

ISCC Module Non-GMO

FOOD AND FEED

Version 2.1

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1 Introduction

The hereinafter-described ISCC standard for “Non-GMO food and feed” is a module for the sole certification of non-genetically modified materials and products. It is applicable for food and feed products and completely independent from the general ISCC EU and PLUS sustainability certification on farm/plantation and supply chain level.

*ISCC Non-GMO
certification for
food and feed*

The objective of this document is to set requirements for a labelling of “Non-GMO food and feed” products in accordance with the EC Genetic Engineering Implementation Act §3a and 3b (EGGenTDurchfG). It is globally applicable.

Producers of food or feed products, which fulfil the respective requirements of this document can label their products with the respective claim. According to Secs. 3a and Sec. 3b of the EC Genetic Engineering Implementation Act (EGGenTDurchfG) food products for the German market may only be labelled with the words “Ohne Gentechnik”. In this regard ISCC certified Non-GMO products must be labelled as “Ohne Gentechnik” under ISCC. For markets outside Germany a respective translation of the words “Ohne Gentechnik” may be used after consulting ISCC. Under the ISCC Non-GMO certification the threshold for GMO in food is $< 0.1\%$. Next to fulfilling the ISCC standard requirements, the respective national laws of the country the product is sold in are to be obliged. For feed the claim “ISCC Non-GMO for feed” applies. The threshold of GMO contamination is $> 0,1\%$ and $\leq 0,9\%$. If both standards are fulfilled by a product, it can be sold into both markets (to the feed market with the label “ISCC Non-GMO for feed” and to the food market with the ISCC label for “Ohne Gentechnik”).

*Labelling
obligations*

The requirements of this document only refer to plant-based (non-animal) raw materials and products. If animal-based components are used, further requirements under the EC Genetic Engineering Implementation Act become valid, which are currently not covered by ISCC Non-GMO for food and feed.

*Plant-based
(non-animal) raw
materials and
products*

2 Legal frameworks

The most relevant legal bases for the ISCC Non-GMO standard are the EC Genetic Engineering Implementation Act (EGGenTDurchfG) as well as Regulations (EC) No. 1829/2003 and 1830/2003.

Legal framework

2.1 Regulations (EC) No. 1829/2003 and 1830/2003

A basic requirement regarding feed and food ingredients for the production of food/feed labelled “Ohne Gentechnik” under ISCC or “ISCC Non-GMO for feed” is that they be exempt from labelling according to the requirements of Regulations (EC) No. 1829/2003 and No. 1830/2003. Contamination with GMOs permitted in the EU by law has no impact on labelling obligations according to Regulations (EC) No. 1829/2003 and No. 1830/2003 provided that two requirements are fulfilled:

EU Regulations

- > The threshold value of the GMO content of 0.9% per single-component feed/ingredient (feed/food) is not exceeded and
- > The presence of the GMO content is “adventitious or technically unavoidable”.

*GMO
contamination
thresholds*

Contamination with approved GMO content < 0.1% are generally considered as “technically unavoidable” or “adventitious”.

Contamination present in a magnitude of > 0,1% and ≤ 0,9% is considered as labelling-compliant if the business has installed and demonstrably implemented organisational measures to avoid introduction of GMO material.

Please also see the “Guideline on controlling GMOs in feed” of the German Federal Office of Consumer Protection and Food Safety for further guidance¹.

*Assistance for
labelling feed*

2.2 EC Genetic Engineering Implementation Act (EGGenTDurchfG)

For food ingredients, the requirements of the EGGenTDurchfG go beyond the absence of a labelling obligation according to Regulations (EC) No. 1829/2003 and No. 1830/2003. According to the EGGenTDurchfG, no ingredients and additives may be used for the production of food, which are GMOs, may contain them or be produced from GMOs. In general, adventitious or technically unavoidable traces of genetically modified material are tolerated up to a threshold of at most 0.1% per ingredient. Processing aids may not be produced from GMOs. In cases where necessary additives such as vitamins are demonstrably not available in the market in Non-GMO quality, additives produced by GMOs may be used. Prerequisite for this exception is that these substances be listed by the EU Commission according to the procedure provided by Regulation (EC) No. 834/2007 on organic production and labelling of organic products. Currently, no substances are listed.

*German
regulative
framework food*

Feed for use in the Non-GMO system must not be subject to compulsory labelling pursuant to Regulation (EC) No. 1829/2003 or 1830/2003. Suitable steps must be demonstrably taken to prevent the presence of GMOs (see “Guideline on controlling GMOs in feed”). Feed additives must be taken into consideration only if they are made from GMOs or GMO components and therefore must be labelled themselves. According to the existing legal provisions, any feed additives that are produced using (or with the help of) GMOs need not be labelled and may be used without restrictions.

*German
regulative
framework feed*

For the production/ processing of ISCC Non-GMO products, no processing aids or other substances within the meaning of Sec. 3 Par. 5 of the EC Genetic Engineering Implementation Act (EGGenTDurchfG) may be used which contain, consist of, or are produced from GMOs labelled in accordance with Regulation (EC) 1829/2003 or 1830/2003, or which would have to be so labelled were they placed into circulation. Sec. 3 Par. 5 of the

*Labelling
processing aids
and other
substances*

¹ German Federal Ministry of Food and Agriculture, German Federal Office of Consumer Protection and Food Safety (2011). Guideline on controlling GMOs in feed: https://www.bvl.bund.de/SharedDocs/Downloads/02_Futtermittel/fm_leitfaden_kontrolle_GVO.html?nn=2734088

EGGenTDurchfG refers to the fact that “no foods, food ingredients, processing aids and substances within the meaning of Article 5(2) of the German Food Labelling Ordinance most recently amended by Article 1 of the Ordinance of 18 December 2007 (Federal Law Gazette Part I p. 3011), that have been produced by GMOs may have been used to prepare, treat, process or mix an item of food or an ingredient. (...) shall not apply to foods, food ingredients, processing aids and substances within the meaning of Article 5(2) of the Food Labelling Ordinance for which an exemption is permitted on the basis of a ruling or order of the European Commission in accordance with Article 22(2) (g) in conjunction with Article 37(2) of Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ EU L 189 p. 1).” (Federal Ministry of Food and Agriculture, 2018 - EGGenTDurchfG)

3 Requirements for Certification Bodies and Auditors

For certification bodies and auditors who would like to audit and issue certificates for ISCC Non-GMO Food and Feed, the requirements as specified in the ISCC EU System Document 103 “Requirements for Certification Bodies and Auditors” apply. The auditor needs the same audit competency as for a normal ISCC audit. ISCC EU and ISCC PLUS sustainability specifics such as verification of greenhouse gas (GHG) emissions, land use change verification, good agricultural practices, etc. do not need to be covered by an auditor compiling Non-GMO audits. Participation in an ISCC training is nevertheless required in order to gain knowledge on the ISCC System.

ISCC audit competencies

Combined audits with the VLOG standard are possible in order to gain synergy effects. The VLOG checklists are regarded as equivalent with the ISCC “Non-GMO for food and feed” checklist.

Combined VLOG audits

4 Requirements for System Users

The following operators are eligible to be certified under the ISCC Non-GMO scheme:

Feed processing

Feed processing is defined as any type of operation that includes process steps, going beyond simple, external processing, e.g. the manufacture of post-extraction rapeseed meal (which arises as a by-product during the extraction of oil from rapeseed/canola). It applies for bulk and/or bagged/package compound and single-component feed produced in the business and, if applicable, is also used in the Non-GMO production of food.

Operators processing feed

Food processing

Food processing is defined as any type of operation that includes the preparation or processing of products. Preparation comprises sorting and labelling unprocessed products under Regulation (EC) No. 852/2004 on the hygiene of foodstuffs, as well as the activities referred to in Art. 2 (1) n) of Regulation (EC) No. 852/2004 (foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed). Processing comprises a significant change in the original food, e.g. through heating, smoking, curing, aging, desiccating, marinating, extracting, extruding or a combination of these various processes (Regulation (EC) No. 852/2004). It applies for plant-based food/ingredients products which are to be labelled as “Ohne Gentechnik” under ISCC.

*Operators
processing food*

Sub-contractors are also subject to on-site audits. They can also file an independent application for certification with an ISCC-recognised Certification Body. Audits performed on the basis of contractual agreements are limited to the assessment of the sub-contractor's production for compliance with the ISCC Standard and no certificate will be issued.

4.1 Audit and Certification Procedure

Prior to certification, ISCC System Users would need to register with ISCC. For registration, the economic operator must use the registration form provided on the ISCC website, and must complete this form completely and truthfully. When filing the registration the economic operator agrees to accept the ISCC Terms of Use in force at the time being (available on the ISCC website).

*Acceptance of
ISCC Terms of
Use*

ISCC System Users receive a certificate upon the successful completion of a certification audit by an eligible auditor as appointed by the Certification Body. These audits are referred to as certification audits. Since ISCC certificates are valid for 12 months, a certification audit is conducted once a year.

*Certificate
validity*

An independent certification by one of ISCC recognized and accredited Certification Bodies is mandatory for the producer of the feed and/ or food products, who want to label their products with the specific claim “Ohne Gentechnik” under ISCC or “ISCC Non-GMO feed”. For upstream processing steps, which do not want to label their products with the specific claim “Ohne Gentechnik” under ISCC or “ISCC Non-GMO feed”, an independent certification is not required.

*Independent
certification
bodies*

In case of reasonable suspicion Certification Bodies are entitled to conduct announced or unannounced surveillance audits at any time during the certificate's period of validity. If necessary, ISCC is entitled to request Certification Bodies to conduct surveillance audits at any time during the certificate's period of validity.

*Unannounced/
surveillance
audits*

4.2 General requirements

In general, all regulatory requirements for non-genetically modified products shall be fulfilled. Any materials (including raw materials, auxiliaries, additives) that are used to produce “Ohne Gentechnik” under ISCC or “ISCC Non-GMO feed” shall at no circumstances be genetically modified materials being subject to GM labelling under the 1829/2003/EC or 1830/2003/EC.

Materials of Non-GMO quality

For a successful audit, the following requirements are checked:

- > A facility description
- > Self-control concept of the economic operator
- > Inspection of incoming and outgoing products (including tests for Non-GMO quality)
- > The segregation of good flows/ exclusion of technically avoidable commingling
- > Handling of non-compliant products and related control system
- > Risk analysis, sampling and testing of Non-GMO materials based on the methodology explained in chapter 4.2.7

If a producer does not comply with one of the requirements, corrective actions have to be implemented within a 40-days timeframe prior to issuing a certificate. In case the non-compliances cannot be corrected within this timeframe, the certification process is considered as failed. The Certification Body has to inform ISCC immediately about the failed audit and send the respective audit procedures.

Non-compliances and corrective actions

Although the above requirements generally apply for both feed and food processing, some details are only applicable to food, while others are relevant for feed or raw materials. In this case this is specified in the following chapters as well as in the Non-GMO audit procedure.

With successfully completing the certification audit the Certification Body issues the ISCC certificate for either “Ohne Gentechnik” under ISCC or for “ISCC Non-GMO feed”, or both. The certificate highlights, next to the general information on the economic operator and validity of the certificate, also the products (raw material specific), that have been qualified as “Ohne Gentechnik” under ISCC and/ or the products that have been qualified under “ISCC Non-GMO feed”.

ISCC certificate

4.2.1 Facility description

Each economic operator needs to have a facility description in place, including the portion/ quality of ISCC Non-GMO production, the type and size of the business and of the ISCC Non GMO production, responsibilities of staff working in the Non-GMO section, information on subcontractors (if applicable) and additional documents to be submitted in case a business has not

converted fully to Non-GMO production (e.g. list of all raw materials/feed/ auxiliary substances used for ISCC Non-GMO feed and/ or food).

In addition to the facility description, the economic operator needs to maintain an organizational chart, that should contain the structure of the operational unit, responsibilities assigned to the respective employees and a deputy plan to cover for absence. Plans need to be updated as employees leave, or responsibilities are reassigned.

Organisational chart

4.2.2 Self-control system of the system user

A self-control system must be in place, taking into consideration the required segregated handling of conventional/GMO-containing products and ISCC Non-GMO/GMO-free products. In addition, a risk analysis analogous to the HACCP (Hazard Analysis and Critical Control Point) concept must be conducted to ensure the absence of a need to label according to Regulation (EC) no. 1829/2003 or use of a claim that indicates the suitability of the feed/raw materials for the production of Non-GMO for food or/and feed under ISCC. The risk analysis is done by the system user prior to the audit and will be checked by the auditor.

Risk analysis

It comprises criteria relevant for all types of operation, however, depending on the feed or food sector, some additional aspects must be considered:

General criteria for all types of operation:

- > Records of all raw materials and/or feed
- > Separate handling of products for which ISCC Non-GMO labelling would be permissible and such products not meeting the requirements for ISCC Non-GMO certification
- > Identification and exclusion of sources of contamination and carryover

Additional criteria for feed:

- > Records of all feed for the ISCC Non-GMO part of the business no matter whether subject to labelling obligations or not
- > Individual, batch-specific risk assessment (at risk/not at risk) of single-component feed for ISCC Non-GMO production or labelling analogously to an HACCP. The risk assessment must be documented in writing. If applicable, test results from ISCC-certified (or equivalent) upstream suppliers may also be considered. Risk grading of the various feed (at risk/not at risk) must be transparent for the auditor
- > Specifications for all finished products for ISCC Non-GMO labelling must be in place and must be laid down in writing with the contract partners if required
- > Compounding logs must be available

Additional criteria for food:

- > Risk assessment must include evaluating the use of aromas, enzymes, microorganism cultures, additives, auxiliary substances and other food ingredients
- > Preventative monitoring and controlling measures based on the HACCP must be implemented concerning the correctness of the “Ohne Gentechnik” claim under ISCC

Outsourced tasks must be considered under the self-monitoring and risk analysis concept of the economic operator. Employees of subcontractors must be trained within the scope of the contractual agreement. For risk classification of food please refer to chapter 4.2.9., for feed please see chapter 4.2.8..

4.2.3 Requirements for incoming material

It must be ensured at goods receiving, that no processing aids or other substances within the meaning of Sec. 3 Par. 5 of the EC Genetic Engineering Implementation Act (EGGenTDurchfG) may be used which contain, consist of, or are produced from GMOs labelled in accordance with Regulation (EC) 1829/2003 or 1830/2003, or which would have to be so labelled where they are placed into circulation.

*Exclusion of
GMO labelled
inputs*

4.2.3.1 Incoming goods inspection for feed

Feed for use in the ISCC Non-GMO system must not be subject to compulsory labelling pursuant to Regulation (EC) No. 1829/2003 or 1830/2003. Suitable steps must be demonstrably taken to prevent the presence of GMOs (see “Guideline on controlling GMOs in feed”). Feed additives must be taken into consideration only if they are made from GMOs or GMO components and therefore must be labelled themselves. According to the existing legal provisions, any feed additives that are produced using (or with the help of) GMOs need not be labelled and may be used without restrictions.

Feed additives

Confirmation can be given in the following ways:

*GMO-status of
feed additives*

- > A separate declaration of the GMO-free status of the currently delivered batch/lot by the upstream supplier
- > A current detailed certificate of the upstream supplier in accordance with the ISCC Non-GMO food and feed standard or a recognised equivalent standard
- > A test result according to the requirements of the ISCC standard “Non-GMO food and feed” proving the GMO-free status of the batch/lot being delivered
- > An additional indication on the delivery slip declaring the products to be exempt from labelling
- > A clear contractual regulation regarding the delivery of feed exempt from labelling

Additionally, written confirmation must be available for feed additives and declared auxiliary ingredients, that they are not subject to labelling obligations.

Further, all bills of lading issued by the supplier must be complete. In case of incomplete documents, a complaint is to be issued.

4.2.3.2 Incoming goods inspection for food

It must be ensured at goods receiving that all raw materials, food, additives and auxiliary substances that are used in the production/processing of products with “Ohne Gentechnik” labelling under ISCC are exempt from labelling according to the requirements of Regulations (EC) No. 1829/2003 and No. 1830/2003 (see chapter 2.1) and meet the requirements stated in Secs. 3a and Sec. 3b of the EC Genetic Engineering Implementation Act (EGGenTDurchfG) (see chapter 2.2).

*Food additives
and auxiliary
substances*

Critical raw materials include:

*Critical raw
materials*

- > Imported products with EU GMO clearance (e.g. soybeans, rapeseed/canola, and maize/corn products)
- > European products permitted to be grown in the EU in GM form (e.g. maize/corn products)
- > European products with neither GMO import nor cultivation clearance, but carrying a plausible risk of contamination resulting from imported products (domestic soybeans, canola, or maize/corn products)
- > All products produced using microorganisms

4.2.4 Segregation of Goods Flows/ Exclusion of Technically Avoidable Commingling

The flow of goods must always be separated spatially or temporally during storage, handling and transport and all products must be labelled. In the case of temporal segregation any carryover of GMO-containing or non-compliant material must be reduced to technically unavoidable minimum. Simultaneous storage of GMO and Non-GMO material is only permissible if they are spatially segregated. Vehicles must be verifiably dry- cleaned after transporting bulk raw materials, feed or food labelled as genetically modified pursuant to Regulations (EC) No. 1829/2003 and No. 1830/2003. Documents of all process steps are available and included in the self-monitoring process.

*Segregation and
labelling*

Labelling of raw materials/partially finished products/finished products must be properly done during all stages of handling and storing within the production facility with regard to their suitability for Non-GMO production and in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003.

All risk-preventing process steps must be documented for each facility with a proof of adequate spatial, temporal or logistical measures. Documentation is part of the self-monitoring concept and should be considered during the self-monitoring process.

*Documentation
of risk-
prevention*

4.2.5 Requirements for outgoing material and traceability

Only those products meeting the full statutory requirements of ISCC Non-GMO labelling must leave the business as such. If no delivery slips or shipping documents can be prepared, a clear contractual provision must be in place regarding the delivery.

Documents

A traceability system must be installed, which ensures that all products with Non-GMO labelling can be traced back at all time, clearly and without delay. It must also be ensured that all products, that are not at the company's site anymore, can be traced back within one workday and that employees of all stages are aware of the GMO status of individual products and batches. All documents need to be collected in line with Regulation (EC) No. 178/2002 (laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety):

Traceability system

- > Information on the origin (country, supplier, if applicable: certificates for ISCC Non-GMO labelling/or equivalent)
- > Batch/lot formation, if applicable (including re-working)
- > Documentation of production/manufacture
- > Information regarding the raw materials, additives, and auxiliary materials used, and their origin (including rework)
- > Information on delivery date and market participants supplied
- > Quantity

4.2.6 Requirements for internal handling of material

For the event of positive test results or any other findings leading to a lack of compliance with ISCC Non-GMO requirements for food, a system must be in place to handle non-compliant products. Regarding feed, samples collected are tested for their compliance with Non-GMO criteria. Positive results are permitted to be analysed a second or third time for the respective batch, if it is done immediately. If two test results with different conclusions are obtained for a single sample, the following procedure is to be undertaken:

Handling positive test results

- > If the results overlap, considering the expanded measurement uncertainty, the average value of the two test results is used.
- > If the results do not overlap, considering the expanded measurement uncertainty, a third test of the batch is ordered.

In case of a test result >0,9% for feed samples, certain measures are to be taken. Positive GMO test results for feed are handled under the ISCC in accordance with the following steps:

1. Sampling at feed stage
2. GMO test, possibly including species quantification

3. If the initial result is within the threshold ($> 0,1\% \leq 0,9\%$) the animal feed supplier should be informed
4. If the initial result is higher than the threshold ($> 0,9\%$) all parties involved should be informed: feed producer, feed supplier, agricultural facility, and bundler if applicable)
5. For results $> 0,9\%$, the following tasks are applicable:
 - a. Assessment, if needed: Is there any botanical contamination that need not be declared
 - b. Repeat testing / comparison testing by second laboratory, if needed
 - c. Test retained samples / loading sample, if needed
6. If final results now show a value within the threshold ($> 0,1\% \leq 0,9\%$)², the feed supplier must confirm, that the tested feed is not subject to compulsory labelling. Only if this confirmation can be given the material is permissible for the ISCC Non-GMO production.
7. If final results still show a value of $> 0,9\%$, the feed batch must be banned from being labelled "ISCC Non-GMO" and thus cannot also not be used for the production of ISCC "Ohne Gentechnik" products (food).
8. In case of $> 0,9\%$ contamination of feed material, the according food products, might need to be tested. If a certification has already been granted, customers and Certification Bodies have to be informed.
9. All test results must be recorded in the self-monitoring system (test result & evaluation, causes, and measures taken).

Notification of relevant parties

The results of the test for GMO carryover in feed are shared with the relevant system partner for the given situation. Both the feed supplier and the affected agricultural operation must comment on the matter.

In the event of an inaccurately labelled delivered feed or food product, the producer's customers and Certification Body must be notified.

The internal audit and ISCC audit of the independent CB have to examine whether the test results were evaluated correctly and if necessary corrective measures were properly implemented.

Internal and external audit

A control system is in place, handling errors and claiming of non-compliant or blocked products if test results show a contamination of $>0,9\%$ for feed or $>0,1\%$ for food, or other non-conformities.

Control system

4.2.6.1 Training of personnel

All employees involved in the operating procedures of Non-GMO materials must be instructed in all Non-GMO requirements before starting their activities. Intensity of the training depends on staff members and their responsibilities. Training sessions must be documented regarding their content, their participants, training date, training facility and instructors. Documentation needs to cover training contents, participants lists, date and

Documentation of trainings

² Or $> 0,9\%$ GMO for botanical contamination requiring no GMO declaration

place of the training and name of the respective trainer. Training for employees shall take place at least annually.

4.2.6.2 Records keeping

All relevant documents (e.g. delivery slips, way bills, orders, declarations, specifications of seeds, feeds, records of production, clearance certificates, etc.) must be kept from the time of delivery for a min. shelf-life of a batch +1 year but not less than 2 years. Documents must be easily legible, stored in a periodical manner and authentic and kept in such a manner that post facto manipulation is not possible.

Timing and storage

4.2.6.3 Complaint, crisis and recall systems

A complaint management system shall be in place for handling complaints regarding Non-GMO requirements by clients or other bodies. Deviations within the self-monitoring system must be documented and evaluated appropriately and corrective actions initiated. Complaints and deviations are to be documented and records taken of corrective actions.

Complaint management system

If non-compliances are detected in Non-GMO certified food products or feed still in the market, a recall system must provide immediate (written) notification of the customers. If needed, feed and/or food must be taken back at the expense of the supplying business.

Recall system

The system user also needs to have a crisis management system in place and potential dangers must be analysed. A description of the procedure to follow in an event of crisis must be in place, including e.g. list of emergency numbers/contact details of suppliers and clients.

Crisis management system

Further, an internal system to block rejected products needs to be in place at the operational unit.

Additionally, the system user must take measures to continuously reduce GMO contaminations of adventitious and technically unavoidable contamination with GMO to a minimum. The handling of positive test results must be taken into consideration in particular. The measures must be monitored and evaluated after a certain period of time. This includes corrective actions from the last audit as well. Internal audits shall take place annually to verify the self-monitoring system.

Measures to reduce contamination risks

4.2.7 General requirements for sampling and testing

Food and feed material that is subject to a Non-GMO certification must be tested for its compliance with Act §3a and 3b of the EGGenTDurchfG in accredited laboratories based on a risk analysis for both food and feed material.

4.2.7.1 General requirements for laboratories and testing

Laboratories conducting tests for food or feed materials subject to Non-GMO certification must be accredited according to DIN EN ISO/IEC 17025 (in its

Certified laboratories

most recent version) for all qualitative and quantitative GMO test parameters. This may be in the form of a flexible accreditation for the entire field or separately for all procedures to be carried out.

The respective laboratory must comply with certain methodological requirements. DIN standards and protocols of the Joint Research Centre are to be used (if available/present). For methods from other sources, the laboratory must verify that similar minimum requirements are fulfilled. Other methodological requirements are described in the next section.

*Compliance with
recognized
standards*

System users commissioning a GMO test need to regularly, at least annually, examine the accreditation of the respective laboratory. Further, system users need to provide all relevant information to the laboratory that is commissioned with a test. This information includes:

*Annual
accreditation
check of
laboratory*

- > Tests in accordance with ISCC Non-GMO requirements
- > The composition of the sample: If containing soy, maize/corn, rapeseed/canola and/or rice single-component feed or ingredients, it must be indicated in what form these are contained (e.g. maize/corn as maize/corn mash, soy as soy extraction meal). Copies of the feed delivery slips/shipping documents/declarations are to be sent to the laboratory along with the samples.

When receiving the test results, the system user needs to verify whether the laboratory confirms the compliance with the methodology and requirements laid out in this procedure. Confirmation may be done for every test result in the audit report or in a separate confirmation that is issued by the laboratory once a year.

*Confirmation of
test result*

4.2.7.2 Testing process

Milling:

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

*Specific
requirements for
testing*

- > Feed: min. 400g, max. 1kg, entirely milled
- > Raw materials (whole maize/corn kernels, soy beans or rapeseed/canola grains, etc.): at least 3000 grains or approx. the respectively corresponding sample amount (maize/corn at least 1000g; soy at least 700g, rapeseed/canola at least 60g), entirely milled

DNA extraction:

- > At least two DNA extractions from each sample will be carried out after every milling/ homogenisation. The required weight is at least 2000mg for feed, seeds and materials that are suspected of being not homogeneously distributed. In exceptional cases (for otherwise non-extractable material), the weight may be only 500mg.

PCR (Polymerase Chain Reaction) test:

- > Real-time PCR methods with the 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).

4.2.7.3 Protecting the analytical 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.

*ISO and DIN
quality of results*

To prevent repeat errors, instability of reagents etc., methods for regularly carrying out and documenting quality control (QC) measures must be established and implemented (e.g. control charts).

*Regular quality
control*

4.2.7.4 Approval of test results

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

4.2.7.5 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:

*Content of test
reports*

- > Quantity of sample milled and sent
- > Quantity of sample used in the DNA extraction
- > Exact description of the sample
- > Detection limits (Limit of Detection - LOD in % or as copy number of target)
- > Method applied
- > Test result
- > Error margin of the procedure
- > Confirmation that the result was determined according to the requirements of the ISCC. In the alternative, this confirmation may take place in a separate letter to be submitted to the Certification Body (CB) once a year.
- > Additionally, for identification/quantification:
- > Warning if the amount of species-specific DNA is not sufficient for quantitative statements regarding the relevant threshold value (0.1% GMO DNA for food/ food additives or 0.9% GMO DNA for feed).

When quantifying, to indicate the average deviation of the sub-samples (at least double preparation); indicating the pLOQ (practical limit of quantification) is recommended.

4.2.7.6 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 ISCC non-GMO standard for the parameter analysed. The standard deviation must be taken into consideration for each evaluation in order to consider the inhomogeneous distribution of GMOs in feed or food: In keeping with Regulation (EC) No. 691/2013 on the methods of sampling and analysis, the analysed GMO content, after deduction of the expanded error margin, is to be used for evaluation.

Documentation requirements

Chapter 5 and Annexes 1 and 2 of the “Guideline on controlling GMOs in feed” must be respected for the evaluation of feed.

“Guideline on controlling GMOs in feed”

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

4.2.8 Requirements for sampling and testing of raw materials and feed

It must be noted that, regarding the requirements, further specified in this section, for the scope of analysis for minimum requirements for raw soy material/ soy-based, raw corn materials/corn-based, and raw canola materials/canola-based single-component feed, and for rice and rice products, for compound feed containing soya, and for soy-free compound feed, 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. Furthermore, 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).

Requirements for tolerated GMO-components

A) For the scope of analysis for raw materials and single component feed minimum requirements include the following:

Analysis of raw materials and single component feed

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

- > Quantification of GTS 40-3-2 (RRS-1)
- > Quantification of MON89788 (RRS-2)
- > Qualitative detection of A2704-12 (if A2704 results are positive over 0,1%, GMO quantities can be estimated using the ct or similar methods)

- > Alternately, the laboratory may work with screening parameters that detect at least the GMOs mentioned. In subsequent identification/quantification of positive findings, at least all GMOs (if corresponding elements are positive) mentioned here must be quantified

Raw corn materials/corn-based single-component feed:

- > Screening for 35S Promoter (p35S) and NOS Terminator (tNOS) and other screening elements to narrow down corresponding GMOs
- > If the screening is positive an analysis should be done for min. NK603, TC1507, MON810, MON89034 + RRS-1
- > If using the positive screening parameters, one or more of these GM corn types can be ruled out, then the same number of commercialised GM corn types that come into question must be searched for instead. Positive screening results must be clarified; if none of the 4 GM corn types are positive, other GM types must be analysed
- > If the estimation of concentration leads to values over 0.1% by using the e.g. the ct method or another similar method ensuring that sufficient quantities of species DNA are present, the identified varieties must be quantified
- > If the tests are RRS-1 positive, the soy mass and amount of soy shall be estimated and assessed, considering the relevance of the amount. If botanical contamination is found containing GMO, an assessment must take place according to the "Guideline on controlling GMOs in feed"

Raw canola materials/canola-based single-component feed:

- > Triple screening, detecting all relevant GM canola varieties (e.g. tNOS, pat gene/LibertyLink construct, CTP2-CP4epsps/pFMV)
- > ID depending on positive screening results:
 - tNOS positive: at least RRS+ bar gene for MS8/RF3 or both directly
 - pat gene/LibertyLink positive: at least canola T45
 - CTP2-CP4epsps/pFMV positive: at least GT73
- > If the estimation of concentration leads to values over 0.1% by using the e.g. the ct method or another similar method ensuring that sufficient quantities of species DNA are present, the identified varieties must be quantified
- > Positive results must be clarified
- > In case no canola GMO is detected, the presence of a botanical contaminant containing GMO with soy or corn GMO must be clarified

regarding its relevant quantity. If a botanical contamination is found, an assessment must take place according to the “Guideline on controlling GMOs in feed”

Rice/rice products:

- > Preparation of laboratory samples: two sub-samples 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 sub-sample)
- > Element-specific screening: p35S+tNOS+cry1Ab/cry1Ac sequence
- > Design-specific proof: identification of GMO events that cause a positive screening result, by agreement between the company and the laboratory
- > Exclusion of botanical impurities: GMO carryovers from corn, 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, an investigation is to be made of whether the sample contains genetically modified rice
- > 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 the batch. The batch cannot be marketed in the EU and cannot be labelled with the non-GMO claim

B) For the scope of analysis for compound feed minimum requirements include the following:

*Analysis of
compound feed*

Compound feed containing soya

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

Soy

- > Quantification of GTS 40-3-2 (RRS-1)
- > Quantification of MON89788 (RRS-2)
- > Qualitative detection of A2704-12 (Positive results: GMO quantities can be estimated using the ct or similar methods ensuring that sufficient quantities of species DNA are present. If values are > 0,1%, a post-quantification must take place)
- > If the analysability of soy ingredients is limited, the practical LOD must be indicated

For canola ingredient

- > Additional to steps described under soy, a qualitative detection of GT73 must take place
- > Positive results: GMO quantities can be estimated using the ct or similar methods ensuring that sufficient quantities of species DNA are present. If values are > 0,1%, a post-quantification must take place)
- > If the analysability of soy ingredients is limited, the practical LOD must be indicated

For corn ingredient

- > Additional to steps described under soy, a qualitative detection of NK603, TC1507, MON810
- > Positive results: GMO quantities can be estimated using the ct or similar methods ensuring that sufficient quantities of species DNA are present. If values are > 0,1%, a post-quantification must take place)
- > If the analysability of soy ingredients is limited, the practical LOD must be indicated

Soy-free compound feed

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

Estimating the soy mass

- > Estimation of mass of soy in feed (>0,9%: the quantity of soy GM must be determined, and an assessment must take place according to the "Guideline on controlling GMOs in feed")

For canola ingredient

- > Qualitative evidence of canola GT73+ canola MS8 or canola RF3 (or bar gene)
- > Positive identification: If the estimation of concentration leads to values over 0.1% by using e.g. the ct method or another similar method ensuring that sufficient quantities of species DNA are present, the identified varieties must be quantified
- > If the analysability of soy ingredients is limited, the practical LOD must be indicated

For corn ingredient

- > Qualitative evidence of 3 corn varieties used commercially: NK603, TC1507, MON810
- > Positive identification: If the estimation of concentration leads to values over 0.1% by using e.g. the ct method or another similar method ensuring that sufficient quantities of species DNA are present, the identified varieties must be quantified

- > If the analysability of soy ingredients is limited, the practical LOD must be indicated
- > Alternately, the laboratory may work with screening parameters that detect at least the GMOs mentioned. In subsequent identification/quantification of positive findings, at least all GMOs (if corresponding elements are positive) mentioned here must be quantified

Other raw materials/ products

Agreeing upon strategies for analysing GMOs in other single-component feeds/raw materials/ingredients must be continued with the respective laboratory, considering composition and origin of products. Testing and sampling of feed materials must be done according to the respective regulations.

4.2.8.1 Risk assessment and sampling for feed

Risk assessment is the process of identifying and evaluating a risk according to its probability to occur and the significance of its consequences. Risk indicators can be used to identify potential risks. For ISCC Non-GMO food and feed criteria, risk classification is done in order to identify and estimate potential sources and risks of carryover of GMOs and/or any risk of commingling with products not of Non-GMO quality at the operational unit.

*Potential
sources/ risks of
carry-over*

Feed businesses are obligated to carry out an individual risk grading of the raw materials/ single-component feeds used (at risk/not at risk). The business is responsible for assessing the feed. The risk grading must be verifiable for the auditor within the scope of the ISCC Non-GMO certification.

Steps relevant for the risk assessment of feeds:

*Risk assessment
of feeds*

- (1) Checking documentation (e.g. declaration without GMO label, additional certifications, product data sheet/contractual provisions proves that the product is not subject to compulsory labelling, test results from accredited labs)
- (2) Assessing the origin of the raw materials, esp. for feed from countries where growing GM-plants is allowed:

Potential "at risk" origin of plants for feed production (as of February 2018)

	Growing (specific) genetically modified plants is prohibited	Growing specific genetically modified plants is allowed	Types of genetically modified plants known
Soy	European Union	Moldova	North, Middle and South America, Ukraine, China, South America, Romania
Rapeseed/ Canola	European Union		Northe, Middle and South America, Australia

	Growing (specific) genetically modified plants is prohibited	Growing specific genetically modified plants is allowed	Types of genetically modified plants known
Corn	Remaining EU countries/ regions	Belgium (except Wallonia), United Kingdom (except Northern Ireland, Scotland, Wales), Estonia, Romania, Czech Republic, Finland, Sweden, Ireland, Bulgaria	Portugal, Spain, Slovakia, North, Middle and South America, Ukraine
Sugar beet	European Union		North America

- (3) Considering packaging, transportation, storage and processing (e.g. product in question transported by own or external feed business, agreement in place regarding the cleaning of transportation vehicles, product transported, handled/processed before by ISCC Non-GMO certified businesses or equivalent?)

If the system user, in the internal assessment, reaches the conclusion that the feed is “at risk”, then the goods receiving is to be sampled in lots.

Internal “at risk” evaluation

Within the scope of the evaluation/ review of the ISCC audit, the grading of the auditor in the completed checklist and the information indicated in the facility description will be re-checked by the Certification Body for completeness and plausibility. In this regard – if relevant for the respective stage – the risk grading is also to be reviewed by the Certification Body and corrected, if appropriate. If the risk grading is corrected, the business must be informed thereof as soon as possible.

Review of internal risk grading by CB

A risk assessment of any single-component feed used for ISCC Non-GMO production and labelling of single-component feeds must be conducted, which will be the basis for risk-targeted sampling and testing of feed for GMO within the scope of the company’s self-monitoring system.

Risk assessment of single-component feed

If the business, for its ISCC Non-GMO production, only uses feed in which, due to technical limitations, genetic modification cannot be detected through PCR tests, no sampling/GMO test is necessary. In this case the test plan must provide for a risk analysis that concludes that it is not necessary to sample/analyse any feed.

No GMO-detection possible for feed

The frequency of sampling and tests results from the business’ individual risk assessment of single- component feed for ISCC Non-GMO production and the feed quantity produced. The business must have a test plan that describes the sampling and testing procedure. The focus of consideration must be on the following: type of samples, sampling locations, sampling of finished product, formation of collective samples, naming the sampler, creation of reference samples, sample size, and sampling frequency. The test plan must be implemented as scheduled and evenly over the audit period.

Sampling and testing frequency

Sampling and testing frequency:

The numbers of samples/tests listed below are the annual minimums. Supplementary samples should be taken during the audit on a risk-targeted basis and in suspicious cases. The samples and tests serve to test the self-monitoring system. The results may also be incorporated into the self-monitoring system and thereby reduce the number of samples in the self-monitoring system.

Single-component feed graded as risk-prone based on the business' risk assessment must be sampled in lots. To safeguard the system, outgoing goods (compound and/or single-component feed) intended to be identified as ISCC Non-GMO must be sampled according to the following plan.

All samples must also be analysed. Only test results that are achieved by fulfilling the requirements under 4.2.7.1 and following will be considered. The tests are to be carried out in recognised laboratories.

All feed quantities specified in the following sample categories relate exclusively to feed that is either intended to be used in ISCC Non-GMO production and/or are to be labelled as "ISCC Non-GMO for feed", depending on the respective facility.

A) Feed production sub-stage:

*Sample size at
feed production
sub-stage*

The annual minimum number of samples/tests of Non-GMO certified **incoming** products:

- > In production, that is completely not subject to compulsory labelling, a sample must be taken for every batch of single-component feed graded as risk-prone
- > In dual production, for every batch of single-component feed graded as risk-prone, a sample must be taken

The annual minimum number of samples/tests of Non-GMO certified **outgoing** products:

- > For production, completely not subject to compulsory labelling for every batch of single-component feed graded as risk-prone:

Up to 10,000 t/year: 1 sample

≥ 10,000 to 50,000 t/year: 2 samples

≥ 50,000 to 100,000 t/year: 4 samples

≥ 100,000 to 200,000 t/year: 6 samples

≥ 200,000 to 300,000 t/year: 8 samples

for ever additional 100,000: 2 additional samples

- > For dual production:

Up to 2,000 t/year: 1 sample

- > 2,000 to 5,000 t/year: 3 samples
- > 5,000 to 10,000 t/year: 5 samples
- ≥ 10,000 to 50,000 t/year: 10 samples
- ≥ 50,000 to 100,000 t/year: 15 samples
- ≥ 100,000 to 200,000 t/year: 20 samples
- ≥ 200,000 to 300,000 t/year: 25 samples
- for every additional 100,000 t: 5 additional samples

B) Stage: incorporation of single-component feed not subject to compulsory labelling into ISCC Non-GMO quality

*Sample size for
incorporation
into Non-GMO
quality*

The annual minimum number of samples/tests of Non-GMO certified **incoming** products:

- > In production, completely not subject to compulsory labelling for every batch of single-component feed graded as risk-prone, a sample must be taken
- > In dual production, a sample must be taken for every batch of single-component feed graded as risk-prone

The annual minimum number of samples/tests of non-GMO certified **outgoing** products:

- > Only bulk non-GMO feed and/or bulk feed not subject to compulsory labelling:
 - Up to 10,000 t/year: 1 sample
 - ≥ 10,000 to 50,000 t/year: 2 samples
 - ≥ 50,000 to 100,000 t/year: 4 samples
 - ≥ 100,000 to 200,000 t/year: 6 samples
 - ≥ 200,000 to 300,000 t/year: 8 samples
 - for ever additional 100,000: 2 additional samples
- > Only bulk non-GMO feed and bulk feed subject to compulsory labelling, plus, if applicable, bulk feed not subject to compulsory labelling:
 - Up to 2,000 t/year: 1 sample
 - > 2,000 to 5,000 t/year: 3 samples
 - > 5,000 to 10,000 t/year: 5 samples
 - ≥ 10,000 to 50,000 t/year: 10 samples

- ≥ 50,000 to 100,000 t/year: 15 samples
- ≥ 100,000 to 200,000 t/year: 20 samples
- ≥ 200,000 to 300,000 t/year: 25 samples
- for every additional 100,000 t: 5 additional samples

4.2.8.2 Reference samples

In addition to the provision of data, the business is obligated to retain samples of all batches sent to customers, in suitable containers, so that a conclusion can be drawn as to the quality actually delivered, if necessary. The reference samples must be retained for a period of time appropriate to the intended purpose and product perishability of the feed. This applies both to products delivered in bulk and to packaged products.

*Timing and
storage of
samples*

4.2.8.3 Declarations on delivery documents

GMO labelling in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003 must be properly implemented on labels, production and goods shipping documents, specifications, etc..

*"ISCC Non-GMO
feed"*

Feed certified under ISCC Non-GMO must be marked by the certified feed business with the wording "ISCC Non-GMO feed".

4.2.9 Requirements for sampling and testing of food

Risk assessment for processing of food is done by categorising risks into regular, medium or high probability.

Regular risk:

- > There is no or only very low risk. Businesses that transport, trade, handle, store or process (swappable) GMOs within their business or products produced from them may not be graded into the Regular Risk category.

Medium risk:

- > Businesses and process steps with clear spatial segregation during transport, storage, handling and processing of products for which a "Ohne Gentechnik" label under ISCC would be permissible, and of such products that do not meet the requirements for the Non GMO label.
- > Transport, storage, and handling of food/food ingredients within the scope of the operational unit to be certified: Businesses and process steps without spatial segregation but with temporal segregation during transport, storage and handling of food/food ingredients for which a "Ohne Gentechnik" label under ISCC would be permissible and of such products that do not meet the requirements of the "Ohne Gentechnik" label under ISCC, but which are not themselves GMOs and/or are not produced from or do not contain GMOs.

High risk:

- > High risk of commingling GMO-free raw materials with such containing GMOs
- > Businesses and process steps without spatial but with temporal segregation in the storage, transport and processing of products for which “Ohne Gentechnik” labelling under ISCC would be permissible and such products that do not meet the requirements for “Ohne Gentechnik” certification under ISCC.
- > Transport, storage, handling of food/food ingredients within the scope of the operating unit to be certified: Businesses and process steps without spatial but with temporal segregation during transport, storage and handling of food/food ingredients for which a “Ohne Gentechnik” label under ISCC would be permissible and of GMOs and/or food/food ingredients that are produced from, with, or contain GMOs
- > Food: Test results from the audit period under consideration have indicated that the threshold value of 0.1% GMO per ingredient was exceeded; this resulted from the business’ failing to take measures to avoid carryover.

In case of preparation/processing of raw materials of plant origin, a test plan based on a risk analysis must be present. The focus is on type of samples, sampling facilities, sampling of finished product, compiling of collective samples, naming the sampler, creation of reference samples, and sample size. The sampling plan describes the sampling frequency and the test procedure.

*Test plan for
raw materials*

If a food business only prepares/processes raw materials of plant origin, and genetic modification cannot be proven by PCR testing due to technical limitations, no sampling/GMO test is necessary. In this case the test plan must provide for a risk analysis that concludes that it is not necessary to sample/analyse any raw materials/feed.

*No GMO
detection
possible for food*

The minimum number of samples/tests for plant-based raw materials for “Ohne Gentechnik” labelling under ISCC must be taken according to the relevant risk category:

Test samples

Risk category 0: 2x per year

Risk category 1: 6x per year

Risk category 2: 12x per year

The number of samples may be correspondingly reduced when the number of batches obtained in the audit period is smaller than the minimum number of samples listed in the table.

Specific requirements for risk-prone raw materials are to be determined according to the three steps described 4.2.8.1..

*Risk-prone raw
materials*

Information on risk-prone materials (e.g. table: 'Potential "at risk" origin of plants for feed production') are subject to regular updates and no responsibility is taken for the correctness of its content.