EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11494R1/2021
[…](2021) XXX draft

ANNEXES 1 to 2

ANNEXES

to the

Commission Implementing Regulation

laying down the methods of sampling and analysis for the control of plant toxins in food and repealing Regulation (EU) No 2015/705.

ANNEX I

METHODS OF SAMPLING FOR THE CONTROL OF THE LEVELS OF PLANT TOXINS IN FOOD

A. GENERAL PROVISIONS

The controls shall be performed in accordance with the provisions of Regulation (EU) 2017/625. The following general provisions shall apply without prejudice to the provisions in Regulation (EU) No 2017/625.

A.1. Purpose and scope

Samples intended for official control of the levels of plant toxins in foodstuffs shall be taken according to the methods set out in this Annex. Aggregate samples thus obtained shall be considered as representative of the lots. 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[1], food business operators shall ensure, when samples are taken to control the levels of plant toxins, the applied sampling procedure provides a same level of representativeness as the sampling procedure described in this Annex.

A.2. Definitions

For the purpose of this Annex, the following definitions shall apply:

A.2.1. 'lot' means an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings;

A.2.2. 'sublot' means a designated part of a large lot in order to apply the sampling method on that designated part; each sublot must be physically separate and identifiable;

A.2.3. 'incremental sample' means a quantity of material taken from a single place in the lot or sublot;

A.2.4. 'aggregate sample' means the combined total of all the incremental samples taken from the lot or sublot;

A.2.5. 'laboratory sample' means a sample intended for the laboratory.

[1] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)

A.3. General provisions

A.3.1. *Personnel*

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

A.3.2. *Material to be sampled*

Each lot which is to be examined shall be sampled separately. In accordance with the specific sampling provisions for the different plant toxins, large lots shall be subdivided into sublots to be sampled separately.

A.3.3. *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 plant toxin content, adversely affect the analytical determination or make the aggregate samples unrepresentative;

- the food safety of the lots to be sampled.

Also, all measures necessary to ensure the safety of the persons taking the samples shall be taken.

A.3.4. *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 part A.3.8. of this Annex I.

A.3.5. *Preparation of the aggregate sample*

The aggregate sample shall be made up by combining the incremental samples.

A.3.6. *Replicate samples*

The replicate samples for enforcement, trade (defence) and reference (referee) purposes shall be taken from the homogenised aggregate sample, unless such procedure conflicts with Member States' rules as regards the rights of the food business operator.

A.3.7. *Packaging and transmission of samples*

Each sample shall be placed in a clean, inert container offering adequate protection from contamination 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.

A.3.8. *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 State.

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.

A.4. Different types of lots

Food commodities may be traded in bulk, containers, or individual packings, such as sacks, bags, retail packings. The method of sampling may be applied to all the different forms in which the commodities are put on the market.

Without prejudice to the specific provisions set out in other parts of this Annex, the following formula may be used as a guide for the sampling of lots traded in individual packs, such as sacks, bags, retail packings.

$$\text{Sampling frequency (SF) } n = \frac{\text{Weight of the lot} \times \text{Weight of the incremental sample}}{\text{Weight of the aggregate sample} \times \text{Weight of individual packing}}$$

- weight: in kg

- sampling frequency (SF): every n^{th} sack or bag from which an incremental sample must be taken (decimal figures should be rounded to the nearest whole number).

B. METHODS OF SAMPLING

The methods of sampling to be used for the control of the presence of plant toxins in the different foods, are the methods of sampling established for the control of mycotoxins as established in part II of Annex I to Commission Implementing Regulation (EU) No 2022/XXX[2].

ANNEX II

[2] Commission Implementing Regulation (EU) No 2022/ of xxx laying down the methods of sampling and analysis for the control of mycotoxins in food and repealing Regulation (EC) 401/2006 (OJ L, p).

CRITERIA FOR SAMPLE PREPARATION AND FOR METHODS OF ANALYSIS USED FOR THE CONTROL OF THE LEVELS OF PLANT TOXINS IN FOODSTUFFS

1. INTRODUCTION

The requirements set out in this Annex shall be applied where foodstuffs are analysed for the official control of the levels of plant toxins and for other regulatory purposes, including the controls performed by the food business operator to ensure compliance with provisions in Article 4 of Regulation (EC) No 852/2004.

Precautions

As the distribution of plant toxins is generally non-homogeneous, samples shall be prepared, and especially homogenised, with extreme care.

The complete sample as received by the laboratory shall be homogenized, in case the homogenisation is performed by the laboratory.

2. TREATMENT OF THE SAMPLE AS RECEIVED IN THE LABORATORY

Each laboratory sample shall be mixed thoroughly using a process, including fine grinding if needed, that has been demonstrated to achieve complete homogenisation

In case the maximum level applies to the dry matter, the dry matter content of the product shall be determined on a part of the homogenised sample, using a method that has been demonstrated to determine accurately the dry matter content.

3. REPLICATE SAMPLES

The replicate samples for enforcement, trade (defence) and reference (referee) purposes shall be taken from the homogenised material unless such procedure conflicts with Member States' rules as regards the rights of the food business operator.

4. METHOD OF ANALYSIS TO BE USED BY THE LABORATORY AND LABORATORY CONTROL REQUIREMENTS

4.1. **Definitions**

The following definitions apply:

Recovery (Rec, %)

Rec = x/xref × 100%

where: x = measured concentration (for spiked samples corrected for background concentration if not blank)

xref = reference concentration (concentration of a Certified Reference Material (CRM), Proficiency Test material, or spiked sample)

Precision

RSDr = repeatability relative standard deviation

Relative standard deviation (%) calculated from results generated under repeatability conditions (repeatability precision): using the same method on the same sample material in one laboratory by the same operator, with the same instrument, within a short interval of time (1 day or 1 sequence).

RSDwR= within-laboratory reproducibility relative standard deviation

Relative standard deviation (%) calculated from results generated under within-laboratory reproducibility conditions (intermediate precision): using the same method on the same sample material in one laboratory but different days (preferably a longer time interval), and may include other conditions, e.g. involving different operators and/or different (equivalent) instruments.

RSDR = reproducibility relative standard deviation

Relative standard deviation (%) calculated from results generated under reproducibility conditions (interlaboratory precision), meaning the same material is analysed by different laboratories. The RSDR can be derived from e.g. collaborative studies and proficiency tests).

Limit of Quantification (LOQ)

LOQ = the lowest content of the analyte which can be measured with reasonable statistical certainty. In the context of this regulation this means the lowest successfully validated level: the lowest tested concentration of analyte in a sample material, for which it has been demonstrated that the criteria for recovery, precision, and identification are met.

4.2. **General requirements**

Confirmatory methods of analysis used for food control purposes shall comply with the provisions of items 1 and 2 of Annex III to Regulation (EU) 2017/625.

Wherever possible, the trueness of the method should be verified by analysis of a certified reference material and/or successful participation in proficiency tests on a regular basis.

4.3. **Specific requirements**

4.3.1. *Specific requirements for confirmatory methods*

4.3.1.1. Performance criteria

For confirmatory methods the following performance criteria apply:

Recovery: the average recovery should be between 70 and 120%.

The average recovery is the average value from replicates obtained during validation when determining the precision parameters RSDr and RSDwR. The criterion applies to all concentrations and all individual toxins.

In exceptional cases, average recoveries outside the above range can be acceptable but shall lie within 50-130%, and only when the precision criteria for RSDr and RSDwR are met.

Precision

RSDr shall be ≤ 20%.

RSDwR shall be ≤ 20%.

RSDR should be ≤ 25%.

These criteria apply to all concentrations.

In case the maximum level applies to a sum of toxins, then the criteria for precision apply to both the sum and the individual toxins.

Limit of quantification

When a specific requirement for the LOQ of a plant toxin has been set in the table 1 below, the method shall have an LOQ at or below this value.

Table 1

LOQ requirements for certain plant toxins

Plant toxin	**Comments**	**Food**	**LOQ requirement (µg/kg) or (µg/l)**
Pyrrolizidine alkaloids	LOQ requirement for individual pyrrolizidine alkaloids	Dried product	≤ 10
		Liquid product	≤ 0.15
Tropane alkaloids	LOQ requirement for atropine and scopolamine separately	Processed cereal based foods for infant and young children	≤ 1
		Cereals and cereal products	≤ 2
		Herbal infusions (dried)	≤ 5
		Herbal infusions (liquid)	≤ 0.05
Opium alkaloids	LOQ requirement for morphine and codeine separately	Bakery products	≤ 500

In all other cases, the following applies:

LOQ: shall be ≤ 0.5*ML, and should preferably be lower (≤0.2*ML).

In case the maximum level applies to a sum of toxins, then the LOQ of the individual toxins shall be ≤ 0.5*ML/n, with n being the number of toxins included in the ML definition.

For risk assessment, fit-for-purpose LOQs are generally lower compared to what is required for official control for checking compliance with a ML. The aim is to generate numerical data for the major part of the samples analysed (i.e. avoid left-censored data) in order to be able to perform accurate exposure assessments. Therefore, to generate monitoring data for risk assessment, validation needs to be done at the estimated lowest possible level(s) for which

acceptable performance is expected and it is appropriate to determine also the Limit of Detection (LOD) as it might be required to report both LOQ and LOD. The determination of the LOD and LOQ for monitoring purposes should be done following the statistical approach according to the Guidance document on the estimation of LOD and LOQ for measurements in the field of contaminants in feed and food.

4.3.1.2. Extension of the scope of the method

4.3.1.2.1. Extension of scope to other plant toxins:

When new plant toxins are added to the scope of an existing confirmatory method, a full validation is required to demonstrate the suitability of the method.

4.3.1.2.2. Extension to other commodities:

If the confirmatory method is known or expected to be applicable to other commodities, the validity to these other commodities shall be verified. As long as the new commodity belongs to a commodity group (see Table 2 in this Annex) for which an initial validation has already been performed, a limited additional validation is sufficient.

4.3.2. *Specific requirements for semi-quantitative screening methods*

4.3.2.1. Scope

The scope applies to bioanalytical methods based on immuno-recognition or receptor binding (such as ELISA, dip-sticks, lateral flow devices, immuno-sensors) and physicochemical methods based on chromatography or direct detection by mass spectrometry (e.g. ambient MS). Other methods (e.g. thin layer chromatography) are not excluded provided the signals generated relate directly to the plant toxins of interest and allow that the principle described hereunder is applicable.

The specific requirements apply to methods of which the result of the measurement is a numerical value, for example a (relative) response from a dip-stick reader, a signal from LC-MS, etc., and that normal statistics apply.

The requirements do not apply to methods that do not give numerical values (e.g. only a line that is present or absent), which require different validation approaches. Specific requirements for these methods are provided in point 4.3.3.

This document describes procedures for the validation of screening methods by means of an inter-laboratory validation, the verification of the performance of a method validated by means of an inter-laboratory exercise and the single-laboratory validation of a screening method.

4.3.2.2. Terminology

***Screening target concentration (STC)*:** the concentration of interest for detection of the plant toxin in a sample. When the aim is to test compliance with regulatory limits, the STC is equal to the applicable maximum level. For other purposes or in case no maximum level has been established, the STC is predefined by the laboratory.

Screening method: means method used for selection of those samples with levels of plant toxins that exceed the screening target concentration (STC), with a given certainty. For the purpose of plant toxin screening, a certainty of 95% is considered fit-for-purpose. The result of the screening analysis is either “negative” or “suspect”. Screening methods shall allow a cost-effective high sample-throughput, thus increasing the chance to discover new incidents

with high exposure and health risks to consumers. These methods shall be based on bio-analytical, LC-MS or HPLC methods. Results from samples exceeding the cut-off value shall be verified by a full re-analysis from the original sample by a confirmatory method.

'*Negative sample'* means the plant toxin content in the sample is < STC with a certainty of 95% (i.e. there is a 5% chance that samples will be incorrectly reported as negative).

'False negative sample' means the plant toxin content in the sample is >STC but it has been identified as negative.

'Suspect sample' (screen positive) means the sample exceeds the cut-off level (see below) and may contain the plant toxin at a level higher than the STC. Any suspect result triggers a confirmatory analysis for unambiguous identification and quantification of the plant toxin.

'False suspect sample' is a negative sample that has been identified as suspect.

'Confirmatory methods' means methods that provide full or complementary information enabling the plant toxin to be identified and quantified unequivocally at the level of interest.

Cut-off level: the response, signal, or concentration, obtained with the screening method, above which the sample is classified as 'suspect'. The cut-off is determined during the validation and takes the variability of the measurement into account.

Negative control (blank matrix) sample: a sample known to be free[3] of the plant toxin to be screened for, e.g. by previous determination using a confirmatory method of sufficient sensitivity. If no blank samples can be obtained, then material with the lowest obtainable level might be used as long as the level allows the conclusion that the screening method is fit for purpose.

***Positive control sample*:** sample containing the plant toxin at the screening target concentration, e.g. a certified reference material, a material of known content (e.g. test material of proficiency tests) or otherwise sufficiently characterised by a confirmatory method. In the absence of any of the above, a blend of samples with different levels of contamination or a spiked sample prepared within laboratory and sufficiently characterised can be used, provided it can be proven that the contamination level has been verified.

4.3.2.3. Validation procedure

The aim of the validation is to demonstrate the fitness of purpose of the screening method. This is done by determination of the cut-off value and determination of the false negative and false suspect rate. In these two parameters performance characteristics such as sensitivity, selectivity, and precision are embedded.

Screening methods can be validated by inter-laboratory or by single laboratory validation. If inter-laboratory validation data is already available for a certain plant toxin/matrix/STC combination, a verification of method performance is sufficient in a laboratory implementing the method.

4.3.2.3.1. Initial validation by single laboratory validation

Plant toxins:

The validation shall be performed for every individual plant toxin in the scope. In case of bio-analytical methods that give a combined response for a certain plant toxin group (e.g. pyrrolizidine alkaloids), applicability must be demonstrated and limitations of the test

[3] Samples are considered free of analyte if the amount present in the sample does not exceed more than 1/5th of the STC. If the level can be quantified with an confirmatory method, the level must be taken into consideration for the validation assessment.

mentioned in the scope of the method. Undesired cross-reactivity is not considered to increase the false negative rate of the target plant toxins, but may increase the false suspect rate. This unwanted increasing will be diminished by confirmatory analysis for unambiguous identification and quantification of the plant toxins.

Matrices:

An initial validation should be performed for each commodity, or, when the method is known to be applicable to multiple commodities, for each commodity group. In the latter case, one representative and relevant commodity is selected from that group (see table 2).

Sample set:

The minimum number of different samples required for validation is 20 homogeneous negative control samples and 20 homogeneous positive control samples that contain the plant toxin at the STC, analysed under within-laboratory reproducibility (RSDwR) conditions spread over 5 different days. Optionally, additional sets of 20 samples containing the plant toxin at other levels can be added to the validation set to gain insight to what extent the method can distinguish between different plant toxin concentrations.

Concentration:

For each STC to be used in routine application, a validation has to be performed.

4.3.2.3.2. Initial validation through collaborative trials

Validation through collaborative trials shall be done in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725:1994 or the IUPAC International Harmonised Protocol) which requires inclusion of valid data from at least eight different laboratories. Other than that, the only difference compared to single laboratory validations is that the ≥20 samples per commodity/level can be evenly divided over the participating laboratories, with a minimum of two samples per laboratory.

4.3.2.4. Determination of cut-off level and rate of false suspected results of blank samples

The (relative) responses for the negative control and positive control samples are taken as basis for the calculation of the required parameters.

Screening methods with a response proportional with the plant toxin concentration

For screening methods with a response proportional with the plant toxin concentration the following applies:

$$Cut\text{-}off = R_{STC} - t\text{-}value_{0.05} * SD_{STC}$$

R_{STC} = mean response of the positive control samples (at STC)

t-value: one tailed t-value for a rate of false negative results of 5% (see table 3)

SD_{STC} = standard deviation

Screening methods with a response inversely proportional with the plant toxin concentration

Similarly, for screening methods with a response inversely proportional with the plant toxin concentration, the cut-off is determined as:

$$Cut\text{-}off = R_{STC} + t\text{-}value_{0.05} * SD_{STC}$$

By using this specific t-value for establishing the cut-off value, the rate of false negative results is by default set at 5 %.

Fitness for purpose assessment

Results from the negative control samples are used to estimate the corresponding rate of false suspect results. The t-value is calculated corresponding to the event that a result of a negative control sample is above the cut off value, thus erroneously classified as suspect.

t-value = (cut off - $mean_{blank}$)/SD_{blank}

for screening methods with a response proportional with the plant toxin concentration

or

t-value = ($mean_{blank}$ - cut off)/SD_{blank}

for screening methods with a response inversely proportional with the plant toxin concentration

From the obtained t-value, based on the degrees of freedom calculated from the number of experiments, the probability of false suspect samples for a one tailed distribution can either be calculated (e.g. spread sheet function "TDIST") or taken from a table for t-distribution (see table 3) .

The corresponding value of the one tailed t-distribution specifies the rate of false suspect results.

This concept is described in detail with an example in Analytical and Bioanalytical Chemistry DOI 10.1007/s00216 -013-6922-1.

4.3.2.5. Extension of the scope of the method

4.3.2.5.1. Extension of scope to other plant toxins:

When new plant toxins are added to the scope of an existing screening method, a full validation is required to demonstrate the suitability of the method.

4.3.2.5.2. Extension to other commodities:

If the screening method is known or expected to be applicable to other commodities, the validity to these other commodities shall be verified. As long as the new commodity belongs to a commodity group (see Table 2 in this Annex) for which an initial validation has already been performed, a limited additional validation is sufficient. For this, a minimum of 10 homogeneous negative control and 10 homogeneous positive control (at STC) samples shall be analysed under within-laboratory reproducibility conditions. The positive control samples shall all be above the cut-off value. In case this criterion is not met, a full validation is required.

4.3.2.6. Verification of methods already validated through collaborative trials

For screening methods that have already been successfully validated through a collaborative laboratory trial, the method performance shall be verified. For this a minimum of 6 negative control and 6 positive control (at STC) samples shall be analysed. The positive control samples shall all be above the cut-off value. In case this criterion is not met, the laboratory has to perform a root-cause analysis to identify why it cannot meet the specification as obtained in the collaborative trial. Only after taking corrective action it shall re-verify the method performance in its laboratory. In case the laboratory is not capable to verify the results from the collaborative trial, it will need to establish its own cut-off in a complete single laboratory validation.

4.3.2.7. Continuous method verification / on-going method validation

After initial validation, additional validation data are acquired by including at least two positive control samples in each batch of samples screened. One positive control sample is a known sample (e.g. one used during initial validation), the other is a different commodity from the same commodity group (in case only one commodity is analysed, a different sample of that commodity is used instead). Inclusion of a negative control sample is optional. The results obtained for the two positive control samples are added to the existing validation set.

At least once a year the cut-off value is re-established and the validity of the method is re-assessed. The continuous method verification serves several purposes:

- quality control for the batch of samples screened
- providing information on robustness of the method at conditions in the laboratory that applies the method
- justification of applicability of the method to different commodities
- allowing to adjust cut-off values in case of gradual drifts over time.

4.3.2.8. Validation report

The validation report shall contain:

- A statement on the STC
- A statement on the obtained cut-off.

Note: The cut-off must have the same number of significant figures as the STC. Numerical values used to calculate the cut-off need at least one more significant figure than the STC.

- A statement on calculated false suspected rate
- A statement on how the false suspected rate was generated.

Note: The statement on the calculated false suspected rate indicates if the method is fit-for-purpose as it indicates the number of blank (or low level contamination) samples that will be subject to verification.

Table 2

Commodity groups for the validation of screening methods

Commodity groups	**Commodity categories**	**Typical representative commodities included in the category**
High water content	Fruit Juices Alcoholic beverages Root and tuber vegetables Cereal or fruit based purees	Apple juice, grape juice Wine, beer, cider Fresh ginger Purees intended for infants and small children
High oil content	Tree nuts Oil seeds and products thereof Oily fruits and products thereof	Walnut, hazelnut, chestnut Oilseed rape, sunflower, cotton-seed, soybeans, peanuts, sesame etc. Oils and pastes (e.g. peanut butter, tahina)
High starch and/or protein content and	Cereal grain and products thereof	Wheat, rye, barley, maize, rice, oats Wholemeal bread, white bread,

Commodity groups	Commodity categories	Typical representative commodities included in the category
low water and fat content	Dietary products	crackers, breakfast cereals, pasta Dried powders for the preparation of food for infants and small children
High acid content and high water content (*)	Citrus products	
"Difficult or unique commodities" (**)		Cocoa beans and products thereof, copra and products thereof, coffee, tea Spices, liquorice
High sugar low water content	Dried fruits	Figs, raisins, currants, sultanas
Milk and milk products	Milk Cheese Dairy products (e.g. milk powder)	Cow, goat and buffalo milk Cow, goat cheese Yogurt, cream

(*) If a buffer is used to stabilise the pH changes in the extraction step, then this commodity group can be merged into one commodity group "High water content".

(**) "Difficult or unique commodities" should only be fully validated if they are frequently analysed. If they are only analysed occasionally, validation may be reduced to just checking the reporting levels using spiked blank extracts.

Table 3

One tailed t-value for a false negative rate of 5%

Degrees of Freedom	Number of replicates	t-value (5%)
10	11	1.812
11	12	1.796
12	13	1.782
13	14	1.771
14	15	1.761
15	16	1.753
16	17	1.746
17	18	1.74
18	19	1.734
19	20	1.729
20	21	1.725
21	22	1.721
22	23	1.717
23	24	1.714
24	25	1.711
25	26	1.708

26	27	1.706
27	28	1.703
28	29	1.701
29	30	1.699
30	31	1.697
40	41	1.684
60	61	1.671
120	121	1.658
∞	∞	1.645

4.3.3. *Requirements for qualitative screening methods (methods that do not give numerical values)*

The development of validation guidelines for binary test methods is currently subject of various standardization bodies (e.g. AOAC, ISO). Very recently AOAC has drafted a guideline on this matter. This document can be regarded as the current state of the art in its field. Therefore methods that give binary results (e.g. visual inspection of dip-stick tests) should be validated according to this guideline

https://academic.oup.com/jaoac/article-pdf/97/5/1492/32425003/jaoac1492.pdf

4.4. Estimation of measurement uncertainty, recovery calculation and reporting of results[4]

4.4.1. *Confirmatory methods*

The analytical result shall be reported as follows:

(a) Corrected for recovery, where appropriate and relevant, ad when corrected it has to be so stated. The recovery rate is to be quoted unless automatic recovery correction is part of the procedure. The correction for recovery is not necessary in case the recovery rate is between 90-110 %.

(b) As x +/– U whereby x is the analytical result and U is the expanded analytical measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

For food of animal origin, the taking into account of the measurement uncertainty can also be done by establishing the decision limit (CCα) in accordance with Commission Implementing Regulation (EU) 2021/808[5] (point 2.6 (2) of Annex I of that Implementing Regulation) .

[4] More details on procedures for the estimation of measurement uncertainty and on procedures for assessing recovery can be found in the report 'Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation' https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_sampling_analysis-report_2004_en.pdf

[5] Commission Implementing Regulation (EU) 2021/808 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the

In case the maximum level has been set for the sum of toxins, the analytical results of all individual toxins should be reported.

Recovery correction, if applicable, is done for each of the individual toxins before summation of the concentrations.

For compliance verification with the sum-ML, a lower-bound approach is applied which means that results for individual toxins that are <LOQ will be replaced by zero for the calculation of the sum.

The present interpretation rules of the analytical result in view of acceptance or rejection of the lot apply to the analytical result obtained on the sample for official control. In case of analysis for defense or referee purposes, the national rules apply.

4.4.2. *Screening methods*

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

'Suspected to be non-compliant' means the sample exceeds the cut-off level and may contain the plant toxin at a level higher than the STC. Any suspect result triggers a confirmatory analysis for unambiguous identification and quantification of the plant toxin.

'Compliant' means that the plant toxin content in the sample is < STC with a certainty of 95 % (i.e. there is a 5 % chance that samples will be incorrectly reported as negative). The analytical result is reported as '< level of STC' with the level of STC specified.

4.5. **Laboratory quality standards**

Laboratory must comply with the provisions of Article 37(4) and (5) of Regulation (EU) No 2017/625.

interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC (OJ L 180, 21.5.2021, p. 84)