

GUIDELINE ON THE RISK-BASED MONITORING OF GMO-FREE PRODUCTION

**Proposal for revision by *Arbeitsgemeinschaft für Gentechnik-frei erzeugte Lebensmittel*
(Platform for GMO-free Food Products), also referred to as *ARGE Gentechnik-frei* (Platform
GMO-free)**

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1 INTRODUCTION

The present Guideline implements the *Richtlinie zur Definition der "Gentechnikfreien Produktion" von Lebensmitteln und deren Kennzeichnung* (Guideline on the Definition of "GMO-Free Production" of Food and its Labelling) published in the Austrian Codex Alimentarius, IV edition (published with decree reference BMGFJ-75210/0014-IV/B/7/2007 from 6 December 2007, as amended on 9 September 2010).

2 SCOPE OF APPLICATION

This Guideline is valid for inspections and certifications conducted for the purpose of monitoring compliance with the characteristic "GMO-free" according to the Austrian Codex Alimentarius, IV edition.

All products subject to a monitoring procedure may be labelled as "GMO-free" in terms of the above-mentioned Codex Guideline.

As for raw materials or agricultural components used, a distinction is made between safe and "critical raw materials" or "critical crops" in terms of GMO-free production:

- Raw materials which cannot be genetically modified (e.g. minerals) or crops which have genetically modified varieties that have not been granted marketing authorisation (e.g. barley, rye, based on the situation as at October 2014) are to be considered safe (uncritical). These raw materials or crops are hereinafter referred to as "uncritical raw materials or crops".
- Crops which have genetically modified varieties that are agriculturally cultivated (e.g. maize, soya beans) as well as raw materials or products which are made from such crops are to be considered critical in any case. These raw materials or crops are hereinafter referred to as "critical raw materials or crops".

This Guideline covers monitoring and certification for compliance with the characteristic "GMO-free" for individual businesses and organisations (including "projects") in the following sectors:

- agricultural production of plants and livestock,
- processing (food and feed production),
- trade, storage, and transportation.

"Projects" consist of individual sectors such as agricultural production, processing, trade, and storage. In case of projects, the requirements for these individual sectors shall apply as a whole whilst ensuring that monitoring is conducted throughout the entire production chain.

3 PURPOSE

This Guideline aims to implement risk-based monitoring for compliance with the characteristic "GMO-free", conducted in each case under the best possible

technical conditions. Throughout Austria, monitoring shall be conducted in a uniform way, applying high technical and methodological standards.

4 GENERAL PROVISIONS

Monitoring and certification for compliance with the characteristic “GMO-free” are equivalent to a product certification in terms of ISO 17065.

A vital requirement imposed by the above-mentioned standard is that assessment shall be conducted along well-defined criteria such as are normally specified in standards or normative documents. In case of projects, the project operator shall prepare a project description specifying these criteria, presenting the overall system (including his own business premises participating in the project and their methods of production), inclusive of other partner businesses participating in the project and their tasks (e.g. marketing, sale), and specifying the criteria for the different types of businesses to participate in the project. This project description shall be available to all stakeholders involved and interested in the project.

Certification bodies (CB) conducting inspections for the purpose of monitoring and certifying compliance with the characteristic “GMO-free” are only authorised to do so when in possession of a valid accreditation in accordance with the Austrian Accreditation Act (AkkG) and ISO 17065 for the scope “monitoring and certification for compliance with the characteristic GMO-free” (“GMO-free” according to the Austrian Codex Alimentarius, as amended).

Monitoring for compliance with the characteristic “GMO-free” shall be conducted, *mutatis mutandis*, in accordance with the requirements for organic farming. Practices not complying with these requirements are either specified in this Guideline or have to be brought to the accreditation body’s attention.

In agricultural production, a distinction is made between inspections conducted at individual businesses (individual inspection contract, annual inspection) and group certifications in livestock and plant production (projects with project operators).

Certification bodies may only be accredited for the scope of projects if they conduct inspections for the purpose of monitoring key areas of the entire production chain.

Monitoring for compliance with the characteristic “GMO-free” consists of the following important stages:

- initial survey and risk classification of farm businesses (livestock production),
 - initial survey conducted by the certification body, or
 - initial survey within the scope of the client’s self-monitoring system, completed by supervisory monitoring and validation by the certification body,
 - business description and risk classification;
- inspection of farm businesses (plant production);
- first inspection of processing and trading businesses (animal feed, food, trade in critical raw materials, agricultural collectors...);
- certification;
- regular inspection;

- imposition and enforcement of remedial measures (conducting additional risk-based sampling where applicable);
- annual certification.

An inspection contract shall be formed between the certification body and the client; this contract shall cover all rights and obligations of both parties in order to ensure monitoring in accordance with external standards. In case of “projects”, the inspection contract shall include provisions ensuring that the rights and obligations under this contract are imposed on all participants in the project.

4.1 General Remarks

The extent to which clients (organisations) implement self-monitoring systems, depends on their resources and strategies. If self-monitoring systems are implemented, these are taken into account when determining the frequency of external inspections for the initial survey. In case of self-monitoring systems, the certification body shall indiscriminately have access to self-monitoring data at any time by contract, and the client’s staff shall operate in conformity with the specifications provided by the certification body during the initial survey.

The measures taken by the certification body shall ensure that the entire production chain within the client’s scope of business (including all business premises and suppliers) is under control. This shall preferably be achieved by documentation on purchase orders and delivery notes, e.g. by specifying that products originate “from GMO-free cultivation” or “from GMO-free production”.

The certification body shall keep a register of critical crops¹ (relevant for seeds, food and feed²). In case of crops not classified as critical crops in this register, no further monitoring procedure is required.

Laboratory analyses for sample examinations shall be commissioned based on the “events” listed in this register. This register has to be kept up to date. The results of this risk assessment shall be included in the training of inspecting staff, the planning of inspections, and the information provided to clients.

4.2 Dealing with Contamination

According to the Austrian Codex Alimentarius, IV edition, the use of GMOs is not allowed in GMO-free production and GMO contamination shall be kept at the lowest possible level. In terms of the Austrian Codex Alimentarius, food labelled as “GMO-free” or animal feed labelled as “geeignet zur Herstellung gentechnikfreier Lebensmittel”/“suitable for the production of GMO-free food” must therefore not be subject to GMO labelling according to the provisions of Regulations (EC) No 1829/2003 and (EC) No 1830/2003, i.e. the threshold of 0.9% per ingredient must not be exceeded.

¹ As a minimum requirement, the types of genetically modified crops approved in the EU (seeds, food and feed) shall be specified in this register, indicating the type of crop, event, and unique identifier.

² For food and feed, the Community register of GM food and feed (publicly available on the website of the European Commission) may be consulted.

In case of a positive result for the presence of GMOs showing GMO contents between the limit of quantification³ and the labelling threshold of 0.9%, the business shall take organisational measures to avoid contamination with GMOs and GMO material, and shall also document these measures. This documentation shall be checked by the inspection body no later than during the next inspection.

Contamination with GMOs approved in the EU, at levels below the limit of quantification (0.1% as a rule) per ingredient, are generally regarded as technically unavoidable or accidental.

Please note: Analysis results for raw materials or animal feed materials which, according to their formulation, do not contain the detected critical type of crop (e.g. soya beans) may lead to unjustified objections or rejections. The problem results from the fact that the GMO content of each individual ingredient of the material (and not of the material as a whole) is determined in quantitative analyses. The results of analyses may therefore be distorted by the slightest contamination, e.g. dust. For the interpretation of such results, please refer to the statement by the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW) on this problem. In case of raw materials, the extent of botanical impurity may also be determined by appropriate methods (microscopy).

4.3 Declaration of Goods

With regard to the labelling or declaration of goods, a product shall, on its packaging or on the business documents accompanying the product, bear a label in accordance with the requirements specified in paragraph 7 of the Codex Guideline. The connection between the goods and the business documents (e.g. delivery note) has to be ensured. This labelling requirement shall not only apply to the product when sold to the final consumer but shall apply throughout the entire production chain.

This means that a clear reference and the name of the inspection body shall be placed either directly in conjunction with the product (packaging, container, means of transportation of the product) or on the business documents accompanying the goods, ensuring that the labelling and the product can be linked to one another at any time.

³ The limit of quantification is defined by the Community Reference Laboratory for genetically modified organisms (Joint Research Centre in Ispra, Italy) as the value at which the GMO content can be quantified with appropriate accuracy (relative standard deviation $\leq 25\%$). As a rule, this value is equivalent to a GMO content of 0.1%, which is the value required for most methods of quantification in order to be validated by the Community Reference Laboratory. Measured values that are below this limit of quantification are usually very inaccurate and therefore not meaningful.

4.4 Special Remarks

4.4.1 Supervisory Monitoring

It has to be ensured that a balanced distribution of the risk levels established in the self-monitoring system is re-verified.

4.4.2 Certification

Certification shall take place upon completion of the initial survey or first inspection.

In case of group certifications of farm businesses, certificates shall be issued to project operators only (product certificates granted after a positive inspection). The data regarding the approved farm businesses participating in the project are to be submitted to the project operator in an appropriate form.

4.4.3 Additional Inspections

By way of derogation from the monitoring plan depending on and determined by the risk classification, additional risk-based sampling may take place in all cases, even if 100% of the businesses are inspected.

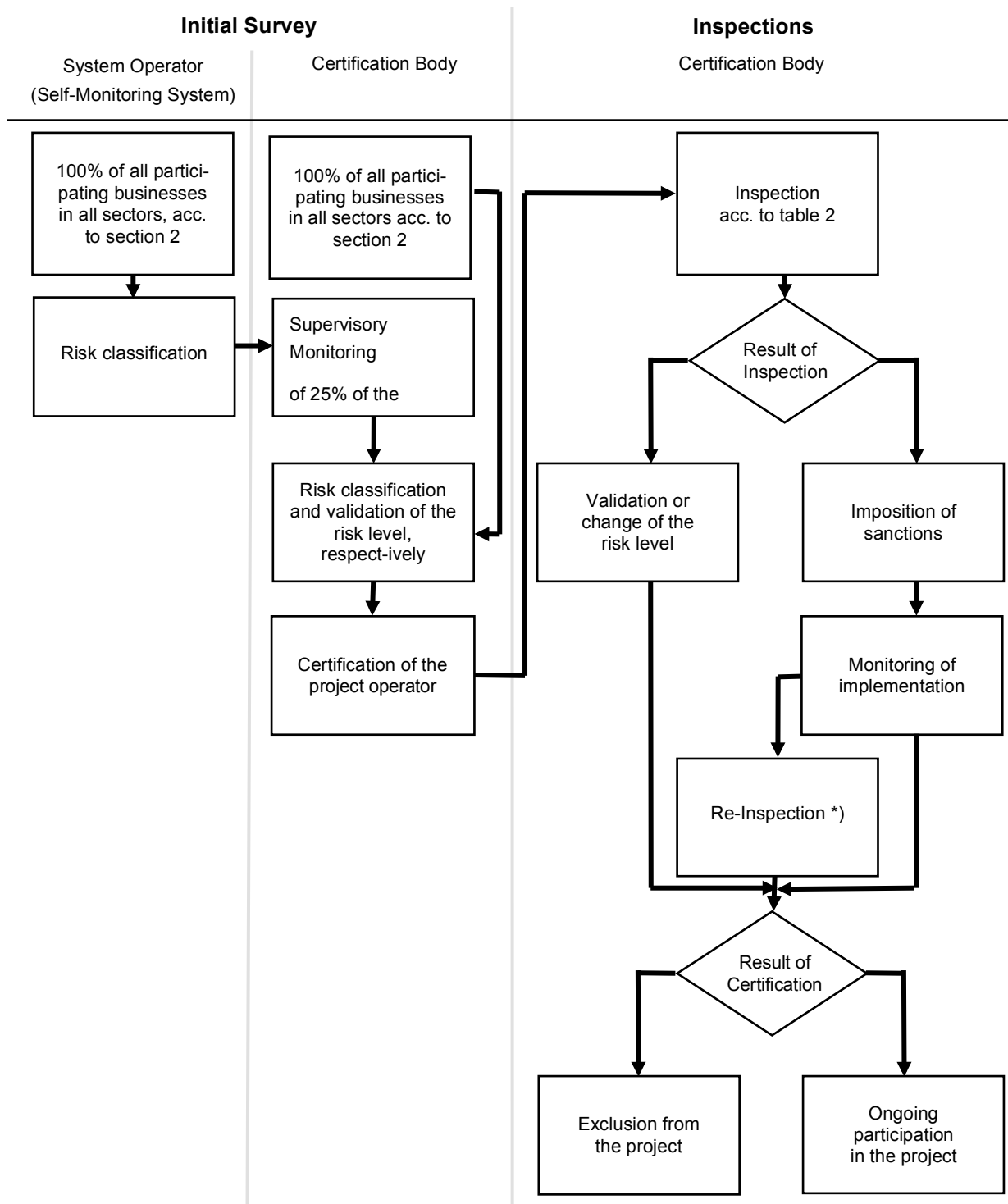
4.5 Monitoring System for Individual Businesses

Monitoring for compliance with the characteristic “GMO-free” shall be conducted, mutatis mutandis, in accordance with the requirements for organic farming.

4.6 Chart of the Risk-Based Monitoring System Within the Scope of Group Certifications (Projects)

In the following two subsections, charts of the monitoring system in case of group certifications within the scope of projects in livestock and plant production can be found.

4.6.1 Livestock Production



Section 2 can be found on page 5, Table 2 can be found on page 19 of this Guideline.

*) „Re-inspection“ is not in any case to be understood as a re-inspection on site. Re-inspection may also mean verifying the implementation of remedial measures (e.g. submission of missing information).

4.6.2 Plant Production

For group certifications in plant production, no initial survey is required. An annual inspection in accordance with the risk classification is undertaken, resulting in approval or disapproval of businesses.

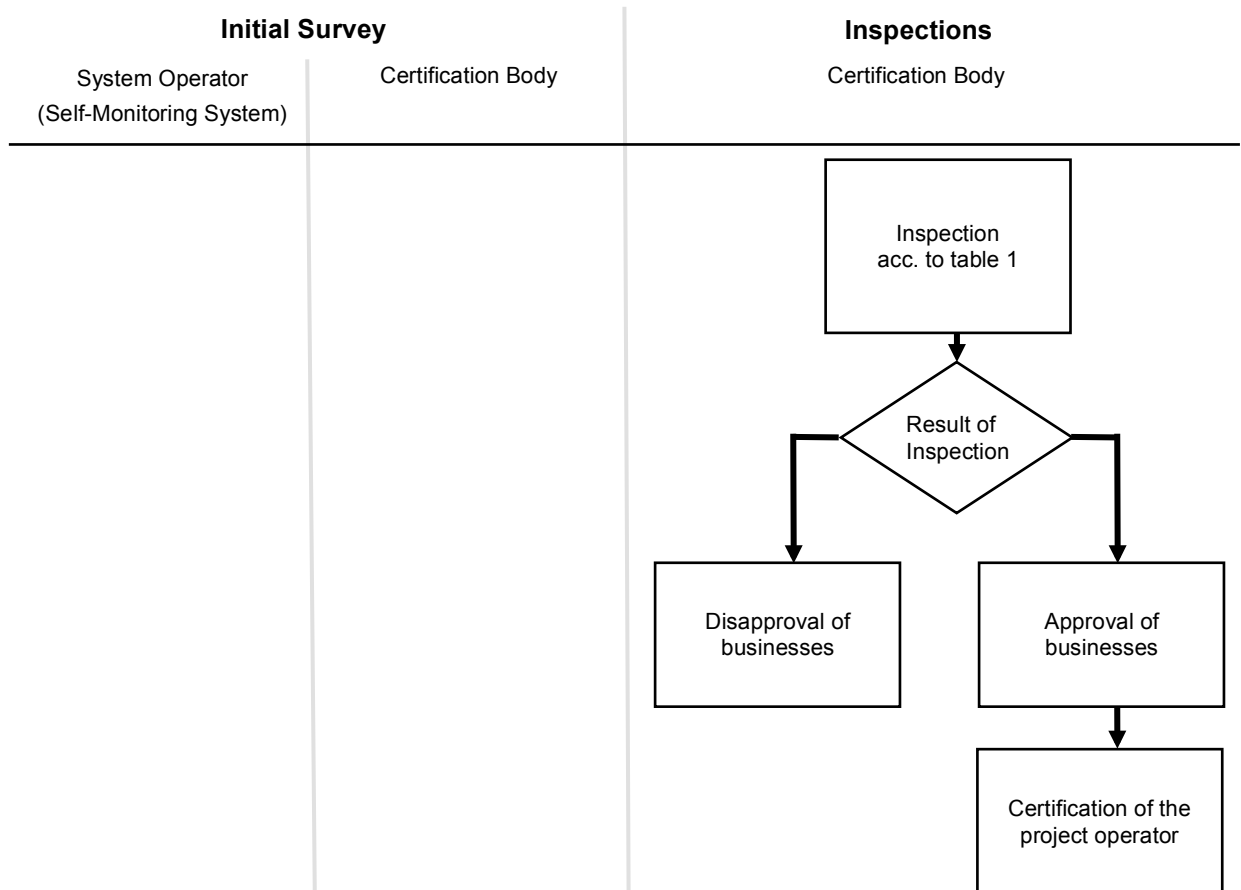


Table 1 can be found on page 17 of this Guideline.

5 QUALIFICATIONS OF INSPECTING STAFF

The following shall apply to monitoring for compliance with the characteristic “GMO-free”:

- the requirements of clause 6.1 of ISO 17065,
- all other requirements of ISO 17065 to be met by the staff of the certification body.

In addition, inspecting staff conducting inspections for the purpose of monitoring compliance with the characteristic “GMO-free” shall comply with the following requirements:

- they shall have successfully completed at least one additional one-day training course covering GMO-free production and its monitoring, as well as undergo annual training;
- they shall be trained to the specific requirements for sampling;
- they shall be trained to applying this Guideline;
- they shall comply with an annual minimum number and duration of inspections; this minimum is to be laid down by the certification body in its QM system.

6 QUALIFICATIONS OF CERTIFYING STAFF

The staff

- a) responsible for imposing and enforcing remedial measures, or
- b) responsible for certifying compliance with the characteristic “GMO-free” and performing these certifications

shall at least possess the same qualifications as inspecting staff. In addition, this staff shall be trained in the specific requirements for imposing and enforcing remedial measures for non-compliance with GMO free production (case a) or for certifying compliance with GMO-free production (case b). This training needs to be documented.

7 INITIAL SURVEY AND RISK CLASSIFICATION

The results of the initial survey together with all corresponding annexes (plans, process descriptions, organisational charts, etc.) shall be summarised in a business description. This business description serves as the basis for risk classification.

The businesses subject to inspection shall be classified on a 4-tier risk scale: risk-0, risk-1, risk-2, risk-3. Businesses classified at risk level 3 cannot be certified for compliance with the characteristic “GMO-free”.

Risk classification may be prepared by the certification body's client within the scope of self-monitoring and shall be checked by the certification body and, where applicable, completed or amended.

Risk classification is the basis for calculating the frequency of the following annual inspections.

7.1 Initial Survey in Livestock Production Projects

The initial survey is based, without exception, on an on-site inspection conducted by an inspector trained and authorised for this purpose.

The initial survey may be conducted:

- 100% by the certification body, or
- by the certification body, completed by initial surveys within the scope of the client's self-monitoring system,

in each case based on a complete description of the individual business or the organisation (project) by the client.

The initial survey forms part of the monitoring procedure, determining the current status of the business and establishing measures to be taken by the client

- a) prior to certification and,
- b) where applicable, after certification.

The initial survey is conducted by using an initial survey form for clients. This initial survey form for clients contains all the aspects necessary for complying with the Codex Guideline. The inspector shall document these aspects and the client shall take cognisance of them by signature.

If clients have more than one business premise, or if clients have suppliers included in the inspection contract, the initial survey form for clients shall also contain all information on all business premises required by the certification body and all suppliers to be included in the inspection contract, respectively.

All measures to be taken by the client for achieving compliance with the Codex Guideline "GMO-free" according to the specifications provided by the certification body shall be accurately documented during the initial survey.

The certification body shall lay down implementation deadlines for the measures to be taken.

When doing so, the certification body shall make a distinction between:

- a) measures which have to be taken prior to certification given that a non-compliance issue negatively affects or may negatively affect the GMO-free status of products, and
- b) measures which may also be taken after certification given that they have no effect on the GMO-free status of products.

The decision regarding the choice of a) or b) shall be documented.

The client's obligation to implement the required measures within the specified period of time shall be confirmed by the client with the company signature in

terms of an annex to the inspection contract, and shall also be confirmed by the suppliers by signature on the survey form.

7.1.1 Implementation of Initial Surveys in Livestock Production Projects (Group Certifications)

The following two options are available:

- 1) initial surveys conducted by the certification body

The certification body conducts an initial survey at 100% of the businesses in the form of on-site inspections.

or

- 2) initial surveys conducted both within the scope of a self-monitoring system and by the certification body

In 100% of the businesses, the initial survey is conducted by the client within the scope of his self-monitoring system and according to the specifications provided by the certification body. In 25% of the businesses, the results are verified on site by the inspection body.

The results of the initial survey conducted within the scope of self-monitoring, the results of the initial survey conducted by the certification body, and the results of supervisory monitoring of the initial survey by the certification body shall be checked, *inter alia*, for possible differences, and corresponding measures shall be implemented should this prove necessary.

7.1.2 Validation and Completion of the Initial Survey by the Certification Body

All initial survey forms of clients shall be verified for completeness by the certification body. The client's initial survey form shall be checked and completed by:

- a) any facts and circumstances not yet mentioned in the client's initial survey form, but necessary for risk classification and further inspections,
- b) any measures the client has to implement for the purpose of maintaining the contractual relationship. The measures shall be confirmed by the client by signature and shall be constantly adapted to new findings during the contractual relationship.

If the initial survey is complemented by a self-monitoring system managed by the client (such as inspections conducted by dairy staff for the purpose of milk suppliers' self-monitoring), the following shall apply:

- The self-monitoring system shall be fully specified in the project description and shall be formally approved by the certification body (i.e. the certifier).

- The client's self-monitoring system does not replace but rather complements the certification body's work. This has the following implications:
 - The certification body may only delegate an exactly defined quantitative part as well as an exactly defined qualitative part of its work to the self-monitoring system. The inspection contract between the certification body and the client shall govern the nature and scope of these parts as well as the parties' responsibilities.
 - The staff conducting inspections for the purpose of self-monitoring shall be trained and approved by the certification body or by other institutions authorised by the accreditation body for this purpose. Self-monitoring activities conducted by staff which has not been approved by the certification body shall lead to the immediate imposition of remedial measures contractually agreed with the client and to be provided by the certification body in the catalogue of remedial measures.
 - The certification body is entitled to check and complete initial surveys conducted within the scope of a self-monitoring system by conducting further initial surveys on site on its own at any time.
- All measures for the initial survey planned within the scope of a self-monitoring system shall be implemented before completion of the business description.

8 RISK CLASSIFICATION OF BUSINESSES AND CROPS

The structure of the following monitoring areas refers to the different areas of production of GMO-free food. This structure does not reflect the chronological order of production or monitoring.

The corresponding requirements for risk classification and monitoring in these areas apply to businesses producing in accordance with the Austrian Codex Guideline or storing, dealing in, or transporting goods in accordance with this Guideline.

For raw materials of a certain plant species (e.g. maize, soya bean) used for the production of animal feed there is no mandatory certification unless any GMO of the same plant species is approved for cultivation and cultivated in the country of origin.

Critical raw materials (as defined in section 2) and raw animal materials used for the production of food shall have been certified as GMO-free by an accredited certification body. This applies to cultivation both in Austria and in other countries of origin.

8.1 Agricultural Production

8.1.1 Risk Classification in Plant Production

“Plant production” is to be understood as the cultivation of crops, vegetables, and fruits on fields and in gardens only, such as cereals, oilseeds, potatoes, etc. Risk classification therefore applies to the acquisition of seeds and planting materials as well as to the possible contamination of the harvest on the field, e.g. by the spread of pollen. The further processing of the harvest into food and feed is dealt with in sections 8.2.1 and 8.2.2.

The following classification in risk levels refers to the respective crop. This classification is also used for the monitoring of projects in plant production. A minimum frequency of inspections is stipulated in monitoring systems of plant production. Self-monitoring systems may also be taken into account when determining this minimum frequency of inspections.

Minimal risk = risk level 0

As a rule, there is a minimal risk if, according to the current state of knowledge, no GMO seed or GMO planting material of the plant species concerned can be found anywhere in the world.

In addition, there is a minimal risk if GMO seeds or GMO planting materials are approved outside the EU only and the risk of contamination on the field is to be considered low (e.g. in case of self-pollinators).

Low risk = risk level 1

Businesses are classified as low risk e.g. if GMO seeds or GMO planting materials are approved and cultivated outside the EU only, but if the risk is to be considered higher due to various factors such as possible contamination on the field. In addition, there is a low risk if GMO plants are cultivated to a limited extent within the EU. In this case, adequate measures shall be taken for the purpose of preventing contamination on the field, such as exclusive cultivation of selected GMO-free varieties or legal protection preventing GMO plants from being grown.

Medium risk = risk level 2

Businesses are classified as medium risk if GMO seeds or GMO planting materials are approved and cultivated in the EU or in Austria and there is a high risk of contamination on the field; e.g. if GMO seeds are sown in the surrounding area and plant species-specific distances required to avoid cross-pollination or contamination (e.g. due to wind transport) are, at the same time, adhered to.

High risk = risk level 3

Businesses are classified as high risk if GMO seeds or GMO planting materials are approved in Austria and are sown or grown in the surrounding area and if plant species-specific distances required to avoid cross-pollination or contamination (e.g. due to wind transport) are, at the same time, not adhered to.

Inspection and sampling

Table 1: percentage of certified businesses subject to annual inspection at each risk level.

Risk Level	Percentage of Inspected Businesses	Frequency of Sampling/Harvest
0	0	
1	25%	Sampling Plan (see note below)
2	50%	Sampling Plan (see note below)
3	No Certification Possible	

Please note: A sampling plan shall be available. If goods are sampled at the next stage of the value chain (= agricultural collector), no sampling on the field needs to be conducted. In this case, possible contamination by other raw materials stored on this agricultural collector's premises shall also be addressed in sampling.

8.1.2 Risk Classification in Livestock Production

Only entire production lines (business units) may be converted, e.g. the entire dairy farming unit and/or the entire poultry farming unit. Mixed farming systems (with and without GMOs) within a production line cannot be certified.

The practice of operating different production lines in different ways (with/without GMOs) shall result in a higher business risk taken into account when calculating the risk level; this practice shall, as a rule, only be possible if the production lines are adequately segregated. (This also applies to different production lines where the same livestock species is kept.)

Businesses with production lines where only soya-containing animal feed is used (e.g. egg-producing poultry, fattening poultry, fattening pigs) shall be classified, at least, at risk level 1.

Minimal risk = risk level 0

There is a minimal risk if only products which cannot be genetically modified (e.g. minerals) or crops with genetically modified varieties that have not been granted marketing authorisation in the EU (e.g. wheat) are used for feeding and feed mixing in animal processing and if only such products or crops are stored;

if only raw materials not subject to GMO labelling according to Regulation (EC) No 1829/2003 are used; and if only non-substitutable GMO animal feed is used on the farm.⁴

There may also be a minimal risk if only animal feed suitable for the production of GMO-free food that is labelled accordingly and subject to a monitoring system is used.

Critical raw materials originating from countries where GMOs are approved for cultivation and cultivated shall have been certified as GMO-free by an accredited certification body.

Low risk = risk level 1

Businesses are classified as low risk if substitutable, non-compliant animal feed is available on the farm, but not the same facilities (e.g. mixers, vultes, stores, stables) are used for feeding, feed mixing, storage, and/or internal feed transportation, thus avoiding contamination.

Raw materials for GMO-free production shall not be subject to GMO labelling according to Regulation (EC) No 1829/2003 and shall originate from GMO-free cultivation. Critical raw materials originating from countries where GMOs are approved for cultivation and cultivated shall have their origin from GMO-free cultivation; this needs to be documented on purchase orders and delivery notes.

Medium risk = risk level 2

Businesses are classified as medium risk if the same facilities (e.g. mixers, vultes, stores, stables) are used for feeding, feed mixing, storage, and/or internal feed transportation, which may result in contamination. It is assumed that there is a risk, which, however, can be minimised by taking appropriate measures.

Should the risk not be minimised by taking appropriate measures, the business cannot be certified (risk level 3).

Raw materials for GMO-free production shall not be subject to GMO labelling according to Regulation (EC) No 1829/2003.

⁴ Animal feed produced for another animal species than the animal species (family or subfamily) kept within the scope of the certified production line is regarded as non-substitutable. E.g. in the production of GMO-free milk, egg-producing poultry feed is considered non-substitutable, whereas beef cattle feed is considered substitutable given that the same animal species (family: Bovidae; subfamily: domestic cattle) is involved. Conversely, when it comes to certifying egg-producing poultry, beef cattle feed is to be considered non-substitutable, whereas fattening poultry feed (poultry; Galliformes) is to be considered substitutable.

High risk = risk level 3

Businesses are classified as high risk if the risk of GMO-free feed being mixed with GMO feed during feeding, feed mixing, storage, and internal feed transportation is assumed to be high.

Inspection and sampling

Table 2: percentage of certified businesses subject to annual inspection at each risk level.

Risk Level	Percentage of Inspected Businesses
0	25%
1	50%
2	100%
3	No Certification Possible

If 25% of the businesses are subject to annual inspection, it shall be ensured that each business is inspected at least once within a period of 4 years. If 50% of the businesses are subject to annual inspection, each business shall be inspected at least once within 2 years. Each inspection with a negative result shall entail an additional inspection.

Animal feed containing critical raw materials shall be given priority when it comes to sampling and analysis. For duly justified reasons or if large quantities of animal feed containing critical raw materials are used, the frequency of sampling may be higher than specified.

Sampling is also required in case of home mixers and mobile mixers. Sampling may be waived if only animal feed certified as "geeignet zur Herstellung gentechnikfreier Lebensmittel"/"suitable for the production of GMO-free food" and/or only uncritical raw materials are used on the farm.

8.2 Processing

8.2.1 Risk Classification of Animal Feed

The area addressed in this section includes both fixed installations (feed mills) and mobile mixers.

Minimal risk = risk level 0

There is a minimal risk if only raw materials which cannot be genetically modified (e.g. minerals) or crops with genetically modified varieties that have not been granted marketing authorisation in the EU (e.g. wheat) are used at the business premises and if only raw materials not subject to GMO labelling according to Regulation (EC) No 1829/2003 are used at the business premises. Critical raw materials originating from countries of origin where GMOs are

approved for cultivation and cultivated shall have been certified as GMO-free by an accredited certification body.

Low risk = risk level 1

Businesses are classified as low risk if GMOs are used at the business premises, but not the same facilities (e.g. mixers, volutes, stores) are used for feed mixing, storage and/or internal transportation, thus avoiding contamination. Raw materials for GMO-free production shall not be subject to GMO labelling according to Regulation (EC) No 1829/2003 and shall originate from GMO-free cultivation according to the Codex Guideline. Critical raw materials originating from countries where GMOs are approved for cultivation and cultivated shall have their origin from GMO-free cultivation; this needs to be documented on purchase orders and delivery notes.

Medium risk = risk level 2

Businesses are classified as medium risk if GMOs are used at the business premises and the same facilities (e.g. mixers, volutes, stores) are used for feed mixing, storage and/or internal transportation, which poses a risk of contamination, but if the risk involved can assumedly be minimised by taking appropriate measures (e.g. cleaning batches).

Should the risk not be minimised by taking appropriate measures, the business cannot be certified (risk level 3).

Raw materials for GMO-free production shall not be subject to GMO labelling according to Regulation (EC) No 1829/2003.

High risk = risk level 3

Businesses are classified as high risk if GMOs are used at the business premises and the risk of GMO-free feed being mixed with GMO feed during feed mixing, storage, and/or internal transportation is assumed to be high.

Inspection and sampling

At risk levels 0 to 2, the percentage of inspected businesses is 100%. At risk level 3, no certification is possible.

A minimum number of samples per produced quantity is established, taking into account samples taken within the scope of the businesses' self-monitoring systems. Sampling shall focus on animal feed containing soya or another critical raw material in their formulation.

The frequency of inspections and sampling will be increased for the following reasons:

- no segregated point of entry of GMO-free raw materials and GMO raw materials,
- a low proportion of GMO-free products (resulting in a high risk of contamination).

As a rule, the following shall apply for animal feed production: Incoming raw materials shall be continuously monitored, focusing particularly on critical raw materials (as defined in section 2). It is recommended to conduct a risk assessment of these raw materials and implement protective measures including but not limited to information given on documents accompanying goods (certificate of origin), rapid test procedures (strip tests), certificates, and analysis results.

8.2.2 Risk Classification of Food

Minimal risk = risk level 0

There is a minimal risk if only critical raw materials or crops and raw animal materials which have been certified as GMO-free by an accredited certification body or have genetically modified varieties that have not been granted marketing authorisation in the EU (e.g. wheat) are used at the business premises.

Low risk = risk level 1

Businesses are classified as low risk if critical raw plant materials not certified as GMO-free by an accredited certification body, but not subject to GMO labelling according to Regulation (EC) No 1829/2003 are used at the business premises. There is also a low risk if raw plant materials subject to GMO labelling and/or raw materials of animal origin not certified as GMO-free are used, but not the same facilities are used for processing and transportation at the business premises, thus avoiding contamination. In addition, there is a low risk if critical raw plant materials are purchased from countries where GMOs are approved for cultivation and cultivated and if these raw materials have been certified as GMO-free by an accredited certification body.

Medium risk = risk level 2

Businesses are classified as medium risk if raw plant materials subject to GMO labelling (according to Regulation [EC] No 1829/2003) and/or raw materials of animal origin not certified as GMO-free by an accredited certification body are used at the business premises and the same facilities are used for processing and/or transportation, which poses a risk of contamination, but if the risk involved can assumedly be minimised by taking appropriate measures (e.g. cleaning).

Should the risk not be minimised by taking appropriate measures, the business cannot be certified (risk level 3).

High risk = risk level 3

Businesses are classified as high risk if raw materials subject to GMO labelling (according to Regulation [EC] No 1829/2003) and/or raw materials of animal origin not certified as GMO-free by an accredited certification body are used at the business premises; if the risk of GMO-free food being mixed with GMO food is assumed to be high when it comes to food mixing, storage, and internal transportation; and if critical raw materials are purchased from countries where GMOs are approved for cultivation and if these raw materials have not been certified as GMO-free by an accredited certification body.

Inspection and sampling

In GMO-free food production, inspections shall take place annually, by analogy with inspections in the organic food sector. Samples shall be taken from risk components, provided that these components can be analysed. Additional risk-based sampling shall be conducted depending on the inspection body's risk assessment.

8.3 Trade, Storage, and Transportation

This section deals with the trade in unpacked critical crops (e.g. soya beans, maize) and unpacked products produced from critical crops (e.g. soya bean meal, maize gluten) as well as with the storage and transportation of such crops and products. The trade in packaged goods as well as the storage and transportation of such goods (e.g. food retailers) are not covered in this section. Goods packed in bulk bags and open containers shall be treated in the same way as unpacked goods.

The area addressed in this section includes the storage of raw plant materials, regardless of whether such storage takes place on the premises of an individual farmer or on the premises of a company. If a farmer stores his own agricultural produce subject to certification on his own premises instead of delivering this produce straight from the field, this farmer shall also be considered an agricultural collector (irrespective of the duration of storage). A farmer shall likewise be considered an agricultural collector if he conducts post-harvest treatment (drying, cleaning, conditioning) on his own premises.

Minimal risk = risk level 0

There is a minimal risk if only products which cannot be genetically modified (e.g. minerals) or crops with genetically modified varieties that have not been granted marketing authorisation in the EU (e.g. wheat) are stored and transported on the business premises. Animal feed and raw materials for animal feed production shall not be subject to GMO labelling according to Regulation (EC) No 1829/2003. Food and raw materials for food production (ingredients, additives, etc.) derived from critical crops or of animal origin shall have been certified as GMO-free by an accredited certification body. The latter shall also

apply to animal feed and raw materials for animal feed production originating from countries of origin where GMOs are approved for cultivation and cultivated.

Low risk = risk level 1

Businesses are classified as low risk if GMOs are used at the business premises, but not the same facilities (e.g. conveying paths, stores) are used for food and feed mixing, storage, and transportation at the business premises, thus avoiding contamination.

The above-mentioned provisions for the quality of food and feed and their respective raw materials shall apply, *mutatis mutandis*, to risk level 1.

Medium risk = risk level 2

Businesses are classified as medium risk if GMOs or products produced from GMOs are stored or transported on the business premises and the same facilities are used for storage and/or transportation, which poses a risk of contamination, but if the risk involved can assumedly be minimised by taking appropriate measures (e.g. cleaning of silos and vehicles).

Should the risk not be minimised by taking appropriate measures, the business cannot be certified (risk level 3).

The above-mentioned provisions for the quality of food and feed and their respective raw materials shall apply, *mutatis mutandis*, to risk level 2.

High risk = risk level 3

Businesses are classified as high risk if GMOs are stored or transported on the business premises and the risk of GMO-free food and feed being mixed with GMO food and feed is assumed to be high when it comes to storage and transportation.

Inspection and sampling

Inspections shall take place annually, by analogy with all processing businesses; sampling shall be conducted on a risk basis and in accordance with a defined sampling plan. A minimum number of samples per produced, stored, or traded quantity is established, taking into account samples taken within the scope of the businesses' self-monitoring systems. In any event, one representative analysis per season shall be conducted, unless analyses are systematically laid down in a subsequent process.

9 CERTIFICATION FOLLOWING THE INITIAL SURVEY AND INSPECTION

In order to obtain certification, businesses shall comply with the following conditions:

- availability of a complete business description together with all initial surveys of all business premises and suppliers included in the inspection contract with the client,
- successful completion of an initial survey and inspection in nature and scope as determined in the QM system,
- no ongoing imposition and enforcement of remedial measures impeding certification according to the catalogue of remedial measures.

10 INSPECTIONS

10.1 Frequency of Inspections

Inspections shall be conducted at the frequency specified for the different areas of production and the risk-based classification. Self-monitoring systems managed by the client may complement but not replace inspections conducted by the certification body. The inspection contract shall provide that the results of self-monitoring activities have to be presented to the certification body, provided that such activities have taken place.

10.2 Scope of Inspections

The nature and scope of inspections depend on the risk classification. The criteria for selecting the businesses to be inspected shall be established and defined in the certification body's QM system.

Inspections shall be conducted by staff properly trained in their specific field (according to ISO 17065) and employing the methods usually used for this activity. Inspectors shall, inter alia:

- base their inspection on the business description,
- fully work through the inspection documentation form using the information and documents provided by the business and its representatives,
- avoid leading questions,
- actively inspect all areas belonging to the business premises,
- challenge facts,
- check documentation and challenge the facts found there,
- perform calculations where applicable.

10.2.1 Farm businesses

Inspections conducted on farms shall include questions, control points (records, visits of relevant sites), and calculations covering the following topics (where applicable) and their relevance in GMO-free production:

- seeds,
- plant protection products,
- fertilisers,
- silage additives,
- animal feed,
- number of animals kept on the farm,
- purchase of additional animals.

10.2.2 Processing, Storage, and Trade

Inspections of clients and/or inspections conducted on the premises of processors, agricultural collectors, and traders shall include questions, control points (records, visits of relevant sites), and calculations covering the topics (where applicable) and their relevance in GMO-free production as shown in table 3.

Table 3: content of inspections according to the type of business.

Type of Business	Content of Inspections
Processing	Formulations Incoming Goods Quantitative Flow Analysis Outgoing Goods Declaration
Trade & Storage	Incoming Goods Outgoing Goods Quantitative Flow Contamination Analysis Declaration
Management	Documentation Declaration

10.3 Inspection Report

Inspections shall be documented in an inspection documentation form.

In case of non-compliance issues, the required objective evidence of these issues shall be provided in this form.

The inspection documentation form shall also contain objective evidence of compliance at appropriate control points stipulated by the certification body.

Inapplicable sections of the inspection documentation form shall be visibly crossed out and marked as “not applicable”. If necessary for understanding, it shall be explained why the respective control point is not applicable.

11 IMPOSITION AND ENFORCEMENT OF REMEDIAL MEASURES

Measures to be taken in case of non-compliance (particularly in case of thresholds being exceeded) shall be established in the QM system. Remedial measures imposed for non-compliance shall entail an increase in the frequency of inspections.

The scope of such increase shall be determined in the QM system.

12 SAMPLING AND ANALYSES OF SAMPLES

The methods of sampling for the monitoring of GMO-free production shall be established in the QM system and shall comply with the applicable legal and normative provisions.

Samples shall be taken at all stages of production (agricultural producers, processing) and shall be analysed where technically possible. The number of samplings and analyses shall be determined on a risk basis and shall be specified in the QM system.

13 SUBSEQUENT ANNUAL CERTIFICATION

In order to obtain certification, businesses shall comply with the following conditions:

- availability of a complete updated business description together with all initial surveys of all business premises and suppliers included in the inspection contract with the client,
- no ongoing imposition and enforcement of remedial measures impeding certification according to the catalogue of remedial measures,

in case of clients with multiple suppliers: no ongoing imposition and enforcement of remedial measures on the part of all suppliers (self-monitoring system and monitoring system of the certification body) impeding certification according to the catalogue of remedial measures.