Commission Regulation (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014 (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/644

of 5 April 2017

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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)], and in particular Article 11(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006[(2)] sets out the maximum levels for non-dioxin-like polychlorinated biphenyls (PCBs) dioxins and furans and for the sum of dioxins, furans and dioxin-like PCBs in certain foodstuffs.

(2) Commission Recommendation 2013/711/EU[(3)] sets out action levels in order to stimulate a proactive approach to reduce the presence of polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans (PCDD/Fs) and dioxin-like PCBs in food. Those action levels are a tool used by competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take the necessary measures in order to reduce or eliminate it.

(3) Commission Regulation (EC) No 589/2014[(4)] establishes specific provisions concerning the sampling procedure and the methods of analysis to be applied for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs.

(4) The provisions laid down in this Regulation relate only to the sampling and analysis of dioxins, dioxin-like PCBs and non-dioxin-like PCBs for the implementation of Regulation (EC) No 1881/2006 and Recommendation 2013/711/EU. They do not affect the sampling strategy, sampling levels and frequency as set out in Annexes III and IV to Council Directive 96/23/EC[(5)]. They do not affect the targeting criteria for sampling as laid down in Commission Decision 98/179/EC[(6)].

(5) It is appropriate to ensure that food business operators applying the controls performed within the framework of Article 4 of Regulation (EC) No 852/2004 of the European

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Parliament and of the Council[7] apply sampling procedures equivalent to the sampling procedures provided for by this Regulation in order to ensure that samples taken for those controls are representative samples. Furthermore, the European Union Reference Laboratory for Dioxins and PCBs has provided evidence that analytical results in certain cases are not reliable when the performance criteria as provided in this Regulation are not applied by laboratories performing the analysis of samples taken by food business operators within the framework of Article 4 of Regulation (EC) No 852/2004. It is therefore appropriate to make the application of the performance criteria also obligatory for the analysis of those samples.

(6) Given that the approach of the use of a decision limit to ensure that an analytical result is above the maximum level with a certain probability, as provided for in Commission Decision 2002/657/EC[8], is no longer applied for the analysis of dioxins and PCBs in food, it is appropriate to delete this approach and to keep only the approach of the expanded uncertainty using the coverage factor of 2, giving a level confidence of approximately 95 %.

(7) In line with the reporting requirements for bioanalytical screening methods, it is appropriate to also provide for physico-chemical methods used for screening specific reporting requirements.

(8) Given that the analysis of dioxins, dioxin-like PCBs and non-dioxin-like PCBs are in most cases determined together it is appropriate to align the performance criteria for the non-dioxin-like PCBs to the performance criteria for dioxins and dioxin-like PCBs. This is a simplification, without substantial changes in practice as in the case of non-dioxin-like PCBs the relative intensity of qualifier ions compared to target ions is > 50 %.

(9) Furthermore there are several other minor modifications proposed to the current provisions, requiring the repeal of Regulation (EU) No 589/2014 and its replacing by a new Regulation to maintain the readability of the text.

(10) 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

For the purposes of this Regulation, the definitions and abbreviations set out in Annex I shall apply.

Article 2

Sampling for the official control of the levels of dioxins, furans, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs listed in Section 5 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the methods set out in Annex II to this Regulation.

Article 3

Sample preparation and analyses for the control of the levels of dioxins, furans and dioxin-like PCBs in foodstuffs listed in Section 5 of the Annex to Regulation (EC) No

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1881/2006 shall be carried out in accordance with the methods set out in Annex III to this Regulation.

Article 4

Analyses for the control of the levels of non-dioxin-like PCBs in foodstuffs listed in Section 5 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the requirements for analytical procedures set out in Annex IV to this Regulation.

Article 5

Regulation (EU) No 589/2014 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 6

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, 5 April 2017.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX I

DEFINITIONS AND ABBREVIATIONS

I.DEFINITIONS

For the purposes of this Regulation the definitions laid down in Annex I to Decision 2002/657/EC shall apply.

Further to those definitions, the following definitions shall apply for the purposes of this Regulation:

1.1. 'Action level' means the level of a given substance, as laid down in the Annex to Recommendation 2013/711/EU, which triggers investigations to identify the source of that substance in cases where increased levels of the substance are detected.

1.2. 'Screening methods' means methods used for the selection of those samples with levels of PCDD/Fs and dioxin-like PCBs that exceed the maximum levels or the action levels. They shall allow for a cost-effective high sample-throughput, thus increasing the chance of discovering new cases where high exposure may lead to health risks for consumers. Screening methods shall be based on bioanalytical or GC-MS methods. Results from samples exceeding the cut-off value established to check compliance with the maximum level shall be verified by a full re-analysis from the original sample using a confirmatory method.

1.3. 'Confirmatory methods' means methods that provide full or complementary information enabling the PCDD/Fs and dioxin-like PCBs to be identified and quantified unequivocally at the maximum or, in case of need, at the action level. Such methods utilise gas chromatography/high resolution mass spectrometry (GC-HRMS) or gas chromatography/tandem mass spectrometry (GC-MS/MS).

1.4. 'Bioanalytical methods' means methods based on the use of biological principles such as cell-based assays, receptor-assays or immunoassays. They do not give results at the congener level but merely an indication[(9)] of the TEQ level, expressed in Bioanalytical Equivalents (BEQ) to acknowledge the fact that not all compounds present in a sample extract that produce a response in the test may meet all requirements of the TEQ-principle.

1.5. 'Bioassay apparent recovery' means the BEQ level calculated from the TCDD or PCB 126 calibration curve corrected for the blank and then divided by the TEQ level determined by the confirmatory method. It attempts to correct factors like the loss of PCDD/Fs and dioxin-like compounds during the extraction and clean-up steps, co-extracted compounds increasing or decreasing the response (agonistic and antagonistic effects), the quality of the curve fit, or differences between the TEF and the REP values. The bioassay apparent recovery is calculated from suitable reference samples with representative congener patterns around the maximum or action level.

1.6. 'Duplicate analysis' means separate analysis of the analytes of interest using a second aliquot of the same homogenised sample.

1.7. 'Accepted specific limit of quantification[(10)] of an individual congener in a sample' means the lowest content of the analyte that can be measured with reasonable statistical certainty, fulfilling the identification criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 ('Animal feed — Determination of dioxins and dioxin-like PCBs by GC/HRMS and of indicator PCBs by GC/HRMS') and/or in EPA methods 1613 and 1668 as revised.

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The limit of quantification of an individual congener may be identified as

(a) the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions to be monitored with a S/N (signal/noise) ratio of 3:1 for the less intensive raw data signal;

or, if for technical reasons the signal-to-noise calculation does not provide reliable results,

(b) the lowest concentration point on a calibration curve that gives an acceptable (≤ 30 %) and consistent (measured at least at the start and at the end of an analytical series of samples) deviation to the average relative response factor calculated for all points on the calibration curve in each series of samples[(11)].

1.8. 'Upper-bound' means the concept which requires using the limit of quantification for the contribution of each non-quantified congener.

1.9. 'Lower-bound' means the concept which requires using zero for the contribution of each non-quantified congener.

1.10. 'Medium-bound' means the concept which requires using half of the limit of quantification calculating the contribution of each non-quantified congener.

1.11. 'Lot' means an identifiable quantity of food delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings. In the case of fish and fishery products, also the size of fish shall be comparable. In case the size and/or weight of the fish is not comparable within a consignment, the consignment may still be considered as a lot but a specific sampling procedure has to be applied.

1.12. 'Sublot' means designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable.

1.13. 'Incremental sample' means a quantity of material taken from a single place in the lot or sublot.

1.14. 'Aggregate sample' means the combined total of all the incremental samples taken from the lot or sublot.

1.15. 'Laboratory sample' means a representative part/quantity of the aggregate sample intended for the laboratory.

II. ABBREVIATIONS USED

BEQ	Bioanalytical Equivalents
GC	Gas chromatography
HRMS	High resolution mass spectrometry
LRMS	Low resolution mass spectrometry
MS/MS	Tandem mass spectrometry
PCB	Polychlorinated biphenyl
Non-dioxin-like PCBs	PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180
PCDD	Polychlorinated dibenzo-p-dioxins
PCDF	Polychlorinated dibenzofurans
QC	Quality control
REP	Relative potency
TEF	Toxic Equivalency Factor