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#### COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	30 March 2022
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	DO79361/03
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1881/2006 as regards maximum levels of delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC) in hemp seeds and products derived therefrom

Delegations will find attached document DO79361/03.

Encl.: DO79361/03



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/10670/2021  
(POOL/E2/2022/10670/10670-EN.docx)  
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[...](2022) **XXX** draft

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

**of **XXX****

**amending Regulation (EC) No 1881/2006 as regards maximum levels of delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC) in hemp seeds and products derived therefrom**

(Text with EEA relevance)

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

of **XXX**

**amending Regulation (EC) No 1881/2006 as regards maximum levels of delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC) in hemp seeds and products derived therefrom**

(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<sup>1</sup>, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006<sup>2</sup> sets maximum levels for certain contaminants, including delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC), in foodstuffs.
- (2) In 2015, the European Food Safety Authority ('the Authority') Panel on Contaminants in the Food Chain adopted a scientific opinion on the risks to human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin<sup>3</sup>. THC, more precisely  $\Delta^9$ -THC, is the most relevant constituent of the hemp plant *Cannabis sativa*. The Authority established an acute reference dose (ARfD) of 1  $\mu\text{g}$   $\Delta^9$ -THC/kg body weight (bw).
- (3) In order to obtain more data on the presence of  $\Delta^9$ -THC and other relevant non-psycho-active precursors in hemp-derived foods and foods containing hemp or hemp-derived ingredients, Commission Recommendation (EU) 2016/2115<sup>4</sup> was adopted.
- (4) On 7 January 2020, the Authority published a scientific report assessing acute human exposure to  $\Delta^9$ -THC<sup>5</sup>, 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  $\Delta^9$ -THC in the Union, the current exposure to  $\Delta^9$ -THC is a potential health concern.
- (5) Maximum levels should therefore be set in hemp seeds and hemp seed derived products to ensure a high level of human health protection. Since delta-9-tetrahydrocannabinolic acid ( $\Delta^9$ -THCA) can be converted into  $\Delta^9$ -THC through

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<sup>1</sup> OJ L 37, 13.2.1993, p. 1.

<sup>2</sup> 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).

<sup>3</sup> European Food Safety Authority (EFSA) Journal 2015;13(6):4141

<sup>4</sup> Commission Recommendation (EU) 2016/2115 of 1 December 2016 on the monitoring of the presence of  $\Delta^9$ -tetrahydrocannabinol, its precursors and other cannabinoids in food (OJ L 327, 2.12.2016, p. 103).

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

processing, the maximum levels should be set for the sum of  $\Delta^9$ -THC and  $\Delta^9$ -THCA, expressed in  $\Delta^9$ -THC equivalents.

- (6) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (7) To enable economic operators to prepare for the new rules introduced by this Regulation, it is appropriate to provide for a reasonable time until the maximum levels apply. It is also appropriate to provide for a transitional period for foodstuffs lawfully placed on the market before the date of application of this Regulation.
- (8) 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, lawfully placed on the market before 1 January 2023, may remain on the market until their date of minimum durability or use-by date.

#### *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 January 2023.

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*