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[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.

EN

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 252/2012

of 21 March 2012

laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006

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

Whereas:

(1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs [2] provides for maximum levels for non-dioxin-like PCBs, dioxins and furans and for the sum of dioxins, furans and dioxin-like PCBs in certain foodstuffs.

(2) Commission Recommendation 2011/516/EU of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food [3] sets out action levels in order to stimulate a pro-active approach to reduce the presence of polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans (PCDD/Fs) and dioxin-like PCBs in food. Those action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination.

(3) Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs [4] establishes specific provisions concerning the sampling procedure and the methods of analysis to be applied for the official control.

(4) The application of new maximum levels for non-dioxin-like PCBs, established following the availability of a scientific opinion from the European Food Safety Authority (EFSA) on non-dioxin-like PCBs and also to provide a harmonisation at Union level and the update of the criteria for screening methods require significant amendments. Therefore, for reasons of clarity, it is appropriate to replace Regulation (EC) No 1883/2006 by this Regulation.

(5) The provisions laid down in this Regulation relate only to the sampling and analysis of dioxins, dioxin-like PCBs and non-dioxin-like PCBs for the implementation of Regulation (EC) No 1881/2006. They do not affect the sampling strategy, sampling levels and frequency as specified in Annexes III and IV to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC [5]. They do not affect the targeting criteria for sampling as laid down in Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products [6].

[1] OJ L 165, 30.4.2004, p. 1.
[2] OJ L 364, 20.12.2006, p. 5.
[3] OJ L 218, 24.8.2011, p. 23.
[4] OJ L 364, 20.12.2006, p. 32.
[5] OJ L 125, 23.5.1996, p. 10.
[6] OJ L 65, 5.3.1998, p. 31.

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

(7) For the sampling of very large fish, it is necessary that the sampling is specified in order to ensure a harmonised approach throughout the Union.

(8) In fish of the same species originating from the same region, the level of dioxins, dioxin-like PCBs and non-dioxin-like PCBs can be different depending on the size and/or the age of the fish. Moreover, the level of dioxins, dioxin-like PCBs and non-dioxin-like PCBs is not necessarily the same in all parts of the fish. Therefore, it is necessary that the sampling and sample preparation is specified in order to ensure a harmonised approach throughout the Union.

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

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

HAS ADOPTED THIS REGULATION:

Article 1

For the purposes of this Regulation, the definitions and abbreviations set out in Annex I shall apply.

Article 2

Sampling for the official control of the levels of dioxins, furans, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs listed in Section 5 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the methods set out in Annex II to this Regulation.

Article 3

Sample preparation and analyses for the official control of the levels of dioxins, furans and dioxin-like PCBs in foodstuffs listed in Section 5 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the methods set out in Annex III to this Regulation.

Article 4

Analyses for the official control of the levels of non-dioxin-like PCBs in foodstuffs listed in Section 5 of the Annex to Regulation (EC) No 1881/2006 shall be carried out in accordance with the requirements for analytical procedures set out in Annex IV to this Regulation.

Article 5

Regulation (EC) No 1883/2006 is hereby repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 6

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from the date of entry into force.

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

Done at Brussels, 21 March 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Definitions and abbreviations

I. DEFINITIONS

For the purposes of this Regulation the definitions laid down in Annex I to Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results [1] shall apply.

Further to these definitions, the following definitions shall apply for the purposes of this Regulation:

1.1. 'Action level' means the level of a given substance, as laid down in Annex to Recommendation 2011/516/EU, which triggers investigations to identify the source of that substance in cases where increased levels of the substance are detected.

1.2. 'Bioanalytical methods' means methods based on the use of biological principles like cell-based assays, receptor-assays or immunoassays. They do not give results at the congener level but merely an indication [2] 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.

1.3. '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 GC/HRMS determined TEQ level. It attempts to correct 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 TEF and the REP values. The bioassay apparent recovery is calculated from suitable reference samples with representative congener patterns around the level of interest.

1.4. 'Semi-quantitative methods' means methods which give an approximate indication of the concentration of the putative analyte, while the numerical result does not meet the requirements for quantitative methods.

1.5. 'The accepted specific limit of quantification of an individual congener' means the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions to be monitored with an S/N (signal/noise) ratio of 3:1 for the less intensive signal and fulfilment of identification criteria as described, for example, in standard prEN 16215 (Animal feed — Determination of dioxins and dioxin-like PCBs by GC/HRMS and of indicator PCBs by GC/HRMS) and/or in EPA method 1613 revision B.

1.6. 'Upper-bound' means the concept which requires using the limit of quantification for the contribution of each non-quantified congener.

1.7. 'Lower-bound' means the concept which requires using zero for the contribution of each non-quantified congener.

1.8. 'Medium-bound' means the concept which requires using half of the limit of quantification calculating the contribution of each non-quantified congener.

1.9. 'Lot' means an identifiable quantity of food delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings. In the case of fish and fishery products, also the size of fish shall be comparable. In case the size and/or weight of the fish is not comparable within a consignment, the consignment may still be considered as a lot but a specific sampling procedure has to be applied.

1.10. 'Sublot' means designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable.

1.11. 'Incremental sample' means a quantity of material taken from a single place in the lot or sublot.

1.12. 'Aggregate sample' means the combined total of all the incremental samples taken from the lot or sublot.

1.13. 'Laboratory sample' means a representative part/quantity of the aggregate sample intended for the laboratory.

II. ABBREVIATIONS USED

BEQ Bioanalytical Equivalents

GC Gas chromatography

[1] OJ L 221, 17.8.2002, p. 8.

[2] 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.

HRMS High resolution mass spectrometry

LRMS Low resolution mass spectrometry

PCB Polychlorinated biphenyls

PCDD Polychlorinated dibenzo-p-dioxins

PCDF Polychlorinated dibenzofurans

QC Quality control

REP Relative potency

TEF Toxic Equivalency Factor

TEQ Toxic Equivalents

TCDD Tetrachlorodibenzodioxin

U Expanded measurement uncertainty

ANNEX II

Methods of sampling for offical control of levels of dioxins (PCDD/PCDF), dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs

I. SCOPE

Samples intended for the official control of the levels of dioxins (PCDD/PCDF), dioxin-like PCBs and non-dioxin-like PCBs, hereafter referred to as dioxins and PCBs, in foodstuffs shall be taken according to the methods described in this Annex. Aggregate samples thus obtained shall be considered as representative of the lots or sublots from which they are taken. Compliance with maximum levels laid down in Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs shall be established on the basis of the levels determined in the laboratory samples.

II. GENERAL PROVISIONS

1. **Personnel**

Sampling shall be performed by an authorised person as designated by the Member State.

2. **Material to be sampled**

Each lot or sublot, which is to be examined, shall be sampled separately.

3. **Precautions to be taken**

In the course of sampling and preparation of the samples, precautions shall be taken to avoid any changes, which would affect the content of dioxins and PCBs, adversely affect the analytical determination or make the aggregate samples unrepresentative.

4. **Incremental samples**

As far as possible incremental samples shall be taken at various places distributed throughout the lot or sublot. Departure from such procedure shall be recorded in the record provided for under point II.8 of this Annex.

5. **Preparation of the aggregate sample**

The aggregate sample shall be made up by combining the incremental samples. It shall be at least 1 kg unless not practical, e.g. when a single package has been sampled or when the product has a very high commercial value.

6. **Replicate samples**

The replicate samples for enforcement, defence and reference purposes shall be taken from the homogenised aggregate sample, unless such procedure conflicts with Member States' rules as regard the rights of the food business operator. The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

7. **Packaging and transmission of samples**

Each sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the sample, which might arise during transportation or storage.

8. **Sealing and labelling of samples**

Each sample taken for official use shall be sealed at the place of sampling and identified following the rules of the Member States.

A record shall be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

III. SAMPLING PLAN

The sampling method applied shall ensure that the aggregate sample is representative for the (sub)lot that is to be controlled.

1. **Division of lots into sublots**

Large lots shall be divided into sublots on condition that the sublot can be separated physically. For products traded in large bulk consignments (e.g. vegetable oils) Table 1 shall apply. For other products Table 2 shall apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %.

Table 1

Subdivision of lots into sublots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 1 500	500 tonnes
> 300 and < 1 500	3 sublots
≥ 50 and ≤ 300	100 tonnes
< 50	—

Table 2

Subdivision of lots into sublots for other products

Lot weight (ton)	Weight or number of sublots
≥ 15	15-30 tonnes
< 15	—

2. **Number of incremental samples**

The aggregate sample uniting all incremental samples shall be at least 1 kg (see point II.5 of this Annex).

The minimum number of incremental samples to be taken from the lot or sublot shall be as given in Tables 3 and 4.

In the case of bulk liquid products the lot or sublot shall be thoroughly mixed in so far as possible and in so far as it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of contaminants is assumed within a given lot or sublot. It is therefore sufficient to take three incremental samples from a lot or sublot to form the aggregate sample.

The incremental samples shall be of similar weight. The weight of an incremental sample shall be at least 100 grams.

Departure from this procedure must be recorded in the record provided for under point II.8 of this Annex. In accordance with the provisions of Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products [1], the aggregate sample size for hen eggs is at least 12 eggs (for bulk lots as well for lots consisting of individual packages, Tables 3 and 4 shall apply).

Table 3

Minimum number of incremental samples to be taken from the lot or sublot

Weight or volume of lot/sublot (in kg or litre)	Minimum number of incremental samples to be taken
< 50	3
50 to 500	5
> 500	10

If the lot or sublot consists of individual packages or units, then the number of packages or units which shall be taken to form the aggregate sample is given in Table 4.

[1] OJ L 303, 6.11.1997, p. 12.

Table 4

Number of packages or units (incremental samples) which shall be taken to form the aggregate sample if the lot or sublot consists of individual packages or units

Number of packages or units in the lot/sublot	Number of packages or units to be taken
1 to 25	at least 1 package or unit
26 to 100	about 5 %, at least 2 packages or units
> 100	about 5 %, at maximum 10 packages or units

3. **Specific provisions for the sampling of lots containing whole fishes of comparable size and weight**

Fishes are considered as being of comparable size and weight in case the difference in size and weight does not exceed about 50 %.

The number of incremental samples to be taken from the lot are defined in Table 3. The aggregate sample uniting all incremental samples shall be at least 1 kg (see point II.5).

— In case the lot to be sampled contains small fishes (individual fishes weighing < about 1 kg), the whole fish is taken as incremental sample to form the aggregate sample. In case the resulting aggregate sample weighs more than 3 kg, the incremental samples may consist of the middle part, weighing each at least 100 grams, of the fishes forming the aggregate sample. The whole part to which the maximum level is applicable is used for homogenisation of the sample.

The middle part of the fish is where the centre of gravity is. This is located in most cases at the dorsal fin (in case the fish has a dorsal fin) or halfway between the gill opening and the anus.

— In case the lot to be sampled contains larger fishes (individual fishes weighing more than about 1 kg), the incremental sample consists of the middle part of the fish. Each incremental sample weighs at least 100 grams.

For fishes of intermediate size (about 1-6 kg) the incremental sample is taken as a slice of the fish from backbone to belly in the middle part of the fish.

For very large fishes (e.g. > about 6 kg), the incremental part is taken from the right side (frontal view) dorso-lateral muscle meat in the middle part of the fish In case the taking of such a piece of the middle part of the fish would result in a significant economic damage, taking of three incremental samples of at least 350 grams each may be considered as being sufficient, independently of the size of the lot or alternatively an equal part of the muscled meat close to the tail part and the muscle meat close to the head part of one fish may be taken to form the incremental sample being representative for the level of dioxins in the whole fish.

4. **Sampling of lots of fish containing whole fishes of different size and/or weight**

— The provisions of point III.3 as regards sample constitution shall apply.

— In case a size or weight class/category is predominant (about 80 % or more of the lot), the sample is taken from fishes with the predominant size or weight. This sample is to be considered as being representative for the whole lot.

— In case no particular size or weight class/category predominates, then it must be ensured that the fishes selected for the sample are representative for the lot. Specific guidance for such cases is provided in 'Guidance on sampling of whole fishes of different size and/or weight' ([2]).

5. **Sampling at retail stage**

Sampling of foodstuffs at retail stage shall be done where possible in accordance with the sampling provisions set out in point III.2 of this Annex.

Where this is not possible, an alternative method of sampling at retail stage may be used provided that it ensures sufficient representativeness for the sampled lot or sublot.

([2]) http://ec.europa.eu/food/food/chemicalsafety/contaminants/dioxins_en.htm

IV. COMPLIANCE OF THE LOT OR SUBLOT WITH THE SPECIFICATION

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

The lot is accepted, if the analytical result does not exceed the maximum level of non-dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006 taking into account the measurement uncertainty.

The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 1881/2006, if the upperbound analytical result confirmed by duplicate analysis ([3]), exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty.

The measurement uncertainty may 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 established permitted level,

— by establishing the decision limit (CCα) according to the provisions of Decision 2002/657/EC (point 3.1.2.5 of Annex I to that Decision — the case of substances with an established permitted level). A lot or sublot is non-compliant if the measured value is equal to or above the CCα.

The abovementioned rules shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules apply.

2. **As regards dioxins (PCDD/PCDF) and dioxin-like PCBs**

The lot is accepted, if the result of a single analysis

— performed by a screening method with a false-compliant rate below 5 % indicates that the level does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006,

— performed by a confirmatory method does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006 taking into account the measurement uncertainty.

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

The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 1881/2006, if the upperbound analytical result obtained with a confirmatory method and confirmed by duplicate analysis ([3]), exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty.

The measurement uncertainty may 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 established permitted level. In case of a separate determination of PCDD/Fs and dioxin-like-PCBs the sum of the estimated expanded uncertainty of the separate analytical results of PCDD/Fs and dioxin-like PCBs has to be used for the estimated expanded uncertainty of the sum of PCDD/Fs and dioxin-like PCBs,

— by establishing the decision limit (CCα) according to the provisions of Decision 2002/657/EC (point 3.1.2.5 of Annex I to that Decision — the case of substances with established permitted level) a lot or sublot is non-compliant if the measured value is equal to or above the CCα.

The abovementioned rules shall apply for the analytical result obtained on the sample for official control. In case of analysis for defence or reference purposes, the national rules apply.

([3]) The duplicate analysis is necessary to exclude the possibility of internal cross-contamination or an accidental mix-up of samples. The first analysis, taking into account the measurement uncertainty is used for verification of compliance. 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.

V. EXCEEDANCE OF ACTION LEVELS

Action levels serve as tool for selection of samples in those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination. Screening methods shall establish appropriate cut-off values for selection of these samples. The efforts necessary to identify a source and to reduce or eliminate the contamination shall be deployed only if exceedance of the action level is confirmed by duplicate analysis using a confirmatory method and taking into account the measurement uncertainty ([4]).

([4]) Identical explanation and requirements for duplicate analysis for control of action levels as in footnote 3 for maximum levels.

ANNEX III

Sample preparation and requirements for methods of analysis used in offical control of the levels of dioxins (PCDD/PCDF) and dioxin-like PCBS in certain foodstuffs

1. FIELD OF APPLICATION

The requirements set out in this Annex shall be applied where foodstuffs are 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 foodstuffs may be performed with two different goals:

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

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

2. CLASSIFICATION OF METHODS BY THEIR DEGREE OF QUANTIFICATION [1]

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

For control of maximum and action levels for PCDD/Fs and dioxin-like compounds in food, screening methods may be applied which are based on comparison of the analytical result with a cut-off value and give a yes/no-decision for indication for the possible exceedance of the level of interest. For this purpose, bioanalytical methods were introduced. Generally, also physico-chemical methods could be developed; however, with regard to the TEQ-based maximum and action levels and the complex analysis with required determination of the relevant individual congeners, there are no practical examples.

'Semi-quantitative methods' give an approximate indication of the concentration which may be useful as information on the range of the analyte concentration and helpful for the analyst in deciding the calibration range for the confirmatory test subsequently to be performed and for quality control purposes. Examples include:

— bioanalytical methods which are able to detect the analytes of interest, include a calibration curve, give a yes/no-decision for indication for the possible exceedance of the level of interest and allow to report the result as Bioanalytical Equivalents (BEQ), being an indication of the TEQ value in the sample,

— physico-chemical test (e.g. GC-MS/MS or GC/LRMS) where the measured method precision characteristics do not meet the requirements for quantitative tests.

[1] Adapted to PCDD/Fs and dioxin-like compounds from 'Guidelines for the validation of screening methods for residues of veterinary medicines', EU Reference Laboratories (EURLs) for residues of veterinary medicines and contaminants in food of animal origin in Fougeres, Berlin and Bilthoven, 20/1/2010, http://ec.europa.eu/food/food/chemicalsafety/residues/lab_analysis_en.htm

'Quantitative methods' meet the same requirements for accuracy, dynamic range, and precision as confirmatory tests. When the quantification is required, these methods shall be validated as confirmatory methods, as detailed in this document for PCDD/Fs and dioxin-like PCBs.

3. BACKGROUND

For calculation of Toxic Equivalents (TEQ) concentrations, the concentrations of the individual substances in a given sample shall be multiplied by their respective Toxic Equivalency Factor (TEF), as established by the World Health Organisation and listed in the Appendix to this Annex, and subsequently summed to give the total concentration of dioxin-like compounds expressed as TEQs.

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

4. QUALITY ASSURANCE REQUIREMENTS

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

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

— The sample storage and transportation has to be performed in a way that maintains the integrity of the foodstuff sample.

— In so far as relevant, finely grind and mix thoroughly each laboratory sample using a process that has been demonstrated to achieve complete homogenisation (e.g. ground to pass a 1 mm sieve); samples have to be dried before grinding if moisture content is too high.

— Control of reagents, glassware and equipment for possible influence of TEQ- or BEQ-based results is of general importance.

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

— For bioanalytical methods, it is of great importance that 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/and heated at temperatures suitable to remove traces of PCDD/Fs, dioxin-like compounds and interfering compounds from its surface.

— Sample quantity used for the extraction must be sufficient to fulfil the requirements with respect to a sufficiently low working range including the concentrations of interest.

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

— In the case of fish, the skin has to be removed as the maximum level applies to muscle meat without skin. However it is necessary that all remaining muscle meat and fat tissue on the inner side of the skin are carefully and completely scraped off from the skin and added to the sample to be analysed.

5. 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.

— Laboratory proficiency shall be proven by the continuous successful participation in interlaboratory studies for the determination of PCDD/Fs and dioxin-like PCBs in relevant food matrices and concentration ranges.

— Laboratories applying screening methods for 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.

6. BASIC REQUIREMENTS TO BE MET BY ANALYTICAL PROCEDURE FOR DIOXINS (PCDD/FS) AND DIOXIN-LIKE PCBS

6.1. **Low working range and limits of quantification**

— For PCDD/Fs, detectable quantities have to 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. However, for the measurement of the more toxic dioxin-like PCB congeners (in particular non-ortho substituted congeners) the lower end of the working range must reach the low picogram (10^{-12} g) levels.

6.2. **High selectivity (specificity)**

— A distinction is required between PCDD/Fs 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 gas chromatography/mass spectrometry (GC/MS) methods, a differentiation among various congeners is necessary, such as between toxic (e.g. the 17 2,3,7,8-substituted PCDD/Fs, and 12 dioxin-like PCBs) and other congeners.

— Bioanalytical methods shall be able to detect the target compounds as the sum of PCDD/Fs, 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.

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

— For GC/MS methods, the determination shall provide a valid estimate of the true concentration in a sample. High accuracy (accuracy of the measurement: the closeness of the agreement between the result of a measurement with the true or assigned value of the measurand) is necessary 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 percentage of this value) and 'precision' (RSD_R relative standard deviation calculated from results generated under reproducibility conditions).

— For bioanalytical methods, the bioassay apparent recovery shall be determined.

6.4. **Validation in the range of level of interest and general quality control measures**

— Laboratories shall demonstrate the performance of a method in the range of the level of interest, e.g. 0,5 ×, 1 × and 2 × the level of interest with an acceptable coefficient of variation for repeated analysis, during the validation procedure and/or during routine analysis.

— 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 (QC) 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.

6.5. **Limit of quantification**

— For a bioanalytical screening method, establishment of the 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 a S/N ratio or an assay blank.

— Limit of quantification (LOQ) for a confirmatory method shall be about one fifth of the level of interest.

6.6. **Analytical criteria**

— For reliable results from confirmatory or screening methods, the following criteria must be met for the TEQ value respectively the BEQ value, whether determined as total TEQ (as sum of PCDD/F and dioxin-like PCBs) or separately for PCDD/F and dioxin-like PCBs.

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

(*) with respect to the maximum levels

6.7. **Specific requirements for screening methods**

— Both GC/MS and bioanalytical methods may be used for screening. For GC/MS methods the requirements as laid down in point 7 of this Annex are to be used. For cell based bioanalytical methods specific requirements are laid down in point 8 of this Annex.

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

— Performance verification of the screening method is required during routine analysis, by analytical quality control and on-going method validation. There must be a continuous programme for control of compliant results.

— *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 level of interest, to check if the response is possibly suppressed by interfering substances present in the sample extract. The measured concentration of the spiked sample is 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 a potential signal suppression and the respective sample must be submitted to GC/HRMS confirmatory analysis. Results shall be monitored in quality control charts.

— *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.

— *Determination of false-compliant rates from QC data*

The rate of false-compliant results from screening of samples below and above the maximum level or the action level shall be determined. Actual false-compliant rates shall be below 5 %.

After 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, e.g. 2 × 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 level, the criterion for determining false-compliant rates is the maximum level, taking into account the measurement uncertainty of the confirmatory method.

— Potential non-compliant results from screening shall always be verified by a confirmatory method of analysis (GC/HRMS). 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' is the fraction of results confirmed to be compliant from GC/HRMS confirmatory analysis, while in previous screening the sample had been declared to be suspected to be non-compliant. However, 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.

— 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.

7. SPECIFIC REQUIREMENTS FOR GC/HRMS METHODS TO BE COMPLIED WITH FOR SCREENING OR CONFIRMATORY PURPOSES

7.1. **General requirements**

— The difference between upper-bound level and lower bound level shall not exceed 20 % for foodstuffs with a contamination of about 1 pg WHO-TEQ/g fat (based on the sum of PCDD/Fs and dioxin-like PCBs). For foodstuffs with a low fat content, the same requirements for contamination levels of about 1 pg WHO-TEQ/g product have to be applied. For lower contamination levels, for example 0,5 pg WHO-TEQ/g product, the difference between upper-bound and lowerbound level may be in the range of 25 % to 40 %.

7.2. **Control of recoveries**

— Addition of ^{13}C-labelled 2,3,7,8-chlorine substituted internal PCDD/F standards and of ^{13}C-labelled internal dioxin-like PCB standards must 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/Fs and at least one congener for each of the homologous groups for dioxin-like PCBs must be added (alternatively, at least one congener for each mass spectrometric selected ion recording function used for monitoring PCDD/Fs and dioxin-like PCBs). In case of confirmatory methods, all 17 ^{13}C-labelled 2,3,7,8-substituted internal PCDD/F standards and all 12 ^{13}C-labelled internal dioxin-like PCB standards shall be used.

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

— For foodstuffs of plant origin and foodstuffs of animal origin containing less than 10 % fat, the addition of the internal standards is mandatory prior to extraction. For foodstuffs of animal origin containing more than 10 % fat, the internal standards may 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.

— Prior to GC/MS analysis, 1 or 2 recovery (surrogate) standard(s) must be added.

— Control of recovery is necessary. 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, are 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/F and dioxin-like PCBs). For GC/MS screening methods, the recoveries shall be in the range of 30 to 140 %.

7.3. **Removal of interfering substances**

— Separation of PCDD/Fs 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 sufficient (< 25 % peak to peak between 1,2,3,4,7,8-HxCDF and 1,2,3,6,7,8-HxCDF).

7.4. **Calibration with standard curve**

— The range of the calibration curve shall cover the relevant range of levels of interest.

8. 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 8 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 8.3). Samples below the cut-off value are declared compliant, samples equal or above the cut-off value as 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 the most suitable cut-off value ensuring a false-compliant rate below 5 % and an acceptable rate for false-non-compliant results. 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 levels, an appropriate percentage of the respective level of interest 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 8.1.1 and 8.1.6).

8.1. **Evaluation of the test response**

8.1.1. *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) must further be set significantly (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 (8.3) must 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 %.

8.1.2. *Calibration*

8.1.2.1. Calibration with standard curve

— Levels in samples may be estimated by comparison of the test response with a calibration curve of TCDD (or PCB 126 or a PCDD/F/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 will be achieved by minimising the difference between calculated and observed levels in the working range of the curve (e.g. by minimising the sum of squared residuals).

— The estimated level in the sample extract is 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 level of interest). For performing a recovery correction, the apparent recovery must always be within the required range (see point 8.1.4). Reference samples used for recovery correction must comply with requirements as given in point 8.2.

8.1.2.2. Calibration with reference samples

Alternatively, a calibration curve prepared from at least 4 reference samples (see point 8.2: one matrix blank, plus three reference samples at 0,5 ×, 1,0 × and 2,0 × the level of interest) around the level of interest 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 8.3) may be calculated directly from these samples and used as cut-off value. For checking of samples exceeding the action levels, an appropriate percentage of these action levels would suit as cut-off value.

8.1.3. *Separate determination of PCDD/Fs and dioxin-like PCBs*

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

8.1.4. *Bioassay apparent recoveries*

The 'bioassay apparent recovery' shall be calculated from suitable reference samples with representative congener patterns around the level of interest and expressed as percentage of the BEQ level in comparison to the TEQ level. Depending on the type of assay and TEFs [1] used, the differences between TEF and REP factors for dioxin-like PCBs may cause low apparent recoveries for dioxin-like PCBs in comparison to PCDD/Fs. Therefore, if a separate determination of PCDD/Fs and dioxin-like PCBs is performed, bioassay apparent recoveries shall be: for dioxin-like PCBs 25 % to 60 %, for PCDD/Fs 50 % to 130 % (ranges apply for TCDD calibration curve). As the contribution of dioxin-like PCBs to the sum of PCDD/Fs and dioxin-like PCBs may vary between different matrices and samples, bioassay apparent recoveries for the sum parameter reflect these ranges and shall be between 30 % to 130 %.

8.1.5. *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 GC/HRMS analysis. The recovery shall be within 60 to 120 % especially for congeners contributing more than 10 % to the TEQ-level in various mixtures.

8.1.6. *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 must be taken into account. The reporting limit must be set significantly (at least by a factor of three) above the procedure blanks.

8.2. **Use of reference samples**

— Reference samples shall represent sample matrix, congener patterns and concentration ranges for PCDD/Fs and dioxin-like PCBs around the level of interest (maximum or action levels).

— A procedure blank, or preferably a matrix blank, and a reference sample at the level of interest have to be included in each test series. These samples must be extracted and tested at the same time under identical conditions. The reference sample must 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.

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

— Extra reference samples at, e.g. 0,5 × and 2 × the level of interest may be included to demonstrate the proper performance of the test in the range of interest for the control of the level of interest. Combined, these samples may be used for calculating the BEQ-levels in test samples (8.1.2.2).

8.3. **Determination of cut-off values**

The relationship between bioanalytical results in BEQ and GC/HRMS results in TEQ shall be established (e.g. by matrix-matched calibration experiments, involving reference samples spiked at 0, 0,5 ×, 1 × and 2 × 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 each test series by including procedure/matrix blanks and recovery samples (8.2).

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

In practice, the cut-off value (in BEQ) may be calculated from the following approaches (see Figure 1):

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

8.3.1. Use of the *lower* band of the 95 % prediction interval at the GC/HRMS decision limit

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

with:

BEQ_{DL} BEQ corresponding to the GC/HRMS decision limit, being the ML 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 GC/HRMS sample concentration (in TEQ) of calibration point i

$\bar{x}$ mean of the concentrations (in TEQ) of all calibration samples

$Q_{xx} = \sum_{j=1}^{m}(x_i - \bar{x})^2$ square sum parameter, i = index for calibration point i

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

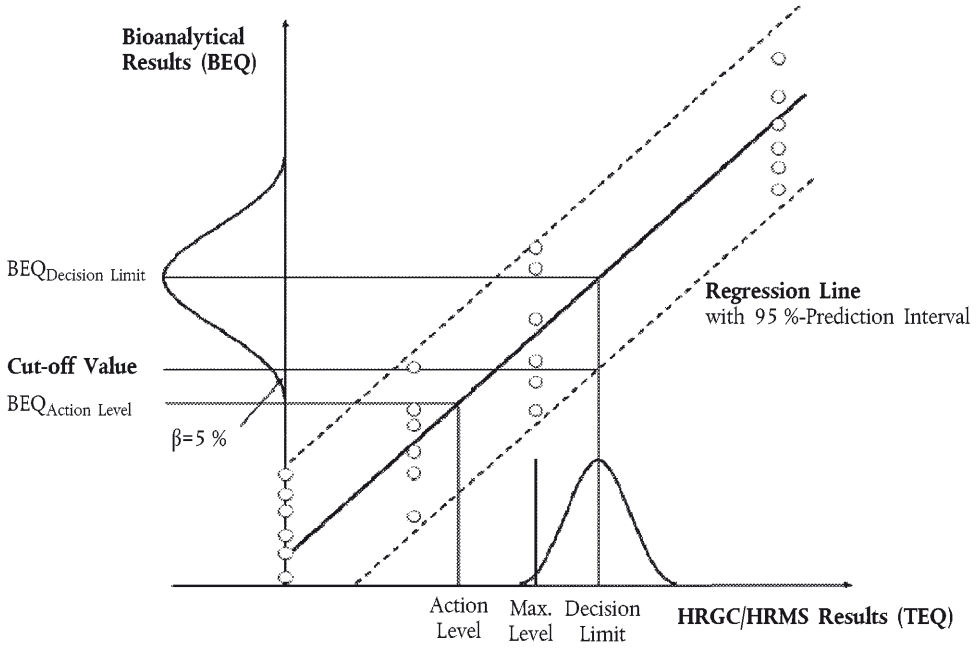
$$\text{Cut-off value} = BEQ_{DL} - 1{,}64 \times SD_R$$

with:

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

8.3.3. 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 the level of interest. This is based on the observation that this level will be around the cut-off determined under 8.3.1 or 8.3.2.

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 HRGC/HRMS decision limit, 2. from multiple analysis of samples (n ≥ 6) contaminated at the HRGC/HRMS decision limit as the *lower* endpoint of the data distribution (represented in the figure by a bell-shaped curve) at the corresponding mean BEQ value.

8.3.4. *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 levels of interest 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 level of interest shall be preferred.

8.4. **Performance characteristics**

— Since no internal standards can be used in bioanalytical methods, tests on repeatability 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 BEQs after blank and recovery correction.

— As part of the validation process, the test must 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 8.1.2).

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

— 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 shall not be above 15 %.

— The uncorrected results of the reference sample(s) expressed in BEQs (blank and level of interest) shall be used for evaluation of the performance of the bioanalytical method over a constant time period.

— Quality control (QC) 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 must be well controlled in order to avoid false-compliant results when subtracted.

— The results from the GC/HRMS analyses of suspected samples 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 BEQs and TEQs. This database might be used for re-evaluation of cut-off values applicable to routine samples for the validated matrices.

— 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. 2 × ML, may also 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.

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

9. REPORTING OF THE RESULT

Confirmatory methods

— In so far as the used analytical procedure makes it possible, the analytical results shall contain the levels of the individual PCDD/F 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.

— The report shall also include the method used for extraction of PCDD/Fs, dioxin-like PCBs and lipids. The lipid content of the sample shall be determined and reported for food samples with maximum or action levels expressed on fat basis and an expected fat concentration in the range of 0-2 % (in correspondence to existing legislation), for other samples is the determination of the lipid content optional.

— The recoveries of the individual internal standards must be made available in case the recoveries are outside the range mentioned in point 7.2, in case the maximum level is exceeded and in other cases upon request.

— 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 %. In case of a separate determination of PCDD/Fs and dioxin-like-PCBs the sum of the estimated expanded uncertainty of the separate analytical results of PCDD/Fs and dioxin-like PCBs has to be used for the sum of PCDD/Fs and dioxin-like PCBs.

— If the uncertainty of measurement is taken into account by applying CCα (as described in Annex II, point IV. 2), this parameter shall be reported.

— 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 Regulation (EC) No 1881/2006.

Bioanalytical screening methods

— The result of the screening shall be expressed as compliant or suspected to be non-compliant ('suspected').

— In addition, a result for PCDD/F and/or dioxin-like PCBs expressed in Bioanalytical Equivalents (BEQ) (not TEQ) may be given (see Annex III, point 2).

— If measurement uncertainty on the calculated BEQ-level is given, e.g. as standard deviation, it must be based on at least a triplicate analysis (including extraction, clean up and determination of the test response) of the sample.

— Samples with a response below the reporting limit shall be expressed as lower than the reporting limit.

— For each type of sample matrix, the report shall mention the level of interest (maximum level, action level) on which the evaluation is based.

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

— The report shall also include the method used for extraction of PCDD/Fs, dioxin-like PCBs and lipids. The lipid content of the sample shall be determined and reported for food samples with maximum or action levels expressed on fat basis and an expected fat concentration in the range of 0-2 % (in correspondence to existing legislation), for other samples is the determination of the lipid content optional.

Appendix to ANNEX III

WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation (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 Reevaluation 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')		**'Dioxin-like' PCBs Non-ortho PCBs and 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		
Dibenzofurans ('PCDFs')		*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' = chlorodibenzodioxin; 'CDF' = chlorodibenzofuran; 'CB' = chlorobiphenyl.

ANNEX IV

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

1. **Applicable detection methods**

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

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

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

— 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.

Note: Congeners often found to co-elute are, e.g. PCB 28/31, PCB 52/69 and PCB 138/163/164. For GC/MS also possible interferences from fragments of higher chlorinated congeners have to be considered.

— For GC/MS techniques:

— Monitoring of at least:

— two specific ions for HRMS,

— two specific ions of m/z > 200 or three specific ions of m/z > 100 for LRMS,

— 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 % (*)	± 50 % (*)

(*) 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.

— For GC/ECD:

Confirmation of results exceeding the tolerance with two GC columns with stationary phases of different polarity.

3. **Demonstration of performance of method**

Validation in the range of the level of interest (0,5 to 2 times the level of interest) with an acceptable coefficient of variation for repeated analysis (see requirements for intermediate precision in point 8).

4. **Limit of quantification**

The blank values shall not be higher than 30 % of the level of contamination corresponding to the maximum level [1].

5. **Quality control**

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

[1] 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.

6. **Control of recoveries**

— Use of suitable internal standards with physico-chemical properties comparable to analytes of interest.

— Addition of internal standards:

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

  — Addition also possible to extracted fat (before clean-up process), if maximum level is expressed on fat basis.

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

  — Correction of results for recoveries of internal standards,

  — Generally acceptable recoveries of isotope-labelled internal standards are between 50 and 120 %,

  — Lower or higher recoveries for individual congeners with a contribution to the sum of the six indicator PCBs below 10 % are acceptable.

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

  — Control of recovery of internal standard(s) for every sample,

  — Acceptable recoveries of internal standard(s) between 60 and 120 %,

  — Correction of results for recoveries of internal standards.

— The recoveries of unlabelled congeners shall be checked by spiked samples or quality control samples with concentrations in the range of the level of interest. Acceptable recoveries for these congeners are between 70 and 120 %.

7. **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.

8. **Performance characteristics: Criteria for the sum of the six indicator PCBs at the level of interest**

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

9. **Reporting of results**

— In so far 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.

— The report shall also include the method used for extraction of PCBs and lipids. The lipid content of the sample shall be determined and reported for food samples with maximum levels expressed on fat basis and an expected fat concentration in the range of 0-2 % (in correspondence to existing legislation), for other samples is the determination of the lipid content optional.

— The recoveries of the individual internal standards must be made available in case the recoveries are outside the range mentioned in point 6, in case the maximum level is exceeded and in other cases upon request.

— 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 %.

— If the uncertainty of measurement is taken into account by applying CCα (as described in Annex II, point IV.1), this parameter shall be reported.

— 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 Regulation (EC) No 1881/2006.

COMMISSION IMPLEMENTING REGULATION (EU) No 253/2012

of 22 March 2012

amending for the 167th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al Qaida network

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al-Qaida network, [1] and in particular Article 7(1)(a), 7a(1) and 7a(5) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.

(2) On 12 March 2012 the Sanctions Committee of the United Nations Security Council decided to add two natural persons and one entity to its list of persons, groups and entities to whom the freezing of funds and economic resources should apply. On 14 March 2012 it decided to add another four natural persons to the list and amend one entry on the list.

(3) Annex I to Regulation (EC) No 881/2002 should therefore be updated accordingly.

(4) In order to ensure that the measures provided for in this Regulation are effective, this Regulation should enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with 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, 22 March 2012.

For the Commission,
On behalf of the President,
Head of the Service for Foreign Policy Instruments

[1] OJ L 139, 29.5.2002, p. 9.

ANNEX

Annex I to Regulation (EC) No 881/2002 is amended as follows:

(1) The following entry shall be added under the heading 'Legal persons, groups and entities':

'Jemmah Anshorut Tauhid (JAT) (*alias* (a) Jemaah Anshorut Tauhid, (b) Jemmah Ansharut Tauhid, (c) Jem'mah Ansharut Tauhid, (d) Jamaah Ansharut Tauhid, (e) Jama'ah Ansharut Tauhid, (f) Laskar 99). Address: Jl. Semenromo number 58, 04/XV Ngruki, Cemani, Grogol, Sukoharjo, Jawa Tengah, Indonesia, Telephone: 0271-2167285, Email: info@ansharuttauhid.com. Other information: (a) Founded and led by Abu Bakar Ba'asyir; (b) Established on 27 Jul. 2008 in Solo, Indonesia; (c) Associated with Jemmah Islamiya (JI); (d) Website: http:/ansharuttauhid.com/. Date of designation referred to in Article 2a(4)(b): 12.3.2012.'

(2) The following entries shall be added under the heading 'Natural persons':

(a) 'Mochammad **Achwan** (*alias* (a) Muhammad Achwan, (b) Muhammad Akhwan, (c) Mochtar Achwan, (d) Mochtar Akhwan, (e) Mochtar Akwan). Address: Jalan Ir. H. Juanda 8/10, RT/RW 002/001, Jodipan, Blimbing, Malang, Indonesia. Date of birth: (a) 4.5.1948 (b) 4.5.1946. Place of birth: Tulungagung, Indonesia. Nationality: Indonesian. National Identification No.: 3573010405480001 (Indonesian Identity Card under name Mochammad Achwan). Date of designation referred to in Article 2a(4)(b): 12.3.2012.'

(b) 'Abdul Rosyid Ridho **Ba'asyir** (*alias* (a) Abdul Rosyid Ridho Bashir, (b) Rashid Rida Ba'aysir, (c) Rashid Rida Bashir). Address: Podok Pesantren AL Wayain Ngrandu, Sumber Agung Magetan, East Java, Indonesia. Date of birth: 31.1.1974. Place of birth: Sukoharjo, Indonesia. Nationality: Indonesian. National Identification No.: 1127083101740003 (Indonesian Identity Card under name Abdul Rosyid Ridho Ba'asyir). Date of designation referred to in Article 2a(4)(b): 12.3.2012.'

(c) 'Mustafa Hajji Muhammad **Khan** (*alias* (a) Hassan Ghul, (b) Hassan Gul, (c) Hasan Gul, (d) Khalid Mahmud, (e) Ahmad Shahji, (f) Mustafa Muhammad, (g) Abu Gharib al-Madani, (h) Abu-Shaima, (i) Abu- Shayma). Date of birth: (a) between August 1977 and September 1977, (b) 1976. Place of birth: (a) Al-Madinah, Saudi Arabia, (b) Sangrar, Sindh Province, Pakistan. Nationality: (a) Pakistani, (b) Saudi Arabian. Date of designation referred to in Article 2a(4)(b): 14.3.2012.'

(d) 'Hafiz Abdul Salam **Bhuttavi** (*alias* (a) Hafiz Abdul Salam Bhattvi, (b) Hafiz Abdusalam Budvi, (c) Hafiz Abdussalaam Bhutvi, (d) Abdul Salam Budvi, (e) Abdul Salam Bhattwi, (f) Abdul Salam Bhutvi, (g) Mullah Abdul Salaam Bhattvi, (h) Molvi Abdursalam Bhattvi). Title: (a) Maulavi, (b) Mullah. Date of birth: 1940. Place of birth: Gujranwala, Punjab Province, Pakistan. Nationality: Pakistani. Date of designation referred to in Article 2a(4)(b): 14.3.2012.'

(e) 'Zafar **Iqbal** (*alias* (a) Zaffer Iqbal, (b) Malik Zafar Iqbal Shehbaz, (c) Malik Zafar Iqbal Shahbaz, (d) Malik Zafar Iqbal, (e) Zafar Iqbal Chaudhry, (f) Muhammad Zafar Iqbal). Date of birth: 4.10.1953. Place of birth: Masjid al-Qadesia, 4 Lake Road, Lahore, Pakistan. Nationality: Pakistani. Passport No.: DG5149481 (passport issued on 22.8.2006, expired on 21.8.2011, passport booklet number A2815665). National identification No.: (a) 35202-4135948-7 b) 29553654234. Other information: other title - Professor. Date of designation referred to in Article 2a(4)(b): 14.3.2012.'

(f) 'Abdur **Rehman** (*alias* (a) Abdul Rehman, (b) Abd Ur-Rehman, (c) Abdur Rahman, (d) Abdul Rehman Sindhi, (e) Abdul Rehman al-Sindhi, (f) Abdur Rahman al-Sindhi, (g) Abdur Rehman Sindhi, (h) Abdurahman Sindhi, (i) Abdullah Sindhi, (j) Abdur Rehman Muhammad Yamin. Address: Karachi, Pakistan. Date of birth: 3.10.1965. Place of birth: Mirpur Khas, Pakistan. Nationality: Pakistani. Passport No.: CV9157521 (Pakistani passport issued on 8.9.2008, expires on 7.9.2013). National identification No.: 44103-5251752-5. Date of designation referred to in Article 2a(4)(b): 14.3.2012.'

(3) The entry 'Lashkar e-Tayyiba (*alias* (a) Lashkar-e-Toiba, (b) Lashkar-i-Taiba, (c) al Mansoorian, (d) al Mansooreen, (e) Army of the Pure, (f) Army of the Righteous, (g) Army of the Pure and Righteous, (h) Paasban-e-Kashmir (i) Paasban-i-Ahle- Hadith, (j) Pasban-e-Kashmir, (k) Pasban-e-Ahle-Hadith, (l) Paasban-e-Ahle-Hadis, (m) Pashan-e-ahle Hadis, (n) Lashkar e Tayyaba, (o) LET, (p) Jamaat-ud-Dawa, (q) JUD (r) Jama'at al-Dawa, (s) Jamaat ud-Daawa, (t) Jamaat ul-Dawah, (u) Jamaat-ul-Dawa, (v) Jama'at-i-Dawat, (w) Jamaiat-ud-Dawa, (x) Jama'at-ud-Da'awah, (y) Jama'at-ud- Da'awa, (z) Jamaati-ud-Dawa. Date of designation referred to in Article 2a (4) (b): 2.5.2005.' under the heading 'Legal persons, groups and entities' shall be replaced by the following:

'Lashkar e-Tayyiba (*alias* (a) Lashkar-e-Toiba, (b) Lashkar-i-Taiba, (c) al Mansoorian, (d) al Mansooreen, (e) Army of the Pure, (f) Army of the Righteous, (g) Army of the Pure and Righteous, (h) Paasban-e-Kashmir (i) Paasban-i-Ahle- Hadith, (j) Pasban-e-Kashmir, (k) Pasban-e-Ahle-Hadith, (l) Paasban-e-Ahle-Hadis, (m) Pashan-e-ahle Hadis, (n) Lashkar e Tayyaba, (o) LET, (p) Jamaat-ud-Dawa, (q) JUD (r) Jama'at al-Dawa, (s) Jamaat ud-Daawa, (t) Jamaat ul-Dawah, (u) Jamaat-ul-Dawa, (v) Jama'at-i-Dawat, (w) Jamaiat-ud-Dawa, (x) Jama'at-ud-Da'awah, (y) Jama'at-ud- Da'awa, (z) Jamaati-ud-Dawa, (aa) Falah-i-Insaniat Foundation (FIF). Date of designation referred to in Article 2a (4) (b): 2.5.2005.'

COMMISSION IMPLEMENTING REGULATION (EU) No 254/2012

of 22 March 2012

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, 22 March 2012.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
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	CR	52,7
	IL	188,6
	JO	64,0
	MA	45,8
	TN	68,9
	TR	90,6
	ZZ	85,1
0707 00 05	JO	107,2
	TR	206,0
	ZZ	156,6
0709 91 00	EG	79,1
	ZZ	79,1
0709 93 10	JO	225,1
	MA	59,1
	TR	128,8
	ZZ	137,7
0805 10 20	BR	35,0
	EG	47,2
	IL	80,8
	MA	51,2
	TN	58,4
	TR	67,2
	ZZ	56,6
0805 50 10	EG	43,8
	TR	46,7
	ZZ	45,3
0808 10 80	AR	89,5
	BR	86,3
	CA	125,0
	CL	90,8
	CN	112,4
	MK	31,8
	US	159,9
	UY	74,9
	ZA	119,9
	ZZ	98,9
0808 30 90	AR	92,2
	CL	112,3
	CN	63,0
	ZA	92,7
	ZZ	90,1

(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'.

COMMISSION IMPLEMENTING REGULATION (EU) No 255/2012

of 22 March 2012

amending the representative prices and additional import duties for certain products in the sugar sector fixed by Implementing Regulation (EU) No 971/2011 for the 2011/12 marketing year

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 Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector ([2]), and in particular Article 36(2), second subparagraph, second sentence thereof,

Whereas:

(1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2011/12 marketing year are fixed by Commission Implementing Regulation (EU) No 971/2011 ([3]). Those prices and duties were last amended by Commission Implementing Regulation (EU) No 235/2012 ([4]).

(2) The data currently available to the Commission indicate that those amounts should be amended in accordance with Article 36 of Regulation (EC) No 951/2006.

(3) 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

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Implementing Regulation (EU) No 971/2011 for the 2011/12 marketing year, are hereby amended as set out in the Annex hereto.

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, 22 March 2012.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and Rural Development

([1]) OJ L 299, 16.11.2007, p. 1.
([2]) OJ L 178, 1.7.2006, p. 24.
([3]) OJ L 254, 30.9.2011, p. 12.
([4]) OJ L 78, 17.3.2012, p. 16.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 23 March 2012

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 12 10 (1)	44,97	0,00
1701 12 90 (1)	44,97	1,12
1701 13 10 (1)	44,97	0,00
1701 13 90 (1)	44,97	1,41
1701 14 10 (1)	44,97	0,00
1701 14 90 (1)	44,97	1,41
1701 91 00 (2)	49,59	2,59
1701 99 10 (2)	49,59	0,00
1701 99 90 (2)	49,59	0,00
1702 90 95 (3)	0,50	0,22

(1) For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007.
(2) For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.
(3) Per 1 % sucrose content.

COMMISSION IMPLEMENTING REGULATION (EU) No 256/2012

of 22 March 2012

amending Regulation (EC) No 1484/95 as regards 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 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]), and in particular Article 143 in conjunction with Article 4 thereof,

Having regard to Council Regulation (EC) No 614/2009 of 7 July 2009 on the common system of trade for ovalbumin and lactalbumin ([2]), and in particular Article 3(4) 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.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

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, 22 March 2012.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and Rural Development

([1]) OJ L 299, 16.11.2007, p. 1.
([2]) OJ L 181, 14.7.2009, p. 8.
([3]) OJ L 145, 29.6.1995, p. 47.

ANNEX

'ANNEX I

CN code	Description of goods	Representative price (EUR/100 kg)	Security pursuant to Article 3(3) (EUR/100 kg)	Origin [1]
0207 12 10	Fowls of the species *Gallus domesticus*, not cut in pieces, presented as "70 % chickens", frozen	131,3	0	AR
0207 12 90	Fowls of the species *Gallus domesticus*, not cut in pieces, presented as "65 % chickens", frozen	137,8	0	AR
		129,0	0	BR
0207 14 10	Fowls of the species *Gallus domesticus*, boneless cuts, frozen	288,1	4	AR
		228,1	22	BR
		325,0	0	CL
0207 27 10	Turkeys, boneless cuts, frozen	325,1	0	BR
		415,6	0	CL
0408 11 80	Dried egg yolks	335,6	0	AR
0408 91 80	Eggs, not in shell, dried	345,0	0	AR
1602 32 11	Preparations of fowls of the species *Gallus domesticus*, uncooked	291,6	0	BR
		353,2	0	CL
3502 11 90	Egg albumin, dried	522,3	0	AR

[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".'

COMMISSION IMPLEMENTING REGULATION (EU) No 257/2012

of 22 March 2012

fixing the export refunds on beef and veal

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]), and in particular Article 164(2), and Article 170, in conjunction with Article 4 thereof,

Whereas:

(1) Article 162(1) of Regulation (EC) No 1234/2007 provides that the difference between prices on the world market for the products listed in Part XV of Annex I to that Regulation and prices for those products on the Union market may be covered by an export refund.

(2) Given the present situation on the market in beef and veal, export refunds should therefore be set in accordance with the rules and criteria provided for in Articles 162, 163, 164, 167, 168 and 169 of Regulation (EC) No 1234/2007.

(3) Article 164(1) of Regulation (EC) No 1234/2007 provides that the refund may vary according to destination, especially where the world market situation, the specific requirements of certain markets, or obligations resulting from agreements concluded in accordance with Article 300 of the Treaty make this necessary.

(4) Refunds should be granted only on products that are allowed to move freely in the Union and that bear the health mark as provided for in Article 5(1)(a) of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ([2]). Those products must also satisfy the requirements laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ([3]) and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ([4]).

(5) The third subparagraph of Article 7(2) of Commission Regulation (EC) No 1359/2007 of 21 November 2007 laying down the conditions for granting special export refunds on certain cuts of boned meat of bovine animals ([5]) provides for a reduction of the special refund if the quantity of cuts of boned meat to be exported amounts to less than 95 %, but not less than 85 %, of the total weight of cuts produced by boning.

(6) The currently applicable refunds have been fixed by Commission Implementing Regulation (EU) No 1318/2011 ([6]). Since new refunds should be fixed, that Regulation should therefore be repealed.

(7) In order to prevent divergence with the current market situation, to prevent market speculation and to ensure efficient management, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

1. Export refunds as provided for in Article 164 of Regulation (EC) No 1234/2007 shall be granted on the products and for the amounts set out in the Annex to this Regulation subject to the conditions provided for in paragraph 2 of this Article.

2. The products eligible for a refund under paragraph 1 shall meet the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004, and, in particular, shall be prepared in an approved establishment and comply with the health marking requirements laid down in Annex I, Section I, Chapter III to Regulation (EC) No 854/2004.

Article 2

In the case referred to in the third subparagraph of Article 7(2) of Regulation (EC) No 1359/2007, the rate of the refund on products falling within product code 0201 30 00 9100 shall be reduced by EUR 3,5/100 kg.

Article 3

Regulation (EU) No 1318/2011 is hereby repealed.

([1]) OJ L 299, 16.11.2007, p. 1.
([2]) OJ L 139, 30.4.2004, p. 55.
([3]) OJ L 139, 30.4.2004, p. 1.
([4]) OJ L 139, 30.4.2004, p. 206.
([5]) OJ L 304, 22.11.2007, p. 21.
([6]) OJ L 334, 16.12.2011, p. 21.

Article 4

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, 22 March 2012.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and Rural Development

ANNEX

Export refunds on beef and veal applicable from 23 March 2012

Product code	Destination	Unit of measurement	Refunds
0102 21 10 9140	B00	EUR/100 kg live weight	12,9
0102 21 30 9140	B00	EUR/100 kg live weight	12,9
0102 31 00 9100	B00	EUR/100 kg net weight	12,9
0102 31 00 9200	B00	EUR/100 kg net weight	12,9
0102 90 20 9100	B00	EUR/100 kg net weight	12,9
0102 90 20 9200	B00	EUR/100 kg net weight	12,9
0201 10 00 9110 (1)	B02	EUR/100 kg net weight	18,3
	B03	EUR/100 kg net weight	10,8
0201 10 00 9130 (1)	B02	EUR/100 kg net weight	24,4
	B03	EUR/100 kg net weight	14,4
0201 20 20 9110 (1)	B02	EUR/100 kg net weight	24,4
	B03	EUR/100 kg net weight	14,4
0201 20 30 9110 (1)	B02	EUR/100 kg net weight	18,3
	B03	EUR/100 kg net weight	10,8
0201 20 50 9110 (1)	B02	EUR/100 kg net weight	30,5
	B03	EUR/100 kg net weight	17,9
0201 20 50 9130 (1)	B02	EUR/100 kg net weight	18,3
	B03	EUR/100 kg net weight	10,8
0201 30 00 9050	US (3)	EUR/100 kg net weight	3,3
	CA (4)	EUR/100 kg net weight	3,3
0201 30 00 9060 (6)	B02	EUR/100 kg net weight	11,3
	B03	EUR/100 kg net weight	3,8
0201 30 00 9100 (2) (6)	B04	EUR/100 kg net weight	42,4
	B03	EUR/100 kg net weight	24,9
	EG	EUR/100 kg net weight	51,7
0201 30 00 9120 (2) (6)	B04	EUR/100 kg net weight	25,4
	B03	EUR/100 kg net weight	15,0
	EG	EUR/100 kg net weight	31,0

Product code	Destination	Unit of measurement	Refunds
0202 10 00 9100	B02	EUR/100 kg net weight	8,1
	B03	EUR/100 kg net weight	2,7
0202 20 30 9000	B02	EUR/100 kg net weight	8,1
	B03	EUR/100 kg net weight	2,7
0202 20 50 9900	B02	EUR/100 kg net weight	8,1
	B03	EUR/100 kg net weight	2,7
0202 20 90 9100	B02	EUR/100 kg net weight	8,1
	B03	EUR/100 kg net weight	2,7
0202 30 90 9100	US ([3])	EUR/100 kg net weight	3,3
	CA ([4])	EUR/100 kg net weight	3,3
0202 30 90 9200 ([6])	B02	EUR/100 kg net weight	11,3
	B03	EUR/100 kg net weight	3,8
1602 50 31 9125 ([5])	B00	EUR/100 kg net weight	11,6
1602 50 31 9325 ([5])	B00	EUR/100 kg net weight	10,3
1602 50 95 9125 ([5])	B00	EUR/100 kg net weight	11,6
1602 50 95 9325 ([5])	B00	EUR/100 kg net weight	10,3

N.B.: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1).

The destination codes are set out in Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19).

The other destinations are defined as follows:

B00: all destinations (third countries, other territories, victualling and destinations treated as exports from the Union).

B02: B04 and destination EG.

B03: Albania, Croatia, Bosnia-Herzegovina, Serbia, Kosovo (*), Montenegro, former Yugoslav Republic of Macedonia, stores and provisions (destinations referred to in Articles 33 and 42, and if appropriate in Article 41, of Commission Regulation (EC) No 612/2009 (OJ L 186, 17.7.2009, p. 1).

B04: Turkey, Ukraine, Belarus, Moldova, Russia, Georgia, Armenia, Azerbaijan, Kazakhstan, Turkmenistan, Uzbekistan, Tajikistan, Kyrgyzstan, Morocco, Algeria, Tunisia, Libya, Lebanon, Syria, Iraq, Iran, Israel, West Bank/Gaza Strip, Jordan, Saudi Arabia, Kuwait, Bahrain, Qatar, United Arab Emirates, Oman, Yemen, Pakistan, Sri Lanka, Myanmar (Burma), Thailand, Vietnam, Indonesia, Philippines, China, North Korea, Hong Kong, Sudan, Mauritania, Mali, Burkina Faso, Niger, Chad, Cape Verde, Senegal, Gambia, Guinea-Bissau, Guinea, Sierra Leone, Liberia, Côte-d'Ivoire, Ghana, Togo, Benin, Nigeria, Cameroun, Central African Republic, Equatorial Guinea, Sao Tome Principe, Gabon, Congo, Congo (Democratic Republic), Rwanda, Burundi, Saint Helena and dependencies, Angola, Ethiopia, Eritrea, Djibouti, Somalia, Uganda, Tanzania, Seychelles and dependencies, British Indian Ocean Territory, Mozambique, Mauritius, Comoros, Mayotte, Zambia, Malawi, South Africa, Lesotho.

(*) As defined by United Nations Security Council Resolution 1244 of 10 June 1999.

([1]) Entry under this subheading is subject to the submission of the certificate appearing in the Annex to Commission Regulation (EC) No 433/2007 (OJ L 104, 21.4.2007, p. 3).

([2]) The refund is granted subject to compliance with the conditions laid down in amended Commission Regulation (EC) No 1359/2007 (OJ L 304, 22.11.2007, p. 21), and, if applicable, in Commission Regulation (EC) No 1741/2006 (OJ L 329, 25.11.2006, p. 7).

([3]) Carried out in accordance with Commission Regulation (EC) No 1643/2006 (OJ L 308, 8.11.2006, p. 7).

([4]) Carried out in accordance with Commission Regulation (EC) No 1041/2008 (OJ L 281, 24.10.2008, p. 3).

([5]) The refund is granted subject to compliance with the conditions laid down in Commission Regulation (EC) No 1731/2006 (OJ L 325, 24.11.2006, p. 12).

([6]) The lean bovine meat content excluding fat is determined in accordance with the procedure described in the Annex to Commission Regulation (EEC) No 2429/86 (OJ L 210, 1.8.1986, p. 39).

The term 'average content' refers to the sample quantity as defined in Article 2(1) of Commission Regulation (EC) No 765/2002 (OJ L 117, 4.5.2002, p. 6). The sample is to be taken from that part of the consignment presenting the highest risk.

DECISIONS

COMMISSION DECISION

of 22 March 2012

terminating the anti-dumping proceeding concerning imports of certain stainless steel fasteners and parts thereof originating in India

(2012/163/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community [1] (the 'basic Regulation'), and in particular Article 9 thereof,

After consulting the Advisory Committee,

Whereas:

1. PROCEDURE

1.1. Initiation

(1) On 13 May 2011, the European Commission ('the Commission') announced, by a notice published in the *Official Journal of the European Union* [2] ('notice of initiation'), the initiation of an anti-dumping proceeding with regard to imports into the Union of certain stainless steel fasteners and parts thereof originating in India ('the product concerned').

(2) On the same day, the Commission announced by a notice published in the *Official Journal of the European Union* [3], the initiation of an anti-subsidy proceeding with regard to imports into the Union of certain stainless steel fasteners and parts thereof originating in India and commenced a separate investigation.

(3) The anti-dumping proceeding was initiated following a complaint lodged on 31 March 2011 by the European Industrial Fasteners Institute EiFi ('the complainant') on behalf of producers representing more than 25 % of the total Union production of certain stainless steel fasteners and parts thereof. The complaint contained *prima facie* evidence of dumping of the said product and of material injury resulting thereof, which was considered sufficient to justify the initiation of an investigation.

1.2. Parties concerned by the proceeding

(4) The Commission officially advised the complainant, other known Union producers, the known exporting producers, known importers, users known to be concerned, and the Indian authorities of the initiation of the proceeding. Interested parties were given an opportunity to make their views known in writing and to request a hearing within the time limit set in the notice of initiation.

(5) All interested parties, who so requested and showed that there were particular reasons why they should be heard, were granted a hearing.

1.2.1. *Sampling for exporting producers in India*

(6) In view of the apparent large number of exporting producers in India, sampling was provided for in the notice of initiation for the determination of dumping, in accordance with Article 17(1) of the basic Regulation.

(7) In order to enable the Commission to decide whether sampling would be necessary and, if so, to select a sample, exporting producers in India were requested to make themselves known within 15 days from the date of the initiation of the investigation and to provide basic information on their export and domestic sales, their precise activities with regard to the production and sales of the product concerned and the names and activities of all their related companies involved in the production and sales of the product concerned during the period from 1 April 2010 to 31 March 2011 ('investigation period' or 'IP').

(8) In total, five exporting producers, including a group of related companies in India, provided the requested information and agreed to be included in the sample within the deadline set in the notice of initiation. These cooperating companies reported exports of the product concerned to the Union during the investigation period. The comparison between Eurostat import data and the volume of exports to the Union of the product concerned reported for the investigation period by the five cooperating companies revealed that the cooperation of Indian exporting producers was close to 100 %. Thus, the sample was chosen on the basis of the information submitted by these five exporting producers.

(9) In accordance with Article 17(1) of the basic Regulation, a sample was selected based on the largest representative

[1] OJ L 343, 22.12.2009, p. 51.
[2] OJ C 142, 13.5.2011, p. 30.
[3] OJ C 142, 13.5.2011, p. 36.

volume of exports of the product concerned to the Union which could reasonably be investigated within the time available. On the basis of the information received from the exporting producers, the Commission selected a sample of three exporting producers having the largest volume of exports to the Union. Based on the sampling information, the selected companies or groups accounted for 99 % of the total volume of exports to the Union of the product concerned in the IP reported by the cooperating exporting producers. It was therefore considered that such a sample would allow to limiting the investigation to a reasonable number of exporting producers which could be investigated within the time available while ensuring a high level of representativeness.

1.2.2. *Selection of the sample of cooperating exporting producers in India*

(10) In accordance with Article 17(1) of the basic Regulation, the parties concerned and the Indian authorities were consulted on the selection of the sample. The two non-sampled exporting producers insisted to be also included in the sample. However, in view of the representativity of the proposed sample, as mentioned in recital (8) above, it was concluded that it was not necessary to amend or enlarge the sample.

1.2.3. *Individual examination of companies not selected in the sample*

(11) Two co-operating exporting producers, which were not included in the sample requested individual examination and replied to the anti-dumping questionnaire within the time limit.

(12) Given the conclusion that the present anti-dumping proceeding should be terminated for the reasons mentioned further below, the requests for individual examination were not further considered.

1.2.4. *Sampling of Union producers*

(13) In view of the apparent large number of Union producers, sampling was provided for in the Notice of initiation for the determination of injury, in accordance with Article 17 of the basic Regulation.

(14) In the Notice of initiation the Commission announced that it had provisionally selected a sample of Union producers. This sample consisted of five companies, out of the 15 Union producers that were known prior to the initiation of the investigation, selected on the basis of their sales volume, size and geographic location in the Union. They represented 37 % of the total estimated Union production during the IP. Interested parties were invited to consult the file and to comment on the appropriateness of this choice within 15 days of the date of publication of the Notice of initiation. No interested party opposed to the proposed sample composed of five companies.

(15) Subsequently one of the five sampled Union producers withdrew its cooperation. The remaining four sampled companies represented 31 % of the total estimated Union production during the IP. Hence the sample was considered to be representative of the Union industry.

1.2.5. *Sampling of unrelated importers*

(16) In view of the potentially large number of importers involved in the proceeding, sampling was envisaged for importers in the notice of initiation in accordance with Article 17 of the basic Regulation. Two importers provided the requested information and agreed to be included in the sample within the deadline set in the notice of initiation. Given the low number of importers who made themselves known, it was decided not to apply sampling.

1.3. **Questionnaire replies and verifications**

(17) The Commission sent questionnaires to all parties known to be concerned and to all other parties that made themselves known within the deadline set out in the notice of initiation. Questionnaires were thus sent to the sampled exporting producers in India, the sampled Union producers, the cooperating importers in the Union and to all users known to be concerned by the investigation.

(18) Replies were received from the sampled exporting producers and four sampled Union producers. None of the importers or users replied to the questionnaire.

(19) The Commission sought and verified all the information provided by interested parties and deemed necessary for the determination of dumping, resulting injury and Union interest.

(20) One party claimed that one of the exporting producers made too many claims for confidentiality and did not provide a sufficiently meaningful public version of its questionnaire response. Hence, the information submitted by this company should not be taken into consideration and it should be treated as a non-cooperative party in the investigation.

(21) The non-confidential version of the reply of this exporting producer however, consisting of an initial reply and a completed version based on a deficiency letter, has once more been assessed and found to be sufficiently complete to qualify as a meaningful public reply. This claim was therefore rejected.

(22) Verification visits were carried out at the premises of the following parties:

Producers in the Union:

— Inox Viti di Cattinori Bruno & C.s.n.c., Grumello del Monte, Italy;

— Bontempi Vibo S.p.A., Rodengo Saiano, Italy;

— Ugivis S.A., Belley, France

Exporting producers in India:

— Viraj Profiles Limited, Boisar, Dist. Thane, Maharashtra

— Agarwal Fastners Pvt. Ltd., Vasai (East), Dist. Thane, Maharashtra

— Raajratna Ventures Ltd., Ahmedabad, Gujarat

1.4. **Investigation period**

(23) The investigation of dumping and injury covered the period from 1 April 2010 to 31 March 2011. The examination of trends relevant for the assessment of injury covered the period from January 2008 to the end of the IP ('period considered').

2. **PRODUCT CONCERNED AND LIKE PRODUCT**

2.1. **Product concerned**

(24) The product concerned is stainless steel fasteners and parts thereof ('SSF') originating in India, currently falling within CN codes 7318 12 10, 7318 14 10, 7318 15 30, 7318 15 51, 7318 15 61 and 7318 15 70.

2.2. **Like product**

(25) The product concerned and the product produced and sold on the domestic market of India as well as the product produced and sold on the Union market by the Union industry were found to have the same basic physical, chemical and technical characteristics as well as the same basic uses. They were therefore considered to be alike within the meaning of Article 1(4) of the basic Regulation.

3. **DUMPING**

3.1. **Normal value**

(26) For the determination of normal value in accordance with Article 2(2) of the basic Regulation, the Commission first established whether the domestic sales of the like product of the sampled Indian exporting producers to independent customers were made in representative volumes, i.e. whether the total volume of such sales represented at least 5 % of their total export sales volume to the Union during the IP.

(27) In the case of one sampled exporting producer it was found that it had no representative sales of the like product on the domestic market. For this exporting producer, normal value had to be constructed on the basis of Article 2(3) of the basic Regulation.

3.1.1. *Sampled cooperating exporting producers with overall representative domestic sales volume*

(28) For the sampled exporting producers with overall representative domestic sales, the Commission subsequently identified those product types sold on the domestic market by the exporting producers, which were identical or directly comparable to the types sold for export to the Union.

(29) Domestic sales of a particular product type were considered as sufficiently representative when the volume of that product type sold on the domestic market to independent customers during the IP represented 5 % or more of the total volume of the comparable product type sold for export to the Union.

(30) The Commission subsequently examined whether the domestic sales of the companies concerned could be considered as being made in the ordinary course of trade pursuant to Article 2(4) of the basic Regulation. This was done by establishing for each product type the proportion of profitable sales to independent customers on the domestic market during the investigation period.

(31) Where the sales volume of a product type, sold at a net sales price equal to or above the calculated cost of production, represented more than 80 % of the total sales volume of that type, and where the weighted average price of that type was equal to or above the cost of production, normal value was based on the actual domestic price. This price was calculated as a weighted average of the prices of all domestic sales of that type made during the IP, irrespective of whether these sales were profitable or not.

(32) Where the volume of profitable sales of a product type represented 80 % or less of the total sales volume of that type, or where the weighted average price of that type was below the cost of production, normal value was based on the actual domestic price, calculated as a weighted average of profitable sales of that type only.

(33) For product types not sold in representative quantities on the domestic market, normal value had to be constructed on the basis of Article 2(3) of the basic Regulation. To this end, the selling, general and administrative ('SG&A') expenses and a reasonable profit margin were added to the exporter's own average cost of manufacturing per product type during the IP. In accordance with Article 2(6) of the basic Regulation, the percentage for SG&A and profit margin were based on the weighted average SG&A and profit margin of sales of each product type in the ordinary course of trade of the respective exporting producer.

3.1.2. *Sampled cooperating exporting producer without overall representative domestic sales volume*

(34) For the cooperating exporting producer without representative domestic sales, normal value was constructed in accordance with Article 2(3) of the basic Regulation by adding to the company's own manufacturing costs for the like product the SG&A expenses and a reasonable profit margin per product type during the IP. In accordance with Article 2(6) of the basic Regulation, the percentage for SG&A and profit margin were based

on the weighted average SG&A and profit margin of sales of each product type in the ordinary course of trade of the exporting producer.

3.2. **Export price**

(35) Export sales prices were established on the basis of the prices actually paid or payable for the product concerned in accordance with Article 2(8) of the basic Regulation.

3.3. **Comparison**

(36) The comparison between normal value and export price was made on an ex-works basis.

(37) For the purpose of ensuring a fair comparison between the normal value and the export price, due allowance in the form of adjustments was made for differences affecting prices and price comparability in accordance with Article 2(10) of the basic Regulation.

(38) On this basis, allowances for transport, ocean freight and insurance costs, handling loading and ancillary costs, packing costs, credit costs, discounts not mentioned on the invoice and commissions have been made where applicable and justified.

3.4. **Dumping margins**

3.4.1. *For the sampled cooperating exporting producers*

(39) For the sampled companies, the weighted average normal value of each type of the product concerned exported to the Union was compared with the weighted average export price of the corresponding type of the product concerned, as provided for in Article 2(11) and (12) of the basic Regulation.

(40) On this basis of the above methodology the dumping margins, expressed as a percentage of the CIF Union frontier price, duty unpaid, are the following:

Company	Dumping margin
Viraj Profiles Ltd.	0 %
Agarwal Fasteners Pvt. Ltd.	37,6 %
Raajratna Ventures Ltd.	12,0 %

(41) However, it should be noted that the Indian exporting producer, for which no dumping was found, represented 87 % of Indian exports to the Union.

(42) Based on its analysis of the Commission's disclosure document, the complainant calculated a difference of 25 % between the normal value established for the exporting producers in the sample found to be dumping and the company not found to be dumping. The complainant argued that such a difference cannot exist on a competitive market and is not realistic for the stainless steel fasteners industry. Moreover, the complainant alleged that the exporting producer not found to be dumping procured stainless steel scrap from related companies in the Union and that as a consequence the purchase prices of this raw material were not reliable for the determination of the cost of production.

(43) The normal value for the cooperating exporter not found to be dumping has been based on its cost of production per product type which is lower than for the other sampled exporting producers. This results mainly from the fact that the former company produces stainless steel itself from stainless steel scrap, and is therefore fully integrated and benefits from economies of scale, while the latter companies purchase stainless steel wire rod, the main raw material for production of stainless steel fasteners, in the open market, including from the cooperating exporter not found to be dumping.

(44) The normal value for the cooperating exporting producers found to be dumping has been mostly determined based on the domestic sales prices per product type. There is only limited competition on India's domestic market and the cooperating exporter not found to be dumping only sold unrepresentative quantities during the IP domestically.

(45) With regard to the procurement of stainless steel scrap by the exporting producer not found to be dumping, the investigation showed that this company obtained scrap from both related and unrelated suppliers, the latter representing more than 70 % of the quantities obtained. The purchase price levels for both types of procurement were comparable, also when taking the type of scrap grade into account.

(46) As a consequence, the normal value determination of the sampled exporting producers is confirmed and the claims made by the complainant have been rejected.

3.4.2. *For the other cooperating exporting producers*

(47) The weighted average dumping margin of the cooperating exporting producers not included in the sample was calculated in accordance with the provisions of Article 9(6) of the basic Regulation, on the basis of the margins established for the sampled exporting producers who were found to be dumping. On this basis, the dumping margin calculated for the cooperating companies not included in the sample was set at 24,6 % of the CIF Union frontier price, duty unpaid.

(48) One cooperating Indian exporting producer, after disclosure of the Commission's intention to terminate the proceeding, insisted that its request for individual examination should be accepted, arguing that the dumping margin disclosed for cooperating exporting producers not included in the sample did not reflect its situation.

(49) The request for individual examination has not been assessed by the Commission since in case of termination the margin determination ceases to be an issue.

3.4.3. *For the non-cooperating exporting producers*

(50) With regard to all other exporters in India, the Commission first established the level of cooperation. A comparison was made between the total export quantities indicated in the sampling replies received from all cooperating exporting producers and the total imports from India as derived from Eurostat statistics. The percentage of cooperation found was 97 %. On this basis, the level of cooperation was deemed to be high. It was considered appropriate to set the dumping margin for the non-cooperating exporting producers at the level corresponding to the average dumping margin established for the sampled cooperating exporting producers. Indeed information available suggests that the average export prices of the non-cooperating Indian exporters in the IP were in line with those found for the cooperating exporting producers. In addition there are no indications available that would point to different normal values for the non-cooperating exporting producers.

(51) On this basis, the country-wide level of dumping was established at 24,6 % of the CIF Union frontier price, duty unpaid.

4. UNION INDUSTRY

4.1. Union production

(52) All available information concerning Union producers, including information provided in the complaint, data collected from Union producers before and after the initiation of the investigation, and the verified questionnaire responses of the sampled Union producers, was used in order to establish the total Union production.

(53) On that basis, the total Union production was estimated to be around 52 000 tonnes during the IP. This figure includes the production of all Union producers that made themselves known and the estimated production volume of producers that did not come forward in the proceeding.

(54) As indicated in recital (13) above, sampling was applied for investigating Union producers. Of the 15 Union producers who provided data prior to the initiation of the proceeding, a sample of five companies was selected. Subsequently, as explained in recital (15) above, one company decided not to cooperate in the investigation. The remaining cooperating sampled companies represented around 32 % of the total estimated Union production during the IP and were deemed to be representative of the Union industry.

4.2. Union industry

(55) All known Union producers referred to in recital (52) above are deemed to constitute the Union industry within the meaning of Article 4(1) and Article 5(4) of the basic Regulation and will hereinafter be referred to as the 'Union industry'

5. INJURY

5.1. Preliminary remarks

(56) The relevant Eurostat import statistics, together with data provided in the complaint and data collected from Union producers before and after the initiation of the investigation, including the verified questionnaire responses of the sampled Union producers were used also in the evaluation of the relevant injury factors.

(57) The injury analysis with regard to macroeconomic data, such as production capacity, capacity utilization, sales volume, market share, growth, employment and productivity is based on the data of the Union industry as a whole.

(58) The injury analysis with regard to microeconomic data such as transaction prices, profitability, cash flow, investment and return on investment, ability to raise capital, stocks, and wages, is based on the data of the sampled Union producers.

(59) The four sampled Union producers were also sampled in the expiry review of the anti-dumping measures applicable to imports of SSF originating in China and Taiwan, concluded on 7 January 2012 [1]. In that review one other company, which was not sampled in the present investigation, was included in the sample. Given that the period considered for the injury analysis overlaps with that of the expiry review, data for the years 2008 and 2009 are identical except for that of one company. By disclosing figures for 2008 and 2009 it would be possible to deduce the figures of the company which was not included in the sample in the present case. Therefore, micro indicators such as stocks, wages, investments, cash flow, return on investments and profitability have been indexed.

5.2. Union consumption

(60) Union consumption was established on the basis of the sales volume of the Union industry in the Union as

[1] OJ L 5, 7.1.2012, p. 1.

provided in the complaint and cross checked by the replies to the sampling questionnaires and the verified data obtained from the sampled producers. In addition, the volume of imports based on data from Eurostat for the period considered was also taken into account.

(61) On this basis the Union consumption developed as follows:

Table 1

	2008	2009	2010	IP
Union consumption (tonnes)	120 598	101 143	122 345	131 457
Index (2008 = 100)	100	84	101	109

Source: Eurostat, complaint data and questionnaire replies.

(62) Total consumption on the EU market increased by 9 % during the period considered. Between 2008 and 2009 there was a drastic decrease by 16 %, allegedly due to the global negative effects of the economic crisis on the market, after which consumption recovered again by 21 % between 2009 and 2010 and further by 7 % between 2010 and the IP.

5.3. **Imports from the India**

(63) Imports into the Union from India developed as follows during the period considered:

Table 2

	2008	2009	2010	IP
Volume of imports from India (tonnes)	14 546	18 883	21 914	24 072
Index (2008 = 100)	100	130	151	165
Market share	12,1 %	18,7 %	17,9 %	18,3 %
Index (2008 = 100)	100	155	149	152

Source: Eurostat and questionnaire replies from exporting producers.

(64) Imports from India increased significantly by 65 % over the period considered. This increase was strongest between 2008 and 2009 when imports surged by 30 % and when consumption decreased by 16 %. On a year to year basis, Indian imports continued to increase during 2010 (+16 %) and during the IP (+10 %).

5.4. **Prices of imports and price undercutting**

Table 3

	2008	2009	2010	IP
Average import price in EUR/tonne	3 531	2 774	2 994	3 216
Index (2008 = 100)	100	79	85	91

Source: Eurostat and questionnaire replies from sampled EU producers.

(65) Average prices of imports from India decreased overall by 9 % during the period considered. This explains the increase in the market share of India from 12,1 % to 18,3 % over the same period. The highest increase occurred between 2008 and 2009, when Indian exporters gained more than 6 percentage points of market share.

(66) In order to determine price undercutting during the IP, the weighted average sales prices per product type of the sampled Union producers charged to unrelated customers on the Union market, adjusted to an ex-works level, were compared to the corresponding weighted average prices of the imports from India to the first independent customer on the Union market, established on a CIF basis, with appropriate adjustments for the existing customs duties and post-importation costs.

(67) The price comparison was made on a type-by-type basis for transactions at the same level of trade, duly adjusted where necessary, and after deduction of rebates and discounts. The result of the comparison, when expressed as a percentage of the sampled Union producers' turnover during the IP, showed price undercutting ranging between 3 % and 13 %. It should be noted in this respect that the Indian exporting producer not found to be dumping had the highest undercutting margin.

5.5. **Economic situation of the Union industry**

(68) In accordance with Article 3(5) of the basic Regulation, the examination of the impact of dumped imports on the Union industry included an evaluation of all economic indicators established for the Union industry over the period analysed.

5.5.1. *Production capacity, production and capacity utilisation*

Table 4

	2008	2009	2010	IP
Production volume (*tonnes*)	69 514	56 396	62 213	51 800
Index (2008 = 100)	100	81	89	75
Production capacity (tonnes)	140 743	127 200	128 796	111 455
Index (2008 = 100)	100	90	92	79
Capacity utilisation	49 %	44 %	48 %	46 %
Index (2008 = 100)	100	90	98	94

Source: Total Union industry.

(69) The table above shows that production decreased significantly by 25 % over the period considered. In line with a decrease in demand, production decreased sharply by 19 % in 2009, after which it recovered by around 10 % in 2010. In the IP, although the Union consumption increased by 7 %, Union production decreased again by around 17 % compared to the previous year.

(70) The production capacity of the Union industry decreased by around 21 % over the period considered. Capacity utilisation also decreased over the period considered, constantly remaining below 50 %.

5.5.2. *Sales volume and, market share*

Table 5

	2008	2009	2010	IP
Sales volume (*tonnes*)	56 042	44 627	45 976	48 129
Index (2008 = 100)	100	80	82	86
Market share	46,5 %	44,1 %	37,6 %	36,6 %
Index (2008 = 100)	100	95	81	79

Source: Total Union industry

(71) In the context of an increasing consumption (+ 9 %), sales volume of the like product when sold to the first independent customer in the Union decreased by 14 % over the period considered. Consequently market share dropped from 46,5 % in 2008 to 36,6 % in the IP. After a sharp decrease i in 2009 (– 20 %), sales volume recovered slightly in 2010 and in the IP.

5.5.3. *Growth*

(72) Union consumption increased by 9 % between 2008 and the IP. However, sales volume and market share of the Union industry decreased in the same period, by 14 % and 21 % respectively. At the same time imports from India increased significantly by 65 %.

5.5.4. *Employment*

Table 6

	2008	2009	2010	IP
Number of employees	1 007	863	821	761
Index (2008 = 100)	100	86	82	76
Productivity (unit/employee) Index (2008 = 100)	100	95	110	99

Source: Total Union industry

(73) Due to the downsizing activities of the Union industry, the number of employees was reduced accordingly during the period considered by 24 %. Between 2008 and the IP labour costs per employee increased by 6 %.

(74) Productivity of the Union industry workforce, measured as output per person employed per year, decreased slightly by 1 % over the period considered. It reached its lowest level in 2009, after which it started to recover towards the IP.

5.5.5. *Average unit prices in the Union*

Table 7

	2008	2009	2010	IP
Unit price in EU to unrelated customers (Euro per tonne)	4 336	2 792	3 914	4 244
Index (2008 = 100)	100	64	90	98

Source: questionnaire replies sampled producers

(75) Average sales prices decreased by 2 % over the period considered. In 2009 the Union industry was forced to reduce its sales prices by 36 %, in the context of the economic downturn and of a sharp decrease of import prices from India (– 21 %). During 2010 and the IP the Union industry sales prices recovered again.

(76) The investigation showed that the decrease in sales prices in 2009 reflected the decrease in costs which dropped by 18 % compared to 2008 levels. This decrease in costs was mainly due to the decrease in raw material prices, especially those of nickel, which has an unstable price dynamic. However, the Union industry was forced to decrease its sales prices more than the decrease in costs, in view of the expansion of the low-priced Indian imports in 2009.

5.5.6. *Profitability, cash flow, investments, return on investments and ability to raise capital*

Table 8

	2008	2009	2010	IP
Profitability of EU sales (*% of net sales*) Index (2008 = 100)	– 100	– 442	– 74	– 24
Cash Flow Index (2008 = 100)	– 100	– 1 827	– 40	– 171
Investments (EUR) Index (2008 = 100)	100	29	59	6
Return on Investments Index (2008 = 100)	– 100	– 284	– 59	– 28

Source: Questionnaire replies sampled EU producers

(77) The investigation showed that, even if the decrease in sales prices partly reflected the decrease in costs, the price of the Union industry was under pressure by the imports of SSF from India. The profitability of the Union industry was negative since the beginning of the period concerned. Especially in 2009 the Union industry was forced to decrease its sales prices more than the decrease in costs, in view of the expansion of the low-priced Indian imports. This lead to a significant deterioration of profitability in that year. However, in 2010 and the IP profitability improved, but it still remained negative.

(78) Cash flow, which is the ability of the industry to self-finance its activities, followed a similar trend as profitability. It reached its lowest level in 2009, after which it showed an increasing trend and turned positive in the IP.

(79) After making investments in 2008 in the production of SSF, investments decreased by about 94 % during the period considered. The return on investment showed a similar negative development in line with the negative results achieved by the Union industry over the period considered and remained always negative.

(80) The evolution of profitability, the cash flow and the low level of investments points to the fact that the sampled EU producers may have experienced difficulties to raise capital.

5.5.7. *Stocks*

Table 9

	2008	2009	2010	IP
Closing stock of Union industry *Index (2008 = 100)*	100	92	100	103

Source: Questionnaire replies sampled EU producers

(81) The stock level of the sampled Union industry increased by 3 % during the period considered. In 2009 the level of closing stock decreased by 8 %; afterwards, in 2010 and in the IP it increased by 8 % and 3 % respectively.

5.5.8. *Magnitude of the actual margin of dumping and recovery from past dumping*

(82) It is recalled that the largest Indian exporting producer representing 87 % of the Indian exports to the Union in the IP was found not to be dumping. Consequently dumped imports accounted for 13 % of the total volume of SSF exported from India to the Union. Given the volume, market share and prices of the dumped imports from India, the impact on the Union industry of the actual dumping margins may be considered to be negligible.

5.6. **Conclusion on injury**

(83) The investigation showed that most injury indicators such as production (– 25 %), capacity utilisation (– 6 %), sales volume (– 14 %), market share (– 21 %), and employment (– 24 %) deteriorated during the period considered. In the context of an increasing consumption, both sales volume and market share dropped. Sales

volume recovered slightly in 2010 and the IP when compared to 2009; however, the Union industry was unable to regain its lost market share in view of the expansion of the Indian imports which increased steadily over the period considered, at prices constantly undercutting those of the Union industry.

(84) Furthermore, the injury indicators related to the financial performance of the Union industry, such as cash flow and profitability were seriously affected. This means that the ability of the Union industry to raise capital was undermined.

(85) In the light of the foregoing, it was concluded that the Union industry suffered material injury within the meaning of Article 3(5) of the basic Regulation.

6. CAUSATION

6.1. Introduction

(86) In accordance with Article 3(6) and Article 3(7) of the basic Regulation, it was examined whether the dumped imports originating in India have caused injury to the Union industry to a degree that enables it to be classified as material. Known factors other than the dumped imports, which could at the same time be injuring the Union industry, were also examined to ensure that possible injury caused by these other factors was not attributed to the dumped imports.

(87) It is recalled, that the largest Indian exporting producer, referred to in recitals (40) and (41), accounting for 87 % of Indian exports to the Union in the IP was found not to be dumping. Therefore, a mere 13 % of the Indian exports of the product concerned to the Union during the IP were made at dumped prices. These dumped imports had a market share of 2 % in the IP.

6.2. Effect of the dumped imports

(88) The investigation showed that the Union consumption increased by 9 % over the period considered, while sales volume of the Union industry decreased by 14 % and market share dropped by 21 %.

(89) With regard to prices, the average import prices of the dumped imports were found to undercut the average sales prices of the Union industry on the Union market. However, they were around 12 % higher than the prices of the Indian company not found to the dumping.

(90) Based on the above it is considered that the limited import volume of the dumped imports from India, which had higher prices than the non-dumped imports, may only have played a very limited role, if any, in the deterioration of the situation of the Union industry.

6.3. Effect of other factors

6.3.1. *Non- dumped imports from India*

(91) The total volume of imports from India increased dramatically by 65 % over the period considered, increasing their market share from 12,1 % to 18,3 %. However, as explained above, non-dumped imports represented 87 % of the total Indian export volume in the IP, corresponding to a market share of 15 % in the IP, as opposed to the market share of 2 % of the dumped imports from India in the same period.

(92) Prices of imports from India decreased overall by 9 % in the period considered, remaining always lower than import prices from the rest of the world and sales prices of the Union industry. It is noteworthy, however, that as explained in recital (89), the average prices of the non-dumped imports were found to undercut the prices of the Union industry more than those of the dumped imports.

6.3.2. *Imports from other third countries*

Table 10

	2008	2009	2010	IP
Volume of imports from other third countries in tonnes	50 010	37 633	54 454	59 255
Index (2008 = 100)	100	75	109	118
Market share of imports from other third countries	41,5 %	37,2 %	44,5 %	45,1 %
Index (2008 = 100)	100	90	107	109
Average price of imports from other third countries in EUR/tonne	5 380	5 236	5 094	5 234

	2008	2009	2010	IP
Index (2008 = 100)	100	97	95	97
Volume of imports from Malaysia (tonnes)	13 712	9 810	9 611	9 966
Market share of imports from Malaysia	11,4 %	9,7 %	7,9 %	7,6 %
Average price of imports from Malaysia in EUR/ tonne	4 203	2 963	3 324	3 633
Volume of imports from Philippines (tonnes)	7 046	5 406	15 576	18 149
Market share of imports from Philippines	5,8 %	5,3 %	12,7 %	13,8 %
Average price of imports from Philippines in EUR/tonne	4 645	3 474	3 714	3 912
Volume of imports from the People's Republic of China (tonnes)	2 332	2 452	3 217	3 288
Market share of imports from the People's Republic of China	1,9 %	2,4 %	2,6 %	2,5 %
Average price of imports from the People's Republic of China in EUR/tonne	4 004	4 561	5 272	5 648
Volume of imports from Taiwan (tonnes)	4 304	3 703	6 451	6 640
Market share of imports from Taiwan	3,6 %	3,7 %	5,3 %	5,1 %
Average price of imports from Taiwan in EUR/tonne	5 092	4 719	4 755	4 943

Source: Eurostat

(93) Based on Eurostat data, the volume of imports into the Union of SSF originating in other third countries increased by 18 % during the period considered. At the same time, average import prices decreased by about 3 % during the period considered and their market share increased by about 9 %.

(94) There have been anti-dumping measures in force on imports of SSF from the People's Republic of China and Taiwan as of 19 November 2005. Despite the measures, imports from these two countries have increased significantly over the period considered, although market shares remained rather modest, at 2,5 % and 5,1 % respectively in the IP. Other main sources of imports are the Philippines and Malaysia. Imports especially from the Philippines increased significantly over the period considered, increasing their market share from 5,8 % in 2008 to 13,8 % in the IP.

(95) As regards Malaysia, there was a decreasing trend over the period considered, however, imports still had a market share of 7,6 % in the IP. Import volume from the Philippines increased significantly during the period considered. However, as it emerged from the investigation the average import price from the Philippines was much higher, namely, about 20 %, than the average price of the Indian SSF.

(96) With regard to import prices, the overall average prices of imports from other third countries remained relatively stable over the period considered and were always above the average sales prices of the Union industry and the average import prices from India.

(97) On the basis of the above, it was concluded that imports from other third countries did not cause the material injury suffered by the Union industry.

6.3.3. *Economic crisis*

(98) The economic crisis partially explains the contraction of the Union consumption in 2009. However, it is noteworthy that despite the decrease of 16 % in consumption in 2009, the volume of Indian imports increased by 30 %.

(99) In 2010 and the IP Union consumption increased in line with the general economic recovery. However, sales volume of the Union industry increased only slightly, by 3 % in 2010 and by 4,7 % in the IP This compares to an annual increase in Indian imports by 16 % and 10 % respectively.

(100) Under normal economic conditions and in the absence of strong price pressure and increased import levels from India, the Union industry might have had some difficulty in coping with the decrease in consumption and the increase in fixed costs per unit due to the decreased capacity utilisation it experienced. However, the low-priced Indian imports, majority of which were found not to be dumped, have intensified the effect of the economic downturn and even during the general economic recovery, the Union industry was unable to recover and to regain the market share lost to the Indian imports.

(101) Therefore, although the economic crisis 2008-2009 may have contributed to the Union industry's poor performance, it cannot be considered to have a material impact on the injurious situation of the Union industry.

6.3.4. *Export performance of the sampled Union industry*

Table 12

	2008	2009	2010	IP
Export sales in tonnes	967	689	933	884
Index (2008 = 100)	100	71	97	91
Unit selling price in euro	4 770	3 060	4 020	4 313
Index (2008 = 100)	100	64	84	90

Source: Questionnaire replies sampled EU producers

(102) During the period considered the volume of export sales of the sampled Union industry decreased by 9 % while average export prices dropped by 10 %. While it cannot be excluded that the negative trend in the export performance may have had a further negative impact on the Union industry, it is considered that, given the low volume of exports in relation to sales on the Union market, this impact was not material in respect of the injury found.

6.4. **Conclusion on causation**

(103) The above analysis demonstrated that there was a substantial increase over the period considered in the volume and market share of the low-priced imports originating in India. It was also found that these imports were constantly undercutting the prices charged by the Union industry on the Union market.

(104) However, in view of the finding that the largest Indian exporting producer, which represented 87 % of the Indian exports to the Union in the IP did not export SSF to the Union at dumped prices, it is considered that a causal link between the dumped imports, accounting for a mere 13 % of the total quantity exported from India, and the injury suffered by the Union industry cannot be sufficiently established. Indeed, it cannot be argued that the dumped Indian exports, in view of their limited volume and very limited market share (2 %) and the fact that their prices were on average 12 % higher than those of the non-dumped imports, would be causing the injury suffered by the Union industry.

(105) The analysis of the other known factors, which could have caused injury to the Union industry, including the non-dumped imports, imports from other third countries, the economic crisis and the export performance of the sampled Union industry showed that the injury suffered by the Union industry appears to be due to the impact of the non-dumped imports from India which represented 87 % of all Indian exports to the Union in the IP and which were made at significantly lower prices than the dumped imports.

7. TERMINATION OF THE ANTI-DUMPING PROCEEDING

(106) In the absence of a material causal link between the dumped imports and the injury suffered by the Union industry, it is considered that anti-dumping measures are unnecessary and therefore the present anti-dumping proceeding should be terminated in accordance with Article 9(2) of the basic Regulation.

(107) The complainant and all other interested parties were informed accordingly and were given the opportunity to comment. The comments received did not alter the conclusion that the present anti-dumping proceeding should be terminated,

HAS ADOPTED THIS DECISION:

Article 1

The anti-dumping proceeding concerning imports of certain stainless steel fasteners and parts thereof, currently falling within CN codes 7318 12 10, 7318 14 10, 7318 15 30, 7318 15 51, 7318 15 61 and 7318 15 70, originating in India, is hereby terminated.

Article 2

This Decision shall enter into force on the day following its publication in the *Official Journal of the European Union*.

Done at Brussels, 22 March 2012.

For the Commission
The President
José Manuel BARROSO

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