ANNEX 07, Version 01

Requirements for laboratories and GMO testing

The minimum requirements for the GM-free production of raw materials and animal feed that must be met by laboratories and in tests

- for the purpose of Europe Soya certification, and
- according to the testing requirements laid down in the Europe Soya Guidelines

are described below.

Test results for companies to be certified will only be recognised if the requirements described here are met by the laboratories. In this respect, the Europe Soya Standard is based on the current specifications laid down by the German Association for Food without Genetic Engineering (Verband Lebensmittel ohne Gentechnik e.V., or VLOG for short) in its guide "Guideline for Laboratories and GMO Testing – Binding Requirements"[1] as well as by the Austrian Platform for GMO-Free Food Products (Arbeitsgemeinschaft für Gentechnik-frei erzeugte Lebensmittel, or ARGE Gentechnik-frei for short) in its guide "Empfehlungen zu GVO-Analysen gemäß Codex-Richtlinie zur Definition der Gentechnikfreien Produktion" (Recommendations for GMO testing according to the Guideline on the Definition of "GMO-Free Production" in the Austrian Food Codex, 4th edition; not yet available in English)[2].

1 Requirements for commissioning a test

The commissioner of the GMO test shall undertake to

- verify regularly, at least once per calendar year, that the laboratory commissioned is accredited according to the DIN EN ISO/IEC 17025 standard.

2 Requirements for laboratories

2.1 General requirements

- The laboratory shall be accredited according to the DIN EN ISO/IEC 17025 standard (in its most recent version) for all qualitative and quantitative GMO test parameters. This accreditation can be available either in the form of a flexible accreditation for the entire parameter or separately for all procedures carried out.
- The scope of accreditation must clearly indicate for which GMO detection methods the laboratory is accredited.

The laboratory shall participate annually in the following interlaboratory tests, achieving satisfactory results:

- An interlaboratory test for quantitative GMOs results with a satisfactory z-score (at least 75% of the results are in the ± 2 range of the z-score);
- An interlaboratory test for qualitative GMOs results (100% accurate positive or negative results) for the matrix of feed or plant-based raw materials / plant-based processed products.

2.2 Methodological requirements

EN and ISO standards and protocols of the Joint Research Centre (JRC) shall be used (if available). If methods from other sources are used, the laboratory shall verify that comparable minimum requirements are met.

[1] Guideline for Laboratories and GMO Testing – Binding Requirements: https://www.ohnegentechnik.org/fileadmin/user_upload/03_prueflabore/Guideline_for_VLOG-Recognition_of_Laboratories.pdf

[2] ARGE Gentechnik-frei (2018): Empfehlungen zu GVO-Analysen gemäß Codex-Richtlinie zur Definition der Gentechnikfreien Produktion

2.2.1 Testing process

Milling:
Depending on the sample matrix, the following minimum amount of sample material shall be milled completely in each case:

- feed: at least 400 g and no more than 1 kg;
- raw materials: at least 3000 grains or approx. the sample amount corresponding to this number in each case (soya: at least 700 g).

DNA extraction:
At least 2 DNA extractions from each sample shall be performed following milling/ homogenisation. The minimum weight of the sample shall be 2000 mg for feed, seeds, food and materials with suspected inhomogeneous distribution. In exceptional cases (for otherwise non-extractable materials), the sample weight may be as low as 500 mg.

PCR testing:
Real-time PCR methods with probe technology (45 cycles) are recommended. When using conventional endpoint PCR methods, an additional confirmatory reaction (e.g. real-time PCR with probe technology, restriction test or sequencing) shall be performed in case of positive results.

2.2.2 Analytical quality control

All quality controls according to the relevant EN and ISO standards shall achieve the results required by these standards. The laboratory shall ensure that the test results are not affected by inhibitory effects. If the test results deviate from the control values to such an extent that the tolerance limits set by the laboratory for deviations or quality specifications are exceeded the PCR process shall be repeated.
Procedures for the regular performance and documentation of QA measures shall be established and implemented (e.g. control charts) in order to detect systematic errors, reagent instabilities, etc. in a timely manner and to initiate appropriate measures.

2.2.3 Requirements for test reports

In addition to the information required according to the EN ISO 24276, EN ISO 21569 and EN ISO 21570 standards, a test report shall contain at least the following data:

- the quantity of sample milled and sent,
- the quantity of sample used in DNA extraction,
- a precise description of the sample,
- the limit of detection (LOD in % or as copy number of target),
- the method used,
- the test result,
- the measurement uncertainty of the method used (when quantitative methods are used),
- a 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); it is recommended to indicate the practical limit of quantification (pLOQ),
- a confirmation that the result was obtained in accordance with the requirements of the Europe Soya Standard; alternatively, this confirmation may be provided in a separate letter sent to the commissioner of the GMO test once a year.

2.2.4 Interpretation of test results – test and evaluation criteria

For each sample, a final assessment as to whether or not the sample complies with the requirements of the Europe Soya Standard for the analysed parameters shall be included in the test report. The tested GMO content, after deduction of the expanded error margin, shall be used for evaluation.

If multiple GM events (same species) are present in an ingredient, the individual values shall

be summed up to a cumulative value. This cumulative value, taking into account the measurement uncertainty, shall be the most important factor for assessing exceedances of the GM content.

3. Requirements for the scope of analysis

Please note that the following minimum requirements for the scope of analysis do not cover all GMOs that are authorised in the EU or tolerated in feed under Commission Regulation (EU) No 619/2011. Likewise, the minimum requirements do not cover GMOs that are not authorised in the EU. In the event of an examination of the marketability and proper labelling of a feed, other GMOs will be taken into account (this includes additional GMOs authorised in the EU, additional GMOs tolerated in feed in the EU under Commission Regulation (EU) No 619/2011 as well as GMOs not authorised in the EU).

3.1 Minimum requirements for raw soya materials / soya-based single-component feed

- Screening for the presence of at least the following GM soya events:
  MON40-3-2 (e.g. 35S or tNOS),
  MON89788 (e.g. CTP2-CP4EPSPS or pFMV),
  A2704-12 (e.g. PAT), and
  MON87701 (event-specific detection).

Additional screening elements may be used to determine the presence of GMOs.

In the event of positive results for the screening elements and/or MON87701, the quantity of these GMOs can be estimated, for example, by using the ΔΔct method or a comparable method. In case of multiple positive findings, the estimated individual values shall be summed up. For estimated values over 0.1%, an identification/quantification shall be carried out.

3.2 Minimum requirements for compound feed containing soya

- Screening for the presence of at least the following GM soya events:
  MON40-3-2 (e.g. 35S or tNOS),
  MON89788 (e.g. CTP2-CP4EPSPS or pFMV),
  A2704-12 (e.g. PAT), and
  MON87701 (event-specific detection).

Additional screening elements may be used to determine the presence of GMOs.

In the event of positive results for the screening elements and/or MON87701, the quantity of these GMOs can be estimated, for example, by using the ΔΔct method or a comparable method. In case of multiple positive findings, the estimated individual values shall be summed up. For estimated GM values over 0.1%, an identification/quantification shall be carried out.

If the analysability of the soya ingredient is limited, the practical limit of detection (LOD) shall be provided.

If positive screening results (with estimated GM levels exceeding 0.1%) cannot be adequately explained by the presence of GM soya events, further testing for the presence of GM maize and/or GM rapeseed shall be performed.

If maize is used as an ingredient:

- In addition to the aforementioned screening, the presence of the following commercialised maize varieties shall be qualitatively assessed: NK603, TC1507, MON810, MON89034.

In the event of positive results, the quantity of these GMOs can be estimated, for example, by using the ΔΔct method or a comparable method that ensures that a sufficient amount of species-specific DNA is present in the sample. Regular quantification of the GMOs detected shall be carried out for values over 0.1%.

If the analysability of the maize ingredient is limited, the practical limit of detection (LOD) shall be provided.

If rapeseed is used as an ingredient:

- In addition to the aforementioned screening, the presence of the following commercialised rapeseed varieties shall be qualitatively assessed: GT73 + MS8 or RF3,

In the event of positive results, the quantity of these GMOs can be estimated, for example, by using the ΔΔct method or a comparable method that ensures that a sufficient amount of species-specific DNA is present in the sample. Regular quantification of the GMOs detected shall be carried out for values over 0.1%.

If the analysability of the rapeseed ingredient is limited, the practical limit of detection (LOD) shall be provided.

3.3 Other products / raw materials

The GMO testing strategies for other raw materials, single-component feed, food and feed ingredients, intermediate products or food shall continue to be agreed upon with the laboratory commissioned, taking into account the composition and origin of these materials and products.

The VLOG and ARGE Gentechnik-frei guides listing the requirements for laboratories and testing, as amended, shall be considered equivalent and may be applied for the purpose of Europe Soya certification.