Commission Regulation (EU) No 519/2014 of 16 May 2014 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 519/2014

of 16 May 2014

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(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 rules[(1)], in particular Article 11(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006[(2)] 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 401/2006[(3)] 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 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 (tonne)	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[a]	1-10

a 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, points 4.2 ‘General requirements’, 4.3 ‘Specific requirements’ and 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, 16 May 2014.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 519/2014. (See end of Document for details)*

ANNEX I

L. METHOD OF SAMPLING FOR VERY LARGE LOTS OR LOTS STORED OR TRANSPORTED IN A WAY WHEREBY SAMPLING THROUGHOUT THE LOT IS NOT FEASIBLE

L.1. **General principles**

In case the way of transport or storage of a lot does not enable to take incremental samples throughout the whole lot, sampling of such lots should preferably be done when the lot is in flow (dynamic sampling).

In the case of large warehouses destined to store food, operators should be encouraged to install equipment in the warehouse enabling (automatic) sampling across the whole stored lot.

When the sampling procedures as provided for in this part L are applied, the food business operator or his representative should be informed of the sampling procedure. If the sampling procedure is questioned by the food business operator or his representative, the food business operator or his representative shall enable the competent authority to sample throughout the whole lot at his/her own cost.

Sampling of a part of the lot is allowed, on the condition that the quantity of the sampled part is at least 10 % of the lot to be sampled. If a part of a lot of food of the same class or description has been sampled and identified as not satisfying Union requirements, it shall be presumed that the entire lot is also affected, unless further detailed assessment shows no evidence that the rest of the lot is unsatisfactory.

The relevant provisions, such as weight of the incremental sample, provided for in the other parts of this Annex are applicable for the sampling for very large lots or lots stored or transported in a way whereby sampling throughout the lot is not feasible.

L.2. **Number of incremental samples to be taken in the case of very large lots**

In the case of large sampled portions (sampled portions > 500 tonnes), the number of incremental samples to be taken = 100 incremental samples + √tonnes. However in case the lot is less than 1 500 tonnes and can be subdivided into sublots in accordance with the table 1 of part B and on the condition that the sublots can be separated physically, the number of incremental samples as provided for in part B have to be taken.

L.3. **Large lots transported by ship**

L.3.1. *Dynamic sampling of large lots transported by ship*

The sampling of large lots in ships is preferably carried out while the product is in flow (dynamic sampling).

The sampling is to be done per hold (entity that can physically be separated). Holds are however emptied partly one after the other so that the initial physical separation no longer exists after transfer into storage facilities. Sampling can therefore be performed based on initial physical separation or based on the separation after transfer into the storage facilities.

The unloading of a ship can last for several days. Normally, sampling has to be performed at regular intervals during the whole duration of unloading. It is however not always feasible or appropriate for an official inspector to be present for sampling during the whole operation of unloading. Therefore sampling of part of the lot is allowed to be undertaken (sampled portion).

The number of incremental samples is determined by taking into account the size of the sampled portion.

Even if the official sample is taken automatically, the presence of an inspector is necessary. However if the automatic sampling is done with pre-set parameters which cannot be changed during the sampling and the incremental samples are collected in a sealed receptacle, preventing any possible fraud, then the presence of an inspector is only required at the beginning of the sampling, every time the receptacle of the samples needs to be changed and at the end of the sampling.

L.3.2. *Sampling of lots transported by ship by static sampling*

In cases where the sampling is done in a static way the same procedure as foreseen for storage facilities (silos) accessible from above has to be applied (see point L.5.1).

The sampling has to be performed on the accessible part (from above) of the lot/hold. The number of incremental samples is determined by taking into account the size of the sampled portion.

L.4. **Sampling of large lots stored in warehouses**

The sampling has to be performed on the accessible part of the lot. The number of incremental samples is determined by taking into account the size of the sampled portion.

L.5. **Sampling of storage facilities (silos)**

L.5.1. *Sampling of silos (easily) accessible from above*

The sampling has to be performed on the accessible part of the lot. The number of incremental samples is determined by taking into account the size of the sampled portion.

L.5.2. *Sampling of silos not accessible from above (closed silos)*

L.5.2.1. *Silos not accessible from above (closed silos) with individual sizes > 100 tonnes*

Food stored in such silos cannot be sampled in a static way. Therefore when the food in the silo has to be sampled and there is no possibility to move the consignment, the agreement has to be made with the operator that he or she has to inform the inspector about when the silo will be unloaded, partially or completely, in order to enable sampling when the food is in flow.

L.5.2.2. *Silos not accessible from above (closed silos) with individual sizes < 100 tonnes*

Contrary to the provision in part point L.1 (sampled part at least 10 %), the sampling procedure involves the release into a receptacle of a quantity of 50 to 100 kg and taking the sample from it. The size of the aggregate sample corresponds to the whole lot and the number of incremental samples relate to the quantity of the food from the silo released into the receptacle for sampling.

L.6. **Sampling of loose food in large closed containers**

Such lots can often only be sampled when unloaded. In certain cases it is not possible to unload at the point of import or control and therefore the sampling should take place when such containers are unloaded. The operator has to inform the inspector about the place and time of unloading the containers.

M. METHOD OF SAMPLING OF FOOD SUPPLEMENTS BASED ON RICE FERMENTED WITH RED YEAST *MONASCUS PURPUREUS*

This method of sampling is applicable to the official control of the maximum level established for citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus.*