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[...] (2022) **XXX** draft

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

**of **XXX****

**amending Regulation (EU) No 2023/xxxx as regards maximum levels of T-2 and HT-2  
toxin in certain food**

(Text with EEA relevance)

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

of **XXX**

## **amending Regulation (EU) No 2023/xxxx as regards maximum levels of T-2 and HT-2 toxin in certain food**

(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 2023/xxxx<sup>2</sup> sets maximum levels for certain contaminants in foodstuffs.
- (2) T-2 toxin and HT-2 toxin are mycotoxins produced by various *Fusarium* species. T-2 toxin is rapidly metabolised to a large number of products, HT-2 toxin being a major metabolite.
- (3) The European Food Safety Authority ('the Authority') adopted in 2011 a scientific opinion on the risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed<sup>3</sup>. The Authority established a group tolerable daily intake (TDI) of 100 ng/kg b.w. for the sum of T-2 and HT-2 toxins. Estimates of chronic human dietary exposure to the sum of T-2 and HT-2 toxins based on the available occurrence data were below the TDI for populations of all age groups, and thus not an immediate health concern.
- (4) Taking into account the conclusions of that scientific opinion, Commission Recommendation 2013/165/EU<sup>4</sup> was adopted to collect more data on T2 and HT-2 toxin in cereals and cereal products to gain more insight in the year-to-year variation in occurrence, to obtain more information on the effects of food processing (i.e. cooking) and on the influence of agronomic factors on the presence of T-2 and HT-2 toxin.
- (5) In 2017, the Authority adopted a scientific opinion on the appropriateness to set a group health based guidance value for T-2 and HT-2 toxin and its modified forms<sup>5</sup>. A group acute reference dose (ARfD) of 0.3 µg/kg for the sum of T-2 and HT-2 toxin and its

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

<sup>2</sup> Commission Regulation (EU) No 2023/xxxx of on maximum levels for certain contaminants in food (OJ L).

<sup>3</sup> Scientific Opinion on the risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed. EFSA Journal 2011; 9(12):2481. 187 pp. <https://doi.org/10.2903/j.efsa.2011.2481>.

<sup>4</sup> Commission Recommendation 2013/165/EU of 27 March 2013 on the presence of T-2 and HT-2 toxin in cereals and cereal products (OJ L 91, 3.4.2013, p. 12)

<sup>5</sup> Scientific opinion on the appropriateness to set a group health based guidance value for T2 and HT2 toxin and its modified forms. EFSA Journal 2017; 15(1):4655, 53 pp. <https://doi.org/10.2903/j.efsa.2017.4655>.

modified forms. A group TDI for sum of T-2 and HT-2 toxin and their modified forms of 20 ng/kg b.w. was established replacing the previous TDI of 100 ng/kg b.w.

- (6) Also in 2017, the Authority published a scientific report on the human and animal dietary exposure to T-2 and HT-2 toxin<sup>6</sup>. Acute dietary exposure estimates did not indicate an exceedance of the ARfD. However certain chronic exposure scenarios indicated an exposure to T-2 and HT-2 toxin exceeding the tolerable daily intake for certain population groups.
- (7) In order to ensure a high level of public health protection, it is therefore appropriate to establish maximum levels for the sum of T-2 and HT-2 toxin taking into account the most recent occurrence data. The maximum levels are established for the sum of T-2 and HT-2 toxin only as there are only very limited occurrence data available on the presence of the modified forms from T-2 and HT-2 toxin and no routine method of analysis for their analysis is available.
- (8) Regulation (EU) No 2023/xxxx should therefore be amended accordingly.
- (9) 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 new 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.
- (10) 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 (EU) No 2023/xxxx 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 2024, 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 2024.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*

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<sup>6</sup> Scientific report on human and animal dietary exposure to T-2 and HT-2 toxin. EFSA Journal 2017; 15(8):4972, 57 pp. <https://doi.org/10.2903/j.efsa.2017.4972>.

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[ANNEX \[...\]](#)

In the Annex to Regulation (EU) No 2023/xxxx, section 1, the following entry 1.9 is added:

1.9	T-2 and HT-2 toxin	Maximum levels (µg/kg) Lower bound sum of T-2 and HT-2 toxin	Remarks
1.9.1	Unprocessed cereal grains - malting barley - barley other than malting barley, maize and durum wheat - oats with husk - other cereals	150 100 1250 50	Except rice.  Except unprocessed maize grains for which it is evident e.g. through labelling or destination, that it is intended for use in a wet milling process only (starch production).  The maximum level applies to unprocessed cereal grains placed on the market for first-stage processing <sup>(6)</sup> .
1.9.2	Cereals placed on the market for the final consumer - <b>oats</b> , barley, maize and durum wheat - other cereals	<b>50</b> 20	Except rice
1.9.2	Cereals placed on the market for the final consumer - <b>oats</b> - barley, maize and durum wheat - other cereals	<b>100</b> 50 20	Except rice

1.9.3	Cereal milling products - oat milling products (including oat flakes and oat bran) - bran from other cereals and maize milling products - other cereal milling products	 100 50 20	Except rice milling products
1.9.4	- breakfast cereals composed of at least 75 % of cereal bran, oat milling products, maize milling products and/or whole grains of oats, barley, maize and durum wheat and with less than 40 % oat milling products and whole grains of oats - breakfast cereals composed of at least 75 % of cereal bran, oat milling products, maize milling products and/or whole grains of oats, barley, maize and durum wheat and with at least 40 % oat milling products and whole grains of oats - Oat cakes	 50 75 100	
1.9.5	Bakery wares, pasta, cereal snacks and breakfast cereals other than those referred to in 1.9.4	20	Except rice milling products. Pasta means pasta (dry) with a water content of approximately 12 %.
1.9.6	Processed cereal-based foods for infants and young children and baby food <sup>(3)</sup>	10	Except rice products. The maximum level applies to the dry matter <sup>(5)</sup> of the product as placed on the market.

1.9.7	Dietary food for special medical purposes intended for infants and young children <sup>(3)</sup>	10	The maximum level applies in the case of milk, milk products and similar products to the products ready to use (placed on the market as such or reconstituted as instructed by the manufacturer) and in the case of products other than milk, milk products and similar products to the dry matter <sup>(5)</sup> .'
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