Official Journal of the European Union

L 188

Volume 57

English edition

Legislation

27 June 2014

Contents

[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

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.

(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,

([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).

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

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) ([1])* 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 ([2])* 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 ([3])* analytical result confirmed by duplicate analysis ([4])* 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.

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 ([5])* 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 ([6])*. 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 is confirmed by duplicate analysis using a confirmatory method and taking into account the measurement uncertainty ([7])*.

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-HRMS. For confirming compliance or non-compliance with the maximum level, also GC-MS/MS can be used.

2. **Background**

For calculation of Toxic Equivalent (TEQ) concentrations, the concentrations of the individual substances in a given sample shall be multiplied by their respective Toxic Equivalency Factor (TEF) (see footnote (1)* of Chapter I) and subsequently summed to give the total concentration of dioxin-like compounds expressed as TEQs.

For the purposes of this Part B, the accepted specific limit of quantification of an individual congener means the lowest content of the analyte that can be measured with reasonable statistical certainty, fulfilling the identification criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC-HRMS and of indicator PCBs by GC-HRMS) and/or in EPA methods 1613 and 1668 as revised.

The limit of quantification of an individual congener may be identified as

(a) the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions to be monitored with a S/N (signal/noise) ratio of 3:1 for the less intensive raw data signal; or

(b) if for technical reasons the signal-to-noise calculation does not provide reliable results, the lowest concentration point on a calibration curve that gives an acceptable (≤ 30 %) and consistent (measured at least at the start and at the end of an analytical series of samples) deviation to the average relative response factor calculated for all points on the calibration curve in each series of samples. The LOQ is calculated from the lowest concentration point taking into account the recovery of internal standards and sample intake.

Bioanalytical screening methods will not give results at the congener level but merely an indication ([8])* of the TEQ level, expressed in Bioanalytical Equivalents (BEQ) to acknowledge the fact that not all compounds present in a sample extract that produce a response in the test may obey all requirements of the TEQ-principle.

Screening and confirmatory methods can only be applied for control of a certain matrix if the methods are sensitive enough to detect levels reliably at the action threshold or maximum level.

3. **Quality assurance requirements**

3.1. Measures shall be taken to avoid cross-contamination at each stage of the sampling and analysis procedure.

3.2. The samples shall be stored and transported in glass, aluminium, polypropylene or polyethylene containers suitable for storage without any influence on the levels of PCDD/PCDFs and dioxin-like PCBs in the samples. Traces of paper dust shall be removed from the sample container.

3.3. The sample storage and transportation shall be performed in a way that maintains the integrity of the feed sample.

3.4. Insofar as relevant, each laboratory sample shall be finely grinded and mixed thoroughly using a process that has been demonstrated to achieve complete homogenisation (for example, ground to pass a 1 mm sieve). Samples shall be dried before grinding if the moisture content is too high.

3.5. Control of reagents, glassware and equipment for possible influence of TEQ- or BEQ-based results shall be carried out.

3.6. A blank analysis shall be performed by carrying out the entire analytical procedure omitting only the sample.

3.7. For bioanalytical methods, all glassware and solvents used in analysis shall be tested to be free of compounds that interfere with the detection of target compounds in the working range. Glassware shall be rinsed with solvents or heated at temperatures suitable to remove traces of PCDD/PCDFs, dioxin-like compounds and interfering compounds from its surface.

3.8. Sample quantity used for the extraction shall be sufficient to fulfil the requirements with respect to a sufficiently low working range including the concentrations of maximum levels or action threshold.

3.9. The specific sample preparation procedures used for the products under consideration shall follow internationally accepted guidelines.

4. **Requirements for laboratories**

4.1. In accordance with the provisions of Regulation (EC) No 882/2004, laboratories shall be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance. Laboratories shall be accredited following the EN ISO/IEC 17025 standard.

4.2. Laboratory proficiency shall be proven by the continuous successful participation in inter-laboratory studies for the determination of PCDD/PCDFs and dioxin-like PCBs in relevant feed matrices and concentration ranges.

4.3. Laboratories applying screening methods for the routine control of samples shall establish a close cooperation with laboratories applying the confirmatory method, both for quality control and confirmation of the analytical result of suspected samples.

5. **Basic requirements to be met by analytical procedure for dioxins (PCDD/PCDFs) and dioxin-like PCBs.**

5.1. *Low working range and limits of quantification*

For PCDD/PCDFs, detectable quantities shall be in the upper femtogram (10^{-15}g) range because of extreme toxicity of some of these compounds. For most PCB congeners limit of quantification in the nanogram (10^{-9}g) range is already sufficient. For the measurement of the more toxic dioxin-like PCB congeners (in particular non-ortho substituted congeners), the lower end of the working range shall reach the low picogram (10^{-12}g) levels. For all other PCB congeners a limit of quantification in the nanogram (10^{-9}g) range is sufficient.

5.2. *High selectivity (specificity)*

5.2.1. A distinction is required between PCDD/PCDFs and dioxin-like PCBs and a multitude of other, coextracted and possibly interfering compounds present at concentrations up to several orders of magnitude higher than those of the analytes of interest. For GC-MS methods, a differentiation among various congeners is required, such as between toxic (for example, the seventeen 2,3,7,8-substituted PCDD/PCDFs, and twelve dioxin-like PCBs) and other congeners.

5.2.2. Bioanalytical methods shall be able to detect the target compounds as the sum of PCDD/PCDFs, and/or dioxin-like PCBs. Sample clean-up shall aim at removing compounds causing false non-compliant results or compounds that may decrease the response, causing false compliant results.

5.3. *High accuracy (trueness and precision, bioassay apparent recovery)*

5.3.1. For GC-MS methods, the determination shall provide a valid estimate of the true concentration in a sample. High accuracy is required to avoid the rejection of a sample analysis result on the basis of poor reliability of the determined TEQ level. Accuracy is expressed as *trueness* (difference between the mean value measured for an analyte in a certified material and its certified value, expressed as a percentage of this value) and *precision* (RSD_R relative standard deviation calculated from results generated under reproducibility conditions).

5.3.2. For bioanalytical methods, the bioassay apparent recovery shall be determined. Bioassay apparent recovery means the BEQ level calculated from the TCDD or PCB 126 calibration curve corrected for the blank and then divided by the TEQ level determined by the confirmatory method. It aims at correcting factors like the loss of PCDD/PCDFs and dioxin-like compounds during the extraction and clean-up steps, co-extracted compounds increasing or decreasing the response (agonistic and antagonistic effects), the quality of the curve fit, or differences between the Toxic Equivalency Factor (TEF) and the Relative Potency (REP) values. The bioassay apparent recovery is calculated from suitable reference samples with representative congener patterns around the level of interest.

5.4. *Validation in the range of maximum level and general quality control measures*

5.4.1. Laboratories shall demonstrate the performance of a method in the range of the maximum level, for example, 0,5x, 1x and 2x the maximum level with an acceptable coefficient of variation for repeated analysis, during the validation procedure and during routine analysis.

5.4.2. Regular blank controls and spiking experiments or analysis of control samples (preferably, if available, certified reference material) shall be performed as internal quality control measures. Quality control charts for blank controls, spiking experiments or analysis of control samples shall be recorded and checked to make sure the analytical performance is in accordance with the requirements.

5.5. *Limit of quantification*

5.5.1. For a bioanalytical screening method, the establishment of the limit of quantification (LOQ) is not an indispensable requirement but the method shall prove that it can differentiate between the blank and the cut-off value. When providing a BEQ level, a reporting level shall be established to deal with samples showing a response below this level. The reporting level shall be demonstrated to be different from procedure blank samples at least by a factor of three, with a response below the working range. It shall therefore be calculated from samples containing the target compounds around the required minimum level, and not from an S/N ratio or an assay blank.

5.5.2. The LOQ for a confirmatory method shall be about one fifth of the maximum level.

5.6. *Analytical criteria*

For reliable results from confirmatory or screening methods, the following criteria shall be met in the range of the maximum level or action threshold for the TEQ or BEQ value, respectively, whether determined as total TEQ (as sum of PCDD/PCDFs and dioxin-like PCBs) or separately for PCDD/PCDFs and dioxin-like PCBs:

	Screening with bioanalytical or physico-chemical methods	Confirmatory methods
False-compliant rate ([1])	< 5 %	
Trueness		− 20 % to + 20 %
Repeatability (RSD_r)	< 20 %	
Within-laboratory reproducibility (RSD_R)	< 25 %	< 15 %

([1]) With respect to the maximum levels.

5.7. *Specific requirements for screening methods*

5.7.1. Both GC-MS and bioanalytical methods may be used for screening. For GC-MS methods the requirements laid down in point 6 shall be met. For cell based bioanalytical methods specific requirements are laid down in point 7.

5.7.2. Laboratories applying screening methods for the routine control of samples shall establish a close cooperation with laboratories applying the confirmatory method.

5.7.3. Performance verification of the screening method is required during routine analysis, by analytical quality control and ongoing method validation. There shall be a continuous programme for the control of compliant results.

5.7.4. Check on possible suppression of the cell response and cytotoxicity:

20 % of the sample extracts shall be measured in routine screening without and with 2,3,7,8-TCDD added corresponding to the maximum level or action threshold, to check if the response is possibly suppressed by interfering substances present in the sample extract. The measured concentration of the spiked sample shall be compared to the sum of the concentration of the unspiked extract plus the spiking concentration. If this measured concentration is more than 25 % lower than the calculated (sum) concentration, this is an indication of potential signal suppression and the respective sample shall be submitted to GC-HRMS confirmatory analysis. Results shall be monitored in quality control charts.

5.7.5. Quality control on compliant samples:

Approximately 2 to 10 % of the compliant samples, depending on sample matrix and laboratory experience, shall be confirmed by GC-HRMS.

5.7.6. Determination of false-compliant rates from quality control data:

The rate of false-compliant results from screening of samples below and above the maximum level or the action threshold shall be determined. Actual false-compliant rates shall be below 5 %. When a minimum of 20 confirmed results per matrix/matrix group is available from the quality control of compliant samples, conclusions on the false compliant rate shall be drawn from this database. The results from samples analysed in ring trials or during contamination incidents, covering a concentration range up to for example 2x the maximum level (ML), may also be included in the minimum of 20 results for evaluation of the false-compliant rate. The samples shall cover most frequent congener patterns, representing various sources.

Although screening assays shall preferentially aim at detecting samples exceeding the action threshold, the criterion for determining false-compliant rates is the maximum level, taking into account the measurement uncertainty of the confirmatory method.

5.7.7. Potentially non-compliant samples from screening shall always be verified by a full re-analysis of the original sample by a confirmatory method of analysis. These samples may also be used to evaluate the rate of false non-compliant results. For screening methods, the rate of false non-compliant results shall be the fraction of results confirmed to be compliant from confirmatory analysis, while in previous screening the sample has been declared to be potentially non-compliant. Evaluation of the advantageousness of the screening method shall be based on comparison of false-non-compliant samples with the total number of samples checked. This rate shall be low enough to make the use of a screening tool advantageous.

5.7.8. At least under validation conditions, bioanalytical methods shall provide a valid indication of the TEQ level, calculated and expressed as BEQ.

Also for bioanalytical methods carried out under repeatability conditions, the intra-laboratory RSD_r would typically be smaller than the reproducibility RSD_R.

6. Specific requirements for GC-MS methods to be complied with for screening or confirmatory purposes

6.1. *Acceptable differences between upper-bound and lower-bound WHO-TEQ results*

The difference between upper-bound level and lower-bound level shall not exceed 20 % for confirmation of exceedance of maximum level or in case of need of action thresholds.

6.2. *Control of recoveries*

6.2.1. Addition of ^{13}C-labelled 2,3,7,8-chlorine substituted internal PCDD/PCDF standards and of ^{13}C-labelled internal dioxin-like PCB standards shall be carried out at the very beginning of the analytical method, e.g. prior to extraction in order to validate the analytical procedure. At least one congener for each of the tetra- to octa-chlorinated homologous groups for PCDD/PCDFs and at least one congener for each of the homologous groups for dioxin-like PCBs shall be added (alternatively, at least one congener for each mass spectrometric selected ion recording function used for monitoring PCDD/PCDFs and dioxin-like PCBs). In the case of confirmatory methods, all 17 ^{13}C-labelled 2,3,7,8-substituted internal PCDD/PCDF standards and all 12 ^{13}C-labelled internal dioxin-like PCB standards shall be used.

6.2.2. Relative response factors shall also be determined for those congeners for which no ^{13}C-labelled analogue is added by using appropriate calibration solutions.

6.2.3. For feed of plant origin and feed of animal origin containing less than 10 % fat, the addition of the internal standards shall be mandatory prior to extraction. For feed of animal origin containing more than 10 % fat, the internal standards shall be added either before or after fat extraction. An appropriate validation of the extraction efficiency shall be carried out, depending on the stage at which internal standards are introduced and on whether results are reported on product or fat basis.

6.2.4. Prior to GC-MS analysis, 1 or 2 recovery (surrogate) standard(s) shall be added.

6.2.5. Control of recovery is required. For confirmatory methods, the recoveries of the individual internal standards shall be in the range of 60 to 120 %. Lower or higher recoveries for individual congeners, in particular for some hepta- and octa- chlorinated dibenzo-p-dioxins and dibenzofurans, shall be acceptable on the condition that their contribution to the TEQ value does not exceed 10 % of the total TEQ value (based on sum of PCDD/PCDF and dioxin-like PCBs). For GC-MS screening methods, the recoveries shall be in the range of 30 to 140 %.

6.3. *Removal of interfering substances*

— Separation of PCDD/PCDFs from interfering chlorinated compounds such as non-dioxin-like PCBs and chlorinated diphenyl ethers shall be carried out by suitable chromatographic techniques (preferably with a florisil, alumina and/or carbon column).

— Gas-chromatographic separation of isomers shall be < 25 % peak to peak between 1,2,3,4,7,8-HxCDF and 1,2,3,6,7,8-HxCDF.

6.4. *Calibration with standard curve*

The range of the calibration curve shall cover the relevant range of maximum level or action thresholds.

6.5. *Specific criteria for confirmatory methods*

— For GC-HRMS:

In HRMS, the resolution shall typically be greater than or equal to 10 000 for the entire mass range at 10 % valley.

Fulfilment of further identification and confirmation criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC-HRMS and of indicator PCBs by GC-HRMS) and/or in EPA methods 1613 and 1668 as revised.

— For GC-MS/MS:

Monitoring of at least 2 specific precursor ions, each with one specific corresponding transition product ion for all labelled and unlabelled analytes in the scope of analysis.

Maximum permitted tolerance of relative ion intensities of ± 15 % for selected transition product ions in comparison to calculated or measured values (average from calibration standards), applying identical MS/MS conditions, in particular collision energy and collision gas pressure, for each transition of an analyte.

Resolution for each quadrupole to be set equal to or better than unit mass resolution (unit mass resolution: sufficient resolution to separate two peaks one mass unit apart) in order to minimise possible interferences on the analytes of interest.

Fulfilment of the further criteria as described in internationally recognised standards, for example, in standard EN 16215:2012 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC-HRMS and of indicator PCBs by GC-HRMS) and/or in EPA methods 1613 and 1668 as revised, except the obligation to use GC-HRMS.

7. Specific requirements for bioanalytical methods

Bioanalytical methods are methods based on the use of biological principles like cell-based assays, receptor-assays or immunoassays. This point 7 establishes requirements for bioanalytical methods in general.

A screening method in principle classifies a sample as compliant or suspected to be non-compliant. For this, the calculated BEQ level is compared to the cut-off value (see 7.3). Samples below the cut-off value are declared compliant, samples equal or above the cut-off value are suspected to be non-compliant, requiring analysis by a confirmatory method. In practice, a BEQ level corresponding to 2/3 of the maximum level may serve as cut-off value provided that a false-compliant rate below 5 % and an acceptable rate for false non-compliant results are ensured. With separate maximum levels for PCDD/Fs and for the sum of PCDD/Fs and dioxin-like PCBs, checking compliance of samples without fractionation requires appropriate bioassay cut-off values for PCDD/Fs. For checking of samples exceeding the action thresholds, an appropriate percentage of the respective action threshold would suit as cut-off value.

Furthermore, in the case of certain bioanalytical methods, an indicative level expressed in BEQs may be given for samples in the working range and exceeding the reporting limit (see 7.1.1 and 7.1.6).

7.1. *Evaluation of the test response*

7.1.1. General requirements

— When calculating the concentrations from a TCDD calibration curve, values at the lower and higher end of the curve will show a high variation (high coefficient of variation (CV)). The working range is the area where this CV is smaller than 15 %. The lower end of the working range (reporting limit) shall be set at least by a factor of three above the procedure blanks. The upper end of the working range is usually represented by the EC_{70} value (70 % of maximal effective concentration), but lower if the CV is higher than 15 % in this range. The working range shall be established during validation. Cut-off values (see point 7.3) shall be well within the working range.

— Standard solutions and sample extracts shall be tested at least in duplicate. When using duplicates, a standard solution or a control extract tested in 4 to 6 wells divided over the plate shall produce a response or concentration (only possible in the working range) based on a CV < 15 %.

7.1.2. Calibration

7.1.2.1. Calibration with standard curve

— Levels in samples shall be estimated by comparison of the test response with a calibration curve of TCDD (or PCB 126 or a PCDD/PCDF/dioxin-like PCB standard mixture) to calculate the BEQ level in the extract and subsequently in the sample.

— Calibration curves shall contain 8 to 12 concentrations (at least in duplicates), with enough concentrations in the lower part of the curve (working range). Special attention shall be paid to the quality of the curve-fit in the working range. As such, the R^2 value is of little or no value in estimating the goodness of fit in non-linear regression. A better fit shall be achieved by minimising the difference between calculated and observed levels in the working range of the curve, for example by minimising the sum of squared residuals.

— The estimated level in the sample extract shall be subsequently corrected for the BEQ level calculated for a matrix/solvent blank sample (to account for impurities from solvents and chemicals used), and the apparent recovery (calculated from the BEQ level of suitable reference samples with representative congener patterns around the maximum level or action threshold). To perform a recovery correction, the apparent recovery shall be within the required range (see point 7.1.4). Reference samples used for recovery correction shall comply with the requirements laid down in point 7.2.

7.1.2.2. Calibration with reference samples

Alternatively, a calibration curve prepared from at least four reference samples (see point 7.2.4: one matrix blank, plus three reference samples at 0,5x, 1,0x and 2,0x the maximum level or action threshold) may be used, eliminating the need to correct for blank and recovery. In this case, the test response corresponding to 2/3 of the maximum level (see point 7.3) may be calculated directly from these samples and used as cut-off value. For checking of samples exceeding the action thresholds, an appropriate percentage of these action thresholds would suit as cut-off value.

7.1.3. Separate determination of PCDD/PCDFs and dioxin-like PCBs

Extracts may be split into fractions containing PCDD/PCDFs and dioxin-like PCBs, allowing a separate indication of PCDD/PCDFs and dioxin-like PCB TEQ levels (in BEQ). A PCB 126 standard calibration curve shall preferentially be used to evaluate results for the fraction containing dioxin-like PCBs.

7.1.4. Bioassay apparent recoveries

The "bioassay apparent recovery" shall be calculated from suitable reference samples with representative congener patterns around the maximum level or action threshold and expressed as percentage of the BEQ level in comparison to the TEQ level. Depending on the type of assay and TEFs ([9])* used, the differences between TEF and REP factors for dioxin-like PCBs can cause low apparent recoveries for dioxin-like PCBs in comparison to PCDD/PCDFs. Therefore, if a separate determination of PCDD/PCDFs and dioxin-like PCBs is performed, bioassay apparent recoveries shall be: for dioxin-like PCBs 20 % to 60 %, for PCDD/PCDFs 50 % to 130 % (ranges apply for the TCDD calibration curve). As the contribution of dioxin-like PCBs to the sum of PCDD/PCDFs and dioxin-like PCBs can vary between different matrices and samples, bioassay apparent recoveries for the sum of PCDD/PCDFs and dioxin-like PCBs reflect these ranges and shall be between 30 % and 130 %. Any implication of substantially revised TEF values for the Union legislation for PCDD/PCDFs and dioxin-like PCBs requires the revision of these ranges.

7.1.5. Control of recoveries for clean-up

The loss of compounds during the clean-up shall be checked during validation. A blank sample spiked with a mixture of the different congeners shall be submitted to clean-up (at least n = 3) and the recovery and variability checked by a confirmatory method. The recovery shall be within 60 % to 120 % especially for congeners contributing more than 10 % to the TEQ-level in various mixtures.

7.1.6. Reporting Limit

When reporting BEQ levels, a reporting limit shall be determined from relevant matrix samples involving typical congener patterns, but not from the calibration curve of the standards due to low precision in the lower range of the curve. Effects from extraction and clean-up shall be taken into account. The reporting limit shall be set at least by a factor of three above the procedure blanks.

7.2. *Use of reference samples*

7.2.1. Reference samples shall represent sample matrix, congener patterns and concentration ranges for PCDD/PCDFs and dioxin-like PCBs around the maximum level or action threshold.

7.2.2. A matrix blank, and where it is not possible, a procedure blank, and a reference sample at the maximum level or action threshold shall be included in each test series. These samples shall be extracted and tested at the same time under identical conditions. The reference sample shall show a clearly elevated response in comparison to the blank sample, thus ensuring the suitability of the test. These samples may be used for blank and recovery corrections.

7.2.3. Reference samples chosen to perform a recovery correction shall be representative for the test samples, meaning that congener patterns may not lead to an underestimation of levels.

7.2.4. Extra reference samples at e.g. 0,5x and 2x the maximum level or action threshold may be included to demonstrate the proper performance of the test in the range of interest for the control of the maximum level or action threshold. Combined, these samples may be used for calculating the BEQ levels in test samples (see point 7.1.2.2).

7.3. *Determination of cut-off values*

The relationship between bioanalytical results in BEQ and results from the confirmatory method in TEQ shall be established, for example by matrix-matched calibration experiments, involving reference samples spiked at 0, 0,5x, 1x and 2x the maximum level (ML), with 6 repetitions on each level (n = 24). Correction factors (blank and recovery) may be estimated from this relationship but shall be checked in accordance with point 7.2.2.

Cut-off values shall be established for decisions over sample compliance with maximum levels or for the control of action thresholds, if relevant, with the respective maximum levels or action threshold set for either PCDD/PCDFs and dioxin-like PCBs alone, or for the sum of PCDD/PCDFs and dioxin-like PCBs. They are represented by the *lower* end-point of the distribution of bioanalytical results (corrected for blank and recovery) corresponding to the decision limit of the confirmatory method based on a 95 % level of confidence, implying a false-compliant rate < 5 %, and on a RSD_R < 25 %. The decision limit of the confirmatory method is the maximum level, taking into account the measurement uncertainty.

The cut-off value (in BEQ) may be calculated in accordance with one of the approaches set out in points 7.3.1, 7.3.2 and 7.3.3 (see Figure 1).

7.3.1. Use of the *lower* band of the 95 % prediction interval at the decision limit of the confirmatory method:

$$\text{Cut-off value} = BEQ_{DL} - S_{y,x} * t_{\alpha,f=m-2} \sqrt{1/n + 1/m + (x_i - \overline{x})^2 / Q_{xx}}$$

with:

BEQ_{DL}	BEQ corresponding to the decision limit of the confirmatory method, being the maximum level including measurement uncertainty
$s_{y,x}$	residual standard deviation
$t_{\alpha,f=m-2}$	Student factor (α = 5 %, f = degrees of freedom, single-sided)
m	total number of calibration points (index j)
n	number of repetitions on each level
x_i	Sample concentration (in TEQ) of calibration point i determined by a confirmatory method
$\overline{x}$	mean of the concentrations (in TEQ) of all calibration samples
$Q_{xx} = \sum_{j=1}^{m} (x_i - \overline{x})^2$	square sum parameter, i = index for calibration point i

7.3.2. Calculation from bioanalytical results (corrected for blank and recovery) of multiple analyses of samples (n≥ 6) contaminated at the decision limit of the confirmatory method, as the *lower* endpoint of the data distribution at the corresponding mean BEQ value:

$$\text{Cut-off value} = BEQ_{DL} — 1{,}64 \times SD_R$$

With:

SD_R standard deviation of bioassay results at BEQ_{DL}, measured under within-laboratory reproducibility conditions

7.3.3. Calculation as mean value of bioanalytical results (in BEQ, corrected for blank and recovery) from multiple analysis of samples (n ≥ 6) contaminated at 2/3 of the maximum level or action threshold, based on the observation that this level will be around the cut-off value determined under point 7.3.1 or point 7.3.2:

Figure 1

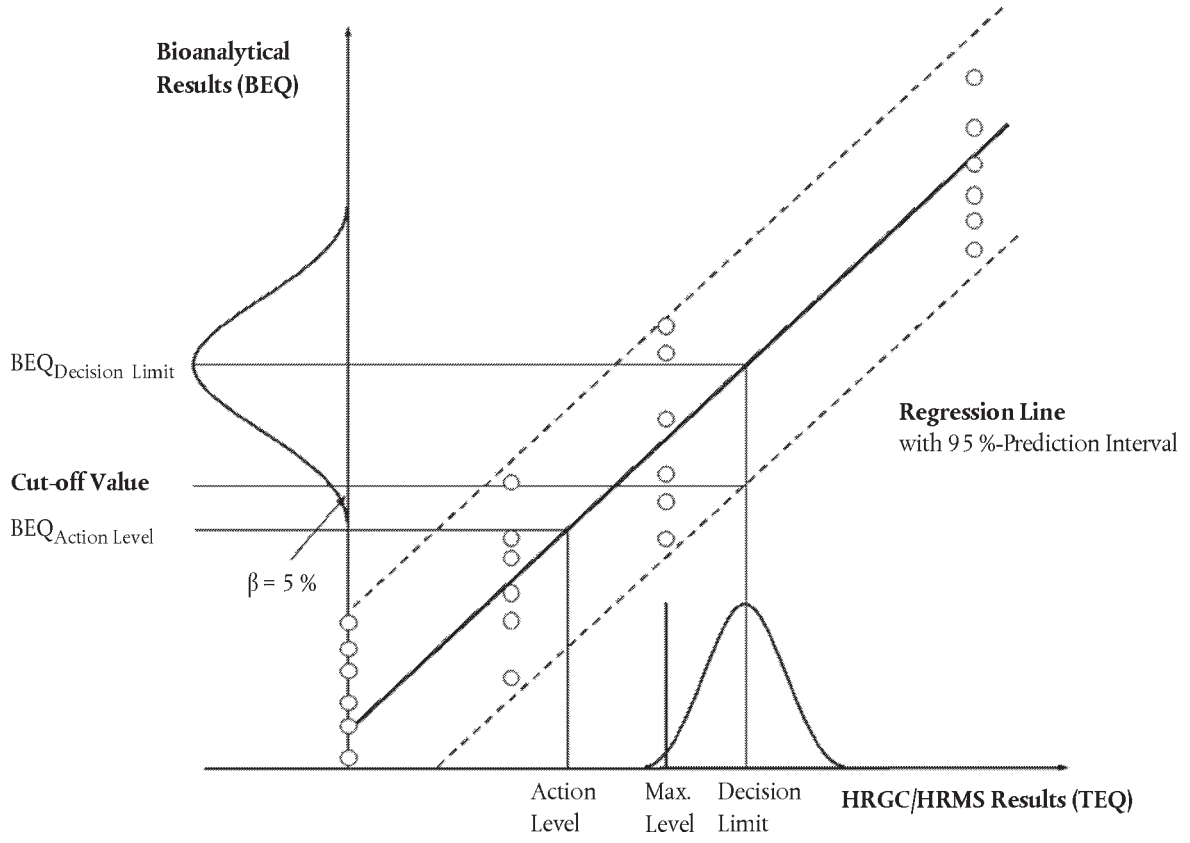

Figure 1 Calculation of cut-off values based on a 95 % level of confidence implying a false-compliant rate < 5 %, and a RSD_R < 25 %:

1. from the *lower* band of the 95 % prediction interval at the decision limit of the confirmatory method,

2. from multiple analysis of samples (n ≥ 6) contaminated at the decision limit of the confirmatory method as the *lower* end-point of the data distribution (represented in the figure by a bell-shaped curve) at the corresponding mean BEQ value.

7.3.4. Restrictions to cut-off values

BEQ-based cut-off values calculated from the RSD_R achieved during validation using a limited number of samples with different matrix/congener patterns may be higher than the TEQ-based maximum levels or action thresholds due to a better precision than attainable in routine when an unknown spectrum of possible congener patterns has to be controlled. In such cases, cut-off values shall be calculated from an RSD_R = 25 %, or two-thirds of the maximum level or action threshold shall be preferred.

7.4. *Performance characteristics*

7.4.1. Since no internal standards can be used in bioanalytical methods, tests on the repeatability of bioanalytical methods shall be carried out to obtain information on the standard deviation within and between test series. Repeatability shall be below 20 %, intra-laboratory reproducibility below 25 %. This shall be based on the calculated levels in BEQ after blank and recovery correction.

7.4.2. As part of the validation process, the test shall be shown to discriminate between a blank sample and a level at the cut-off value, allowing the identification of samples above the corresponding cut-off value (see point 7.1.2).

7.4.3. Target compounds, possible interferences and maximum tolerable blank levels shall be defined.

7.4.4. The percent standard deviation in the response or concentration calculated from the response (only possible in working range) of a triplicate determination of a sample extract may not be above 15 %.

7.4.5. The uncorrected results of the reference sample(s) expressed in BEQ (blank and at the maximum level or action threshold) shall be used for evaluation of the performance of the bioanalytical method over a constant time period.

7.4.6. Quality control charts for procedure blanks and each type of reference sample shall be recorded and checked to make sure the analytical performance is in accordance with the requirements, in particular for the procedure blanks with regard to the requested minimum difference to the lower end of the working range and for the reference samples with regard to within-laboratory reproducibility. Procedure blanks shall be controlled in a manner to avoid false-compliant results when subtracted.

7.4.7. The results of suspected samples obtained by the confirmatory methods and 2 to 10 % of the compliant samples (minimum of 20 samples per matrix) shall be collected and used to evaluate the performance of the screening method and the relationship between BEQ and TEQ. This database may be used for the re-evaluation of cut-off values applicable to routine samples for the validated matrices.

7.4.8. Successful method performance may also be demonstrated by participation in ring trials. The results from samples analysed in ring trials, covering a concentration range up to e.g. 2x maximum level, may be included in the evaluation of the false-compliant rate, if a laboratory is able to demonstrate its successful performance. The samples shall cover most frequent congener patterns, representing various sources.

7.4.9. During incidents, the cut-off values may be re-evaluated, reflecting the specific matrix and congener patterns of this single incident.

8. **Reporting of the results**

8.1. *Confirmatory methods*

8.1.1. Insofar as the used analytical procedure makes it possible, the analytical results shall contain the levels of the individual PCDD/PCDF and dioxin-like PCB congeners and be reported as lower-bound, upper-bound and medium-bound in order to include a maximum of information in the reporting of the results and thereby enabling the interpretation of the results according to specific requirements.

8.1.2. The report shall include the method used for extraction of PCDD/PCDFs and dioxin-like PCBs.

8.1.3. The recoveries of the individual internal standards shall be made available in case the recoveries are outside the range referred to in point 6.2.5, in case the maximum level is exceeded (in this case, the recoveries for one of the two duplicate analysis) and in other cases upon request.

8.1.4. As the uncertainty of measurement is to be taken into account when deciding about the compliance of a sample, this parameter shall be made available. Thus, analytical results shall be reported as x +/- U whereby x is the analytical result and U is the expanded measurement uncertainty using a coverage factor of 2 which gives a level of confidence of approximately 95 %. In the 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/Fs and dioxin-like PCBs.

8.1.5. If the uncertainty of measurement is taken into account by applying CCα (as described in point 2.2 of Chapter I of this part B), this parameter shall be reported.

8.1.6. The results shall be expressed in the same units and with at least the same number of significant figures as the maximum levels laid down in Directive 2002/32/EC.

8.2. *Bioanalytical screening methods*

8.2.1. The result of the screening shall be expressed as “compliant” or “suspected to be non-compliant” (“suspected”).

8.2.2. In addition, a result for PCDD/PCDF and/or dioxin-like PCBs expressed in BEQ, and not TEQ, may be given.

8.2.3. Samples with a response below the reporting limit shall be expressed as “lower than the reporting limit”.

8.2.4. For each type of sample matrix, the report shall mention the maximum level or action threshold on which the evaluation is based.

8.2.5. The report shall mention the type of the test applied, the basic test principle and the kind of calibration.

8.2.6. The report shall include the method used for extraction of PCDD/PCDFs and dioxin-like PCBs.

8.2.7. In case of samples suspected to be non-compliant, the report needs to include a note on the action to be taken. The concentration of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs in those samples with elevated levels has to be determined/confirmed by a confirmatory method.

CHAPTER III

Sample preparation and requirements for methods of analysis used in official control of the levels of non-dioxin-like PCBs (PCB # 28, 52, 101, 138, 153, 180)

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 non-dioxin-like polychlorinated biphenyls (non-dioxin-like PCBs) and for other regulatory purposes.

2. **Applicable detection methods**

Gas chromatography/Electron Capture Detection (GC-ECD), GC-LRMS, GC-MS/MS, GC-HRMS or equivalent methods.

3. **Identification and confirmation of analytes of interest**

3.1. Relative retention time in relation to internal standards or reference standards (acceptable deviation of +/- 0,25 %).

3.2. Gas chromatographic separation of all six indicator PCBs (PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180) from interfering substances, especially co-eluting PCBs, in particular if levels of samples are in the range of legal limits and non-compliance is to be confirmed.

[Congeners often found to co-elute are for example PCB 28/31, PCB 52/69 and PCB 138/163/164. For GC-MS also possible interferences from fragments of higher chlorinated congeners shall be considered.]

3.3. *Requirements for GC-MS techniques*

Monitoring of at least:

(a) two specific ions for HRMS;

(b) two specific ions of m/z > 200 or three specific ions of m/z > 100 for LRMS;

(c) 1 precursor and 2 product ions for MS-MS.

Maximum permitted tolerances for abundance ratios for selected mass fragments:

Relative deviation of abundance ratio of selected mass fragments from theoretical abundance or calibration standard for target ion (most abundant ion monitored) and qualifier ion(s):

Relative intensity of qualifier ion(s) compared to target ion	GC-EI-MS (relative deviation)	GC-CI-MS, GC-MS^n (relative deviation)
> 50 %	± 10 %	± 20 %
> 20 % to 50 %	± 15 %	± 25 %
> 10 % to 20 %	± 20 %	± 30 %
≤ 10 %	± 50 % (1)	± 50 % (1)

(1) Sufficient number of mass fragments with relative intensity > 10 % available, therefore not recommendable to use qualifier ion(s) with a relative intensity of less than 10 % compared to the target ion.

3.4. *Requirements for GC-ECD techniques*

Results exceeding the tolerance shall be confirmed with two GC columns with stationary phases of different polarity.

4. **Demonstration of performance of method**

The performance of the method shall be validated in the range of the maximum level (0,5 to 2 times the maximum level) with an acceptable coefficient of variation for repeated analysis (see requirements for intermediate precision in point (9).

5. **Limit of quantification**

The blank values shall not be higher than 30 % of the level of contamination corresponding to the maximum level ([10])*.

6. **Quality control**

Regular blank controls, analysis of spiked samples, quality control samples, participation in inter-laboratory studies on relevant matrices.

7. **Control of recoveries**

7.1. Suitable internal standards with physico-chemical properties comparable to analytes of interest shall be used.

7.2. Addition of internal standards:

Addition to products (before extraction and clean-up process).

7.3. Requirements for methods using all six isotope-labelled indicator PCB congeners:

(a) results shall be corrected for recoveries of internal standards;

(b) recoveries of isotope-labelled internal standards shall be between 50 and 120 %;

(c) lower or higher recoveries for individual congeners with a contribution to the sum of the six indicator PCBs below 10 % are acceptable.

7.4. Requirements for methods using not all six isotope-labelled internal standards or other internal standards:

(a) recovery of internal standard(s) shall be controlled for every sample;

(b) recoveries of internal standard(s) shall be between 60 and 120 %;

(c) results shall be corrected for recoveries of internal standards.

7.5. The recoveries of unlabelled congeners shall be checked by spiked samples or quality control samples with concentrations in the range of the maximum level. Recoveries for these congeners shall be considered acceptable, if they are between 70 and 120 %.

8. **Requirements for laboratories**

In accordance with the provisions of Regulation (EC) No 882/2004, laboratories shall be accredited by a recognised body operating in accordance with ISO Guide 58 to ensure that they are applying analytical quality assurance. Laboratories shall be accredited following the EN ISO/IEC 17025 standard.

9. **Performance characteristics: criteria for the sum of the six indicator PCBs at the maximum level**

Trueness	− 30 to + 30 %
Intermediate precision (RSD %)	≤ 20 %
Difference between upper and lower-bound calculation	≤ 20 %

10. **Reporting of the results**

10.1. Insofar as the used analytical procedure makes it possible, the analytical results shall contain the levels of the individual PCB congeners and be reported as lower-bound, upper-bound and medium-bound in order to include a maximum of information in the reporting of the results and thereby enabling the interpretation of the results according to specific requirements.

10.2. The report shall include the method used for extraction of PCBs and lipids.

10.3. The recoveries of the individual internal standards shall be made available in case the recoveries are outside the range referred to in point 7, in case the maximum level is exceeded and in other cases upon request.

10.4. As the uncertainty of measurement is to be taken into account when deciding about the compliance of a sample, this parameter shall also be made available. Thus, analytical results shall be reported as x +/- U whereby x is the analytical result and U is the expanded measurement uncertainty using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

10.5. If the uncertainty of measurement is taken into account by applying CCα (as described in point 2.1 of Chapter I), this parameter shall be reported.

10.6. The results shall be expressed in the same units and with at least the same number of significant figures as the maximum levels laid down in Directive 2002/32/EC.

(1)* Table of TEF (= toxic equivalency factors) for dioxins, furans and dioxin-like PCBs:
WHO-TEFs for human risk assessment based on the conclusions of the World Health Organization (WHO) — International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223-241 (2006)).

Congener	TEF value	Congener	TEF value
Dibenzo-p-dioxins ("PCDDs") and Dibenzo-p-furans ("PCDFs")		*"Dioxin-like" PCBs* ***Non-ortho PCBs + Mono-ortho PCBs***	
2,3,7,8-TCDD	1		
1,2,3,7,8-PeCDD	1	**Non-ortho PCBs**	
1,2,3,4,7,8-HxCDD	0,1	PCB 77	0,0001
1,2,3,6,7,8-HxCDD	0,1	PCB 81	0,0003
1,2,3,7,8,9-HxCDD	0,1	PCB 126	0,1
1,2,3,4,6,7,8-HpCDD	0,01	PCB 169	0,03
OCDD	0,0003		
		Mono-ortho PCBs	
2,3,7,8-TCDF	0,1	PCB 105	0,00003
1,2,3,7,8-PeCDF	0,03	PCB 114	0,00003
2,3,4,7,8-PeCDF	0,3	PCB 118	0,00003
1,2,3,4,7,8-HxCDF	0,1	PCB 123	0,00003
1,2,3,6,7,8-HxCDF	0,1	PCB 156	0,00003
1,2,3,7,8,9-HxCDF	0,1	PCB 157	0,00003
2,3,4,6,7,8-HxCDF	0,1	PCB 167	0,00003
1,2,3,4,6,7,8-HpCDF	0,01	PCB 189	0,00003
1,2,3,4,7,8,9-HpCDF	0,01		
OCDF	0,0003		

Abbreviations used: "T" = tetra; "Pe" = penta; "Hx" = hexa; "Hp" = hepta; "O" = octa; "CDD" = chlorodibenzo-dioxin; "CDF" = chlorodibenzofuran; "CB" = chlorobiphenyl.

([2])* 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 (OJ L 221, 17.8.2002, p. 8.)

([3])* The concept of "upper-bound" requires using the limit of quantification for the contribution of each non-quantified congener. The concept of "lower-bound" requires using zero for the contribution of each non-quantified congener. The concept of "medium-bound" requires using half of the limit of quantification calculating the contribution of each non-quantified congener.

([4])* In general, the requirements for duplicate analysis as provided for in Annex II, Chapter C point 3 apply. However, for confirmatory methods with the use of ^{13}C-labelled internal standard for the relevant analytes, the duplicate analysis is only necessary if the result of the first determination applying such confirmatory methods is not compliant. The duplicate analysis is necessary to exclude the possibility of internal cross-contamination or an accidental mix-up of samples. In case the analysis is performed in the frame of a contamination incident, confirmation by duplicate analysis might be omitted in case the samples selected for analysis are through traceability linked to the contamination incident and the level found is significantly above the maximum level.

([5])* The concept of "upper-bound" requires using the limit of quantification for the contribution of each non-quantified congener to the Toxic Equivalent (TEQ). The concept of "lower-bound" requires using zero for the contribution of each non-quantified congener to the TEQ. The concept of "medium-bound" requires using half of the limit of quantification calculating the contribution of each non-quantified congener to the TEQ.

([6])* In general, the requirements for duplicate analysis as provided for in Annex II, Chapter C point 3 apply. However, for confirmatory methods with the use of ^{13}C-labelled internal standard for the relevant analytes, the duplicate analysis is only necessary if the result of the first determination applying such confirmatory methods is not compliant. The duplicate analysis is necessary to exclude the possibility of internal cross-contamination or an accidental mix-up of samples. In case the analysis is performed in the frame of a contamination incident, confirmation by duplicate analysis might be omitted in case the samples selected for analysis are through traceability linked to the contamination incident and the level found is significantly above the maximum level.

([7])* Identical explanation and requirements for duplicate analysis for control of action thresholds as in footnote (5)* for maximum levels.

([8])* Bioanalytical methods are not specific to those congeners included in the TEF-scheme. Other structurally related AhR-active compounds may be present in the sample extract which contribute to the overall response. Therefore, bioanalytical results cannot be an estimate but rather an indication of the TEQ level in the sample.

([9])* Current requirements are based on the TEFs published in: M. Van den Berg et al, Toxicol Sci 93 (2), 223-241 (2006).

([10])* It is highly recommendable to have a lower contribution of the reagent blank level to the level of a contaminant in a sample. It is in the responsibility of the laboratory to control the variation of blank levels, in particular, if the blank levels are subtracted.'

COMMISSION IMPLEMENTING REGULATION (EU) No 710/2014

of 23 June 2014

laying down implementing technical standards with regard to conditions of application of the joint decision process for institution-specific prudential requirements according to Directive 2013/36/EU of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC [1], and in particular the third subparagraph of Article 113(5) thereof,

Whereas:

(1) Efficient exchange of appropriate information is essential for reaching a joint decision on the adequacy of own funds, the supervisory measures relating to liquidity supervision, the level of liquidity and capital requirements applied to each institution of a group and the group.

(2) In order to ensure a consistent application of the process for the reaching of a joint decision, it is important that each step is well defined. A clear process also facilitates exchange of information, promotes mutual understanding, develops relationships between supervisory authorities and promotes effective supervision.

(3) In order to perform the risk assessment and the assessment of the liquidity risk profile for a group of institutions, the consolidating supervisor should have an overview of the activities carried out by all of the institutions within the group, including institutions operating outside the Union. Interaction between the competent authorities in the Union and third-country supervisors should therefore be promoted in order to enable the former to assess the global risks faced by the group.

(4) Timely and realistic planning for the joint decision process is essential. Every competent authority involved should provide the consolidating supervisor with relevant information on a timely basis. In order for individual assessments to be presented and interpreted in a consistent and uniform manner, it is necessary to introduce a common template for the results of the supervisory review and evaluation processes specific to each institution.

(5) To ensure uniform condition of application, the steps to be followed for the performance of the joint risk assessment and the reaching of the joint decision should be established, recognising that some tasks of the joint risk assessment and joint decision process may be performed in parallel and others sequentially.

(6) To facilitate the reaching of joint decisions, it is important that the competent authorities involved in the decision-making process engage in a dialogue with each other, in particular before finalizing the risk assessment reports and joint decisions.

(7) The consolidating supervisor should provide the competent authorities involved with all relevant information necessary for the preparation of their individual risk assessment and the reaching of the capital and liquidity joint decisions.

(8) The report containing the risk assessment of the group is a core document enabling competent authorities to understand and record the assessment of the overall risk profile of the banking group for the purpose of reaching a joint decision on the adequacy of own funds and level of own funds that the group is required to hold. The report containing the assessment of the liquidity risk profile of the group is an important document enabling competent authorities to understand and record the assessment of the overall liquidity profile of the group. In order to present the overall risk assessment and liquidity risk assessment of the group in a consistent manner, support meaningful discussions among competent authorities and enable a robust assessment of cross border banking group risks, common templates for these reports should be established.

[1] OJ L 176, 27.6.2013, p. 1.

(9) Whilst recognising that outcomes of the supervisory review and evaluation process specified in Article 97 of Directive 2013/36/EU may be documented differently across the Member States depending on the implementation of that Article in the national legislation while taking into account the guidelines issued by the European Supervisory Authority (European Banking Authority) (EBA) in accordance with Article 107(2) of Directive 2013/36/EU, standard templates should provide consistent formats for the communication of findings and outcomes of the supervisory review process for the purposes of reaching joint decisions.

(10) Neither the group risk assessment report nor the report containing the group liquidity risk assessment should be limited to an aggregation of individual contributions from competent authorities. Both reports should be used as a tool for performing the joint assessment of the risks of the whole group and analysing the interaction of intra-group items.

(11) Establishing clear processes for the content and articulation of the joint decision should ensure that joint decisions are fully reasoned and facilitate the monitoring of joint decisions and their enforcement.

(12) In order to clarify the process to be followed once the joint decision is reached, provide transparency on the treatment of the outcome of the decision and facilitate appropriate follow-up action where needed, standards regarding the communication of the fully reasoned joint decision and the monitoring of its implementation should be established.

(13) The process to be followed for the updates of joint decisions should be established in order to ensure a consistent and transparent approach as well as appropriate involvement of competent authorities and the communication of the outcomes.

(14) The joint decision process under Article 113 of Directive 2013/36/EU includes the process to be followed where no joint decision is reached. To ensure uniform conditions of application on this aspect of the process, the articulation of fully reasoned decisions and the treatment of views and reservations expressed by host supervisors, standards covering the timeline for taking decisions in the absence of a joint decision and the communication of the details of such decisions should be established.

(15) This Regulation is based on the draft implementing technical standards submitted by EBA to the Commission;

(16) EBA has conducted open public consultations on the draft implementing technical standards on which this Regulation is based, analysed the potential related costs and benefits and requested the opinion of the Banking Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council ([1]);

HAS ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER AND DEFINITIONS

Article 1

Subject matter

This Regulation specifies the following joint decision processes referred to in Article 113 of Directive 2013/36/EU:

(a) the process of reaching a joint decision on matters referred to in point (a) of Article 113(1), taking account of any waiver granted pursuant to Articles 7, 10 or 15 of Regulation (EU) No 575/2013 of the European Parliament and of the Council ([2]);

(b) the process of reaching a joint decision on matters referred to in point (b) of Article 113(1), taking account of any waiver granted pursuant to Articles 6, 8 or 10 of Regulation (EU) No 575/2013, and of any consolidated level of application pursuant to Article 11(3) of that Regulation.

([1]) Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

([2]) Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1).

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) 'relevant competent authorities' means competent authorities responsible for the supervision of subsidiaries of an EU parent institution, of an EU parent financial holding company or of an EU parent mixed financial holding company in a Member State;

(2) 'other competent authorities' means any of the following:

(a) competent authorities which are not a relevant competent authority;

(b) public authorities or bodies officially recognized by national law, which are empowered by national law to supervise financial sector entities, as defined in point 27 of Article 4(1) of Regulation (EU) No 575/2013, which operate in the Member State concerned and which are neither a credit institution nor an investment firm;

(3) 'SREP report' means the report presenting the outcome of the supervisory review and evaluation process referred to in Article 97 of Directive 2013/36/EU;

(4) 'liquidity risk assessment report' means the report presenting the outcome of the part of the supervisory review and evaluation process referred to in Article 97 of Directive 2013/36/EU concerning liquidity risks;

(5) 'group risk assessment report' means the report containing the risk assessment of the group of institutions referred to in point (a) of Article 113(2) of Directive 2013/36/EU;

(6) 'group liquidity risk assessment report' means the report containing the assessment of the liquidity risk profile of the group of institutions referred to in point (b) of Article 113(2) of Directive 2013/36/EU;

(7) 'capital joint decision' means a joint decision on matters referred to in point (a) of Article 1;

(8) 'liquidity joint decision' means a joint decision on matters referred to in point (b) of Article 1.

CHAPTER II

JOINT DECISION PROCESS

Article 3

Planning of the steps of the joint decision process

1. Prior to the start of the joint decision process the consolidating supervisor and the relevant competent authorities shall agree on a timetable of steps to be followed in that process (hereinafter 'joint decision timetable'). In case of disagreement, the consolidating supervisor shall set the joint decision timetable after considering the views and reservations expressed by the relevant competent authorities.

2. The joint decision timetable shall be updated at least annually and shall include the following steps:

(a) agreement on the involvement of other competent authorities and competent authorities of third countries pursuant to Article 4;

(b) submission of the SREP reports and liquidity risk assessment reports from the relevant competent authorities pursuant to Article 5 and contributions from the other competent authorities and competent authorities of third countries involved pursuant to Article 4(2);

(c) submission of the draft group risk assessment report and draft group liquidity risk assessment report by the consolidating supervisor to the relevant competent authorities pursuant to Article 6(6) and to other competent authorities and competent authorities of third countries pursuant to Article 4(3), and Article 6(7);

(d) dialogue between the consolidating supervisor and relevant competent authorities on the draft group risk assessment report and draft group liquidity risk assessment report pursuant to Article 7;

(e) submission of the group risk assessment report and group liquidity risk assessment report by the consolidating supervisor to the relevant competent authorities pursuant to Article 8(2) and other competent authorities and competent authorities of third countries pursuant to Article 4(3) and Article 8(5);

(f) submission of contributions to the draft capital joint decision and draft liquidity joint decision by relevant competent authorities to the consolidating supervisor pursuant to Article 9(1);

(g) submission of the draft capital joint decision document and draft liquidity joint decision document from the consolidating supervisor to the relevant competent authorities pursuant to Article 10(6) and Article 11(5);

(h) consultation on the draft capital joint decision and draft liquidity joint decision documents with the EU parent institution and institutions of the group, where required by the legislation of a Member State;

(i) dialogue between the consolidating supervisor and relevant competent authorities on the draft capital joint decision and draft liquidity joint decision;

(j) reaching of the capital joint decision and liquidity joint decision pursuant to Article 12;

(k) communication of the capital joint decision and liquidity joint decision by the consolidating supervisor and relevant competent authorities to the EU parent institution and institutions of the group pursuant to Article 13;

(l) agreement on the following year's timetable for the planning of the joint decision process.

3. The joint decision timetable shall fulfil all of the following requirements:

(a) it shall reflect the scope and complexity of each task, taking into account the size, systemic importance, nature, scale and complexity of the activities of the group as well as its risk-profile;

(b) it shall take account, so far as possible, of the commitments of the consolidating supervisor and the relevant competent authorities under the supervisory examination programme referred to in point (c) of the third subparagraph of Article 116(1) of Directive 2013/36/EU.

4. Where appropriate, in particular to reflect the urgency of any extraordinary update undertaken pursuant to Articles 20 and 21, the joint decision timetable shall be reviewed.

5. The consolidating supervisor and relevant competent authorities shall communicate to the institutions of the group for which they are respectively responsible an indicative date for the consultation referred to in point (h) of paragraph 2 on the aspects of the draft joint decision documents insofar as these institutions are concerned.

The consolidating supervisor and relevant competent authorities shall communicate to the institutions of the group for which they are respectively responsible an estimated date for the communication referred to in point (k) of paragraph 2.

Article 4

Involvement of other competent authorities and competent authorities of third countries in the group risk assessment process

1. The consolidating supervisor may decide to involve other competent authorities and competent authorities of third countries in the production of the group risk assessment report or group liquidity risk assessment report. That decision is based on the relevance of the branch or institution within the group and its significance for the local market.

Such involvement shall be subject to confidentiality requirements equivalent to those of Section II of Chapter 1 of Title VII of Directive 2013/36/EU and, where applicable, Articles 54 and 58 of Directive 2004/39/EC of the European Parliament and of the Council [1].

The equivalence shall be assessed by the consolidating supervisor and all relevant competent authorities.

2. Where the consolidating supervisor decides to involve another competent authority as defined in Article 2(2) or a competent authority of a third country, both authorities shall reach an agreement on the scope of involvement of the other competent authority or competent authority of the third country. Such agreements are allowed for the following purposes:

(a) providing the consolidating supervisor with contributions to the group risk assessment report or group liquidity risk assessment report;

(b) adding as annexes the contributions referred to in point (a) of this paragraph to the draft or final group risk assessment report or group liquidity risk assessment report.

[1] Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments amending Council Directives 85/611/EEC and 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC (OJ L 145, 30.4.2004, p. 1).

3. Where the consolidating supervisor decides to involve other competent authorities or competent authorities of third countries, the consolidating supervisor shall not provide the draft and final group risk assessment reports and group liquidity risk assessment reports to the other competent authorities and competent authorities of third countries without consent from all relevant competent authorities.

4. The consolidating supervisor shall keep the relevant competent authorities fully informed on the scope, level and nature of involvement of other competent authorities and competent authorities of third countries in the group risk assessment process and the extent to which the group risk assessment report has benefited from their contributions.

Article 5

Preparation of the SREP reports and liquidity risk assessment reports

1. In order to facilitate due consideration of the risk assessment of subsidiaries in the joint decision in accordance with Article 113(2) of Directive 2013/36/EU, the relevant competent authorities shall provide the consolidating supervisor with their SREP reports and liquidity risk assessment reports in a timely manner and in any event by the deadline specified in the joint decision timetable pursuant to point (b) of Article 3(2).

2. The SREP reports shall be prepared using the template in Annex I. These reports shall be supplemented with the summaries of scores using Table 1 of Annex II and the summary of capital adequacy assessment using Table 2 of Annex II.

The liquidity risk assessment reports shall be prepared using the template in Annex V. These reports shall be supplemented with the summaries of scores using Table 1 of Annex VI and the summary of liquidity assessment using Table 2 of Annex VI.

SREP reports and liquidity risk assessment reports may include additional relevant information.

Article 6

Preparation of the draft group risk assessment report and draft group liquidity risk assessment report

1. The consolidating supervisor shall prepare a draft group risk assessment report and draft group liquidity risk assessment report based on all of the following:

(a) its own SREP report or liquidity risk assessment report on the EU parent institution and the group;

(b) the SREP reports or liquidity risk assessment reports on subsidiaries provided by the relevant competent authorities pursuant to Article 5;

(c) contributions from other competent authorities and competent authorities of third countries, pursuant to Article 4(2).

2. The SREP reports and liquidity risk assessment reports referred to in points (a) and (b) of paragraph 1 together with contributions referred to in point (c) of that paragraph shall be added as annexes to the draft group risk assessment report or draft group liquidity risk assessment report.

3. The draft group risk assessment report and draft group liquidity risk assessment report shall contain the results of the assessment of whether the arrangements, strategies, processes and mechanisms implemented by the group and its institutions and the own funds and liquidity held by these ensure a sound management and coverage of their risks.

4. The draft group risk assessment report shall be prepared using the template in Annex III. This report shall be supplemented with the summaries of scores using Table 1 of Annex IV and the summary of capital adequacy assessment using Table 2 of Annex IV.

The draft group liquidity risk assessment report shall be prepared using the template in Annex VII. This report shall be supplemented with the summaries of scores using Table 1 of Annex VIII and the summary of liquidity assessment using Table 2 of Annex VIII.

5. In accordance with the principle of proportionality, the consolidating supervisor shall ensure all of the following:

(a) the joint assessment reflects the relevance of the institutions within the group and their significance in the local market;

(b) the draft group risk assessment report and draft group liquidity risk assessment report indicate how this relevance and significance were taken into account.

6. The consolidating supervisor shall provide the draft reports to the relevant competent authorities in a timely manner and in any event by the deadline specified in the joint decision timetable pursuant to point (c) of Article 3(2).

7. Subject to the agreement referred to in Article 4(3), the consolidating supervisor may provide the draft group risk assessment report and draft group liquidity risk assessment report to the other competent authorities and competent authorities of third countries.

Article 7

Dialogue on the draft group risk assessment report and draft group liquidity risk assessment report

1. The consolidating supervisor shall decide on the form and scope of the dialogue with the relevant competent authorities on the draft group risk assessment report and draft group liquidity risk assessment report.

2. The consolidating supervisor and the relevant competent authorities shall discuss the reconciliation of the quantitative proposals included in the individual SREP reports and liquidity risk assessment reports referred to Article 6(1) with the quantitative proposals in the draft group risk assessment report and draft group liquidity risk assessment report, as applicable.

3. The quantitative proposals referred to in paragraph 2 shall at least consist of the following proposals:

(a) the proposed levels of own funds that a group of institutions at consolidated level and all institutions of this group at individual level are required to hold pursuant to point (a) of Article 104(1) of Directive 2013/36/EU;

(b) the proposed levels of specific liquidity requirements that a group of institutions at consolidated level and all institutions of this group at individual level are required to meet pursuant to Article 105 of Directive 2013/36/EU.

Article 8

Finalisation of the group risk assessment report and group liquidity risk assessment report

1. Based on the dialogue referred to in Article 7, the consolidating supervisor shall finalise the group risk assessment report and group liquidity risk assessment report using the format and content of the draft group risk assessment report and draft group liquidity risk assessment report, as referred to in Article 6. The consolidating supervisor shall explain any material changes introduced in the group risk assessment report or group liquidity risk assessment report. Changes shall reflect the outcome of the dialogue and include the appropriate updates of the annexes to the group risk assessment report or group liquidity risk assessment report.

2. The consolidating supervisor shall provide the group risk assessment report and group liquidity risk assessment report to the relevant competent authorities in a timely manner and in any event by the deadline specified in the joint decision timetable pursuant to point (e) of Article 3(2).

3. In accordance with point (a) of Article 113(2) of Directive 2013/36/EU the submission of the group risk assessment report to the relevant competent authorities shall initiate the start of the four-month period for reaching the capital joint decision.

4. In accordance with point (b) of Article 113(2) of Directive 2013/36/EU the submission of the group liquidity risk assessment report to the relevant competent authorities shall initiate the start of the one-month period for reaching the liquidity joint decision.

5. Subject to the agreement referred to in Article 4(3), the consolidating supervisor may provide the group risk assessment report and group liquidity risk assessment report to the other competent authorities and competent authorities of third countries.

Article 9

Preparation of the contributions to the draft capital joint decision and draft liquidity joint decision

1. The relevant competent authorities shall provide their contributions to the draft capital joint decision and draft liquidity joint decision to the consolidating supervisor in a timely manner and in any event by the deadline specified in the joint decision timetable pursuant to point (f) of Article 3(2). Contributions shall cover all institutions within a group of institutions falling within the scope of the joint decision process.

2. The consolidating supervisor shall contribute to the draft capital joint decision. Its contributions shall include all of the following:

(a) all institutions of a group at individual level which are authorised in the jurisdiction of the consolidating supervisor and which fall into the scope of the joint decision process;

(b) the group of institutions at consolidated level.

3. The consolidating supervisor shall contribute to the draft liquidity joint decision. Its contributions shall include all of the following:

(a) all institutions of a group at individual level where these institutions are authorised in the jurisdiction of the consolidating supervisor and which fall into the scope of the joint decision process;

(b) the group of institutions at consolidated level.

4. Contributions to the draft capital joint decision shall set out each of the items referred to in Article 10.

5. Contributions to the draft liquidity joint decision shall set out each of the items referred to in Article 11.

Article 10

Preparation of the draft capital joint decision

1. The consolidating supervisor shall prepare a fully reasoned draft capital joint decision covering the group and the institutions of this group. The draft capital joint decision shall set out each of the following items:

(a) the names of the consolidating supervisor and relevant competent authorities involved in the capital joint decision process;

(b) the name of the group of institutions and a list of all institutions within the group to which the draft capital joint decision relates and applies;

(c) the references to the applicable Union and national law relating to the preparation, finalisation and application of capital joint decisions;

(d) the date of the draft capital joint decision and of any relevant update thereto;

(e) the conclusion on the application of Articles 73 and 97 of Directive 2013/36/EU;

(f) the conclusion on the adequacy of own funds held by the group of institutions at consolidated level;

(g) the conclusion on the adequacy of own funds held by each institution of the group at individual level;

(h) the conclusion on the level of own funds that each institution of the group is required to hold at individual level pursuant to point (a) of Article 104(1) of Directive 2013/36/EU;

(i) the conclusion on the level of own funds that the group of institutions is required to hold at consolidated level pursuant to point (a) of Article 104(1) of Directive 2013/36/EU;

(j) information on the minimum prudential requirements which apply to each institution pursuant to Article 92 of Regulation (EU) No 575/2013 and Articles 103, 129, 130, 131 and 133 of Directive 2013/36/EU and on any other relevant prudential or macro-prudential requirements, guidelines, recommendations or warnings;

(k) the reference date to which the conclusions referred to in points (e) to (i) relate;

(l) the timeline for the implementation of the conclusions referred to in points (h) and (i), where applicable.

2. The conclusion referred to in point (e) of paragraph 1 shall set out each of the following items:

(a) the assessment of whether the institutions of the group have in place sound, effective and complete strategies and processes to assess, maintain and distribute internal capital and whether such strategies and processes are up to date;

(b) the assessment of whether the amounts, types and distribution of internal capital is adequate to cover the nature and level of risks to which the institutions of the group are exposed or might be exposed;

(c) the assessment of whether the institutions of the group have implemented appropriate arrangements, strategies, processes and mechanisms to comply with all requirements of Directive 2013/36/EU and Regulation (EU) No 575/2013;

(d) the assessment of whether the arrangements, strategies, processes and mechanisms implemented by the institutions of the group ensure a sound management and coverage of their risks;

(e) information on the application of supervisory measures and powers pursuant to Article 102 and points (b) to (l) of Article 104(1) of Directive 2013/36/EU to address deficiencies identified under points (a) to (d).

3. The conclusions referred to in points (f) and (g) of paragraph 1 shall be linked to and supported by the conclusion referred to in point (e) of paragraph 1.

4. The conclusions referred to in points (h) and (i) of paragraph 1 shall meet all of the following requirements:

(a) they shall be formulated as an amount or a ratio or a combination of both;

(b) they shall provide details of the quality of additional own funds required;

(c) they shall be linked to and supported by the conclusion referred to in point (e) of paragraph 1.

5. The conclusions regarding each institution of the group at individual level and the group of institutions at consolidated level shall be clearly identifiable in the draft capital joint decision document.

6. The consolidating supervisor shall provide the draft capital joint decision document to the relevant competent authorities in a timely manner and in any event by the deadline specified in the joint decision timetable pursuant to point (g) of Article 3(2).

Article 11

Preparation of the draft liquidity joint decision

1. The consolidating supervisor shall prepare a fully reasoned draft liquidity joint decision covering the group and the institutions of this group. The draft liquidity joint decision shall set out each of the following items:

(a) the names of the consolidating supervisor and relevant competent authorities involved in the liquidity joint decision process;

(b) the name of the group of institutions and a list of all institutions within the group to which the draft liquidity joint decision relates and applies;

(c) the references to the applicable Union and national law relating to the preparation, finalisation and application of liquidity joint decisions;

(d) the date of the draft liquidity joint decision and of any relevant update thereto;

(e) the conclusion on the liquidity adequacy for the group at consolidated level;

(f) the conclusion on the liquidity adequacy for each institution within the group at individual level;

(g) the conclusion on measures taken to address any significant matters and material findings relating to liquidity supervision including relating to the adequacy of the organisation and the treatment of risks as required pursuant to Article 86 of Directive 2013/36/EU and relating to the need for specific liquidity requirements in accordance with Article 105 of that Directive for each institution within the group at individual level and for the group at consolidated level;

(h) information on any other relevant prudential or macro-prudential requirements, guidelines, recommendations or warnings;

(i) the reference date to which the conclusions referred to in point (e) to (g) relate;

(j) the timeline for the implementation of the conclusion referred to in point (g), where applicable.

2. The conclusion referred to in points (e) and (f) of paragraph 1 shall set out each of the following items:

(a) the assessment of whether the institutions of the group have implemented robust strategies, policies, processes and systems for the identification, measurement, management and monitoring of liquidity risk over an appropriate set of time horizons;

(b) the assessment of whether the liquidity held by the institutions of the group at individual level and the group at consolidated level provides sufficient coverage of liquidity risks;

(c) the assessment of whether the institutions of the group have implemented appropriate arrangements, strategies, processes and mechanisms to comply with all requirements of Directive 2013/36/EU and Regulation (EU) No 575/2013.

3. The conclusion referred to in point (g) of paragraph 1 shall provide details on the nature of the measures taken. Where these measures relate to the need for specific liquidity requirements in accordance with Article 105 of Directive 2013/36/EU, the conclusion shall provide details on the articulation of those specific liquidity requirements.

4. The conclusions regarding each institution of the group at individual level and the group of institutions at consolidated level shall be clearly identifiable in the draft liquidity joint decision document.

5. The consolidating supervisor shall provide the draft liquidity joint decision document to the relevant competent authorities in a timely manner and in any event by the deadline specified in the joint decision timetable pursuant to point (g) of Article 3(2).

Article 12

Reaching of the capital joint decision and liquidity joint decision

1. Following the dialogue with the relevant competent authorities on the draft capital joint decision and draft liquidity joint decision as referred to in point (i) of Article 3(2), the consolidating supervisor shall revise the draft capital joint decision and draft liquidity joint decision, as necessary, in order to finalise those decisions.

2. An agreement on the capital joint decision and liquidity joint decision shall be reached by the consolidating supervisor and all relevant competent authorities.

3. The agreement shall be evidenced in writing by representatives of the consolidating supervisor and relevant competent authorities with appropriate authority to commit their respective competent authorities.

Article 13

Communication of the capital joint decision and liquidity joint decision

1. The consolidating supervisor shall provide the capital joint decision document and liquidity joint decision document to the management body of the EU parent institution in a timely manner and in any event by the deadline specified in the joint decision timetable pursuant to point (k) of Article 3(2). The consolidating supervisor shall confirm this communication to the relevant competent authorities.

2. The relevant competent authorities in a Member State shall provide to the management bodies of institutions which are authorised in that Member State the respective parts of the capital joint decision document and liquidity joint decision document that are relevant to each of those institutions in a timely manner and in any event by the deadline specified in the joint decision timetable pursuant to point (k) of Article 3(2).

3. The consolidating supervisor shall, where appropriate, discuss the capital joint decision document and liquidity joint decision document with the EU parent institution to explain the details of the decisions and their application.

4. The relevant competent authorities in a Member State shall, where appropriate, discuss with the institutions established in this Member State the respective parts of the capital joint decision document and liquidity joint decision document that are relevant to each of these institutions to explain the details of the decisions and their application.

Article 14

Monitoring of the application of the capital joint decision and liquidity joint decision

1. The consolidating supervisor shall communicate the outcome of the discussion referred to in Article 13(3) to the relevant competent authorities where an EU parent institution is required to take any of the following actions:

(a) to meet additional own funds requirements pursuant to point (a) of Article 104(1) of Directive 2013/36/EU at individual or consolidated level,

(b) to address significant matters or material findings relating to liquidity supervision or to meet specific liquidity requirements pursuant to Article 105 of Directive 2013/36/EU, at individual or consolidated level.

2. The relevant competent authorities in a Member State shall communicate the outcome of the discussion referred to in Article 13(4) to the consolidating supervisor where an institution authorised in that Member State is required to take any of the following actions:

(a) to meet additional own funds requirements pursuant to point (a) of Article 104(1) of Directive 2013/36/EU at individual level;

(b) to address significant matters or material findings relating to liquidity supervision or to meet specific liquidity requirements pursuant to Article 105 of Directive 2013/36/EU at individual level.

3. The consolidating supervisor shall forward the outcome of the discussion referred to in paragraph 2 to the other relevant competent authorities.

4. The consolidating supervisor and relevant competent authorities shall monitor the application of the capital joint decisions and liquidity joint decisions that are relevant to each of the institutions of the group for which they are respectively responsible.

CHAPTER III

DISAGREEMENTS AND DECISIONS TAKEN IN THE ABSENCE OF JOINT DECISION

Article 15

Decision process in the absence of joint decision

1. In the absence of a capital joint decision or a liquidity joint decision between the consolidating supervisor and the relevant competent authorities within the time periods referred to in Article 8(3) or 8(4), respectively, the decisions referred to in Article 113(3) of Directive 2013/36/EU shall be evidenced in writing and shall be taken by the latest of the following dates:

(a) the date one month after the expiry of the time period referred to in Article 8(3) or (4), as applicable;

(b) the date one month after the provision of any advice by the EBA following a request for consultation in accordance with the third subparagraph of Article 113(2) of Directive 2013/36/EU;

(c) the date one month after any decision taken by the EBA in accordance with the first or second subparagraphs of Article 113(3) of Directive 2013/36/EU or any other date set by the EBA in such a decision.

2. The relevant competent authorities shall communicate to the consolidating supervisor the decisions they have taken at individual level in the absence of a joint decision.

3. The consolidating supervisor shall include the decisions referred to in paragraph 2 with its decisions taken at individual and consolidated levels into a single document and shall provide this document to all relevant competent authorities.

4. Where the EBA has been consulted, the document referred to in paragraph 3 shall include an explanation of any deviations from the advice of the EBA.

Article 16

Drafting of the capital decisions taken in the absence of capital joint decision

1. A capital decision taken in the absence of capital joint decision shall be set out in a document that contains all of the following items:

(a) the name of the consolidating supervisor or relevant competent authority taking the capital decision;

(b) the name of the group of institutions or the institution of the group to which the capital decision relates and applies;

(c) the references to the applicable Union and national law relating to the preparation, finalisation and application of capital decisions;

(d) the date of the capital decision;

(e) the conclusion on the application of Articles 73 and 97 of Directive 2013/36/EU;

(f) for capital decisions taken on a consolidated basis, the conclusion on the adequacy of own funds held by the group of institutions at consolidated level;

(g) for capital decisions taken on an individual basis, the conclusion on the adequacy of own funds held by the relevant institution at individual level;

(h) for capital decisions taken on a consolidated basis, the conclusion on the level of own funds that the group of institutions is required to hold at consolidated level pursuant to point (a) of Article 104(1) of Directive 2013/36/EU;

(i) for capital decisions taken on an individual basis, the conclusion on the level of own funds that the relevant institution is required to hold at individual level pursuant to point (a) of Article 104(1) of Directive 2013/36/EU;

(j) information on the minimum prudential requirements which apply to the relevant institutions pursuant to Article 92 of Regulation (EU) No 575/2013 and Articles 103, 129, 130, 131 and 133 of Directive 2013/36/EU and on any other relevant prudential or macro-prudential requirements, guidelines, recommendations or warnings;

(k) the reference date to which the conclusions referred to in points (e) to (i) relate;

(l) the description of how the risk assessment, views and reservations expressed by the other relevant competent authorities or consolidating supervisor are considered, where applicable;

(m) the timeline for the implementation of the conclusions referred to in points (h) and (i), where applicable.

2. The capital decisions taken in the absence of a capital joint decision at individual or consolidated level shall meet the requirements set out in Article 10(2) to (4), where applicable.

Article 17

Drafting of the liquidity decisions taken in the absence of a liquidity joint decision

1. A liquidity decision taken in the absence of liquidity joint decision shall be set out in a document that contains all of the following items:

(a) the name of the consolidating supervisor or relevant competent authority taking the liquidity decision;

(b) the name of the group of institutions or the institution of the group to which the liquidity decision relates and applies;

(c) the references to the applicable Union and national law relating to the preparation, finalisation and application of liquidity decisions;

(d) the date of the liquidity decision;

(e) for liquidity decisions taken on a consolidated basis, the conclusion on the liquidity adequacy for the group of institutions at consolidated level;

(f) for liquidity decisions taken on an individual basis, the conclusion on the liquidity adequacy for the relevant institution at individual level;

(g) for liquidity decisions taken on a consolidated basis, the conclusion on measures taken to address any significant matters and material findings relating to liquidity supervision including relating to the adequacy of the organisation and the treatment of risks as required pursuant to Article 86 of Directive 2013/36/EU and relating to the need for specific liquidity requirements in accordance with Article 105 of that Directive for the group at consolidated level;

(h) for liquidity decisions taken on an individual basis, the conclusion on measures taken to address any significant matters and material findings relating to liquidity supervision including relating to the adequacy of the organisation and the treatment of risks as required pursuant to Article 86 of Directive 2013/36/EU and relating to the need for liquidity requirements specific to the relevant institution at individual level in accordance with Article 105 of that Directive;

(i) the reference date to which the conclusions referred to in points (e) to (h) relate;

(j) information on any other relevant prudential or macro-prudential requirements, guidelines, recommendations or warnings;

(k) a description of how the risk assessment, views and reservations expressed by the other relevant competent authorities or consolidating supervisor are considered, where applicable;

(l) the timeline for the implementation of the conclusions referred to in points (g) to (h), as applicable.

2. The liquidity decisions taken in the absence of a liquidity joint decision at individual or consolidated level shall meet the requirements set out in Articles 11(2) to (3).

Article 18

Communication of capital decisions and liquidity decisions taken in the absence of capital joint decision or liquidity joint decision

1. The consolidating supervisor shall provide the decision document referred to in Article 15(3) to the management body of the EU parent institution.

2. The relevant competent authorities in a Member State shall provide to the management bodies of institutions which are authorised in that Member State the respective parts of the decision document referred to in paragraph 1 that are relevant to each of these institutions.

3. The consolidating supervisor shall, where appropriate, discuss the decision document with the EU parent institution to explain the details and application of the capital decisions or liquidity decisions taken in the absence of a capital joint decision or liquidity joint decision.

4. The relevant competent authorities in a Member State shall, where appropriate, discuss with the institutions established in this Member State the respective parts of the decision document that are relevant to each of these institutions to explain the details and application of the capital decisions or liquidity decisions taken in the absence of a capital joint decision or a liquidity joint decision.

Article 19

Monitoring of the application of the capital decisions and liquidity decisions taken in the absence of capital joint decision or liquidity joint decision

The consolidating supervisor and relevant competent authorities shall monitor the application of the capital decisions and liquidity decisions, taken in the absence of a capital joint decision or liquidity joint decision, that are relevant to each of the institutions of the group for which they are respectively responsible.

CHAPTER IV

UPDATE AND EXTRAORDINARY UPDATE OF JOINT DECISIONS AND DECISIONS TAKEN IN THE ABSENCE OF JOINT DECISION

Article 20

Extraordinary update of joint decisions

1. Where a request for an extraordinary update of a capital joint decision or a liquidity joint decision is initiated by the consolidating supervisor or a relevant competent authority pursuant to Article 113(4) of Directive 2013/36/EU, the consolidating supervisor shall communicate this request to all relevant competent authorities. The extraordinary update shall follow the process set out in Articles 9 to 14.

2. Where a relevant competent authority requests to update a joint decision in relation to an institution other than an EU parent institution, an EU parent financial holding company or an EU parent mixed financial holding company with the consolidating supervisor on a bilateral basis, the request shall be made in writing and be fully reasoned.

The consolidating supervisor shall communicate the request referred to in the first subparagraph to all relevant competent authorities. The request shall include a draft capital joint decision document that complies with the requirements set out in Article 10 or a draft liquidity joint decision that complies with the requirements set out in Article 11. The consolidating supervisor shall set a deadline for relevant competent authorities to comment whether the update should be addressed on a bilateral basis.

Where none of the relevant competent authorities requests to address the update on a non-bilateral basis within the specified deadline, the consolidating supervisor and the relevant competent authority which requested the extraordinary update shall contribute to and reach an agreement on the joint decision on a bilateral basis.

3. Where a relevant competent authority does not wish to submit a contribution to the updated joint decision in accordance with Article 9, the consolidating supervisor shall prepare the updated joint decision on the basis of the most recent contribution to the joint decision document received from the relevant competent authority.

Article 21

Annual and extraordinary update of decisions taken in the absence of joint decision

1. The annual update of decisions taken in the absence of joint decision shall follow the steps pursuant to Article 3(2), in so far as each step is relevant for the application of Article 97(4) of Directive 2013/36/EU.

2. Any extraordinary update of decisions taken in the absence of joint decision pursuant to Article 113(4) of Directive 2013/36/EU shall follow the process set out in Articles 9 to 14.

CHAPTER V

FINAL PROVISIONS

Article 22

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, 23 June 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX I

SREP REPORT TEMPLATE

The SREP report is supplemented with summaries of scores (Table 1) and the capital adequacy assessment (Table 2).

Institution:	
Category of the institution:	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]
Reference date:	
Total assets (million EUR) at reference date:	
Competent authority:	

Overall SREP assessment	**Overall SREP score** (following the capital and liquidity adequacy assessment):
This section should contain a summary of the assessments made in the sections below.	

Capital adequacy assessment
Within this section please provide: (1) a summary of the assessment of the capital adequacy; (2) the preliminary proposal for the joint decision, including a statement on the adequacy of own funds at the respective entity level and any required level of own funds in excess of the requirements set out in Chapter Four of Title VII of Directive 2013/36/EU (CRD) and in Regulation (EU) No 575/2013 (CRR); (3) the outlook for next assessment period; and, (4) a description of any other capital-related supervisory measures ([1]). *Within this section please also describe how SREP capital estimates have been derived and how ICAAP capital estimates have been taken into account, if assessed as reliable.*

Liquidity Adequacy Assessment
Within this section please provide: (1) a summary of the assessment of the liquidity adequacy; (2) the proposal for the joint decision, including a statement on the adequacy of liquidity at the respective entity level and any required supervisory measures, where applicable; (3) the outlook for the next assessment period; and, (4) a description of any other supervisory measures to address the deficiencies identified, where applicable. *Depending on the timing of the joint decision on liquidity, this assessment should either mirror the findings summarised in the Liquidity SREP report (see template in Annex 5), or provide an updated assessment.*

([1]) E.g. dividend restrictions.

A. Business model analysis (viability and sustainability)	Score:
Within this section please provide: (1) a description of the evolution of the business model, strategy and financial position within the observed period; (2) the supervisory assessment of the viability of the current business model and sustainability of the strategy; and, (3) any relevant supervisory measures, including capital and non-capital supervisory measures.	

B. Internal governance arrangements	Score:
Within this section please provide: (1) a description of the evolution of the internal governance framework within the observed period; (2) deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to internal governance requirements; (4) the outlook for the next assessment period; (5) actions to be taken by the institution, and, (6) any relevant supervisory measures, including capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C. Risks to solvency	
C.1 Credit and counterparty risk	**Score:**
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.2 Settlement/delivery risk	Score:
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.3 Inter-concentration risk	Score:
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.4 **Market risk**	**Score:**
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.5 **IRRBB**	**Score:**
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.6 **Operational risk**	**Score:**
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.7 **Risk of excessive leverage**	**Score:**
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.8 **Other risks material to the institution, as applicable** (please specify)	**Score:**
Within this section please provide: (1) a description of the evolution of other identified risks to solvency in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

D. Risks to liquidity	Overall liquidity risk score:
Within this section please provide: (1) a description of the evolution of liquidity and funding risks in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues. *Depending on the timing of the joint decision on liquidity, this assessment should either mirror the findings summarised in the Liquidity SREP report (see template in Annex 5), or provide an updated assessment.*	
Should the assessment of liquidity and funding risks highlight significant issues in relation to funding risk requiring the allocation of capital to mitigate impacts from an increased cost of funding, please describe how it is reflected in the additional own funds requirements, if relevant.	

E. Systemic risk
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) the outlook for the next assessment period; and, (3) any supervisory measures, including capital and non-capital supervisory measures.

F. ICAAP review
Within this section please provide: (1) a summary of the findings of the assessment of the reliability of the ICAAP framework and institution's own quantification of risks and the consequent allocation of appropriate internal capital; (2) a description of the evolution of ICAAP framework in the observed period; (3) deficiencies identified; (4) issues of non-compliance with the CRR and the CRD in relation to the ICAAP; (5) mitigating actions to be taken by the institution; and (6) any relevant supervisory measures, including capital and non-capital supervisory measures to address the deficiencies and non-compliance issues. *The section should also have a statement on whether ICAAP estimates are considered reliable and could serve as an input into the assessment of capital adequacy.*

G. Inter-risk diversification effects
Taking into account the outcome of the ICAAP assessments and internal capital estimates, and only in case diversification effects are recognised, please provide within this section a description of the impact of diversification effects and define the extent to which benefits from the diversification effects can be taken into account in the determination of capital adequacy.

H. Stress test outcomes
Within this section please summarise the results and their impact on capital adequacy of institutions own stress tests and their reconciliation with supervisory stress tests, including the explanation of how the stress testing buffer was derived, where applicable.

Other relevant information
Within this section please provide other information deemed relevant by the competent authority for the purposes of the group risk assessment and not provided above.

Quantitative Indicators agreed by the consolidating supervisor and the host EEA competent authorities (pursuant to RTS/ITS on colleges of supervisors)
Please list any quantitative indicators agreed to be shared while developing the joint risk assessment report for the purposes of reaching a joint decision.

ANNEX II

SREP REPORT TEMPLATE

Table 1

Summary of scores

Institution:	
Category of the institution:	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]
Reference date:	
Total assets (mln EUR) at reference date:	
Competent authority:	

SREP elements		Score
A.	**Business Model (viability and sustainability)**	
B.	**Internal governance arrangements**	
C.	**Risks to solvency**	
C.1	Credit and counterparty risk	
C.2	Settlement / Delivery risk	
C.3	Inter-concentration risk	
C.4	Market risk	
C.5	IRRBB	
C.6	Operational risk	
C.7	Risk of excessive leverage	
C.8	Other risks material to the institution, as applicable (please specify)	
C.9	Other risks material to the institution, as applicable (please specify)	
D.	**Risks to liquidity**	[as per the outcome of the Liquidity SREP report] These scores should be consistent with the respective assessments under the liquidity joint decision. Depending on the timing of the joint decision on liquidity, this assessment should either mirror the findings summarised in the liquidity SREP report, or provide updated assessment.
E.	**Systemic risk (risk that institution poses to financial system)**	
Overall SREP Score		

Table 2

Summary of capital adequacy assessment

Institution:				
Category of the institution:		[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]		
Reference date:				
Total assets (mln EUR) at reference date:				
Competent authority:				
SREP elements		**Memoranda items**		**Overall SREP capital requirement/estimate** (including supervisory proxy, where applicable) (in mln EUR)
		Pillar 1 capital requirements, where applicable (in mln EUR)	**ICAAP estimate** (in mln EUR)	
A.	**Business Model (viability and sustainability)**			
B.	**Internal governance arrangements**			
C.	**Risks to solvency (risks and controls)**			
C.1	Credit and counterparty risk			
C.2	Settlement / Delivery risk			
C.3	Inter-concentration risk			
C.4	Market risk			
C.5	IRRBB			
C.6	Operational risk			
C.7	Risk of excessive leverage			
C.8	Other risks material to the institution, as applicable (please specify)			
C.9	Other risks material to the institution, as applicable (please specify)			
D.	**Risks to liquidity — Funding risk (cost of funding perspective)**			
E.	**Systemic risk (risk that institution poses to financial system)**			
F.	**Inter-risk diversification effects**			
G.	**Capital planning / stress test buffer (where applicable)**		*Capital planning / Stress testing buffer based on the outcomes of ICAAP stress tests, where applicable*	*Reconciliation of ICAAP stress tests with supervisory stress tests and resulting capital planning / stress testing buffer, where applicable*

H.	**SREP capital outcome** (preliminary proposal for joint decision discussion)			
	Overall capital requirement/estimate	*Total Pillar 1 capital requirement*	*Total ICAAP capital estimate*	*Total SREP capital estimate*
	Capital adequacy assessment (capital is assessed as adequate/inadequate)			*Adequate/Inadequate*
	Additional own funds requirement			***Sum of components or holistic approach (formulated as an amount or ratio, or combination of both)***
Memoranda items (values at reference date)				
	Total own funds (mln EUR) at reference date			
	Tier 1 own funds (mln EUR) at reference date			
	Common Equity Tier 1 own funds (mln EUR) at reference date			
	Total risk weighted assets (mln EUR) at reference date			
	The own funds requirements applicable in the home Member State in accordance with Article 92 of Regulation (EU) No 575/2013, taking into account any measures adopted or recognised in accordance with Article 458 of that Regulation and the transitional arrangements laid down in Part X of that Regulation			
	The level of the capital conservation buffer that the institution is required to maintain in accordance with Article 129 of Directive 2013/36/EU			
	The level of the institution-specific countercyclical capital buffer to be maintained by the institution in accordance with Article 130 of Directive 2013/36/EU			
	The level of any systemic risk buffer that the institution is required to maintain in accordance with Article 133 of Directive 2013/36/EU			
	The level of any G-SII buffer or O-SII buffer that the institution is required to maintain in accordance with Article 128(3) and (4) of Directive 2013/36/EU			
	Any other prudential requirements applicable to the institution, including under Article 103 of Directive 2013/36/EU, macro-prudential measures and recommendations of EBA and ESRB			

ANNEX III

GROUP RISK ASSESSMENT REPORT TEMPLATE

The Group risk assessment report shall include as annexes all SREP reports submitted by the relevant competent authorities. The group risk assessment report shall be supplemented with summaries of scores (Table 1) and the capital adequacy assessment (Table 2).

Group:	
Category of the group:	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]
Reference date:	
Total assets (million EUR) at reference date:	

Overall SREP assessment of the Group	**Overall SREP score** (following the capital and liquidity adequacy assessment):
This section should contain a summary of the assessments made in the sections below,	

Capital adequacy assessment
Within this section please provide: (1) a summary of the assessment of the capital adequacy; (2) the proposal for the joint decision, including a statement on the adequacy of own funds at the group level and any required level of own funds in excess of the requirements set out in Chapter Four of Title VII of Directive 2013/36/EU (CRD) and in Regulation (EU) No 575/2013 (CRR); (3) the outlook for the next assessment period; and, (4) a description of any other capital-related supervisory measures ([1]).
Within this section please also describe how SREP capital estimates have been derived and how ICAAP capital estimates have been taken into account, if assessed as reliable.

Liquidity Adequacy Assessment
Within this section please provide: (1) a summary of the assessment of the liquidity adequacy; (2) the proposal for the joint decision, including a statement on the adequacy of liquidity at the group level and any required supervisory measures, where applicable; (3) the outlook for the next assessment period; and, (4) a description of any other supervisory measures to address the deficiencies identified, where applicable.
Depending on the timing of the joint decision on liquidity, this assessment should either mirror the findings summarised in the Group liquidity risk assessment report (see template in Annex 7), or provide an updated assessment.

([1]) E.g. dividend restrictions.

A. Business model analysis (viability and sustainability)	Score:
Within this section please provide: (1) a description of the evolution of the business model, strategy and financial position within the observed period; (2) the supervisory assessment of the viability of the current business model and sustainability of the strategy; and, (3) any relevant supervisory measures, including capital and non-capital supervisory measures.	

B. Internal governance arrangements	Score:
Within this section please provide: (1) a description of the evolution of the internal governance framework within the observed period; (2) deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to internal governance requirements; (4) the outlook for the next assessment period; (5) actions to be taken by the institution, and, (6) any relevant supervisory measures, including capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C. Risks to solvency	
C.1 Credit and counterparty risk	**Score:**
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.2 Settlement/delivery risk	Score:
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.3 Inter-concentration risk	Score:
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.4 Market risk	Score:
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.5 IRRBB	Score:
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.6 Operational risk	Score:
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.7 Risk of excessive leverage	Score:
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

C.8 Other risks material to the institution, as applicable (please specify)	Score:
Within this section please provide: (1) a description of the evolution of other identified risks to solvency in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues.	

D. Risks to liquidity	Overall liquidity risk score:
Within this section please provide: (1) a description of the evolution of liquidity and funding risks in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures including, capital and non-capital supervisory measures to address the deficiencies and non-compliance issues. *Depending on the timing of the joint decision on liquidity, this assessment should either mirror the findings summarised in the Group liquidity risk assessment report (see template in Annex 7), or provide an updated assessment.*	
Should the assessment of liquidity and funding risks highlight significant issues in relation to funding risk requiring the allocation of capital to mitigate impacts from an increased cost of funding, please describe how it is reflected in the additional own funds requirements, if relevant.	

E. Systemic risk
Within this section please provide: (1) a description of the evolution of the risk in the observed period; (2) the outlook for the next assessment period; and, (3) any supervisory measures, including capital and non-capital supervisory measures.

F. ICAAP review
Within this section please provide: (1) a summary of the findings of the assessment of the reliability of the ICAAP framework and institution's own quantification of risks and the consequent allocation of appropriate internal capital; (2) a description of the evolution of ICAAP framework in the observed period; (3) deficiencies identified; (4) issues of non-compliance with the CRR and the CRD in relation to the ICAAP; (5) mitigating actions to be taken by the institution; and (6) any relevant supervisory measures, including capital and non-capital supervisory measures to address the deficiencies and non-compliance issues. *The section should also have a statement on whether ICAAP estimates are considered reliable and could serve as an input into the assessment of capital adequacy.*

G. Inter-risk diversification effects
Taking into account the outcome of the ICAAP assessments and internal capital estimates, and only in case diversification effects are recognised, please provide within this section a description of the impact of diversification effects and define the extent to which benefits from the diversification effects can be taken into account in the determination of capital adequacy.

H. Stress test outcomes
Within this section please summarise the results and their impact on capital adequacy of institutions own stress tests and their reconciliation with supervisory stress tests, including the explanation of how the stress testing buffer was derived, where applicable.

Other relevant information
Within this section please provide other information deemed relevant by the competent authorities for the purposes of the group risk assessment and not provided above (e.g. information needed to meet requirements of Article 6(5) of this Implementing Regulation.

Quantitative Indicators agreed by the consolidating supervisor and the host EEA competent authorities (pursuant to RTS/ITS on colleges of supervisors)
Please list any quantitative indicators agreed to be shared while developing the joint risk assessment report for the purposes of reaching a joint decision.

ANNEX IV

GROUP RISK ASSESSMENT REPORT TEMPLATE

Table 1

Summary of scores

Institution:		*Entity X/ Sub-group X*	*Entity Y / Sub-group Y*	***Consolidated group***
Category of the institution:				
Reference date:				
Total assets (mln EUR) at reference date:				
Competent authority:				
SREP elements		**Score**	**Score**	**Score**
A.	**Business Model (viability and sustainability)**			
B.	**Internal governance arrangements**			
C.	**Risks to solvency**			
C.1	Credit and counterparty risk			
C.2	Settlement / Delivery risk			
C.3	Inter-concentration risk			
C.4	Market risk			
C.5	IRRBB			
C.6	Operational risk			
C.7	Risk of excessive leverage			
C.8	Other risks material to the institution, as applicable (please specify)			
C.9	Other risks material to the institution, as applicable (please specify)			
D.	**Risks to liquidity**	[as per the outcome of the Liquidity SREP report]	[as per the outcome of the Liquidity SREP report]	[as per the outcome of the Liquidity SREP report]
E.	**Systemic risk (risk that institution poses to financial system)**			
Overall SREP Score				

Table 2

Summary of capital adequacy assessment

Institution:	*Entity X/ Sub-group X*	*Entity Y/ Sub-group Y*	*Consolidated Group*
Category of the institution:			
Reference date:			
Total assets (mln EUR) at reference date:			
Competent authority:			

SREP elements		**Memoranda items**		Overall SREP capital requirement/estimate (including supervisory proxy, where applicable) (in mln EUR)	**Memoranda items**		Overall SREP capital requirement/estimate (including supervisory proxy, where applicable) (in mln EUR)	**Memoranda items**		Overall SREP capital requirement/estimate (including supervisory proxy, where applicable) (in mln EUR)
		Pillar 1 capital requirements, where applicable (in mln EUR)	**ICAAP estimate (in mln EUR)**		**Pillar 1 capital requirements, where applicable (in mln EUR)**	**ICAAP estimate (in mln EUR)**		**Pillar 1 capital requirements, where applicable (in mln EUR)**	**ICAAP estimate (in mln EUR)**	
A.	**Business Model (viability and sustainability)**									
B.	**Internal governance arrangements**									
C.	**Risks to solvency (risks and controls)**									
C.1	Credit and counterparty risk									
C.2	Settlement / Delivery risk									
C.3	Inter-concentration risk									

C.4	Market risk									
C.5	IRRBB									
C.6	Operational risk									
C.7	Risk of excessive leverage									
C.8	Other risks material to the institution, as applicable (please specify)									
C.9	Other risks material to the institution, as applicable (please specify)									
D.	**Risks to liquidity — Funding risk (cost of funding perspective)**									
E.	**Systemic risk (risk that institution poses to financial system)**									
F.	**Inter-risk diversification effects**									
G.	**Capital planning / stress test buffer (where applicable)**		*Capital planning / Stress testing buffer based on the outcomes of ICAAP stress tests, where applicable*	*Reconciliation of ICAAP stress tests with supervisory stress tests and resulting capital planning / stress testing buffer, where applicable*		*Capital planning / Stress testing buffer based on the outcomes of ICAAP stress tests, where applicable*	*Reconciliation of ICAAP stress tests with supervisory stress tests and resulting capital planning / stress testing buffer, where applicable*		*Capital planning / Stress testing buffer based on the outcomes of ICAAP stress tests, where applicable*	*Reconciliation of ICAAP stress tests with supervisory stress tests and resulting capital planning / stress testing buffer, where applicable*

H.	**SREP capital outcome** (preliminary proposal for joint decision discussion)								
	Overall capital requirement/estimate	*Total Pillar 1 capital requirement*	*Total ICAAP capital estimate*	*Total SREP capital estimate*	*Total Pillar 1 capital requirement*	*Total ICAAP capital estimate*	*Total SREP capital estimate*	*Total Pillar 1 capital requirement*	*Total ICAAP capital estimate*	*Total SREP capital estimate*
	Capital adequacy assessment (capital is assessed as adequate/inadequate)			*Adequate/Inadequate*			*Adequate/Inadequate*			*Adequate/Inadequate*
	Additional own funds requirement			*Sum of components or holistic approach (formulated as an amount or ratio, or combination of both)*			*Sum of components or holistic approach (formulated as an amount or ratio, or combination of both)*			*Sum of components or holistic approach (formulated as an amount or ratio, or combination of both)*
I.	***Diversification effects, including intra-group (-)***									
	Intra-group concentration (+)									
	Intra-group support arrangements (-)									
	Other intra-group items (+/-)									
J.	**Joint decision outcome** (based on preliminary proposal (H), reflecting impact of intra-group items, and results of the dialogue between competent authorities)								
	Overall capital requirement/estimate			***Total SREP capital estimate***			***Total SREP capital estimate***			***Total SREP capital estimate***
	Capital adequacy assessment (capital is assessed as adequate/inadequate)			***Adequate/Inadequate***			***Adequate/Inadequate***			***Adequate/Inadequate***
	Additional own funds requirement			***Sum of components or holistic approach (formulated as an amount or ratio, or combination of both)***			***Sum of components or holistic approach (formulated as an amount or ratio, or combination of both)***			***Sum of components or holistic approach (formulated as an amount or ratio, or combination of both)***

Memoranda items (values at reference date)							
	Total own funds (mln EUR) at reference date						
	Tier 1 own funds (mln EUR) at reference date						
	Common Equity Tier 1 own funds (mln EUR) at reference date						
	Total risk weighted assets (mln EUR) at reference date						
	The own funds requirements applicable in the home Member State in accordance with Article 92 of Regulation (EU) No 575/2013 taking into account any measures adopted or recognised under Article 458 of that Regulation and the transitional arrangements under Part X of that Regulation						
	The level of the capital conservation buffer required to be maintained by the institution in accordance with Article 129 of Directive 2013/36/EU						
	The level of the institution-specific countercyclical capital buffer to be maintained by the institution in accordance with Article 130 of Directive 2013/36/EU						

	The level of the systemic risk buffer to be maintained by the institution, if applicable, in accordance with Article 133 of Directive 2013/36/EU						
	The level of the any G-SII buffer or O-SII buffer, as defined in paragraphs (3) and (4) respectively of Article 128 of Directive 2013/36/EU, to be held by the institution						
	Any other prudential requirements applicable to the institution, including under Article 103 of Directive 2013/36/EU, macro-prudential measures and recommendations of EBA and ESRB						

ANNEX V

LIQUIDITY RISK ASSESSMENT REPORT TEMPLATE

Liquidity risk assessment report is supplemented with summary of scores (Table 1) and overall liquidity assessment (Table 2).

Institution:	
Category of the institution:	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]
Reference date:	
Total assets (million EUR) at reference date:	
Competent authority:	

Overall Assessment of Liquidity Risk in SREP	**Overall liquidity risk Score**:
This section should contain a summary of the individual assessments below.	

Liquidity Adequacy Assessment
Within this section please provide: (1) a summary of the assessment of the liquidity adequacy; (2) the proposal for the joint decision, including a statement on the adequacy of liquidity at the respective entity level and any supervisory measures, where applicable, to address significant matters and material findings; and, (3) the outlook for the next assessment period.

A. Assessment of liquidity risk	**Score:**
Within this section please provide: (1) a description of the evolution of liquidity risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures to address the deficiencies and non-compliance issues.	

B. Assessment of funding risk	**Score:**
Within this section please provide: (1) a description of the evolution of funding risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures to address the deficiencies and non-compliance issues.	

C. Assessment of liquidity and funding risk management	Score:
Within this section please provide: (1) a description of the evolution of liquidity and funding risk management in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures to address the deficiencies and non-compliance issues.	

Other relevant information
Within this section please provide other information deemed relevant by the competent authority for the purposes of the group risk assessment and not provided above.

ANNEX VI

LIQUIDITY RISK ASSESSMENT REPORT TEMPLATE

Table 1

Summary of scores

Institution:		
Category of the institution:		[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]
Reference date:		
Total assets (mln EUR) at reference date:		
Competent authority:		
Liquidity elements in SREP		**Score**
A.	**Liquidity risk**	
B.	**Funding risk**	
C.	**Liquidity and funding risk management**	
E. Overall liquidity risk score		

Table 2

Summary of capital adequacy assessment

Institution:		
Category of the institution:		[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]
Reference date:		
Total assets (mln EUR) at reference date:		
Competent authority:		
Liquidity elements in SREP		**Outcome of liquidity risk assessment**
		(in mln euros or ratio or narrative information on measures)
A.	**Liquidity adequacy assessment**	*Adequate/Inadequate*
B.	**Proposal for joint decision - Quantitative measures (Articles 104 and 105)**	
	Specific liquidity buffer requirements [To be specified in terms of LCR eligible assets post-introduction of LCR as a standard (optional before)]	
	Specific stable funding requirements [To be specified on NSFR definition post-NSFR introduced as a standard (optional before)]	
	Other quantitative restrictions/requirements	
D	**Proposal for joint decision — Qualitative measures (Articles 104 and 105)**	
Memoranda items (values at reference date)		
	Actual LCR ratio or any other equivalent domestic ratio (until LCR implementation in CRR)	
	Actual NSFR ratio or any other equivalent domestic ratio (until NSFR implementation in CRR)	
	LCR buffer requirement, if any ('Pillar 1')	
	NSFR stable funding requirement, if any ('Pillar 1')	
	Any other prudential requirements applicable to the institution, including under Article 103 of Directive 2013/36/EU, macro-prudential measures and recommendations of EBA and ESRB	

ANNEX VII

GROUP LIQUIDITY RISK ASSESSMENT REPORT TEMPLATE

The Group liquidity risk assessment report includes as annexes all liquidity risk assessment reports submitted by the relevant competent authorities. The group risk assessment report is supplemented with summaries of scores (Table 1) and liquidity adequacy assessment (Table 2).

Group:	
Category of the group:	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]
Reference date:	
Total assets (million EUR) at reference date:	

Overall Assessment of Liquidity Risk in SREP	**Overall liquidity risk Score**:
This section should contain a summary of the individual assessments below.	

Liquidity Adequacy Assessment
Within this section please provide: (1) a summary of the assessment of the liquidity adequacy; (2) the proposal for the joint decision, including a statement on the adequacy of liquidity at the group level and any supervisory measures, where applicable, to address significant matters and material findings; and, (3) the outlook for the next assessment period.

A. Assessment of liquidity risk	**Score:**
Within this section please provide: (1) a description of the evolution of liquidity risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures to address the deficiencies and non-compliance issues.	

B. Assessment of funding risk	**Score:**
Within this section please provide: (1) a description of the evolution of funding risk in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures to address the deficiencies and non-compliance issues.	

C. Assessment of liquidity and funding risk management	Score:
Within this section please provide: (1) a description of the evolution of liquidity and funding risk management in the observed period; (2) control deficiencies identified; (3) issues of non-compliance with the CRR and the CRD in relation to risk; (4) the outlook for the next assessment period; (5) risk mitigating actions to be taken by the institution; and, (6) any relevant supervisory measures to address the deficiencies and non-compliance issues.	

Other relevant information
Within this section please provide other information deemed relevant by the competent authorities for the purposes of the group risk assessment and not provided above (e.g. information needed to meet requirements of Article 6(5) of this Implementing Regulation

ANNEX VIII

GROUP LIQUIDITY RISK REPORT TEMPLATE

Table 1

Summary of scores

Institution:	*Entity X/ Sub-group X*	*Entity Y/ Sub-group Y*	***Consolidated group***
Category of the institution:	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]
Reference date:			
Total assets (mln EUR) at reference date:			
Competent authority:			
Liquidity elements in SREP	**Score**	**Score**	**Score**
A. Liquidity risk			
B. Funding risk			
C. Liquidity and funding risk management			
E. Overall liquidity risk score			

Table 2

Summary of liquidity assessment

Institution:		*Entity X/ Sub-group X*	*Entity Y/ Sub-group Y*	***Consolidated group***
Category of the institution:		[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]	[based on national classification until common categorisation approach is in place as per EBA Guidelines for common SREP methodologies and procedures; the category to which the institution is assigned shall reflect also its systemic importance]
Reference date:				
Total assets (mln EUR) at reference date:				
Competent authority:				
Liquidity elements in SREP		**Outcome of liquidity risk assessment** (in mln Euros or ratio or narrative information on measures]	**Outcome of liquidity risk assessment** (in mln Euros or ratio or narrative information on measures]	**Outcome of liquidity risk assessment** (in mln Euros or ratio or narrative information on measures]
A.	**Liquidity adequacy assessment**	*Adequate/Inadequate*	*Adequate/Inadequate*	*Adequate/Inadequate*
B.	**Proposal for joint decision - Quantitative measures (Articles 104 and 105)**			
	Specific liquidity buffer requirements [To be specified in terms of LCR eligible assets post-introduction of LCR as a standard (optional before)]			
	Specific stable funding requirements [To be specified on NSFR definition post-NSFR introduced as a standard (optional before)]			
	Other quantitative restrictions/requirements			
D	**Proposal for joint decision — Qualitative measures (Articles 104 and 105)**			

Memoranda items (values at reference date)				
	Actual LCR ratio or any other equivalent domestic ratio (until LCR implementation in CRR)			
	Actual NSFR ratio or any other equivalent domestic ratio (until NSFR implementation in CRR)			
	LCR buffer requirement, if any ('Pillar 1')			
	NSFR stable funding requirement, if any ('Pillar 1')			
	Any other prudential requirements applicable to the institution, including under Article 103 of Directive 2013/36/EU, macro-prudential measures and recommendations of EBA and ESRB			

COMMISSION IMPLEMENTING REGULATION (EU) No 711/2014

of 26 June 2014

amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 183(b) thereof,

Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 ([2]), and in particular Article 5(6)(a) thereof,

Whereas:

(1) Commission Regulation (EC) No 1484/95 ([3]) lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.

(2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.

(3) Regulation (EC) No 1484/95 should be amended accordingly.

(4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 26 June 2014.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 150, 20.5.2014, p. 1.
([3]) Commission Regulation (EC) No 1484/95 of 28 June 1995 laying down detailed rules for implementing the system of additional import duties and fixing additional import duties in the poultrymeat and egg sectors and for egg albumin, and repealing Regulation No 163/67/EEC (OJ L 145, 29.6.1995, p. 47).

ANNEX

'ANNEX I

CN code	Description of goods	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin (1)
0207 12 10	Fowls of the species *Gallus domesticus*, not cut in pieces, presented as "70 % chickens", frozen	122,4	0	AR
0207 12 90	Fowls of the species *Gallus domesticus*, not cut in pieces, presented as "65 % chickens", frozen	134,3 147,4	0 0	AR BR
0207 14 10	Fowls of the species *Gallus domesticus*, boneless cuts, frozen	294,3 220,5 315,7 254,6	2 24 0 14	AR BR CL TH
0207 14 60	Fowl of the species *Gallus domesticus*, legs, frozen	135,0	2	BR
0207 27 10	Turkeys, boneless cuts, frozen	312,5 323,6	0 0	BR CL
1602 32 11	Preparations of fowls of the species *Gallus domesticus*, uncooked	267,9	6	BR

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). The code "ZZ" represents "other origins".'

COMMISSION IMPLEMENTING REGULATION (EU) No 712/2014

of 26 June 2014

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ([1]),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 26 June 2014.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 299, 16.11.2007, p. 1.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	MK	67,9
	TR	78,3
	ZZ	73,1
0707 00 05	MK	27,7
	TR	74,4
	ZZ	51,1
0709 93 10	TR	106,4
	ZZ	106,4
0805 50 10	AR	101,8
	BO	130,6
	TR	125,4
	ZA	116,4
	ZZ	118,6
0808 10 80	AR	110,6
	BR	99,0
	CL	112,0
	NZ	135,4
	US	147,4
	ZA	128,8
	ZZ	122,2
0809 10 00	TR	225,5
	ZZ	225,5
0809 29 00	TR	336,8
	ZZ	336,8

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COUNCIL DECISION

of 20 June 2014

appointing three Italian members and four Italian alternate members of the Committee of the Regions

(2014/398/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Italian Government,

Whereas:

(1) On 22 December 2009 and on 18 January 2010, the Council adopted Decisions 2009/1014/EU [1] and 2010/29/EU [2] appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2010 to 25 January 2015.

(2) Three members' seats have become vacant following the end of the terms of office of Mr Luis DURNWALDER, Mr Ugo CAPPELLACCI and Mr Luciano CAVERI. Four alternate members' seats have become vacant following the end of the terms of office of Mr Vito DE FILIPPO, Mr Roberto BOMBARDA, Ms Federica SEGANTI and Ms Alessia ROSOLEN,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2015:

(a) as members:

— Mr Arno KOMPATSCHER, *Consigliere e Presidente della Provincia Autonoma di Bolzano*

— Mr Raffaele CATTANEO, *Consigliere della Regione Lombardia e Presidente del Consiglio regionale*

— Mr Augusto ROLLANDIN, *Presidente della Regione Autonoma Valle d'Aosta*

and

(b) as alternate members:

— Mr Marcello Maurizio PITTELLA, *Presidente della Regione Basilicata*

— Mr Ugo ROSSI, *Presidente della Provincia Autonoma di Trento*

— Mr Francesco PERONI, *Assessore della Regione Friuli Venezia Giulia*

— Mr Franco IACOP, *Consigliere e Presidente del Consiglio della Regione Friuli Venezia Giulia*.

[1] OJ L 348, 29.12.2009, p. 22.
[2] OJ L 12, 19.1.2010, p. 11.

Article 2

This Decision shall enter into force on the day of its adoption.

Done at Luxembourg, 20 June 2014.

For the Council
The President
G. A. HARDOUVELIS

COUNCIL DECISION

of 24 June 2014

establishing the position to be adopted on behalf of the European Union within the General Council of the World Trade Organization on the accession of the Islamic Republic of Afghanistan to the World Trade Organization

(2014/399/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91, Article 100(2) and the first subparagraph of Article 207(4), in conjunction with Article 218(9), thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) On 21 November 2004, the Government of the Islamic Republic of Afghanistan applied for accession to the Marrakesh Agreement establishing the World Trade Organization (WTO), pursuant to Article XII of that Agreement.

(2) A Working Party on the accession of the Islamic Republic of Afghanistan was established on 13 December 2004 in order to reach agreement on terms of accession acceptable to the Islamic Republic of Afghanistan and all WTO Members.

(3) The Commission, on behalf of the Union, has negotiated a comprehensive series of market opening commitments on the part of the Islamic Republic of Afghanistan which satisfy the Union's requests.

(4) Those commitments are now embodied in the Protocol of Accession of the Islamic Republic of Afghanistan to the WTO ('the Protocol of Accession').

(5) Accession to the WTO is expected to make a positive and lasting contribution to the process of economic reform and sustainable development in the Islamic Republic of Afghanistan.

(6) The Protocol of Accession should therefore be approved.

(7) Article XII of the Agreement establishing the WTO provides that the terms of accession are to be agreed between the acceding Member and the WTO, and that the Ministerial Conference of the WTO approves the terms of accession on the WTO side. Article IV.2 of the Agreement establishing the WTO provides that in the intervals between meetings of the Ministerial Conference, its functions shall be conducted by the General Council.

(8) Accordingly, it is necessary to establish the position to be adopted on the Union's behalf within the General Council of the WTO on the accession of the Islamic Republic of Afghanistan to the WTO,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on behalf of the European Union within the General Council of the World Trade Organization on the accession of the Islamic Republic of Afghanistan to the World Trade Organization is to approve the accession.

Article 2

This Decision shall enter into force on the day of its adoption.

Done at Luxembourg, 24 June 2014.

For the Council
The President
E. VENIZELOS

COUNCIL DECISION 2014/400/CFSP

of 26 June 2014

extending the mandate of the European Union Special Representative in Kosovo [1]

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 31(2) and Article 33 thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 25 January 2012, the Council adopted Decision 2012/39/CFSP [2] appointing Mr Samuel ŽBOGAR as the European Union Special Representative (EUSR) in Kosovo. The EUSR's mandate is to expire on 30 June 2014.

(2) The mandate of the EUSR should be extended for a further period of eight months.

(3) The EUSR will implement the mandate in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

European Union Special Representative

The mandate of Mr Samuel ŽBOGAR as the European Union Special Representative (EUSR) is hereby extended until 28 February 2015. The Council may decide that the mandate of the EUSR be terminated earlier, based on an assessment by the Political and Security Committee (PSC) and a proposal of the High Representative of the Union for Foreign Affairs and Security Policy (HR).

Article 2

Policy objectives

The mandate of the EUSR shall be based on the policy objectives of the Union in Kosovo. These include playing a leading role in promoting a stable, viable, peaceful, democratic and multi-ethnic Kosovo; strengthening stability in the region and contributing to regional cooperation and good neighbourly relations in the Western Balkans; promoting a Kosovo that is committed to the rule of law and to the protection of minorities and of cultural and religious heritage; supporting Kosovo's progress towards the Union in accordance with the European perspective of the region and in line with the relevant Council Conclusions.

Article 3

Mandate

In order to achieve the policy objectives, the mandate of the EUSR shall be to:

(a) offer the Union's advice and support in the political process;

(b) promote overall Union political coordination in Kosovo;

(c) strengthen the presence of the Union in Kosovo and ensure its coherence and effectiveness;

---

[1] This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

[2] OJ L 23, 26.1.2012, p. 5.

(d) provide local political guidance to the Head of the European Union Rule of Law Mission in Kosovo (EULEX KOSOVO), including on the political aspects of issues relating to executive responsibilities;

(e) ensure consistency and coherence of Union action in Kosovo, including in guiding the EULEX transition locally;

(f) support Kosovo's progress towards the Union, in accordance with the European perspective of the region, through targeted public communication and Union outreach activities designed to ensure a broader understanding and support from the Kosovo public on issues related to the Union, including the work of EULEX;

(g) monitor, assist and facilitate progress on political, economic and European priorities, in line with respective institutional competencies and responsibilities;

(h) contribute to the development and consolidation of respect for human rights and fundamental freedoms in Kosovo, including with regard to women and children and protection of minorities, in accordance with the Union's human rights policy and Union Guidelines on Human Rights;

(i) assist in the implementation of the Belgrade-Pristina dialogue facilitated by the Union.

Article 4

Implementation of the mandate

1. The EUSR shall be responsible for the implementation of the mandate, acting under the authority of the HR.

2. The PSC shall maintain a privileged link with the EUSR and shall be the EUSR's primary point of contact with the Council. The PSC shall provide the EUSR with strategic guidance and political direction within the framework of the mandate, without prejudice to the powers of the HR.

3. The EUSR shall work in close coordination with the European External Action Service (EEAS) and the relevant departments thereof.

Article 5

Financing

1. The financial reference amount intended to cover the expenditure related to the mandate of the EUSR in the period from 1 July 2014 to 28 February 2015 shall be EUR 1 450 000.

2. The expenditure shall be managed in accordance with the procedures and rules applicable to the general budget of the Union. Nationals of the countries of the Western Balkan region shall be allowed to tender for contracts.

3. The management of the expenditure shall be subject to a contract between the EUSR and the Commission. The EUSR shall be accountable to the Commission for all expenditure.

Article 6

Constitution and composition of the team

1. Dedicated staff shall be assigned to assist the EUSR to implement his mandate and to contribute to the coherence, visibility and effectiveness of Union action in Kosovo overall. Within the limits of his mandate and the corresponding financial means made available, the EUSR shall be responsible for constituting his team. The team shall include the expertise on specific policy issues as required by the mandate. The EUSR shall keep the Council and the Commission promptly informed of the composition of his team.

2. Member States, institutions of the Union and the EEAS may propose the secondment of staff to work with the EUSR. The salary of such seconded personnel shall be covered by the Member State, the institution of the Union concerned or the EEAS, respectively. Experts seconded by Member States to the institutions of the Union or the EEAS may also be posted to work with the EUSR. International contracted staff shall have the nationality of a Member State.

3. All seconded personnel shall remain under the administrative authority of the sending Member State, institution of the Union or the EEAS and shall carry out their duties and act in the interests of the mandate of the EUSR.

Article 7

Privileges and immunities of the EUSR and his staff

The privileges, immunities and further guarantees necessary for the completion and smooth functioning of the mission of the EUSR and the members of his staff shall be agreed with the host parties, as appropriate. Member States and the EEAS shall grant all necessary support to such effect.

Article 8

Security of EU classified information

1. The EUSR and the members of his team shall respect the security principles and minimum standards established by Council Decision 2013/488/EU ([1]).

2. The HR shall be authorised to release to NATO/KFOR EU classified information and documents up to the level 'CONFIDENTIEL UE/EU CONFIDENTIAL' generated for the purposes of the action, in accordance with the security rules for protecting EU classified information.

3. The HR shall be authorised to release to the United Nations (UN) and the Organisation for Security and Co-operation in Europe (OSCE), in accordance with the operational needs of the EUSR, EU classified information and documents up to the level 'RESTREINT UE/EU RESTRICTED' which are generated for the purposes of the action, in accordance with the security rules for protecting EU classified information. Local arrangements shall be drawn up for this purpose.

4. The HR shall be authorised to release EU non-classified documents related to the deliberations of the Council with regard to the action covered by the obligation of professional secrecy pursuant to Article 6(1) of the Council's Rules of Procedure ([2]) to third parties associated with this Decision.

Article 9

Access to information and logistical support

1. Member States, the Commission and the General Secretariat of the Council shall ensure that the EUSR is given access to any relevant information.

2. The Union delegation and/or Member States shall, as appropriate, provide logistical support in the region.

Article 10

Security

In accordance with the Union's policy on the security of personnel deployed outside the Union in an operational capacity under Title V of the Treaty, the EUSR shall take all reasonably practicable measures, in conformity with the EUSR's mandate and the security situation in the area of responsibility, for the security of all personnel under the EUSR's direct authority, notably by:

(a) establishing a specific security plan based on guidance from the EEAS, including specific physical, organisational and procedural security measures, governing management of the secure movement of personnel to, and within, the area of responsibility, as well as management of security incidents and a mission contingency and evacuation plan;

([1]) Council Decision 2013/488/EU of 23 September 2013 on the security rules for protecting EU classified information (OJ L 274, 15.10.2013, p. 1).
([2]) Decision 2009/937/EU of 1 December 2009 adopting the Council's Rules of Procedure (OJ L 325, 11.12.2009, p. 35).

(b) ensuring that all personnel deployed outside the Union are covered by high risk insurance as required by the conditions in the area of responsibility;

(c) ensuring that all members of the EUSR's team to be deployed outside the Union, including locally contracted personnel, have received appropriate security training before or upon arriving in the area of responsibility, based on the risk ratings assigned to that area;

(d) ensuring that all agreed recommendations made following regular security assessments are implemented, and providing the HR, the Council and the Commission with written reports on their implementation and on other security issues within the framework of the progress and mandate implementation reports.

Article 11

Reporting

The EUSR shall regularly provide the HR and the PSC with reports. The EUSR shall also report to Council working parties, as necessary. Regular reports shall be circulated through the COREU network. The EUSR may provide the Foreign Affairs Council with reports. In accordance with Article 36 of the Treaty, the EUSR may be involved in briefing the European Parliament.

Article 12

Coordination

1. The EUSR shall contribute to the unity, consistency and effectiveness of the Union's action and shall help to ensure that all Union instruments and Member States' actions are engaged consistently, to attain the Union's policy objectives. The activities of the EUSR shall be coordinated with those of the Commission, as well as those of other EUSRs active in the region, as appropriate. The EUSR shall provide regular briefings to Member States' missions and Union delegations.

2. In the field, close liaison shall be maintained with the Heads of Union delegations in the region and Member States' Heads of Mission. They shall make every effort to assist the EUSR in the implementation of the mandate. The EUSR shall provide local political guidance to the Head of the EULEX KOSOVO, including on the political aspects of issues relating to executive responsibilities. The EUSR and the Civilian Operation Commander shall consult each other as required.

3. The EUSR shall also liaise with relevant local bodies and other international and regional actors in the field.

4. The EUSR, with other Union actors present in the field, shall ensure the dissemination and sharing of information among Union actors in theatre with a view to achieving a high degree of common situation awareness and assessment.

Article 13

Assistance in relation to claims

The EUSR and his staff shall assist in providing elements to respond to any claims and obligations arising from the mandates of the previous EUSRs in Kosovo, and shall provide administrative assistance and access to relevant files for such purposes.

Article 14

Review

The implementation of this Decision and its consistency with other contributions from the Union to the region shall be kept under regular review. The EUSR shall present the HR, the Council and the Commission with a comprehensive mandate implementation report by the end of November 2014.

Article 15

Entry into force

This Decision shall enter into force on the date of its adoption.

It shall apply from 1 July 2014.

Done at Brussels, 26 June 2014.

For the Council
The President
E. VENIZELOS

COUNCIL DECISION 2014/401/CFSP

of 26 June 2014

on the European Union Satellite Centre and repealing Joint Action 2001/555/CFSP on the establishment of a European Union Satellite Centre

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 28 and Article 31(1) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 20 July 2001, the Council adopted Joint Action 2001/555/CFSP [1] establishing a European Union Satellite Centre (SATCEN). On 23 May 2011, the Council adopted Decision 2011/297/CFSP [2].

(2) The functioning of SATCEN as a European autonomous capability providing products and services resulting from exploitation of relevant space assets and collateral data, including satellite and aerial imagery, is essential for strengthening early warning and crisis monitoring functions within the context of the common foreign and security policy (CFSP) and, in particular, of the common security and defence policy (CSDP).

(3) On 14 September 2012, pursuant to Article 22 of Joint Action 2001/555/CFSP, the High Representative of the Union for Foreign Affairs and Security Policy (HR) presented a report to the Council on the functioning of SATCEN.

(4) On 27 November 2012, the Political and Security Committee (PSC) took note of that report and recommended that the Council amend Joint Action 2001/555/CFSP accordingly.

(5) It is appropriate, for reasons of legal clarity, to consolidate previous amendments and the additional proposed changes into a single new Decision and to repeal Joint Action 2001/555/CFSP, including Article 23 thereof on transitional provisions with regard to the Western European Union (WEU).

(6) In accordance with Article 5 of the Protocol (No 22) on the position of Denmark annexed to the Treaty on European Union (TEU) and to the Treaty on the Functioning of the European Union (TFEU), Denmark does not participate in the elaboration and implementation of decisions and actions of the Union which have defence implications. This provision, however, does not exclude the participation of Denmark in the civilian activities of SATCEN on the basis of a declared willingness of Denmark to contribute towards covering the expenses of SATCEN which do not have defence implications,

HAS ADOPTED THIS DECISION:

Article 1

Continuity and location

1. The European Union Satellite Centre established by Joint Action 2001/555/CFSP (SATCEN) shall hereby continue and develop its mission in accordance with this Decision.

2. This Decision shall not affect existing rights and obligations and rules adopted in the framework of Joint Action 2001/555/CFSP. In particular, it shall not affect the validity of existing employment contracts and rights arising therefrom.

3. SATCEN shall have its headquarters at Torrejón de Ardoz, Spain.

---

[1] Council Joint Action 2001/555/CFSP of 20 July 2001 on the establishment of a European Union Satellite Centre (OJ L 200, 25.7.2001, p. 5).

[2] Council Decision 2011/297/CFSP of 23 May 2011 amending Joint Action 2001/555/CFSP on the establishment of a European Union Satellite Centre (OJ L 136, 24.5.2011, p. 62).

Article 2

Mission and activities

1. SATCEN shall support the decision making and actions of the Union in the field of the CFSP and in particular the CSDP, including European Union crisis management missions and operations, by providing, at the request of the Council or the HR, products and services resulting from the exploitation of relevant space assets and collateral data, including satellite and aerial imagery, and related services, in accordance with Article 3.

2. In the framework of SATCEN's mission, the HR shall also, upon request and if the capacity of SATCEN so allows and without prejudice to its core tasks set out in paragraph 1, direct SATCEN to provide products or services to:

(i) a Member State, the European External Action Service (EEAS), the Commission, or Union agencies or bodies with which SATCEN cooperates pursuant to Article 18;

(ii) third States having agreed to the provisions set out in the Annex on the association with SATCEN's activities;

(iii) if the request is relevant in the field of the CFSP, in particular of the CSDP, international organisations such as the United Nations, the Organisation for Security and Cooperation in Europe and the North Atlantic Treaty Organisation (NATO).

3. SATCEN may also, in accordance with Article 18 and without prejudice to its core tasks set out in paragraph 1, cooperate with the Commission and with Union agencies, bodies or Member States, with a view to maximising synergies and complementarity with other Union activities that have a bearing on SATCEN and where SATCEN's activities are relevant to those Union activities, in particular in the area of space and security.

4. In order to facilitate the organisation of activities in Brussels, SATCEN shall have a liaison office in Brussels.

5. Following the dissolution of the WEU, SATCEN shall perform the administrative tasks set out in Article 23. The unit in charge of the continuation of those residual administrative tasks shall be based in Brussels.

Article 3

Political supervision and operational direction

1. The PSC shall, under the responsibility of the Council, exercise political supervision over SATCEN's activities and issue political guidance on SATCEN's priorities.

2. The HR, in accordance with the HR's responsibilities for the CFSP and, in particular, for the CSDP, shall give operational direction to SATCEN, without prejudice to the responsibilities of the Board and of the Director of SATCEN, respectively, as set out in this Decision. In particular, on the basis of the guidance referred to in paragraph 1, and taking into account the level of resources available, the HR shall prioritise between requests addressed to SATCEN in accordance with tasking guidelines which shall be subject to regular review by the Board.

3. In the execution of the HR's tasks as set out in this Article, the HR shall report as appropriate, and at least once every six months, to the Council, including on the Board's assessment of the implementation by SATCEN of the political guidance referred to in paragraph 1 and of the operational direction referred to in paragraph 2.

Article 4

Products and services of SATCEN

1. The products and services of SATCEN in response to requests made in accordance with Article 2(1) and Article 2(2)(ii) and 2(2)(iii) shall be made available to Member States, the EEAS, the Commission, and Union agencies or bodies with which SATCEN cooperates pursuant to Article 18, and to the requesting party, in accordance with applicable security provisions. Those products and services shall be made available to third States having agreed to the provisions set out in the Annex and in accordance with the detailed rules specified in those provisions.

2. In the interest of transparency, the HR shall make available without delay all requests made in accordance with Article 2 to the Member States, the EEAS, the Commission and Union agencies or bodies with which SATCEN cooperates pursuant to Article 18, and to third States having agreed to the provisions set out in the Annex in accordance with the detailed rules specified in those provisions.

3. The products and services of SATCEN resulting from requests made in accordance with Article 2(2)(i) shall be made available to the Member States, the EEAS, the Commission and Union agencies or bodies with which SATCEN cooperates pursuant to Article 18, and/or to third States having agreed to the provisions set out in the Annex, upon a decision of the requesting Party.

4. The PSC may direct the HR to make available products of SATCEN resulting from requests made in accordance with Article 2(1) and 2(2) to any designated third State or organisation on a case-by-case basis.

Article 5

Legal personality

SATCEN shall have the legal personality necessary to perform its functions and attain its objectives. It may, in particular, enter into contracts, acquire or dispose of movable and immovable property and be a party to legal proceedings. SATCEN shall be non-profit making. Member States shall take steps to accord SATCEN the legal capacity accorded to legal persons under their national laws, as necessary.

Article 6

Board

1. SATCEN shall have a Board that approves its annual and long-term work programme and the appropriate budget. The Board shall be a forum for discussing issues related to SATCEN's functioning, staff and equipment. The Board shall assess on a regular basis the implementation by SATCEN of the political guidance and operational direction referred to in Article 3. The Board shall adopt all relevant decisions relating to the fulfilment of SATCEN's mission, including proposals for activities under Articles 18, 19 and 20, provided that they are not reserved, under this Decision, for the Council or the Director of SATCEN.

2. The Board shall be chaired by the HR or by the HR's representative. The HR shall report to the Council on the work of the Board.

3. The Board shall be composed of one representative appointed by each Member State and one representative appointed by the Commission. Each member of the Board may be represented or accompanied by an alternate. Letters of appointment, duly authorised by the Member State or the Commission, as appropriate, shall be directed to the HR.

4. The Director of SATCEN or the Director's representative shall, as a rule, attend Board meetings. The Chairman of the European Union Military Committee, the Director General of the European Union Military Staff and the European Union Civilian Operations Commander may attend Board meetings. Representatives of other relevant Union bodies may also be invited to Board meetings.

5. Unless otherwise provided in this Decision, decisions of the Board shall be taken on a vote by the representatives of the Member States by qualified majority, the votes being weighted in accordance with Article 16(4) and 16(5) TEU. The Board shall adopt its rules of procedure.

6. The Board may decide to create ad hoc working groups or standing committees with the same format as the Board itself dealing with specific subjects or issues within its overall responsibility and acting under its supervision. The decision to create such a working group or committee shall set out its mandate, composition and duration.

7. The Board shall be convened by the Chairman at least twice a year and also at the request of at least one third of its members.

Article 7

Director

1. The Board shall select and appoint the Director of SATCEN from among nationals of the Member States on a recommendation from an advisory panel. The Director shall be appointed for a period of three years, which period may be extended by one two-year term.

2. Taking into account the technical and operational nature of the mission of SATCEN, the candidates for the position of Director should be persons with recognised long-standing expertise and experience in the field of geospatial information and imagery or in the field of foreign relations and security policy. Member States shall submit candidatures to the Board. The advisory panel, composed of the HR (or his/her representative) who shall chair the panel, of three representatives of the Member States from among the Trio Presidency and of one representative of the EEAS, shall recommend at least three candidates to the Board with a view to the selection and appointment of the Director.

3. The Director shall be the legal representative of SATCEN.

4. The Director shall be responsible for recruiting all other SATCEN staff.

5. After approval by the Board, the Director shall appoint the Deputy Director of SATCEN. The Deputy Director shall be appointed for a period of three years, with a possible extension of a further three-year term with the approval of the Board.

6. The Director shall ensure the execution of the mission of SATCEN as set out in Article 2. The Director shall uphold a high level of expertise and professionalism at SATCEN, as well as ensuring efficiency and effectiveness in carrying out SATCEN's activities. The Director shall take all necessary measures to that end, including the training of personnel and the conduct of research and development projects in support of its mission.

The Director shall also be responsible for the tasks assigned to him/her in this Decision:

(a) preparing the work of the Board, in particular the draft annual work programme of SATCEN;

(b) the day-to-day administration of SATCEN;

(c) preparing the statement of income and expenditure and implementing SATCEN's budget;

d) security aspects;

(e) all personnel matters;

(f) informing the PSC about the annual work programme;

(g) establishing working relations and cooperation with the Commission and Union agencies or bodies, in accordance with Article 18;

(h) establishing working relations and cooperation with Member States' institutions, in accordance with Article 19;

(i) establishing working relations and cooperation with third States, organisations or entities, in accordance with Article 20;

(j) negotiating administrative arrangements, in accordance with the procedure laid down in Articles 18 and 20.

7. Within the work programme and budget of SATCEN, the Director shall be empowered to enter into contracts, to recruit staff approved in the budget and to incur any expenditure necessary for the operation of SATCEN.

8. The Director shall prepare an annual report on SATCEN's activities by 31 March of the following year. The annual report shall be forwarded to the Board and, through the HR, to the Council, which shall forward the report to the European Parliament and to the Commission.

9. The Director shall be accountable to the Board.

Article 8

Staff

1. The staff of SATCEN, including the Director, shall consist of contract staff recruited on the broadest possible basis from among nationals of the Member States, and of seconded experts.

2. The contract staff shall be appointed by the Director on the basis of merit and through fair and transparent competition procedures.

3. The need for secondment of staff to SATCEN shall be determined by the Board in consultation with the Director of SATCEN. In agreement with the Director, experts from Member States and officials from the EEAS, Union institutions agencies or bodies may be seconded to SATCEN for an agreed period, either to posts within SATCEN's organisational structure and/or for specific tasks and projects.

4. Contract staff may be seconded for a limited period to a post outside SATCEN, in accordance with SATCEN staff rules.

5. The Board shall draw up, on a proposal from the Director, SATCEN staff rules which shall be adopted by the Council.

6. The provisions relating to seconded experts shall be adopted by the Board on a proposal from the Director.

Article 9

Work programme

1. By 30 September of each year, the Director shall establish a draft annual work programme for the following year accompanied by a draft long-term work programme containing indicative perspectives for two additional years, and shall submit them to the Board for approval.

2. By 30 November of each year, the Board shall approve the annual and long-term work programmes.

Article 10

Budget

1. All items of income and expenditure of SATCEN shall be included in estimates to be drawn up for each financial year, which shall correspond to the calendar year. They shall be shown in the budget of SATCEN which shall include a list of staff.

2. The income and expenditure shown in the budget of SATCEN shall be in balance.

3. The income of SATCEN shall consist of contributions from the Member States, except Denmark, according to the gross national income scale, payments made in remuneration for services rendered and miscellaneous income.

4. Products and services provided in accordance with Article 2(2) and those concerning crisis management missions and operations are subject to cost recovery charges pursuant to the guidelines laid down in SATCEN's financial rules, as referred to in Article 12, except for the Member States and the EEAS.

5. In exceptional circumstances, third party cost recovery may be waived upon a decision by the PSC.

6. In the framework of arrangements that may be authorised in accordance with Article 18, 19 or 20, SATCEN may receive in its budget as earmarked revenue for a specific purpose financial contributions from:

(a) the general budget of the Union on a case-by-case basis, in full compliance with the rules, procedures and decision-making processes applicable to it;

(b) Member States, third States or other third parties.

7. Earmarked revenue may only be used for the specific purpose to which it is assigned.

Article 11

Budgetary procedure

1. By 30 September of each year, the Director shall submit to the Board an annual draft budget for SATCEN covering administrative expenditure, operational expenditure and expected income, including earmarked revenue, for the following financial year as well as long-term indicative estimates on expenditure and income in view of the draft long-term work programme.

2. By 30 November of each year, the Board shall approve the annual budget of SATCEN by unanimity of the representatives of Member States.

3. In the case of unavoidable, exceptional or unforeseen circumstances, the Director may propose a draft amending budget to the Board. The Board, with due regard to any urgency, shall approve the amending budget by unanimity of the representatives of Member States.

4. Control of the commitment and payment of all expenditure and the recording and collection of all income shall be carried out by an independent financial controller appointed by the Board.

5. By 31 March of each year, the Director shall submit to the Council and to the Board the detailed accounts of all income and expenditure from the previous financial year and the report on SATCEN's activities.

6. The Board shall give discharge to the Director in respect of the implementation of the budget of SATCEN.

Article 12

Financial rules

The Board, with the approval of the Council, shall draw up, on a proposal from the Director, detailed financial rules specifying, in particular, the procedure to be followed for establishing, implementing and controlling the budget of SATCEN.

Article 13

Privileges and immunities

1. The privileges and immunities of the Director and SATCEN staff are provided for in the Decision of the Representatives of the Governments of the Member States, meeting within the Council, of 15 October 2011 on the privileges and immunities granted to the European Union Institute for Security Studies and the European Union Satellite Centre, and to their bodies and staff. Pending the entry into force of that Decision, the host State may grant to the Director and SATCEN staff the privileges and immunities provided therein.

2. The privileges and immunities of SATCEN are those provided for in the Protocol (No 7) on the privileges and immunities of the European Union, annexed to the TEU and to the TFEU.

Article 14

Legal liability

1. The contractual liability of SATCEN shall be governed by the law applicable to the contract concerned.

2. The Court of Justice of the European Union shall have jurisdiction pursuant to any arbitration clause contained in a contract concluded by SATCEN.

3. The personal liability of staff towards SATCEN shall be governed by the relevant provisions applying to SATCEN staff.

Article 15

Protection of EU classified information

1. SATCEN shall apply Council Decision 2013/488/EU ([1]).

2. In their relations with SATCEN and with respect to its products and services, the third States having agreed to the provisions set out in the Annex on association with SATCEN's activities shall, in an Exchange of Letters with SATCEN, confirm that they apply the security principles and minimum standards established by Decision 2013/488/EU, as well as those set out by possible providers of classified data.

Article 16

Access to documents

Upon a proposal by the Director, the Board shall adopt rules on public access to the documents of SATCEN, taking into account the principles and limits laid down in Regulation (EC) No 1049/2001 of the European Parliament and of the Council ([2]).

Article 17

The position of Denmark

1. The Danish member of the Board shall take part in the work of the Board in full respect of Article 5 of the Protocol (No 22) on the position of Denmark annexed to the TEU and to the TFEU.

Denmark may address requests not having defence implications to the HR in accordance with Article 2(2)(i) of this Decision.

2. Products and services arising from SATCEN's mission under Article 2 shall be made available to Denmark under the same conditions as to the other Member States, except for requests having defence implications under Article 2(2) and for the resulting products.

3. Denmark shall have the right to second staff to SATCEN in accordance with Article 8.

Article 18

Cooperation in other Union activities

1. SATCEN may establish working relations and cooperate with the Commission and Union agencies or bodies with a view to maximising synergies and complementarity with other Union activities that have a bearing on SATCEN's mission and where SATCEN's activities are relevant to those Union activities, in particular in the area of space and security.

2. In the framework of such cooperation and after approval by the Board, SATCEN may, inter alia, liaise, exchange expertise and advice, contribute to relevant Union programmes and projects, receive contributions from relevant Union programmes and projects, and make available products in accordance with Article 2(2)(i).

3. In order to further such cooperation, SATCEN may enter into administrative arrangements with the Commission, relevant Union agencies and bodies or Member States. The Board shall decide to authorise the Director to negotiate such administrative arrangements and shall address directives in this regard to the Director. The negotiations shall be conducted in consultation with the Board. Every such arrangement shall be concluded by SATCEN upon approval thereof by the Board.

([1]) Council Decision 2013/488/EU of 23 September 2013 on the security rules for protecting EU classified information (OJ L 274, 15.10.2013, p. 1).

([2]) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Article 19

Cooperation with Member States' institutions

Upon a proposal by the HR or by a Member State and after approval by the Board, SATCEN may establish working relations and cooperate with Member States' institutions in the area of space and security that have a bearing on SATCEN's mission and where SATCEN's activities are relevant to those institutions.

Article 20

Cooperation with third States, organisations and entities

1. For the purpose of fulfilling its mission, SATCEN may establish working relations and cooperate with third States, organisations or entities. To this effect, it may enter into administrative arrangements with competent authorities of third States, international organisations or entities.

2. The Board shall decide to authorise the Director to negotiate such administrative arrangements and shall address directives in this regard to the Director. The negotiations shall be conducted in consultation with the Board. Every such arrangement shall be concluded by SATCEN upon approval by the Council and shall be signed by the Director.

3. Non-EU NATO members and other States which are candidates for accession to the Union shall be entitled to be involved in SATCEN's activities on a case-by-case basis in accordance with Article 4 of this Decision and the provisions set out in the Annex.

Article 21

Data Protection

Upon a proposal by the Director, the Board shall adopt implementing rules concerning Regulation (EC) No 45/2001 of the European Parliament and of the Council ([1]).

Article 22

Reporting

By 31 July 2019, the HR shall present a report to the Council on the functioning of SATCEN accompanied, if necessary, by appropriate recommendations with a view to its further development.

Article 23

Administrative tasks following the dissolution of the WEU

1. Following the dissolution of the WEU, SATCEN shall, on behalf of Belgium, Germany, Greece, Spain, France, Italy, Luxembourg, the Netherlands, Portugal, and the United Kingdom ('the ten Member States'), perform the following residual administrative tasks of the WEU:

(a) the administration of the pensions of former staff of the WEU;

(b) the administration of the medical insurance of retired former staff of the WEU;

(c) the administration of the WEU Social Plan;

([1]) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(d) the administration of any disputes between the WEU and any member of its former staff and the implementation of the decisions of the WEU Appeals Board or competent court;

(e) assistance to the ten Member States in relation to WEU residual and other administrative tasks, including the liquidation of the WEU's assets.

2. The administration of the pensions of former staff of the WEU shall:

(a) take place in accordance with the pension scheme of the WEU, as in force on 30 June 2011, which scheme may be amended by the Board referred to in paragraph 7, within the framework of the Coordinated Organisations;

(b) be managed by a specialised authority, organisation or financial institution as approved by the Board referred to in paragraph 7 upon a proposal by the Director of SATCEN.

Any disputes relating to those pensions and involving former staff of the WEU shall be settled in accordance with paragraph 5.

3. The administration of the medical insurance of retired former staff of the WEU shall take place in accordance with the WEU staff rules as in force on 30 June 2011 and as subsequently amended by the Board referred to in paragraph 7.

4. The administration of the WEU Social Plan shall take place in accordance with the Social Plan adopted by the WEU on 22 October 2010. It shall also be in accordance with any subsequent binding decision by the competent Appeals Board and with any decisions taken by the WEU or the Board referred to in paragraph 7, to implement that decision.

5. Any disputes in relation to former staff of the WEU arising from the implementation of the residual tasks of the WEU shall be subject to the dispute settlement procedure of WEU staff rules as in force on 30 June 2011 and subsequently amended by the Board referred to in paragraph 7.

The status of former staff of the WEU shall be governed by the WEU staff rules as in force on 30 June 2011, as subsequently amended by the Board referred to in paragraph 7, and any applicable decision, including the WEU Social Plan.

6. Assistance to the ten Member States shall include the administration of current affairs and of any legal or financial issue arising from the closure of the WEU, performed under the guidance from the Board referred to in paragraph 7.

7. Any decisions in relation to the tasks set out in this Article, including decisions by the Board referred to in this Article, shall be adopted unanimously by the Board composed of representatives of the ten Member States. The Board in this configuration shall decide on how it is to be chaired by one of its members. The Director of SATCEN or the Director's representative shall, as appropriate, attend meetings of the Board in this configuration. The Board shall be convened by the Chairperson at least once a year or at the request of at least three of its members. Ad hoc meetings of the Board may be convened at expert level in order to deal with specific subjects or issues. Decisions of the Board may be taken by written procedure.

8. SATCEN shall recruit the staff necessary to perform the tasks mentioned in paragraph 1. If any of the ten Member States offers to second a person for that purpose, that person shall be recruited. If that is not the case, or if secondment does not fill all the required posts, the necessary staff shall be recruited. SATCEN's staff regulations shall be applicable, subject to this Article.

9. All items of expenditure resulting from and revenue related to the implementation of this Article shall be part of a separate budget from that of SATCEN. That budget shall be drawn up for each financial year, which shall correspond to the calendar year, and shall be adopted by the Board referred to in paragraph 7, acting upon a proposal by the Director of SATCEN, by 30 November of each year. The revenue and expenditure shown in that budget shall be in balance. That budget shall include a list of the staff recruited in accordance with paragraph 8. The revenue shall consist of contributions from the ten Member States, determined in accordance with the rules applicable to their contributions to the WEU as in force on 30 June 2011, and of miscellaneous revenue.

The Board as referred to in paragraph 7 shall adopt detailed financial rules, separate from those of SATCEN, specifying in particular the procedure to be followed for establishing and implementing the budget referred to in the first subparagraph of this paragraph.

10. A start-up fund of EUR 5,3 million funded by the ten Member States shall constitute a further guarantee of availability of financial resources for the implementation of the residual administrative tasks of the WEU referred to in this Article, in particular with regard to pension rights.

Article 24

Repeal

Joint Action 2001/555/CFSP is hereby repealed.

Article 25

Entry into force

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 26 June 2014.

For the Council
The President
E. VENIZELOS

ANNEX

PROVISIONS ON THE ASSOCIATION OF THIRD STATES WITH SATCEN'S ACTIVITIES

Article 1

Purpose

These provisions set up the scope of and detailed rules for the involvement of third States in the activities of SATCEN.

Article 2

Scope

Third States mentioned in Article 20(3) of this Decision shall be entitled to:

(a) submit national requests for imagery analysis to be implemented by SATCEN;

(b) submit candidates for secondment as image analysts to SATCEN for a limited time;

(c) have access to products and services of SATCEN in accordance with Article 5 of these provisions.

Article 3

Requests

1. Any requests for imagery analysis tasks to be implemented by SATCEN may be submitted by third States to the HR in accordance with Article 2(2)(ii) of this Decision.

2. If the capacity of SATCEN allows, the HR shall direct SATCEN accordingly, in conformity with Article 3 of this Decision.

3. Third States shall accompany each request by collateral data as appropriate, and shall reimburse SATCEN in accordance with Article 10(4) of this Decision and the rules for cost recovery charges specified in SATCEN's financial rules. Third States shall indicate whether requests and/or products should be made available to other third States and international organisations.

Article 4

Secondment of experts

1. Third States shall be entitled to submit candidates to SATCEN for secondment as experts for a limited time with a view to familiarising themselves with its functioning.

2. Candidatures shall be taken into consideration subject to the availability of positions.

3. The duration of the secondment shall be based on a proposal by the Director of SATCEN and shall depend on SATCEN's available capabilities. The broadest possible rotation among candidates from interested third States shall be taken into consideration.

4. Candidates shall be experienced experts possessing sufficient professional qualifications. Experts on secondment shall normally take part in those operational activities of SATCEN that use commercial imagery.

5. Experts from third States shall comply with Decision 2013/488/EU and enter into a confidentiality commitment with SATCEN.

6. Third States shall cover the salary of their seconded experts, all related costs such as allowances, social charges, installation and travel costs, as well as any additional costs to the budget of SATCEN as determined in the detailed rules referred to in paragraph 8.

7. Mission expenses inherent in the activities of the seconded image analyst from third States in SATCEN shall be met by SATCEN's budget.

8. The detailed rules for secondment shall be drawn up by the Director of SATCEN.

Article 5

Availability of SATCEN's products

1. The HR shall inform third States when products requested in accordance with Article 2 of this Decision are available at the EEAS.

2. Requests and products made in accordance with Article 2(1) of this Decision shall be made available to third States when the HR deems it to be relevant for dialogue, consultation and cooperation between those States and the Union on CSDP.

3. Requests and products of SATCEN made in accordance with Article 2(2) of this Decision shall be made available to third States upon the decision of the requesting Party.

Article 6

Consultative Committee

1. A Consultative Committee shall be set up, chaired by the Director of SATCEN, or his or her representative, and composed of representatives of the members of the Board and representatives of third States having accepted the provisions set out in this Annex. The Consultative Committee may meet in different compositions.

2. The Consultative Committee shall address matters of common interest falling within the scope of the provisions set out in this Annex.

3. The Consultative Committee shall be convened by the Chairman at his or her initiative or at the request of at least one third of its members.

Article 7

Entry into force

1. The provisions set out in this Annex shall become effective with regard to each third State on the first day of the month following a notification to the HR by the competent authority of the third State on the acceptance of the terms set out in these provisions.

2. The third State shall notify the HR of its decision not to avail itself any longer of these provisions, at least one month before that decision takes effect.

COMMISSION IMPLEMENTING DECISION

of 25 June 2014

regarding restrictions of authorisations of biocidal products containing IPBC notified by Germany in accordance with Directive 98/8/EC of the European Parliament and of the Council

(notified under document C(2014) 4167)

(Text with EEA relevance)

(2014/402/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 36(3) thereof,

Whereas:

(1) Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) contained the list of active substances approved at Union level for use in biocidal products. By Commission Directive 2008/79/EC ([3]), the active substance IPBC for use in products belonging to product-type 8, Wood preservatives, as defined in Annex V to Directive 98/8/EC, was added to the list. By virtue of Article 86 of Regulation (EU) No 528/2012, IPBC is therefore an approved active substance included in the list referred to in Article 9(2) of that Regulation.

(2) The United Kingdom has authorised products containing IPBC for industrial and professional application on wood by automated dipping through immersion in a dip tank containing the wood preservative. The authorisations have subsequently been mutually recognised by other Member States.

(3) The German competent authority for biocidal products received applications for mutual recognition of authorisations according to Article 4(1) of Directive 98/8/EC for some of those products ('the contested products'). The contested products are listed in the Annex to this Decision.

(4) On 4 October 2012 and 6 November 2012, Germany notified the Commission, the other Member States and the applicants of its proposal to restrict the authorisations of the contested products in accordance with Article 4(4) of Directive 98/8/EC. Germany proposed not to authorise the products for automated dipping since it considered that the products would not meet the requirements of Article 5(1) of Directive 98/8/EC with regards to effects on the human health under such circumstances. According to the notifications, Germany identified some concerns with regard to the dermal exposure to IPBC of professional users when the products are applied by automated dipping. Those concerns were of particular relevance for Germany, where a significant share of premises using this application method are reported to have a low level of automation, and thus high likelihood of skin contact with treated wood or contaminated surfaces.

(5) For each notification, the Commission invited the other Member States and the applicants to submit comments in writing within 90 days in accordance with Article 27(1) of Directive 98/8/EC. Comments were submitted within that deadline by several Member States and the applicants. The notifications were also discussed between the Commission and Member States' Competent Authorities for biocidal products and, where appropriate the applicants, in meetings of the Product Authorisation and Mutual Recognition Facilitation Group and of the Co-ordination Group referred to in Article 35 of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).
([3]) Commission Directive 2008/79/EC of 28 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include IPBC as an active substance in Annex I thereto (OJ L 200, 29.7.2008, p. 12).

(6) From those discussions and comments received, it followed that existing models for assessing human exposure for dipping processes should be adapted. Adapted models for exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping were developed by the Human Exposure Expert Group, whose opinion was endorsed by the Biocides Technical Meeting of 16-20 September 2013 ([1]). The adapted models show that, where the contested products are used in fully automated processes, exposure to IPBC of professional operators is not expected to have unacceptable effects for human health within the meaning of Article 5(1) of Directive 98/8/EC.

(7) Consequently, the contested products should be authorised subject to instructions on the label restricting the use to fully automated dipping.

(8) Regulation (EU) No 528/2012 applies to the contested products in accordance with the provisions of Article 92(2) of that Regulation. Since the legal basis for this Decision is Article 36(3) of that Regulation, this Decision should be addressed to all Member States in accordance with Article 36(4) of Regulation (EU) No 528/2012.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The proposal by Germany not to authorise the biocidal products listed in the Annex for automated dipping is rejected.

Article 2

Authorisations of the biocidal products listed in the Annex shall include a condition that the label of the products contains the following instruction:

'Product (insert name of the product) must only be used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to the draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry.'

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 25 June 2014.

For the Commission
Janez POTOČNIK
Member of the Commission

([1]) Available at http://echa.europa.eu/documents/10162/19680902/heeg_opinion_18_fully_automated_dipping_en.pdf

ANNEX

The biocidal products referred to in Article 1 and 2 of this Decision include the biocidal products listed in the table below, identified by their application reference number in the Register for Biocidal Products, as well as all products concerned by an application for mutual recognition of the authorisations of these products:

2010/7969/7206/UK/AA/8794	2010/7969/7232/UK/AA/8805	2010/8209/8150/UK/AA/10438
2010/7969/7206/UK/AA/9165	2010/7969/7232/UK/AA/9172	
2010/7969/7226/UK/AA/8795	2010/7969/7233/UK/AA/8806	
2010/7969/7226/UK/AA/9166	2010/7969/7233/UK/AA/9173	
2010/7969/7227/UK/AA/8796	2010/7969/7234/UK/AA/8807	
2010/7969/7227/UK/AA/9167	2010/7969/7234/UK/AA/9174	
2010/7969/7228/UK/AA/8797	2010/7969/7759/UK/AA/8808	
2010/7969/7228/UK/AA/9168	2010/7969/7786/UK/AA/8825	
2010/7969/7229/UK/AA/8798	2010/7969/7786/UK/AA/9176	
2010/7969/7229/UK/AA/9169	2010/7969/7787/UK/AA/8826	
2010/7969/7230/UK/AA/8799	2010/7969/7787/UK/AA/9177	
2010/7969/7230/UK/AA/9170	2010/7969/7788/UK/AA/8827	
2010/7969/7231/UK/AA/8800	2010/7969/7788/UK/AA/9175	
2010/7969/7231/UK/AA/9171	2010/1349/8153/UK/AA/10515	

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN