Commission Regulation (EU) No 836/2011 of 19 August 2011 amending Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs (Text with EEA relevance)

COMMISSION REGULATION (EU) No 836/2011

of 19 August 2011

amending Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs

(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 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[(2)] established, inter alia, maximum levels for the contaminant benzo(a)pyrene.

(2) The Scientific Panel on Contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted an opinion on Polycyclic Aromatic Hydrocarbons in Food on 9 June 2008[(3)]. The EFSA concluded that benzo(a)pyrene is not a suitable marker for the occurrence of polycyclic aromatic hydrocarbons (PAH) in food and that a system of four specific substances or eight specific substances would be the most suitable markers of PAH in food. The EFSA also concluded that a system of eight substances would not provide much added value compared to a system of four substances.

(3) As a consequence Commission Regulation (EU) No 835/2011[(4)] amended Regulation (EC) No 1881/2006 in order to set maximum levels for the sum of four polycyclic aromatic hydrocarbons (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene).

(4) Commission Regulation (EC) No 333/2007[(5)] lays down analytical performance criteria only for benzo(a)pyrene. It is therefore necessary to lay down analytical performance criteria for the other three substances for which maximum levels are now set out in Regulation (EC) No 1881/2006.

(5) The European Union Reference Laboratory for Polycyclic Aromatic Hydrocarbons (EU-RL PAH) in collaboration with the national reference laboratories carried out a survey among official control laboratories to assess which analytical

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 836/2011. (See end of Document for details)*

performance criteria would be achievable for benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene in relevant food matrices. The outcome of this survey was summarised by the EU-RL PAH in the Report on 'Performance characteristics of analysis methods for the determination of 4 polycyclic aromatic hydrocarbons in food'[6]. The results of the survey show that the analytical performance criteria currently applicable to benzo(a)pyrene are also suitable for the other three substances.

(6) Experience acquired while implementing Regulation (EC) No 333/2007 revealed that in some cases the current sampling provisions may be impracticable or may lead to unacceptable economic damage to the sampled lot. For such cases, departure from the sampling procedures should be allowed, provided that sampling remains sufficiently representative of the sampled lot or sublot and that the procedure used is fully documented. For sampling at the retail stage, flexibility to depart from the sampling procedures existed already. The provisions for sampling at retail stage should be aligned with the general sampling procedures.

(7) More detailed provisions are needed as regards the material of sampling containers when samples are taken for PAH analysis. Plastic containers are widely used by enforcement authorities, but they are not suitable when sampling is carried out for PAH analysis, as the PAH content of the sample can be altered by these materials.

(8) Clarification is needed for some aspects of the specific requirements for analytical methods, in particular the requirements regarding the use of the performance criteria and the 'fitness-for-purpose' approach. Furthermore, the presentation of the tables with the performance criteria should be modified to appear more uniform across all analytes.

(9) Regulation (EC) No 333/2007 should therefore be amended accordingly. Since Regulation (EU) No 835/2011 and this Regulation are inter-linked, both Regulations should become applicable on the same date.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 333/2007 is amended as follows:

(1) the title is replaced by the following:
Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs;

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

1. Sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons ("PAH") listed

in Sections 3, 4 and 6 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the Annex to this Regulation.;

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

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union.*

It shall apply from 1 September 2012.

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

Done at Brussels, 19 August 2011.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 836/2011. (See end of Document for details)

ANNEX

The Annex to Regulation (EC) No 333/2007 is amended as follows:

(1) in point B.1.7 'Packaging and transmission of samples', the following second paragraph is added:

> In case of sampling for PAH analysis plastic containers shall be avoided if possible as they could alter the PAH content of the sample. Inert, PAH-free glass containers, adequately protecting the sample from light, shall be used wherever possible. Where this is practically impossible, at least direct contact of the sample with plastics shall be avoided, e.g. in case of solid samples by wrapping the sample in aluminium foil before placing it in the sampling container.;

(2) points B.2 and B.3 are replaced by the following:

B.2. SAMPLING PLANS

B.2.1. **Division of lots into sublots**

Large lots shall be divided into sublots on condition that the sublot may be separated physically. For products traded in bulk consignments (e.g. cereals) Table 1 shall apply. For other products Table 2 shall apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

B.2.2. **Number of incremental samples**

The aggregate sample shall be at least 1 kg or 1 litre except where it is not possible, e.g. when the sample consists of 1 package or unit.

The minimum number of incremental samples to be taken from the lot or sublot shall be as given in Table 3.

In the case of bulk liquid products the lot or sublot shall be thoroughly mixed in so far as possible and in so far it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of contaminants is assumed within a given lot or sublot. It is therefore sufficient to take three incremental samples from a lot or sublot to form the aggregate sample.

The incremental samples shall be of similar weight/volume. The weight/volume of an incremental sample shall be at least 100 grams or 100 millilitres, resulting in an aggregate sample of at least about 1 kg or 1 litre. Departure from this method shall be recorded in the record provided for under point B.1.8 of this Annex.

TABLE 1

Subdivision of lots into sublots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 1 500	500 tonnes
> 300 and < 1 500	3 sublots
≥ 100 and ≤ 300	100 tonnes
< 100	—

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TABLE 2

Subdivision of lots into sublots for other products

Lot weight (ton)	Weight or number of sublots
≥ 15	15-30 tonnes
< 15	—

TABLE 3

Minimum number of incremental samples to be taken from the lot or sublot

Weight or volume of lot/sublot (in kg or litre)	Minimum number of incremental samples to be taken
< 50	3
≥ 50 and ≤ 500	5
> 500	10

If the lot or sublot consists of individual packages or units, then the number of packages or units which shall be taken to form the aggregate sample is given in Table 4.

TABLE 4

Number of packages or units (incremental samples) which shall be taken to form the aggregate sample if the lot or sublot consists of individual packages or units

Number of packages or units in the lot/sublot	Number of packages or units to be taken
≤ 25	at least 1 package or unit
26-100	about 5 %, at least 2 packages or units
> 100	about 5 %, at maximum 10 packages or units

The maximum levels for inorganic tin apply to the contents of each can, but for practical reasons it is necessary to use an aggregate sampling approach. If the result of the test for an aggregate sample of cans is less than but close to the maximum level of inorganic tin and if it is suspected that individual cans might exceed the maximum level, then it might be necessary to conduct further investigations.

Where it is not possible to carry out the method of sampling set out in this chapter because of the unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot, etc.) or where it is practically impossible to apply the abovementioned method of sampling, an alternative method of sampling may be applied provided that it is sufficiently representative for the sampled lot or sublot and is fully documented.

B.2.3. **Specific provisions for the sampling of large fish arriving in large lots**

In case the lot or sublot to be sampled contains large fishes (individual fishes weighing more than about 1 kg) and the lot or sublot weighs more than 500 kg, the incremental