

(***) The terms "herbal infusions (dried product)" and "tea (*Camellia sinensis*) (dried product)" refer to:

- herbal infusions (dried product) from flowers, leaves and herbs, roots, and any other parts of the plant (in sachets or in bulk)/tea (*Camellia sinensis*) (dried product) from dried leaves, stalks and flowers (in sachets or in bulk) used for the preparation of herbal infusion (liquid product)/tea (liquid product)
- instant herbal teas/teas. In the case of powdered tea extracts, a concentration factor of 4 has to be applied.

(****) Flavoured tea is tea with flavourings and certain food ingredients with flavouring properties, as defined in Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).
For teas with fruits and other herbs, Article 2 of Regulation (EC) No 1881/2006 applies.”
