Commission Regulation (EU) No 709/2014 of 20 June 2014 amending Regulation (EC) No 152/2009 as regards the determination of the levels of dioxins and polychlorinated biphenyls (Text with EEA relevance)

COMMISSION REGULATION (EU) No 709/2014

of 20 June 2014

amending Regulation (EC) No 152/2009 as regards 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) and dioxin-like polychlorinated biphenyls (PCBs) in feed.

(2) Requirements should be set out concerning screening methods which identify the samples with significant levels of PCDD/Fs and dioxin-like PCBs (preferably selecting samples exceeding action thresholds and ensuring the selection of samples exceeding maximum levels) and which have a high throughput. With respect to the maximum levels, the false-compliant rate of those screening methods should be below 5 %.

(3) Where the results achieved with the screening method exceed the cut-off value, the original sample should be analysed by means of a method capable of identifying and quantifying the PCDD/Fs and dioxin-like PCBs contained in the sample. Hereinafter such methods are referred to as ‘confirmatory methods’. Technical progress and developments have shown that the use of gas chromatography/tandem mass spectrometry (GC-MS/MS) should be allowed for use as a confirmatory method for checking compliance with the maximum level, in addition to gas chromatography/high resolution mass spectrometry (GC-HRMS).

(4) Following the experience gained with the application of the rules currently in place, an amendment is appropriate to the current provisions as regards the necessity of duplicate analysis, the judgement of compliance in case of duplicate analysis and the requirement on the acceptable difference between upper-bound and lower-bound results.

(5) Regulation (EC) No 152/2009 should therefore be amended accordingly.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 709/2014. (See end of Document for details)*

(6) 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 is binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 709/2014. (See end of Document for details)*

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. **Purpose and Scope**

The samples intended for the official control of the levels of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like polychlorinated biphenyls (PCBs)[(3)] 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 in 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[(4)] 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 to check compliance with the maximum level shall be verified by a full re-analysis from the original sample by 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 utilise 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 complies with the maximum level if the analytical result does not exceed the maximum level of non-dioxin-like PCBs laid down by Directive 2002/32/EC, taking into account the measurement uncertainty.

The lot does not comply with the maximum level if the upper-bound[(5)] analytical result confirmed by duplicate analysis[(6)] exceeds the maximum level laid down by Directive 2002/32/EC, taking into account the measurement uncertainty. The mean of two determinations, taking into account the measurement uncertainty is used for verification of compliance.

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The measurement uncertainty shall be taken into account according to one of the following approaches:

— by calculating the expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %. A lot or sublot is noncompliant if the measured value minus U is above the maximum level,

— by establishing the decision limit (CCα) in accordance with point 3.1.2.5 of Annex I to Decision 2002/657/EC. A lot or sublot is non-compliant if the measured value is equal to or above the CCα.

Paragraphs 1, 2 and 3 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/F and dioxin-like PCBs*

The lot complies with the maximum levels 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/PCDFs and the sum of PCDD/PCDFs 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/PCDFs and the sum of PCDD/PCDFs and dioxin-like PCBs laid down by Directive 2002/32/EC, taking into account the 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/PCDFs, or for the sum of PCDD/PCDFs and dioxin-like PCBs.

The lot does not comply with the maximum level if the upper-bound[7] analytical result obtained with a confirmatory method and confirmed by duplicate analysis exceeds the maximum level laid down by Directive 2002/32/EC, taking into account the measurement uncertainty[8]. The mean of two determinations, taking into account the measurement uncertainty, is used for verification of compliance.

The measurement uncertainty shall be taken into account according to one of the following approaches:

— by calculating the expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %. A lot or sublot is non-compliant if the measured value minus U is above the maximum level. In case of a separate determination of PCDD/PCDFs and dioxin-like-PCBs, the sum of the estimated expanded uncertainty of the separate analytical results of PCDD/PCDFs and dioxin-like PCBs shall be used for the sum of PCDD/PCDFs and dioxin-like PCBs,

— by establishing the decision limit (CCα) in accordance with point 3.1.2.5 of the Annex I to Decision 2002/657/EC. A lot or sublot is non-compliant if the measured value is equal to or above the CCα.

Paragraphs 1 to 4 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 to reduce or eliminate it. Screening methods shall establish appropriate cut-off values for the selection of those samples. In case significant efforts are necessary to identify a source and to reduce or eliminate the contamination, it might be appropriate to confirm exceedance of the action thresholds

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is confirmed by duplicate analysis using a confirmatory method and taking into account the measurement uncertainty[(9)].

CHAPTER II

Sample preparation and requirements for methods of analysis used in official control of the levels of dioxins (PCDD/PCDF) 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 polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/Fs) and dioxin-like polychlorinated biphenyls (dioxin-like PCBs) and for other regulatory purposes.

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 should allow cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks of consumers. Their application should aim at avoiding 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 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 must be determined/confirmed by a confirmatory method.

In addition, screening methods may give an indication of the levels of PCDD/Fs and dl-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 at congener level. Therefore, these 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-