"Ohne Gentechnik"
Production and Certification Standard

Verband Lebensmittel ohne Gentechnik e.V.
(German Association Food without Genetic Engineering)

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Part 1 of the VLOG Standard

1. Introduction and Legal Background

1.1. Development of the "Ohne GenTechnik" Seal

The EC Genetic Engineering Implementation Act (EGGenTDurchfG) has been in force since May 2008. It governs the labelling of food produced without the "use of genetic engineering processes".

In August 2009, Ilse Aigner, Minister of Food, Agriculture and Consumer Protection, introduced a uniform seal, with which this food can henceforth be labelled.

Consumer associations and interested members of the food industry had long advocated such a seal which enhances the consumer's freedom of choice and provides the consumer with information and safety.

1.2. Main Prerequisites for the Use of the Seal

In general, any company that meets the statutory prerequisites can label its products with its own "Ohne Gentechnik" logo or the words "ohne Gentechnik"[1]. In both cases, Sect. 3a and Sect. 3b of the EC Genetic Engineering Implementation Act (EGGenTDurchfG) apply. However, any company that wishes to use the uniform "Ohne GenTechnik" seal shall apply to the German Association Food without Genetic Engineering (VLOG).

The Federal Ministry of Food, Agriculture and Consumer Protection (BMEL) has exclusively commissioned VLOG with the task of issuing and administering licences for the use of the "Ohne GenTechnik" seal. Licensing is only possible after VLOG has been presented with *prima facie* evidence that all legal requirements for labelling a product as "ohne Gentechnik" are fulfilled.

For this purpose, the companies shall present *prima facie* evidence that their products meet the statutory prerequisites under Sect. 3a and Sect. 3b of the EGGenTDurchfG. The requirements vary by industry and product. The applicant shall fill out a questionnaire and submit relevant documentation for VLOG to issue the seal.

Whether certification by a neutral certification body under this Standard or a review of the documentation is sufficient to provide the *prima facie* evidence to VLOG will be determined based on the criteria set forth in Chapter 2.1.1.

1.3. Statutory Source

The following regulations form the statutory source of the Standard at hand. In case of doubt, the current versions of the relevant legal regulations shall be binding.

- EC Genetic Engineering Implementation Act (Gesetz zur Durchführung der Verordnungen der Europäischen Gemeinschaft auf dem Gebiet der Gentechnik und über die Kennzeichnung ohne Anwendung gentechnischer Verfahren hergestellter Lebensmittel, EG-Gentechnik-Durchführungsgesetz, abbreviated EGGenTDurchfG), dated 22 June 2004 (Federal Law Gazette I p. 1244, as last amended by the promulgation of 27 May 2008, Federal Law Gazette I p. 919).
- Regulation (EC) No. 1829/2003 of the European Parliament and of the European Council concerning genetically modified food and feed, dated 22 September 2003
- Regulation (EC) No. 1830/2003 of the European Parliament and of the European Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, dated 22 September 2003
- Regulation (EC) No. 178/2002 of the European Parliament and of the European Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down the procedures in matters of food safety, Article 18 1, dated 28 January 2002

[1] Official translation: "Non-GMO"

- Regulation (EC) No. 619/2011 of the European Commission laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which is about to expire, dated 24 June 2011
- Regulation (EC) No. 834/2007 of the European Council on organic production and labelling of organic products and repealing Regulation (EEC) No. 2092/91, dated 28 June 2007

Compliance with the requirements for the use of "Ohne Gentechnik" labelling is monitored on German territory by the local authorities of the *Länder* (German States) by means of random samples. For this purpose, [to prove compliance] food operators shall provide the required evidence. To generate this documentary evidence and to ensure conformity, the present Standard may be consulted. The implementation of this Standard shall be verified by an auditor of a neutral certification body. In case of a positive audit result the certification body shall issue a written confirmation to certify conformity with the Standard.

1.3.1. Relevance of the EU Labelling Obligation for "Ohne Gentechnik" Labelling

A basic requirement for feed and food ingredients for the production of food labelled "ohne Gentechnik" is that they must not bear any labelling according to the rules of Regulations (EC) No. 1829/2003 and No. 1830/2003.

Commingling with GMOs permitted in the EU by law shall be exempt from labelling according to Regulations (EC) No. 1829/2003 and No. 1830/2003 provided that two requirements are fulfilled:

- The threshold value of the GMO content of 0.9 % per component (feed / food) must not be exceeded and
- The presence of the GMO content must be "adventitious" or "technically unavoidable".

Commingling with GMOs permitted in the EU below the limit of quantification of generally 0.1% per species shall be regarded as "adventitious" or "technically unavoidable".

Commingling in an order of magnitude that is between the detection limit and the threshold value of 0.9% is considered conforming if the feed company initiates and verifiably implements organizational measures to avoid the entry of GMO materials.

1.3.2. Labelling Obligations for Food

For food ingredients to qualify for the "Ohne GenTechnik" label the requirements go clearly beyond the absence of a labelling obligation according to Regulations (EC) No. 1829/2003 and No. 1830/2003. Ingredients, additives and auxiliary substances that are produced by or from GMOs, are themselves GMOs or consist of GMOs must not be used in the production of "ohne Gentechnik" food. In general, adventitious or technically unavoidable traces of genetically modified material shall usually be tolerated up to a threshold of at most 0.1 % per ingredient. In cases where required additives such as vitamins are demonstrably not available anymore on the market in "ohne Gentechnik" quality, additives produced by GMOs may be used. Prerequisite for this exception is the listing of these substances by the EU Commission according to the procedure provided by Regulation (EC) No. 834/2007; currently, no substances are listed.

1.3.3. Labelling Obligation for Animal Feed

Feedstuffs used in the "Ohne Gentechnik" system must neither bear any labels according to the rules of Regulations (EC) No. 1829/2003 and / or No. 1830/2003 nor must they be subject to labelling obligations if they were brought onto the market.

Appropriate steps shall be demonstrably undertaken to avoid and prevent the presence of any genetically modified material.

Commingling with GMOs permitted in the EU below a limit of quantification of generally 0.1% per species shall be regarded as "adventitious" or "technically unavoidable".

With respect to the assessment whether a cross-contamination is adventitious or technically unavoidable or not, the following criteria shall be examined:

- Does a written contract with the supplier exist to avoid the presence of GMOs?

- Have consistent suitable measures been taken to spatially and / or temporally segregate GMO-containing workflows from GMO-free workflows (e. g. by flushing batches etc.)?
- Are the required precautions in place for goods imported from third countries, where no labelling obligations according to EU regulations exist (contract, certificate, analysis result, sampling regimes, etc.)?
- How high is the frequency of non-conforming results?

Feed additives shall only be taken into consideration if they are made of GMOs or of GMO components and therefore require labelling themselves. According to the existing legal provisions feed additives that are produced by or with the help of GMOs need not be labelled and may be used without restrictions.

1.4. Objectives of the Standard

The present Standard is aimed at

- Producers and processors of foods and their components who wish to label their products with an “Ohne Gentechnik” logo or the words “ohne Gentechnik”.
- Producers and merchants of feedstuffs who wish to label their products with the “VLOG geprüft” seal.

Furthermore, in addition to agricultural operations and logistics companies, certification under this Standard, separate from the aforementioned product labelling option, can also be extended to food producers and processors and feed manufacturers and vendors.

If the present Standard is used for the purpose of certification, a contractual agreement between VLOG and the company to be certified is required.

Certification using this Standard can also be a prerequisite for the use of the uniform “Ohne GenTechnik” Seal (see Chapter 1.5). The “Ohne GenTechnik” Seal (see 1.5) is a trademarked word mark and logo owned by the Federal Republic of Germany, represented by the BMEL.

1.5. Use of the “Ohne GenTechnik” Seal

In Germany, only the term “Ohne Gentechnik” may be used on a food advertised or placed in circulation and indicating production without the use of genetic modification processes.

The use of the German nation-wide legally protected “Ohne GenTechnik" seal (see Figure 1) for labelling foods is only permitted with consent by VLOG; use is regulated by a separate contract between VLOG and the operator placing the product on the market.

Due to an exclusive agreement with the proprietor of the seal, the right to use this registered trademark may exclusively be granted exclusively by:

®

Figure 1: Official "Ohne GenTechnik" Seal

Due to an exclusive agreement with the proprietor of the seal, the **right to use this registered trademark may exclusively be granted by**:

Verband Lebensmittel ohne Gentechnik e.V. (VLOG)
Chausseestrasse 8/ Aufgang F
10115 Berlin, Germany
Tel: +49 30 788 90 682
Fax: +49 30 788 90 686
info@ohnegentechnik.org
www.ohnegentechnik.org/en

The conduct of audits under the VLOG Standard and the use of the uniform “Ohne GenTechnik" Seal on certificates are governed by an agreement between the certification body and VLOG.

1.6 Use of the "VLOG geprüft" Seal for Animal Feed

In order to point out explicitly in the case of animal feedstuffs and their accompanying bill of lading the absence of any an obligation to label the product in accordance with Regulations (EC) No. 1829/2003 and No. 1830/2003, and thus of their suitability for "Ohne GenTechnik" food production, the trademarked "VLOG geprüft"[2] seal (see Fig. 2) may be used. The use of the "VLOG geprüft" seal is only permissible with the consent of the proprietor of the trademark (VLOG), and is regulated by a separate agreement between VLOG and the operator placing the product into the market. The basis for the agreement is certification in accordance with the VLOG "Ohne Gentechnik" standard by a VLOG recognised certification body.

The owner of the trademark is:
Verband Lebensmittel ohne Gentechnik e.V. (VLOG)
Chausseestrasse 8/ Aufgang F
10115 Berlin, Germany
Tel: +49 30 788 90 682
Fax: +49 30 788 90 686
info@ohnegentechnik.org
www.ohnegentechnik.org

Figure 2: Official seal in German and English version for animal feed certified in accordance with the VLOG "Ohne Gentechnik" Standard

2. Necessary *Prima Facie* Prerequisites

2.1. *Prima Facie* Evidence on the Basis of External Certification or Review of Documentation

The use of the "Ohne GenTechnik" Seal is only permitted after prior *prima facie* evidence to VLOG that the criteria of the EGGenTDurchfG are complied with. Whether certification is mandatory in order for *prima facie* evidence to VLOG depends on

- the complexity of the production process,
- the raw materials used which could cause commingling with GMO material, and
- the size of the licensee's company.

2.1.1. Obligation of External Certification

In case at least two of the following five criteria apply to the VLOG licensee or party interested in using the "Ohne GenTechnik" seal, external certification is obligatory.

1) In the production process plants or raw materials are used, which originate from a producing country where the cultivation of genetically modified varieties is approved.

   E. g.: To produce eggs labelled "Ohne Gentechnik", soybean meal from Brazil is added to feed rations for laying hens.

2) The agricultural, animal raw materials to produce "Ohne Gentechnik" labelled food do not originate from contract farmers or a contractually bound producer group. There is no organisational structure (see Glossary) with a superordinate internal monitoring system.

   E.g.: A dairy operator buys also "Ohne Gentechnik" milk on the spot market for its "Ohne Gentechnik" labelled dairy products.

[2] Official translation: "VLOG verified"

3) A producer of food labelled "Ohne Gentechnik" or a producer of agricultural raw materials, which are used to produce food labelled "Ohne Gentechnik" also produces similar food that is not suitable for an "Ohne Gentechnik" label.

   E.g.: A dairy produces "Ohne Gentechnik" labelled plain yoghurt, but also fruit yoghurt that is not subject to labelling.

   E.g.: An egg-producing operation also produces eggs that are not suitable for an "Ohne Gentechnik" label.

4) At least one "Ohne Gentechnik" labelled food product is a product with more than five ingredients (water not included). If the ingredient itself consists of several components, they are counted individually. The legally required information on the list of ingredients is controlling.

   E.g.: A strawberry yoghurt is made from yoghurt, sugar and strawberry mix. The mix consists of strawberries, strawberry juice, red beet juice, sugar and natural flavourings. This fruit yoghurt is therefore made from seven ingredients.

5) The licensee has a total annual turnover of more than 50 million euros.

   E.g.: A producer of sausages markets "Ohne Gentechnik" labelled products in the amount of 10 million euros every year. The annual revenue of the overall company, however, is 80 million euros.

If an independent company processes, prepares, or packages animal products in VLOG-certified quality and itself labels them with the uniform “Ohne GenTechnik” seal, Criteria 1) and 2) above are not taken into consideration. In this case, the obligation to undergo external certification applies as long as at least one of the remaining Criteria 3) through 5) applies to the VLOG licensee.

Producers and processors outside of Germany producing foods labelled with “Ohne GenTechnik” and containing

- animal products or
- plant products for which a cultivation permit is required in a given country

must generally undergo external certification as they cannot be monitored by the food supervising authorities of the *Länder* (German States) and, particularly in the case of food containing animal products, the use of genetically modified raw materials in the manufacturing process is not detectable in the end product through analysis.

VLOG only accepts certificates of certification bodies that have signed a contract with VLOG (http://www.ohnegentechnik.org/zertifizierer).

2.1.2. *Prima Facie* Evidence by Inspection of Documents

If a company is not required to obtain certification under the above criteria, VLOG may grant permission for use of the seal without requiring external certification if the company can credibly demonstrate that production is carried out without the use of GMOs. This evidence shall be renewed each year.

2.2. Level of the Obligation to Provide Proof and Conduct Audits

To comply with the VLOG standard, the obligation to provide proof that the legal criteria have been observed in order to market "Ohne Gentechnik" labelled food or feed with the label “VLOG geprüft” generally extends back to the direct supplier of the first marketer. If the distributor is a food or animal feed retailer, the requirements are transferred to the producer of the food or animal feed product. If the direct supplier is not the producer or processor of the food product, ingredients or processing aids or animal feed, individual feed component, or processing aids, the obligation to provide proof applies to the preceding processing or manufacturing stage in the manufacturing chain. For example, a suitable proof can be a certificate issued by a certification body in accordance with the VLOG Standard, or a legally binding declaration (for food products, ingredients, and processing aids: template in Appendix II) of the preliminary supplier. The probative value of various suppliers’ declarations is set out in Appendix III.

If the "Ohne Gentechnik" food product or a component thereof is of animal origin, the obligation to provide proof and conduct an audit extends from compliance with the minimum feeding conversion periods in accordance with Chapter 2.4.2 using suitable feed material (see Chapter 2.4.3) and all stages between production and distribution of

the food, unless they already have valid certification according to the VLOG standard, QS standard including VLOG requirements, or Regulation (EC) No. 834/2007.[3]

Exceptions to the obligation to provide proof and conduct audits are possible in justified individual cases, subject to the consent of VLOG. Such individual cases can include products from a GMO-free production system, which have been reviewed according to a different standard. In any case, the requirements of Sect. 3b of the EC Genetic Engineering Implementation Act (EGGenTDurchfG) shall be complied with.

It is urgently recommended to include feed producers and logistics companies in the audit concept.

- Feed traders who do not move the goods physically (so-called drop shippers) and
- Traders who move the goods, but do not otherwise treat them within the meaning of the Regulation (EC) No. 178/2002.

do not have to be audited if the requirements of Chapter 2.3.3 are complied with. Traders who treat feed material in the meaning of Regulation (EC) No. 178/2002 (e.g. warehousing, sacking) shall be classified as feed producers. Product traceability shall be guaranteed in any case.

2.3. Possibility of Combined Audits and Recognition of Audits/Certifications under Other Systems

The VLOG Standard may be examined in combination with other standards in order to use synergy effects. All of the prescribed VLOG facility descriptions and checklists shall also be used in such combined audits.

For a transitional period, it is sufficient if, during the audit of a feed producer and distributor who is regularly monitored by a renowned quality assurance system, such as QS, KAT or GMP+, that only those aspects are examined that are specific to the VLOG Standard. For the transitional period, this reduced audit is equivalent to a complete certification according to the VLOG Standard. The transitional period is valid until the next audit of the renowned quality assurance system, however, no longer than 2 years following the reduced audit.

2.3.1. Recognition of Organic Certifications

For businesses in the feed, agricultural and logistics sector that are certified “organic” and do not have any conventional [i.e. non-organic] part to their business, no auditing is required. This is proven by a certification that the business is “organic” in accordance with Regulation (EC) No. 834/2007. This does not apply to food processing businesses.

2.3.2. Recognition of Baden-Württemberg Quality Mark Certificates (QZ BW)

Under certain conditions, certificates issued in accordance with the Baden-Württemberg Quality Mark (QZ BW) at the agricultural and processing stages are considered equivalent to a certificate issued in accordance with the VLOG standard. The prerequisites for this are:

- That the QZ BW criteria include compliance with the criteria under the EGGenTDurchfG.
- Independent verification is carried out by a certification body which is recognised by VLOG (www.ohnegentechnik.org/zertifizierer).
- For eggs, the print numbers for which the QZ BW certification was granted are listed on the QZ BW certificate, its appendix, or a separate confirmation by the certification body.

2.3.3. Recognition of Certifications in the Area of Logistics

The following applies at the logistics stage: If a company is QS or GMP+ certified and maintaining exemption from labelling in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003 is part of the HACCP system, a separate "Ohne Gentechnik" audit or certification can be dispensed with.

[3] Applies strictly only to animal products in their natural state and to components of animal origin conforming to EGGenTDurchfG (see bioXgen operations manual).

2.3.4. Recognition of Certifications in Accordance with the VLOG Supplementary Module in the QS system

A supplementary VLOG module for QS audits was developed in cooperation with QS GmbH. It complies strictly with the specifications for the VLOG standard. QS system partners from the animal feed and agricultural industry as well as slaughterhouses and meat packing and processing businesses can optionally have the VLOG supplementary module audited during a QS audit. It checks compliance only with requirements relevant for "Ohne Gentechnik" that exceed QS requirement. For recognition of such an audit as equivalent to an audit according to the VLOG Standard, a successful audit of QS requirements and the supplementary VLOG module is mandatory. Auditors and certification bodies which use the supplementary VLOG module, must be recognised by VLOG and comply with the requirements in Chapter 3.

2.3.5. Recognition of Other Audits/Certifications of Other Systems

Additional standards may be accepted by VLOG upon application, after reviewing.

2.4. Prerequisites in the Company

2.4.1. Facility Description

A facility description shall be compiled. The templates in Appendix XI-XIV can be used for this, depending on the stage of production. Whether, for a certification process in accordance with the VLOG standard, the facility descriptions are compiled in preparation for an initial survey / audit or during it shall be agreed between the company, the organisational structure / the superordinate bundler, if applicable, and the certification body. In all cases, the statements provided by the company shall be reviewed on site by the auditor or the trained personnel of the organisational structure / bundler and confirmed by their signature.

2.4.2. Minimum Feeding Conversion Periods for Farm Animals

Before animal foods (meat, milk, eggs) are authorised to be marketed with the “Ohne GenTechnik” label, a minimum feeding conversion period using exclusively GMO-free feed is mandatory, specifically defined for each animal species and purpose of use in the EGGenTDurchfG (in the current version). This shall also be taken into account when new animals are purchased.

Animal species	**Period**
Equids and cattle (including water buffaloes and bison species) for meat production	Twelve months and in any case at least three quarters of their life
Small ruminants	Six months
Pigs	Four months
Milk-producing animals	Three months
Poultry intended for meat production put in stables before the age of 3 days	Ten weeks
Poultry for egg production	Six weeks

Source: EGGenTDurchfG, most recently amended by Art. 58 V of 31 August 2015 | 1474

Animal species not listed here shall be fed with GMO-free feed from the time of birth / hatching.

The minimum feeding conversion period for poultry for meat production in the table given above is equivalent to a flat period of ten weeks prior to slaughter, not including the first three days of life.

If the entire population of animals is converted, GMO-free feeding within the defined timeframe shall be documented as a one-time measure. After general conversion to GMO-free feeding has been completed, observance of the above defined conversion periods shall be documented for newly acquired animals.

2.4.3. Feeding Compliant with the "Ohne GenTechnik" Standard

In accordance with EGGenTDurchfG, for the production of animal food products or food ingredients labelled with the "Ohne GenTechnik" seal it is only permissible to use such animal feeds which do not carry or would not have to carry a declaration label in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003, if these feeds were placed on the market.

It shall be assumed that prior to the conversion to GMO-free feeding a great number of carryover of, and cross-contaminations with, GMO-containing feed products occurred, and residues are still present in the facilities.

Unless these residues are systematically eliminated, they are very likely to lead to GMO-positive test results for a long time which will cause problems in securing GMO-free feeding even if great care is taken regarding all newly acquired feed.

Before converting an agricultural production unit to GMO-free feeding, a risk analysis of the facility's individual processes and evaluation of the related risks shall be performed, with at least the following sources of contamination to be taken into account:

- Contamination through GMO-containing feeds which are subject to labelling obligations;
- Contamination through feed from the grower's own cultivation;
- Carryover and commingling through third parties;
- Carryover within the business (e.g. via equipment or personnel)

Detailed measures tailored to the business in question shall be documented and performed on the basis of this identification of the various sources of carryover and contamination. These measures shall preclude the possibility of future contamination by, and carryover from, animal feed requiring a GMO declaration.

In all cases, a fundamental clean-up of the facility is necessary at the beginning of the conversion to GMO-free feeding. This concerns all equipment, storage areas, installations, mixing installations, vehicles, etc., which come into contact with the feedstuffs. During cleaning operations, it shall be taken into consideration that the analysis of genetically modified organisms is carried out on the DNA level, and that even dusts are detectable. This means that a residual amount in a mixing installation or a piece of a deposit in a feed silo that breaks off and falls into a subsequent batch will result in a positive test during analysis. Commissioning a suitably qualified specialist company with the cleaning of the silos prior to switching to non-GMO production should therefore be considered.

If a business unit/division regularly switches between "Ohne Gentechnik" feeding and feeding with animal feed labelled in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003, the measures specified in accordance with the procedure described above shall be performed and documented before the start of non-GMO feeding in accordance with the above procedure. It shall also be documented where any residual quantities of feed labelled in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003 were moved to. The effectiveness of the residue removal, cleaning of installations, and any other measures carried out shall be tested by means of suitable GMO analyses after every switching to "Ohne Gentechnik" feeding.

If it is determined that an animal was fed with feed labelled in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003 during or after the minimum conversion period, the minimum conversion period shall start anew for this animal. In case the feed was subject to labelling obligations but was not labelled accordingly (e. g. due to an unintended carryover), the residual contaminated feed shall be removed replaced or used outside the area dedicated to the "ohne Gentechnik" production once the erroneous labelling becomes known. Foods which have already been marketed (e. g. milk with "ohne Gentechnik" labelling) does not need to be recalled.

If a serious infraction of the non-GMO feeding intended by "Ohne Gentechnik" labelling occurred through faulty labelling of feed, the minimum feeding conversion period shall start anew, if applicable, shortened according to specific circumstances. The severity of the infraction shall be examined in each individual case by the respective certification body; it is influenced in particular by the following factors:

- The farmer was aware that the feed should have been labelled according to Regulation (EC) No. 1829/2003 and No. 1830/2003
- Lack of due diligence at reception of feed deliveries
- Volume of the wrongly declared feed that was actually fed
- GMO portion in the feedstuff
- Time during which the wrongly declared feed was fed

A legal opinion commissioned by VLOG offers on-site staff and certification bodies additional guidance for determining whether the feeding conversion period shall start anew[4].

2.4.4. Exclusion of Commingling and Swapping

If in an operation products, which are suitable for the "Ohne Gentechnik" system and such that are not, are manufactured or handled in parallel, measures shall be taken to ensure that no commingling or swapping of products of different qualities occurs. These measures are determined through a risk analysis. They need to be documented in writing and to be checked for their efficacy within the scope of internal self-monitoring.

2.4.5. Avoidance of Carryover of GMO-contaminated Feed, Commingling and Swapping

If in addition to the GMO-free feed other animals are fed in an agricultural operation with feed potentially containing GMO which is labelled according to Regulation (EC) No. 1829/2003 and No. 1830/2003, or which is grown in the vicinity of genetically modified crops, there is a strongly increased risk of carryover through residual feed, shared use of equipment, dust, etc. In this case, the measures taken for their avoidance shall be documented.

Parallel feeding of GMO-free feed and GMO-containing feed to the same category of animals is prohibited. A division into, e. g., cattle and pigs, and dairy cows and calves, would be permissible. There is an exception for the use of non-interchangeable animal feeds (e.g. special feeds for pullets and laying hens). Fully separated operating units where storage and handling of feed are also fully segregated, are another exemption from the rule.

In the presence of feed, the suitability of which for GMO-free feeding is not ensured, the intended use thereof and the segregation from areas dedicated to "ohne Gentechnik" production shall be clearly documented (e. g. conventional complete or supplementary feed for breeding sows in an operation where dairy cattle are fed "Ohne Gentechnik" feed is unproblematic).

In the case of feed for which the intended use is not clearly defined or which can be used in several ways for a number of animal categories (e. g. soy bean meal as complete feed) the simultaneous use of labelled and non-labelled feed varieties is only permissible if the feed is stored and used in separate facilities or operating units. In addition, the respective feed shall be labelled with the intended use (class of animal category to which the feed is intended to be fed).

Agricultural self-mixers with their own, stationary grinding and/or mixing installation using both labelled and unlabelled feed and mixing it in the same plant shall take appropriate measures to prevent carryover of genetically modified feed. The measures are to be recorded and their efficacy to be examined by means of regular analyses. The analyses can be commissioned by the self-mixer or the auditor.

Operators of mobile grinding and/or mixing installations that grind and/or mix labelled as well as unlabelled feed shall take appropriate measures to prevent carryover of genetically modified feed. The measures are to be recorded. Purges or a removal of residues, each in combination with an audited and renowned quality assurance system, are suitable measures.

[4] Legal opinion by [GGSC], a law firm commissioned by VLOG, dated 23 November 2015
http://www.ohnegentechnik.org/ggsc_stellungnahme_fuetterungsfrist/

2.4.6. Conversion Requirements for the Transport, Logistics and Processing Sectors

Where necessary, the conversion of facilities is to be initiated with a cleaning of the transportation, storage and processing areas, e.g., by conducting a system purge. The measures taken are to be documented and, where necessary, the result is to be verified by appropriate analyses. Any equipment, storage areas, plants, means of conveyance etc. that can come into contact with the feed or foods are to be considered.

3. Qualifications and Requirements for Certification Bodies and Auditors

3.1. Requirements for Certification Bodies

The certification body shall prove that it is validly accredited according to ISO/IEC 17065 for at least one standard each of the food and feed industry to ensure the processes in the certification body. The certification body shall review and confirm the professional qualification and competence of the auditors and evaluators/certifiers, and shall use qualified and trained auditors and evaluators/certifiers only. Evaluation and certification may be performed by the same person. The certification body shall describe the qualification requirements in its quality management manual as well as in the respective education and training documents for the auditors.

All documents, including training materials, which prove the qualifications of the certification body's personnel and the auditors shall be available in writing at the certification body and provided to the VLOG if requested.

The certification body shall have at least two auditors under contract who have the qualifications described in Chapter 3.2.

The "four-eyes" principle shall be used for audits and certification according to the VLOG standards. The auditor is not permitted to make final decisions on certification for audits he himself performed.

The certification body shall maintain sufficient personnel for evaluating and certifying VLOG audits. The following qualifications shall be required of personnel performing the evaluation and/or making the certification decisions:

- The evaluator/ certifier shall have participated in a VLOG-approved training program for the VLOG "Ohne Gentechnik" standard; such training is valid for 2 years. After expiry of this period, no further "Ohne Gentechnik" evaluations / certifications may be performed unless the evaluator / certifier has completed a further training session[5].

No later than eight weeks after the VLOG "Ohne GenTechnik" audit, the certification body shall release to VLOG the audit results (standard audit: current facility description including a list of "Ohne GenTechnik" or "VLOG geprüft" products, VLOG checklist, VLOG certificate, each including appendices of relevance to certification, follow-up audit / sample audit / audits for cause: VLOG checklist including appendices of relevance to certification, VLOG certificate if applicable). If the information regarding the certification decision or the participating auditing and certification personnel is not clear from the audit results provided, these shall be reported to VLOG separately.

In the event of violations of these requirements, the sanctions specified in the contract between the certification body and VLOG shall apply.

3.2. Requirements for Auditors and Auditors` Qualifications

- Evidence of competence shall be furnished by an appropriate number of annual audits in the respective area (agriculture, feed industry or preparation / manufacture of food products; at least 10 full audits of different companies per area in the preceding two years), appropriate training and qualification for this area in at least one of the following certification procedures: QS, GLOBALG.A.P., IFS, GMP+.
- The auditor shall have participated in a VLOG-approved training program for the VLOG "Ohne Gentechnik" standard; such training is valid for 2 years. After expiry of this period, no further "Ohne Gentechnik" audits may be performed unless the auditor has completed a further training session

[5] This requirement is mandatory as of 1 July 2017.

- An auditor may only perform a standard audit of the same operation three consecutive times.
- An auditor may not perform audits of companies, producers, or producer groups for which he performed consulting work in the previous two years.
- The auditor shall comply precisely with the company's and the certification body's procedures for the confidential treatment of information and records.

Justified deviations from the qualification requirements shall require the written consent of the VLOG office.

4. Planning and Performance of Audits

The performance of audits varies according to the size of business and the production stage (feed producer, logistics company, agriculture and food processing).

4.1. Planning of Audits

- Initial assessment within the framework of the licensee's or the superordinate bundler's self-monitoring system, complemented by external supervision and risk classification by the certification body

or

- Initial assessment of agricultural operations (animal production) by an auditor from the certification body

or

- Initial assessment in non-agricultural businesses
- Facility description and risk assessment
- Contract between the certification body and the client
- Contract between VLOG and the client/company
- Determination of the audit duration[6]
- Clarification of the temporal scope of the audit
- Determination of the auditing scope
- Initial certification

4.2. Performance of the Audit

Introductory Meeting:

- Introduction of the auditor and the persons involved
- Explanation of the planned auditing schedule
- Clarification of fundamental questions regarding the auditing schedule by both parties

Document inspection 1:

- Inspection of the relevant documents of the business (e. g. organisational chart / organisation, quality management system, waybills)
- Verification of compliance with the system requirements (e. g. declaration of raw materials, self-monitoring system, etc.)

Inspection of facility:

- Inspection of production areas and sites

[6] Standard audits may also be performed without advance notice.

- Interview of staff
- Verification of compliance with the system requirements (e. g. segregated handling, awareness of the risk of introduction and carryover of GMOs, etc.)
- Taking of samples if scheduled

Document inspection 2:

- Mass flow control
- Further document inspection, if applicable

Closing meeting:

- Summary of findings
- Clarification of non-compliances
- Discussion of corrective action and the respective deadlines
- Completion of the preliminary audit report
- Clarification of open questions

4.3. Requirements for Issuing a VLOG Certificate

The certification body is entitled to perform follow-up audits, audits for cause, and/or additional random audits.

After the successful completion of the auditing process, the certification body shall issue to the business a certificate of compliance with the VLOG standard.

The certificate shall be issued to the entity that holds a contract with the certification body and also with VLOG. In systems with organisational structures and / or superordinate bundlers that have a closed chain of production, this would be the distributor of the "Ohne Gentechnik" products. The businesses and facilities involved in the production chain shall receive an audit report including any deviations found and measures to be implemented. The distributor or contract partner shall receive an overview of the actual status of its contractually affiliated businesses as well as the audit results. The distributor may pass on the audit report to the facility.

VLOG only accepts certificates issued in accordance with the VLOG Standard from certification bodies that have signed a contract with VLOG.

4.4. Requirements for VLOG Certificates

The certificate in accordance with the VLOG standard shall include the following components:

- Full name of the certification body
- Name(s) of the auditor(s).
  Alternatively, the certification body may send the names to VLOG in a separate document.
- Complete name of the certified business and specification of the audited site
- Audit date
- Date of issue of the certificate
- Expiration date
- Certificate number
- Area of application (see Chapter 4.4.1).
- Position of the certified business in the production and / or processing chain: Animal feed production, agriculture, preparation / processing
- Indication of compliance with the German EC Genetic Engineering Implementation Act (EGGenTDurchfG)

- Information regarding the “Ohne Gentechnik“ Standard and the version number: optionally with the "Ohne GenTechnik" seal[7]
- For animal feed: Notice that the animal feed may be labelled as “VLOG geprüft”
- VLOG membership number of the certification body
- Name and signature of the certifier

4.4.1. Area of application

The company requests the area of application for certification, which is then reviewed during the audit and confirmed together with the certification. Areas of application can include animal types or categories, products, or services (e.g. “trade in xy (product group)”, “packing of eggs”). Products are listed on the certificate in product groups.

- Animal types are specified in accordance with Appendix IX.
- For food products, product groups descriptions are selected in compliance with the legally mandated descriptions according to Art. 17 of Regulation (EC) No. 1169/2011. For agricultural products, Regulation (EC) No. 1308/2013, Appendix II serves as the relevant basis, supplemented by German regulations such as the “Konsummilch-Kennzeichnungs-Verordnung” (Consumer Milk Labelling Regulation), “Milch- und Margarinegesetz” (Milk and Margarine Act), “Milcherzeugnis-Verordnung” (Milk Product Regulation), “Käse-Verordnung” (Cheese Regulation), etc. If no specific description is legally mandated, either a description which has become standard may be used, such as in the “Leitsätzen für Fleisch- und Fleischerzeugnisse” (Principles for Meat and Meat Products), or a descriptive designation which “may not be misleading”.
- For the production, packing, or trading with eggs, the print numbers of the eggs for which the certificate applies shall be included in an appendix.
- For animal feed, the product group description consists of the feed category and the type or category of animal for which the feed is intended, in accordance with Appendix IX.[8]

New product categories shall be confirmed by the certification body by an updating of the certification. The certification body decides whether certification is to be made on the basis of a new audit or using the already available documentation.

4.5. Validity Period of the VLOG Certificate

For agricultural businesses, processing plants, logistics enterprises and feed producers, the certificate is valid until a new certificate is issued, but no longer than until the end of the following year. The new audit should be conducted no later than four weeks before the expiration of the certificate.

5. Evaluation of Requirements

5.1. Evaluation in the Area of Agriculture

The auditor evaluates each requirement of the Standard and its compliance. Requirements are evaluated as fulfilled or not fulfilled and complemented by a description of the divergence from the Standard and an explanation for the farmer as to what corrective action is to be implemented.

[7] If VLOG certification is conducted on the basis of another VLOG-recognised auditing program, reference shall be made to the auditing program in accordance with VLOG.

[8] Examples: Floury compound feed for laying hens, mineral feed for beef cattle, soybean extraction meal, byproducts of commercial fermentation processes.

5.2. Evaluation of All Other Areas

The auditor evaluates each requirement of the Standard and its compliance according to the following levels of grading:

Grading	Description	Points
A	Full compliance with a criterion	10 points
B	Slight to medium deviations with reference to a criterion	5 points
C	Non-compliance or major deviation from a criterion	- 10 points
N/A	Not applicable (shall be explained)	-
Risk	There is a risk in the case of non-compliance	- 15% of total points[9]
KO	The risk is not controllable and/or the legal requirements are not met	Audit not passed

Unless the grade is A, an explanation shall be provided.

If more than 75% of the maximum possible points are achieved and no “KO” grades were given, the audit is considered to have been passed.

The audit shall be regarded as not passed if there is documentary evidence of the presence of GMOs in the “ohne Gentechnik” production process, which would have been technically avoidable. In the area of food processing, the VLOG certificate shall be withdrawn and any use of the seal “Ohne GenTechnik” or any production according to the “Ohne GenTechnik” Standard shall be prohibited.

5.3. Determination and Implementation of Corrective Action

For all B and C grading as well as Risk (and "KO" grading) corrective action and their respective deadlines shall be fixed. The implementation of these corrective action shall be monitored by the certification body. It decides whether a follow-up audit is necessary. This may be performed unannounced or with prior notification.

B and C deviations may be remedied by subsequent submission and filing of representative records or, if this is not feasible, by an on-site follow-up audit.

In the case of **deviations that endanger the security of the system (risk)**, the VLOG certificate shall only be issued after the corrective action was carried out and verified. If the agreed deadlines are not met, the certification body shall have the option, based on the gravity of the deviation, of suspending or withdrawing certification.

If deviations from the Standard are found with respect to certain criteria, there is an increased risk. Therefore, these criteria have been established:

- The self-monitoring system is insufficient
- The sample and analysis plan has not been adequately implemented
- The traceability system is incomplete
- Transportation is not secured
- Missing / insufficient training of staff / staff not aware of responsibilities
- VLOG certificates or certificates of GMO-free status are not available
- Mixing processes are not secured
- Storage is not clearly segregated

A **“KO” grade** leads to a failure of the audit; such grades are marked accordingly in the checklists.

[9] 15% of the point total is deducted for each criterion classified as a risk.

Examples of Labelling for Animal Feed

For examples of feeds that are subject to labelling according to (EC) No. 1829/2003 and No. 1830/2003, we refer to Appendices 1 and 2 of the Guideline of the Supervising Authorities of the 16 *Länder* for Monitoring GMOs in Feed. http://www.ohnegentechnik.org/Leitfaden_animal feed (PDF file available in German only).

For example 4.b1 in the appendix of the abovementioned Guideline, it is explicitly noted that the withdrawal of the GMO label relates only to the case of botanical contamination of a single feed. Carryover of GMO material during the production process in an animal feed plant cannot be classified as botanical contamination with the resulting labelling options.

6. Risk Assessment and Sampling

6.1. Risk Assessment

The goal of the risk assessment is the discovery and evaluation of potential sources of introduction and carryover risks for GMO material in the business. All production processes in the business are examined with an eye to this issue.

As a basic principle, a use of GMO material in a company results in classification at a higher risk level. Companies in the agriculture, logistics and processing / preparation stages are classified into risk categories by the certification body in accordance with the following Chapters 6.1.1– 6.1.3. With increasing risk, the frequency of monitoring and the number of samples to be analysed also increase.

At each audit, the criteria for risk classification shall be reviewed or revised by the auditor, with the risk assessment of the company being repeated during each audit as part of evaluation / certification. This shall be documented or adjusted in the facility description.

6.1.1. Risk Category 0

- There is no or only very low risk
- As a matter of principle, plants that process or store replaceable GMOs on their premises cannot be classified as Risk Category 0

Classification Criteria, Agriculture:

- No genetically modified feed / raw materials on the premises or only non-replaceable ones (see Glossary – Definition of Terms);
- Once “Ohne Gentechnik” feeding has commenced, no switch is made to feeding with feed products which must be labelled in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003.
- Procurement of raw materials which are risk-prone materials from a genetic engineering perspective, (see Appendix VII) only from feed producers and suppliers who are certified according to the VLOG Standard[10],
- Mobile grinding and/or mixing facilities or stationary grinding and/or mixing facilities of agricultural self-mixers verifiably and exclusively process feed which is not subject to labelling requirements or which is certified according to the VLOG Standard[11],
- Cooperation only with logistics providers certified according to the VLOG Standard or GMP+, QS, as far as commissioned by the farmer.

[10] This criterion becomes valid as soon as the farmer has access to a sufficient number of VLOG-certified/monitored feed producers in his region. The assessment as to whether there is a sufficient number is regularly discussed by industry stakeholders and the VLOG. However, this criterion will take effect no later than 1 August 2018.

[11] This criterion becomes valid as soon as the farmer has access to an adequate selection of VLOG-certified mobile grinding and mixing facilities, or facilities processing feed not requiring labeling, for animal feed processing. The assessment as to whether there is a sufficient number is regularly discussed by industry stakeholders and the VLOG. However, the criterion will take effect no later than 1 August 2018.

6.1.2. Risk Category 1

- There is a medium risk.
- Businesses and stages of the process with clear physical segregation of the processing of products for which "Ohne GenTechnik" labelling would be permissible and products not meeting the requirements for "Ohne Gentechnik" certification

Classification Criteria for Agriculture:

- No genetically modified feed / raw materials in the facility or only non-replaceable ones (see Glossary – Definition of Terms)
- No feed / raw materials containing GMOs are used in the same installations (or in the facility)
- Mobile grinding and / or mixing facilities or stationary grinding and/or mixing facilities process both feed subject to labelling requirements and feed not subject to such requirements. System purges are performed. The mobile grinding and/or mixing facilities are certified by a recognised quality assurance system (e.g. QS, KAT), but do not have VLOG certification. Measures for the prevention of GMO carryover are described in the QM manual[11].

6.1.3. Risk Category 2

- High risk of commingling GMO-free raw materials with GMO-containing ones.
- Businesses and process stages for products for which "Ohne Gentechnik" labelling would be permissible in the same space, but at different times from production not meeting the requirements for "Ohne Gentechnik" certification
- The results of the analysis from the most recent sampling resulted in an obligation that the products be labelled, resulting from a failure to implement measures to prevent carryover.

Classification Criteria for Agriculture:

- Replaceable GMO-containing feeds / raw materials present in the facility and in installations;
- Mobile grinding and compounding facilities process both feeds / raw materials subject to mandatory labelling, and those for which labelling is not required. System purges are performed. The mobile grinding and compounding installations are not certified by a recognised quality assurance system (e.g. QS, KAT)[11]
- Regular switching between "Ohne Gentechnik" feeding and feeding using feeds labelled in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003 in one business unit/area
- Procurement of raw materials without certification of producers or suppliers[10]

6.2. Sampling and Analysis / Audit Intervals

6.2.1. Sampling and Analysis

In addition to securing the self-monitoring system, *prima facie* evidence towards VLOG, or external certification, analyses of critical raw materials and finished and interim products (see Appendix VII) are a further important component of the review. Thus, risk-oriented sampling and analyses for GMOs are carried out at all application stages (feed producer, logistics provider, agriculture and food processing) of the Standard.

Sampling and analysis for GMOs shall be carried out within the self-monitoring system in accordance with the following explanations. The indicated number of samples / analyses constitutes a minimum value. The analytical results from the self-monitoring system and any resulting (corrective) measures are to be reviewed during the audit. It is the auditor's responsibility to take supplementary samples during the audit on a risk-targeted basis.

The frequency of sampling and analysis shall be determined from the risk assessment of the company and the quantity of products sold. For documentation purposes, each company has an individual sampling and analysis plan, or it is as a minimum recorded when samples are taken, analyses performed, and which samples and analyses are planned.

Appendix IV can be used for initially determining the categories for which sampling and analytical testing for GMOs would be indicated.

Feed samples in the agriculture area shall be taken jointly by the supplier and the customer. At this point, please refer to the sampling protocol (Appendix V). Exceptions are permitted in well-founded cases, upon consultation with VLOG.

For the agricultural stage, it is required that, when risk-prone complete or mixed feeds of non-VLOG-certified quality are procured, the last three samples, and at a minimum the samples taken in the last two months, shall be preserved. Alternatively, the samples may also be stored elsewhere, provided that they are easily accessible to the auditor.

The samples shall be taken of mixed feed with or from risk-prone feed materials (see Appendix VII). The sampling of mixed feed provided for "Ohne Gentechnik" production is carried out for both mixtures containing risk-prone components and mixtures without such components. Sampling of bagged goods in the Logistics and Agriculture production stages is not required.

In the processing area, reference samples shall be retained for the last three deliveries of raw materials and interim and finished products for which an analysis for GMO is indicated.

6.2.1.1. Sampling Frequency at the Feed Stage (including Use of Mobile Grinding and Compounding Facilities in Agricultural Operations)

The production method applied is the decisive factor for the risk classification of an operation producing animal feed. If the entire facility/site is operated using feed material not subject to labelling requirements, the risk of cross-contamination is lower than that in plants using both categories of material, which spatially or temporally separate production with or without (complete) feeds necessitating labelling in accordance with Regulation (EC) No. 1829/2003.

If a mobile grinding and mixing facility is used, the owner of the feed / the client is responsible for sampling and analysis.

All feed quantities given in the table refer exclusively to feed material not labelled in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003, or, in the case of a single feed, to products to be used in the production of non-labelled feeds.

Sector / **Production**	**Raw Feed Testing**	**Feed Producer**	**Use of Mobile Grinding and Compounding Facilities for "Ohne Gentechnik" Production***
Sample Material	**Product Receiving Single feed**	**Product Dispatching VLOG-Certified Complete and Mixed Feed**	**Mixed Feed for "Ohne Gentechnik" Production**
Material not subject to labelling requirements	Every batch of critical raw material	< 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 t/year: 10 samples	Ruminants: 1/1000t Non-ruminants: 1/2500t
Dual Production	Every batch of critical raw material	< 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 t/year: 25 samples	Ruminants: 1/400t Non-ruminants: 1/1200t

* If risk-prone single feed is procured, a sample shall be taken of each batch delivered, unless such feed is procured exclusively in VLOG-certified quality or in accordance with a recognised VLOG-equivalent standard

6.2.1.2. Sampling Frequency in the Logistics (Storage and Transport), Agriculture, and Processing / Preparation Stages

The sampling frequency shall be as follows:

Sector / Risk category	Logistics	Agriculture*	Processing**
Sample material	Mixed feed, if applicable	Single and mixed feed	
0	2 x per year	Each delivery	2 x per year
1	1 / 10,000 tons	Each delivery	6 x per year
2	1 / 10,000 tons	Each delivery	12 x per year

*Farmers procuring risk-prone feed material exclusively in VLOG-certified quality or in accordance with a VLOG-recognised equivalent standard, and/or have feed mixed only by VLOG-certified mobile grinding and mixing facilities are exempt from the requirement of drawing reference samples.

** Sampling in processing is not required if only raw materials are processed in which genetic modification cannot be analysed for technical reasons.

6.2.1.3. Frequency of Analysis

All samples in the sectors of raw materials, feed production, logistics and processing shall also be analysed. In the agricultural sector – other than beekeeping -, at least one analytical result in each audit interval shall come from the production system of the agricultural unit[12], unless the unit procures risk-prone feed material exclusively of VLOG-certified quality that is declared as "VLOG geprüft" on the documents accompanying the goods.

If, for the production of "Ohne Gentechnik" food, only

- VLOG-certified risk-prone mixed feed or feed certified according to a VLOG-recognised equivalent standard, and/or
- VLOG-certified risk-prone single feed or feed certified according to a VLOG-recognised equivalent standard in accordance with Appendix VII

is fed to livestock, the generally required sampling and analysis of feed materials for GMOs may be dispensed with. If risk-prone (single) feeds from non-VLOG-certified producers are (also) used in producing "Ohne Gentechnik" food products, the obligation to draw samples, store reference samples, and analyse the products for GMOs as part of the self-monitoring system applies.

Samples analysed by VLOG system participants or entities certified according to a VLOG-recognised standard (bundlers, mixed or single feed producers) may be "credited" in the agricultural business in the analysis plan for both the individual unit and the organisational structure / the superordinate bundler (e.g. dairy, egg packing plant). However, the samples shall be from the raw materials actually used, and the batch of mixed feed actually delivered.

The auditor in the agriculture sector shall also decide on a risk-targeted basis whether additional samples are to be analysed. In assessing risk, the following points are taken into consideration:

- Use of grinding and compounding facilities
- Procurement of risk-prone feed (see Appendix VII) from a producer not certified in accordance with the VLOG standard (higher risk)
- Regular switching between "Ohne Gentechnik" feeding and feeding with animal feed labelled in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003 in one business unit/section.

The samples and analyses 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.

[12] If collective samples of feed are analyzed, the results cannot be factored as analytical results pertaining to individual operations. For each agricultural operation at least one analytical result that refers to a specific delivery of risk-prone single-component or compound feeds is to be produced for each auditing interval.

Handling of expenses shall be carried out between the certification body and the certification client.

In analysing / assessing analytical results, the standard deviation shall always be considered in order to account for the non-homogeneous distribution of GMOs in products. In keeping with Regulation (EC) No. 691/2013, the analysed GMO content, after deduction of the expanded measuring margin of error, is used to make the assessment.

6.2.2. Requirements for Laboratories and Scope of Analysis

Appendix VI describes the requirements for laboratories and the analytical scope of GMO analyses. For the purposes of VLOG certification and verification in accordance with EGGenTDurchfG / VLOG Standard, only analytical results determined in accordance with the requirements of Appendix VI shall be recognised.

6.2.3. Audit Intervals

In general, regular audits shall be carried out annually; these may also be performed without prior notice.

The agricultural sector shall be examined separately. For farms that are part of an organisational structure exclusively (see Glossary – Definition of Terms) or contractually bound to a superordinate bundler, the audit interval may be extended depending on the respective risk category. However, neither applies to feed and food manufacturers (including mobile grinding and compounding facilities) nor to logistics providers.

Risk Category	**Audit frequency in the agricultural sector (structured organisations)**
Risk Category 0	Every three years
Risk Category 1	Every two years
Risk Category 2	Annually

In the event of any alterations or modifications within the facility, the certification body or the licensor shall be informed and an additional audit outside of the regular schedule shall be undertaken if necessary.

6.3. Auditing and Certification at the Agricultural Stage

For agricultural operations, there are two options for auditing and certification:

- Individual certification of the individual agricultural operation
- Auditing and certification of agricultural operations as part of the group certification of the organisational structure / the superordinate bundler, subject to the following conditions:
  - The agricultural operations are contractually integrated in the organisational system / bound to the superordinate bundler.
  - For “Ohne Gentechnik” production, a self-monitoring system is operated in the organisational structure / by the superordinate bundler which includes the producer group and also comprises PCR analyses of the animal feed used in the production of animal products.
  - The marketing of products labelled “Ohne GenTechnik” is performed primarily by the superordinate bundler. If products labelled “Ohne GenTechnik” are also marketed at the agricultural stage (e.g. direct marketing), this shall be taken into account in the audit of the superordinate bundler (calculation of goods flow).
  - If products labelled “Ohne GenTechnik” are marketed by a contractually bound agricultural operation to another organisational structure / another bundler, the consent of the “actual” superordinate bundler is required; this also includes consent for audit report of the agricultural operations to be made available to third parties. Alternatively, the agricultural operation is included in the audit of the various organisational structures / superordinate bundlers, and thus potentially audited multiple times.
  - If, on the basis of the audit results, the certification of the organisational structure / the superordinate bundler was withdrawn, the marketing of products with the “Ohne GenTechnik” label is not permitted for the entire organisational structure / the bundler and all linked companies.

6.3.1. Group Certification of the Organisational Structure / the Superordinate Bundler

The following procedure is shown schematically in Appendix VIII.

6.3.1.1. Initial Assessment Within the Organisational Structure / by the Bundler

As part of its facility description, the bundler sets out the organisational structure of the contractually bound companies. This includes all affiliated producers, and any preparers, processors, or logistics firms also involved. A full facility description of the relevant stage, including plans, organisational chart, process descriptions, etc. is prepared for each contractually bound company.

As part of the self-monitoring system of the organisational structure / the bundler, initial assessments (on-site self-monitoring by trained personnel of the organisational structure / the bundler on the basis of the VLOG checklists) are performed for 100% of the affiliated businesses. On the basis of the initial assessments and self-monitoring performed, the organisational structure / bundler performs an initial risk assessment of all affiliated companies in accordance with the specifications set out in Chapter. 6.1.

Alternatively, after consultation with the organisational structure / the bundler, the initial assessments of the affiliated companies may be entirely performed by the certification body; in this case, further audits are not necessary, and evaluation and certification are performed on the basis of the initial assessments.

6.3.1.2. Initial Assessment and Certification by the Certification Body

The initial assessments and self-monitoring within the organisational structure / by the bundler are evaluated by the certification body. In 25% of the contractually bound companies, the results shall be verified on site through audits performed by the certification body. The certification body is responsible for a balanced distribution of the audits amongst the contractually affiliated companies, in accordance with the preceding initial risk assessment.

The results of the initial assessments and self-monitoring are examined along with the audit results for any discrepancies, and measures derived from these results as appropriate. The certification body has the right to reject the initial assessment carried out in the framework of self-monitoring if duly justified and to insist that the initial assessment be carried out 100% by the certification body.

All plant descriptions of the organisational structure / the bundler and the affiliated companies shall be verified for completeness by the certification body and shall be completed if necessary. Classification of the businesses into risk categories is finally performed by the certification body, from which results the audit interval of each affiliated company for the coming audit period.

The certification decision is made on the basis of the initial assessments and self-monitoring within the organisational structure / by the bundlers and the audits by the certification body; follow-up audits may be performed if needed.

The initial assessment procedure in the scope of the self-monitoring system may also be applied to new agricultural suppliers within an existent system.

Part 2 of the VLOG Standard

7. Catalogue of Requirements

7.1. Requirements Regarding the Feed Stage

Feed traders who do not physically move goods (so-called drop shippers) and traders who also move goods, but do not otherwise treat them within the meaning of Regulation (EC) No. 178/2002 do not have to be audited if the requirements of Chapter 2.3.3 are complied with. Traders who treat feeds in the meaning of Regulation (EC) No. 178/2002 (e.g. warehousing, sacking) shall be classified as feed producers. However, product traceability shall be guaranteed.

For a transitional period, it is sufficient if, during the audit of an animal feed producer and trader subject to regular auditing / certification under a recognised quality management system such as QS, KAT or GMP+, only those aspects are examined which are specific to the VLOG Standard. For the transitional period, this reduced audit is equivalent to a complete certification according to the VLOG Standard. The transitional period is valid until the next audit of the recognised quality assurance system, however, no longer than two years following the reduced audit.

7.1.1. Facility Description

A facility description is complete when it contains the following information, which shall be updated as needed:

- Overview of all locations, production sites, production lines, including any outsourced production processes
- Overview of subcontractors/contract processors involved in the “Ohne Gentechnik” process. These shall be contractually bound into the process.
- All raw materials and feeds that are produced, stored, transported and traded by the company / location being monitored
- List of suppliers
- Specification of all feeds bearing the “VLOG geprüft” mark
- List of “Ohne Gentechnik” formulations. (Formulations / formulation changes shall be approved by a manager in the company).

Information provided in electronic form shall be accepted. For the audit, the current facility descriptions, appendices, and documents listed therein shall be submitted to the auditor for review. At the request of the company, documents/information other than the facility descriptions may remain on the company premises in order to maintain confidentiality, provided that they have been reviewed by the auditor and inspection of the facility description has been noted at the relevant part of the document, and data relevant to the certification process has been included in the facility description and / or checklist.

At the latest by the next audit, an updated facility description shall be submitted. A report or communication to the certification body is only required in the case of material changes relating to the risk assessment.

7.1.2. Assignment of Responsibilities / Organisational Chart

The company or facility structure and an organisational chart shall be available in written and in its latest form on the premises and shall contain details on the responsibilities and a deputy plan to cover for absence.

An overview of all persons employed in the operational process of relevance to “Ohne Gentechnik” certification shall be compiled, including temporary workers, trainees, interns, etc. By means of this overview, it can be determined who is responsible for the “Ohne Gentechnik” production processes, and which additional persons are to be involved, and thus shall be trained. This overview is to be updated as persons join or leave the process or responsibilities are reassigned.

7.1.3. Self-Monitoring Concept / Risk Analysis

The self-monitoring concept of the feed business shall take into consideration the required segregated handling of GMO-containing and GMO-free products as well as any possibilities of introduction and contamination, and shall reflect the production situation of the facility / company. Analogously to the HACCP, a risk assessment shall be carried out, which includes the cleaning. In addition, preventative, monitoring and control measures shall be introduced concerning the correctness of the absence of a label according to Regulation (EC) No. 1829/2003 and No. 1830/2003 or regarding the use of a claim that indicates the suitability of the feed for the production of "Ohne Gentechnik" foods or the use of the "VLOG geprüft" mark.

The self-monitoring concept of the feed business shall take into consideration the following criteria:

- Registration of all raw materials and feeds for the "Ohne Gentechnik" sector, irrespective of whether they are subject to labelling obligations or not
- Segregated handling of raw materials and feeds that are subject to labelling and that are not subject to labelling, on all stages of storage, processing and transport
- Identification and exclusion of sources of introduction and contamination
- Risk analysis, taking into consideration potential risks from certain feeds, countries of origin and production processes as well as facility parameters
- Specifications for all finished products for "Ohne Gentechnik" labelling shall be in place and shall be laid down in writing with the contract partners if required
- Compounding logs shall be available
- The objective shall be to avoid any presence of GMO components so that the criteria for labelling according to EU guidelines can be reliably met.

7.1.4. Sampling and Analysis Plan

The suitability of the raw materials, the efficacy of the measures taken for segregating the goods, and the suitability of the final product for labelling as "VLOG geprüft" is to be verified on the basis of representative PCR analyses.

An analysis plan shall be available on the basis of a risk assessment, meeting at a minimum the requirements of Chapter 6.2.1 and including a description of the sampling procedure. The focus of consideration shall 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, sampling frequency, and the analytical procedure. The analysis plan is implemented according to plan.

7.1.5. Staff Training

All staff members involved in the operating procedures of relevance to "Ohne Gentechnik" certification, including drivers of transport vehicles, shall be trained concerning the "Ohne Gentechnik" requirements and the operating procedures laid down for this purpose. Training shall take place before they begin with their activity, as well as on an ongoing basis, and at least once a year.

The intensity of training varies depending on the staff member and shall be oriented towards the responsibility of the staff member for the proper flow of the "Ohne Gentechnik" production.

These training sessions shall be documented regarding their content, their participants, as well as the training date, the training location, and the instructors.

7.1.6. Documentation and Retention Periods

The records shall be easily legible and authentic. They are to be kept in such a manner that subsequent manipulation can be excluded. All documents in connection with the production process for "VLOG geprüft" labelling, e. g., way bills, certificates of non-objection, records of production and of product flow (including re-working), training documents, etc. shall be kept for at least six years from the time of delivery, unless statutory requirements stipulate a longer retention time.

7.1.7. Traceability System

A traceability system has been installed permitting at any time to identify instantly all products in the plant / monitored site, to which "Ohne Gentechnik" labelling applies. In addition, it is possible to trace back within one working day any products that have left the facility / monitored site and to compile quantitative statements and evaluations, which permit conclusions on flows of goods and their plausibility. According to Regulation (EC) No. 178/2002 the following data shall be collected for this purpose:

- Information regarding origin (country, supplier)
- Batch formation, if applicable (including re-working)
- Documentation of production / manufacture
- Information on delivery date and market participants supplied
- Quantity

7.1.8. Reference Samples

In addition to the provision of data, the business shall be required to retain samples of batches sent to all customers, in sealed containers, so that a conclusion can be drawn as to the quality actually delivered, if necessary. The samples shall be retained for the listed minimum shelf life of the product. This applies both to products delivered in bulk and to packaged products.

7.1.9. Incoming Goods Inspection

At the incoming goods department, it shall be ensured that all risk-prone raw materials and feeds used for the "Ohne Gentechnik" sector meet the requirements described below.

For a current overview of risk-prone raw materials, see Appendix VII.

In order to ensure this, a confirmation for critical raw materials shall be obtained from the upstream supplier. This may be achieved e.g. by:

- A separate declaration of the GMO-free status of the currently delivered lot
- A current, detailed certificate in accordance with the VLOG Standard or a recognised VLOG-equivalent standard
- A test result proving the GMO-free status of the lot being delivered
- An additional indication on the waybill declaring the products to be "Ohne Gentechnik"
- A clear contractual regulation regarding the delivery of GMO-free products

For feed additives and declared auxiliary ingredients, an additional specification shall be presented clearly indicating that the product is not subject to GMO labelling obligations.

7.1.10. Segregation of Goods Flows / Exclusion of Technically Avoidable Commingling

It shall be ensured that at no time raw materials or feeds not suitable for producing "Ohne Gentechnik" food can make their way into the flow of raw materials and feeds intended for the production of "VLOG geprüft" foods. For this purpose, the flow of goods shall be separated spatially and/or temporally, and the clear and complete labelling of all products ensured.

In the case of temporal segregation, it shall be ensured by suitable process steps that any carryover of genetically modified material is reduced to a technically unavoidable minimum.

During handling and storage in the production facility, the labelling of raw materials / partially finished products / finished products regarding GMO shall be properly implemented in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003.

These risk-preventing process steps (e. g. transport and mixing processes) shall be documented for each facility with a separate proof of adequate spatial, temporal or logistical measures e.g. as part of the self-monitoring concept, and are taken into account during self-monitoring.

7.1.11. Corrective Action / Continuous Improvement Process

The company is urged to continually reduce the occurrences of adventitious contamination with GMO material through regular verification of the implemented system. For this purpose, the company shall take measures, so-called corrective action, in order to eliminate the causes of adventitious and technically unavoidable contaminations with GMO material and to reduce their entry to a minimum. The measures taken shall be monitored and will be subjected to evaluation after an adequate period of time.

This applies also to the corrective action from the last audit.

In particular, the handling of positive analytical results shall be taken into consideration.

7.1.12. Handling of Non-Conforming Products

For the event of positive analytical results or other findings regarding a lack of proven compliance with the “Ohne Gentechnik” requirements, a system of defect handling and labelling / blocking of non-compliant products with appropriate measures shall be installed before the goods are shipped. In the event of a contamination in critical orders of magnitude, appropriate corrective action shall be initiated and documented. The efficacy of such measures is reviewed as part of self-monitoring.

7.1.13. Complaint and Recall Management

Complaints concerning GMOs by clients or other bodies (e. g. local authorities) or deviations within the self-monitoring system shall be documented and evaluated appropriately. For this purpose, suitable corrective action, including the determination of responsibilities, shall have been initiated.

If non-compliances are detected in feeds that are still on the market, a recall system shall be in place that shall provide for a written notification to customers. If necessary, feeds shall be taken back at the expense of the feed producer.

7.1.14. Crisis Management

A crisis management system shall be in place and potential dangers analysed. As part of this system, a process is in place that prescribes the procedure to follow in the event of a crisis. Emergency telephone numbers / contact information of the suppliers and clients shall be available.

An internal system for blocking rejected products shall be in place.

The company shall inform its customers as soon as possible of any problems related to product specifications, in particular non-conformities relating to “Ohne Gentechnik” which have, had, or could have a defined influence on the process safety and / or legality of the relevant products. This shall occur in accordance with the precautionary principle, but is not limited to it.

7.1.15. Protecting the Self-Monitoring System

Internal audits shall be carried out in the business annually in order to review and to protect the self-monitoring system.

7.1.16. Declaration on Waybills

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

VLOG-certified animal feeds shall be marked by the certified feed company with the wording “VLOG geprüft” and / or the seal “VLOG geprüft” (see Figure 2). If the seal “VLOG geprüft” is used, the requirements of Chapter 1.6 shall be complied with.

On waybills for non-VLOG-certified products that are not subject to mandatory labelling under Regulations (EC) No. 1829/2003 and No. 1830/2003, the statement “suitable for the production of ‘Ohne Gentechnik’ food” is recommended.

7.1.17. Commissioning of Carriers

The feed producer may only commission those carriers for the transport of “VLOG geprüft” feeds that are regularly monitored by a recognised quality assurance system. The quality assurance system shall define appropriate measures for cleaning vehicles in order to prevent carryover of genetically modified material. Proof is to be provided on request.

Vehicles shall be verifiably dry cleaned after transporting bulk animal feed that shall be labelled as genetically modified under Regulations (EC) No. 1829/2003 and No. 1830/2003.

7.2. Requirements for the Logistics Stage (Storage and Transport)

A separate inspection of the logistics area shall take place if it is operated separately. In the case of a sub-contractor, e. g., a sub-contractor of feed mills, the inspection may be carried out by the feed mill itself, provided a contractual agreement is in place. The same is true for customers collecting their merchandise themselves They will be monitored via the Agriculture stage.

If the goods in question are animal feeds and the company is QS or GMP+ certified, maintaining exemption from labelling in accordance with Regulations (EC) No. 1829/2003 and No. 1830/2003 is part of the HACCP system, and if the success of the measures is demonstrated by regular analyses, a separate "Ohne Gentechnik" audit or certification can be dispensed with.

7.2.1. Facility Description

A facility description shall be provided containing the following information, always updated as applicable:

- All raw materials and feed that are stored, transported or traded in and by the business / at the monitored site
- Specification of all feeds that are marked “VLOG geprüft” and “suitable for the production of ‘Ohne Gentechnik’ food”
- List of suppliers
- Overview of the subcontractors / contract processors involved in the “Ohne Gentechnik” process. They shall be contractually tied into the process.
- Overview of all sites and transport units

Information provided in electronic form shall be accepted. For the audit, the current facility descriptions, appendices, and documents listed therein shall be submitted to the auditor for review. At the request of the company, documents/information other than the facility descriptions may remain on the company premises in order to maintain confidentiality, provided that they have been reviewed by the auditor and inspection of the facility description has been noted at the relevant part of the record, and data relevant to the certification process have been included in the facility description and / or checklist.

At the latest by the next audit, an updated facility description shall be submitted. A report or communication to the certification body is only required in the case of material changes relating to the risk assessment.

7.2.2. Assignment of Responsibilities / Organisational Chart

The company or facility structure and an organisational chart shall be available in written form on the premises and shall contain details of responsibilities and a deputy plan to cover for absences.

An overview of all persons employed in the operational process of relevance to “Ohne Gentechnik” certification shall be compiled, including temporary workers, trainees, interns, etc. By means of this overview, it can be determined who is responsible for the “Ohne Gentechnik” production processes, and which additional persons are to be involved, and thus shall be trained. This overview is to be updated as persons join or leave the process or responsibilities are reassigned.

7.2.3. Self-Monitoring Concept / Risk Analysis

The self-monitoring concept shall take into consideration the required segregated handling of GMO-free products and products containing GMOs, as well as potential sources of introduction and carryover. A risk analysis analogous to the HACCP shall be carried out. In addition, precautionary, monitoring and controlling measures shall be introduced concerning the correctness of the absence of a label according to Regulations (EC) No. 1829/2003 and No. 1830/2003 or regarding the use of a claim which indicates the suitability of the feed and raw materials for the production of “Ohne Gentechnik” food or the use of the “VLOG geprüft” label.

The self-monitoring concept shall take into consideration the following criteria:

- Registration of all raw materials and feeds for the “Ohne Gentechnik” sector that are not subject to labelling obligations
- Segregated handling of raw materials and feeds that are subject to labelling obligations and that are not subject to labelling obligations in all stages of storage and transport
- Identification and exclusion of sources of introduction and contamination
- Risk assessment taking into consideration potential risks from certain feeds, countries of origin, and production processes as well as facility parameters
- The objective shall be to avoid the presence of any GMO components
- Procedures for cleaning, inspection of the loading process, previous freight in the case of vehicles

7.2.4. Sampling and Analysis Plan

The efficacy of the measures taken for segregating the goods and the suitability of the final product for labelling as “VLOG geprüft” is to be verified on the basis of representative PCR analyses.

An analysis plan is in place on the basis of a risk assessment, meeting at a minimum the requirements of Chapter 6.2.1 and including a description of the sampling procedure. The focus shall be on the following: type of samples, sampling locations, sampling of finished product, compiling of collective samples, naming the sampler, creation of reference samples, sample size, sampling frequency, and the analytical procedure. The analysis plan is implemented according to plan.

7.2.5. Staff Training

All staff members involved in operating procedures of relevance to “Ohne Gentechnik” labelling, including vehicle operators, shall be instructed in the “Ohne Gentechnik” requirements and the operating procedures laid down for this purpose. Instruction shall take place before they take up their activity as well as on an ongoing basis, at least once a year.

These trainings shall be documented regarding their content, their participants, as well as the training date, the training location, and the instructors.

7.2.6. Documentation and Retention Periods

All documents relating to the production process for the “Ohne Gentechnik” transport and storage process, e. g., waybills / records, certificates of non-objection, training documents, etc. shall be retained for at least five years from the time of delivery unless legal requirements stipulate a longer retention period.

7.2.7. Traceability System

A traceability system has been installed permitting instant identification of all products in the company to which the "Ohne Gentechnik" or "VLOG geprüft" labelling applies. In addition, it is possible to trace back within one working day any products that have left the company and to compile lists of quantities and evaluations which permit conclusions on flows of goods and their plausibility. According to Regulation (EC) No. 178/2002 the following data shall be collected for this purpose:

- Information regarding origin
- Creation of batches, if applicable
- Information on delivery date and market participants supplied

7.2.8. Incoming Goods Inspection

At the incoming goods department, it shall be ensured that all critical raw materials and feeds (see Appendix VII) used for the "Ohne Gentechnik" sector meet the requirements. For this purpose, a confirmation shall be obtained for every delivery from the upstream supplier. This may be achieved in particular by:

- A separate declaration of the GMO-free status of the currently delivered lot
- A current, detailed certificate in accordance with the VLOG Standard or a recognised VLOG-equivalent standard
- A test result proving the GMO-free status of the lot being delivered
- An additional indication on the waybill that the products are "Ohne Gentechnik"
- A clear contractual regulation regarding the delivery of GMO-free products

For feed additives and declared auxiliary ingredients, an additional specification shall be presented which clearly indicates that the product is not subject to GMO labelling obligations.

7.2.9. Segregation of Goods Flows / Exclusion of Commingling

It shall be ensured that at no time raw materials or feeds not suitable for producing "Ohne Gentechnik" food can make their way into the flow of raw materials and feeds intended for the production of "Ohne Gentechnik" foods or labelling as "VLOG geprüft". For this purpose, the goods flow shall be separated spatially and/or temporally during storage and transport.

In the case of temporal segregation, it shall be ensured by means of suitable process steps that any crossover of genetically modified material is reduced to a minimum. Vehicles shall be verifiably dry-cleaned after transporting bulk animal feed that shall be labelled as GMO in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003.

The risk-targeted procedural steps (e. g. transport and mixing processes) shall be documented for each facility with separate proof of adequate physical, temporal or logistical measures, e.g. as part of the self-monitoring concept, and shall be taken into account in the self-monitoring process.

7.2.10. Corrective Action / Continuous Improvement Process

The company is urged to continually reduce the occurrences of adventitious contamination with GMO material through regular verification of the implemented system. For this purpose, the company shall take measures, so-called corrective action, in order to eliminate the causes of adventitious and technically unavoidable contaminations with GMO material and to reduce their entry to a minimum. The measures taken shall be monitored and will be subjected to evaluation after an adequate period of time. This applies also the corrective action from the last audit.

In particular, the handling of positive analytical results shall be taken into consideration.

7.2.11. Handling of Non-Conforming Products

For the event of positive analytical results or other findings regarding a lack of proven compliance with the "Ohne Gentechnik" requirements, a system of defect handling and labelling / blocking of non-compliant products with appropriate measures shall be installed before the goods are shipped.

7.2.12. Complaint and Recall Management

Complaints concerning GMOs by clients or other bodies (e. g. local authorities) or deviations within the self-monitoring system shall be documented and evaluated appropriately. For this purpose, suitable corrective action, including the determination of responsibilities, shall have been initiated.

If non-compliances are detected in "VLOG geprüft" feeds or products related to the "Ohne Gentechnik" or "VLOG geprüft" labels, which are still on the market, a recall system shall be in place that shall provide for written notification of the customers. If necessary, feeds shall be taken back at the expense of the logistics company.

7.2.13. Crisis Management

A crisis management system is in place and potential dangers have been analysed. As part of this system, a process is available prescribing the procedure to follow in the event of a crisis. Emergency telephone numbers / contact information of the suppliers and clients shall be available.

An internal system for blocking the release of incriminated products shall be in place.

The company shall inform its customers as rapidly as possible of any problems related to product specifications, in particular nonconformities relating to "Ohne Gentechnik" which have, had, or could have a defined influence on the process safety and / or legality of the relevant products. This shall occur in accordance with the precautionary principle, but is not limited to it.

7.2.14. Protecting the Self-Monitoring System

Internal audits shall be carried out in the business annually.

7.2.15. Declaration on Waybills

VLOG-certified animal feed shall be marked by the certified logistics company with the wording "VLOG geprüft" and / or the seal "VLOG geprüft" (see Figure 2). If the seal "VLOG geprüft" is used, the requirements of Chapter 1.6 shall be complied with.

Waybills for non-VLOG-certified products that are not subject to mandatory labelling under Regulation (EC) No. 1829/2003 and No. 1830/2003 may contain the statement "suitable for the production of 'Ohne Gentechnik' food". If no information regarding the logistics company is contained on the waybill, additional documents are available that protect the process.

7.3. Requirements for the Agriculture Stage

7.3.1. Facility Description

The facility description serves to fully record those local conditions that are relevant for "Ohne Gentechnik" feeding. It serves as a foundation for the internal risk assessment as well as for the evaluation by the external auditor.

For the audit, the current facility descriptions, appendices, and documents listed therein shall be submitted to the auditor for review. At the request of the company, documents/information other than the facility descriptions may remain on the company premises in order to maintain confidentiality, provided that they have been reviewed by the auditor, and inspection of the facility description has been noted at the relevant part of the record, and data relevant to the certification process is included in the facility description and / or checklist.

At the latest by the next audit, an updated facility description shall be submitted. A report or communication to the certification body is only required in the case of material changes relating to the risk assessment.

The facility description shall take into account those points that could lead to an introduction of genetically modified feed or operating resources (e.g. seeds) into the facility.

If, besides feed in compliance with the German EC Genetic Engineering Implementation Act (EGGenTDurchfG), non-compliant feed is also produced, stored or processed or fed, a facility block diagram / sketch shall be drawn up pointing out all stables including their holding capacities and species kept therein, feed storage areas and installations for feed production and feed handling (mixing facilities, equipment storage , feeding installations, etc.) including all facilities that are not located directly at the farmstead.

7.3.2. Assignment of Responsibilities / Organisational Chart

The company or facility structure and an organisational chart shall be available in written form on the premises and shall contain details of responsibilities and a deputy plan to cover for absences.

An overview of all persons employed in the operational process of relevance to “Ohne Gentechnik” certification shall be compiled, including temporary workers, trainees, interns, etc. By means of this overview, it can be determined who is responsible for the “Ohne Gentechnik” production processes, and which additional persons are to be involved, and thus shall be trained. This overview is to be updated as persons join or leave the process or responsibilities are reassigned.

For small operations (for their definition, see Glossary – Definition of Terms), this may be carried out as part of the facility description.

7.3.3. Feed Ordering

For the protection, the following procedure should be followed when ordering animal feeds:

Ordering:

The agricultural operation should order feeds in writing so as to prevent confusion. It shall be explicitly stated in the orders that the feeds shall not be subject to labelling according to the EC Regulations No. 1829/2003 and No. 1830/2003 and shall be suitable for the production of “Ohne Gentechnik” labelled food products.

Alternatively, it may be contractually agreed with the supplier that all feeds delivered shall not be subject to mandatory labelling in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003, and shall be suitable for the production of “Ohne Gentechnik”-labelled foods.

Accompanying document:

The animal feed supplier should be urged to add a line on the waybill/accompanying document: “Animal feed not subject to declaration in accordance with Regulation (EC) No. 1829/2003 or No. 1830/2003”, or “suitable for the production of ‘Ohne Gentechnik’ food”. Animal feeds certified in accordance with the VLOG standard are to be declared with the mark “VLOG geprüft”.

7.3.4. Self-Monitoring System

7.3.4.1. Animal Inventory and Observance of Minimum Conversion Feeding Periods

All species that are kept in the facility for the production of food shall be registered. In addition, it shall be established whether these animals are fed in compliance with the “Ohne Gentechnik” Standard or not.

When additional animals are acquired, the minimum conversion feeding periods shall be observed and the requirements met. The proceeding shall be described accordingly. If new animals are bought, the minimum conversion period shall be deemed to be observed also if the previous owner fed the animals in compliance with the “Ohne Gentechnik” Standard. Proof for such feeding can be, for example, a confirmation of the previous owner or a reliable excerpt of the livestock catalogue of an auction.

7.3.4.2. Feed Rations

For all animal species and category of animals that are registered in the animal inventory the feed rations shall be listed. For this purpose, an individual overview shall be compiled for each animal species. In case there are different

feed rations depending on the phase of life (e. g. dry cow treatment), season (grazing season / indoor husbandry in winter), etc., they shall be listed separately.

The feed components shall be named precisely, e. g., the exact designation of the type of feed and the producer of a compound feed instead of simply “milk performance feed”, or “rape seed meal” instead of simply “canola”. The declarations, in particular for composed components, shall be filed together with the records on feed rations.

7.3.4.3. Feed Lists

The agricultural operation shall keep a feed list. The feed list gives an overview of all feeds that are currently used in the facility, their origin as well as their purpose (i.e. for which species). Based on this list, further considerations concerning the protection of “Ohne Gentechnik” feeding are indicated:

- The list may serve as a basis to verify and ensure that for every delivery of feed or seed / of every supplier appropriate certificates are at hand, certifying that this feed / these seeds are not subject to declaration according to Regulations (EC) No. 1829/2003 and No. 1830/2003.
- Identification of overlaps in the purpose of feed for different animal species. This is particularly decisive if the business uses both GMO-containing feed and GMO-free feed at the same time.

The feed list shall initially be drawn up within the scope of a first assessment. After that it shall be kept up to date by adding new feeds and new suppliers, and by deleting those that no longer exist. However, the latter shall only be done once the concerning feed has been fully consumed and is no longer present on the premises. Additions and deletions shall be noted with the date of the first purchase or the date of the last consumption. All self-produced feed shall also be entered in the feed list. If any seed / seed stock has been acquired in addition to that, the supplier shall be named.

An alternative for small businesses (for their definition, see Glossary – Definition of Terms), is a feed list realised by a chronologically filed compilation of invoices and waybills.

7.3.4.4. External Service Providers

External service providers such as mobile grinding and mixing facilities can cause crossover of GMOs, e.g., if GMO-containing feed and “Ohne Gentechnik” feed are mixed in succession. shippers of feed, machinery groups, drying plants etc. shall be equally included in these considerations.

In the case of mobile grinding and mixing devices the avoidance of crossover shall be guaranteed and documented accordingly. This can be done by confirming a system purge carried out by the external service provider. In order to avoid commingling or to keep it at a minimum, delivery conditions shall stipulate that, for example, the agreements concerning the cleaning and the use of GMO-free oils are observed.

The agricultural operation shall only commission such shippers for the transport of feeds suitable for the production of “Ohne Gentechnik”-labelled food products as are regularly audited in accordance with a recognised quality assurance system (e.g. QS, GMP+). The quality assurance system shall specify suitable measures for the cleaning of vehicles in order to prevent crossover of GMO material. Proof shall be submitted as required. Vehicles shall be verifiably dry-cleaned after transporting bulk animal feed subject to mandatory labelling as a GMO in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003.

7.3.5. Staff Training

It shall be ensured that all staff members involved in operating procedures of relevance to “Ohne Gentechnik” labelling, including vehicle operators, have comprehensive knowledge of the measures necessary for ensuring “ohne Gentechnik” feeding. Instruction/information regarding the “Ohne Gentechnik” requirements and the relevant operating procedures shall take place before they take up their activity as well as on an ongoing basis, at least once a year. This may take the form of practical instruction.

These training/instructional sessions shall be documented regarding their content, their participants, as well as the training date, the training location, and the instructors.

In the case of small facilities (for their definition see Glossary – Definition of Terms), it shall be ensured that all persons involved in the operating processes relevant to “Ohne Gentechnik” have comprehensive knowledge of the measures necessary for ensuring “ohne Gentechnik” feeding. If no separate training session is provided for this, a declaration shall be made in the facility description.

7.3.6. Documentation and Retention Periods

All waybills / records, invoices (e.g. for seeds) for operating resources, documents accompanying feed, documentation, orders, declarations, etc. shall be retained for a period of at least five years, unless statutory requirements stipulate a longer retention period.

7.3.7. Sample and Analysis Plan

The following requirements for implementing an analysis plan apply only to agricultural operations not included in the group certification of an organisational structure / a superordinate bundler.

An analysis plan shall be available on the basis of a risk assessment, meeting at a minimum the requirements of Chapter 6.2.1; it shall be implemented according to plan. The analysis plan also describes the sampling procedure (type of samples, sampling locations, naming the sampler, creation of reference samples, sample size), sampling frequency, and the analytical procedure.

7.3.8. Traceability System

A traceability system shall be installed permitting the instant identification of all products in the company that are related to the “Ohne Gentechnik” labelling process. In addition, it shall be possible to trace back within one working day any feeds and other products that have left the company, and to compile lists of quantities and evaluations which permit conclusions on goods flows and their plausibility. According to Regulation (EC) No. 178/2002 the following data shall be collected for this purpose:

- Information regarding origin
- Creation of batches, if applicable
- Information on delivery date and market participants supplied

7.3.9. Incoming Goods Inspection

At the incoming goods department, it shall be ensured that all raw materials and feeds used for the “Ohne Gentechnik” sector meet the requirements. For critical raw materials and feeds, suitable proof shall be provided. This is, first and foremost, the absence of labelling in accordance with Regulation (EC) No. 1829/2003 and No. 1830/2003 on the feed and seed labels or accompanying documents.

See Appendix VII for a current overview of critical raw materials.

In order to ensure traceability in the agricultural sector, all waybills for purchased feeds shall be reviewed for completeness of the information provided and filed in chronological order. If mixing and grinding vehicles are used, confirmation of compliance with the requirements and documentation of system purging shall be provided, if applicable.

For critical raw materials and feeds procured from VLOG-certified suppliers with the label “VLOG geprüft”, the obligation to take samples, keep reference samples, and perform analyses in accordance with the specifications in Chapter 6.2.1 does not apply.

7.3.10. Segregation of Goods Flows / Exclusion of Crossover

It shall be ensured in a traceable manner that at no time feeds not suitable for producing “Ohne Gentechnik” foods can make their way into the flow of raw materials and feeds intended for the production of “Ohne Gentechnik” foods. For this purpose, the goods flow shall be segregated spatially, temporally, and compliance documented by clear and seamless labelling of all products.

Simultaneous storage of GMO and non-GMO material is only permissible if they are spatially segregated.

In the case of temporal segregation, it shall be ensured by means of suitable process steps that any crossover of genetically modified material is reduced to a minimum. Thus, e.g.

- Vehicles shall be verifiably dry-cleaned after transporting bulk animal feed that shall be labelled as GMO in accordance with Regulation (EC) No.1829/2003 and No. 1830/2003.

- In the case of routine switching between “Ohne Gentechnik” feeding and feeding with animal feeds labelled in accordance with Regulation (EC) No.1829/2003 and No. 1830/2003 in one business unit / business section, the measures in Chapter 2.4.3 shall be implemented and documented.

If the company simultaneously produces or handles products it produces itself that are suitable for the “Ohne Gentechnik” system, and products not suitable for the “Ohne Gentechnik” system, it shall be ensured by appropriate measures that no commingling or swapping of products of the different qualities occurs.

In the case of purchases of additional livestock, the minimum conversion feeding conversion period in accordance with Chapter 2.4.2 shall be observed and the measures for the segregation of animal products documented and reviewed as part of the self-monitoring process.

The risk-targeted procedural steps (e. g. transport and mixing processes) shall be documented for each operation with a separate proof of adequate spatial, temporal or logistical measures and their efficacy reviewed as part of the self-monitoring process.

7.3.11. Outgoing Goods Inspection

Employees shall be aware of the GMO status of the feed and the conversion status of the individual animals / fattening batches at all stages, from receiving the feed through animal production to delivery / transport of the animal products / animals.

It shall be ensured that only products meeting in full the statutory requirements for “Ohne Gentechnik” labelling leave the facility as such. Compliance with minimum feed conversion periods after the purchase of new livestock or conversion to new feed shall particularly be observed.

Labelling in accordance with the EGGenTDurchfG shall be correctly carried out on documents accompanying the goods, labels, etc. For advertising and marketing, only the statement “Ohne Gentechnik” may be used, and care shall be taken to comply with the statutory requirements regarding the “Ohne Gentechnik” declaration, taking into account Section 11, para. (1), item 3 LFGB.

For suppliers whose animal products come from production systems in which switching between EGGenTDurchfG-conforming and non-conforming production conditions is realistic (e.g. egg production: through production of eggs within constantly restarting feed conversion periods), a specific identification regarding the EGGenTDurchfG shall be stated on the documents accompanying the goods.

7.3.12. Handling of Non-Conforming Products

For the event of positive analytical results or other findings regarding a lack of definite compliance with the “Ohne Gentechnik” requirements, a system of defect handling and labelling / blocking of non-compliant products with appropriate measures shall be installed before the goods are shipped.

In the case of positive analyses of non-labelled feeds which are nonetheless clearly subject to mandatory labelling, the requirements of Chapter 2.4.3 shall be complied with.

7.3.13. Corrective Action

The procedure to follow in the event of non-conformity is described, along with responsibilities, and corresponding measures are initiated in the event of complaints regarding “Ohne Gentechnik” production (e.g. in the case of customer complaints or positive analysis results). The effective corrective action is recorded and implemented. This applies also to the corrective action from the last audit.

The process descriptions may be given as part of the facility description or in another form.

7.3.14. Complaint and Recall Management

Complaints concerning GMOs by clients or other bodies (e. g. local authorities) or deviations within the self-monitoring system, respectively, shall be documented and evaluated appropriately. For this purpose, suitable corrective action, including the determination of responsibilities, shall have been initiated. If the agricultural operation is part of a group certification of an organisational structure / a superordinate bundler, the latter shall be informed and corrective action coordinated.

If deviations are detected in food that is still on the market, a recall system shall be in place that shall provide for written notification of the customers.

7.3.15. Crisis Management

A crisis management protocol is required only for agricultural operations not included in the group certification of an organisational structure / a superordinate bundler.

A crisis management system shall be in place and potential dangers analysed. As part of this system, a process is available prescribing the procedure to follow in the event of a crisis. Emergency telephone numbers / contact information of the suppliers and clients shall be available.

An internal system for blocking the release of incriminated products shall be in place.

The company shall inform its customers as rapidly as possible of any problems related to product specifications, in particular nonconformities relating to “Ohne Gentechnik” which have, had, or could have a defined influence on the process safety and / or legality of the relevant products. This shall occur in accordance with the precautionary principle, but is not limited to it.

7.3.16. Protecting the Self-Monitoring System

An internal process audit is performed once per year. During this audit, the facility description is checked and updated as appropriate.

7.4. Requirements for the Processing Stage

7.4.1. Facility Description

A facility description shall be compiled containing the following information, updated as appropriate:

- Overview of all locations, production sites, and production lines including outsourced production processes, if applicable
- Formulations and specifications of all “Ohne Gentechnik” products that are produced in the facility, also taking re-working into account
- List of suppliers
- Organisational chart which names the responsibilities
- Overview of the subcontractors / contract processors involved in the “Ohne Gentechnik” process. They shall be contractually tied into the process.
- List of “Ohne Gentechnik” formulations, also taking into account re-working (Formulations / formulation changes shall be approved by a manager in the facility).

Information provided in electronic form shall be accepted. For the audit, the current facility descriptions, appendices, and documents listed therein shall be submitted to the auditor for review. At the request of the company, documents/information other than the facility descriptions may remain on the company premises in order to maintain confidentiality, provided that they have been reviewed by the auditor and inspection of the facility description has been noted at the relevant place in the document, and data relevant to the certification process is included in the facility description and / or checklist.

At the latest by the next audit, an updated facility description shall be submitted. A report or communication to the certification body is only required in the case of material changes relating to the risk assessment.

7.4.2. Assignment of Responsibilities / Organisational Chart

The facility structure and an organisational chart shall be available in written form on the premises and shall contain details of responsibilities and a deputy plan to cover for absences.

An overview of all persons employed in the operational process of relevance to “Ohne Gentechnik” certification shall be compiled, including temporary workers, trainees, interns, etc. By means of this overview, it can be determined who is responsible for the “Ohne Gentechnik” production processes, and which additional persons are to be involved, and thus shall be trained. This overview is to be updated as persons join or leave the process or responsibilities are reassigned.

7.4.3. Self-Monitoring Concept / Risk Assessment

The self-monitoring concept of the food processing business shall take into consideration the required segregated handling of GMO-containing and GMO-free products, including re-working as well as any possibilities of introduction and crossover of GMOs. A risk assessment analogous to the HACCP shall be carried out; in addition to that, preventative, monitoring and controlling measures shall be implemented concerning the correctness of the “Ohne Gentechnik” claim.

In addition, the risk assessment shall include the possibility of evaluating the use of aromas, enzymes, microorganism cultures, additives, auxiliary substances and other feed ingredients on the basis of certificates presented by the suppliers. A template of a correct certificate confirming the GMO-free status of a product is included in this Standard, see Appendix II.

7.4.4. Sampling and Analysis Plan

An analysis plan is available on the basis of a risk assessment, meeting at a minimum the requirements of Chapter 6.2 and including a description of the sampling procedure; it shall be implemented according to plan. The focus is to be on the following: type of samples, sampling locations, 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 analytical procedure.

This relates primarily to plant raw materials.

As the use of GMO feed generally cannot be proven in animal products such as milk, meat, and eggs, these analyses focus mainly on animal production (animal feed).

For the operator of a food business that processes raw materials of animal origin, the focus of the self-monitoring concept is thus on the verifiable and reliable segregation of animal products with an “Ohne Gentechnik” label from those without, ensuring the use of EGGenTDurchfG-conforming products, and correct supplier declarations for food ingredients.

As part of a group certification, the marketer of the organisational structure or superordinate bundler shall develop and implement analysis plans in the self-monitoring system which, in addition to above requirements, also at a minimum comply with the specifications in Chapter 6.2.1 for contractually bound agricultural operations. If, at an agricultural stage, only VLOG-certified mixed feed or VLOG-certified risk-prone single feed in accordance with Appendix VII is used for the production of “Ohne Gentechnik” food products, the otherwise mandatory sampling and analysis of feeds for GMOs may be dispensed with. If risk-prone (single) feed materials from non-VLOG-certified producers or suppliers are (also) fed to livestock for the production of “Ohne Gentechnik” food, the obligation to take samples, keep reference samples, and perform analyses for GMO as part of the self-monitoring system applies.

7.4.5. Staff Training

All staff members involved in operating procedures of relevance to “Ohne Gentechnik” labelling, including vehicle operators, shall receiving training before commencing their work as well as on an ongoing basis, at least once per year, regarding the requirements for “Ohne Gentechnik” labelling and the operating processes specified for it.

The intensity of the training varies for different employees, depending on the employee’s responsibility for the proper performance of “Ohne Gentechnik” production.

These trainings shall be documented regarding their content, their participants, as well as the training date, the training location, and the instructors.

7.4.6. Documentation and Retention Periods

All documents related to the “Ohne Gentechnik” label, e.g. waybills, clearance certificates, production and goods flow records (including re-working), training documents, etc. shall be retained for a period of at least five years, unless statutory requirements stipulate a longer retention period.

7.4.7. Traceability System

A traceability system shall be installed permitting the instant identification of all products in the company that are related to the “Ohne Gentechnik” labelling process. Employees at all stages, from goods receiving through production to delivery / transport shall be aware of the GMO status of the individual products and batches.

In addition, it shall be possible to trace back within one working day any products that have left the company and to compile quantitative statements and evaluations which permit conclusions on flows of goods and their plausibility. According to Regulation (EC) No. 178/2002 the following data shall be collected for this purpose:

- Information regarding origin, including proof of “Ohne Gentechnik” status
- Creation of batches, if applicable (including re-working)
- Information regarding the raw materials, additives, and auxiliary materials used, and their origin (including rework)
- Information on delivery date and market participants supplied
- Communication information of the upstream and downstream stages

7.4.8. Incoming Goods Inspection

At the incoming goods department, it shall be ensured that all raw materials, food products, and additives and auxiliary materials used to manufacture / process / market products with the “Ohne Gentechnik” label meet the requirements.

Critical raw materials include:

- Imported products with an EU GMO clearance (e.g. soybeans, 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 having a plausible risk of contamination with imported products (domestic soybeans, canola, or maize/corn products)
- All animal raw materials
- All products produced by microorganisms

7.4.8.1. Producer and Supplier Certificates

For every delivery a confirmation shall be obtained from the upstream supplier attesting that the currently delivered products / components meet the requirements of the EGGenTDurchfG. In keeping with the requirements of Chapter 2.2, the use of foods / components of animal origin is only permitted if they are certified in accordance with the VLOG standard, QS standard including VLOG criteria, or Regulation (EC) No. 834/2007. Honey or other apiary products that are not certified under the VLOG standard or Regulation (EC) No. 834/2007 may be processed into “Ohne Gentechnik" food, if it can be evidenced that no GMOs are cultivated or released within a circumference of 10 km from the beehives or, alternatively, that there is an analytical result for a batch available that was assessed pursuant to VLOG specifications and that shows no genetic modification.

For all components of non-animal origin, this can be achieved by:

- A pertinent general confirmation concerning delivered goods issued by the supplier once a year
- An endorsement on the waybill
- A clear contractual regulation

Such documents shall confirm that the ingredients, additives and auxiliary substances used are not GMOs themselves, are not composed of GMOs, and were neither produced from or by GMOs. In general, adventitious or technically unavoidable traces of genetically modified material shall be tolerated up to a threshold of at most 0.1 % per ingredient. A formally correct template may be found in Appendix II; the probative value of other suppliers' declarations is clarified in Appendix III.

If, in the case of aromas, enzymes, cultures of micro-organisms, additives or auxiliary substances, there are any long-term supplier certificates, the company shall verify once a year in an adequate manner whether these certificates are still valid in the issued form and whether the specifications for the item in question have not been modified.

For suppliers of products made in production systems in which switching between EGGenTDurchfG-conforming and non-conforming production conditions is realistically possible (e.g. in egg production, through the constant restarting of minimum feeding conversion periods), specification of "Ohne Gentechnik" status is required on the documents accompanying each shipment of goods, in addition to the abovementioned general confirmations.

7.4.9. Segregation of Goods Flows / Exclusion of Crossover and Swapping

It shall be ensured that at no time can products not meeting the "Ohne Gentechnik" standards make their way into the flow of "Ohne Gentechnik" goods. For this purpose, the goods flow shall be segregated spatially, temporally, and by means of clear and seamless labelling of all products. Where necessary, interim cleaning should be performed.

In the case of temporal segregation, it shall be ensured by means of suitable process steps that any crossover of genetically modified material is reduced to a minimum. Simultaneous storage of GMO and non-GMO material is only permissible if they are spatially separated.

During handling and storage, the labelling of raw materials / semi-finished products / finished products with regard to their suitability for "Ohne Gentechnik" production shall be correctly implemented.

These risk-targeted procedural steps (e. g. transport and compounding processes) shall be documented in each facility with a separate proof of adequate spatial, temporal or logistical measures and their efficacy reviewed as part of the self-monitoring process. In addition, the efficacy of the measures shall be demonstrated by means of representative analysis results.

7.4.10. Outgoing Goods Inspection / Handling of Non-Conforming Products

Labelling in accordance with the EGGenTDurchfG shall be correctly carried out on labels, production documents and documents accompanying goods, specifications, etc. For advertising and marketing, only the statement "Ohne Gentechnik" may be used.

Care shall be taken to comply with the statutory requirements regarding the declaration "Ohne Gentechnik", taking into account Art. 7 of the Regulation (EU) 1169/2011.

It shall be ensured that only products meeting in full the statutory requirements for "Ohne Gentechnik" labelling leave the facility as such.

For the event of positive analytical results or other findings regarding a lack of definite compliance with the "Ohne Gentechnik" requirements, a system of defect handling and labelling / blocking of non-compliant products with appropriate measures shall be installed before the goods are shipped.

7.4.11. Corrective action / Continuous Improvement Process

In the event of complaints, the company shall take corrective action in order to permanently eliminate the cause of contamination with GMO material. The measures taken are monitored and subjected to evaluation after an appropriate period. This applies also to the corrective action imposed by the last audit.

The handling of positive analytical results shall particularly be taken into account.

7.4.12. Complaint and Recall Management

Complaints concerning GMOs by clients or other bodies (e. g. local authorities) shall be documented and evaluated appropriately. For this purpose, suitable corrective action, including the determination of responsibilities, shall have been initiated.

If deviations are detected in food that is still on the market, a recall system shall be in place that shall provide for written notification of the customers.

7.4.13. Crisis Management

A crisis management system shall be in place and potential dangers analysed. As part of this system, a procedure shall be in place prescribing the procedure to follow in the event of a crisis. Emergency telephone numbers / contact information of the suppliers and clients shall be available.

An internal system for blocking the release of products under suspicion shall be in place.

The company shall inform its customers as rapidly as possible of any problems related to product specifications, in particular nonconformities relating to “Ohne Gentechnik” which have, had, or could have a defined influence on the process safety and / or legality of the relevant products. This shall occur in accordance with the precautionary principle, but is not limited to it.

7.4.14. Protecting the Self-Monitoring System

Internal audits are performed by the company every year.

8. Rules for Import from the European Union and Third Countries

If goods that are imported into Germany from other European countries are to be labelled “Ohne GenTechnik”, the legal standards of these countries shall be considered and compared to the German Standard. Only after consulting with VLOG may such products may be imported and labelled accordingly.

8.1. Recognition of Products from Austria

The legal standards for production, labelling and auditing of “Gentechnik-frei” produced in Austria are determined in the Guideline defining “Gentechnik-frei” of foods and their labelling in the Austrian Foods Codex. In essential points the regulations in Austria and Germany are congruent or the Austrian criteria go beyond the scope of the German ones. GMO-free raw materials that are in compliance with the Austrian criteria may therefore be used for the production of “Ohne Gentechnik” food without any difficulties. Minor differences in the requirements can, however, lead to difficulties in the recognition of Austrian “Gentechnik-frei” raw materials.

As far as the requirements are congruent in terms of content, existing certifications according to the Austrian regulations may be recognised as equivalent. A special additional certificate according to the German Standard is not required.

8.1.1. Animal Feeds

The legal requirements for feed are the same in Austria and Germany. The regulations of both countries refer to Regulations (EC) No. 1829/2003 and No. 1830/2003.

8.1.2. Conversion Periods

Depending on the animal category the feeding conversion periods of the two national regulations differ. The following is a table of comparison:

Animal category	**Feeding conversion period in Austria**	**Feeding conversion period in Germany**	**Suitability of raw materials**
Milk-producing animals	2 weeks	3 months	additional certificate required
Poultry for egg-production	Six weeks	Six weeks	compliance with Austrian standard sufficient
Poultry for meat production	entire life span	10 weeks	compliance with Austrian standard sufficient
Pigs	fattening period	Four months	additional certificate required
Equids and cattle for meat production	12 months	12 months and in any case at least three quarters of their life	additional certificate required for meat of animals above the age of 16 months
Fish	fattening period	entire life span	additional certificate required

In cases where the feeding conversion period in Austria is shorter, importers of raw material from Austria shall provide assurances regarding the compliance with German feeding conversion periods.

8.1.3. Food Ingredients, Additives and Auxiliary Substances

In both regulations the use of substances that were produced “by GMOs” is prohibited. In general, this concerns the production with genetically modified microorganisms.

A difference exists between the standards of these two countries in the tolerance of cross-contaminations regarding the production “with” and “from” GMOs. The Austrian regulation refers to EU Regulations (EC) No. 1829/2003 and No. 1830/2003. This means that adventitious or technically unavoidable cross-contaminations up to 0,9% are tolerated. In the German regulation no threshold value is indicated, which means the limit of quantification of 0,1% per ingredient applies (see chapter 1.3.1).

8.1.4. Free Movement of Goods

If packaged food was brought into distribution in Austria legally labelled “Gentechnik-frei” or “Ohne Gentechnik”, it may be sold in Germany according to the German regulations notwithstanding any differences. This is demanded by the provision for the free movement of goods within the European Union. Irrespective of this regulation the re-labelling of Austrian “Gentechnik-frei” products that are exported to Germany, and for which the national regulations prescribe different requirements, is not permissible (e. g., refer to the German EGGenTDurchfG).

8.2. Recognition of Products from Third Countries

In the event of resorting to the acquisition of raw material from third countries Identity Preserved goods shall generally be preferred. In addition to the delivery certificate for the acquisition of GMO-free raw material a self-monitoring system shall be in place, which shall outline the analytical results of risk-prone raw material (see Appendix VII) in particular.

In the feed production sector representative samples of risk-prone raw material (see Appendix VII) shall be taken upon delivery.

Long-term supply contracts shall be preferred.

9. Sanctions Catalogue

Activator Examples	**Sanction(s)**
Slight non-compliance	Written notification (not a sanction in the actual sense but a means to avoid future violations)
Violations of documentation duties, which may endanger the security of the system	Increased obligation of registration and reporting
Non-compliances that endanger the securing of the GMO-free food or feed production, e. g., use of conventional raw materials, lack of compliance with minimum conversion periods, no segregation of batches, etc.	Warning in combination with a fee-based follow-up control
Detection of GMOs in the identification of a tangibly affected quantity / batch or lot (e. g., a lot in a feed processing plant, etc.)	Exclusion of non-compliant goods / products from the GMO-free claim
Repeated violation of the system	Suspension of certification with temporally limited marketing ban on food products labelled “Ohne Gentechnik” or “VLOG geprüft” animal feeds; before re-certification, a complete follow-up audit shall take place at the violator’s expense.
Severe violations; Lack of willingness to comply with the guidelines; Misuse of the VLOG certificate for non-certified products or use in a misleading way; Refused or non-compliant follow-up audit after suspension of certification	Termination of the monitoring contract Withdrawal of the VLOG certificate

10. Glossary – Definition of Terms

For the sake of simplification, the following definitions and abbreviations are provided:

Auditor: Personnel to be made available by the certification body for the auditing of companies. The auditor's responsibilities are described in ISO/IEC 17065.

Animal category: Animals which fundamentally differ in their husbandry conditions are regarded as different animal categories (e. g. breeding pigs / fattening pigs, laying hens / chickens for fattening, heavy livestock / dairy cattle) (Swiss Confederation: Instructions and Explanations 2012, February 2012).

Bundler: See organisational structure

Certificate: Certificate of compliance with the Standard.

Certifier: Personnel to be made available by the certification body for certifying companies. The certifier's responsibilities are described in ISO/IEC 17065.

Correction: A correction is a measure to eliminate a known fault.

Corrective action: Action / actions, leading to the elimination of the causes of a fault, a shortcoming or any other undesired situation in order to avoid their reoccurrence or to reduce the frequency of reoccurrence.

EGGenTDurchfG: Germany's Introductory Act for the Implementation of European Union Regulations in the Area of Genetic Engineering and Concerning the Labelling of Food that Was Produced without any Implementation of Processes or Genetic Modification (German EGGenTDurchfG).

Evaluator: Personnel to be made available by the certification body for the auditing of companies. All information and results related to the on-site audit (evaluation) is to be evaluated. The evaluator may not be involved in the on-site audit. The evaluator issues the certifier a recommendation regarding whether certification should be granted. If the evaluator and certifier are different people, the result of the evaluator shall be documented separately.

Feed: Substances or products, including additives, be it in processed, partially processed or unprocessed form, which are intended for oral feeding of animals.

Feed business: All businesses, no matter whether they are profit-oriented or not and whether they are publicly or privately held, that are involved in the production, manufacturing, processing, storage, transportation or distribution of feed, including producers who produce, process or store feed to be fed to animals in their own business.

Feed not subject to compulsory labelling: Feeds which, according to Regulations (EC) No. 1829/2003 or No. 1830/2003, are not subject to compulsory labelling as "genetically modified".

Feed subject to compulsory labelling: Feeds which, according to Regulations (EC) No. 1829/2003 and No. 1830/2003, have to be labelled as "genetically modified".

Food business: All businesses, no matter whether they are profit-oriented or not and whether they are publicly or privately held, that are involved in an activity connected to the production, processing, and distribution of food.

GMO: Genetically modified organisms. According to Regulation (EC) No. 2001/18 these are organisms in which the genetic material has been modified by means of molecular biological methods in a way that naturally is not possible by interbreeding and / or recombination.

Logistics enterprise: Every business, which carries out logistical activities with food- and feeds, e. g., transport, storage, distribution, loading and unloading (IFS Logistics, Version 2). Mobile grinding and mixing devices come under the category of logistics enterprises as well.

Operating unit: Parts of the business which are completely separate from each other, except for their organisation. This may apply for, e. g., different stables or storage sites for feed.

Organisational structure: Placement on the market with contractually associated producer groups with proven self-monitoring systems which include the producer group and also comprise PCR analyses of the animal feed used in the production of animal-based foods.

Processed product: Food which has been produced from unprocessed products; these products may contain ingredients that are necessary for their production or for imparting special qualities. "Processing" (Regulation (EC) No. 852/2004).

Processing: A considerable modification of the initial product, e. g., through heating, smoking, curing, ripening, desiccating, marinating, extracting, extruding, or through a combination of these different procedures (Regulation (EC) No. 852/2004).

Products (food): All substances or products that are intended for, or which in reasonable discretion can be expected to be intended for, human consumption, be it in processed, partially processed or unprocessed form.

Replaceable or non-replaceable GM feed/raw materials: GM feeds are replaceable if their use would also be possible in "Ohne Gentechnik" production; e.g. GM soy meal in the area of pig farming and an "Ohne Gentechnik" milk production. Feeds are non-replaceable if they are clearly assigned to a production line and their use in "Ohne Gentechnik" production is remote from actual practice; e.g. GM milk replacers for calf rearing and an "Ohne Gentechnik" milk production

Small farm:

- The main production focus is on milk, with a dairy herd of less than 40 lactating animals.
- The main production focus is on eggs, with less than 10,000 animals.
- The main production focus is on broiler chicken, with less than 16,000 fattening places.
- The main product ion focus is on fattening pigs, with space for less than 600 animals.
- Or a facility, independent of the main product and number of animals, with not more than 1 full-time employee (at least 38 hrs/week) other than the facility manager and any members of the manager's family.
- Upon request, the VLOG will provide a definition of the main production focus of small farms that are not mentioned here.

Supervision: Higher-level control program carried out by the certification body if individual facilities of an organisational structure have already been monitored by the bundler beforehand.

VLOG certificate: Confirmation of successful compliance with the VLOG "Ohne Gentechnik" standard issued by a certification body recognised by VLOG.

11. Literature

Guidelines

The following guidelines were used for the compilation of this Standard:

- Guideline for the Control of GMOs in feed (German: Leitfaden zur Kontrolle von GVO in Tierfutter – version of November 2011). Monitoring of the production, of handling, of use and of bringing to market of feed in connection with genetically modified organisms (GMOs). Policy guidelines for the implementation of legal regulations. Compiled by the 'GMOs in Feed' project group of the Feed Working Group within the Working Group for Consumer Protection of the German *Länder* (German: LAV – Länderarbeitsgemeinschaft Verbraucherschutz) with the participation of the Federal Government and the Association of German Agricultural Analytic and Research Institutes (VDLUFA) - available in German only.
- Sampling of feed for the analysis of GMO components authorised in the EU within the framework of an examination of compulsory labelling; compiled by the Working Group PCR Analytics of the Feed Expert Group of the Association of German Agricultural Analytic and Research Institutes (VDLUFA), dated July 2010
- Concept of analysis of genetically modified feed. Working paper of the Working Group PCR Analytics of the Feed Expert Group of the Association of German Agricultural Analytic and Research Institutes (VDLUFA), dated February 2011
- Practical Handbook for GMO-free Organic Products from the German Association of Organic Farmers, Food Processors and Traders (Bund Ökologische Lebensmittelwirtschaft – BÖLW), Ökoinstitut and the Research Institute for Biological Agriculture (Forschungsinstitut für biologischen Landbau – FiBL, URL: http://boelw.de/themen/gentechnik/bioxgen).

12. Appendices

I. Data Sheet for Purchasers of Milk / Eggs / Meats, etc., specified as "Ohne Gentechnik"
II. GMO-free Certificate according to EGGenTDurchfG
III. Probative value of various “Ohne Gentechnik” Suppliers’ Declarations
IV. Overview of GMO and Analytical Verifiability
V. Sampling Log
VI. Requirements for Laboratories and Scope of Analysis
VII. Explanatory Note on Risk-Prone Animal Feeds and Raw Materials
VIII. VLOG Group Certification Process
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XI. Facility Description Feed Manufacturers and Traders
XII. Facility Description Agriculture – Animal Products
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XV. Checklist for the Feed Stage
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