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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2783

of 14 December 2023

laying down the methods of sampling and analysis for the control of the levels of plant toxins in food and repealing Regulation (EU) 2015/705

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([1]), and in particular Article 34(6) thereof,

Whereas:

(1) Commission Regulation (EU) 2023/915 ([2]) sets maximum levels for certain plant toxins in food.

(2) Sampling plays a crucial part in the precision of the determination of the levels of plant toxins in a certain lot since plant toxins within a lot maybe be heterogeneously distributed. It is therefore appropriate to establish sampling methods for the official control of the levels of plant toxins in food.

(3) Commission Implementing Regulation (EU) No 2023/2782 ([3]) lays down the methods of sampling to be used for the official control of the levels of mycotoxins in food. Given that both plant toxins and mycotoxins are heterogeneously distributed within lots, it is appropriate to apply those methods of sampling also as regards plant toxins.

(4) Official controls can be performed on foods for which no specific maximum level has been established for plant toxins and for which no specific sampling procedure has been established. It is therefore appropriate to provide criteria to determine which sampling procedure should be applied in such cases.

(5) It is also necessary to set out general performance criteria which the method of analysis should comply with to ensure that control laboratories use methods of analysis with comparable levels of performance. Since the European Union Reference Laboratory on mycotoxins and plant toxins have determined the analytical performance criteria for the analysis of plant toxins in food on the basis of the best available scientific information, it is appropriate to lay down those criteria in this Regulation.

([1]) OJ L 95, 7.4.2017, p. 1.

([2]) Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103).

([3]) Commission Implementing Regulation (EU) 2023/2782 of 14 December 2023 laying down the methods of sampling and analysis for the control of the levels of mycotoxins in food and repealing Regulation (EC) No 401/2006 (OJ L, 2023/2782, 15.12.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2782/oj).

(6) Commission Regulation (EU) 2015/705 ([4]) lays down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs. Since the methods of sampling and the analytical performance criteria laid down in this Regulation are also adequate for the control of the plant toxin erucic acid in food, it is appropriate, in the interest of simplication to repeal Regulation (EU) 2015/705.

(7) It is necessary to provide the control laboratories with a sufficient time to meet the new requirements introduced by this Regulation. Therefore, it is appropriate to provide for a reasonable time until this Regulation applies.

(8) In order to ensure continuity in the performance of official controls and other regulatory activities on maximum levels of plant toxins and in order to allow enough time for methods of analysis to be re-validated, it is appropriate to provide that methods of analysis which have been validated before the date of application of this Regulation can remain in use for a defined period.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

For the purposes of this Regulation, the definitions set out in Article 1 of Commission Implementing Regulation (EU) 2023/2782 shall apply.

Article 2

(1) Sampling for the control of the levels of plant toxins in food shall be carried out in accordance with the methods set out in Annex I.

(2) In case of a food that cannot be classified in a food category for which a sampling procedure has been established in Annex I, the sampling procedure shall be determined having regard to the particle size of that food or the similarity of that food with a product that can be classified in one of the food categories in Annex I.

(3) In case of a food that cannot be classified in any food category listed in Annex I and provided that there is evidence that the plant toxin is homogeneously distributed in such a food, the food shall be sampled using the sampling method laid down in Part B of the Annex to Commission Regulation (EC) No 333/2007 ([5]).

Article 3

Sample preparation and methods of analysis used for the control of the levels of plant toxins in foodstuffs shall comply with the criteria set out in Annex II.

Article 4

Regulation (EU) 2015/705 is hereby repealed. References to the repealed Regulation shall be construed as references to this Implementing Regulation.

([4]) Commission Regulation (EU) 2015/705 of 30 April 2015 laying down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs and repealing Commission Directive 80/891/EEC (OJ L 113, 1.5.2015, p. 29).

([5]) Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29.3.2007, p. 29).

Article 5

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

It shall apply from 1 April 2024. However, methods of analysis which have been validated before the entry into application of this Regulation may remain in use until 1 July 2028, even if they do not comply with all specific requirements provided for in point 4.2 in Annex II to this Regulation.

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

Done at Brussels, 14 December 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Methods of sampling for the control of the levels of plant toxins in food

PART I

GENERAL PROVISIONS

A.1. **General provisions**

A.1.1. *Personnel*

Sampling shall be performed by a person as designated by the competent authority of the Member State.

A.1.2. *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.1.3. *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;

— affect 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.1.4. *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.1.8. of this Annex.

A.1.5. *Preparation of the aggregate sample*

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

A.1.6. *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 regards the rights of the food business operator.

A.1.7. *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.1.8. *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 of each sampling shall be kept, 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.2. **Different types of lots**

Food commodities may be traded in bulk, containers, or individual packages, such as sacks, bags, retail/individual packages. The method of sampling may be applied to commodities put on the market in bulk, containers, or individual packages, such as sacks, bags, retail/individual packages or any other different form.

Without prejudice to the specific sampling provisions set out in other parts of this Annex, the following formula shall be used as a guide for calculating the sampling frequency of lots put on the market in individual packages, such as sacks, bags, retail/individual packages.

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

— weight: in kg

— sampling frequency (SF): every n^{th} individual package from which an incremental sample shall be taken (decimal figures should be rounded to the nearest whole number).

A.3. **Sampling of commodities with a high volume/weight ratio**

With the exception of the food commodities falling under part L and M of part II of Annex I to Implementing Regulation (EU) 2023/2782, in the case of sampling food commodities which have a high volume in comparison to their weight (i.e. volume (dm^3)/weight (kg) > 5) the weight requirements can be replaced by equivalent volume requirement (i.e. 1 kg replaced by 1 dm^3).

PART II

METHODS OF SAMPLING

The methods of sampling established in part II of Annex I to Commission Implementing Regulation (EU) No 2023/2782 shall apply.

However, for the sampling of potatoes and potato products (glycoalkaloids) and honey (pyrrolizidine alkaloids), part B of the Annex to Regulation (EC) No 333/2007 shall apply.

ANNEX II

Criteria for sample preparation and for methods of analysis used for the control of the levels of plant toxins in food

1. INTRODUCTION 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 homogenised, 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, defence and reference 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. **General requirements**

Confirmatory methods of analysis used for food control purposes shall comply with the provisions of points 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.

4.2. **Specific requirements**

4.2.1. *Specific requirements for confirmatory methods*

4.2.1.1. 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 $RSDw_R$. 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 $RSDw_R$ are met.

Precision

RSDr shall be ≤ 20 %.

RSDwR shall be ≤ 20 %.

RSDR should be ≤ 25 %.

These criteria apply to all concentrations.

In case a laboratory provides the evidence that the RSDwR criterion is complied with, there is no need to provide that evidence for the RSDr criterion as compliance with the RSDwR guarantees compliance with the RSDr criterion.

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	
		Herbal infusions (dried product)	≤ 2
		Herbal infusions (liquid)	≤ 5
			≤ 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.

Identification

For identification the criteria as laid down in the Guidance document on identification of mycotoxins and plant toxins in food and feed ([1]) shall be applied.

4.2.1.2. Extension of the scope of the method

4.2.1.2.1. Extension of scope to other plant toxins:

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

4.2.1.2.2. 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.

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

4.2.2.1. Scope

This section applies to bioanalytical methods based on immuno-recognition or receptor binding (such as ELISA, dipsticks, 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.

([1]) Available at: https://food.ec.europa.eu/system/files/2023-10/cs_contaminants_sampling_guid-doc-ident-mycotoxins.pdf

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 4.2.3.

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.

4.2.2.2. 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 detection capability, selectivity, and precision are embedded.

Screening methods may 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.

4.2.2.2.1. 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 shall be demonstrated and limitations of the test 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 shall be diminished by confirmatory analysis for unambiguous identification and quantification of the plant toxins.

Matrices

An initial validation shall 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 shall be 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 ($RSDw_R$) conditions spread over 5 different days. Additional sets of 20 samples containing the plant toxin at other levels may 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.

4.2.2.2.2. Initial validation through collaborative trials

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

4.2.2.3. Determination of cut-off value and rate of false suspected results of blank samples

The (relative) responses for the negative control and positive control samples shall be 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:

$$Cut\text{-}off\ value = R_{STC} - t\text{-}value_{0,05} * SD_{STC}$$

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 value is determined as:

$$Cut\text{-}off\ value = R_{STC} + t\text{-}value_{0,05} * SD_{STC}$$

By using this specific t-value for determining 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 value- $mean_{blank}$)/SD_{blank}

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

or

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

4.2.2.4. Extension of the scope of the method

4.2.2.4.1. Extension of scope to other plant toxins:

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

4.2.2.4.2. 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.

4.2.2.5. 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 determine its own cut-off value in a complete single laboratory validation.

4.2.2.6. 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 shall be a known sample (e.g., one used during initial validation), the other shall be 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-determined, and the validity of the method is re-assessed (re-evaluation of the available QA/QC data obtained in the last year). The continuous method verification serves several purposes, including:

— 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.

4.2.2.7. Validation report

The validation report shall contain:

— a statement on the STC

— a statement on the determined cut-off value.

Note: The cut-off value shall have the same number of significant figures as the STC. Numerical values used to calculate the cut-off value 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 confirmatory and screening methods

Commodity groups	Commodity categories	Typical representative commodities included in the category
High water content	Beverages Fruits and vegetables Cereal or fruit based purees Fresh culinary herbs	Herbal infusions (liquid), borage leaves, potatoes, purees intended for infants and small children
High oil content	Tree nuts Oil seeds and products thereof Oily fruits and products thereof	Almonds, apricot kernels, rapeseed, cottonseed, linseed, lupin seeds, poppy seeds, hemp seeds etc. Oils and pastes
High starch and/or protein content and low water and fat content	Cereal grain and products thereof Dietary products	Maize, buckwheat, millet, sorghum, cassava flour, potato products, Bread, bakery 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' (**)		Pollen and pollen products, food supplements, herbal infusions (dried product), tea (dried product) Spices, liquorice
High sugar low water content	Dried fruits	Figs, raisins, currants, sultanas, honey
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' needs only to 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

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

The development of validation guidelines for binary test methods is currently carried out by various standardisation bodies (e.g., AOAC, ISO). AOAC has drafted a guideline on the validation of binary test methods. This document can be regarded as the current state of the art in the field of validation of binary test methods. Therefore, methods that give binary results (e.g., visual inspection of dip-stick tests) should be validated according to AOAC International Guidelines for Validation of Qualitative Binary Chemistry Methods ([2])

However, other recognised validation guidelines can be used such as the approach provided for in ISO/TS 23758:2021 | IDF/RM 251 Guidelines for the validation of qualitative screening methods for the detection of residues of veterinary drugs in milk and milk products.

4.3. **Estimation of measurement uncertainty, recovery calculation and reporting of results** ([3])

4.3.1. *Confirmatory methods*

([2]) Available at: https://academic.oup.com/jaoac/article-pdf/97/5/1492/32425003/jaoac1492.pdf

([3]) 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://food.ec.europa.eu/system/files/2016-10/cs_contaminants_sampling_analysis-report_2004_en.pdf

The analytical result shall be reported as follows:

(a) Corrected for recovery, where appropriate and relevant, and when corrected it shall be stated. The recovery rate is to be quoted unless intrinsic correction for bias 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 %.

As a possibility a default expanded measurement uncertainty of 50 % may be reported, provided that the laboratory meets all precision requirements specified in point 4.2. An individual laboratory can demonstrate that by achieving the criteria for the repeatability (RSD_r) and the within-laboratory reproducibility (RSD_{wR}), supplemented by successful participation in proficiency testing programs (unless no suitable proficiency testing program is available), as a mean z-score $|z| \leq 2$ demonstrates that the required reproducibility (RSD_R) is met (based on a target standard deviation of 25 %).

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

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

For compliance verification with the sum-ML, a lower-bound approach shall be applied which means that results for individual toxins that are <LOQ shall 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. In particular, if:

the analytical result of the official control sample indicates a non-compliance beyond reasonable doubt, taking into account the expanded measurement uncertainty and

the analytical result of the defense sample indicates a non-compliance but not beyond reasonable doubt with a larger expanded measurement uncertainty than the one of the official control,

then the analytical result of the defense sample cannot supersede the non-compliance established for the official control sample.

4.3.2. *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 value 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 level of confidence 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.

4.4. **Laboratory quality standards**

A laboratory shall comply with the provisions of Article 37(4) and (5) of Regulation (EU) 2017/625.