Commission Regulation (EU) 2017/771 of 3 May 2017 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) 2017/771

of 3 May 2017

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

Whereas:

(1) Commission Regulation (EC) No 152/2009[(2)] 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 Council[(3)]. 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/EC[(4)], 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 %.

(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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/771. (See end of Document for details)*

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, 3 May 2017.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

In Annex V to Regulation (EC) No 152/2009, Part B 'DETERMINATION OF THE LEVELS OF DIOXINS (PCDD/PCDF) AND PCBs' is replaced by the following:

B. DETERMINATION OF THE LEVELS OF DIOXINS (PCDD/PCDF) AND PCBs

CHAPTER I

Methods of sampling and interpretation of analytical results

1. **Scope and definitions**

The samples intended for the official control of the levels of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like polychlorinated biphenyls (PCBs)[(5)] and non dioxin-like PCBs in feed shall be taken in accordance with the provisions of Annex I. The quantitative requirements in relation to the control of substances or products uniformly distributed throughout the feed as provided for in point 5.1. of Annex I shall be applied. Aggregate samples thus obtained shall be considered representative for the lots or sublots from which they are taken. Compliance with maximum levels laid down by Directive 2002/32/EC shall be established on the basis of the levels determined in the laboratory samples.

For the purposes of this Part B, the definitions laid down in Annex I to Commission Decision 2002/657/EC[(6)] shall apply.

In addition to those definitions, the following definitions shall apply for the purpose of this Part B:

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

"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 threshold. Such methods utilize gas chromatography/high resolution mass spectrometry (GC-HRMS) or gas chromatography/tandem mass spectrometry (GC-MS/MS).

2. **Compliance of the lot or sublot with the maximum level**

2.1. *As regards non-dioxin-like PCBs*

The lot or sublot complies with the maximum level if the analytical result for the sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180 (hereafter referred to as non-dioxin-like PCBs) does not exceed the maximum level laid down by Directive 2002/32/EC, taking into account the expanded measurement uncertainty[(7)]. The lot or sublot does not comply with the maximum level as laid down by Directive 2002/32/EC, if the mean of two upper-bound[(8)] analytical results obtained from duplicate analysis[(9)], taking into account the expanded measurement uncertainty, exceeds the maximum level beyond reasonable doubt, i.e. the analysed concentration after deduction of the expanded measurement uncertainty is used to assess compliance.

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The expanded measurement uncertainty is calculated using a coverage factor of 2 which gives a level of confidence of approximately 95 %. A lot or sublot is non-compliant if the mean of the measured values minus the expanded uncertainty of the mean is above the maximum level.

The rules, mentioned in the paragraphs above under this point, shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules shall apply.

2.2. *As regards PCDD/Fs and dioxin-like PCBs*

The lot or sublot complies with the maximum level if the result of a single analysis

— performed by a screening method with a false-compliant rate below 5 %, indicates that the level does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs laid down by Directive 2002/32/EC,

— performed by a confirmatory method, does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs laid down by Directive 2002/32/EC, taking into account the expanded measurement uncertainty.

For screening assays a cut-off value shall be established for decisions on sample compliance with the respective maximum levels set for either PCDD/Fs, or for the sum of PCDD/Fs and dioxin-like PCBs.

The lot or sublot does not comply with the maximum level as laid down by Directive 2002/32/EC if the mean of two upper-bound[(10)] analytical results obtained from duplicate analysis[(11)] using a confirmatory method, taking into account the expanded measurement uncertainty, exceeds the maximum level beyond reasonable doubt, i.e. the analysed concentration after deduction of the expanded measurement uncertainty is used to assess compliance.

The expanded measurement uncertainty is calculated using a coverage factor of 2 which gives a level of confidence of approximately 95 %. A lot or sublot is non-compliant if the mean of the measured values minus the expanded uncertainty of the mean is above the maximum level.

The sum of the estimated expanded uncertainties of the separate analytical results of PCDD/Fs and dioxin-like PCBs shall be used for the sum of PCDD/Fs and dioxin-like PCBs.

The rules, mentioned in the paragraphs above under this point, shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules shall apply.

3. **Results exceeding action thresholds as laid down in Annex II to Directive 2002/32/EC**

Action thresholds serve as a tool for the selection of samples in those cases where it is necessary to identify a source of contamination and to take measures for its reduction or elimination. Screening methods shall establish the appropriate cut-off values for selection of those samples. Where significant efforts are necessary to identify a source and to reduce or eliminate the contamination, it is appropriate to confirm exceedance of the action thresholds by duplicate analysis using a confirmatory method and taking into account the expanded measurement uncertainty[(12)].

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CHAPTER II

Sample preparation and requirements for methods of analysis used in offical control of the levels of dioxins (PCDD/Fs) and dioxin-like PCBs in feed

1. Field of application

The requirements set out in this Chapter shall be applied where feed is analysed for the official control of the levels of 2,3,7,8-substituted PCDD/Fs and dioxin-like PCBs and as regards sample preparation and analytical requirements for other regulatory purposes, which includes the controls performed by the feed business operator to ensure compliance with the provisions of Regulation (EC) No 183/2005 of the European Parliament and of the Council[(13)].

Monitoring for the presence of PCDD/Fs and dioxin-like PCBs in feed may be performed with two different types of analytical methods:

(a) *Screening methods*

The goal of screening methods is to select those samples with levels of PCDD/Fs and dioxin-like PCBs that exceed the maximum levels or the action thresholds. Screening methods shall ensure cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks of consumers. Their application shall aim to avoid false-compliant results. They may comprise bioanalytical and GC-MS methods.

Screening methods compare the analytical result with a cut-off value, providing a yes/no-decision over the possible exceedance of the maximum level or action threshold. The concentration of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs in samples suspected to be non-compliant with the maximum level shall be determined or confirmed by a confirmatory method.

In addition, screening methods may give an indication of the levels of PCDD/Fs and dioxin-like PCBs present in the sample. In case of application of bioanalytical screening methods the result is expressed as Bioanalytical Equivalents (BEQ), whereas in case of application of physico-chemical GC-MS methods it is expressed as Toxic Equivalents (TEQ). The numerically indicated results of screening methods are suitable for demonstrating compliance or suspected noncompliance or exceedance of action thresholds and give an indication of the range of levels in case of follow-up by confirmatory methods. They are not suitable for purposes such as evaluation of background levels, estimation of intake, following of time trends in levels or re-evaluation of action thresholds and maximum levels.

(b) *Confirmatory methods*

Confirmatory methods allow the unequivocal identification and quantification of PCDD/Fs and dioxin-like PCBs present in a sample and provide full information on congener level. Therefore, those methods allow the control of maximum levels and action thresholds, including the confirmation of results obtained by screening methods. Furthermore, results may be used for other purposes such as determination of low background levels in feed monitoring, following of time trends, exposure assessment and building of a database for possible re-evaluation of action thresholds and maximum levels. They are also important for establishing congener patterns in order to identify the source of a possible contamination. Such methods utilise GC-HRMS. For confirming compliance or non-compliance with the maximum level, also GC-MS/MS can be used.