ANNEX II

METHODS OF SAMPLING FOR OFFICIAL 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/Fs), dioxin-like PCBs and non-dioxin-like 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 shall be established on the basis of the levels determined in the laboratory samples.

To ensure compliance with the provisions in Article 4 of Regulation (EC) No 852/2004, food business operator shall, when samples are taken to control the levels of dioxins (PCDD/Fs), dioxin-like PCBs and non-dioxin-like PCBs, take the samples according to the methods described in Chapter III of this Annex or apply an equivalent sampling procedure which is demonstrated to have a same level of representation as the sampling procedure described in Chapter III of this Annex.

II. GENERAL PROVISIONS

1. **Personnel**

Offcial 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 the 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 a procedure shall be recorded in the record provided for under point II.8.

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 a Member State's 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 in accordance with 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 of 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).

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 insofar as possible and insofar as it does not affect the quality of the product by either manual or mechanical means

immediately prior to sampling. In that 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[(1)], the aggregate sample size for hens' eggs is at least 12 eggs (for bulk lots as well as 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.

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 to be of comparable size and weight where 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).

— Where 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. Where 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.

— Where 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. Where the taking of such a piece of the middle part of the fish would result in significant economic damage, the taking of three incremental samples of at least 350 grams each may be considered as being sufficient independent 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.

— Where 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.

— Where 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 document on sampling of whole fishes of different size and/or weight'[(2)].

5. **Sampling at retail stage**

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

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.

IV. COMPLIANCE OF THE LOT WITH SPECIFICATION

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

The lot is compliant if the analytical result for the sum of non-dioxin-like PCBs does not exceed the respective maximum level, as laid down in Regulation (EC) No 1881/2006 taking into account the expanded measurement uncertainty[(3)].

The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 1881/2006 if the mean of two upperbound analytical results obtained from duplicate analysis[(4)], taking into account the expanded measurement uncertainty, exceeds the maximum level beyond reasonable doubt.

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

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

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

The lot is compliant 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 expanded measurement uncertainty[(5)].

For screening assays a cut-off value shall be established for the decision on the compliance with the respective maximum levels 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 mean of two upperbound analytical results (duplicate analysis[(6)]) obtained using a confirmatory method, taking into account the expanded measurement uncertainty, exceeds the maximum level beyond reasonable doubt.

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

The sum of the estimated expanded uncertainties 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,

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

V. EXCEEDANCE OF ACTION LEVELS

Action levels serve as a tool for the 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 the appropriate cut-off values for selection of those samples. Where significant efforts are necessary to identify a source and to reduce or eliminate the contamination, it might be appropriate to confirm exceedance of the action level by duplicate analysis using a confirmatory method and taking into account the expanded measurement uncertainty[(7)].

(**1**) 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 (OJ L 303, 6.11.1997, p. 12).

(**2**) https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_catalogue_dioxins_guidance-sampling_exemples-dec2006_en.pdf

(**3**) The principles as described in the 'Guidance Document on Measurement Uncertainty for Laboratories performing PCDD/F and PCB Analysis using Isotope Dilution Mass Spectrometry' [link to website] shall be followed when applicable.

(**4**) The duplicate analysis is necessary if the result of the first determination is non-compliant. The duplicate analysis is necessary to exclude the possibility of internal cross-contamination or an accidental mix-up of samples. In case the analysis is performed in the course of a contamination incident, confirmation by duplicate analysis might be omitted in case the samples selected for analysis are through traceability linked to the contamination incident and the level found is significantly above the maximum level.

(**5**) Guidance Document on Measurement Uncertainty for Laboratories performing PCDD/F and PCB Analysis using Isotope Dilution Mass Spectrometry [link to website], Guidance Document on the Estimation of LOD and LOQ for Measurements in the Field of Contaminants in Feed and Food [link to website].

(**6**) The duplicate analysis is necessary if the result of the first determination applying confirmatory methods with the use of ^{13}C-labelled internal standard for the relevant analytes is non-compliant. The duplicate analysis is necessary to exclude the possibility of internal cross-contamination or an accidental mix-up of samples. In case the analysis is performed in the course of a contamination incident, confirmation by duplicate analysis might be omitted in case the samples selected for analysis are through traceability linked to the contamination incident and the level found is significantly above the maximum level.

(**7**) Identical explanation and requirements for duplicate analysis for control of action levels as in footnote 6 for maximum levels.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) 2017/644. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/639 reg. 37
- Annex 1 para. 1.1 words substituted by S.I. 2019/639 reg. 38
- Annex 2 s. 2para. 1 words omitted by S.I. 2019/639 reg. 39(a) (This amendment not applied to legislation.gov.uk. Reg. 39 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 8(12))
- Annex 2 s. 2para. 1 words omitted by virtue of S.I. 2019/639, reg. 39(a) (as substituted) by S.I. 2020/1504 reg. 8(12)
- Annex 2 s. 2para. 6 words substituted by S.I. 2019/639 reg. 39(b) (This amendment not applied to legislation.gov.uk. Reg. 39 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 8(12))
- Annex 2 s. 2para. 8 words substituted by S.I. 2019/639 reg. 39(c) (This amendment not applied to legislation.gov.uk. Reg. 39 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 8(12))
- Annex 2 s. 2para. 6 words substituted by S.I. 2019/639, reg. 39(b) (as substituted) by S.I. 2020/1504 reg. 8(12)
- Annex 2 s. 2para. 8 words substituted by S.I. 2019/639, reg. 39(c) (as substituted) by S.I. 2020/1504 reg. 8(12)
- Annex 5 inserted by S.I. 2019/639 reg. 40Sch.