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| No. Cion doc.: | D111626/02 |
| Subject: | COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EU) 2023/915 as regards maximum levels of delta-9-tetrahydrocannabinol (Δ 9-THC) in hemp leaves for water infusion and hemp leaves infusions |

Delegations will find attached document D111626/02.

Encl.: D111626/02



Brussels, **XXX**
PLAN/2023/1981 D111626/02
[...] (2025) **XXX** draft

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

of **XXX**

amending Regulation (EU) 2023/915 as regards maximum levels of delta-9-tetrahydrocannabinol (Δ^9 -THC) in hemp leaves for water infusion and hemp leaves infusions

(Text with EEA relevance)

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

of **XXX**

amending Regulation (EU) 2023/915 as regards maximum levels of delta-9-tetrahydrocannabinol (Δ^9 -THC) in hemp leaves for water infusion and hemp leaves infusions

(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 food¹, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EU) 2023/915² sets maximum levels for certain contaminants in foodstuffs.
- (2) In 2015, the European Food Safety Authority ('the Authority') Panel on Contaminants in the Food Chain (CONTAM Panel) adopted a scientific opinion on the risks to human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin³. THC, more precisely Δ^9 -THC, is the most relevant constituent of the hemp plant *Cannabis sativa*. The CONTAM Panel established an acute reference dose (ARfD) of 1 μg Δ^9 -THC/kg body weight (bw).
- (3) In order to obtain more data on the presence of Δ^9 -THC in hemp-derived foods and foods containing hemp or hemp-derived ingredients, Commission Recommendation (EU) 2016/2115⁴ was adopted.
- (4) On 7 January 2020, the Authority published a scientific report assessing acute human exposure to Δ^9 -THC⁵, taking into account the occurrence data generated through Recommendation (EU) 2016/2115. The ARfD of 1 $\mu\text{g}/\text{kg}$ bw was exceeded in certain acute exposure estimates. Although the exposure estimates are expected to overestimate acute exposure to Δ^9 -THC in the Union, the current exposure to Δ^9 -THC is considered a potential health concern.

¹ OJ L 37, 13.2.1993, p. 1, ELI: <http://data.europa.eu/eli/reg/1993/315/oj>.

² Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: <http://data.europa.eu/eli/reg/2023/915/oj>).

³ European Food Safety Authority (EFSA) Journal 2015;13(6):4141

⁴ Commission Recommendation (EU) 2016/2115 of 1 December 2016 on the monitoring of the presence of Δ^9 -tetrahydrocannabinol, its precursors and other cannabinoids in food (OJ L 327, 2.12.2016, p. 103, ELI: <http://data.europa.eu/eli/reco/2016/2115/oj>).

⁵ EFSA (European Food Safety Authority), Arcella D, Cascio C and Mackay K, 2020. Acute human exposure assessment to tetrahydrocannabinol (Δ^9 -THC). EFSA Journal 2020;18(1):5953, 41 pp. <https://doi.org/10.2903/j.efsa.2020.5953>

- (5) Maximum levels have been set for the sum of Δ^9 -THC and Δ^9 -THCA, expressed in Δ^9 -THC equivalents, in hemp seeds and hemp seed derived products by Regulation (EU) 2023/915 to ensure a high level of human health protection.
- (6) Since, as stated in the Novel Food status Catalogue, water infusion of hemp leaves (when not accompanied by the flowering and fruiting tops) consumed as such or as part of herbal infusions is not novel⁶ and does not require an authorisation pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council⁷, it is appropriate to also establish a maximum level for the sum of Δ^9 -THC and Δ^9 -THCA, expressed in Δ^9 -THC equivalents, in hemp leaves for water infusion and hemp leaves infusions (ready to drink herbal infusion) to ensure a high level of human health protection.
- (7) The maximum level does not take into account consumption of hemp leaves infusions by infants and young children. It is therefore appropriate that there is a warning on the label that the prepared water infusion should not be consumed by infants and young children. Furthermore, the maximum level takes into account the limited migration of Δ^9 -THC and Δ^9 -THCA from the leaves into the water infusion given that Δ^9 -THC and Δ^9 -THCA are lipophilic. As the migration increases significantly by adding during steeping a fatty ingredient, such as cream or milk, it is necessary to provide the warning that the fatty ingredient is to be added only after steeping.
- (8) Regulation (EU) 2023/915 should therefore be amended accordingly.
- (9) To enable economic operators to prepare for the new rules on hemp leaves for water infusion and hemp leaves infusions (ready to drink herbal infusion), it is appropriate to provide for a reasonable time until the new rules apply. It is also appropriate to provide for a transitional period for food containing delta-9-tetrahydrocannabinol (Δ^9 -THC), which was lawfully placed on the market before the date of application of this Regulation.
- (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

Regulation (EU) 2023/915 is amended as follows:

(1) Article 10(1) is amended as follows:

(a) the introductory phrase is replaced by the following:

‘Food lawfully placed on the market prior to the dates referred to in points (a) to (t) may remain on the market until their date of minimum durability or use-by date.’;

(b) the following point (t) is added:

⁶ Novel Food status Catalogue https://food.ec.europa.eu/food-safety/novel-food/novel-food-status-catalogue_en.

⁷ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, pp. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>).

‘(t) 1 January 2027 as regards the maximum levels for sum of Δ^9 -THC and Δ^9 -THCA, expressed in Δ^9 -THC equivalents, set out in points 2.6.4 and 2.6.5 of Annex I’

(2) Annex I is amended in accordance with the Annex to this Regulation.

Article 2

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 January 2027.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN