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**STANDARD ON THE RISK-BASED
CONTROL OF
GMO-FREE PRODUCTION PROCESSES**
(Non GM Danube Region Inspection Standard)

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1 BACKGROUND AND INTRODUCTION

On the initiative of the Ministry of Agriculture and the Environment of the Republic of Slovenia and the Danube Soya Initiative, the Ministers responsible for Agriculture of the broader Danube region met on 23 August 2013 in Moravske Toplice to discuss the implications of the regional cooperation for protein security in the Danube region. In their joint declaration, Ministers agreed amongst others to „single out the consumer freedom of choice by creating a transparent international standard for the traceability of production, control and certification system of labelling of products as GMO-free for plant-based, processed and animal agricultural products”.

The “Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ GmbH)” is committed to support this process in the context of the regional project “Promotion of GMO-free quality soya from the Danube Region”. The team of Umweltbundesamt (Environment Agency Austria) in close coordination with GIZ and Danube Soya Initiative, was responsible for coordinating and chairing a participatory expert process to establish a GMO-free labelling standard for food products and an associated control system for the Danube Region.

The objective of the overall GIZ project is strengthening of economically, ecologically and socially viable GMO-free soya production in selected areas of the Danube Region.

The titles of the two standards are:

- Standard on the definition of the GMO-free production processes of food and its labelling
- Standard on the risk-based control of the GMO-free production processes

The final texts of the standards will be provided to the participating countries for their consideration and implementation. They intend to support and give guidance especially to the countries which do not yet have their own national approaches for GMO-free labelling and control in place. All other European countries, interested in establishing GMO-free labelling and control, are kindly invited to make use of these final texts of the standards as well.

2 SCOPE OF APPLICATION

This standard is valid for inspections and certifications conducted for the purpose of monitoring compliance with the characteristic “GMO-free” according to the “Draft Standard on the definition of the GMO-free production processes of food and its labelling”.

All products subject to an inspection procedure according to this standard may be labelled as “GMO-free” in accordance with the above-mentioned standard. The two standard documents have to be read and implemented together, if appropriate, links are made between the two documents. In particular, the definitions outlined in Chapter 3 of the above mentioned standard apply also for this standard on the risk-based control of GMO-free production. They are

complemented by more detailed definitions or descriptions relevant in particular for this standard (see e.g. uncritical and critical components in chapter 2.1 below).

This standard aims to implement risk-based control for compliance with the characteristic “GMO-free”, conducted in each case under the best possible technical conditions. Inspections shall be conducted in a uniform way, applying high technical and methodological standards.

This standard covers inspection and certification for compliance with the characteristic “GMO-free” for individual businesses and organisations (including “GMO-free projects”, see below) in the following sectors:

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

All products certified as “organic” comply with the provisions and criteria set in this standard.

3 GENERAL PROVISIONS

Inspection 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.

Certification bodies (CB) conducting inspections for the purpose of control and certifying compliance with the characteristic “GMO-free” are only authorised to do so when in possession of a valid accreditation in accordance with ISO 17065, in particular for the implementation of the standard on the definition of the “GMO-free production processes” of food and its labelling.

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 a comprehensive monitoring. Inspections 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 standard or have to be brought to the accreditation body’s attention.

In agricultural production, a distinction is made between certification of individual businesses and group certifications in livestock and plant production in the context of GMO-free projects.

Inspections of all businesses should be carried out at least once a year. Provisions for inspections and sampling in case of group certification in GMO-free projects are described in chapters 7.1.1.1 and 7.1.2.1.

Analytical laboratories carrying out analysis shall be accredited according to ISO17025.

3.1 Uncritical and critical components

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

uncritical:

- Raw materials which cannot be genetically modified (e.g. minerals) or crops which have genetically modified varieties that have not been granted marketing authorisation anywhere in the world (e.g. barley, rye, based on the situation as of beginning of 2015) are to be considered uncritical. These raw materials or crops are hereinafter referred to as "uncritical raw materials or crops"

critical:

- 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". Crops that do not have a marketing authorization, but e.g. show up in the rapid alert system for food and feed (RASFF) of the EU regularly (such as rice, papaya) may be regarded as critical components as well (see Annex 2 to this standard).
- Food ingredients from animal origin
- Food ingredients such as enzymes, additives etc. are regarded as critical components.

3.2 "GMO-free projects" and "group certification"

"GMO-free Projects" consist of individual sectors such as agricultural production, processing, trade, storage and transportation. In case of GMO-free projects, the requirements for these individual sectors shall apply as a whole whilst ensuring that control is conducted throughout the entire production chain. Charts of risk based monitoring systems within the scope of group certification in the context of GMO-free projects can be found in chapter 2.7.

In case of GMO-free projects, the project operator shall prepare a project description specifying these criteria, presenting the overall system (including his own business premises participating in the GMO-free project and their methods of production). This shall include other partner businesses participating in the GMO-free project and their tasks (e.g. marketing, sale), and specifying the criteria for the different types of businesses to participate in the GMO-free project. This GMO-free project description shall be available to all stakeholders involved and interested in the project.

In these cases, the inspection contract (see above) shall include provisions ensuring that the rights and obligations under this contract are imposed on all participants in the GMO-free project.

Within a GMO-free project several producers (e.g. farmers delivering milk for a dairy production project) can be certified as group without individual certification

of each single producer (group certification). In case of group certifications, certificates shall be issued to project operators only.

Here is a practical example of a GMO-free project including group-certification: a dairy production facility or a slaughter-house issues a contract concerning GMO-free production and control with a group of producers (e.g. farmers). The certification body clarifies in its contract with the dairy production facility or slaughter-house the conditions for inspection and certification of the group of farmers (such as provision of data, any sanctions, information exchange).

3.3 Stages of the control procedure

Control for compliance with the characteristic “GMO-free” consists of the following important stages (see also charts of the control procedure under 2.7.1 and 2.7.2):

- 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-control system, completed by supervisory control and validation by the certification body,
 - business description and risk classification;
- regular inspections of farm businesses (plant production);
- regular inspections of processing and trading businesses (animal feed, food, trade in critical raw materials, agricultural collectors...);
- certification;
- imposition and enforcement of remedial measures (conducting additional risk-based sampling where applicable);
- annual certification.

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

The certification body shall keep a register of critical components, see also Annex 2 to this standard as reference. 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. For food and feed, the EU Register of GM food and feed (publicly available on the website of the European Commission) may be consulted.

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 personnel, the planning of inspections, and the information provided to clients.

3.4 Dealing with Contamination

A basic requirement for feed and food ingredients for the production of food labelled “GMO-free” is that they must not bear any labelling according to the rules of Regulations (EC) No. 1829/2003 and No. 1830/2003 or regulation (EC) No. 619/2011 (Low Level Presence)¹ and would have to be labelled if placed on the EU market.

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 country where this Standard applies below the limit of quantification of generally 0.1% per species shall be regarded as “adventitious” or “technically unavoidable”.

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.

3.5 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 of the standard on the definition of the “GMO-free production” of food and its labelling. 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,

¹ as not all Danube Soya member countries are EU members provisions mentioned in the context of specific EU regulations are subjected to domestic legislation. The same applies for all parts of the text where EU regulations are mentioned.

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.

3.6 Special Remarks on control and certification

3.6.1 Supervisory Control

The supervisory control by the certification body needs to be carried out in a way that all risk levels established in the self-control systems of the companies according to Chapter 7 are covered in a balanced way.

3.6.2 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.

3.6.3 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.

3.7 Chart of the Risk-Based Monitoring System within the Scope of Group Certifications in the context of GMO-free Projects

In the following two subsections, charts of the control system in case of group certifications within the scope of GMO-free projects (see chapter 2.2.) in livestock and plant production can be found.

3.7.1 Livestock Production in GMO-free projects

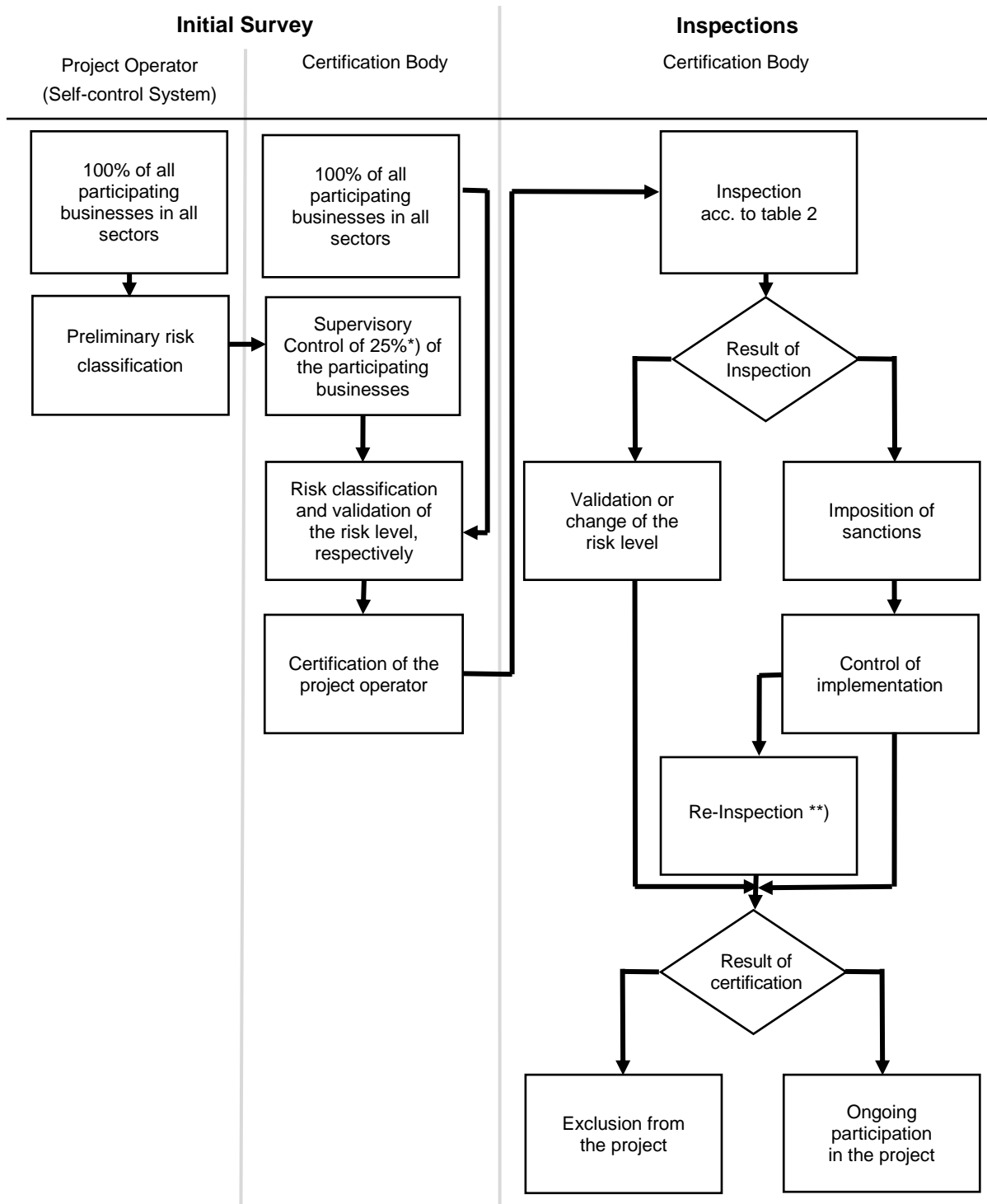


Figure 1: Chart of the control system for GMO-free projects in livestock production. Table 2 can be found on page 20 of this standard.

*) In case of production lines where soya-containing animal feed is used at larger quantities as defined by the certification body and on a daily basis (e. g. egg-producing poultry, fattening poultry, fattening pigs, intensive dairy farming), the initial survey shall cover 50 % of the participating businesses.

**) „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).

3.7.2 Plant Production in GMO-free projects

For group certifications in GMO-free projects 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 in the sense of this Standard.

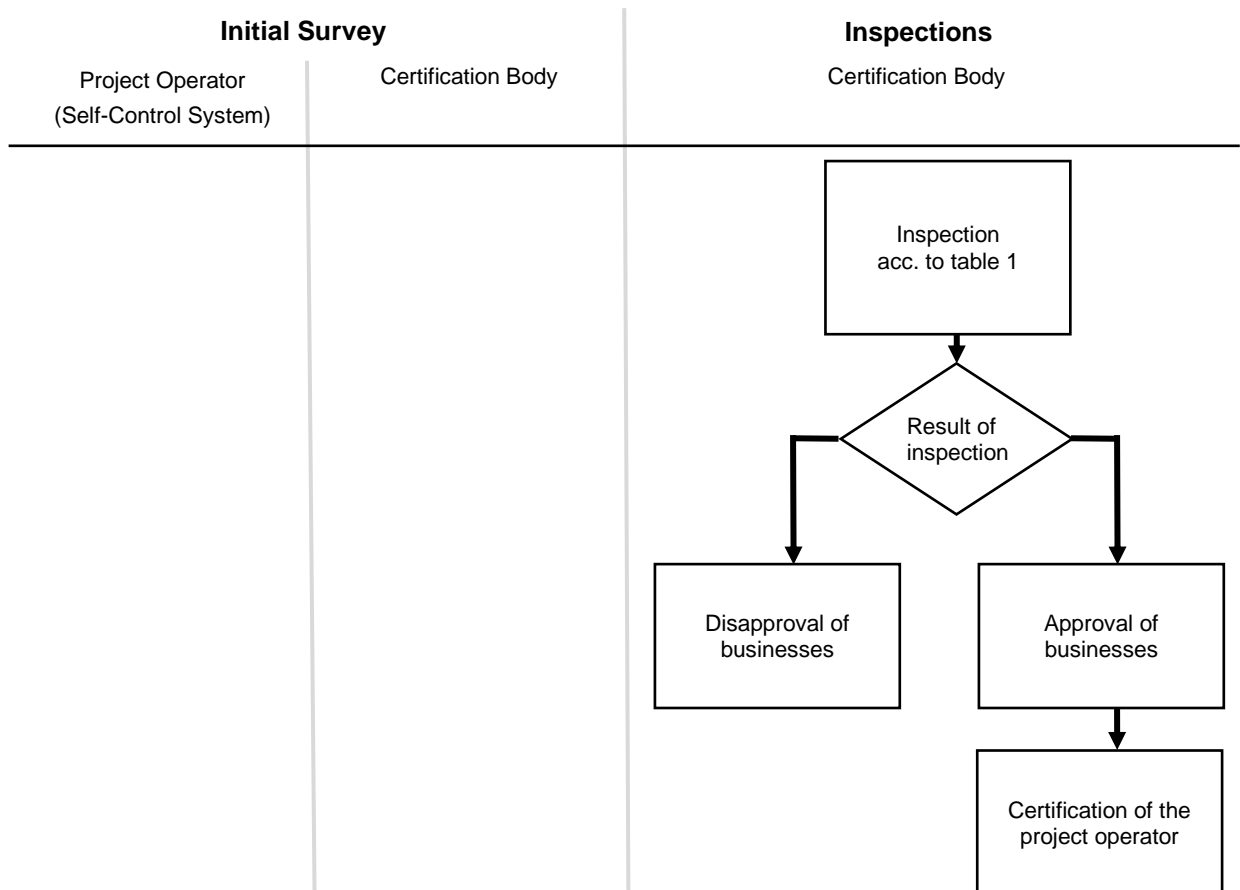


Figure 2: Chart of the control system for GMO-free projects in plant production. Table 1 can be found on page 18 of this standard.

Self monitoring and quality assurance systems (catalogue of requirements)

Production facilities operating under the provision of this standard are requested to implement a system of self-monitoring and quality assurance. The extent to which clients (organisations) implement self-monitoring systems, depends on their resources and strategies. Annex 1 provides practical guidance for the application of the requirements stated in this document.

4 QUALIFICATIONS OF INSPECTING PERSONNEL

The following shall apply to inspection 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 personnel of the certification body.

In addition, inspecting personnel 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 standard;
- 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 Quality Management system.

5 QUALIFICATIONS OF CERTIFYING PERSONNEL

The personnel

- 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 personnel. In addition, this personnel 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 by the certification body.

6 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".

According to ISO 17065 the risk classification has always to be carried out by the certification body.

Referring to projects, risk classification may be prepared by the certification body's client within the scope of self-control 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.

6.1 Initial Survey in Livestock Production Projects

The initial survey is based, without exception, on an on-site inspection conducted by a person 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-control 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 control 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 standard on the definition of the GMO-free production of food and its labelling. 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 standard on production of GM-free food 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.

6.1.1 Implementation of Initial Surveys in Livestock Production GMO-free 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-control 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-control 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. In case of production lines where soya-containing animal feed is used at larger quantities as defined by the certification body and on a daily basis (e. g. egg-producing poultry, fattening poultry, fattening pigs, intensive dairy farming), the initial survey shall cover 50 % of the participating businesses. The results of the initial survey conducted within the scope of self-control, the results of the initial survey conducted by the certification body, and the results of supervisory control 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.

6.1.2 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-control 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-control 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-control 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-control 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 personnel conducting inspections for the purpose of self-control shall be trained and approved by the certification body or by other institutions authorised by the accreditation body for this purpose. Self-control activities conducted by personnel 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-control 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-control system shall be implemented before completion of the business description.

7 RISK CLASSIFICATION OF BUSINESSES AND CROPS

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

The corresponding requirements for risk classification and control in these areas apply to businesses producing in accordance with the standard on production of GM-free food or storing, dealing in, or transporting goods in accordance with this standard.

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. Nevertheless occasional controls (including analytical tests) are recommended.

Critical raw materials (as defined in section 1) 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 the Danube region and in other countries of origin.

7.1 Agricultural Production

7.1.1 Risk Classification in Plant Production

“Plant production” is to be understood as the cultivation of field crops, vegetables, and fruits. Risk classification therefore applies to the acquisition of seeds and planting materials as well as to the possible contamination of the plant products, e.g. by the spread of pollen. The further processing of plant products into food and feed is dealt with in sections 7.2.1 and 7.2.2.

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.

It has an influence on the risk classification according to this Standard, if the respective country has a legal system in place covering the presence of GMOs in seeds and planting material.

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 respective country only and the risk of contamination on the field is to be considered low.

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 respective country 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 Europe. 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 Europe or in the country where the GM-free food is produced and there is a high risk of contamination on the field; e.g. if GMO seeds are sown in the surrounding area/fields 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 the country where the GM-free food is produced 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.

7.1.1.1 Inspection and sampling for group certification within GMO-free projects

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 and accepted by the certification body. 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.

7.1.2 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 soya-containing animal feed is used at larger quantities as defined by the certification body and on a daily basis (e. g. egg-producing poultry, fattening poultry, fattening pigs, intensive dairy farming) 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 in the respective country or crops with genetically modified varieties not subject to Commission Regulation (EU) No 619/2011 (Low Level Presence) 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.²

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.

² 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.

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, volutes, 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, volutes, 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.

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.

7.1.2.1 Inspection and sampling for group certification within GMO-free projects

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 “suitable for the production of GMO-free food” and/or only uncritical raw materials are used on the farm.

7.2 Processing

7.2.1 Risk Classification for the Production 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 in the respective country are used at the business premises and if only raw materials not subject to GMO labelling according to Regulation (EC) No 1829/2003 or raw materials not subject to Commission Regulation (EU) No 619/2011 (Low Level Presence) 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 standard on the definition of GMO-free production and its labelling. 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.

7.2.1.1 Inspection and sampling

All businesses are to be inspected at least annually. 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 1). 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.

7.2.2 Risk Classification for the Production 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 in the respective country 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.

7.2.2.1 Inspection and sampling

In GMO-free food production, inspections shall take place annually. 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.

7.3 Trade, Storage, and Transportation

This section deals with the trade of bulk commodities of critical crops (e.g. soya beans, maize) and unpacked products produced from critical crops (e.g. soya bean meal, maize gluten, compound feed) as well as 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 big 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 in the respective country 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.

7.3.1.1 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.

8 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 (see Annex 1) 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 Quality Management system,
- no ongoing imposition and enforcement of remedial measures impeding certification according to the catalogue of remedial measures.

9 INSPECTIONS

9.1 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.

Not previously announced and short-notice inspections shall take place at a regular level.

9.2 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 Quality Management system.

Inspections shall be conducted by personnel 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.

9.2.1 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:

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

9.2.2 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

9.3 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.

10 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 Quality Management 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 Quality Management system.

11 SAMPLING AND ANALYSES OF SAMPLES

The methods of sampling for the monitoring of GMO-free production shall be established in the Quality Management system and shall comply with the applicable legal and normative provisions (e.g. ISO 24333 or Regulation (EC) 691/2013 amending Regulation (EC) No 152/2009).

Samples shall be taken at all stages of production (feed manufacturer, agricultural producers, processing of food and feed) 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 Quality Management system of the certification body. See the respective chapters in section 7 for further details.

It is recommended to consider at the national level to clarify how many samples have to be taken by the certification body in specific cases.

12 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-control system and control system of the certification body) impeding certification according to the catalogue of remedial measures.

ANNEX 1: CATALOGUE OF REQUIREMENTS

This annex gives additional guidance for the application of the requirements stated in this document. The following requirements apply to agricultural production, storage and transport and feed/food producing facilities and shall be considered where relevant and applicable

1.1 Requirements for the Stage of Agriculture

1.1.1 Facility Description

The facility description serves to fully record those local conditions that are relevant for “GMO-free” production. It serves as a foundation for the internal risk assessment as well as for the evaluation by the external auditor.

For the next audit, an updated facility description is to be provided.

Reporting or forwarding details to the certification body is only necessary in case of fundamental changes that affect risk classification.

The facility description shall take into account those points that could lead to an introduction of genetically modified feed into the facility.

If, besides GMO-free feed, GMO-containing 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 facilities for feed production and feed handling (mixing facilities, equipment storage, feeding installations, etc.) including all facilities that are not located directly at the farmstead.

1.1.2 Distribution of Responsibilities / Organisational Chart

An overview of all persons working in the facility shall be compiled. Temporary employees, apprentices, interns etc. must be included as well. This list shall permit to determine who is responsible for the processes of the “GMO-free” feeding and which other persons are involved and must thus be trained. This overview must be updated when personnel joins or leaves the business

1.1.3 Feedstuff ordering

The farm should order feedstuffs in writing so as to prevent confusion. It must be explicitly stated in the order that the feedstuffs must be suitable for the production of “GMO-free” labelled food products.

1.1.4 Self-Monitoring System

1.1.4.1 Animal Inventory and Observance of Conversion Times

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

When additional animals are acquired, the conversion times shall be observed and the requirements met. The proceeding shall be described accordingly. If new animals are bought, the conversion period shall be deemed to be observed

also if the previous owner fed the animals in compliance with the “GMO-free” Standard. Proof for such feeding can for example be a confirmation of the previous owner or a reliable excerpt of the cattle catalogue of an auction.

1.1.4.2 Feed Rations

For all animal species 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 must 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 “canola extract pellets” instead of simply “canola”. The declarations, in particular for composed components, shall be filed together with the records on feed rations.

1.1.4.3 Feed Lists

The agricultural facility shall keep a feed list. The feed list gives an overview of all feedstuffs that are currently used in the facility, of their origin as well as their purpose (i. e. for which species). Based on this list, necessary further considerations concerning the safeguarding of “GMO-free” feeding are possible:

- The compilation 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 framework of a first compilation. After that it shall be kept up to date by adding new feedstuffs and new suppliers, and by deleting those that no longer exist. However, the latter shall only occur when 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 is a feed list realised by a chronologically filed compilation of invoices and delivery bills.

1.1.4.4 External Service Providers

External service providers such as movable grinding and mixing facilities can cause cross-contaminations of GMOs, e.g., if GMO-containing feed and “GMO-free” feed are mixed in succession. Haulage contractors 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 cross-contamination 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, e. g., the agreements concerning the cleaning and the use of GMO-free oils are observed.

1.1.5 Training of Personnel

All personnel involved in the operating procedure of the “GMO-free” sector, including vehicle operators, shall be trained concerning the “GMO-free” requirements and the operating procedures laid down therein. Training shall take place before they take up their activity as well as on a continuous basis at least once a year.

Moreover, it must be ensured that all persons working in the facility have comprehensive knowledge of all measures necessary for ensuring “GMO-free” feeding.

These instruction courses shall be documented with regard to their content, their participants, as well as the course date, the location and the instructors.

Small businesses must make sure that all persons involved in operating procedures that are relevant for “GMO-free” production have comprehensive knowledge of the measures that are necessary to ensure “GMO-free” feeding. In case no separate course takes place there shall be an explanation included in the facility description.

1.1.6 Documentation and Retention Times

All delivery bills, invoices of equipment (e. g., for seed), shipping documents for feed, documentations, purchase orders, declarations etc. shall be retained by the operator for a minimum period of three years or until the next external audit, respectively, unless legal requirements stipulate longer retention times.

For safeguarding purposes the following procedure shall be followed regarding feed acquisitions:

Purchase order:

Individual purchase orders with the requirement “Feed suitable for production of „GMO-free” labelled food” or “feed not subject to declaration according to Regulations (EC) No. 1829/2003 or No. 1830/2003” or Regulation (EU) No 619/2011 (Low Level Presence) or, alternatively, contractual regulations with the supplier covering all supplies.

Accompanying documents:

The feed supplier shall be urged to add the following entry on the delivery bill / accompanying document: “Feed not subject to declaration according to Regulations (EC) No. 1829/2003 or No. 1830/2003” or Regulation (EU) No 619/2011 (Low Level Presence) or “Feed suitable for production of „GMO-free” labelled food”.

1.1.7 Traceability and Segregation of Commodity Flows

1.1.7.1 Traceability System

A traceability system shall be installed permitting at any time and instantly to identify all products on the facility that are connected to the “GMO-free” labelling process. In addition, it must be possible to trace back feed and products that have left the facility within a short period of time (e.g. one working day) and to compile quantitative statements and evaluations, which permit conclusions on flows of goods and their plausibility. The following data shall be acquired for this purpose:

- Information on origin;
- Formation of lots, if applicable;
- Information on delivery date and supplied market participants.

1.1.7.2 Incoming Goods Monitoring

At the incoming goods department it must be ensured that all critical raw materials and feedstuffs that are used for the “GMO-free” sector meet the requirements. For this purpose, suitable proof must be provided (e.g. the absence of labelling according to Regulations (EC) No. 1829/2003 and No. 1830/2003 or Regulation (EU) No 619/2011 (Low Level Presence) on the accompanying documents of the feed).

Critical raw materials are:

- Imported products approved as GMO varieties in feed (e. g., soy, canola and maize products);
- Products approved for GMO cultivation in one of the Danube-Soya member states (e. g. maize products);
- Products neither approved for GMO import nor cultivation in one of the Danube-Soya member states carrying a plausible contamination risk with imported goods, (domestic soy, canola and maize products).
- Products subject to Regulation (EU) No 619/2011

Noncritical raw materials are:

- Products that cannot be genetically modified (e. g., minerals);
- Products without a GMO approval in one of the Danube-Soya member states for cultivation that are not imported (e. g., grass products);
- Products from Danube-Soya member states that are also globally not, or hardly, cultivated as genetically modified varieties (e. g., wheat, barley, oat, triticale, rye).

For feed additives and auxiliary substances an additional specification must be presented, clearly indicating that the product is not subject to compulsory GMO labelling.

It must be ensured comprehensibly that at no time feedstuffs that are not suitable for “GMO-free” food production can find their way into the flow of raw materials and feed intended for the production of “GMO-free” food. For this purpose the flow of goods must be safeguarded physically as well as temporally, or by unmistakable and complete labelling of all products.

In order to guarantee traceability in the agricultural sector all delivery bills of additionally acquired feed must be examined for the completeness of the information provided and are to be filed chronologically. If any mobile mixing or grinding facilities are used, a confirmation is needed stating that they meet the requirements and any record of system purges must be documented, if applicable.

For additionally acquired animals the conversion times shall be monitored and documented.

1.1.7.3 Segregation of Commodity Streams / Exclusion of Cross-Contamination

Storage / transport of feed not subject to compulsory labelling shall be segregated from feed that is subject to such labelling. The segregation can be realised in a physical or a temporal manner. Simultaneous storage is only possible in case of physical segregation

In the case of temporal segregation appropriate procedures must ensure that any carryover of genetically modified material is reduced to a minimum. The individual risk-assessed procedural steps (e. g. transport and mixing processes) must be documented with separate proof of adequate physical, temporal or logistical measures. In addition, in the case of temporal segregation the efficiency of the measures must be documented with representative research results

1.1.8 Treatment of Flawed Products

In the event of positive analytical results or other findings regarding the non-secured compliance with the “GMO-free” requirements, a system of error handling and of labelling / banning of non-compliant products by appropriate measures must be installed before the goods are shipped.

In the case of positive analyses of feed that is not labelled, but is clearly subject to labelling, feed must be exchanged.

1.1.9 Protection of the Self-Monitoring System

Once a year an internal process review must be carried out with an examination of the facility description and amendments in case of changes.

1.1.10 Corrective Measures

The procedure for non-compliances, including the responsibilities, shall be described and adequate measures shall be taken in the case of complaints concerning “GMO-free” production (e. g., customer complaints or positive analytical results). The effective corrective measures shall be recorded and implemented. This also applies to the corrective measures of the last audit.

Process descriptions may be provided within the framework of the facility description or in some other form.

1.1.11 Crisis Management

A crisis management system is only necessary for farmers who are not included in a “GMO-free” system/project.

A crisis management system shall be in place and potential dangers shall be analysed. Within the framework of this crisis management system a procedure shall be in place that describes the course of action in the case of a crisis. Emergency phone numbers and contact details of the suppliers and clients must be at hand.

The procedure for banning rejected products is defined.

The agricultural facility informs its clients as soon as possible about any problem concerning product specifications, in particular concerning non-compliance(s) with “GMO-free” criteria with a defined possible influence on the security and / or legality of the products concerned in the past, present or future. This shall be effected according, but not limited, to the precautionary principle.

1.2 Requirements regarding Processing (Feed)

Feed distributors who do not move the goods physically (so-called non-store dealers) do not have to be audited. However, product traceability must be guaranteed.

1.2.1 Plant Description

A plant description shall be available containing the following information:

- All raw materials and feedstuffs that are produced, stored, transported and traded by the plant;
- Specification of all feedstuffs as suitable for the production of „GMO-free” food;
- List of suppliers;
- List of production lines;
- Overview of the subcontractors / contract processors who are involved in the “GMO-free” process. They must be integrated into the process by a contract;
- Compilation of “GMO-free” formulations. (Formulations / modifications of formulations must be approved by a person responsible in the plant);
- Overview of all sites, production facilities and production lines, including any outsourced production processes, if applicable.

1.2.2 Provision of Responsibilities / Organisational Chart

The plant structure and an organisational chart must be available in the business in written form and must contain the distribution of responsibilities and the deputy plan to cover for absence.

An overview of all persons working in the plant shall be set up. Temporary personnel, apprentices, trainees etc. must be included as well.

With the help of this list it can be determined who is responsible for the processes of the “GMO-free” production and which other personnel are involved and must thus be trained. This overview must be updated each time personnel join or leave the business.

1.2.3 Self-Monitoring Concept / Risk Assessment

The self-monitoring concept of the feed business must take into consideration the required segregated handling of GMO-containing and GMO-free products as well as any possibilities of introduction and contamination. It must be adequate for the respective production situation of the facility. Analogously to the HACCP, a risk assessment must be carried out, which includes the cleansing. In addition, preventative, monitoring and controlling measures shall be introduced concerning the correctness of the absence of a label according to Regulations (EC) Nos. 1829/2003 and 1830/2003 or regarding the use of a claim that indicates the suitability of the feedstuff for the production of “GMO-free” food.

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

- Registration of all raw materials and feedstuffs for the “GMO-free” sector, irrespective of whether they are subject to labelling obligations or not;
- Segregated handling of raw materials and feed that are subject to labelling and that are not subject to labelling, on all levels of storage, processing and transport;
- Identification and exclusion of any possibilities of introduction or contamination;
- Risk assessment taking into consideration possible risks by certain feedstuffs, countries of origin and production processes as well as facility parameters;
- Specifications for all finished products for “GMO-free” labelling must be in place and shall be laid down in writing with the contract partners if required;
- Logs describing the mixing must be in place;
- The objective must be to avoid any presence of GMO components so that the criteria for labelling according to EU guidelines can be reliably met.

Records must be well readable and authentic. They shall be maintained in such a way that a subsequent manipulation can be ruled out. Product records shall be kept according to the legal requirements. Unless any other archiving periods are stipulated, records shall be retained for at least 6 months after delivery in order to permit verification.

A testing plan shall be in place based on a risk assessment. It shall include the description of the sampling procedure. The focus of consideration shall be: type of samples, sampling locations, sampling of finished product, formation of collective samples, naming the sampler, formation of retained samples, size of

the samples. The sampling plan shall describe the frequency of the sampling as well as the method of testing.

The laboratory shall be named and the accreditation certificate including the appendices shall be at hand.

Moreover, a procedure shall be determined as to how to deal with positive test results. Analytical results from lots delivered by the suppliers may be considered in the testing plan but they cannot replace the final sampling and testing of the finished product.

A system for handling retained samples shall be set up. The feed mill may resort to these retained samples when necessary in order to have a duplicate sample or cross-check available.

1.2.4 Personnel Training

All personnel involved in the operating procedure, including drivers of transport vehicles, shall be trained concerning the „GMO-free” requirements and the operating procedures laid down for this purpose. Training shall take place before they begin with their activity, as well as at least once a year.

The intensity of training varies depending on the personnel and shall be oriented towards the responsibility of the personnel for the proper flow of the „GMO-free” production.

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

1.2.5 Documentation and Retention Times

All documents in connection with the production process and the labelling “Suitable for the production of food labelled „GMO-free”, e. g., delivery bills, certificate of non-objection, records of production and of product flow, training documents, etc. shall be retained for at least three years from the time of delivery, unless legal requirements stipulate a longer retention time.

1.2.6 Traceability and Segregation of Commodity Flows

1.2.6.1 Traceability System

A traceability system shall be installed permitting at any time to identify instantly all products in the plant that are connected to „GMO-free” labelling. In addition, it must be possible within a short period of time (e.g. one day) to trace back products that have left the business and to compile quantitative statements and evaluations that permit conclusions on product flows and their plausibility. The following data shall be collected for this purpose:

- Information on origin (country, supplier);
- Creation of lots, if applicable;
- Documentation of production / manufacture;
- Information on delivery date and market participants catered for;
- Volume.

1.2.6.2 Incoming Goods Monitoring

At the incoming goods department it must be ensured that all critical raw materials and feedstuffs used for the „GMO-free” sector meet the requirements described below.

Critical raw materials are:

- Imported products approved as GMO varieties in feed (e. g., soy, canola and maize products);
- Products approved for GMO cultivation in one of the Danube-Soya member states (e. g. maize products);
- Products neither approved for GMO import nor cultivation in one of the Danube-Soya member states carrying a plausible contamination risk with imported goods, (domestic soy, canola and maize products).

Noncritical raw materials are:

- Products that cannot be genetically modified (e. g., minerals);
- Products without a GMO approval in one of the Danube-Soya member states for cultivation that are not imported (e. g., grass products);
- Products from Danube-Soya member states that are also globally not, or hardly, cultivated as genetically modified varieties (e. g., wheat, barley, oat, triticale, rye).

In order to ensure this, a confirmation for critical raw materials must be obtained from the previous supplier. This can particularly be achieved by:

- A separate declaration about the GMO-free status of the currently delivered lot;
- A current and convincing „GMO-free” certificate by the certification body;
- A test result proving the GMO-free status of the lot being delivered lot;
- An additional indicator on the delivery bill declaring the products to be “GMO-free” ;
- A clear contractual clause regarding the delivery of GMO-free products.

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

It must be ensured that at no time raw materials or feed not suitable for producing „GMO-free” food can find their way into the flow of raw materials and feed intended for the production of „GMO-free” foodstuffs. For this purpose, the flow of goods must be safeguarded physically as well as chronologically, or by clear and complete labelling of all products.

1.2.6.3 Segregation of Commodity Flows / Exclusion of Technically Avoidable Commingling

Production of feed that is not subject to labelling obligations shall be segregated from feed that is subject to labelling obligations. The segregation may be in terms of time or space. Simultaneous production is only possible in case of physical segregation (e. g. through segregated production lines).

In the case of temporal segregation it must be ensured by suitable steps of procedure that any crossover contamination of genetically modified material is reduced to a technically unavoidable minimum. The individual risk-assessed procedural steps (e. g. transport and mixing processes) must be documented with a separate proof of adequate physical, temporal or logistical measures. In addition, the efficiency of the measures must be documented by representative PCR analyses.

1.2.6.4 Handling of Non-Compliant Products

In case of positive analytical results or other findings regarding the non-secured compliance with the "GMO-free" requirements, a system of error handling and labelling / blocking of non-compliant products with appropriate measures must be installed before the goods are shipped. In case of a contamination in critical magnitudes, appropriate corrective measures must be initiated

1.2.6.5 Corrective Measures / Continuous Improvement Process

The plant is urged to keep reducing the occurrence of adventitious contamination with GMO material through regular verification of the implemented system. For this purpose, the business shall take measures, so-called corrective measures, 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 subject to evaluation after an adequate period of time. In particular, the handling of non-compliant test results shall be taken into consideration.

1.2.6.6 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 measures, including the determination of responsibilities, must have been initiated.

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

1.2.7 Safeguarding the Self-Monitoring System

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

1.2.8 Crisis Management

A crisis management system shall be in place and potential dangers shall be analysed. In this context, a procedure shall be in place that describes the

process in case of a crisis. Emergency numbers and contact details of the suppliers and customers must be readily available.

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

The business informs its customers as soon as possible about any problem concerning product specifications, in particular concerning non-compliance(s) with “GMO-free” criteria, which have, had, or could have had a defined influence on the process reliability and / or the legality of the products concerned. This shall be effected according to the precautionary principle but shall not be limited thereto.

1.2.9 Declaration in the Delivery Bill

On delivery bills for products that are not subject to mandatory labelling it is recommended to use the statement “feed suitable for production of food labelled „GMO-free””.

1.2.10 Commissioning of carriers

The feed producer may only commission those carriers for the transport of feedstuffs suitable for the production of „GMO-free” labelled food that are regularly monitored by a reknown quality assurance system. The quality assurance system must define appropriate measures for cleaning vehicles in order to prevent carryover of genetically modified material. Proof is to be provided on request.

1.3 Requirements for the Processing Stage (Food)

1.3.1 Facility Description

A facility description shall be compiled containing the following information:

- Overview of all locations, production sites, and production lines including outsourced production processes, if applicable;
- Specifications of all “GMO-free” products that are produced in the facility;
- List of suppliers;
- Organisational chart which names the responsibilities;
- Overview of the subcontractors / contract processors involved in the “GMO-free” process. They must be involved in the process on the basis of a contract;
- Compilation of “GMO-free” formulations. (Formulations / formulation changes must be approved by a manager in the facility).

1.3.2 Distribution of Responsibilities / Organisational Chart

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

With the aid of this list it can be determined who is responsible for the processes of “GMO-free” production and which other personnel are involved and must thus be trained. This overview shall be updated when personnel joins or leaves the business.

1.3.3 Self-Monitoring Concept / Risk Assessment

The self-monitoring concept of the food processing business must take into consideration the required segregated handling of GMO-containing and GMO-free products as well as any possibilities of introduction and cross-contamination with GMOs. Analogous to the HACCP a risk assessment must be carried out; in addition to that, preventative, monitoring and controlling measures must be implemented concerning the correctness of the “GMO-free” claim.

In addition, the risk assessment shall include the possibility to evaluate the use of aromas, enzymes, cultures of microorganisms, additives, auxiliary substances and other feed ingredients on the basis of certificates presented by the suppliers.

For security reasons risk-assessed sampling regimes shall be drawn up for as far as GMOs are detectable in the product. The analyses shall be carried out in laboratories accredited according to ISO 17025. This applies primarily to raw materials of plant origin.

Since it is generally not possible to detect the use of genetically modified feed in animal products such as milk, meat and eggs, these analyses are principally regulated in the animal husbandry. For this reason, food producers processing raw materials from animal origin shall put primary emphasis on documented and reliable segregation of animal products from GMO and GMO-free origin, on ensuring the use of GMO-free products as well as on appropriate supplier declarations for food ingredients.

1.3.4 Training of Personnel

All personnel involved in operating procedures, including vehicle operators, shall be trained concerning the “GMO-free” 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.

The intensity of training courses varies depending on the personnel and shall be oriented towards the responsibility of the personnel for the proper flow of the “GMO-free” production.

These courses shall be documented with reference to their content, their participants, as well as the training date, the course location, and the instructors.

1.3.5 Documentation and Retention Times

All documents connected with “GMO-free” labelling, e. g. delivery bills, certificates of non-objection, documentation regarding the production and the flow of goods, training documents, etc., shall be retained for at least three years unless legal requirements stipulate a longer retention time.

1.3.6 Traceability and Segregation of Commodity Flows

1.3.6.1 Traceability System

A traceability system shall be installed permitting at any time and instantly to identify all products on the facility that are connected to the “GMO-free” labelling process.

In addition, it must be possible to trace back feed and products that have left the facility within one working day and to compile quantitative statements and evaluations, which permit conclusions on flows of goods and their plausibility.

The following data shall be acquired for this purpose:

- Information on the origin, including certificates for “GMO-free” labelling;
- Creation of lots, if applicable;
- Information on used raw materials, additives and auxiliary substances as well as their origin;
- Information on delivery date and supplied market participants;
- Communication data regarding the previous and subsequent stages.

It must be ensured comprehensibly that at no time products not compliant with the “GMO-free” requirements find their way into the flow of “GMO-free” products. For this purpose the flow of goods must be safeguarded physically as well as temporally, or by unmistakable and complete labelling of all products. Where required intermediate purging shall be undertaken.

Personnel on all levels, from the incoming goods department to production and dispatch / shipment, must be aware of the GMO-status of the individual products and lots.

It must be ensured that only products fully meeting the legal requirements for “GMO-free” labelling leave the business as such.

1.3.7 Incoming Goods Control

At the incoming goods department it must be ensured that all raw materials, food, additives and auxiliary substances that are used for the production / processing / trading of products with “GMO-free” labelling meet the requirements.

Critical raw materials are:

- Imported products approved as GMO varieties in feed (e. g., soy, canola and maize products);
- Products approved for GMO cultivation in one of the Danube-Soya member states (e. g. maize products);
- Products neither approved for GMO import nor cultivation in one of the Danube-Soya member states carrying a plausible contamination risk with imported goods, (domestic soy, canola and maize products).
- All raw material of animal origin;

- All products produced by micro-organisms.

1.3.7.1 Producer and Supplier Confirmations

For every delivery a confirmation must be obtained from the previous supplier attesting that the currently delivered products meet the “GMO-free” requirements.

This can be achieved by:

- A meaningful general confirmation concerning delivered goods issued by the supplier once a year;
- An endorsement on the delivery bill;
- A distinct contractual stipulation
- If appropriate results from analytical testing

Such documents must confirm that the used ingredients, additives and auxiliary substances 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 usually be tolerated up to a threshold of at most 0.1 % per ingredient.

If, in the case of aromas, enzymes, cultures of micro-organisms, additives or auxiliary substances, there are any long-term supplier confirmations the business shall verify once a year in an adequate manner whether these confirmations are still valid in the issued form and whether the specifications are unmodified for the item in question.

1.3.7.2 Outgoing Goods Inspection / Handling of Flawed Products

In case of positive analytical results or other findings regarding the non-secured compliance with the “GMO-free” requirements, a system of error handling and labelling / banning of non-compliant products with appropriate measures must be in place before the outgoing goods department.

1.3.7.3 Segregation of Commodity Flows / Exclusion of Commingling

Storage / transport of GMO-free and GMO-containing products shall be segregated. The segregation may be achieved either temporally or physically. Simultaneous storage is only possible in case of physical segregation.

In the case of temporal segregation suitable procedural steps must ensure that any carryover of material that is unsuitable for “GMO-free” labelling is avoided.

The individual and risk-assessed procedural steps must be documented with a separate proof of adequate physical, temporal or logistical measures. In addition, the efficiency of the measures must be documented with representative research results.

1.3.8 Corrective Measures / Continuous Improvement Process

In case of complaints the business shall take so-called corrective measures to permanently eliminate the sources of cross-contaminations with GMO material. The measures taken shall be monitored and will be subjected to evaluation after an adequate period of time.

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

1.3.9 Complaint and Recall Management

Complaints concerning GMOs by clients and other entities (e. g., local authorities) shall be documented and evaluated in a suitable manner. For this purpose appropriate corrective measures must be taken, including the determination of responsibilities.

In the case of non-compliances in products that are still on the market, a recall system must be in place, which shall include a written notice to the clients.

1.3.10 Safeguarding the Self-Monitoring System

Internal audits shall be carried out in the business annually.

1.3.11 Crisis Management

A crisis management system shall be in place and potential dangers shall be analysed. Within the framework of this crisis management system a procedure shall be in place that describes the course of action in the case of a crisis. Emergency numbers and contact details of the suppliers and clients must be at hand.

An internal system for banning rejected products must be in place.

The business informs its clients as soon as possible about any problem concerning product specifications, in particular concerning non-compliance(s) with "GMO-free" criteria, which have, had, or could have a defined influence on the security and / or legality of the products concerned. This shall be effected according to the precautionary principle but shall not be limited thereto.

1.4 Requirements for the Level of Logistics (Trade, Storage and Transport)

A separate inspection of the logistics sector 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 self-collectors. They will be monitored on the level Agriculture.

1.4.1 Plant Description

A plant description shall be set up containing the following information:

- All raw materials and feed that are stored, transported or traded in and by the business;
- Specification of all feed that is suitable for the production of “GMO-free” food;
- List of suppliers;
- Overview of the sub-contractors / contract processors who are involved in the “GMO-free” process. They must be integrated into the process contractually.
- Overview of all sites and transport units.

1.4.2 Distribution of Responsibilities / Organisational Chart

The plant structure and an organisational chart must be available in the business in written form showing the distribution of responsibilities and a deputy plan to cover (for) absence.

An overview of all persons working in the plant, including temporary staff, apprentices, trainees, etc. shall be compiled.

1.4.3 Self-Monitoring Concept / Risk Assessment

The self-monitoring concept must take into consideration the required segregated handling of products containing GMOs and GMO-free as well as potential sources of introduction and cross-contamination.

Analogous to the HACCP a risk assessment 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 for the production of “GMO-free” food.

The self-monitoring concepts must take into consideration the following criteria:

- Registration of all raw materials and feedstuffs that are not subject to labelling obligations for the “GMO-free” section;
- Segregated handling of raw materials and feed that are subject to labelling obligations and that are not subject to labelling obligations on all levels of storage and transport;
- Identification and exclusion of sources of introduction and contamination;
- Risk assessment taking into consideration potential risks by certain feedstuffs, countries of origin and production processes as well as facility parameters;
- The fixed objective must be to avoid the presence of any GMO components;
- Procedures for cleaning, inspection of the loading process, previous freight in the case of vehicles.

An analysis plan shall be available based on risk assessment. This plan shall include the description of the sampling procedure. The following items shall be taken into consideration: type of samples, sampling locations, sampling of end product, formation of collective samples, nomination of the sampler, creation of retained samples, size of the samples. The sampling plan shall describe the frequency of sampling as well as the method of analysis.

The laboratory shall be designated and the accreditation certificate shall be available including the appendix.

Moreover, a procedure shall be determined as to how positive analyses results are handled. Existing analyses of the delivered lots that are presented by the supplier may be taken into consideration for the analysis plan but cannot replace the control of the end product.

A system for handling retained samples shall be determined. The business may resort to these retained samples when needed in order to have a duplicate or counter sample at hand.

1.4.4 Training of Staff

All personnel involved in the operating procedure, including drivers of transport vehicles, shall be trained concerning the “GMO-free” requirements and the respective operating procedures laid down. Training shall take place before they take up their activity, and as well as on a continuous basis at least once a year.

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

1.4.5 Documentation and Retention Times

All documents in the context of the production process for the labelling “Suitable for production of food labelled „GMO-free” ” or “GMO-free”, e. g., delivery bills / records, certificates of non-objection, training documents, etc. shall be retained for at least three years from the time of delivery unless legal requirements stipulate a longer retention period.

1.4.6 Traceability and Segregation of Commodity Flows

1.4.6.1 Traceability System

A traceability system shall be installed permitting instantly at any time to identify all products in the business that are connected to “GMO-free” labelling. In addition, it must be possible to trace back products that have left the plant within one working day and to compile quantitative statements and evaluations permitting conclusions on flows of goods and their plausibility. According to Regulation (EC) No. 178/2002 the following data shall be acquired for this purpose:

- Information on origin;
- Creation of lots, if applicable;

Information on delivery date and market participants served.

1.4.6.2 Incoming Goods Control

At the incoming goods department it must be ensured that all critical raw materials and feedstuffs used for the “GMO-free” sector meet the requirements.

For this purpose a confirmation must be obtained for every delivery from the previous supplier. This may be achieved in particular by:

- A separate declaration regarding the GMO-free status of the currently delivered lot;
- A current and convincing “GMO-free” certificate of the certification body;
- An additional entry on the delivery bill declaring the products to be “GMO-free”.

For additives and auxiliary substances additional specifications must be presented clearly indicating that the product is not subject to compulsory GMO labelling.

It must be comprehensibly ensured that at no time raw materials or feed not suitable for producing “GMO-free” foodstuffs can find their way into the flow of raw materials and feed earmarked for the production of “GMO-free” food. For this purpose the flow of goods must be physically and temporally ensured.

1.4.6.3 Segregation of Commodity Flows / Exclusion of Commingling

Storage / transport of feed not subject to compulsory labelling shall be segregated from feed that is subject to compulsory labelling. The segregation may be implemented either in a spatial or in a temporal manner. Simultaneous production is only possible in case of physical segregation. In the case of temporal segregation it must be ensured by suitable procedures that any cross-over contamination of genetically modified material is reduced to a minimum. The individual and risk-assessed procedural steps (e. g. transport and mixing processes) must be documented with a separate proof of adequate physical, temporal or logistical measures. In addition, the efficiency of the measures must be proven with representative research results.

1.4.6.4 Treatment of Non-Compliant Products

For the event of positive analyses results or other findings concerning the non-secured compliance with the “GMO-free” requirements a system of error treatment and labelling / blocking of non-compliant products by appropriate measures must be installed before the goods are dispatched

1.4.6.5 Corrective Measures / Continuous Improvement Process

The business shall be admonished to continuously reduce the content of adventitious cross-contamination with GMO material by means of regular verification of the implemented system. For this purpose the business shall take measures, so-called corrective measures, to eliminate the sources of adventitious or technically unavoidable contaminations with GMO material or to reduce their introduction to a minimum, respectively. The measures taken shall be monitored and subject to an evaluation after an adequate time period. In particular, the treatment of positive analytical results shall be taken into consideration.

1.4.6.6 Complaint Management

Complaints concerning GMOs by clients and other entities (e. g. authorities) shall be documented and evaluated in a suitable manner. For this purpose

appropriate corrective measures must be taken, including the determination of responsibilities.

1.4.7 Safeguarding the Self-Monitoring System

Internal audits shall be carried out in the business annually.

1.4.8 Crisis Management

A crisis management system shall be in place and potential dangers shall be analysed. Within the framework of this crisis management system a procedure shall be in place that describes the course of action in the case of a crisis.

Emergency phone numbers and contact details of the suppliers and clients must be at hand.

An internal system for banning rejected products must be in place.

The business informs its clients as soon as possible about any problem concerning product specifications, in particular concerning non-compliance(s) with “GMO-free” criteria, which have, had, or could have a defined influence on the security and / or legality of the products concerned. This shall be effected according but not limited to the principle of precaution.

1.4.9 Declaration on Delivery Bill

On delivery bills for products that are suitable for production of food labelled “GMO-free”, it is recommended to use the statement “feed suitable for production of food labelled “GMO-free”. If the delivery bill does not make any specifications with regard to the logistics provider, further documents shall be available that safeguard the process.

ANNEX 2: CRITICAL 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.

Information on these crops can be found at

<http://www.isaaa.org/>

Crops that do not have a marketing authorization, but e.g. show up in the rapid alert system for food and feed (RASFF) of the EU regularly (such as rice, papaya) may be regarded as critical components as well

The RASFF can be accessed at:

http://ec.europa.eu/food/safety/rasff/portal/index_en.htm

Additional information on the status of GMO-authorisation is available for the European Union at:

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

on an international level (Cartagena Protocol on Biosafety) at:

<http://bch.cbd.int/>