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Guideline for Laboratories and GMO testing – Binding Requirements

Content

Note: For easier readability, the masculine gender is used in the text for personal designations. Nevertheless, the information refers to both genders. All terms not defined in this Guideline have the same meanings as in the glossary for the “Ohne Gentechnik” Production and Certification Standard.

The following describes the requirements that laboratories and testing must meet within the scope of a VLOG certification. Test results for businesses to be certified are recognised only if the requirements of these Guidelines are met by laboratories and the laboratories are recognised by VLOG.

In addition to the requirements to be met, this Guideline also details the recognition process for laboratories.

The list of recognised laboratories can be viewed on VLOG's website https://www.ohnegentechnik.org/en/for-test-laboratories/recognised-laboratories.

1 Requirements to be met by Laboratories

1.1 General Requirements

1.1.1 Accreditation

The laboratory must be accredited according to DIN EN ISO/IEC 17025 (in its most recent version) for all qualitative and quantitative GMO test parameters and determination of soy mass. This may be in the form of a flexible accreditation for the entire parameter or separately for all procedures to be carried out.

Explanation: The minimum requirement for recognition is that all qualitative (screening elements) and/or quantitative tests that are part of a matrix (e.g. soy) are passed.

1.1.2 Requirements for the test scope

The requirements for the test scope in accordance with Annex 1 of this Guideline must be complied with by the laboratory.

If a sample to be tested contains untestable components, the sample shall be tested as if these components were not contained in it. Example: A compound feed contains corn and rapeseed components to be tested and a non-testable refined soybean oil. In this case, the compound feed can be tested in accordance with the requirements of the test scope as if the soy was not an ingredient. This means that the soy mass of the compound feeds must also be estimated.

The VLOG website offers an assessment aid for determining the suitability of raw materials for testing:
https://www.ohnegentechnik.org/fileadmin/user_upload/01_unternehmen/e_standards/e1_der_vlog_standard/Further_Documents/Suitability_of_GMO_Analysis_for_Feed_Raw_Materials_and_Foods.pdf

1.1.3 Participation in interlaboratory tests

The laboratory participates in the following interlaboratory tests and achieves good results:

- An interlaboratory test for qualitative GMOs results (100% correct positive or negative results) for the matrix of feed or plant-based raw materials/plant-based processed products.
  At least two events or screening elements explicitly required by VLOG (see Annex 1) are covered as quantitative tests.

- An interlaboratory test for quantitative GMOs results with a satisfactory z-score[1], in which at least two events explicitly required by VLOG (see Annex 1) are covered as quantitative tests and
- An interlaboratory test for determining the soy mass (the interlaboratory test is organised by VLOG) with a satisfactory z-score[1]

Three GMO test parameters[2]

Following successful initial recognition, the laboratory must prove to VLOG that it has participated in at least two of the aforementioned interlaboratory tests with satisfactory results no later than 31 March of each subsequent year to maintain recognition. Successful participation in each of the audits must be proven at least twice every three years (see Figure 1).

One or two GMO test parameters

Following successful initial recognition, laboratories that only perform part of the required GMO testing parameters (qualitative tests, quantitative tests and/or soy mass determination) (e.g. within the scope of subcontracting or outsourcing) must prove to VLOG successful participation in the number of interlaboratory tests listed in the following figure.

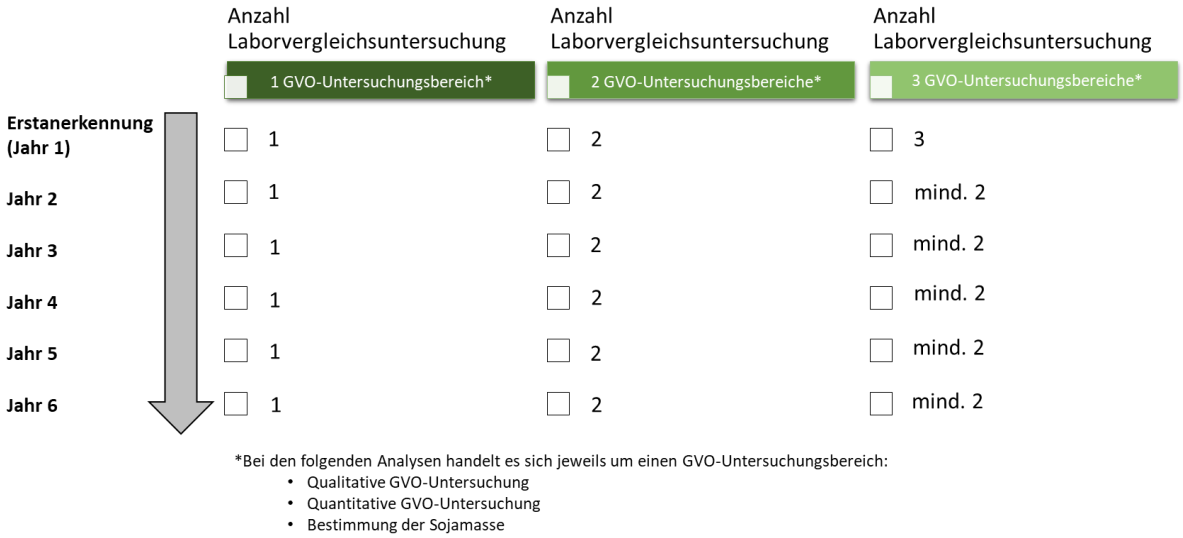

Figure 1: Number of annual interlaboratory tests to be proven

[1] The test is passed if at least 75% of the results are in the +/-2 range of the z-score. A maximum of one value may have a z-score of max. +/- 3. For events not required by VLOG, a value must have a "z score"of no more than >+/- 3 if an appropriate actions log, cause plan or position statement regarding it has been submitted to VLOG.

[2] The following tests respectively deal with a different GMO testing parameter: qualitative GMO test, quantitative GMO test, test for determining soy mass.

Practical example under Figure 1: A laboratory that carries out all the required GMO test parameters itself, must submit, e.g., the following interlaboratory tests to VLOG to maintain recognition:

Year 1-2019 (initial recognition): Qualitative and quantitative GMO tests, determination of soy mass

Year 2–2020: Qualitative and quantitative GMO test

Year 3–2021: In the third year, the laboratory must prove successful participation in soy mass determination and, e.g., qualitative GMO tests.

Year 4–2022: Qualitative and quantitative GMO test

Year 5-2023: No later than the fifth year, the laboratory must again successfully participate in an interlaboratory test for determining soy mass and in a quantitative GMO test, etc.

To maintain recognition, a laboratory that only carries out one or two of the required GMO test parameters itself, must submit successful interlaboratory tests to VLOG for all test parameters carried out by itself no later than 31 March of each year.

An interlaboratory test for determining the soy mass will be organised by VLOG on a regular basis. If the laboratory does not pass the interlaboratory test for determining soy mass, it must outsource the determination of soy mass to another VLOG-recognised laboratory. For this purpose, a new application for VLOG laboratory recognition (master data sheet) and an outsourcing agreement between the laboratories must be submitted to VLOG. If a laboratory voluntarily participates in a round robin test for determining the soy mass and does not pass it, it must also outsource the determination of soy mass to another VLOG-recognised laboratory.

A laboratory can regain recognition for determining soy mass by successfully repeating the interlaboratory test on the next possible date. A new application for VLOG-recognition must be sent to VLOG for this purpose.

If, within the scope of the interlaboratory test, wrong results are found and the correct results from follow-up audits are submitted, then the respective laboratory must give VLOG a plausible reason for the previous wrong results. This statement is used to evaluate laboratory performance and is evaluated by VLOG.

1.2 Outsourcing Requirements[3]

VLOG laboratories have the option of outsourcing GMO tests to be performed according to the "Ohne Gentechnik" Production and Certification Standard to another VLOG-recognised laboratory.

Outsourcing of tests is permitted under the following conditions:

- All laboratories involved in GMO testing must be recognised by VLOG.
- Tests may only be outsourced to VLOG laboratories that perform any pertinent GMO tests themselves and do not further outsource them to other laboratories.

[3] Definition of outsourcing: Outsourcing takes place if the outsourcing laboratory is not accredited for the parameter. The laboratory to which the test is outsourced must also be VLOG-recognised.

- Outsourcing in compliance with VLOG's Guidelines for Laboratories is to be agreed between the participating laboratories in writing, including information on the outsourced GMO tests.
- VLOG-recognised laboratories must document which laboratories they subcontract testing to.
- Samples are to be milled entirely by a single laboratory, which then sends portions of the milled sample to the participating laboratories.
- If multiple laboratories participate in the testing, the conclusive evaluation of the sample per Chapter 1.3.5 must be performed by a VLOG-recognised laboratory. The VLOG recognised laboratory must send a test report to the principal for testing.
- The VLOG-recognised laboratories (at least the name) that perform the GMO tests is to be specified on the customer's test report.

1.3 Methodological Requirements

DIN and ISO standards and protocols of the Joint Research Centre are to be used (if available). For methods from other sources, including in-house methods, the laboratory must verify that similar minimum requirements are fulfilled and that all VLOG-relevant methods are accredited.

1.3.1 Testing process

1.3.1.1 Milling/ Preparation of samples

Depending on the sample matrix, the following minimum amounts of sample material are to be completely milled in each case:

- Feed (feed material such as post-extraction rapeseed meal and compound feed): min. 400 g, max. 1 kg, entirely milled
- Raw materials (whole maize/corn kernels, soy beans or rapeseed/canola grains, among other): at least 3000 grains or approx. the respectively corresponding sample amount (maize/corn at least 1000 g; soy at least 700 g, rapeseed/canola at least 60 g), entirely milled
- Rice: see Annex 1 No. 1.4
- Salmon: see 1.3.1.2 and Annex 1 No. 1.5
- Honey: see Annex 1 No. 1.6

Explanation: The minimum quantities referred to relate to entire grains and/or beans. For raw materials that exhibit better homogeneity (e.g. soya protein concentrate), smaller weighed portions may be used in coordination with the responsible laboratory and the client.

Explanation: The sample quantity of liquid feed to be tested, due to a change of feed from GMO-containing feed to GMO-free feed in the business, is 400 g.

1.3.1.2 Maceration (salmon)

Depending on the testing matrix, the following minimum quantities of sample material are macerated, respectively:

- Salmon filet: at least 5 g each from at least 10 animals, completely macerated
- Salmon products: at least 50 g, completely macerated

1.3.1.3 DNA extraction

At least 2 DNA extractions are performed on each sample following milling/maceration/homogenisation. The required weight is at least 2000 mg for feed, seeds, food, including salmon and salmon products as well as materials that are suspected of not being homogenously distributed. For DNA extraction from pollen in honey, the sample weight is two x 50 g.

Explanation: In exceptional cases (for otherwise non-extractable material), the weight may be only 500 mg.

1.3.1.4 PCR test

Real-time PCR methods with probe technology (45 cycles) **or digital PRC (dPCR)** are recommended. When using conventional endpoint PCR methods, an additional confirmation reaction is carried out (e.g. real-time PCR with probe technology, restriction test or sequencing). Each PCR test is performed in duplicate using the two independent DNA extractions.

added

1.3.2 Protecting the testing procedure

All quality checks according to the relevant ISO and DIN standards must yield the results required by these standards. The laboratory ensures that the measurement results are not affected by any inhibitory effects. If the measurements are so different from the control values that the tolerance limits set by the laboratory for deviations or quality specifications are exceeded, the PCR process must be repeated. Methods for regularly carrying out and documenting QC measures must be established and implemented (e.g. control charts) to recognise systematic errors, instability of reagents etc. in a timely manner and implement corresponding measures.

1.3.3 Approval of test results

The results are to be approved according to the four-eye principle by an authorised person.

1.3.4 Requirements for test reports

Aside from the information required by DIN EN ISO 24276, DIN EN ISO 21569 and DIN EN ISO 21570, test reports must contain at least the following information (Sample test report cf. Annex 2):

- Quantity of sample milled and sent
- Quantity of sample used in the DNA extraction
- Precise sample description (composition, ingredient list)
- Limits of detection (LOD in % or as copy number of target)
- Method applied

- Test result
- Measurement uncertainty of the method (for quantitative methods)
- Confirmation that the result was determined according to the requirements of the VLOG Standard. In the alternative, this confirmation takes place in a separate letter to be submitted to the certification body once a year.
- Additionally, for identification/quantification:
  - Warning if the amount of species-specific DNA is not sufficient for quantitative statements with respect to the relevant threshold value (0.1% or 0.9% GMO DNA).
  - Indicating the pLOQ is recommended.

1.3.5 Interpretation of the test results – Test and evaluation criteria

The test report must contain a conclusive evaluation for each sample regardless of whether or not the sample complies with the requirements of the VLOG Standard for the tested parameter. The use of the standard deviation is mandatory for the evaluation in order to account for the inhomogeneous distribution of GMOs in feed or food: In keeping with Regulation (EU) No. 691/2013[4] as well as the Guideline for Estimation of Measurement Uncertainty published by the German National Accreditation Body (71 SD 4 016) [5], tested GMO content, after deduction of the expanded error margin, is to be used for evaluation.

Chapter 5 and Annexes 1 and 2 of the "Guideline for Testing for GMOs in Feeds" must be taken into account for the evaluation of feed.

If a conclusive evaluation of the test results is not possible, this must be appropriately shown in the test report (note in the event of limited testability of the sample, indication of the practical LOD, missing information for single-component feeds).

The evaluation of the test report shows that the informative value of the test results only relates to the testable components of the sample examined.

2 Recognition of Laboratories

The recognition of the competent laboratories closes the final gap in that it guarantees an entirely secured system and the comparability of test results between the laboratories.

The application for VLOG recognition and the supporting documents must be submitted directly to VLOG in German or English (unless otherwise indicated). Once all the necessary documents are submitted, VLOG will review them and inform the applicant laboratory of the test results. In the event of recognition, VLOG will issue a laboratory-specific VLOG recognition number and include the laboratory in the list of VLOG-recognised laboratories.

[4] Regulation (EU) No. 691/2013 of the Commission of 19 July 2013 amending Regulation (EC) No. 152/2009 as regards methods of sampling and testing.

[5] Guideline on Estimation of Measurement Uncertainty in accordance with the requirements of DIN EN ISO/IEC 17025 for testing laboratories performing chemical testing in the areas of health protection of consumers, agriculture, chemistry and environment (71 SD 4 016, revised version 1.0, 19 January 2017).

If documents are missing or incomplete, VLOG or the service provider assigned by VLOG will request them from the laboratory. If the documents are incomplete after a second additional request, the application may be denied. If an application for recognition is denied, making another application is only possible once all necessary requirements have been met and all necessary supporting documents have been submitted.

2.1 Documents to be Submitted for Initial Recognition of a Laboratory

2.1.1 Laboratory performing tests in-house[6]

The following documents must be submitted by email by the laboratories for recognition by VLOG:

- Application for VLOG recognition of laboratories (master data sheet)
- Accreditation certificate DIN EN ISO/IEC 17025
- Technical annex to the accreditation certificate pursuant to DIN EN ISO/IEC 17025 with qualitative and/or quantitative test parameters for testing samples for genetically modified material including soy mass determination.
- For laboratories with flexible accreditation: scope of the flexibly accredited relevant GMO tests.
- Example test report with a **positive** result (Sample Test Report, cf. Annex 2), including an assessment according to the VLOG Standard as well as a legal assessment of the test results.

  Proof of successful participation (within the last 12 months) in the following interlaboratory tests (see Figure 1):

  - An interlaboratory test (*complete report including the laboratory number*) for qualitative GMOs results (100% correct positive or negative results) for the matrix of feed or plant-based raw materials/plant-based processed products, in which at least two events or screening elements explicitly required by VLOG (see Annex 1) are covered as qualitative tests and
  - An interlaboratory test (complete report including the laboratory number) for quantitative GMOs results with a satisfactory z-score[7], in which at least two events explicitly required by VLOG (see Annex 1) are covered as quantitative tests and

- An interlaboratory test (*complete report including the laboratory number*) for determining the soy mass (the interlaboratory test is organised by VLOG) with a satisfactory z-score[8]

The laboratories must send the following documents to VLOG:

- Signed Recognition Agreement in duplicate

[6] All GMO tests are performed by the laboratory itself and are not subcontracted or outsourced to other VLOG-recognised laboratories.

[7] The test is passed if at least 75% of the results are in the +/-2 range of the z-score. A maximum of one value may have a z-score of max. +/- 3. For events not required by VLOG, a value must have a "z score" of no more than >+/- 3 if an appropriate actions log, cause plan or position statement regarding it has been submitted to VLOG.

2.1.2 Outsourcing laboratory[8]

The following documents must be submitted by laboratories that outsource VLOG samples:

- Application for VLOG recognition of laboratories (master data sheet)
- Recognition Agreement
- Accreditation certificate *DIN EN ISO/IEC 17025**
- Name of the laboratory that is commissioned with the GMO tests*
- Outsourcing agreement between the laboratories, specifying the GMO tests to be outsourced*
- Example test report with a positive result (Sample Test Report, cf. Annex 2)*

* Documents that must be submitted to VLOG every three years after successful initial recognition in order to maintain recognition (see chapter 2.2).

2.1.3 Laboratory performing tests in-house[7] and outsourcing[8]

Laboratories that perform in-house testing of GMO samples and additionally outsource certain GMO tests to another VLOG-recognized laboratory must submit to VLOG, in addition to the documents mentioned in Chapter 2.1.1, the following documents for examination and approval:

- Name of the laboratory that is commissioned with the GMO tests
- Outsourcing agreement between the laboratories, specifying the GMO tests to be outsourced

Explanation: Under special circumstances such as a lack of laboratory employees or resources, VLOG-recognised laboratories have the option of subcontracting GMO tests that are to be performed according to the "Ohne Gentechnik" Production and Certification Standard for a specific parameter to another VLOG-recognised laboratory accredited for said parameter. In the event of subcontracting, the documents specified in Chapter 2.1.1 must be submitted to VLOG, along with the name of the laboratory to which the GMO testing is subcontracted to as well as an agreement between the laboratories governing the subcontracting, including specifying the GMO tests that are being subcontracted.

[8] Definition of outsourcing: Outsourcing takes place if the outsourcing laboratory is not accredited for the parameter. The laboratory to which the test is outsourced must also be VLOG-recognised.

2.2 Documents to be Submitted for a Laboratory to Maintain Recognition

After successful recognition, **laboratories that carry out GMO analyses themselves** are obliged **to upload** proof of successful participation in the previous year's comparative laboratory tests required in accordance with Figure 1 to the **labor portal** by 31.03. of each new year **at the latest for the following three years**. (practical example cf. Chapter 1.1.3). added added

- An interlaboratory test for quantitative GMOs results with a satisfactory z-score[9]
- An interlaboratory test for qualitative GMOs results (100% correct positive or negative results) for the matrix of feed or plant-based raw materials/plant-based processed products
- An interlaboratory test for determining the soy mass (interlaboratory test is organised by VLOG) with a satisfactory z-score[9]
- **Valid accreditation certificate according to DIN EN ISO/IEC 17025 including the technical annex** added

With the third maintenance of recognition, a 2-year recognition period starts and the documents only have to be uploaded to the VLOG in the laboratory portal every two years. added

If, for example, initial recognition as a VLOG laboratory takes place in 2023, recognition must be maintained in 2024, 2025 and 2026. Thereafter, the documents to maintain recognition must only be uploaded to the laboratory portal again in 2028, 2030, etc. added

All important information on this is described in the User guide for the VLOG Lab Portal. The User guide can be found at the following link:

https://www.ohnegentechnik.org/fileadmin/user_upload/03_prueflabore/e_laborportal/User_Guide_VLOG_Lab_Portal.pdf

In order to maintain their recognition, laboratories that exclusively outsource their GMO tests must resubmit to VLOG every three years the documents according to Chapter 2.1.2 required for recognition.

2.3 Documents to be Submitted for Expansion of the Scope of Recognition

- Application for VLOG recognition of laboratories (master data sheet)
- Accreditation certificate DIN EN ISO/IEC 17025
- Submission of corresponding interlaboratory test results (if available)

[9] The test is passed if at least 75% of the results are in the +/-2 range of the z-score. A maximum of one value may have a z-score of max. +/- 3. For events not required by VLOG, a value must have a "z score" of no more than >+/- 3 if an appropriate actions log, cause plan or position statement regarding it has been submitted to VLOG.

2.4 Documents to be Submitted for Renewed Recognition of a Laboratory

In addition to the documents specified in Chapters 2.1.1, 2.1.2 and 2.1.3 the laboratory must submit the following documents for the renewed recognition by VLOG:

- Proof of implementation of the corrective measures established by VLOG and the laboratory for the purposes of renewed recognition
- Additional documents and/or evidence, if necessary

3 Fees

For laboratory recognition and maintenance thereof, a fee applies according to the VLOG Fee Schedule for membership and VLOG-recognised businesses in its current version.

The fee for processing the application is due even if the application is denied.

4 Other important changes

In the event of re-accreditation or a change to the scope of accreditation, the laboratory must submit to VLOG the updated accreditation certificate according to DIN EN ISO/IEC 17025 within 4 weeks without being asked.

VLOG must be informed within two weeks of any changes affecting subcontracting or outsourcing (e.g. change of commissioned laboratory).

In the event of a change of company name, change of address or change of contact person, VLOG must be informed as soon as the changes are known. | added

5 Applicable documents

- Recognition Agreement
- Test scope (Annex 1)
- Sample Test Report (Annex 2)
- Current version of the “Ohne Gentechnik” Production and Certification Standard
- VLOG Fee Schedule for membership and VLOG recognised businesses in the current version