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National Food Chain Safety Office
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Proficiency Testing
general conditions, program

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0 Document information

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1 Brief description of the proficiency testing program

The Proficiency Testing Program (hereinafter: PTP) organized by the National Food Chain Safety Office Food Chain Safety Laboratory Directorate Coordination and Methodology Department (hereinafter: Provider) is announced annually. A short description of the PTP (matrices, parameters, schedules, prices) can be found on the website of the Provider (https://portal.nebih.gov.hu/-/elelmiszerlanc-jartassagi-vizsgalatok), in addition, it is sent to former clients by email.

For proficiency testing rounds not included in the annual PTP, the specific information applicable to the given round, including, where relevant, the test item(s), matrix, parameter(s), schedule, participation fee, sample distribution method, reporting deadline and other relevant details, will be provided to the invited laboratories together with the invitation and/or the notification documents.

2 Provider's details and contact information

Proficiency testing provider accredited by NAH under No NAH-8-0005/2024.

Headquarters:	1024 Budapest, Keleti Károly u. 24.
Site:	1095 Budapest, Mester u. 81.
Tax number:	15598347-2-41
Account number:	10032000-00289782-00000000
E-mail address:	korvizsgalat@nebih.gov.hu
Website:	https://portal.nebih.gov.hu/-/elelmiszerlanc-jartassagi-vizsgalatok

3 Activities outsourced to external service providing laboratories

The Provider is outsourcing the following activities to external service providing laboratories:

- Conducting preliminary examinations,
- Obtaining base samples (except for obtaining reference materials),
- Preparing PT samples,
- Packaging of PT samples,
- Storage under appropriate environmental conditions until delivery to the Provider,
- Performing homogeneity tests,
- Performing stability tests, where the parameters to be tested make it necessary.

The name and address of the external service providing laboratory involved in a PT round can be found in Annex 1.

4 Keeping in touch with participants

The Provider, in the PTP, will communicate with the participants in Hungarian and in English via the e-mail address korvizsgalat@nebih.gov.hu, regarding order confirmation, sample distribution, evaluation of the submitted results (PT results), invoices for the tests and other administration.
Contacts: Viktória Éles coordinator, Gellért Horváth coordinator,

Boglárka Nagy coordinator, Éva Polyákovity coordinator

E-mail: korvizsgalat@nebih.gov.hu

5 How to apply

Please complete the attached *application form*, **sign it with an official company signature, and send it via email** (in PDF format and editable Word format) to the Provider's address korvizsgalat@nebih.gov.hu within the specified application deadline.

To apply for the *Trichinella* PT round, you must fill out the "Application form for *the Trichinella* proficiency test", we are only able to accept that form!

6 Participation fee, payment terms

Receipt of the PT sample package constitutes participation; therefore, the participation fee listed in Annex 1 will be invoiced even if the result is not received or is not in an evaluable form. The PT invoice will be sent by the Provider after the issuance of the *Final Report*. The invoice must be paid by bank transfer to the bank account and by the deadline indicated on the invoice. If the invoice is not settled, the Provider will initiate legal collection of the debt. The Provider reserves the right to modify the payment terms depending on the amendment of VAT and tax laws. A written notification will be sent about any modifications, which will be considered accepted after 15 days if there is no feedback.

Participation in the *Trichinella proficiency test is free of charge for those obliged under Regulation (EU) 2017/625 of the European Parliament and of the Council and will not be invoiced.*

7 Criteria for participation

A given proficiency test will only be organised if a sufficient number of laboratories have applied. The minimum number of participants required will be set for each PT round. If the number of participants is acceptably large ($N \geq 7$), then the given PT round will be organised without further testing. However, if $N < 7$, the Organiser will consider whether it can ensure the reliability of the performance assessment in such case. If there are not enough applicants for a reliable performance assessment, then the Organiser will cancel the relevant PT round from the annual PT programme and notify the applicants of the cancellation of the PT round.

The PT program is open to any laboratory, regardless of its accreditation status. During the tests, participants are free to choose from among the test methods suitable for measuring the parameters in the samples provided in the ordered PT round in a given matrix and concentration range, unless the use of a given method is prescribed by a regulation or by the Provider.

The storage, handling and possible precautions for PT samples are provided in the *Instructions* issued for the relevant PT round.

8 Evaluation of homogeneity and stability tests

The homogeneity and stability testing of PT samples is carried out considering the MSZ EN ISO 17043 and ISO 13528 standards.

Qualitative tests at the microbiological PT round:

1) Artificially contaminated samples: The number of samples to be tested is determined based on ISO 13528, point 11.2.3 (min. 10 samples), then the contamination of the sample (presence of the specified microorganisms) is checked by laboratory tests. Each tested sample must show the expected property value.

2) Samples not artificially contaminated / Homogeneity testing of negative samples of quantitative tests: The homogeneity of samples intended for testing is accepted if all samples gave results below the detection limit of the selected test method.

3) Stability: The external service laboratory preparing the samples checks by testing 3 samples to see if any unexpected microbial growth occurred in the given sample during the PT round, stored under the specified conditions, which would affect the results obtained for the tested parameters.

Qualitative tests at the parasitological PT round:
Homogeneity testing of PT samples is carried out according to **ISO 22117 standard 6.2.** In the case of *Trichinella* detection, the test sample package contains a minimum of 3 samples to be tested. The meat matrix comes from an animal that is verified to be free of *Trichinella.* The number of live larvae required for the preparation of the positive sample must be pipetted onto a watch glass under a stereomicroscope, the number of larvae must be checked again under a stereomicroscope (documented), then the larvae must be washed from the watch glass into the prepared, dispensed sample with PBS solution. The watch glass must then be checked again under a stereomicroscope to ensure that no larvae remain on it (documented). The infection of the samples must be carried out by a minimum of 2 suitably trained persons to ensure the necessary checks.
The external service laboratory preparing the samples checks by examining 3 samples whether *Trichinella* larvae can be adequately detected in the given sample during the PT round, stored under the specified conditions.

For other non-microbiological PT samples (presence / absence):
1) Artificially contaminated samples / homogeneity testing of parameters naturally occurring in the sample: The number of samples to be tested is determined based on point 11.2.3 of ISO **13528** (min. 10 samples), then the results of the tests performed with the chosen test method must show the expected property value for each tested sample.

2) Homogeneity testing of samples not artificially contaminated / parameters not naturally occurring in the sample: The homogeneity of PT samples is accepted if all samples give results below the detection limit of the selected test method.

3) Stability: The external service laboratory preparing the samples checks by testing 3 samples whether any compositional changes occurred in the given sample during the PT round, stored under the specified conditions, that would affect the results obtained for the tested parameters.

Verification of quantitative homogeneity test results:
In the case of PT samples in which the given parameter is present in quantities above the detection limit, we proceed as follows:

1) Filtering out errors resulting from data recording and accidental errors arising during measurement based on visual inspection.

2) *homogeneity tests when the target standard deviation of the PT is known/estimated*: Verification of the criterion that the standard deviation between samples is less than or equal to 30% of the standard deviation of the given PT round (**ISO 13528**). This is done for each parameter subjected to homogeneity test using the **PROLab Plus** software "ISO 13528:2022 – test for adequate homogeneity". If the homogeneity results for the given parameter do not meet the criterion, the following options can be used:

- The acceptance range of the original criterion can be extended based on **ISO 13528**

B.2.3, according to which the modified target standard deviation of the PT round is nothing more than the square root of the sum of the PT target standard deviation and the standard deviation between samples. In the case of the **PROLab Plus** software we determine compliance with the extended criterion using the "ISO 13528:2022 – test for significant heterogeneity ".

- Cochran's outlier analysis (Cochran's test) can be applied to the basic data, after removing the outliers, compliance with the original criterion is re-checked. The Cochran's test is evaluated using the **PROLab Plus software according to the ISO 5725-2 standard**.

3) *Evaluation of homogeneity tests when the target variance of the PT is not known/estimable in advance:* If the $SDPA_{PT}$ is not known or cannot be estimated in advance, the following options may be used to determine homogeneity criteria:

   - Application of F-test analysis of variance at a 95% confidence level (α=0.05), in the case of **PROLab Plus** software, application of "F-test".
   - Post-verification of the homogeneity test: based on the received results of the PT round, the $SDPA_{PT}$ is determined using robust statistics to verify the criterion n, namely that the standard deviation between samples is less than or equal to 30% of the standard deviation of the given PT round (**ISO 13528**). In this case, the Provider assumes the risk that the inadequate homogeneity of the samples intended for the PT round is revealed subsequently after the distribution and the participant measurements. If the criterion is not met, the extended criterion can only be used if the target standard deviation of the PT is not determined from the participant results using robust statistics. This is because the robust target standard deviation already includes the deviation resulting from the inhomogeneity between samples.

4) *Evaluation of stability studies when the target standard deviation of the PT is known/estimated*: checking the criterion that the absolute value of the difference between the means of the homogeneity and stability results is less than or equal to one third of the target standard deviation of the PT. In the case of the **PROLab Plus** software, the "Test for stability ISO 13528:2022" application. If a criterion is not met and it is likely that it is due to the uncertainty and precision of the measurement method used, the acceptance criterion can be extended to include the uncertainty of the homogeneity and stability results based on the following formula:

$$|\bar{H} - \bar{S}| \leq 0{,}3 * SDPA_{PT} + 2\sqrt{u^2(\bar{H}) + u^2(\bar{S})}$$

where,
$\bar{H}$: average of homogeneity results,
$\bar{S}$: average of stability results,
$SDPA_{PT}$:the target standard deviation of the PT round,
$u^2(\bar{H})$: measurement uncertainty of homogeneity results
$u^2(\bar{S})$:measurement uncertainty of stability results.

PROLab Plus software, the "Test for stability ISO 13528:2022 - expanded criterion". The uncertainty is determined according to the following formula:

$$u_{mean} = \sqrt{\frac{s_B^2 - s_W^2}{n_{sample}} + \frac{s_w^2}{n_{sample} * n_{repetitions/sample}}}$$

where,
u_{mean}: uncertainty of homogeneity and/or stability averages,
s_B^2: standard deviation between samples,

s_W^2: within-sample standard deviation,
n_{sample}: number of samples intended for homogeneity and/or stability testing,
$n_{repetition/sample}$: number of repetitions.

Date of performance of homogeneity and stability tests

1) *For homogeneity tests*: The Provider sets the deadline for completing the tests considering the time required to resolve any problems that may arise that cause inhomogeneity (e.g. re-homogenization of the base sample).

In the case of microbiological samples, homogeneity tests are performed after sample distribution on the same day as the processing time of the participant samples. This is because the PT samples need to be prepared the day before sample distribution in order to ensure that their bacterial counts are within the measurable range. Timing the microbiological contamination of the samples to an earlier time is not practical due to the high degree of uncertainty in the temporal development of the viable bacterial count. Homogeneity sample processing at the same time as the participants (in the same way) provides sufficiently reliable results that relate to the time state of the PT samples at the time of processing, which confirm the homogeneity of the bacterial count distribution of the PT samples at the time of processing.

b) *In the case of stability tests*: The requested external service provider will begin the tests no later than the deadline for submitting the results of the given PT round.

Acceptance criteria for samples for proficiency testing:
In case of satisfactory homogeneity results, the sample can be released for the proficiency test. If the PT samples prove not to be homogeneous, the Provider will notify the participants of the new date set or the cancellation of the proficiency test round.
If the stability test results meet one of the criteria, the PT samples can be considered stable. If none of the acceptance criteria are met, the Provider will not evaluate the submitted results and will notify the participants of the PT round about the cancellation of the PT round. After investigating the reasons for the non-compliance with the stability, the Provider may decide to re-organize the given PT round.

9 Distribution of PT samples

The planned time of distribution of PT samples is included in Annex 1. A notification will be sent out prior to sample distribution regarding the exact time and method of sample collection and sample delivery.
The distribution of PT samples takes place at 1095 Budapest, Mester u. 81. In case of different practices, we will inform the participants about the exact location of the collection. In some cases, we will send the samples by post, which is indicated in Annex 1 for the relevant PT rounds.
Samples are sent to Nébih's own laboratories via internal rounds based on the relevant *Nébih Official Sample Transport Procedure.*
During each PT round, on the day of sample collection, the participant will receive a proficiency test code number notification in a sealed envelope on paper with the sample, in order to ensure confidentiality, and detailed instructions and a results sheet will be sent by email.
If the PT sample is damaged or lost during transport, or if the participant does not receive it for some reason, the person concerned will receive a new sample after consultation with the coordinator.

10 How to submit results

The measurement results are sent to the Providers via e-mail on the previously sent Microsoft Excel-based *result sheets* to the address korvizsgalat@nebih.gov.hu. The Provider confirms the

submitted results by e-mail. After the deadline for submitting the results, the participant is no longer able to modify the result sheet.

11 Determination of the assigned value

Assigned value and uncertainty of the certified reference material (CRM) and reference material (RM): in the case of CRM made according to ISO 17034, the assigned value and uncertainty are given by the value determined by the manufacturer, in **the case of RM, the reference value** and uncertainty determined by measurement, analysis or comparison (e.g. based on the results of previous proficiency tests).

Determination of the assigned value of spiked PT samples (Formulation): can be used by the Provider in PT rounds where PT samples are prepared by spiked material, where the added property value is precisely known. For example, spiked toxins to a matrix, spiked contaminants to a seed sample, etc. For the correct implementation of the formulation, it is important to know the amount of the parameter originally present in the matrix, which is modified by spiked material. The uncertainty estimate is determined by calculation in the **PROLab Plus** statistical software. The Provider does not apply this approach in the case of microbiological samples, where, although spiked material is used, the uncertainty of the living material does not allow for a sufficiently reliable estimate using the formulation.

Determination of the assigned value and its uncertainty using the results of an external service laboratory: In this approach, the assigned value and its uncertainty are determined using the homogeneity test results of the external service laboratory commissioned to perform the homogeneity tests, as an expert laboratory.

Consensus assigned value and its uncertainty from participant results: The assigned value is calculated from the participant results (consensus value) as described in **ISO 13528.** In this approach, the assigned value is considered as a location indicator (location indicator e.g. robust -, arithmetic mean, median, mode, etc.).

- Robust method evaluation: The Provider decides whether the robust data analysis method can be applied based on the graphical representation of the results. The coordinator uses a density function (Kernel density distribution) for the display, the advantage of which compared to the histogram is that it can better determine the shape of the distribution. The robust method can be used on a data set with a normal or near-normal distribution contaminated with outliers, but not in the case of a bi- or multimodal distribution. In the case of a bi- or multimodal distribution, it is necessary to switch to the formation of a subgroup of the results. Most often, these phenomena are caused by the differences in the methods used, in which case the results given by the different methods must be evaluated separately. Exceptions are cases where the formation of subgroups would cause a distorted performance assessment due to the small number of results (e.g., in the case of 10 participants with a 6-2-1-1 method application distribution, there would be nothing to compare the participants who were the only ones to use a method).

  If the nature of the data allows the use of robust methods, the coordinator should prefer the Q/ Hampel method when determining the assigned value, as it shows the best properties in terms of breakpoint and efficiency.

  When determining the uncertainty of the assigned value, the following model shall be used:

$$u(x_{pt}) = 1{,}25 * \frac{s^*}{\sqrt{p}}$$

where

s^*= robust standard deviation of results (here a result = the average of the measurement results of a participant),

p = number of participants,

1.25 = factor based on the standard deviation of the median.

- Non-robust evaluation method: The coordinator performs outlier treatment on the results in **PROLab Plus** software as appropriate. After removing gross errors and outliers, a simple average can be calculated per sample.

Determination of the assigned value of qualitative tests: Confirmatory tests are required (exception: CRM and RM samples). The Provider primarily considers measurements performed to test homogeneity as confirmatory tests.

12 Determining the target variance of PT

Regulatory or "fit for" purpose" principle for determining the target spread: In this approach, a "fit for purpose" assessment is made by a regulation, a regulatory authority, an accreditation body, the Provider's experts or a professional source. This principle is applied to determine the SDPA.

In the case of microbiological PT rounds, according to the **MSZ EN ISO 22117:2019** standard, the SDPA "fit for purpose" is usually 0.25 log CFU /g (or log CFU / ml) value, unless the given matrix-microorganism combination has a sensitivity resulting in a higher standard deviation, which is inferred from the homogeneity test results. In such a case, we set an SDPA value of 0.5 log CFU /g (or log CFU / ml) for the matrix-microorganism combination concerned, using the "0.5 $\log_{10}$ rule" described in the **MSZ EN ISO 22117:2019** standard.

SDPA based on a previous PT round: if data with sufficient reliability and experience from a previous PT round for the same matrix/parameter combination is available, then this approach can be applied. In this case, an SDPA determined using a robust approach should be used.

Modified Horwitz model from the results of the current PT round: can be used for analytical methods, considering the requirements of inapplicability. The Provider performs the calculation of SDPA in the **PROLab Plus software.**

Thompson's modification of the empirical Horwitz curve equation is shown in the following formula:

$$\mathrm{RSD}_R = 2^{(1-0{,}5log_{10}C)} \Rightarrow \sigma_R = \sigma_{pt} = \begin{cases} 0{,}22 * C & ha \quad C < 1{,}2 * 10^{-7} \\ 0{,}02 * \mathrm{C}^{0{,}8495} & ha \quad 1{,}2 * 10^{-7} < C < 0{,}318 \\ 0{,}01 * \mathrm{C}^{0{,}5} & ha \quad C > 0{,}138 \end{cases}$$

where: σ_R = reproducibility standard deviation;

σ_{PT} = SDPA

C = concentration expressed as a mass fraction

The concentration of AC is equal to the assigned value:$C = x_{pt}$

SDPA using the results of an external service laboratory: In this approach, the SDPA is determined using the homogeneity test results of an external service laboratory commissioned to perform the homogeneity tests, as an expert laboratory.

SDPA as a consensus value from participant results: SDPA is determined based on participant results (consensus value) as described in **ISO 13528.**

- In robust method evaluation: In this approach, the SDPA is determined using robust methods whenever possible. The coordinator should also prefer the Q/Hampel method when determining the SDPA, as it shows the best properties in terms of breakeven point

and efficiency.

- In case of evaluation using a non-robust method: After removing gross errors and outliers, the standard deviation can be calculated per sample.

13 Statistical evaluation of test results

The statistical evaluation of the test results is different for each round.

If the number of results submitted per parameter is <10 and results from a homogeneity test are available, the assigned value and SDPA are determined from these. If no results from a homogeneity test are available, the evaluation is carried out under non-accredited conditions due to low statistical reliability.

Handling of serious errors:

Obvious gross mistakes (= blunder = gross error) will be excluded from the statistical evaluation by the Provider, after the data has been aggregated, but before the data analysis begins. The same applies to incorrect data resulting from administrative errors and calculation errors - i.e. formally incorrect results will be excluded from the evaluation as gross errors. In this case, the received test results will also be indicated in the Final Report of the PT round as a result of an "inadequate" performance value, with the comment "gross error/outlier". If it is not clear whether it is a gross error, the coordinator will keep the values in question in the data set and proceed to handle the outliers.

Handling outliers:

When test results are included in the statistical evaluation, the Provider, if possible, handles outliers by applying a robust statistical method. In this case, no separate outlier handling is required, since the sensitivity of the robust mean and robust standard deviation statistical indicators is not sensitive to the presence of values that deviate significantly from the basic tendency of the grouping (i.e., outliers).
If we do not use a robust method, after removing the gross errors, we perform an outlier analysis in **PROLab Plus** software.
Although graphical and numerical outlier tests (Table 1) follow similar principles, significant differences between them can lead to different results for the same data set. Therefore, a value should be considered an outlier if both graphical and numerical outlier analysis identify it as an outlier.

Table 1: Choice of outlier analysis methods

To be decided: Are repeated measurement results available?	**Graphical method available**	**Numerical method available**
Repeated measurement results are **not available** – Deviation from the average	Mandel's h statistics	Grubbs test
Repeated measurement results **available** – Deviation from variability of test results	Mandel's k statistics	Cochran test

Mandel's h & k statistics
In the case of *Mandel h*, an interlaboratory consistency statistic (h) is calculated for each laboratory.

$$h = \frac{\text{laboratory mean} - \text{overall mean}}{\text{standard deviation of the laboratory mean}}$$

In the case of *Mandel k*, an intra-laboratory consistency statistic (k) is calculated for each laboratory.

$$k = \sqrt{\frac{\text{number of the laboratories} - \text{variance of the laboratories}}{\sum \text{variance of the laboratories}}}$$

The plot shows the calculated h or k values as a function of the laboratory codes in a bar chart. The columns of values that are statistically significantly different from the other values are given a different colour:

- yellow bars: significant difference at 5% significance level;
- red bars: significant difference at 1% significance level.

In the case of the Mandel's h statistic, each laboratory can have both positive and negative h values, while in the Mandel's k statistic the k value is always positive.
If one laboratory stands out on the k statistical curve with many large values, it means that it has poorer reproducibility accuracy than the other laboratories.

Grubbs and Cochran test:
The Grubbs and Cochran tests are performed by the **PROLab Plus** software in accordance with the requirements of the **MSZ ISO 5725-2** standard.
The Grubbs test is similar to Mandel's h statistics, calculating the standard deviation of the mean, while the Cochran test is similar to Mandel's k statistics, working with analysis of variance. The calculation results pop up in a separate tab with the relevant legend.
The outlier results flagged by the software are reviewed by the Provider and manually set which results the system will consider as outliers when calculating the assigned value and the standard deviation of the PT (SDPA). According to **ISO 13528 6.6.3.,** results identified as outliers are not excluded from the statistical evaluation, they are only excluded when calculating the consensus assigned value and the SDPA.

Evaluation of quantitative results (except for seed PT samples and radioactively labelled PT samples):

In the case of quantitative studies, only numerical measurement results may be included in the statistical performance evaluation. Results that the participant provides with the notation "<" or ">" cannot be evaluated using quantitative statistical methods and are excluded from the statistical evaluation. The method of handling results provided with the notation "<" and ">" applies uniformly to all participants.

When evaluating participants' results, they are converted into performance statistics, enabling comparison with defined objectives. The goal here is to present the deviation from the assigned value in a simple way that is understandable to the participants.

In the case of microbiological PT, the first step in evaluating the results is to apply a logarithmic transformation using **Excel® software** to conform the data set to the normal distribution requirement. In this process, all values are replaced by their base ten logarithms according to the following function:

$$x_i' = \log_{10} x_i$$

The results are evaluated in accordance with **MSZ EN ISO/IEC 17043** and **ISO 13528 using PROLab Plus** software. Before determining the performance evaluation method for the participants, the standard uncertainty of the assigned value and the target value of the standard deviation are compared for the test parameter based on the following formula:

$$u(x_{pt}) < 0.3\sigma_{pt} \Rightarrow \frac{u(x_{pt})}{\sigma_{pt}} < 0.3$$

where: $u(x_{pt})$ = standard uncertainty of assigned value,
σ_{pt} = standard deviation target = SDPA.

If the quotient in the above formula for a given parameter is less than 0.3, then the Z- score is calculated, if it is greater, then the Z'- score is calculated according to the **ISO 13528** standard. In the latter case, the standard uncertainty of the assigned value is then so large that it would significantly influence the Z- score value.

$$Z_i = \frac{x_i - x_{pt}}{\sigma_{pt}} \qquad Z_i' = \frac{x_i - x_{pt}}{\sqrt{\sigma_{pt}^2 + u^2(x_{pt})}}$$

where: x_i = measurement result of the participating laboratory;
x_{pt} = the assigned value of the component to be determined;
σ_{pt} = target standard deviation;
$u(x_{pt})$ = standard uncertainty of assigned value.

Z- and Z'- score:

- |Z- or Z'- score| ≤ 2.0	Adequate performance;
- 2.0 < | Z- or Z'- score | < 3.0	Questionable performance, the result has a warning sign;
- |Z- or Z'- score| ≥ 3.0	Inadequate performance, the participant's activity requires intervention, does not meet the requirements.

The results are given at a 95% probability level.

Evaluation of seed proficiency test results:

The evaluation is based on the *Tattersfield* method (1979 - Seed Science and Technology 7, (2), 247-257) using the **PROLab Plus** software, and the Z- score or Z'- score values are calculated from the averages of the test results of each sample according to the following formulas:

$$Z_i = \frac{x_i - x_{pt}}{\sigma_{pt}} \qquad Z_i' = \frac{x_i - x_{pt}}{\sqrt{\sigma_{pt}^2 + u^2(x_{pt})}}$$

where: x_i = measurement result of the participating laboratory;
x_{pt} = the assigned value of the component to be determined;
σ_{pt} = target standard deviation;
$u(x_{pt})$ = standard uncertainty of assigned value.

The obtained Z- scores /Z'- scores are then simply added together to calculate an absolute Z- score /Z'- score for each participant using **Excel®** software. Performance is assessed based on the absolute Z- score /Z'- score.

the absolute Z- score /Z'- score:

-	|absolute Z- or Z'- score| ≤ 3.5	A (excellent) performance
-	3.5 < | absolute Z- or Z'- score | ≤ 5.3	B (good) performance
-	5.3 < | absolute Z- or Z'- score | ≤ 7.0	C (adequate) performance
-	|absolute Z- or Z'- score| > 7.0	D (inadequate) performance

The results are given at a 95% probability level.

In case of *foreign seed content* testing, the evaluation is based on the detection and identification

rates of foreign seeds added to the samples, given at least at the genus level, in percentage form, considering the relative difficulty of detecting each added seed type.
There are three levels of foreign seed identification, all of which are accepted during evaluation:

1. *Correct species?* – Correct definition at the species or lower taxonomic category level;
2. *Correct genus?* – Correct definition at the genus level;
3. *Wrong name (different species)?* – Correct genus, but incorrect species level definition.

If the species cannot be determined with certainty based on the seed characteristics, the determination should be made according to the most accurate taxon possible. We do not accept the use of synonymous names as correct. Any extraneous seeds that may be present in the basic sample will be ignored in the evaluation.
The number of found and determined seeds must be counted per foreign seed-type, then divided by the number of added foreign seeds included in the participant samples (i=number of participant samples), this gives the current detection percentage (m%).

$$\text{Actual found foreign seed \%} = \frac{\sum_{i=1}^{n} \text{number of found and determined seeds}}{\text{number of added foreign seeds} * \text{i(number of the participant's samples)}}$$

From this, the factor (f) assigned to the given species is determined as described in Table 2, which expresses the difficulty of finding it.

2: Determination of factors that can be assigned to a given species

Foreign core detection percentage [%]	**Factor**
From 90	3
From 85 to 90	2
Under 85	1

The number of seeds added must be multiplied by the factor per seed type (a) and the values added together (a_{sum}).

$$a_j = \text{number of added foreign seeds} * f,$$
$$a_{sum} = \sum_{j=1}^{n} a_j,$$

where,
j= added foreign seeds

The number of seeds actually found must also be multiplied by the factor per seed type (m) and the values added together (m_{sum}).

$$m_j = \text{number of seeds actually found} * f,$$
$$m_{összeg} = \sum_{j=1}^{n} m_j,$$

The sum of the values of the actually found seeds multiplied by the factor shall be expressed as a percentage of the sum of the values of the added cores multiplied by the factor (E%). = the sum/ (m sum/100).

$$(E\%) = \frac{m_{sum}}{a_{sum}} * 100$$

The result can be evaluated based on E%:

Evaluation	**Percentage**
Excellent	90
Good	80
Suitable	70
Not suitable	< 70

Radiolabelled radioanalytical proficiency test results:

The assessment is carried out by the **IAEA (International Atomic Energy Agency). Energy Agency)- TEL-2018-04 ALMERA Proficiency Test Exercise, Individual Evaluation Report Part I.** The submitted test result ($A_{reported}$) and measurement uncertainty ($u_{reported}$) are compared with the activity determined based on the activity of the reference solution (A_{target}) and the associated measurement uncertainty (u_{target}). When estimating the uncertainty of the target value, the requested external service laboratory considers the uncertainty of the reference solution, the uncertainty of sample preparation, the physical background of the radioanalytical methods, the level of radioactivity and the complexity of the task.
This evaluation method emphasizes the importance of measurement accuracy (the relative deviation between the target value and the reported result). The first condition for accepting the result reported by laboratories is the permissible relative deviation, while the warning refers to an underestimated or overestimated measurement uncertainty.
The evaluation consists of several steps:
1.) Relative difference between the submitted result and the target value (relative bias) is determined by the following formula:

$$\mathrm{Bias}_{\mathrm{relative}}\ (\%) = \frac{\mathrm{A}_{\mathrm{reported}} - \mathrm{A}_{\mathrm{target}}}{\mathrm{A}_{\mathrm{target}}} * 100$$

2.) The relative deviation is then compared with the maximum acceptable relative deviation (Maximum Acceptable Relative Bias – MARB) for each individual test, considering the physical background of the radioanalytical method, the relationship between the activity concentration of the sample and the detection limit, and the complexity of the task.
If the
$|\mathrm{Bias}_{\mathrm{relatív}}\ (\%)| \leq \mathrm{MARB}$,
then the result will be **"acceptable"** in terms of accuracy.
If the above condition is not met, the result is considered a **"failure"** in terms of the final evaluation, regardless of precision.
3.) Precision (P) considers not only the reported result but also its uncertainty, thus providing information on how well the given method was controlled in the laboratory.

$$\mathrm{P}\ (\%) = 100 * \sqrt{\left(\frac{\mathrm{u}_{\mathrm{target}}}{\mathrm{A}_{\mathrm{target}}}\right)^2 + \left(\frac{\mathrm{u}_{\mathrm{reported}}}{\mathrm{A}_{\mathrm{reported}}}\right)^2}$$

When evaluating precision, two conditions must be met:

$$\mathrm{Bias}_{\mathrm{relative}}\ (\%) \leq \mathrm{k} * \mathrm{P}$$

and
$\mathrm{P}(\%) < \mathrm{MARB}$,
where k is the expansion factor (2.56 at the 99% confidence level).

The first criterion helps to decide if the reported result falls within the target value ± MARB range, but the uncertainty of the target value and the uncertainty of the reported result do not overlap. Excessive measurement uncertainty is ruled out by checking that the second criterion is met.
If both conditions are met, the result is **"accepted",** if one of them is not met, the result will be **"failed"** in terms of precision.
4.) Final evaluation: The result is **"accepted"** if both accuracy and precision are accepted. The result **is "failed"** if it failed the accuracy assessment, regardless of the precision assessment. The laboratory receives a **"warning"** if its accuracy is accepted but the measurement uncertainty is over- or underestimated.

Evaluation of qualitative results for microbiological PT samples:

In the case of those parameters of qualitative tests where the results are below the detection limit of the test method used during the homogeneity test (samples not artificially

contaminated), in the case of submitted "less than" results, this or the results above this are considered, the quantified results below this are accepted as adequate, the quantified results above this are not accepted, the evaluation will require intervention.
In quantitative determination, only the participant who achieved a satisfactory result for both negative and positive samples will receive a "Pass" rating.
During detection tests, the qualitatively confirmed result (i.e. whether the given sample is positive or negative) is provided by the homogeneity test result of the external service laboratory. Only the participant who can adequately detect the presence or absence of the relevant parameter in all samples will receive a "Satisfactory" rating.

Evaluation of qualitative results in parasitological (*Trichinella*) PT samples:

According to Commission Implementing Regulation (EU) 2015/1375, the test should only determine the presence or absence of the parasite. Accordingly, the evaluation of the participant results received is based on the number of false positive (false positives) and false negative (false negatives) samples.
For proper classification, testing sites should not have false positive or false negative samples.
The qualitative assessment is carried out according to the recommendation of the International Commission on Trichinellosis (Gajadhar AA, Noeckler K, Boireau P, Rossi P, Scandrett B, Gamble HR. International Commission tin Trichinellosis: Recommendations for quality assurance in digestion testing programs for Trichinella. Food Waterborne Parasitol. 2019 Jun 5; 16:e 00059. doi : 10.1016/j.fawpar.2019.e00059. PMID: 32095629; PMCID: PMC7033998.).

Evaluation of qualitative Trichinella tests:
- For positive samples spiked with 3-5 larvae:
    - Adequate result: ≥1 larva recovered (true positive);
    - Inappropriate result: The participant classified the sample as negative, no *Trichinella* larvae were recovered. (false negative)
- Regarding negative samples:
    - Correct result: The PT sample did not contain larvae (true negative)
    - Inconsistent result: Sample contained ≥1 larva (false positive)

Evaluation of quantitative Trichinella tests:
The recovery rate is considered to be acceptable, if the recovery percentage of *Trichinella larvae* recovered from samples given to participants is ≥75.
During the evaluation of the PT round, we perform the compliance assessment from the qualitative data based on the above-mentioned aspects. We do not consider the recovery percentages as quantitative results, they are evaluated for informational purposes only.

Handling of participant-reported measurement uncertainty (u_i) and expanded measurement uncertainty (U_i):
Zeta score (ζ score) and $E_n$score performance values is not widely used for performance evaluation of testing laboratories outside of PT programs covering various areas of calibration (**ISO 13528:2022 9.8.1.**).
The Provider does not use the measurement uncertainty and expanded measurement uncertainty values reported by participants for the statistical evaluation of performance $E_n$for the purpose of calculating ζ or score values, but may request them for informative purposes.

The advantages of this type of data collection include:

a) the accrediting bodies can ensure that participants communicate uncertainties consistent with their area of accreditation;

b) Participants can cross-check their reported uncertainties with those of other participants to determine consistency (or lack thereof) and thus have the opportunity to identify relevant components that may have been overlooked or over-considered in their uncertainty assessment;

c) PT can be used to confirm uncertainty statements, which is easiest when the uncertainty is communicated with the result (**ISO 13528:2022 9.8.2.)**.

14 Method of publishing results

The final report will be sent to the participants by e-mail as soon as possible after the deadline for receipt of the results of a PT round. In the final report, the participants will only be listed with an identification code when indicating the results in order to maintain confidentiality. **Since 2024, the Provider has also been publishing the final reports on its website.**

In the event of any interpretation or dispute concerning a final report issued in a foreign language, the final report in force issued and approved in Hungarian language will be considered decisive, except if the given final report was issued only in the specific foreign language.

15 Participant's responsibility

By applying for the PT program, the participant undertakes to perform the necessary tests in his own laboratory, with his own equipment and his own personnel, and to submit his own, independent results to the Provider as test results.

16 Confidential case management

The management of the Nébih Food Chain Safety Laboratory Directorate and the staff organizing the proficiency test declare that during their work, the data, code and results of the participants will be treated secretly and confidentially, unless the participant waives confidentiality or if the law provides otherwise.

The evaluation of the measurement result in the final report and publications is done only with a code number.

The Provider will transfer the code, results and performance evaluation of the participants in the *Trichinella* PT round to the regulatory authority specified in the application form in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council, without sending a separate notification to the Laboratories concerned.

Pursuant to Section 4 (1) a) of Regulation 180/2009. (XII.29.) of the Ministry of Agriculture and Rural Development on certain rules for the control of salmonellosis, and Annex II d) of Decision 2004/564/EC on Community reference laboratories for the epidemiology of zoonoses and for salmonella and national reference laboratories for *Salmonella*, the Organiser will send the codes, results and performance evaluations of the participants in the PT round of the " Determination of the presence of *Salmonella spp.* from poultry environmental hygiene samples, followed by further examination of the isolated Salmonella bacterial strains to exclude the presence of *S.* Enteritidis and *S.* Typhimurium based on serogroup "O" to the regulatory authority, of which no separate notification will be sent to the participants concerned.

If another regulatory authority directly requests the results of the proficiency test, the

Laboratory will be notified in writing.

17 Complaint handling

The Provider shall accept complaints regarding the PT results from the client/participant within 8 calendar days of sending the final report. If the complaint concerns the administration, the handling of the PT sample, the conduct of the staff or the activities of the Provider in a manner not specifically related to the statistical evaluation of the participant's performance, then, after proper identification of the client/participant, the complaint shall also be accepted within 30 calendar days from the triggering event. The Provider shall investigate complaints in all cases within the shortest possible time. The documentation shall include the corrective measures taken to eliminate the cause of the complaint and the Provider shall inform the complainant in writing about the measures taken.

Application deadline:
06 February 2026

For detailed direct information about the proficiency testing program, please contact:

E-mail: korvizsgalat@nebih.gov.hu

We look forward to your order!

Budapest, 05 October 2026

Sincerely,

Péter Bogáth
department head

Attachments

Annex 1: 2026.Annual proficiency test plan (available on the website).

Annex 2: Application form 2026 (can be found on the website).

Annex 3: Trichinella application form_ 2026 (can be found on the website)