

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION REGULATION (EU) 2021/1399

of 24 August 2021

amending Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia and ergot alkaloids in certain foodstuffs

(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 1881/2006 <sup>(2)</sup> sets maximum levels for certain contaminants, including ergot sclerotia and ergot alkaloids, in foodstuffs.
- (2) The term ergot or ergot sclerotia refers to fungal structures from *Claviceps* species replacing kernels on grain ears or seeds on grass heads, visible as large discoloured sclerotia. These sclerotia contain different classes of alkaloids.
- (3) On 28 June 2012, the European Food Safety Authority ('the Authority') adopted an opinion on ergot alkaloids in food and feed <sup>(3)</sup>. The Authority based its risk assessment on the main *Claviceps purpurea* ergot alkaloids, namely ergometrine, ergotamine, ergosine, ergocristine, ergocryptine, ergocornine, as well as the corresponding –inine epimers. It 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. per day. It concluded that, although the available data did not indicate that there was cause for concern for any population subgroup, the dietary exposure estimates related to a limited number of food groups, and a possible unknown contribution from other foods could not be discounted.
- (4) On 6 July 2017, the Authority published a scientific report on human and animal dietary exposure to ergot alkaloids <sup>(4)</sup>. For certain population groups, exposure estimates to ergot alkaloids indicate an exposure close to the tolerable daily intake. For the highest exposure estimates, the main contributors to chronic dietary exposure were different types of bread and rolls, in particular those containing or made exclusively of rye. The highest acute exposure estimates indicate an acute exposure close to the acute reference dose.

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

<sup>(2)</sup> 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).

<sup>(3)</sup> Scientific Opinion on Ergot alkaloids in food and feed. *EFSA Journal* 2012;10(7):2798. [158 pp.] doi:10.2903/j.efsa.2012.2798.

<sup>(4)</sup> Arcella, D., Gomez Ruiz, J-A., Innocenti, ML and Roldán, R., 2017. Scientific report on human and animal dietary exposure to ergot alkaloids. *EFSA Journal* 2017;15(7):4902, 53 pp. <https://doi.org/10.2903/j.efsa.2017.4902>

- (5) The Authority also examined the relationship between the presence of ergot sclerotia and of ergot alkaloids. At higher levels, a statistically significant linear relationship between the content of sclerotia and the levels of ergot alkaloids could be observed. However, this relationship could not always be demonstrated at lower levels which indicates that the absence of sclerotia does not exclude the presence of ergot alkaloids. A reason is that the handling of cereals breaks the sclerotia, resulting in ergot dust, which is then adsorbed to the cereal grains.
- (6) It is therefore appropriate to lower the maximum level for ergot sclerotia and establish maximum levels for ergot alkaloids in those foodstuffs with significant levels of such alkaloids, contributing significantly to human exposure, and in foodstuffs that are relevant for the exposure of vulnerable population groups.
- (7) Lower levels of ergot sclerotia can already be achieved in most cereals by the application of good agricultural practices and by the application of sorting and cleaning techniques. The existing maximum level for cereals should therefore be reduced in consequence. In this regard, it is also appropriate to clarify the stage at which maximum levels for ergot sclerotia in unprocessed cereals apply in order to eliminate problems as regards their application.
- (8) As regards milling products, it is appropriate to establish different maximum levels for ergot alkaloids depending on the cereal species. Since rye is the cereal species with higher risk of contamination by ergot sclerotia, lower levels of ergot alkaloids are more difficult to achieve and, therefore, a specific maximum level should be set for rye milling products while a lower level should be set for milling products of other cereals. However, as regards milling products of other cereals, different maximum levels should be set depending on the ash content of the products in order to take account of the fact that products containing more bran (higher ash content) have naturally higher levels of ergot alkaloids as dust of ergot sclerotia is adsorbed to bran.
- (9) Furthermore, since it is expected that achievable levels of contamination will continue to decrease for some milling products, it is appropriate to provide that stricter maximum levels should apply in the mid-term to those products. In order to allow the Commission to monitor the progression towards those stricter maximum levels and to assess the possible changes in the levels due to the changes in agricultural practices, as well as in climatic and environmental factors, Member States and interested parties should be required to provide the necessary data and information.
- (10) Wheat gluten, as a by-product of the wet milling process, has been shown to contain higher levels of ergot alkaloids despite the application of good practices as ergot alkaloids concentrate as a consequence of its production process. Therefore, a higher maximum level for ergot alkaloids in wheat gluten should be established.
- (11) Due to changes in Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council <sup>(7)</sup>, a corresponding footnote in the Annex of Regulation (EC) No 1881/2006 should be modified.
- (12) In order to enable economic operators to prepare for the application of the new rules introduced by this Regulation, it is appropriate to provide for a reasonable time until the maximum levels apply and to provide for a transitional period for foodstuffs lawfully placed on the market before the date of application of this Regulation. However, as regards rye, lower levels of contamination by ergot sclerotia may not be reasonably achieved yet and it is therefore appropriate to allow a longer period to allow for a stricter application of good agricultural practices and for the application of improved sorting and cleaning techniques.
- (13) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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<sup>(7)</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 1881/2006 is amended as follows:

(1) in Article 9, paragraph 4 is replaced by the following:

'4. Member States and interested parties shall communicate by 1 January 2023 to the Commission the results of investigations undertaken and the progress with regard to the application of prevention measures to avoid contamination by ergot sclerotia and ergot alkaloids in rye and rye milling products and ergot alkaloids in milling products of barley, wheat, spelt and oats grains.

Member States and interested parties shall report on a regular basis to the EFSA database the occurrence data on ergot sclerotia and ergot alkaloids in rye and rye milling products and on ergot alkaloids in milling products of barley, wheat, spelt and oats grains.;

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

*Article 2*

Foodstuffs listed in the Annex lawfully placed on the market before 1 January 2022, 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 January 2022.

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

Done at Brussels, 24 August 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

The Annex to Regulation (EC) No 1881/2006 is amended as follows:

(1) In section 2, the entries '2.9 Ergot sclerotia and ergot alkaloids' are replaced by the following:

	Foodstuffs <sup>(1)</sup>	Maximum level
'2.9	<b>Ergot sclerotia and ergot alkaloids</b>	
2.9.1.	<b>Ergot sclerotia</b>	
2.9.1.1.	Unprocessed cereals <sup>(18)</sup> with the exception of — maize, rye and rice	0,2 g/kg
2.9.1.2.	Unprocessed rye <sup>(18)</sup>	0,5 g/kg until 30.6.2024 0,2 g/kg as from 1.7.2024
2.9.2.	<b>Ergot alkaloids (*)</b>	
2.9.2.1.	Milling products of barley, wheat, spelt and oats (with an ash content lower than 900mg/100g)	100 µg/kg 50 µg/kg as from 1.7.2024
2.9.2.2.	Milling products of barley, wheat, spelt and oats (with an ash content equal or higher than 900mg/100g)  Barley, wheat, spelt and oats grains placed on the market for the final consumer	150 µg/kg
2.9.2.3.	Rye milling products Rye placed on the market for the final consumer	500 µg/kg until 30.6.2024 250 µg/kg as from 1.7.2024
2.9.2.4.	Wheat gluten	400 µg/kg
2.9.2.5.	Processed cereal based food for infants and young children <sup>(3)</sup> <sup>(29)</sup>	20 µg/kg

(\*) The maximum level for ergot alkaloids refers to the lowerbound sum of the following 12 ergot alkaloids: ergocornine/ergocorninine; ergocristine/ergocristinine; ergocryptine/ergocryptinine ( $\alpha$ - and  $\beta$ -form); ergometrine/ergometrinine; ergosine/ergosinine; ergotamine/ergotaminine. In the lowerbound sum, the contribution of each non-quantified epimer is set at zero.'

(2) Footnote 1 is replaced by the following:

'(1) As regards fruits, vegetables and cereals, reference is made to the foodstuffs listed in the relevant category as defined in Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1). This means, inter alia, that buckwheat (*Fagopyrum* sp) is included in 'cereals' and buckwheat products are included in 'cereal products'. Tree nuts are not covered by the maximum level for fruit.'

(3) Footnote 18 is replaced by the following:

'(18) The maximum level applies to unprocessed cereals placed on the market before first-stage processing. In integrated production and processing systems the maximum level applies in the production chain at the stage before first-stage processing. Integrated production and processing systems means systems where all incoming lots are cleaned, sorted and processed in the same establishment.'

Drying and cleaning, including sorting (colour sorting where applicable) and scouring, are not considered to be "first-stage processing" insofar as the whole grain remains intact.

Scouring is cleaning cereals by brushing or scrubbing it vigorously, combined with dust removal (e.g. aspiration).

In case scouring is applied in the presence of ergot sclerotia the cereals need to firstly undergo a cleaning step before scouring.'

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