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Subject:	COMMISSION REGULATION (EU) .../... of XXX 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

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Delegations will find attached document D045998/044.

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**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**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) .../...

of **XXX**

**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)

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<sup>1</sup>, and in particular Article 11(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006<sup>2</sup> 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<sup>3</sup> 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<sup>4</sup> 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

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<sup>1</sup> OJ L 165, 30.4.2004, 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> Commission Recommendation 2013/711/EU of 3 December 2013 on the reduction of the presence of dioxins, furans and PCBs in feed and food (OJ L 323, 4.12.2013, p. 37).

<sup>4</sup> Commission Regulation (EU) No 589/2014 of 2 June 2014 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012 (OJ L 164, 3.6.2014, p. 18).

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<sup>5</sup>. They do not affect the targeting criteria for sampling as laid down in Commission Decision 98/179/EC<sup>6</sup>.

- (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 Parliament and of the Council<sup>7</sup> 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<sup>8</sup>, 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,

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<sup>5</sup> Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

<sup>6</sup> Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products (OJ L 65, 5.3.1998, p. 31).

<sup>7</sup> Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

<sup>8</sup> Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (OJ L 221, 17.8.2002, p. 8).

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 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,

*For the Commission*  
*Jean-Claude JUNCKER*  
*The President*