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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 152/2009 as regards the methods for the determination of the levels of dioxins and polychlorinated biphenyls
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Delegations will find attached document D47571/03.

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[...](2016) **XXX** draft

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

of **XXX**

amending Regulation (EC) No 152/2009 as regards the methods for the determination of the levels of dioxins and polychlorinated biphenyls

(Text with EEA relevance)

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

of **XXX**

amending Regulation (EC) No 152/2009 as regards the methods for the determination of the levels of dioxins and polychlorinated biphenyls

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

Whereas:

- (1) Commission Regulation (EC) No 152/2009² includes methods for the determination of the levels of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like polychlorinated biphenyls (PCBs) and non-dioxin-like PCBs in feed.
- (2) EU reference laboratory for dioxins and PCBs in feed and food has provided evidence that analytical results for dioxins and PCBs in certain cases are not reliable when the performance criteria provided for in Part B of Annex V to Regulation (EC) No 152/2009 are not applied by laboratories performing the analysis of samples taken by feed business operators in accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council³. It is therefore appropriate to make the application of the performance criteria for the analysis of samples obligatory.
- (3) Given that the method of using a decision limit to ensure, with a certain probability, that an analytical result is above the maximum level, as provided for in Commission Decision 2002/657/EC⁴, is no longer applied for the analysis of dioxins, furans and PCBs in feed, it is appropriate to delete that method and to keep only the method of the expanded uncertainty using the coverage factor of 2, which gives a level of confidence of approximately 95 %.

¹ OJ L 165, 30.4.2004, p. 1.

² Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

³ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

⁴ 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).

- (4) Guidance documents for the measurement uncertainty and for the estimation of the Limit of Detection (LOD) and Limit of Quantification (LOQ) have been developed. It is appropriate to make reference to them.
- (5) In line with the reporting requirements for bioanalytical screening methods provided for in Part B of Annex V to Regulation (EC) No 152/2009, it is appropriate to provide also for physico-chemical methods, to be used for screening, specific reporting requirements in Chapter II of that Part.
- (6) 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 provided for in point 3.3 of Chapter III of Part B of Annex V to Regulation (EC) No 152/2009 to the performance criteria for dioxins and dioxin-like PCBs. This is a simplification without substantial changes in practice as for non-dioxin-like PCBs the relative intensity of qualifier ions compared to target ions is > 50 %.
- (7) Following experience gained, it is appropriate to adapt some technical specifications such as recoveries of isotope-labelled standards provided for in points 7.3 and 7.5 of Chapter III of Part B of Annex V to Regulation (EC) No 152/2009.
- (8) Furthermore, there are several other minor modifications proposed to the current provisions to improve the consistency in the terminology used, requiring replacing the whole Part B of Annex V to Regulation (EC) No 152/2009 to maintain the readability of the text.
- (9) Regulation (EC) No 152/2009 should therefore be amended accordingly.
- (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,

HAS ADOPTED THIS REGULATION:

Article 1

Part B of Annex V to Regulation (EC) No 152/2009 is amended in accordance with the Annex 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*.

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

Done at Brussels,

*For the Commission
The President
Jean-Claude JUNCKER*