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To:	General Secretariat of the Council

No. Cion doc.:	D088012/03
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EU) 2023/... [<i>Publications Office: please insert number of C(2023) 35</i>] as regards maximum levels of cadmium in tiger nuts and certain cultivated fungi.

Delegations will find attached document D088012/03.

Encl.: D088012/03



Brussels, **XXX**
PLAN/2022/1614
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D088012/03
[...](2023) **XXX** draft

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

of **XXX**

amending Regulation (EU) 2023/... [*Publications Office: please insert number of C(2023) 35*] as regards maximum levels of cadmium in tiger nuts and certain cultivated fungi.

(Text with EEA relevance)

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

of **XXX**

amending Regulation (EU) 2023/... [*Publications Office: please insert number of C(2023) 35*] as regards maximum levels of cadmium in tiger nuts and certain cultivated fungi.

(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/...² [*Publications Office: please insert number of C(2023) 35*] sets maximum levels for cadmium in a range of foodstuffs.
- (2) On 30 January 2009, the European Food Safety Authority ('the Authority') adopted a scientific opinion on cadmium in food³. The Authority concluded that cadmium is primarily toxic to the kidney, especially to the proximal tubular cells where it accumulates over time and may cause renal dysfunction. In view of the toxic effects of cadmium on kidneys, the Authority established a tolerable weekly intake for cadmium of 2,5 µg/kg body weight. The Authority further concluded that the mean exposure for adults across the Union is close to, or slightly exceeds, the tolerable weekly intake. It also concluded that subgroups such as vegetarians, children, smokers and people living in highly contaminated areas may exceed the tolerable weekly intake by about twofold. Therefore, the Authority concluded that the current exposure to cadmium at the population level needs to be reduced. Following that scientific opinion, the Authority issued, on 17 January 2012, a scientific report where it confirmed that children and adults at the 95th percentile exposure could exceed the health-based guidance values.⁴

¹ OJ L 37, 13.2.1993, p. 1.

² Commission Regulation (EU) .../... (...) on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ ..., p. ...) [*Publications Office: please insert the number, date and OJ reference to C(2023) 35*].

³ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific opinion on cadmium in food. EFSA Journal 2009(980) 1-139, <https://doi.org/10.2903/j.efsa.2009.98>.

⁴ Scientific Report of EFSA on Cadmium dietary exposure in the European population. EFSA Journal 2012;10(1), 2551 [37 pp.], <https://doi.org/10.2903/j.efsa.2012.2551>.

- (3) Taking into account the Authority's scientific opinion and scientific report, new maximum levels for cadmium in baby foods and chocolate/cocoa products were established under Commission Regulation (EU) No 2014/488⁵. Commission Recommendation (EU) 2014/193/EU⁶ was adopted, which called on Member States to ensure that the available mitigation methods were communicated and promoted to farmers and started or continued to be implemented, to regularly monitor the progress of the mitigation measures by collecting occurrence data on cadmium levels in foodstuffs and to report the data, in particular on cadmium levels close to or exceeding the maximum levels, by February 2018.
- (4) On the basis of the occurrence data, gathered after the implementation of the mitigation measures, by means of Commission Regulation (EU) 2021/1323⁷ the maximum levels for cadmium were lowered in a wide range of foods.
- (5) Since the publication of Regulation (EU) 2021/1323, new occurrence data have become available for tiger nuts and for some less consumed species of cultivated fungi.
- (6) The maximum level for cadmium in radishes, which by Regulation (EU) 2021/1323, was lowered from 0,10 to 0,020 mg/kg applies to tiger nuts.. This maximum level was lowered on the basis of the at that time available occurrence data for the most consumed species within the commodity group of radishes (*Raphanus sativus var. sativus*). However, in the meanwhile more recent occurrence data have become available specifically for tiger nuts, which show that tiger nuts contain higher concentrations of cadmium than other radishes. Therefore, it has become clear that the maximum level established for cadmium in tiger nuts is not in line with the 'As Low As Reasonably Achievable (ALARA)' principle'. Furthermore in view of the low consumption volume of tiger nuts, their contribution to the consumer exposure to cadmium is limited.
- (7) By Regulation (EU) 2021/1323 the maximum levels for cultivated fungi were lowered from 0,20 mg/kg for *Agaricus bisporus*, *Lentinula edodes* and *Pleurotus ostreatus* and 1,0 mg/kg for other cultivated fungi to 0,15 mg/kg for *Lentinula edodes* and *Pleurotus ostreatus* and 0,050 mg/kg for all other cultivated fungi, including *Agaricus bisporus*. The maximum level for cultivated fungi other than *Lentinula edodes* and *Pleurotus ostreatus* was lowered on the basis of the at that time available occurrence data for the most consumed species of this commodity group (*Agaricus bisporus*). However, in the meanwhile more recent occurrence data have become available for some specific species of cultivated fungi less consumed than *Agaricus bisporus*, *Lentinula edodes* and *Pleurotus ostreatus*, which show that these contain higher cadmium concentrations than *Agaricus bisporus*. Therefore, it has become clear that the maximum level established for cadmium in cultivated fungi other than *Agaricus bisporus*, *Lentinula edodes* and *Pleurotus ostreatus* is not in line with the 'ALARA' principle. Furthermore, as the species *Agaricus bisporus*, *Lentinula edodes* and *Pleurotus ostreatus* represent the main fraction of the total volume of fungi consumed

⁵ Commission Regulation (EU) No 2014/488 of 12 May 2014 amending Regulation (EC) No 1881/2006 as regards maximum levels of cadmium in foodstuffs (OJ L 138, 13.5.2014, p. 75).

⁶ Commission Recommendation 2014/193/EU of 4 April 2014 on the on the reduction of the presence of cadmium in foodstuffs (OJ L 104, 8.4.2014, p. 80).

⁷ Commission Regulation (EU) 2021/1323 of 10 August 2021 amending Regulation (EC) No 1881/2006 as regards maximum levels of cadmium in certain foodstuffs (OJ L 288, 11.8.2021, p. 13).

in the Union, the contribution of the other cultivated fungi to the consumer exposure to cadmium is limited.

- (8) In order to take into account the ‘ALARA’ principle and avoid disproportionate non-compliance rates for tiger nuts and cultivated fungi other than *Agaricus bisporus*, *Lentinula edodes* and *Pleurotus ostreatus*, while maintaining a high level of food safety, the maximum levels for cadmium in those species should be increased.
- (9) Therefore, Regulation (EU) 2023/... [*Publications Office: please insert number of C(2023) 35*] should be amended accordingly.
- (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) 2023/... [*Publications Office: please insert number of C(2023) 35*] is amended in accordance with the Annex to this Regulation.

Article 2

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