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To:	General Secretariat of the Council		
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Subject: ANNEX to the COMMISSION REGULATION (EU)/ ame Regulation (EC) 1881/2006 as regards maximum levels of py alkaloids in certain foodstuffs			

Delegations will find attached document D067816/03 ANNEX.

Encl.: D067816/03 ANNEX



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EUROPEAN COMMISSION

> Brussels, XXX SANTE/12170/2019 Rev. 1 ANNEX (POOL/E2/2019/12170/12170R1-EN ANNEX.docx) D067816/03 [...](2020) XXX draft

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ANNEX

to the

COMMISSION REGULATION (EU) .../...

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

<u>ANNEX</u>

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 (**)	1000
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 and senecionine)
- integerrimine-N-oxide (possible co-elution with senecivernine-N-oxide and senecionine-N-oxide)
- heliosupine (possible co-elution with echimidine)
- heliosupine-N-oxide (possible co-elution with echimidine-N-oxide)
- spartioidine (possible co-elution with seneciphylline)
- spartioidine-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.'