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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia in certain unprocessed cereals and the provisions on monitoring and reporting

Delegations will find attached document D038125/03.

Encl.: D038125/03



Brussels, **XXX**
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[...](2015) **XXX** draft

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

of **XXX**

amending Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia in certain unprocessed cereals and the provisions on monitoring and reporting

(Text with EEA relevance)

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amending Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia in certain unprocessed cereals and the provisions on monitoring and reporting

(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 (EC) No 1881/2006² sets maximum levels for certain contaminants in foodstuffs.
- (2) The Scientific Panel on Contaminants in the Food Chain ('CONTAM') of the European Food Safety Authority ('EFSA') adopted an opinion on ergot alkaloids in food and feed³. The CONTAM Panel established a group acute reference dose of 1 µg/kg body weight ('b.w.') and a group tolerable daily intake of 0.6 µg/kg b.w.
- (3) The presence of ergot alkaloids in cereal grains is to a certain extent related to the presence of ergot sclerotia in cereal grains. This relationship is not absolute, as ergot alkaloids can also be present in the dust from ergot sclerotia adsorbed to the cereal grains. It is therefore important to set maximum levels for ergot sclerotia as a first step while gathering further data on the presence of ergot alkaloids in cereals and cereal products. However it is acknowledged that compliance with the maximum level for ergot sclerotia does not necessarily guarantee the safety of food as regards the presence of ergot alkaloids. Therefore, competent authorities may take appropriate measures, in accordance with Article 14(8) of Regulation (EC) 178/2002 of the European Parliament and of the Council⁴, to impose restrictions on the placing of food on the market or to require withdrawal of such food from the market, where the food is

¹ OJ L 37, 13.2.1993, p. 1.

² 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).

³ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Ergot alkaloids in food and feed. EFSA Journal 2012;10(7):2798. [158 pp.] doi:10.2903/j.efsa.2012.2798. Available online: www.efsa.europa.eu/efsajournal

⁴ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

found unsafe because of the level of ergot alkaloids, despite its compliance with the maximum level on ergot sclerotia.

- (4) It is necessary to specify at which stage of marketing the maximum levels for ergot sclerotia should apply as cleaning and sorting operations can reduce the presence of ergot sclerotia. It is appropriate to apply the maximum levels for ergot sclerotia on cereal grains at the same stages of marketing as those for other mycotoxins.
- (5) Experience with the application of Regulation (EC) No 1881/2006 indicates that it is appropriate to clarify the term “first-stage processing” in particular as regards integrated production and processing systems and as regards scouring.
- (6) It is important to gather data on the presence of ergot alkaloids in cereals and cereal products in order to establish the relationship between the presence of ergot alkaloids and the presence of ergot sclerotia. The findings on ergot alkaloids should be reported by 30 September 2016 in order to allow setting appropriate and achievable maximum levels of ergot alkaloids, providing a high level of human health protection.
- (7) Although it is important to continue to apply prevention measures to avoid and reduce ochratoxin A contamination, it is not necessary to report each year on the findings, the outcome of the investigations and the progress in application of the prevention measures. It is appropriate to update the provisions on monitoring and reporting as provided for in Article 9 of Regulation (EC) No 1881/2006.
- (8) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (9) 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 (EC) No 1881/2006 is amended as follows:

- (1) Article 9 is replaced by the following:

“Article 9 Monitoring and reporting

1. Member States shall monitor nitrate levels in vegetables which may contain significant levels, in particular green leafy vegetables, and communicate the results to EFSA on a regular basis.
2. Member States shall communicate to the Commission a summary of the findings on aflatoxins obtained in accordance with Commission Implementing Regulation (EU) No 884/2014(*) and the individual occurrence data shall be reported to EFSA by the Member States.
3. Member States and professional stakeholder organisations shall communicate each year to the Commission the results of investigations undertaken and the progress with regard to the application of prevention measures to avoid

contamination by deoxynivalenol, zearalenone, fumonisin B₁ and B₂, T-2 and HT-2 toxin. The Commission shall make the results available to the Member States. The related occurrence data shall be reported to EFSA.

4. Member States and professional stakeholder organisations are strongly recommended to monitor the presence of ergot alkaloids in cereals and cereal products.

Member States and professional stakeholder organisations are strongly recommended to report to EFSA their findings on ergot alkaloids by 30 September 2016. Those findings shall include occurrence data and specific information on the relationship between the presence of ergot sclerotia and the level of individual ergot alkaloids.

The Commission shall make those findings available to the Member States.

5. Occurrence data on other contaminants than those referred to in paragraphs 1 to 4 collected by Member States and professional stakeholder organisations may be reported to EFSA.
6. Occurrence data shall be provided to EFSA in the EFSA data submission format in accordance with the requirements of EFSA's Guidance on Standard Sample Description (SSD) for Food and Feed (**) and the additional EFSA's specific reporting requirements for specific contaminants. The occurrence data from professional stakeholder organisations may be provided to EFSA, if appropriate, in a simplified data submission format, defined by EFSA.

(*) Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009 (OJ L 242, 14.8.2014, p. 4).

(**) <http://www.efsa.europa.eu/en/datex/datexsubmitdata.htm>

- (2) The Annex 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
Jean-Claude JUNCKER