



Council of the
European Union

Brussels, 17 November 2023
(OR. en)

15604/23

DENLEG 57
FOOD 87
SAN 675

COVER NOTE

From:	European Commission
date of receipt:	10 November 2023
To:	General Secretariat of the Council
No. Cion doc.:	D092049/2
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EU) 2023/915 as regards maximum levels of deoxynivalenol in food

Delegations will find attached document D092049/2.

Encl.: D092049/2



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2017/1539 Rev1
(POOL/E2/2017/1539/1539-R1-
EN.docx) D092049/02
[...](2023) **XXX** draft

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

of **XXX**

**amending Regulation (EU) 2023/915 as regards maximum levels of deoxynivalenol in
food**

(Text with EEA relevance)

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

of **XXX**

amending Regulation (EU) 2023/915 as regards maximum levels of deoxynivalenol 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 food¹, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EU) 2023/915² sets maximum levels for certain contaminants, including deoxynivalenol (DON) in food.
- (2) In 2017, the European Food Safety Authority ('the Authority') adopted a scientific opinion on the risks to human and animal health related to the presence of deoxynivalenol and its acetylated and modified forms in food and feed³. The Authority concluded in that opinion that the tolerable daily intake (TDI) of 1 µg/kg body weight (bw) per day for DON, was to be considered as a group-TDI for the sum of DON, 3-acetyl-deoxynivalenol (3-Ac-DON), 15-acetyl-deoxynivalenol (15-Ac-DON) and deoxynivalenol-3-glucoside (DON-3-glucoside). In order to assess acute human health risk, a group acute reference dose (ARfD) of 8 µg/kg bw per eating occasion was calculated. Estimates of acute dietary exposures were below this dose and did not raise a health concern in humans. However, the estimated mean chronic dietary exposures were above the group-TDI in infants, toddlers and other children, and at high exposures also in adolescents and adults, indicating a potential health concern.
- (3) In light of the Authority's opinion, the Commission has considered the possibility of setting maximum levels for the sum of DON, 3-Ac-DON, 15-Ac-DON and DON-3-glucoside. However given the limited amount of occurrence data for the sum of DON, 3-Ac-DON, 15-Ac-DON and DON-3-glucoside and given that 3-Ac-DON, 15-Ac-

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 to human and animal health related to the presence of deoxynivalenol and its acetylated and modified forms in food and feed. EFSA Journal 2017;15(9):4718, <https://doi.org/10.2903/j.efsa.2017.4718>.

DON and in particular DON-3-glucoside are not yet analysed on a routine basis, there is insufficient information at this time to set such maximum levels until the method of analysis for the routine analysis of the acetylated and modified forms of DON is further developed and the presence of the sum of DON and its acetylated and modified forms is monitored. In the meantime, in order to ensure a high level of public health protection, it is appropriate to lower certain existing maximum levels for DON following the principle that maximum levels are to be set at a level as low as reasonably achievable by applying good practices to minimize contamination and thereby taking into account recent occurrence data.

- (4) In order to ensure that good agricultural practices are applied to minimize the presence of DON 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 DON in unprocessed oat grains should apply to the unprocessed oat grains with the husk included, even if the husk is inedible.
- (5) Regulation (EU) 2023/915 should therefore be amended accordingly.
- (6) 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.
- (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 new maximum levels apply.
- (8) 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

Annex I to Regulation (EU) 2023/915 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