

## Guidelines for VLOG Recognition of Laboratories

Part I of the “Ohne Gentechnik” Production and Certification Standard (Version 18.01) describes the requirements that laboratories and analyses must meet within the scope of a VLOG certification. Analysis results for businesses to be certified are recognised only if the requirements of the “Ohne Gentechnik” Production and Certification Standard are met by the laboratories.

In addition, to comply with these requirements, the interested laboratories must be recognised by VLOG at the latest by 01 January 2019 to be able to carry out GMO analyses for VLOG-certified businesses.

The recognition of the competent laboratories closes the final gap in that it guarantees an entirely secured system and the comparability of analysis results between the laboratories. This guideline describes the requirements that a laboratory must meet for VLOG recognition.

VLOG recognition is generally limited to three years and, unless terminated, will automatically be extended for one year. Subsequently, a request for re-recognition can be made. The request for VLOG recognition and the supporting documents are to be submitted directly to VLOG. VLOG will examine the documents submitted and inform the applying laboratory of the result of the examination.

If documents are missing or incomplete, then VLOG or the service provider assigned by VLOG will request them from the laboratory. If the documents are incomplete after a second additional request, then the application may be refused.

The list of recognised laboratories will be posted on <http://www.ohnegentechnik.org/links/> by VLOG or in another suitable location on VLOG’s homepage.

### 1. Requirements to be met by the laboratories

The basic requirement for recognition is accreditation of the laboratory according to DIN EN ISO/IEC 17025 and compliance with the requirements in I 2 and I 3 of the “Ohne Gentechnik” Production and Certification Standard (Version 18.01).

For first-time recognition, successful participation in an interlaboratory test with good results for GMO detection must be shown. Successful participation within the last 12 months in the following interlaboratory test must be proven for VLOG recognition:

- An interlaboratory test regarding GMOs for quantitative results with a satisfactory z-score<sup>1</sup> and
- An interlaboratory test regarding GMOs for qualitative results (100% correct positive or negative results) for the matrix of feed or plant-based raw materials/plant-based processed products, and

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<sup>1</sup> 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.

- An interlaboratory test to determine the soy mass (interlaboratory test is organised by VLOG) with a satisfactory z-score<sup>Fehler! Textmarke nicht definiert.</sup>

If the laboratory does not pass the interlaboratory test for soy mass determination, then it can maintain its recognition through successful repetition of 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, results from follow-up audits are submitted, then the respective laboratory must give VLOG a plausible reason for the worse results. This statement is used and evaluated to assess the laboratory's performance.

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 test with satisfactory results. Successful participation in each of the audits must be proven at least twice every three years (see Table 1).

Laboratories that carry out only part of the required GMO analyses (qualitative and/or quantitative analyses, 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 test listed in the following table.

	1 GMO analysis parameters	2 GMO analysis parameters	3 GMO analysis parameters
Year 1/Initial Recognition	1	2	3
Year 2	1	2	At least 2
Year 3	1	2	At least 2

Table 1: Number of interlaboratory tests to be proven

## 2. Requirements of the scope of analysis

The requirements concerning the scope of analysis pursuant to Annex III of the "Ohne Gentechnik" Production and Certification Standard (Version 18.01, or the respective valid version) must be complied with.

## 3. Documents to be submitted for initial recognition by VLOG

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

1. Accreditation certificate according to ISO/IEC 17025
2. Technical annex to the accreditation certificate pursuant to ISO/IEC 17025 with the qualitative and/or quantitative analysis parameters for analysing samples for genetically modified material.
3. A typical analysis report of a positive result including the information required in the "Ohne Gentechnik" Production and Certification Standard.
4. Proof of successful participation (within the last 12 months) in the following interlaboratory tests (see Table 1):
  - An interlaboratory test regarding GMOs for quantitative results with a satisfactory z-score<sup>Fehler! Textmarke nicht definiert.</sup> and

- An interlaboratory test regarding GMOs for qualitative results (100% correct positive or negative results) for the matrix of feed or plant-based raw materials/plant-based processed products, and
- An interlaboratory test to determine the soy mass (interlaboratory test is organised by VLOG) with a satisfactory z-score<sup>Fehler! Textmarke nicht definiert.</sup>

5. Signed Recognition Agreement in duplicate including Master Data Sheet

#### 4. Documents to be submitted to maintain recognition by VLOG

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 required pursuant to Table 1:

- An interlaboratory test regarding GMOs for quantitative results with a good z-score<sup>1</sup>
- An interlaboratory test regarding GMOs for qualitative 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 good z-score<sup>Fehler! Textmarke nicht definiert.</sup>

In the first calendar year after initial recognition, proof of an interlaboratory test from the previous year is not necessary.

#### 5. Subcontracting<sup>2</sup>

VLOG-recognised laboratories have the option of subcontracting GMO analyses to be performed according to the “Ohne Gentechnik” Production and Certification Standard to another **VLOG-recognised** laboratory. Subcontracting is authorised by VLOG only if at least one GMO parameter is analysed for by the assigned laboratory itself (e.g. if the laboratory carries out the qualitative GMO analysis itself and subcontracts the quantitative GMO analysis to another laboratory) and the subcontracting requirements of the “Ohne Gentechnik” Production and Certification Standard are met. For laboratories that are subcontracted to analyse VLOG samples, besides the documents mentioned in Chapter Documents to be submitted for initial recognition by VLOG the subcontracting laboratory must submit the following documents to VLOG for examination and approval:

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

#### 6. Outsourcing<sup>3</sup>

Laboratories have the option of outsourcing GMO analyses to be performed according to the “Ohne Gentechnik” Production and Certification Standard to another **VLOG-recognised** laboratory. Outsourcing is authorised by VLOG only if in the client’s audit report, there is a note (at least the name)

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<sup>2</sup> 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 analysis is subcontracted must also be recognised by VLOG.

<sup>3</sup> Definition of outsourcing: Outsourcing takes place if the outsourcing laboratory is not accredited for the parameter. The laboratory to which the analysis is outsourced must also be VLOG-recognised.

of the VLOG-recognised laboratory that is to carry out the GMO analyses. The following documents must be submitted by laboratories that outsource VLOG samples:

- Recognition Agreement including Master Data Sheet
- Name of the laboratory that is commissioned with the GMO analyses
- Outsourcing agreement between the laboratories, specifying the GMO analyses to be outsourced

## **7. Costs**

Laboratory recognition is subject to a fee of €1,000 per recognition and a yearly maintenance fee of €1,000, both including statutory VAT.

For laboratories that outsource all GMO analyses to be performed according to the VLOG Standard, the fee for recognition and yearly maintenance is €300.

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

## **8. 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 ISO/IEC 17025 within 4 weeks without being asked.

## **9. Applicable documents**

- Recognition Agreement including Master Data Sheet
- VLOG Standard and annexes
- VLOG Guideline for dealing with breaches