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Delegations will find attached document D071865/02.

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Brussels, **XXX**  
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**COMMISSION REGULATION (EU) .../...**

**of **XXX****

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

(Text with EEA relevance)

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

of **XXX**

## **amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane 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 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 tropane alkaloids, in foodstuffs.
- (2) Atropine is the racemic mixture of (-)-hyoscyamine and (+)-hyoscyamine of which only the (-)-hyoscyamine enantiomer exhibits anticholinergic activity. It is not always possible to distinguish between the enantiomers of hyoscyamine, for analytical reasons. However, as the synthesis of tropane alkaloids in plants leads to (-)-hyoscyamine and (-)-scopolamine and not to (+)-hyoscyamine and (+)-scopolamine, analytical results on atropine and scopolamine in food of plant origin reflects the occurrence of (-)-hyoscyamine and (-)-scopolamine respectively.
- (3) The European Food Safety Authority ('the Authority') adopted in 2013 an opinion on tropane alkaloids in food and feed<sup>3</sup>. The Authority established a group acute reference dose ('ARfD') of 0.016 µg/kg per body weight ('b.w.') expressed as the sum of (-)-hyoscyamine and (-)-scopolamine, assuming equivalent potency. The Authority concluded that, based on the limited information available, the dietary exposure of toddlers could significantly exceed the group ARfD. It therefore highlighted the need for better characterisation of tropane alkaloids in food and feed, either naturally or as contaminants, and recommended compiling analytical data on the occurrence of tropane alkaloids in cereals and oilseeds.
- (4) Taking into account the conclusions of the opinion, maximum levels for atropine and scopolamine were established by Commission Regulation (EU) 2016/239<sup>4</sup> in processed cereal based foods and baby foods for infants and young children, containing millet, sorghum, buckwheat or their derived products.

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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> Scientific Opinion on tropane alkaloids in food and feed. EFSA Journal 2013;11(10):3386, 113 pp. doi:10.2903/j.efsa.2013.3386.

<sup>4</sup> Commission Regulation (EU) 2016/239 of 19 February 2016 amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane alkaloids in certain cereal-based foods for infants and young children (OJ L 45, 20.2.2016, p. 3)

- (5) The Authority published a call for proposals to investigate the concentrations of tropane alkaloids in a wide range of plant-derived food products across different regions within the Union, following the recommendation in its opinion from 2013. The investigation's findings were published on 8 December 2016<sup>5</sup>.
- (6) On 5 February 2018, the Authority published a scientific report on the assessment of acute dietary exposure to tropane alkaloids in the Union population, taking into account new occurrence data<sup>6</sup>. For several acute exposure estimates, the ARfD was exceeded for several population groups. This makes the presence of tropane alkaloids, in particular atropine and scopolamine, a health concern.
- (7) Maximum levels of those tropane alkaloids should therefore be set for foodstuffs found to contain a high concentration of them and contributing significantly to the exposure of the population, namely certain cereals, products derived from them and herbal infusions. As regards, in particular, cereals and cereals products, good agricultural and harvesting practices minimise contamination of the crop by seeds of species containing tropane alkaloids, such as *Datura stramonium*. In case of contamination, those seeds can be removed for certain cereals by sorting and cleaning. However, they cannot easily be removed from sorghum, millet, maize and buckwheat. Given that the maximum levels for those foodstuffs are higher than the levels set out for foodstuffs for infants and young children, a maximum level for the sum of atropine and scopolamine may be set for each of those foods
- (8) Furthermore, recent monitoring data indicate that processed cereal based foods and baby foods for infants and young children containing maize or maize derived products can also be contaminated with tropane alkaloids. It is therefore appropriate to extend to these foods the existing maximum levels for processed cereal based foods and baby foods for infants and young children.
- (9) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (10) Given that good agricultural and harvesting practices have only recently been introduced or implemented and in order to allow the food business operators to adapt to the new requirements set out in this Regulation while ensuring the protection of vulnerable populations, it is appropriate to provide, as regard foods other than foods for infants and young children containing maize, a reasonable period until the maximum levels start applying and for a transitional period for all foodstuffs which have been lawfully placed on the market before the date of its application.
- (11) 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.

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<sup>5</sup> Mulder, PPJ., De Nijs, M., Castellari, M., Hortos, M., MacDonald, S., Crews, C., Hajslova, J. and Stranska, M., 2016. 'Occurrence of tropane alkaloids in food'. EFSA supporting publication 2016:EN-1140, 200 pp. doi:10.2903/sp.efsa.2016.EN-1140.

<sup>6</sup> Arcella, D., Altieri, A., Horváth, Zs, 2018. 'Scientific report on human acute exposure assessment to tropane alkaloids'. EFSA Journal 2018;16(2):5160, 29 pp. doi:10.2903/j.efsa.2018.5160.

## *Article 2*

Processed cereal-based foods and baby foods for infants and young children, containing maize or their derived products, lawfully placed on the market before the entry into force of this Regulation, may remain on the market until their date of minimum durability or use-by-date.

Foodstuffs listed in points 8.2.2. to 8.2.9. of the Annex, lawfully placed on the market before 1 September 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*.

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*