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**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*