Council of the
European Union

Brussels, 16 November 2023
(OR. en)

15518/23

DENLEG 55
FOOD 85
SAN 669

COVER NOTE

From:	European Commission
date of receipt:	13 November 2023
To:	General Secretariat of the Council
No. Cion doc.:	D(2023) 92050/2
Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Regulation (EU) 2023/915 as regards maximum levels of T-2 and HT-2 toxins in food

Delegations will find attached document D(2023) 92050/2.

Encl.: D(2023) 92050/2

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2017/1196 Rev1
(POOL/E2/2017/1196/1196-R1-EN.docx
D092050/02
[…](2023) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) 2023/915 as regards maximum levels of T-2 and HT-2 toxins in food

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) 2023/915 as regards maximum levels of T-2 and HT-2 toxins in 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[1], and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EU) 2023/915[2] sets maximum levels for certain contaminants in food.

(2) T-2 and HT-2 toxins are mycotoxins produced by various *Fusarium* species. T-2 toxin is rapidly metabolised to a large number of products, with 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 toxins in food and feed[3]. The Authority established a group tolerable daily intake (TDI) of 0,1 µg/kg body weight (bw) 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 group-TDI for populations of all age groups, and thus not an immediate health concern.

(4) Taking into account the conclusions of the 2011 scientific opinion, Commission Recommendation 2013/165/EU[4] was adopted to collect more data on T-2 and HT-2 toxins in cereals and cereal products, to better understand the year-to-year variation in occurrence and to obtain more information on the influence of food processing (e.g. cooking) and agronomic factors on the presence of T-2 and HT-2 toxins.

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1 OJ L 37, 13.2.1993, p. 1.

2 Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103).

3 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, https://doi.org/10.2903/j.efsa.2011.2481.

4 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).

(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 toxins and their modified forms[5]. A group acute reference dose (ARfD) of 0,3 µg/kg bw for the sum of T-2 and HT-2 toxins and their modified forms was established. Additionally, a group-TDI for the sum of T-2 and HT-2 toxins and their modified forms of 0,02 µg/kg bw was established replacing the previous group-TDI of 0,1 µg/kg bw.

(6) Also in 2017, the Authority published a scientific report on the human and animal dietary exposure to T-2 and HT-2 toxins[6]. Acute dietary exposure estimates in that report did not indicate an exceedance of the group ARfD established by the Authority. However, certain chronic dietary exposure scenarios exceeded the group-TDI in infants, toddlers and other children, and at high exposures also in adolescents, indicating a potential health concern.

(7) In order to ensure a high level of public health protection, it is therefore appropriate to establish maximum levels concerning the presence in food of T-2 and HT-2 toxins taking into account the most recent occurrence data. However, since there are very limited occurrence data available on the presence of the modified forms of T-2 and HT-2 toxins and no routine method for their analysis is available, the maximum levels are established at this time only for the sum of T-2 and HT-2 toxins.

(8) In order to ensure that good agricultural practices are applied to minimize the presence of T-2 and HT-2 toxins in cereals, it is important to lay down a maximum level for unprocessed cereals. As unprocessed oats, before milling or before being used in cereal products placed on the market for the final consumer, are placed on the market with the husk, the maximum level for T-2 and HT-2 toxins in unprocessed oat grains should apply to the unprocessed oat grains with the husk included, even if the husk is inedible.

(9) As the levels of occurrence of T-2 and HT-2 toxins are the highest in oat grains, it is important that additional efforts are made to further lower the presence of T-2 and HT-2 toxins in oat grains and that the Commission is informed of the progress made and of the new occurrence data with the aim to lower in the future the maximum level for T-2 and HT-2 toxins in oat grains and oat grain products.

(10) Regulation (EU) 2023/915 should therefore be amended accordingly.

(11) It is appropriate to provide for a transitional period for food lawfully placed on the market before the date of application of this Regulation taking into account that certain foods covered by this Regulation have a long shelf life.

(12) 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.

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5 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, https://doi.org/10.2903/j.efsa.2017.4655.

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

(13) 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

Regulation (EU) 2023/915 is amended as follows:

(1) in Article 8, the following paragraph 5 is added:

‘5. Member States and interested parties shall communicate by 1 January 2028 to the Commission the results of investigations undertaken and progress made with regard to the application of prevention measures to reduce contamination by T-2 and HT-2 toxins in oats and oat products.

Member States and interested parties shall report on a regular basis to the Authority the occurrence data on T-2 and HT-2 toxins in oats and oat products.’;

(2) Annex I is amended in accordance with the Annex to this Regulation.

Article 2

Food 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
Ursula VON DER LEYEN