

Brussell, 4 ta' April 2022
(OR. fr)

7876/22

DENLEG 23
FOOD 21
SAN 205

NOTA TA' TRAŻMISSJONI

minn:	Kummissjoni Ewropea
data meta waslet:	30 ta' Marzu 2022
lil:	Segretarjat Ġenerali tal-Kunsill
Nru dok. Cion:	D079361/03
Suġġett:	REGOLAMENT TAL-KUMMISSJONI (UE) .../... ta' XXX li jemenda r-Regolament (KE) Nru 1881/2006 fir-rigward tal-livelli massimi ta' delta-9-tetraidrokannabinol (Δ 9-THC) fiż-żrieragħ tal-qanneb u fil-prodotti derivati minnhom

Id-delegazzjonijiet għandhom isibu meħmuż id-dokument D079361/03.

Mehmuż: D079361/03



IL-KUMMISSJONI
EWROPEA

Brussell, **XXX**
SANTE/10670/2021
(POOL/E2/2022/10670/10670-EN.docx)
D079361/03
[...] (2022) **XXX** draft

REGOLAMENT TAL-KUMMISSJONI (UE) .../...

ta' **XXX**

li jemenda r-Regolament (KE) Nru 1881/2006 fir-rigward tal-livelli massimi ta' delta-9-tetraidrokannabinol (Δ^9 -THC) fiż-żrieragh tal-qanneb u fil-prodotti derivati minnhom

(Test b'rilevanza għaż-ŻEE)

REGOLAMENT TAL-KUMMISSJONI (UE) .../...

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li jemenda r-Regolament (KE) Nru 1881/2006 fir-rigward tal-livelli massimi ta' delta-9-tetraidrokannabinol (Δ^9 -THC) fiż-żrieragh tal-qanneb u fil-prodotti derivati minnhom

(Test b'rilevanza għaż-ŻEE)

IL-KUMMISSJONI EWROPEA,

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 (EC) No 1881/2006² sets maximum levels for certain contaminants, including delta-9-tetrahydrocannabinol (Δ^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 origin³. THC, more precisely Δ^9 -THC, is the most relevant constituent of the hemp plant *Cannabis sativa*. The Authority 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 and other relevant non-psycho-active precursors 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 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 (Δ^9 -THCA) can be converted into Δ^9 -THC through

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 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).

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>

processing, the maximum levels should be set for the sum of Δ^9 - THC and Δ^9 -THCA, expressed in Δ^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,

ADOTTAT DAN IR-REGOLAMENT:

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.

Magħmul fi Brussell,

Għall-Kummissjoni

Il-President

Ursula VON DER LEYEN