



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 6 February 2014
(OR. en)**

6177/14

**DENLEG 26
AGRI 78
SAN 60**

COVER NOTE

From:	European Commission
date of receipt:	3 February 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

No. Cion doc.:	D030012/03
Subject:	COMMISSION REGULATION (EU) No .../.. of XXX amending Regulation (EC) No 401/2006 as regards methods of sampling of large lots, spices and food supplements, performance criteria for T-2, HT-2 toxin and citrinin and screening methods of analysis

Delegations will find attached document D030012/03.

Encl.: D030012/03



EUROPEAN
COMMISSION

Brussels, **XXX**
SANCO/10556/2013
(POOL/E3/2013/10556/10556-EN.doc)
D030012/03
[...](2013) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

amending Regulation (EC) No 401/2006 as regards methods of sampling of large lots, spices and food supplements, performance criteria for T-2, HT-2 toxin and citrinin and screening methods of analysis

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of **XXX**

amending Regulation (EC) No 401/2006 as regards methods of sampling of large lots, spices and food supplements, performance criteria for T-2, HT-2 toxin and citrinin and screening methods of analysis

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules¹, in particular Article 11 (4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006² provides for maximum limits for certain mycotoxins in certain foodstuffs.
- (2) Sampling plays a crucial part in the precision of the determination of the levels of mycotoxins, which are heterogeneously distributed in a lot. It is therefore necessary to set out criteria which the sampling methods should fulfil.
- (3) Commission Regulation (EC) No 401/2006³ establishes the criteria for the sampling for the control of the levels of mycotoxins.
- (4) It is necessary to amend the rules concerning the sampling of spices in order to take into account the differences in particle size which leads to the heterogeneous distribution of mycotoxin contamination in spices. Furthermore it is appropriate to establish rules for the sampling of large lots in order to ensure a uniform enforcement approach across the Union. It is also appropriate to clarify which method of sampling has to be applied for the sampling of apple juice.
- (5) The performance criteria for T-2 and HT-2 toxin need to be updated in order to take into account scientific and technological progress. Performance criteria for citrinin

¹ OJ L 165, 30.4.2004, 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 Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 9.3.2006, p. 12).

need to be established given the maximum level established for citrinin in food supplements based on rice fermented with the red yeast *Monascus purpureus*.

- (6) For the analysis of mycotoxins, screening methodologies are used more and more. It is appropriate to establish criteria with which the screening methods have to comply with for use for regulatory purposes.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 401/2006 is amended as follows:

- (1) Annex I is amended as follows:

- (a) In part B, footnote (1) is replaced by the following:

"(1) The sampling of such lots shall be performed in accordance with the rules set out in part L. Guidance for sampling large lots shall be provided in a guidance document available on the following website: <http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidance-sampling-final.pdf>

The application of sampling rules in accordance with EN ISO 24333:2009 or GAFTA Sampling Rules 124, applied by food business operators to ensure compliance with provisions in legislation is equivalent to the sampling rules set out in part L.

For the sampling of lots for *Fusarium*-toxins, the application of sampling rules in accordance with EN ISO 24333:2009 or GAFTA Sampling Rules 124, applied by food business operators to ensure compliance with provisions in legislation is equivalent to the sampling rules set out in part B;"

- (b) In part B.2, Table 1 is replaced by the following table:

"Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (ton)	Weight or number of sublots	No incremental samples	Aggregate sample Weight (kg)
Cereals and cereal products	>300 and < 1 500	3 sublots	100	10
	≥ 50 and ≤ 300	100 tonnes	100	10
	< 50	--	3-100*	1-10

* Depending on the lot weight - see Table 2"

- (c) In part B.3, the following sentence is added at the end of the first indent:

"For lots > 500 tonnes, the number of incremental samples is provided for in part L.2 of Annex I"

- (d) In part D.2. the following sentence is added after the first sentence:

"This method of sampling is of also of application for the official control of the maximum levels established for ochratoxin A, aflatoxin B1 and total aflatoxins in spices with a relatively large particle size (particle size comparable with peanuts or larger e.g. nutmeg).";

- (e) In part E, the first sentence is replaced by the following:

"This method of sampling is of application for the official control of the maximum levels established for ochratoxin A, aflatoxin B1 and total aflatoxins in spices except in cases of spices with a relatively large particle size (heterogeneous distribution of mycotoxin contamination).";

- (f) In part I, the heading and the first sentence are replaced by the following:

"I. METHOD OF SAMPLING FOR SOLID APPLE PRODUCTS

This method of sampling is of application for the official control of the maximum levels established for patulin in solid apple products, including solid apple products for infants and young children."

- (g) In part I.1, second paragraph, the following sentences are deleted:

"In case of liquid products the lot shall be thoroughly mixed insofar as possible by either manual or mechanical means immediately prior to sampling. In this case, a homogenous distribution of patulin can be assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate sample"

- (h) New Parts L. and M. as set out in Annex I to this Regulation, are added.

2. In Annex II, point 4.2 'General requirements' and point 4.3. 'Specific requirements' and point 4.4 Estimation of measurement uncertainty, recovery calculation and reporting of results' are replaced by the text set out in Annex II 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*.

It shall apply from 1 July 2014.

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

Done at Brussels,

For the Commission
The President
José Manuel BARROSO