

Guideline for Laboratories

Content

1	Requirements to be Met by Laboratories _____	2
1.1	General Requirements _____	2
1.1.1	Accreditation _____	2
1.1.2	Requirements for the test scope _____	2
1.1.3	Participation in interlaboratory tests _____	2
1.2	Subcontracting Requirements _____	3
1.3	Outsourcing Requirements _____	4
1.4	Methodological Requirements _____	5
1.4.1	Testing process _____	5
1.4.2	Protecting the testing procedure _____	6
1.4.3	Approval of test results _____	6
1.4.4	Requirements for test reports _____	6
1.4.5	Interpretation of the test results – Test and evaluation criteria _____	6
2	Recognition of Laboratories _____	7
2.1	Documents to be Submitted for Initial Recognition of a Laboratory _____	7
2.1.1	Laboratory performing tests in-house _____	7
2.1.2	Subcontracting laboratory _____	8
2.1.3	Outsourcing laboratory _____	8
2.2	Documents to be Submitted for a Laboratory to Maintain Recognition _____	9
2.3	Documents to be Submitted for Expansion of the Scope of Recognition _____	9
2.4	Documents to be Submitted for Renewed Recognition of a Laboratory _____	9
3	Fees _____	9
4	Other important changes _____	9
5	Applicable documents _____	10

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.

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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 will be posted on VLOG's homepage <http://www.ohnegentechnik.org/links/>.

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.

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
- An interlaboratory test for quantitative GMOs results with a satisfactory z-score¹ and
- An interlaboratory test to determine the soy mass (the interlaboratory test is organised by VLOG) with a satisfactory z-score^{Fehler! Textmarke nicht definiert.}

3 GMO test parameters²

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.

² The following tests respectively deal with a different GMO testing parameter: qualitative GMO test, quantitative GMO test, test to determine soy mass.

After successful initial recognition, the laboratory must prove to VLOG as of the following calendar year that it has participated in at least two of the mentioned interlaboratory tests with satisfactory results. Successful participation in each of the audits must be proven at least twice every three years (see Figure 1).

1 or 2 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.

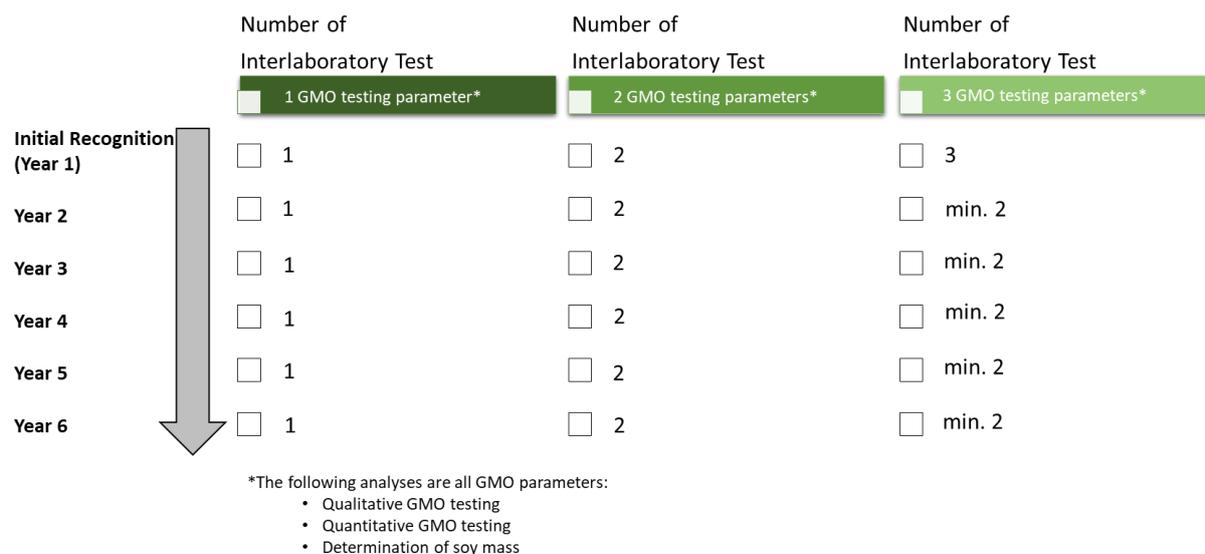


Figure 1: Number of annual interlaboratory tests to be proven



An interlaboratory test to determine the soy mass will be organised by VLOG on a regular basis. If the laboratory does not pass the interlaboratory test for soy mass determination, it can maintain its recognition through successful repetition of the interlaboratory test at the next possible date. However, the laboratory must pass the interlaboratory test within two years. If, within the scope of the interlaboratory test, inaccurate results are found and results from follow-up audits are submitted, then the respective laboratory must give VLOG a plausible reason for the previous worse results. This statement is used and evaluated to assess the laboratory's performance.

1.2 Subcontracting Requirements³

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

³ Definition of subcontracting: Subcontracting means that the laboratory itself is accredited for this parameter, but due to special circumstances such as a lack of laboratory employees or resources, it assigns this parameter to another laboratory accredited for said parameter. The laboratory to which the test is subcontracted must also be recognised by VLOG.

Subcontracting of (partial) tests is permitted under the following conditions:

- All laboratories involved in GMO testing must be recognised by VLOG.
- Subcontracting in compliance with VLOG's *Guidelines for Laboratories* is to be agreed between the participating laboratories in writing, including information on the subcontracted GMO tests.
- VLOG-recognised laboratories document which laboratories they subcontract (partial) testing to, and for which laboratories they perform GMO tests in accordance with the VLOG standard.
- 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 are participating in the test, the laboratory commissioned by the customer is to create a VLOG-compliant test report with conclusive assessment.



Explanation: Subcontracting is authorised by VLOG only if at least one GMO testing parameter is tested by the assigned laboratory itself (e.g. if the laboratory carries out the qualitative GMO test itself and subcontracts the quantitative GMO test to another laboratory) and the subcontracting requirements of the "Ohne Gentechnik" Production and Certification Standard are met.

1.3 Outsourcing Requirements⁴

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.
- 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 **Fehler! Verweisquelle konnte nicht gefunden werden.** 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.

⁴ 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.

1.4 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.

1.4.1 Testing process

1.4.1.1 Milling

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

- 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 1.4.1.2



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.

1.4.1.2 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

1.4.1.3 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 homogeneously distributed.



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

1.4.1.4 PCR test

Real-time PCR methods with probe technology (45 cycles) 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.

1.4.2 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.

1.4.3 Approval of test results

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

1.4.4 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.

1.4.5 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. 691/2013⁵ as well as the Guideline for Estimation of Measurement Uncertainty published by the German National Accreditation

⁵ 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.

Valid as of: 1 October 2019

Version 1.0

Body (71 SD 4 016)⁶, 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).

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.

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-house⁷

The following documents must be submitted electronically 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.

⁶ 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).

⁷ All GMO tests are performed by the laboratory itself and are not subcontracted or outsourced to other VLOG-recognised laboratories.

Valid as of: 1 October 2019

Version 1.0

- Example test report of 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
 - An interlaboratory test (*complete report including the laboratory number*) for quantitative GMOs results with a satisfactory z-score⁸
- An interlaboratory test (complete report including the laboratory number) to determine the soy mass (the interlaboratory test is organised by VLOG) with a satisfactory z-score⁷

The laboratories must send the following documents to VLOG by post:

- Signed Recognition Agreement in duplicate

2.1.2 Subcontracting laboratory⁹

For laboratories that are subcontracted to test VLOG samples, the subcontracting laboratory must submit to VLOG, besides the documents mentioned in Chapter 2.1.1, the following documents for examination and approval:

- Name of the laboratory commissioned with the GMO analyses
- Subcontracting agreement between the laboratories, specifying the GMO tests to be subcontracted

2.1.3 Outsourcing laboratory¹⁰

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

- Application for VLOG recognition of laboratories (master data sheet)
- Recognition Agreement
- DIN EN ISO/IEC 17025 accreditation certificate
- 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)

⁸ 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.

⁹ Definition of subcontracting: The laboratory itself is accredited for this parameter, but due to special circumstances such as a lack of laboratory employees or resources, it assigns this parameter to another laboratory accredited for said parameter. The laboratory to which the test is subcontracted must also be recognised by VLOG.

¹⁰ 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, according to the requirements of the VLOG Standard, the laboratory will submit to VLOG proof of successful participation in the interlaboratory test *of the previous year until the end of the first quarter of each following year* required pursuant to Figure 1:

- An interlaboratory test for quantitative GMOs results with a satisfactory z-score¹¹
- 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 to determine the soy mass (interlaboratory test is organised by VLOG) with a satisfactory z-score **Fehler! Textmarke nicht definiert.**

In the first calendar year after initial recognition, proof of an interlaboratory test from the previous year is not necessary. In order to maintain their recognition, laboratories that exclusively outsource their GMO tests must resubmit to VLOG every three years the documents specified in Chapter **Fehler! Verweisquelle konnte nicht gefunden werden.** 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)
- DIN EN ISO/IEC 17025 accreditation certificate

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 **Fehler! Verweisquelle konnte nicht gefunden werden.**, 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.

¹¹ 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.

Valid as of: 1 October 2019

Version 1.0

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

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

Guideline for Laboratories	Requirements for the Scope of Testing	Annex 1 16.12.19
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It must be noted that, regarding the following minimum requirements for the scope of analysis, not all GMOs were taken into account that are authorised in the EU or tolerated for feed within the meaning of EU Regulation No. 619/2011. Also, GMOs not authorised in the EU are not part of the minimum requirements. In the event of an examination of the marketability and proper labelling of a feed, other GMOs would be taken into account (this includes other GMOs authorised in the EU, GMOs tolerated in feeds pursuant to EU Regulation No. 619/2011, and GMOs not authorised in the EU).

In consultation with laboratories, VLOG regularly checks and updates the following minimum requirements concerning the scope of analysis of raw materials and feeds. In the event that other GMOs become relevant over time (e.g. RASFF reports), VLOG will inform its VLOG-recognised laboratories, members and VLOG-certified companies of any changes in testing requirements/guidelines in a timely manner.

This does not mean, however, that the companies participating in the VLOG system are dispensed from their own due diligence obligations to regularly check and, if necessary, update the scope of testing.

1. Minimum requirements for raw materials/single-component feed

1.1. Minimum requirements for raw soy materials/soy-based single-component feed

Determination and assessment of the summation value of the most relevant soy GMOs:

- Quantification of GTS 40-3-2 (RRS- 1)
- Quantification of MON89788 (RRS-2)
- Qualitative detection of A2704-12 and A5547-127:

In the event of positive result for A2704 and/or A5547-127, the quantity of these GMOs can, for example, be estimated using the $\Delta\Delta\text{ct}$ method or similar method ensuring that sufficient quantities of species DNA are present. For estimated values over 0.1%, a quantification must be carried out.

Alternately, the laboratory may work with screening parameters that detect at least the GMOs mentioned. When using the pat gene (or LibertyLink constructs), A554-127 (or another single copy material) must be used as a reference material for estimation. In the subsequent identification / quantification of positive findings, at least all GMOs (if corresponding elements are positive) mentioned here must be quantified.

1.2. Minimum requirements for raw corn/maize materials or corn/maize-based single-component feeds

1. Screening for 35S Promoter (p35S) and NOS Terminator (tNOS).

Other screening elements can be used to narrow down the corresponding GMO.

2. If positive:

In the event of a positive result for 35S Promotor (p35S) and/or NOS Terminator (tNOS), the quantity of these screening elements can, for example, be estimated using the $\Delta\Delta\text{ct}$ method or a similar method. For estimated values (MON89034 or a suitable reference material for corn/maize that contains 35S in single copy) over 0.1%, identification and subsequent quantification must be carried out. If there are several positive results, the estimated individual values must be added together.

Guideline for Laboratories	Requirements for the Scope of Testing	Annex 1 16.12.19
-----------------------------------	--	-----------------------------

Testing at least for NK603, TC1507, MON810, MON89034.

- 3.** If using the positive screening parameters, one or more of these GM corn/maize types can be ruled out, then the same number of commercialised GM corn/maize types that come into question must be searched for instead.

Positive screening results for values over 0.1% must be clarified; if no GM corn/maize types can be found, other GM types must be analysed, e.g. RRS1.

4. Determining the summation value of the corn/maize GMO

Identified varieties must be quantified if the estimation of the concentration, when using, for example, the $\Delta\Delta$ ct method or another similar method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.

RRS-1 positive:

Estimating the soy mass (weight) and assessing the amount of soy: Is it a relevant amount or minimal traces? If a botanical contamination containing GMO is determined, an assessment according to the official guideline¹ must take place.

1.3. Minimum requirements for raw canola/rapeseed materials / canola/rapeseed-based single-component feeds

There are two possible testing procedures.

First testing procedure:

1. Triple screening that detects all currently relevant GM canola/rapeseed varieties and botanical impurities (e.g. tNOS, CTP2-CP4epsps (or pFMV), pat gene (or LibertyLink construct)).
2. **ID depending on positive screening results**
 - tNOS positive: at least RRS + bar gene or MS8 / RF3 directly
 - CTP2-CP4epsps / pFMV positive: at least GT73

If no canola/rapeseed GMO is detected, the presence of a botanical contaminant containing GMO with ~~other plant varieties~~ soya or corn must be clarified (estimation and assessment of masses). Is it a relevant quantity or minimal traces? If a botanical contamination **containing GMO with GM soy above the 0.5% limit detected is determined, the GM soy content must be determined** (see minimum requirements for feed containing soy). ~~For botanical contamination with corn/maize, the GMO summation value for corn/maize with corn/maize contamination over 0.9% must be determined and an assessment according~~ **new evaluation pursuant to official guidelines¹ must take place.**

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¹ Guideline for the Control of GMOs in feed (German: Leitfaden zur Kontrolle von GVO in Tierfutter – November 2011 version). Monitoring of the production, of handling, of use and of bringing to market of feed in connection with genetically modified organisms (GMOs). ... Developed by the GMOs in Feed Project Group (PG GVO) of the Agricultural Employers Association (LAV) Working Group on Feed, with the participation of the Federal Government and The Association of German Agricultural Investigation and Research Institutions (VDLUFA), https://www.ohnegentechnik.org/fileadmin/ohne-gentechnik/das_siegel/og-standard_english/BVL-Guideline_for_Monitoring_GMOs_in_Feed_180301.pdf

Guideline for Laboratories	Requirements for the Scope of Testing	Annex 1 16.12.19
-----------------------------------	--	-----------------------------

Second testing procedure:

1. Estimating the soy mass:

For quantities over 0.59%, the quantity of soy GM must be determined (cf. Minimum requirements for feed containing soy).

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2. Qualitative evidence of canola GT73 + canola MS8 or canola RF3 (or bar gene)

3. Determining the summation value of GM canola/rapeseed

Identified GM canola/rapeseed varieties must be quantified if the estimation of the quantity, when using, for example, the $\Delta\Delta\text{ct}$ method or another method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.

Positive screening results must be clarified.

1.4. Minimum requirements for rice and rice products

1. Preparation of laboratory samples:

Two subsamples of at least 250 g each are to be created from the laboratory sample sent, and each is to be analysed separately (1 extraction, 2 PCRs per subsample:).

2. Element-specific screening:

p35S + tNOS + cry1Ab/cry1Ac sequence

3. Design-specific proof

Version 19.01 Identification, by agreement between the company and the laboratory, of GMO events that cause a positive screening result (see 1).

4. Exclusion of botanical impurities (GMO carryovers from other plant species) from corn/maize, soy, cotton and (naturally occurring) Cauliflower Mosaic Virus.

If the element-specific screening yields a positive result, design-specific proof is to be provided as the next step. In combination with the exclusion of botanical impurities and the Cauliflower Mosaic Virus, it must be investigated whether the sample contains genetically modified rice.

5. Evaluation of the PCR results

If the targeted sequence of genetically modified rice is proven for at least one of the subsamples analysed, this result is to apply to the entire sample and therefore the batch. The batch cannot be marketed in the EU and cannot be labelled with the "Ohne GenTechnik" seal.

1.5 Requirements for salmon and salmon products

1. Design-specific proof

AquAdvantage® Atlantic salmon (*Salmo salar*).

2. Evaluation of the PCR results:

If the targeted sequence of genetically modified salmon is proven for at least one of the subsamples analysed, this result is to apply to the entire sample and therefore the batch. The batch cannot be marketed in the EU and cannot be labelled with the "Ohne GenTechnik" seal.

Guideline for Laboratories	Requirements for the Scope of Testing	Annex 1 16.12.19
-----------------------------------	--	-----------------------------

2. Minimum requirements for compound feed

2.1. Minimum requirements for compound feed containing soy

Determination and assessment of the summation value of the most relevant GMOs:

Soy:

- Quantification of GTS 40-3-2 (RRS- 1)
- Quantification of MON89788 (RRS-2)
- Qualitative detection of A2704-12 and A5547-127:
In the event of a positive result for A2704 and A5547-127, the quantity of this GMO can, for example, be estimated using the $\Delta\Delta\text{ct}$ method or similar method ensuring that sufficient quantities of species DNA are present. Quantification must be carried out for values over 0.1%,.

In case of limited analysability of the soya ingredient, the practical LOD must be indicated.

For corn/maize ingredient:

Additional qualitative detection of the 4 commercialised corn/maize varieties: NK603, TC1507, MON810, MON89034

In case of a positive result, the quantity of this GMO can, for example, be estimated using the $\Delta\Delta\text{ct}$ method or a similar method ensuring that sufficient quantities of species DNA are present. Regular quantification of the GMOs detected must be carried out for values over 0.1%.

In case of limited analysability of the corn/maize ingredient, the limit of detection (LOD) must be indicated.

For canola/rapeseed ingredient:

Additional qualitative detection of GT73.

In case of positive identification, quantification of GT73 must take place if the estimation of the quantity using, for example, the $\Delta\Delta\text{ct}$ method or another similar method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.

In case of limited analysability of the canola/rapeseed ingredient, the practical LOD must be indicated.

Alternately, the laboratory may also work with screening parameters that detect at least the GMOs mentioned (soy, canola/rapeseed, corn/maize). In the subsequent identification / quantification of positive results, at least all GMOs (if corresponding elements are positive) mentioned here must be identified and, if necessary, quantified.

Guideline for Laboratories	Requirements for the Scope of Testing	Annex 1 16.12.19
-----------------------------------	--	-----------------------------

2.2. Minimum requirements for soy-free compound feed

Determination and assessment of the summation value of the most relevant GMOs:

Estimating the soy mass:

In a first step, the mass of soy in the feed is estimated. For quantities over 0.9%, the proportion of GM soy must be determined (cf. Minimum requirements for feed containing soy) and an assessment according to the official guideline² must take place.

For canola/rapeseed ingredient:

Qualitative evidence of canola GT73 + canola MS8 or canola RF3 (or bar gene).

In the event of positive identification, quantification of GMO or GMOs found must take place if the estimation of the quantity when using, for example, the $\Delta\Delta ct$ method or another similar method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.

In case of limited analysability of the canola/rapeseed ingredient, the practical LOD must be indicated.

For corn/maize ingredient:

Qualitative evidence of 4 corn/maize varieties used commercially: NK603, TC1507, MON810, MON89034

In the event of positive identification, quantification of GMO or GMOs found must take place if the estimation of the quantity when using, for example, the $\Delta\Delta ct$ method or another similar method ensuring that sufficient quantities of species DNA are present, leads to values over 0.1%.

In case of limited analysability of the corn/maize ingredient, the practical LOD must be indicated.

Alternately, the laboratory may work with screening parameters that detect at least the GMOs mentioned (canola/rapeseed and corn/maize). In the subsequent identification / quantification of positive results, at least all GMOs (if corresponding elements are positive) mentioned here must be identified and, if necessary, quantified.

2.3. Other products/raw materials

The strategies for analysing GMOs in other single-component feeds, raw materials, (food) ingredients, intermediate products or foods must continue to be agreed upon with the commissioned laboratory, taking into account the composition and origin of the products.

² Guideline for the Control of GMOs in feed (German: Leitfaden zur Kontrolle von GVO in Tierfutter – November 2011 version). Monitoring of the production, of handling, of use and of bringing to market of feed in connection with genetically modified organisms (GMOs). ... Developed by the GMOs in Feed Project Group (PG GVO) of the Agricultural Employers Association (LAV) Working Group on Feed, with the participation of the Federal Government and The Association of German Agricultural Investigation and Research Institutions (VDLUFA), http://www.ohnegentechnik.org/Leitfaden_Futtermittel

Guideline for Laboratories	Sample Test Report	Annex 2 01/10/2019
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Note: Requirements applicable to the test report and test scope apply per the Guideline for VLOG Recognition of Laboratories. Below is an example of a completed test report based on a compound feed containing soy. This test report serves as an orientation aid and lists all the information that is required to be specified within the scope of VLOG recognition. The form as well as the assessment can vary among the individual laboratories.

Sample Laboratory

Sample Street 1, 10101 Sample City
Sample Country

Client

Sample Street 2, 20202 Sample City
Sample Country

Test Report No.

Sample

Sample No.: #####

Sample type: Compound feed containing soy

Sample designation Strongfeed Xtra
Composition: e.g. soy, maize/corn, wheat

Lot/ Batch: #####

Sampling By the customer/by the laboratory, etc.

Packaging Type of packaging (e.g. PE bag)

Sample received: ##/##/####

Test started: ##/##/####

Test ended: ##/##/####

Quantity of sample: ##### g

Test Results

Parameter	Method	Result	Expanded uncertainty	Detection limit
Milling	XY-SOP-00.00-1 (a)	Performed with ##### g of sample		
DNA-Extraction	DIN EN ISO 21571: 2013-08 mod. (a)	Performed on 2 x 2000 mg		
GTS 40-3-2 (RoundupReady) Soy	DIN EN ISO 21570: 2013-08 mod. (a)	0.48 %	± 0.19 %	0.01
MON89788 (RoundupReady2 – Yield) Soy	DIN EN ISO 21570: 2013-08 mod. (a)	<0.10 %	± 0.4 %	0.01

Guideline for Laboratories	Sample Test Report	Annex 2 01/10/2019
-----------------------------------	---------------------------	-------------------------------

A2704-12-Soy	DIN EN ISO 21570: 2013-08 mod. (a)	<0.10 %	± 0.4 %	0.01
A 5547-127 Soy	DIN EN ISO 21570: 2013-08 mod. (a)	<0.10 %	± 0.4 %	0.01
NK603 Maize/corn	DIN EN ISO 21570: 2013-08 mod. (a)	<0.10 %	± 0.4 %	0.04
TC1507 Maize/corn	DIN EN ISO 21570: 2013-08 mod. (a)	<0.10 %	± 0.4 %	0.04
MON810 Maize/corn	DIN EN ISO 21570: 2013-08 mod. (a)	<0.10 %	± 0.4 %	0.04
MON89034 Maize/corn	DIN EN ISO 21570: 2013-08 mod. (a)	<0.10 %	± 0.4 %	0.04

XY-SOP

In-house method

DIN EN ISO 21570:2013-08 mod.

TaqMan-Real-Time PCR, 45 cycles

(a) Accredited method

< Value less than limit of quantification (LOQ)

Limit of quantification: 0.1 %

Measurement uncertainty: 20 % (relative)

Expanded uncertainty: 40 % (relative) (Expansion factor: 2)

The result was determined according to the requirements of the *Guideline for VLOG Recognition of Laboratories*.

Explanation: This sentence is only necessary if the laboratory does not provide a separate attestation to its client on an annual basis.

The values provided relate to the analyte (GMO) in comparison to the entire species (e.g. portion of GTS 40-3-2 soy of total soy).

Assessment

In the sample tested, 0.48 (± 0.19) % GTS 40-3-2 (RoundupReady) soy was identified, relative to the total content of soy. The content in the sample therefore falls below the labelling threshold of 0.9 % according to EU Regulation (EC) No. 1829/2003 on genetically modified food and feed.

Based on the testing performed, the tested sample is therefore not subject to compulsory labelling regarding genetically modified organisms (GMO), according to EU Regulations (EC) No. 1829/2003 on genetically modified food and feed and (EC) No. 1830/2003 on the traceability and labelling of genetically modified organisms, provided the GMO share is random or technically unavoidable.

The sample meets the requirements of the VLOG Standard.

Reviewed and approved:

Name:

Date: ##/##/####