Commission Regulation (EU) No 278/2012 of 28 March 2012 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 278/2012

of 28 March 2012

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) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[(2)] lays down maximum levels for dioxins, furans and polychlorinated biphenyls (PCBs) in feed and action thresholds triggering investigations by Member States to identify the sources of those substances.

(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[(3)] 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.

(3) A screening method of analysis with widely acceptable validation and high throughput can be used to 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). The levels of PCDD/Fs and dioxin-like PCBs in these samples need to be determined by a confirmatory method of analysis. It is therefore appropriate to establish appropriate requirements for the screening method making sure that the false-compliant rate with respect to maximum levels is below 5 % and strict requirements for the confirmatory methods of analysis. Furthermore, confirmatory methods allow the determination of levels also in the low background range. That is important for the follow-up of time trends, exposure assessment and for the re-evaluation of maximum and action thresholds.

(4) The modification of the maximum levels for dioxins and dioxin-like PCBs and the establishment of non-dioxin-like PCBs in Directive 2002/32/EC and the need to update

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 278/2012. (See end of Document for details)*

the criteria for screening methods makes it necessary to amend the rules on the determination of dioxins and PCBs in feed, as laid down by Part B of Annex V to Regulation (EC) No 152/2009. For reasons of clarity and comprehensibility, it is appropriate to replace Part B of Annex V.

(5) It is of major importance that analytical results are reported and interpreted in a uniform way in order to ensure a harmonised enforcement approach throughout the Union.

(6) Annex V to Regulation (EC) No 152/2009 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

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*.

It shall apply from the date of entry into force.

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

Done at Brussels, 28 March 2012.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 278/2012. (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 DIOXIN-LIKE 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)[(4)] 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.A of Annex I shall be applied. Aggregate samples thus obtained shall be considered representative for the lots or sub-lots 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 of Annex V, the definitions laid down in Annex I to Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and interpretation of results[(5)] shall apply.

2. **Compliance of the lot or sub-lot with the specification**

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

The lot complies with the specification 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 specification if the upper-bound[(6)] analytical result confirmed by duplicate analysis[(7)] exceeds the maximum level laid down by Directive 2002/32/EC, taking into account the measurement uncertainty.

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 sub-lot is non-compliant 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 sub-lot is non-compliant if the measured value is equal to or above the CCα.

These interpretation rules 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 specifications if the analytical result of a single analysis,

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— 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 levels of interest set for either PCDD/PCDFs, or for the sum of PCDD/PCDFs and dioxin-like PCBs.

The lot does not comply with the specification if the upper-bound[8] 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[9].

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 sub-lot 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 sub-lot is non-compliant if the measured value is equal to or above the CCα.

These interpretation rules 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 these samples. The efforts necessary to identify a source and to reduce or eliminate the contamination shall be deployed only if exceedance of the action thresholds is confirmed by duplicate analysis using a confirmatory method and taking into account the measurement uncertainty[10].

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 Annex 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 regulatory purposes.

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

(a) Selection of those samples with levels of PCDD/Fs and dioxin-like PCBs that exceed the maximum levels, or the action thresholds. This approach may involve a screening method allowing cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks of consumers. Screening methods may comprise bioanalytical methods and GC/MS methods. Their application should aim at avoiding false-compliant results. The concentration of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs in those samples with significant levels needs to be determined/confirmed by a confirmatory method.

(b) Determination of the levels of PCDD/Fs and dioxin-like PCBs in feed samples in the range of low background levels. This is important in order to follow time trends, exposure assessment of the population and to build a database for possible re-evaluation of action and maximum levels. This goal is achieved by confirmatory methods enabling the PCDD/Fs and dioxin-like PCBs to be identified and quantified unequivocally at the level of interest. These methods can be used for confirmation of results obtained by screening methods and for determination of low background levels in feed monitoring. They are also important for establishing congener patterns in order to identify the source of a possible contamination. At present such methods utilise high-resolution gas chromatography/high resolution mass spectrometry (HRGC/ HRMS).

2. **Classification of methods by their degree of quantification**[(11)]

2.1. *Qualitative methods* give a yes/no response on the presence of analytes of interest, with no quantified indication of the concentration of the putative analyte. Qualitative methods may have the potential for providing semi-quantitative results but are used solely for report of a yes/no decision as indication of levels above or below certain ranges, e.g. limit of detection, limit of quantification or cut-off values.

For the control of maximum levels and action thresholds for PCDD/PCDFs and dioxin-like PCBs in feed, screening methods may be applied which are based on the comparison of the analytical result with a cut-off value and give a yes/no decision for indication for the possible exceedance of the level of interest.

2.2. *Semi-quantitative methods* are methods which give an approximate indication of the concentration of the putative analyte, while the numerical result does not meet the requirements for quantitative methods. They may be used to provide information on the range of the analyte concentration in order for the analyst to decide on the calibration range for the confirmatory test subsequently to be performed and for quality control purposes. For example, the following methods shall be considered as semi-quantitative methods:

(a) methods based on the use of biological principles like cell-based assays, receptor-assays or immunoassays, hereinafter bioanalytical methods, which are able to detect the analytes of interest, include a calibration curve, give a yes/no decision for indication for the possible exceedance of the level of interest and allow to report the result as bioanalytical equivalents (BEQ), being an indication of the TEQ value in the sample;

(b) physicochemical test (e.g. Gas chromatography-Mass spectrometry/Mass spectrometry (GC-MS/MS) or Gas chromatography/Low resolution mass spectrometry (GC/LRMS)) where the measured method precision characteristics do not meet the requirements for quantitative tests.