



Council of the
European Union

Brussels, 29 July 2021
(OR. en)

11118/21

DENLEG 57
FOOD 34
SAN 481

COVER NOTE

From:	European Commission
date of receipt:	27 July 2021
To:	General Secretariat of the Council

No. Cion doc.:	D074084/03
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1881/2006 as regards maximum levels of opium alkaloids in certain foodstuffs

Delegations will find attached document D074084/03.

Encl.: D074084/03



Brussels, **XXX**
SANTE/10248/2021
(POOL/E2/2021/10248/10248-EN.docx)
D074084/03
[...](2021) **XXX** draft

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

of **XXX**

**amending Regulation (EC) No 1881/2006 as regards maximum levels of opium alkaloids
in certain foodstuffs**

(Text with EEA relevance)

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

of **XXX**

amending Regulation (EC) No 1881/2006 as regards maximum levels of opium alkaloids in certain foodstuffs

(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 (EC) No 1881/2006² sets maximum levels for certain contaminants, including opium alkaloids, in foodstuffs.
- (2) Poppy seeds are obtained from the opium poppy (*Papaver somniferum* L.). The opium poppy plant contains opium alkaloids such as morphine and codeine. Poppy seeds do not contain the opium alkaloids, or contain only very low levels, but can become contaminated with alkaloids as a result of insect damage, or through external contamination of the seeds during harvesting, when particles of dust from the straw (including the capsule wall) adhere to the seeds.
- (3) In 2018, the European Food Safety Authority ('the Authority') adopted an update of the scientific opinion on opium alkaloids in poppy seeds³. The Authority confirmed the acute reference dose (ARfD) of 10 µg morphine/kg body weight (bw) and concluded that the concentration of codeine in the poppy seed samples should be taken into account by converting codeine to morphine equivalents, using a factor of 0.2. The ARfD is therefore a group ARfD for morphine and codeine, expressed in morphine equivalents. Exposure estimates indicate that the group ARfD is likely to be exceeded, in particular, when large portions are consumed, or if foods containing unprocessed poppy seeds are consumed.
- (4) Maximum levels for morphine and codeine, expressed in morphine equivalents, should therefore be set for poppy seeds placed on the market for the final consumer and for bakery products containing poppy seeds or derived products thereof. Those levels should be set taking into account that food processing may reduce the alkaloid content in the raw poppy seeds by 25-100% in the final product. As it is appropriate for the producer of bakery products to have detailed information, including the morphine equivalent content, on the poppy seeds used as ingredients in bakery products, the

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 Update of the Scientific Opinion on opium alkaloids in poppy seeds. EFSA Journal 2018;16(5):5243, 119 pp. <https://doi.org/10.2903/j.efsa.2018.5243>

supplier of poppy seeds should provide that information to the producer of bakery products.

- (5) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (6) 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.
- (7) 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 July 2022, 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 July 2022.

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