



GMP+ Feed Safety Assurance scheme

Quality Control of Feed Material

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GMP+ B2

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History of the document

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0.0 / 09-2010	Transfer of the document from PDV to GMP+ International	Entire document	01-01-2011
0.1 / 09-2011	Introduction has been updated.	1.1;1.2	01-01-2012
	A reference is made in this document to the additional labeling requirements in GMP+ BA6	Section 4.1.6.3	01-01-2012
	Requirements for transport of packed feeds are completed.	Section 4.4	01-01-2012
	Requirements for entry checks of LCI reports are better described.	Section 4.4	01-01-2012
	Responsibility of the participant to provide the carrier with sufficient product information.	Section 4.4	01-01-2012
	Requirements for use of non-certified carriers are removed from this document and placed in GMP+ BA10.	Section 4.4	01-01-2013
	Amendment of the internal traceability-requirements.	Section 5.6	01-01-2012
	Requirements regarding EWS added	Section 5.8	01-01-2012
<p>This standard has been withdrawn on 31-12-2010. From 01-01-2011 onwards new certification and recertification is no longer possible. Existing certification contracts can continue until their end. See for more info the newsletter dated 19-11-2009.</p>			

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1 Introduction

1.1 General

The GMP+ Feed Safety Assurance Scheme (GMP+ FSA scheme) was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

The GMP+ FSA scheme is a complete scheme for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA scheme can facilitate this excellently.

The basic principle of the GMP+ FSA scheme is that the feed chain is part of the food production chain. Proper quality assurance of feed safety throughout the feed chain has a high priority. It is important that companies take their responsibilities in this respect by responding in a proper and convincing way to the need for safe feed materials in the food production chain.

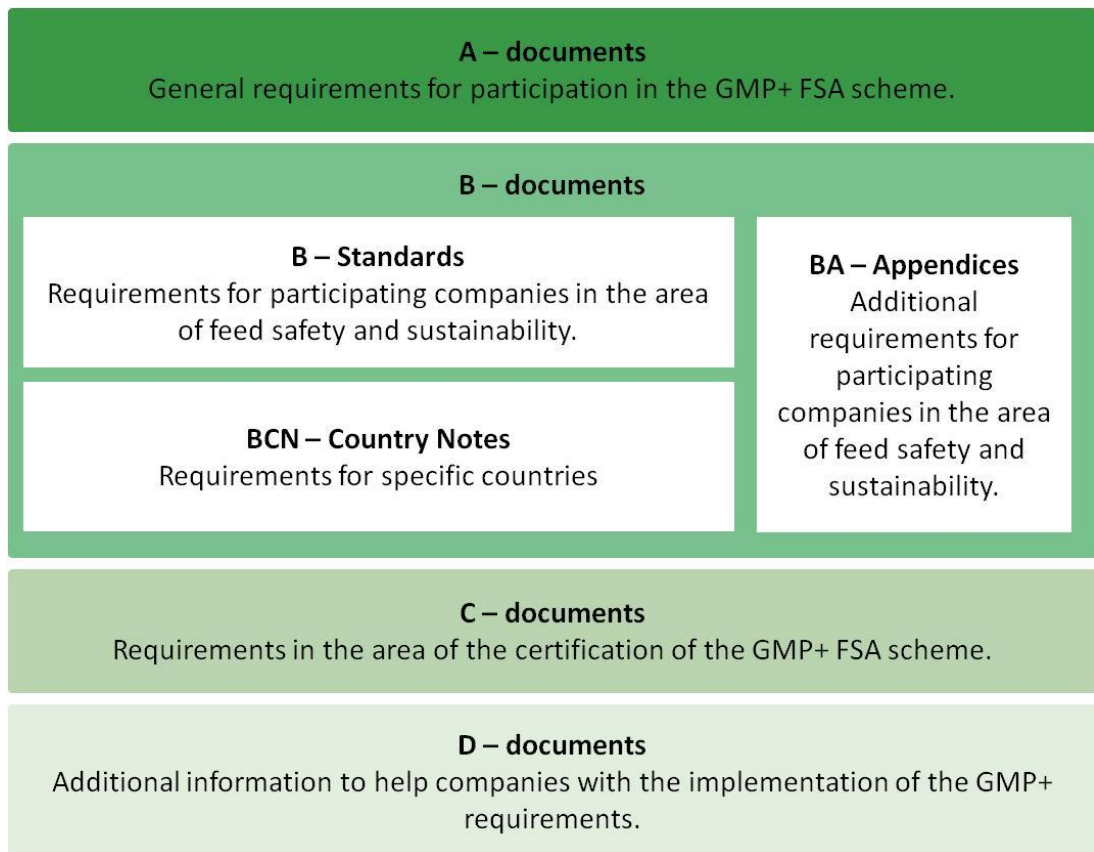
Based on needs in practice, multiple components have been integrated into the GMP+ FSA scheme, such as requirements for the quality management system (ISO 9001), HACCP, product standards, traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

Together with the GMP+ partners, GMP+ International transparently sets clear requirements so that feed safety is guaranteed and certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of its various databases, newsletters, Q&A lists and seminars.

1.2 Structure of the GMP+ Feed Safety Assurance scheme

The documents within the GMP+ FSA scheme are subdivided into a number of series. The next page shows a schematic representation of the contents of the GMP+ FSA scheme:



All these documents are available via the website of GMP+ International (www.gmpplus.org) .

This document is referred to as GMP+ B2 *Quality Control of Feed Material* and is part of the GMP+ FSA scheme.

1.3 Scope and application of this standard

This standard contains the conditions and requirements for the feed safety assurance of

- a. production/processing of feed materials;
- b. trade in feed;
- c. storage and/or transhipment of feed.

The standard is not intended for production of feed additives.

The requirements of this standard apply to organisations, irrespective of their type or size, which carry out activities which are covered within the scope of this standard. It is not important whether a company carries out these activities on its own account or as a (sub)contractor ('service provider').

Each participant must establish the company-specific hazards relating to the safety of feeds and analyse and control them by applying HACCP principles. This standard describes as accurately as possible for activities or feed/feed materials which are covered within the scope of this standard what the requirements are with respect to the various risks and what the associated control measures are. A participant may make these control measures part of a prerequisites programme or

may implement them as specific measures for controlling a particular critical control point. This standard also provides requirements for inspections and audits.

If a participant carries out activities with feeds which are outside the scope of this standard then it may be necessary to apply another GMP+ standard instead of, or in addition to, this standard.

For exact details is referred to GMP+ C1 *Approval Requirements and Procedure for Certification Bodies*, Appendix 1

The participant remains responsible at all times for the safety of the feed/feed materials and activities associated with them, as well as for checking on compliance with the requirements. This must be done by the participant himself. By complying with the requirements of this standard and by being certified accordingly, the participant can demonstrate the safety and quality of his services or feed/feed materials to third parties.

Irrespective of the obligations arising from this standard, the participant will only place on the market or offer services regarding feeds which are safe for animals and (indirectly) safe for the consumers of the animal products..

The participant may not introduce any feeds to the market which represent a danger to the health of consumers of animal products or animals or to the environment.

1.4 The structure of this standard

The structure of this standard differs from a number of other GMP+ standards. In chapter 4 basic requirements for a quality control system are laid down. Also the basic requirements for traders and related to some other items. In chapter 5 the requirements for applying the HACCP-principles are laid down.

GMP+ Appendices (GMP+ BAxx), to which there are also references, are separate GMP+ documents within the B segment. If there is a reference in this standard then it applies within the framework of this standard. See also Chapter 2.

1.5 Exclusion of requirements

It is possible that certain requirements do not apply to a participant. A participant may exclude these requirements. Exclusions must, however, be justified and recorded. The exclusions may in any event not lead to the participant supplying feeds or offering services which do not comply with feed safety as defined in the GMP+ FSA scheme.

No requirements may be excluded because the participant finds them to be not relevant such as because customers do not ask for them or because compliance with these requirements is not a legal obligation or because the company is small.

2 Normative references

2.1 GMP+ documents

In addition to the requirements listed in this GMP+ standard, the participant must also comply with the requirements included in the GMP+ Appendices (GMP+ BAxx) to which reference is made in this standard.

The participant must also comply with the relevant requirements as recorded in the GMP+ A-documents.

These documents can be found on GMP+ International's website (www.gmpplus.org)

2.2 Legal compliance

Special attention was paid when drawing up this standard to the inclusion of the relevant requirements in the applicable feed legislation. Compliance with this standard does not however guarantee that there is compliance with all the legal requirements or mean that feed legislation can then be ignored. It is the participant's own responsibility to comply with the relevant feed legislation.

In addition to the requirements of this standard the participant must also verify and ensure that his product activities and all the feed/feed materials that he produces and supplies are in accordance with the applicable legal.

Guidance

The relevant requirements from the feed legislation means all those requirements which relate to the production or trade of safe feed/feed materials.

A producer should comply with the requirements (production, product standards, etc.) in this standard. Next to this, a producer should make sure that his production method and the produced feed materials also comply with legal requirements from his country. These legal requirements are, of course, not incorporated in this standard.

If a producer also exports to another country, it is important to make sure that his feed materials complies with the legal requirements of that country.

3 Definitions

A part of the management system focussed on specific process steps for fulfilling the quality and safety requirements of the feed material.

GMP+ certified purchaser

The entrepreneur who buys the feed material from a foreign supplier, and is certified according to the GMP+ Feed Safety Assurance schema of GMP+ International. This entrepreneur can be a trader, or a producer/supplier of compound feed or feed materials.

Supplier

The organisation or a person abroad which provides the feed material to a GMP+ certified purchaser

Foreign (or abroad)

All countries except The Netherlands

4 Basic requirements

4.1 Basic requirements for producers

4.1.1 Awareness

The supplier of feed materials for animal feed must always be aware of his responsibility for the feed and food safety of their feed materials (safety for the human and animal consumer). He is a part of the chain of food production: Feed for Food.

4.1.2 Quality Control System

The supplier of feed materials for animal feed must implement a quality control system, which is based on HACCP-principles. The minimum requirements for this quality control system are laid down in this standard. This quality control system must be documented.

4.1.3 Quality Control Documentation

The supplier compiles and maintains a manual which contains or refers to all the required documents (operating procedures, instructions, forms, and other documentation) necessary for operating the Quality Control System, described in this standard.

Also, in this manual at least the following documentation (derived from the HACCP principles) is included:

- a. Product specification: The end product specification of the feed materials: see section 5.2.
- b. Process specification: *The process steps and the process conditions* of the entire production process (cultivation, storage, transfer, treatment, processing, transport, etc.): see section 5.3.
- c. Hazard identification: The identification of the hazards that may cause a contamination of the feed materials with microbiological, chemical or physical contaminants from the environment or the process: see section 5.4.
- d. Risk evaluation and determination of critical control point: see section 5.5.
- e. The control measures taken by the supplier to prevent any possible product contamination, the critical points being controlled at least: see section 5.6.
- f. The measurement points and checks (monitoring and verification) that are performed to determine that the control measures are being realised: see section 5.7.
- g. Evaluation and communication: see section 5.8.

The supplier of feed materials being established abroad commits himself by contract to the GMP+ FSA certified purchaser, to immediately make this document up-to-date if modifications must occur. He also guarantees to perform the above mentioned control measures and internal checks.

Explanation

Documentation concerning the quality control system

Documentation according to the quality control system plays an important role in maintaining a quality control system based on HACCP. Documentation ensures that the HACCP system is demonstrably present. Documents also provide information to employees about the tasks to be carried out and the agreements made within a company. There must be a clear, unambiguous structure in documents, instructions, forms and in the other documentation. For example the requirements to be laid down, the measures to be taken, etc. can be expressed in procedures, plans, instructions, other documents (like registration forms, specifications, etc.).

4.1.4 Independent certification

A certification audit is periodically performed by an certification body, accepted by GMP+ International¹. See also section 6.

4.1.5 Management responsibility

There are a number of requirements relating to animal feed safety, which fall within the responsibilities of management. These include

- a. Formulation of the *scope of the system*: The scope of the system must be indicated. All product(group)s, process lines and production and storage locations for which the organisation is responsible must be involved in the system. The position of the business in the agricultural feed chain must also be indicated.
- b. *Tasks, responsibilities & authorities (TRA's)*: When setting up the system it is also important to lay down the TRA's of employees, especially the tasks, responsibilities and authorities of employees with regard to food and feed safety must be included. All personnel involved in the production, storage or handling of feed materials shall have appropriate training in safe, hygienic and effective working practices. When necessary a training must take place to make sure the personnel is competent to carry out the tasks. Records must be kept of education, experience and training.

4.1.6 Other documentation

4.1.6.1 *Contracts*

All feed materials shall be sold by contracts. These contracts shall clearly state the type, quantity, quality, price and position of goods sold. All terms shall be precise and unambiguous, preferable in accordance with recognised contractual terms. The supplier must provide his client with the necessary information about the scope of his Quality Control System and other important information about the delivered feed materials, so his client (the next link in the chain) can apply an adequate risk assessment himself.

¹ See GMP+ documents regarding certification (C-documents)

4.1.6.2 *Order receipt and processing*

A supplier shall be able to demonstrate appropriate methods for confirming and recording the type, quantity and quality of orders received.

In all cases, the goods provided shall be demonstrably equivalent to those contracted for supply.

4.1.6.3 *Packaging and delivery documents*

These documents shall be clear and unambiguous. All relevant contractual and legal information must be included on delivery documents. For feed materials sold in bulk, this shall include Statutory Statements required under EU Labelling Regulations.

Any information provided on delivery documents must be valid for the feed materials associated with them.

See GMP+ BA6 *Minimum requirements for labelling & delivery* for additional labelling requirements.

4.1.7 Complaints

Participants must document their procedure for handling complaints. This procedure must at least consist of:

- a. The registration of complaints;
- b. The examination of the sources of complaints;
- c. Registration of the measures which were taken as a result of the complaint;
- d. Registration of communication with the customer in question.

4.2 **Basic requirements for traders**

Traders must have a quality control system which is in compliance with the requirements mentioned in chapter 4.1. If necessary, also relevant requirements from chapter 5 must be met.

Explanation:

In the whole of the GMP+ chain it is necessary that all companies in that chain have the required quality assurance system in place. For foreign suppliers the minimum level of quality assurance is laid down in this standard.

When a supplier is not the first part of the GMP+ feed chain (for example a trader) he must make sure he applies the relevant requirements of this standard. For instance requirements

concerning:

- a. *Contract;*
- b. *legislation (labelling, etc.);*
- c. *tracking and tracing;*
- d. *documentation;*
- e. *suppliers (must be at least GMP+ certified, or certified according to another, accepted standard).*

Although a trader may not actually handle the feed materials he must apply the relevant HACCP-principles to analyse his process, to identify and assess the

potential hazards, and to take the necessary steps to control all possible risks. This is especially important when a trader is responsible for any part of the handling of feed materials (for instance: storage or transport of feed materials). A trader must then demonstrably apply the relevant parts of this standard in his quality system.

A trader must especially ensure that when he is delivering feed materials to a GMP+ recognised company, he himself only buys these feed materials from a supplier of feed materials who also is at least GMP+ certified.

The trader must have procedures developed and documented to ensure that a GMP+ company only is supplied with at least GMP+ guaranteed feed materials. In his administration there must be a demonstrable and clear separation between non-GMP+ feed materials and GMP+ feed materials. If a participant trades non-GMP+ certified feeds then their status must be reported in writing to the client. This applies in the event of delivery to GMP+ certified customers or customers who are certified in another certification scheme which has been declared to be equivalent to the GMP+ scheme (see GMP+ BA10 Minimum Requirements for Purchasing). The sentence "The goods delivered do not have the GMP+ status as specified in the GMP+ FSA scheme" (or: "The goods delivered are non-GMP+ certified") must be specified in the sales contract. If there is no sales contract then this must be specified in some other written form by the time of delivery at the latest.

He needs to inform his customer with relevant information about the feed material so this customer can apply an adequate HACCP-analysis himself. A trader must keep adequate recording and documentation procedures in order to verify compliance to this standard.

4.3 Basic requirements for purchase

The supplier purchases exclusively unprocessed agricultural products from growers that are

- a. GMP+B6 *Feed Materials Cultivation* certified, or
- b. certified according to another standard declared as equivalent.

If the grower is not certified as such, the supplier meets the following requirements:

- a. He carries out an intensive goods-inward control programme that is based on the risk assessment and quality assurance that the grower can give.
- b. He has an agreement with the grower.

Further, where an applicant purchases feed materials, they he may only be sourced from companies that are currently certificated against GMP+ or another assurance scheme, accepted as equivalent to GMP+. See for this GMP+ BA10 *Minimum Requirements for Purchasing*.

4.4 Basic requirements for transport

For transport of feed materials in general it applies that before loading, load compartments must be empty, clean, dry and free from any remnants and odours of previous cargoes, in order to prevent load contamination. This includes:

- a. Free of possible "agribulk-unfriendly elements", such as residues of preceding cargo and/or cleansing activities.

- b. Free of vermin, in the broadest sense of the word (insects and vermin, dead or alive).

In order to comply with this, it may be necessary to clean the load compartment (before loading of the feed materials). In any event the participant must provide the carrier with sufficient information with respect to the nature of the product and of the specific product characteristics including its (chemical) composition, to enable the carrier to determine a correct cleaning regime.

If cleaning is necessary, this must be done in a way that is adequate in relation to the nature of the previous cargoes. Depending on this nature of the previous cargoes, this can implicate dry cleaning (e.g. with broom) or - if necessary - cleaning with water and possibly cleansing agents or even disinfectant agents. After this cleansing, the load compartment must be inspected for cleanness.

Furthermore, the load compartment must be adequately shielded to protect the transported cargo against influence from other transported goods and be provided with resources to cover the cargo during transport.

In general, hygienic conditions must constantly be preserved during transport. Pollution with undesired materials and products must be prevented. This includes the requirement that interaction with other products must be prevented. A specific point of attention is that, to obliterate the spread of BSE (Mad Cow Disease), all possible and necessary preventive measures must be taken to preclude contamination of feed materials through proteins forbidden for ruminants.

Transport of packed feeds

If the feeds to be transported are packed (including sealed loading units) then it is also possible to make use of non-certified external carrier and / or fright broker. In that case the participant must acknowledge all possible hazards and control them. In any event the transport of packed products must take place in a clean and dry loading compartment. The loading compartment must be completely emptied and free of load remains and odour from prior loads.

If a third party carries out this transport on behalf of the participant then the participant must make demonstrable agreements about this.

Road transport

Road transport from a GMP+ B2 *Quality Control of Feed Materials* -certified company to a GMP+ B1 *Production, Trade and Services* , GMP+ B3 *Trade* or a GMP+ B5 *Storage & Transhipment* certified company must be certified according to GMP+ B4.1 *Road Transport or equivalent*. The applicant may however exclude from GMP+ B4.1 *Road Transport* all requirements which are marked with a (*). Compliance with these requirements (more or less 'system requirements') is realized by compliance with all GMP+ B2 *Quality Control of Feed Materials* requirements.

For some countries, it is also possible to make use of non-certified carriers. The following requirements are applicable for road transport from a GMP+ B2 *Quality Control of Feed* certified company to a GMP+ B2 *Quality Control of Feed* certified company:

- a. The road transport is carried out by a GMP+ B4.1 *Road Transport* certified company;

If the road transport is not carried out by a GMP+ B4.1 *Road Transport* certified company or equivalent, the following applies: the additional requirements from GMP+BA10 *Minimum requirements for purchasing, appendix 9* apply.

The GMP+ B2 *Quality Control of Feed* certified company and/or the external transport company it has hired provide the following during the transport of feed materials:

- 1 travel log for each load compartment containing records of the previous loads;
- 2 records for each load compartment indicating the cleaning and disinfection procedures that have been carried out;
- 3 record of a cleanliness inspection for the load compartment prior to loading;
- 4 record of the inspections that have been carried out per load compartment.

If the result of the inspection is positive, the load compartment is approved for the transport of feed materials. This inspection is carried out by a loading inspector. "Loading inspector" is a function included in the quality system (see section 4.1.5) and is performed by an employee who, on the basis of training and experience, has the knowledge and skill to inspect a load compartment for suitability for loading with animal feeds.

The receiving GMP+ B2 *Quality Control of Feed Materials* certified company carries out a goods-inward inspection of the incoming transport of feed materials. The company checks if:

- a. the three previous loads were acceptable as previous loads for transport of feed materials;
- b. an adequate cleaning has taken place;
- c. an inspection was carried out before loading.

If the result of the goods-inward inspection is positive, the feed materials can be accepted.

Transport by inland waterway, sea and rail

In case of inland waterway, sea and rail transport an inspection of the cleanliness of the load compartments (LCI = Load Compartment Inspection) has to be carried out before loading commences.

Furthermore, the loading process has to be monitored/safeguarded, in order to maintain feed and food safety. This inspection and monitoring may be carried out by:

- a. an inspection company at the ISO 17020 level, specialised in and accredited for feed/grains or liquid agri-bulk and internationally operating on a certified guarantee system such as ISO 9001 or equivalent;
- b. a company inspector of the chartering party or, at his request, of the supplying party, who is included in the company's own quality system as a qualified loading inspector and whose person, function and ability have been guaranteed.

Explanation on road transport

For transport of packaged products, it is sufficient that the load compartment is clean. This means completely empty, free of remnants and odours from previous loads, and dry.

A company can determine, on the basis of its own HACCP analysis, whether the transport order and applied cleaning methods are acceptable. The regulations in GMP+ B4.1 Road Transport regarding transport order, cleaning and disinfection can serve as a guideline.

If the GMP+ B2 Quality Control of Feed Materials-certified company contracts an external transport company, the company must guarantee that the transport is carried out in conformance with the established requirements. The GMP+ B2-certified company must have a contractual agreement with the transport company regarding this matter.

The function "loading inspector" must be included in the company's quality system. The company must make clear to the Certification Body that the loading inspector possesses the required knowledge and experience and has sufficient authority.

The goods-inward inspection of the incoming transport must be carried out in addition to other inspections that are carried out when goods are received. LCI reports for all received sea transport, short sea shipping, inland waterway transports or rail transport should be available or retrievable.

4.5 Basic requirements for storage

The participant should control all his own storage and transshipment activities using his own feed safety system in accordance with the requirements of this standard. This applies to storage and/or transshipment.

- a. at both own and hired sites, and
- b. both packaged and unpackaged feeds

Storage and transshipment may only be contracted out to a company which is GMP+ certified for this. See GMP+ BA10 *Minimum Requirements for Purchasing*. The exceptions may be:

- a. Temporary (meaning less than 6 consecutive months) bulk storage or transshipment directly adjoining the harvesting of vegetable primary products.
- b. Storage / transshipment of packaged feeds
- c. Storage / transshipment in bulk of feeds abroad (meaning outside the Netherlands).

In these exceptional case, the participant should

- a. have an inspection carried out before usage of the control on feed safety
- b. establish that the storage and transshipment company complies with all the applicable legal obligations relating to feed²
- c. lay down agreements in a contract on the relevant prerequisites (hygiene, T&T, etc.), control measures to be carried out and audits. This should offer guarantees to GMP+ equivalents with respect to the storage of the feeds.
- d. have periodic inspections carried out of compliance with the agreements made

² For Europe, for example, there is a duty of registration under Reg. (EC) 1831/2003.

5 Specific requirements

5.1 General

The requirements mentioned in section 4 are most essential for setting up and putting in place an adequate quality control system, which must be documented. Therefore, in this chapter these minimum requirements are more detailed mentioned.

A supplier must have demonstrably implemented these elements in his operational management.

The required risk assessment and monitoring plan (see the following paragraphs) must, among others, be based on the general risk assessment recorded in the Feed Safety Databank.

Where the feed material concerned is not recorded in the GMP+ Feed Safety Databank, the applicant must initially submit a risk assessment to GMP+ International for inclusion in the database. See www.gmpplus.org for the procedure to achieve this. The above does not apply to feed materials which are only processed in feeds for domestic animals.

Note: A feed material may only be purchased or acquired by a GMP+ certificated company after inclusion in the database.

Explanation:

The steps of a risk assessment are as follows:

- a. *Product definition.*
- b. *Production Process definition*
- c. *Hazard Identification.*
- d. *Risk evaluation*
- e. *Determination of critical points.*

Based on the drawn-up product specification and process specification the potential hazards and risks must be identified, which may influence the quality respectively safety of the product- when used as animal feed or ad material - for the human being (consumer of animal products), animal and environment. After identification of the hazards the critical points in the production process are identified and documented.

When the hazards have been identified, it must be established in which process step(s) there will be a critical control point (CCP) and/or which other control measures are necessary. These CCP's must be defined and documented.

Very helpful for the documentation of the risk assessment process is the following table, which contains each step mentioned hereafter.

Process:

no.	Process step	Hazard description	Cat.	Prob.	Sev	Risk	Motivation of the risk	Type of measures	Reference

5.2 Product specification

A supplier identifies which specifications his feed materials has to meet regarding quality respectively safety, and which additional (quality) requirements his buyer wants to be guaranteed.

This must include:

- a. legal demands (statutory demands in the European Community).
- b. demands from sectoral agreements (chain parties, other market parties) other GMP+ requirements, among others GMP+ BA1 *Product Standards*
- c. additional demands from the client (for example: non GM-demands)

Additionally the following items must be entered in a product specification:

- a. Name of the product
- b. Description of product (chemical, micro-biological, physical, nutritional, etc.)
- c. Intended use
- d. Transport, storage and usage rules to maintain the product characteristics

Explanation:

Information about feed materials and products is necessary for correct estimation of the hazards that could be present in the production process or which hazards may be present in the final products (animal feed), for the animals and/or human beings. Product specifications will give a first indication of possible hazards.

It is also necessary for the supplier to be aware what the client's requirements are and what he has to comply with. For instance, if a client has certain demands about non-GM feed materials, the supplier also needs to make sure these requirements are guaranteed.

5.3 Production Process Specification

The supplier describes the production process, with all process steps and process conditions, also with help of process diagrams and added explanations.

The process specification is specific for each company. Symbols may be used for describing the process. A map with the facilities of a company may be of help for systematically mapping of the processes. The process definition includes the preceding process steps (like cultivation, harvesting, storage and transport) when the supplier is not the primary producer.

Explanation:

A production process specification offers insight into the actions, activities and conditions that a product undergoes in a company and the links that are ahead. Such a process specification also serves as a basis for the estimation of hazards that could possibly arise or develop.

In a production process specification is indicated, which process steps need to be followed to achieve a specified product. This also indicates which feed materials and technical auxiliaries are used, which semi manufacturers, co- and end products result during the process. Also insight is given as to how return flows are processed. Each process, production or processing step, must be shown separately in the process description.

GMP+ International has made several general risk analysis as an example. These risk analysis can be obtained from GMP+ International.

5.4 Hazard identification

The supplier identifies and evaluates all possible hazards which may occur, and classifies these hazards as chemical, physical or microbiological. This must be done for each step of the production process.

Explanation:

The potential hazards must be derived from the process steps and -conditions. Normally chemical, (micro-)biological and physical hazards are distinguished. A classification is given hereafter, including descriptions and examples.

Category	Description	Examples
<i>Chemical hazards</i>	<i>Unwanted chemical substances that are present in the feed materials, by nature, by pollution or by use of auxiliary materials, or that contaminate the product during production.</i>	<i>Residues of pesticides, heavy metals, environmental pollutants, myco-toxins, PCBs, dioxins, cleansing agents, lubricants, mineral oils, auxiliary materials from production, biological decomposition products, minerals, acid remains, etc.</i>
<i>(Micro-) biological hazards</i>	<i>Unwanted micro-organisms, toxins produced by those, and carriers of animal diseases that may enter the product or may develop. Distinction between vegetative, toxigen (forming toxins) and spore forming micro-organisms.</i>	<i>Salmonella, enterobacteriaceae, fungi and yeast (as indicator organisms), mammalian meal (as carrier of BSE), etc.</i>
<i>Physical hazards</i>	<i>Strange substances that may be present in the feed materials or may enter the product during storage, production and transport, and that may become a hazard to the animal</i>	<i>Glass, plastics, metal fragments, stones, bones, remnants of packing materials, asbestos, etc.</i>

Hazards may occur when the product is contaminated with other substances by means of:

- a. The use of auxiliaries, like pesticides, insecticides, fungicides, technological process agents which are applied or added to or may come in contact with the product*
- b. Specific processing steps when substances may be added to the product, like during steam heating, artificial drying*

- c. *Specific conditions during cultivation, harvesting and storage when microbiological contaminants come into existence.*

Especially the following (potential) hazards need attention:

- a. *direct artificial drying*
- b. *steam injection*
- c. *use of technological process agents (like gypsum, free flow agents, acid regulator) and technical agents (like lubricants) and*
- d. *mycotoxins*
- e. *transport.*

*In case of **direct drying** feed materials come in contact with combustion gasses. Depending of the quality of the fuel and the adjustment of the combustion installation undesirable substances can come into existence with which the feed materials can be contaminated.*

It concerns substances like DNMA (dinitroso-methylaminen), poly-aromatic hydrocarbons, PCB's, dioxin, NO_x and SO_x.

Fuels, mentioned in GMP+ BA3 Minimum Requirements Negative List, are forbidden

*In case of **steam injection** the quality of the steam is important because it come into contact with the feed materials. This steam quality is determined by the quality the water used in the boiler and the used technical aid agents, like corrosion preventing agents.*

*During the production and processing of food products and agricultural products **technical** (lubricants) and **technological** (acid regulator, binders, preservatives etc.) **aid agents** are often used. These aid agents can be incorporated in the co-products which are destined as feed material. Therefore, the safety of these aid agents is an important point of attention, especially whether they are of food-grade. In cases where sanitisers are used, the supplier shall ensure that control systems provide the correct and effective dosing levels at all times. Dosing systems shall be calibrated by a competent person and calibration records maintained. Only food compatible sanitisers may be allowed to come into contact with feed materials.*

***Mycotoxins** may come into existence during cultivation of the crops and during storage and processing of harvested products. Especially climate and storage conditions (moisture and temperature) are important. It is necessary to determine whether products are sensitive for mycotoxins or not and what the determining conditions are.*

***Transport** is also an item which must be paid special attention to. The potential hazards can be chemical, microbiological and physical. These hazards can come from the environment or as a result of cross contamination with previous cargoes.*

5.5 Risk evaluation and determination of critical control points

After hazard identification it is important to evaluate whether or not a hazard is a risk or not. The risk level has to be determined in order to determine the critical control points and the kind of control measure to be carried. The supplier determines the risk level, which is the result of the probability that a hazard will occur and the severity if it occurs.

When the risks have been identified and classified, it must be established in which process step(s) there will be a critical control point (CCP) (which may be of influence to the quality respectively safety of the product – when used as animal feed (feed material) - for the human being (consumer of animal products), animal and environment) and/or which other control measures are necessary. These CCP's must be defined and documented.

Explanation:

Four risk levels can be determined with the risk evaluation model. In the event of risk level 1, no measures are necessary. In the event of risk level 2, periodic measures – often activities to be performed just once - have to be carried out. Risk level 3 requires general control measures, such as hygiene programmes, maintenance and calibration, purchasing procedures, etc. These measures are often called Point of Attention (POA) or GMP+ measures. Most of them are already included in this GMP+ standard. In the event of risk level 4, specific control measures are necessary for that particular situation.

The following model can be used:

Risk evaluation model

<i>Severity</i>	<i>Probability of occurrence (in end product; at consumption)</i>		
<i>Great</i>	<i>3</i>	<i>4</i>	<i>4</i>
<i>Medium</i>	<i>2</i>	<i>3</i>	<i>4</i>
<i>Small</i>	<i>1</i>	<i>2</i>	<i>3</i>
	<i>Small</i>	<i>Medium</i>	<i>Great</i>

Part of the CCP decision tree is the risk assessment. This determines which type of control measure is necessary to eliminate a hazard and/or to reduce the risk and to control it at an acceptable level. This assessment must be carried out for every process.

Control measures can vary from technical/technological solutions to organisational and/or procedural measures. There are, therefore, various possibilities for controlling risks.

5.6 Control measures

Based on the hazards and risk evaluation and the determination of the critical points in the production process, the supplier determines which control measures are necessary to eliminate the identified risks or to control them to an acceptable level. These control measures must be documented.

Especially when artificial drying, steam injection, technical or technological aid agents, or mycotoxins are critical points, control measures have to be made clear.

Explanation:

Control measures are necessary to reduce contamination of the products by unwanted substances and products. This can be done by documented en implemented instructions, working regulations, adjustment of process conditions, training of personnel, etc.

In the GMP+ FSA scheme the necessary (generic) control measures are incorporated. If relevant these must at least be applied. When based on risk analysis specific control measures will be necessary, these must be briefly indicated in the document.

Examples of relevant (generic) control measures:

Cultivation and Harvesting

Cultivation and harvest instructions are necessary to guarantee the quality of the feed material. It concerns for example preventing feed materials getting wet, preventing of fungus growth, prevention of presence of contamination (for example residues of pesticides).

Mycotoxins at cultivation, harvesting and/or storage

Control measures for feed materials or animal feed which are sensitive to mycotoxins, must in all stages of cultivation, harvesting and storage of the basic products and storage of the processed feed materials be aimed at making the development of mould growth as unfavourable as possible (for example choice of race of crop, way of manufacturing, way of storage). Existing control measures are:

Cultivation

- a. Choose for less sensitive breeds;*
- b. Apply full crop rotation, without maize before other cereals;*
- c. Apply a turning up side down soil tillage.*

Storage

- a. Avoid damage; store and transport goods dry.*

Control of Non-Conforming Products

The supplier must also ensure that non-conforming feed materials are clearly identified and segregated from both waste and conforming products in a manner that prevents inadvertent or accidental use, at all stages.

All incidences of non-conforming feed materials shall be recorded and decisions regarding actions to be taken shall only be made by nominated members of staff.

Non-conforming feed materials or product in-process would normally be dealt with in one of the following ways:

- a. Scrapped;*
- b. Reworked;*
- c. Accepted by concession (if agreed by the client);*
- d. Downgraded.*

Requirements for reprocessing non-conforming feed materials shall be documented and any affected feed material be re-evaluated on completion to ensure that the batch concerned meets specified requirements. Feed materials that do not fully meet a customer specification shall only be supplied if the customer is notified of the problem in writing and is prepared to accept them.

Site, Building and Process Equipment Requirements

It may be necessary to (re)design, (re)construct and maintain buildings such that conditions within the building are suitable and do not adversely affect the quality, safety or integrity of any feed materials either processed or kept in the building. The production, storage, transport and shipping used by the supplier shall be secure and prevent unauthorised access.

All equipment (such as sieves, screens, filters, separators, etc) used for processing, storing and transporting feed materials shall be fit for the purpose for which it is used.

Such equipment shall be subject to a programme of planned maintenance that ensures equipment is maintained in safe and hygienic working condition.

The supplier shall keep records of maintenance carried out on all critical equipment.

Intake & Loading Facilities

The supplier shall ensure that all intake and loading facilities are designed and constructed in a manner that maintains the quality and safety of feed materials. Neither discharge nor loading shall be carried out in conditions such that inclement weather or risks of contamination may affect the raw materials or feed materials being handled. Intake and loading facilities shall be designed to ensure that access by birds and other pests is kept to an absolute minimum.

In the case of flat stores, facilities shall be organised to ensure that mud, snow and other potential contaminants carried by vehicles cannot adversely affect stored raw materials or feed materials. There shall be sufficient hard-standing (e.g. concreted area) at store entrances to limit the tracking of water and mud into the store.

Conveyors and Handling Equipment

All conveying systems and handling equipment shall be maintained in a sufficiently clean and hygienic condition to avoid adversely affecting the feed materials they contact. Risk assessment procedures shall be used to identify and control any hazards that may arise.

Records shall be kept detailing the time and nature of any cleaning undertaken.

Storage

Feed materials and products must be stored in such a way that they can be identified easily and that confusion with other damaging products is prevented. The way in which these items have to be treated by the supplier, must be included in an instruction.

During storage, rain and stained water must be prevented from entering. Even whilst they are empty, storage and loading compartments must be covered to prevent rain-entry and pollution through bird-droppings. The thereby deployed tarpaulins must be clean and dry. Prior to loading of feeds, the exterior of the vehicle, including chassis, must be cleared of all visible residues of the preceding load.

Hygienically working

During all cultivation, harvest, storage and processing steps operations must be performed hygienically to make sure that the production environment and the personnel can not contribute to contamination of feed materials. It concerns instructions for personal hygiene, industrial clothing, treatment of chemicals, general company rules concerning this, etc. The methods of hygienic working must be documented.

Cleaning

A supplier must set and perform such measures, that adequate company hygiene is assured. The cleaning program must include company equipment where applicable, (company) areas and facilities, installations and (internal) transport systems. Cleaning programs must be documented, cleaning frequency and used cleaning agents must be registered, etc.

Any materials considered to be 'waste' shall be visually identified as such and promptly segregated in a manner that will eliminate the likelihood of accidental or inadvertent use. Waste material may not be collected or stored in any container that may be used for finished feed materials. In order to discourage pests and vermin, containers used to store waste materials shall be covered. They shall also be stored away from feed material storage or production areas and removed from site as frequently as practical.

All waste shall be disposed of legally.

Pest Control Program

A supplier must take measures for the exclusion of vermin and to determine and document a pest control program. It concerns barring out vermin during the cultivation and harvesting process as well as fighting vermin during storage of feed materials. When executing pest control programs, acceptable pest control methods and -means must be used.

Identification and traceability of feed materials

It is of importance in case of problems or questions afterwards, that products in the chain can be identified and traced. Therefore it is necessary that the grower, trader and manufacturer keep a detailed administration. In this administration the relevant data for effective (internal) tracing of feed materials is included.

See D2.4 Guideline for Traceability (specifically Appendix IV) for more information about setting up a internal traceability procedure.

Contamination with specific contaminants

Contamination or pollution of feed materials and products must be prevented where possible. Contamination can happen anywhere. Controls shall be in place to protect feed materials from contamination by foreign bodies.

In particular, intake points, processing equipment, conveying systems and storage facilities shall be designed and operated to minimise the possibility of ingress. Operatives, drivers and maintenance personnel shall all be trained and supervised so as to ensure that the risk of foreign materials ingress is kept to an absolute minimum.

Wherever possible, process and storage facilities shall be enclosed to avoid contact with potential contaminants as well as access for pests and vermin. Where this is not possible, appropriate controls shall be in place to ensure minimal risk to feed material integrity.

Especially adequate control measures must be taken and documented regarding the following:

Contamination during (artificial) drying in direct contact with combustion gases. Important is the quality of the fuel. Control measures could be taken for example in the form of forbidding unsuitable fuels and prevention of uncontrolled combustion. See GMP+ BA3 Minimum Requirements Negative List for forbidden fuels with regard to GMP+ certification.

It is important to make clear in which way the quality of the fuels and the adjustment of the drying installation are guaranteed. Extensive control measures are:

- a. Specification of the fuel quality and appointments with the supplier, based on risk evaluation Use only mineral fuels (gas, coal, petroleum) which are suitable according to the specification of the supplier;
- b. Specification of control measure to avoid contamination of fuels during storage and transport;
- c. Specification of the checks of the fuel's quality;
- d. Specification of the adjustment of the burner and dryer installation to avoid incomplete combustion.

Technical and technological aid agents

The supplier who adds technical and technological aid agents to the feed materials must apply certain control measures to prevent contamination of the feed materials

- a. Specification of the quality of the technical and technological aid agents;
- b. Specification of the quality control of the technical and technological aid agents.

Steam injection

The supplier who uses steam in the production process of the feed materials must be sure that the feed materials are not contaminated due to the poor quality of the water he uses. It is important that there are specifications of:

- a. the quality of the water, which is used for steam injection and the technical aid agents like corrosion preventing agents;
- b. the quality control of the water and the technical aid agents.

5.7 Monitoring and verification

In order to be able to check whether control measures are effective, the critical points in the production process and the products themselves are periodically inspected and sampled (monitoring). This must be done by a documented schedule (plan). All results of inspections, and controls must be recorded.

The monitoring plan must at least comply with the relevant requirements, stipulated in GMP+ BA1 *Product Standards* and GMP+ BA4 *Minimum Requirements for Sampling and Analysis*, especially Protocol P4.

If from these tests it proves that the effectiveness is not sufficient, corrective measures must be taken for the realisation of the desired result. The monitoring and verification strategy, as well corrective measures have to be documented, as well as the way in which the buyers of the results are being informed.

Explanation:

The verification strategy must be based on the performed risk evaluation) and the risk parameters that are part of that. The results are an important source of information for the company and may play a role for the management of the processing. The verification strategy does not only comprise the process

parameters and product parameters that are being monitored, but also the measuring frequencies and -methods. Basic assumption is that the measuring methods for the product quality are based on internationally standardised laboratory methods and performed by qualified laboratories.

Following implementation of a quality control system it is important to plan the quality checks, sampling, analyses, registrations and inspections which must be carried out according to the quality control system. Schedules and/or plans are necessary for this. All results of inspections, and controls must be recorded.

It is necessary that the clients have insight in the measuring results, in order to be able to keep insight in the way of realisation of the risk control during the process. Apart from that it can be useful for the supplier involved to have insight in the development of the presence of critical substances on that particular chain level. GMP+ International has a database available for unwanted substances and products, which is accessible via the internet on-line for whom are participating. A possibility is that participants supply data to the database under certain conditions. Participants can subscribe for this at GMP+ International.

5.8 Evaluation, actualisation and communication

The manual, which consists of the previous steps, must be actualised for modifications in the production process. If there are no modifications, actualisation would be necessary at least every two years based on advancing insight.

It is also important to perform an evaluation preceding to the actualisation. This will also give input to the improvement cycle.

The customer must be informed when a feed material does not meet the agreed specifications. The participant must also comply with the requirements in GMP+ BA5 *Minimum requirements EWS*.

The supplier must also inform his customer when the scope of the system has changed.

6 Periodical external certification audit

In the GMP+ Feed Safety Assurance scheme is stated that the system and the contents of the manual must be verified at least once a year, by an accepted certification body.

This means at the start an initial audit, after one year a surveillance audit, etc, etc.

The inspection bodies for the certification audits accepted by GMP+ International are published on its website, as well the procedure for acceptance of this bodies³.

The performance of a certification audit can be initiated by the supplier himself or the customer. Also other parties involved may initiate a certification audit.

All foreign feed material suppliers who are approved by the accepted inspection bodies, are published by GMP+ International on its Internet site.

Also on GMP+ International's website (www.gmpplus.org) a Frequent Asked Questions-list is published with information about the certification audits, for instance a guideline for the minimum length of time for an audit.

³ see GMP+-documents regarding certification (C-serie)

7 Useful documents

- a. HACCP-manual a useful guide to help implement the required system
- b. Other GMP+ standards for instance GMP+ standard GMP+B1 *Production, Trade and Services*, GMP+B3 *Trade*, GMP+B4.1 *Road Transport* and GMP+B5 *Storage & Transhipment*
- c. Feed Safety Database (www.gmpplus.org)