GMP+ International

Production, Trade & Services

Additional requirements for ISO22000:2005/PAS222:2011

GMP+ B 1.2

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GMP+ Feed Certification scheme

Feed Safety Worldwide

gmpplus.org

History of the document

Revision no. - Date of approval	Amendment	Concerns	Final implementation date
0.0 / 01-2015	This is a new document.	Entire document	01-01-2015
2.0 / 11-2015	Definition domestic animals is changed. The FSP list is not applicable for feed for non-food producing animals.	Par. 7.2.1	01-04-2016
	Requirements for specification of the status of the feed product or service to be purchased has been amended.	Par. 7.10.2	01-04-2016
3.0 / 04-2017	Homogeneity requirements are tightened. Reference is made to the standards in the GMP + BA2. Some textual corrections	6.7.1.3 Entire document	01-07-2018
4.0 / 05-2018	Link is added to the GMP+ B11 *Protocol for GMP+ registration for laboratories*	7.7.1	01-07-2019
5.0 / 10-2021	Requirements for excluding activities, processes, products or services from GMP+ certification are changed	4.1 6.8	01.01.2023
	The list with details that must be recorded is extended due to the update of GMP+ BA2 *Control of residues & Homogeneity of critical feed additives and veterinary medicinal products*	6.5	01.01.2023
	Requirements for mixing and homogeneity are changed due to the update of GMP+ BA2 *Control of residues & Homogeneity of critical feed additives and veterinary medicinal products*	6.7.1.3	01.01.2023
	Requirements for preventing (cross-) contamination are changed due to the update of GMP+ BA2 *Control of residues & Homogeneity of critical feed additives and veterinary medicinal products*	6.7.1.5	01.01.2023

Editorial note:
All changes in this version of the document are made visible. This is how you can recognize:
- New text
- ~~Old text~~
The changes must be implemented by the participant latest at the final implementation date.

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1 Introduction

1.1 General

The GMP+ Feed Certification 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.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focussed on feed safety) and GMP+ Feed Responsibility Assurance (focussed on responsible feed).

GMP+ Feed Safety Assurance is a complete module with standards 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 module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA standards, such as requirements for a feed safety management system, for application of HACCP principles, for traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

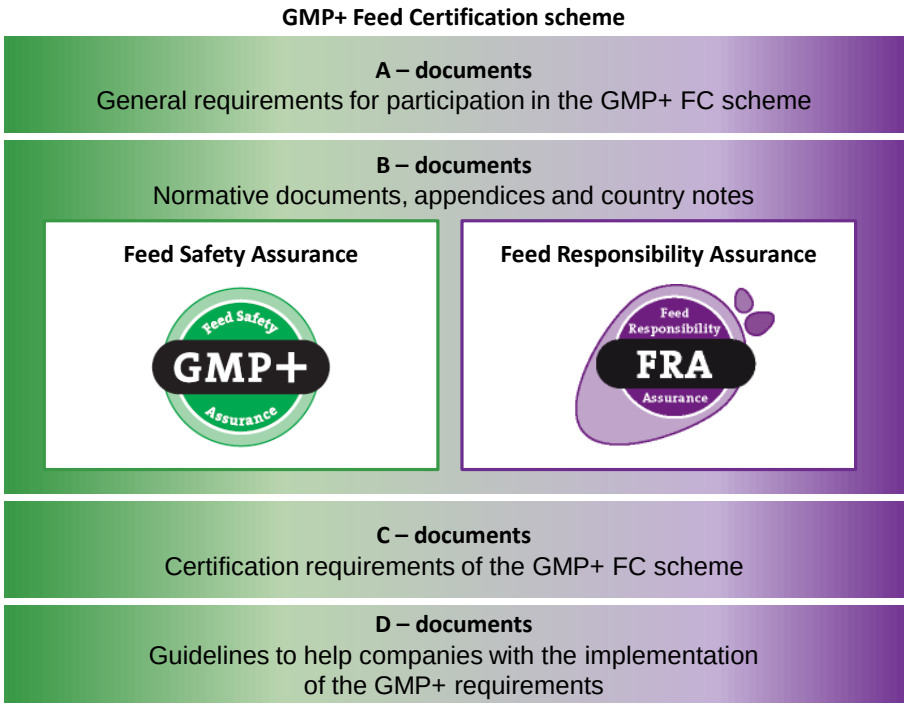
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance. GMP+ International facilitates via independent certification the demands from the market.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

1.2 Structure of the GMP+ Feed Certification scheme

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



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

This document is referred to as GMP+ B1.2 *Production, Trade and Services* and is part of the GMP+ FSA module.

1.3 Scope and application of this standard

This standard gives the conditions and requirements for the feed safety management system to assure:
a. production/processing of all kind of feed
b. trade in all kind of feed;
c. storage and/or transshipment in all kind of feed

For exact details about scopes and scope descriptions is referred to GMP+ C10 *Acceptance requirements and Procedure for Certification Bodies*, Annex 1.

See GMP+ B4 *Transport* for the relevant transport requirements (especially chapter 5 for additional elements for the prerequisite programme and chapter 7 with requirements for a safe operation of the transport activities). To avoid contamination with previous loads, as a minimum the cleaning requirements which are registered in the International Database for Transport of Feed (IDTF) must be met. See further GMP+ B4 *Transport* and http://www.icrt-idtf.com

In this standard often the word ‘production’ is used. In some cases this may be taken to mean ‘processing’ or another form of physical action on or to feed. Examples of physical actions during the production or processing of feed are: collection, drying, cleaning, mixing, packaging, storing, transporting or transhipping.

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 feeds 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 internal audits.

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

The participant remains responsible at all times for the safety of the feeds 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 of his services or feeds 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 is similar to the standard GMP+ *B1 Production, Trade and Services*.

The content of this standard is, however, for a large part based on two public available standards:

- ISO22000:2005 "Food Safety Management Systems – Requirements for any organization in het food chain"
- PAS222:2011 "Prerequisite programmes for food safety in the manufacture of food and feed for animals"
  (Note: where "food" is written in the ISO 22000 / PAS222, it should be read as "feed")

Application of these 2 standards for assuring the safety of feed products, feed production and feed-related services contributes already in a large part to realization of the required level of GMP+ feed safety assurance for the relevant scopes. However, to achieve a full compliance with all relevant GMP+ requirements, still a number of additional GMP+ requirements must be met.

Where the GMP+ requirements and the requirements of either the ISO22000 or the PAS222 are equivalent, in a purple box reference is made to the main relevant clauses of ISO 22000 / PAS222. This standard gives only the additional GMP+ requirements for feed safety assurance, mainly by referring to GMP+ Appendices.

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

Guidance
Guidance has been included for a number of requirements in this standard. This guidance is in a separate green box starting with the word 'Guidance'. The guidance does not include requirements or conditions but is intended only as an aid to the better understanding of the requirement. The box also often contains information which is useful for auditors. In order clearly to distinguish between the guidance boxes and the mandatory requirements, the guidance boxes will preferably make no use of the word 'must'. We did, however, not succeed to apply this in every box. Nevertheless, where the word 'must' is used in a guidance box, it must be read as guidance relating to the requirements set.

1.5 Certification

Certification against this standard is possible when a company, certified against ISO22000/PAS222 for the scope Feed, demonstrates compliance with this standard. Certification requirements as such have been laid down in the GMP+ C-standards.
Certification for these standards must be carried out by the same certification body.

1.6 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 module.

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 Feed Safety Management System objective

Implementation of this standard aims to establish a management system to ensure the safety and quality of the feed products and feed services, as covered under de scope of this standard.

This standard is meant to be aligned with applicable feed legislation as well as feed safety principles and standards that are commonly accepted in the feed sector to be taken into account when producing and delivering safe feed.

The feed safety management system must ensure that the applicable legal requirements and sector requirements are met, as well as applicable statutory, regulatory and contractual arrangements.

Some remarks:

- Regarding the feed legislation, special attention was paid when drawing up this standard to include relevant requirements of applicable feed legislation. However, it remains the responsibility of the participant to ensure full compliance with relevant feed legislation.
- Additionally, regarding the sector requirements, in some GMP+ appendices (coded as GMP+ BAxx), a number of sector specific feed safety standards and conditions have been laid down, which are worldwide to be considered as necessary to meet, in order to produce and deliver safe feed. When this standard makes a reference to such a GMP+annex, it is expected that the participant ensures that the required feed safety management system is effective to meet these sector specific feed safety standards.
- However, both this standard and the appendices, may not cover all sector specific feed safety standards. Therefore, also related this item, it remains the responsibility of the participant to identify all relevant sector specific feed safety standards and to ensure the feed safety management system is able to control them.

Certification of the feed safety management system against the requirements of this standard, does not guarantee legal compliance nor compliance with the sector requirements, but demonstrates that the participant has an effective feed safety management system to achieve and maintain legal compliance as well as compliance with sector specific feed safety requirements.

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

These documents can be found on the GMP+ International's website (www.gmp-plus.org)

3 Terms and Definitions

See GMP+ A2 *Definitions and Abbreviations*.

4 Feed Safety Management System

4.1 Requirements for the feed safety management system

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	4.1
PAS 222	-

The participant must set up the feed safety management system so that it complies with the requirements of this GMP+ standard. The participant must document this, implement it and maintain it as well as continuously improve its effectiveness.

The participant must:

a. establish and record the scope of the feed safety management system. The scope must at least include the activities related to feed for which the participant is responsible:

1. The responsibility of the participant begins where the responsibility of the previous link (the supplier) ends, and ends where the responsibility of the following link (the customer) in the feed chain begins.

2. The participant must specify every feed which he puts on the market, processes, treats or trades.

3. All business locations and processes / process lines where production, treatment, processing, trade, storage & transhipment (whether at owned or hired sites), affreightment and transport of feed (whether packaged or unpackaged) are carried out, must be brought under the scope of the feed safety management system. This might mean application of other GMP+ standards as well. See also GMP+ A1 *General regulations* and the next sub articles 4.1.a.6 up to 4.1.a.8.

4. If a participant decides to outsource a process which influences compliance with the requirements on the product, the participant must ensure that such processes also comply with the requirements of this GMP+ standard. The participant must at least comply with section 7.10.

5. All other activities, which means the activities which are not able to cover under this or other GMP+ standards, must also be described by the participant. The participant must ensure that these activities do not have a negative influence on the safety of the feed.

Possibilities for exclusions ~~from scope of the feed safety management system~~:

6. ~~All activities related to pet foods may be excluded on the condition that they are produced, traded and/or transported as such separately and that they do not have an influence on the safety of feed which are covered under the feed safety system~~.

It is possible to exclude activities, processes, products or services related to the production, trade, storage and transport of feed from the scope of GMP+ certification. See for more detailed requirements chapter 6.8 *Separation*

7. For a company which also carries out trading activities it is permissible to exempt the part of the trade in non – GMP+ certified feeds from the scope of the feed safety management system. This should however be available for checking. The participant will in his records make a clear and demonstrable distinction between the GMP+ assured feed materials and the non – GMP+ assured feed materials.

   See GMP+ BA6 *Minimum requirements for labelling & delivery* for the specific requirements regarding the trade and labelling of non-GMP+ certified feeds.

   Feed materials which are delivered to livestock farmers, irrespective of whether they participate or not in chain quality programmes, should always be covered by the GMP+ certificate.

8. Transport of packaged raw materials or feed
   If a participant makes use of an external carrier for the transport of packaged raw materials of feed, then this external carrier (and / or freight broker) does not have to be GMP+ certified or equivalent. Risk assessments must consider any potential hazards and ensure that controls effectively preclude any serious risk of contamination. Transport of packaged feed must take place in a clean and dry loading compartment.

   Sealed loading units
   Under certain conditions sealed loading units are considered to be packaged products and therefore non-certified external carriers can be used. This is allowed when non-certified external carrier has no influence on the transported raw materials or feed ingredients. The carrier just positions this sealed loading unit on a chassis and brings it to the customer. Additionally to the above requirements this means practically that:

   a) Management of cleaning and inspection of the loading unit is the responsibility of participant.
   b) The loading unit must be closed and sealed on the responsibility of the participant immediately after loading. The seal may only be broken at the customer.
   c) The carrier may not use own loading / unloading equipment (pipes, hoses etc.) unless the participant has agreed this with the customer.

NOTE:
If at one location several companies carry out activities covered by a GMP+ standard, each of them must hold a certificate for these activities. See GMP+ A1 *General Regulation*.

4.2 Documentation

4.2.1 General

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	4.2.1
PAS 222	-

4.2.2 Quality system documentation

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	-

The participant must set up and update a quality manual which includes:

a. the scope of the feed safety management system, including the details of and clear justification for any exclusions
b. the documented procedures as required as a minimum under the GMP+ standard(s) which have been established for the feed safety management system or a reference to them
c. a description of the interactions between the processes of the feed safety management system
d. the structure of the documentation.

4.2.3 Control of the documentation

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	4.2.2; 7.7
PAS 222	-

4.2.4 Control of the records

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	4.2.3
PAS 222	-

The storage period for relevant records is at least three years, unless a longer storage period is required according to the applicable feed legislation or other regulations.

5 Management responsibility

5.1 Management commitment

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.1
PAS 222	-

5.2 Feed safety policy

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.2
PAS 222	-

5.3 Planning

5.3.1 Feed safety objectives

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.2
PAS 222	-

5.3.2 Planning of the feed safety management system

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.3; 8.5.2
PAS 222	-

5.4 Responsibility, authority and communication on feed safety

5.4.1 Responsibility and authority

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.4
PAS 222	-

5.4.2 HACCP-Team

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.3.2
PAS 222	-

5.4.3 Management representative

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.5
PAS 222	-

5.4.4 Provision of resources

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	6.1; 6.2; 6.3; 6.4
PAS 222	-

5.4.5 Internal communication

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.6.2
PAS 222	-

5.5 Management review

5.5.1 General

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.8.1
PAS 222	-

5.5.2 Review input

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.8.2
PAS 222	-

5.5.3 Review output

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.8.3
PAS 222	-

6 Prerequisites Programme

6.1 General

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.1; 7.2; 7.5
PAS 222	Whole document

6.2 Personnel

6.2.1 General

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.4; 5.5; 6.2.1;
PAS 222	13; 19

The production department must be led by a person who has the necessary qualifications.

Where relevant, a person with relevant qualifications, must be responsible for quality control.

An organisation chart must be drawn up. There must also be a description of the qualifications (for example diplomas, professional experience) and the responsibilities of the supervisory personnel which must be made available to the competent authorities who are responsible for inspection.

The personnel must be clearly informed in writing of the tasks, responsibilities and authority, especially in the event of changes, to obtain the desired feed safety.

The participant must ensure that the personnel take care of themselves with respect to feed safety. Protective clothing must be worn if the risk assessment shows that contamination of feed materials may occur.

There must be clear rules with respect to eating, drinking and smoking in the production areas which are aimed at avoiding contamination of feed.

6.2.2 Competence, awareness and training

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	6.2.2
PAS 222	13; 19

6.3 Infrastructure

6.3.1 Basic requirements

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	6.3; 7.2
PAS 222	3; 4.1; 4.2

6.3.2 Requirements for facilities, production areas, installations and other facilities

6.3.2.1 Facilities

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	4.1; 4.2; 10

The facilities must be such that:

a. the chance of errors is as small as possible and contamination, cross-contamination and general harmful effects on the safety and quality of the feed is avoided as much as possible
b. no confusion can occur between different products, the products are properly identified and no incorrect use of the products can take place
c. that a strict and complete physical and organisational separation is applied and maintained between on the one hand feed products and on the other hand products which must not be in feed[1].
   This separation is intended for the prevention of a mixing of feed and these products taking place with risks for feed safety. See section 6.4.4.

6.3.2.2 Production areas

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	4; 5; 9; 10; 11; 12; 21

The production areas are designed and equipped in such a way that:

a. areas or storage units for products which are not part of feed (section 6.3.2.1c) are clearly recognizable and/or marked. If applicable the areas or storage units must be closable to prevent undesirable contamination of feed

[1] *Examples are fertiliser, fuel, cleaning and disinfectant agents, glass, crop protection agents, waste.*

With respect to storage areas the following also applies:
a. feeds must be stored and transported in such a way that they can easily be identified.
b. A separate storage area is intended for the storage of premixtures and feed additives.

If the participant stores products in silos he must prevent the build-up of material and the forming of condensation as much as possible.
a. the participant must record the release of silos clearly.
b. record of date of silo / tank empty report (minimum 1x per 3 months) [2].
If this is not feasible in practice then a company may in certain situations use a lower frequency of silo empty reporting. The reasons for this should be given. The company should realise that any recall will be larger in size because the period of time between two silo empty reports will be longer.
If this is not feasible in practice then a company may in certain situations use a lower frequency of silo empty reporting. The reasons for this should be given. The company should realise that any recall will be larger in size because the period of time between two silo empty reports will be longer.

6.3.2.3 Installations

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	8.3
PAS 222	4.5; 5; 7

Mixing installations

All mixing installations which are used for the production of feed must be appropriate for the range of weights or volumes to be mixed in order to obtain homogenous mixtures and dilutions. The participant must demonstrate the effectiveness of the mixing installations with respect to homogeneity. See the requirements in section 6.7.1.3.

Weighing / dosage equipment

The following must be clearly stated and recorded with respect to the installations:
a the minimum and maximum weight permissible for the weighing equipment or dosage equipment;
b the accuracy of the weighing or dosage installations.

Security must be applied such that the participant is sure that the weighed and/or dosed quantity of component is actually put into the feed (batch) for which it is intended.

If the participant makes use during production of dosage silos when filling these silos a proper locking system must be used.

[2] *For wet by-products from a continuous production process the date of silo empty reporting must be recorded. The time of silo empty reporting depends on the production process.*

Driers / drying installations
In the event of direct drying the participant must show by way of a risk analysis that the drying process leads to feed which comply with the product standards. Special attention is required for the choice of fuel. Undesirable substances (such as dioxins and PAHs) must not be able to contaminate the feed possibly as a result of the drying process.

Measuring devices on process equipment installations
Installations / equipment for heat treatment, chilling, freezer storage and freezing must be designed such that the required product temperatures can be reached and that the temperature can be kept low that the safety and soundness of the feed is maintained. The time and temperature must be registered.

If necessary, the equipment must be provided with effective resources for the control and recording of the humidity, air flow and other process parameters which may have a harmful influence on the safety and soundness of feeds.

Control of monitoring and measurement devices
All devices which are used for the dosing of - for example - feed materials must be calibrated at least once per year.

6.3.2.4 Other facilities

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	5; 8.3

6.4 Work environment

6.4.1 Maintenance

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.2
PAS 222	7.3

6.4.2 Cleaning

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	7; 11

Equipment which comes into contact with dry feed must be dried after wet cleaning or must be dry when they are to be used again.

6.4.3 Pest control

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	12

6.4.4 Waste control

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	6

6.5 Identification and traceability

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.9
PAS 222	-

The participant must record the following details for all products and services

a. Name and address details of suppliers and customers;
b. Date of delivery;
c. Type of product or service;
d. Product quantity;
e. Batch number where appropriate. This can also be designated as a manufacturer's batch number, a reference number, a batch number or a lot number.
f. production order of the whole production process including transport lines (from receiving raw materials up to and including delivery of the feed).
g. transport/ distribution details (if the participant is responsible for transport)

The participant should himself determine whether the recording of other details is necessary.

Retained samples:

In addition, within the framework of traceability, samples of the ingredients and of each batch of feed manufactured and put into circulation or of each specific portion of production in the case of continuous production must be taken in sufficient quantity by a procedure pre-established by the participant and be retained. This applies in any event if the participant receives and processes a feed so that this feed is sent out being no longer as it was received.

These samples must be sealed and labelled in such a way that they are easily identifiable. They must be stored in such a way that any change to the composition or any deterioration of the sample is excluded.

They must be kept available for the competent authorities for a period which has been matched to the use for which the animal feeds were put on the market.

In the case of animal feed for animals which are not intended for human consumption the participant must only keep samples of the manufactured animal feed (end product).

The participant may enter into written agreements with third parties on the taking and storing of samples. This may, for example, be applicable when the participant is not the manufacturer or the recipient of the product.

GMP+ BA13 *Minimum Requirements for Sampling* includes guidelines for sampling.

6.6 EWS and Recall

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.7; 7.10.3; 7.10.4
PAS 222	15

The participant has a documented procedure for the (early) signalling and treatment of signals which indicate that the safety of an animal feed might not match the statutory norms or the norms laid down in the GMP+ FC scheme and which might lead to damage to subsequent links in the chain. Signals will be assessed on this basis.

When an animal feed is discovered which does not comply with
a. the statutory provisions with respect to safety, or
b. usual trading quality, or
c. the essential requirements of the GMP+ FSA scheme.

then the participant will undertake the following actions:
a. immediately inform the customer,
   - In case of exceeding the maximum permitted level(s) of undesirable substances in feed as mentioned in legislation or/and GMP+ BA1 *Specific feed safety limits*, the customers must be informed within 12 hours after confirmation of the contamination.
   - In case of all other perceived non-conformities and irregularities (others than complaints, see GMP+ BA5) not controlled by the participant, which could have consequences for the customers, the customers must be informed, and
b. immediately block the animal feed or have it blocked, and
c. recall the animal feed and make sure that it stays outside the animal feed and livestock farming sectors,

unless the participant can demonstrate that the non-conformity is without harmful consequences for the health of animals or humans and that the statutory norms are not exceeded.

The participant needs to notify GMP+ International and the Certification Body in accordance with GMP+ BA5 *Minimum Requirements EWS*. If it is a legal obligation, the participant also needs to notify the non-conformity to the competent authority in the country or region of residence.

The participant must draw up a recall procedure for the above actions. After the establishment of the recall procedure then a recall simulation must be carried out within three months. The recall simulation must be repeated every year after this. The experience gained during this recall simulation should be recorded.

6.7 Production

6.7.1 Control of production

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7
PAS 222	4; 9; 10

6.7.1.1 Drying

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7
PAS 222	

Fuels specified in Chapter 5 of the GMP+ BA3 *Minimum Requirements Negative List,* may not be used in case of direct drying.

6.7.1.2 Dosage

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	9; 10

Premixes with coccidiostats and histomonostats and veterinary medical products must be added to the main flow of the compound feed as close as possible to or in the mixer but after the hammer mill or milling process.

6.7.1.3 Mixing and Homogeneity

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	7

The certified company must ensure that feed ingredients are mixed uniformly into a feed and that homogeneity remains after mixing.

Tests must be carried out to establish initial (= at first use) effectiveness of the mixing equipment. This equipment must be regularly checked - at time intervals determined by risk assessment - to ensure that no loss of efficiency occurs due to wear and tear. Findings of these tests must be retained as documented information.

The company must define minimum and maximum mixer volumes and mixing times to achieve a good homogeneity. These parameters can be based on the prescribed specification of the mixer manufacturer.

Note: Dry mixtures, containing critical feed additives and / or veterinary medicinal products, must comply with the conditions regarding homogeneity established in the document GMP+ BA2.

Guidance
Feed ingredients could be: feed materials, feed additives, premixtures and/or veterinary medicinal products.

Company takes into account requirements in feed legislation about homogenously mixed ingredients in feed at the moment of delivery. This means that the company assures that the ingredients are mixed uniformly in the feed and that homogeneity remains after mixing.

It's useful to remember that the homogeneity of mixtures can change if they are made of ingredients with different characteristics. Particles with for example different sizes, weight and/or shape will have greater tendency to segregate or not to mix properly.

~~The participant must ensure that feed materials and feed additives and veterinary medical products are mixed uniformly through the feed using the mixing equipment. He must ensure that:~~

~~a. the rate of feed of the mixer lies between established minimum and maximum volume values;~~
~~b. the mixing time amounts to an established and recorded minimum time;~~
~~c. the mixing time must begin once all the ingredients in the mixer have been dosed. The participant must provide the reasons for the chosen mixing time and rate of feed.~~
~~d. the dry mixtures produced comply with the conditions regarding homogeneity established in GMP+ BA2 *Control of residues*.~~

~~Guidance~~
~~After mixing, the ingredients in the mixtures should remain homogenously mixed.~~~~The homogeneity of mixtures can change when there are differences in the characteristics of the present ingredients in mixtures. Most important here are the differences in particle size or particle weight of the individual ingredients.~~

6.7.1.4 Pelletizing / Expansion / Extruding

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	7

In pelletizing / expansion / extrusion the conditions must be attuned to the stability of the processed feed additives and veterinary medical products, in accordance with the processing advice as provided by the supplier.

If the participant produces poultry feed, in which Salmonella-critical feed materials have been processed, a Salmonella killing step must be applied. See GMP+ BA4 *Minimum Requirements for Sampling and Analysis* with additional requirements for the use of Salmonella-critical feed materials.

6.7.1.5 Prevention of Cross contamination

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	7; 9

Certified companies must implement technical and organizational measures to avoid or minimise (cross-) contamination. These control measures must be based on a hazard analysis and must be validated and verified.

(Cross-)contamination via carry-over of critical feed additives and/or veterinary medicinal products must be prevented and/or controlled. See GMP+ BA2.

~~Based on a risk assessment, the participant must implement procedures to control the cross-contamination in order to meet the quality and safety standards. Special attention must be paid to control (legally) defined residue levels of substances.~~

~~Knowledge of the carry-over is necessary as part of Good Manufacturing Practices, and also to establish procedures for controlling cross-contamination.~~
~~Accepted methods to measure the carry-over are laid down in GMP+ BA2 *Control of residues*~~

~~*Guidance*~~
~~*A company must know the carry-over of his production facilities in order to decide if and how cross-contamination may influence the quality and safety of the produced feed.*~~
~~*As a result of carry-over, a part of the produced feed may end up in the next batch, thus introducing a risk that this next feed does not comply with quality and safety standards.*~~

~~*Especially when residue limits have been established by law or elsewhere*~~

~~Specific attention must be paid to the implementation of procedures to control residues levels of feed additives and veterinary medical products.~~

~~Specified residue standards and specific requirements, laid down in GMP+ BA2 *Control of residues*, must be met. The residue standards of feed additives and veterinary medical products, which are laid down in this appendix may not be exceeded. Next to this the participant must assure that all control measures must be validated and their effectiveness must be verified with an appropriate frequency.~~

~~In any event the carry-over must be known for production and transport lines in an installation on which (feed with) coccidiostats or histomonostats or veterinary medical products are processed, produced and/or transported.~~

~~The participant must record the production order used for production and transport lines.~~
~~NOTE: The production order relates to the whole production process from the receipt of the raw materials up to and including delivery of the feed and is particularly important for common transport routes and storage bunkers and silos.~~

6.7.1.6 Returns

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	14

6.8 Separation

The certified company must ensure that the non-GMP+ assured activities, processes, products or services do not have a negative impact on safety of the GMP+ assured feed. This must be supported by a HACCP analysis as described in chapter 7, and ensured by the Feed Safety Management System.

Guidance
Please keep in mind that when excluding a part from certification, it is vital to implement control measures that ensure a separation between the activities, processes, products or services that are subject to GMP+ certification and those that are excluded from certification,
Physical separation can be an effective control measure. Think of separate production lines, separate production areas and equipment. Organizational separation is also possible. Remember that the control measures are demonstrably effective in all cases.

7 Process control

7.1 Planning of the realisation of a safe feed

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.1; 7.3.1; 7.6.1
PAS 222	-

7.2 Requirements for the feed

7.2.1 Determination of feed requirements

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.6.1; 7.3.3; 7.3.4;
PAS 222	-

The requirements laid down in the GMP+ FSA module (see GMP+ BA1 *Specific feed safety limits* and GMP+ BA3 *Minimum Requirements Negative List*) must be met.

If the participant produces a feed material
a. for which there is no generic risk assessment in the Feed Support Products (FSP) of GMP+ International, or
b. using a method of production which does not correspond to a risk assessment which has already been included for the feed material

the participant must ensure that a risk assessment is included in the database in question. The above does not apply to feed materials which are only processed in feeds for non-food producing animals.

7.2.2 Review of feed requirements

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.3.3; 7.3.4
PAS 222	-

7.2.3 Description of the feed based on requirements (specifications)

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.3.3; 7.3.4; 5.6.1
PAS 222	17

7.2.4 Communication with the customer

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	5.6.1
PAS 222	-

7.3 Process information

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.3.5; 7.7
PAS 222	-

7.3.1 Flow diagrams of the process

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.3.5.1
PAS 222	-

7.3.2 Diagram of the organisation

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.3.5.1
PAS 222	-

7.4 Hazard analysis

7.4.1 Identification of hazards

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.4.1; 7.4.2
PAS 222	-

The HACCP team must identify and record all potential hazards which may have a negative effect on feed safety. The hazard identification is also based on the generic risk assessment from the Feed Safety Database (if applicable).

7.4.2 Risk assessment

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.4.3
PAS 222	-

7.5 Establishment of Critical Control Points (CCP's)

7.5.1 Determination of control measures

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.4.4
PAS 222	-

7.5.2 Establishment of Critical Control Points (CCP's)

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.6.2
PAS 222	-

7.6 Standards

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.6.3
PAS 222	-

There must be compliance with the product standards (GMP+ BA1 *Specific feed safety limits*) and residue standards (GMP+ BA2 *Control of residues*).

7.7 Monitoring and measuring

7.7.1 Monitoring plan

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.6.4
PAS 222	-

The monitoring plan must at least be in accordance with the requirements as laid down in GMP+ BA4 *Minimum requirements for Sampling and Analysis*.

If measurement and monitoring takes place by way of an analysis, the GMP+ participant ensures this is done by a laboratory approved for this under the GMP+ FSA module. See GMP+ BA10 *Minimum Requirements for Purchasing*.

7.7.2 Monitoring plan (supplementary for processing of feed additives / veterinary medical products

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.6.4
PAS 222	7; 9

The participant must validate the system of residue control, which will be implemented, and must verify on continuous effectiveness periodically after implementation.

7.8 Corrective actions

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.6.5; 7.10.1; 7.10.2
PAS 222	-

7.9 Validation of the HACCP plan

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.8; 8.2
PAS 222	-

7.10 Purchasing

7.10.1 Purchasing process

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	8; 18

The participant must ensure that purchased feed and services comply with the specified purchasing requirements. This is established in a documented procedure.

The method of control which is used on the purchased product and the supplier must be dependent on the effect of the purchased product on subsequent product realisation or on the feed (end product).

The participant must assess suppliers and choose those suppliers who are able to deliver a product which complies with the requirements of the participant.

At least the following requirements must be met with respect to the above.

a. The participant purchases products or services for which there is a GMP+ standard only from suppliers who are GMP+ certified at the moment of delivery;
b. Contrary to a., the participant may also take products or services from suppliers which are certified based on a standard approved in the GMP+ FSA scheme;.0
c. Contrary to a., certain products and services may also be bought without one of the above certificates. Separate requirements have been established for this.

In GMP+ BA10 *Minimum Requirements for Purchasing* there are details of the above options.

c Prior to the purchase of other products (other than feed) or services[3] (other than storage and transshipment, transport or laboratory) the participant must carry out its own risk assessment based on HACCP principles. Based on this risk assessment and also the quality assurance, which is applied by the supplier, the participant must make a selection of suppliers and must adjust his (entry) check accordingly.

From each type of feed material be purchased or received, there must be a generic risk assessment in the Feed Support Products. If it is a feed material for which there is no risk assessment in the Feed Support Products of GMP+ International, the participant must first offer a risk assessment to GMP+ International for inclusion in the database referred to. Only after inclusion in the database may the feed material be sold or received.

7.10.2 Purchasing data

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	8.1

Purchasing data must describe the product or service to be purchased. This includes in any event and where applicable a description of:

a. required status of the product or service. If the participant wants to purchase an assured product or service (GMP+ assured or equivalent), it is his responsibility to demonstrably communicate this with the supplier.

[3] *Which may (can) not be covered under a GMP+ standard because, for example, no GMP+ standard has been established.*

This is –of course- not applicable when an accepted gatekeeper option for purchasing is applied. See for this GMP+ BA10 *Minimum requirements for Purchasing.*

7.10.3 Verification of the purchased product or service

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	-
PAS 222	8.3

The participant must also check that the transport complies with the stated requirements (as a minimum a check on: the GMP+ certification of the carrier, compliance with the requirements with respect to loading sequence, previous loads and implementation of the necessary cleaning regimes). If the result of the inspection is positive, the loading compartment is approved for the transportation of feed.
This inspection must be carried out by a loading inspector. A 'loading inspector' is a position which is specified in the quality system of the participant.
This role is fulfilled by an employee who, on the basis of training and experience, has the knowledge and skills required for the inspection of a loading compartment for its suitability for the loading of feed.

The LCI reports for all received sea transport, short sea shipping, inland waterway transports or rail transport should be available or retrievable.

The participant will ensure that veterinary medical products are received and processed in accordance with the statutory provisions.

7.11 Production

7.11.1 Customer property

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.2
PAS 222	-

The participant must be careful with the property of the customer when it is under the control of or used by the participant.

The participant must establish, verify, protect and store the property of the customer when it is delivered for use or is part of the product. If any customer property is lost, damaged or is otherwise considered to be inappropriate for use this must be reported to the customer and records must be kept of this (see 4.2.4).

The participant must control, handle, assess and secure the property of the customer throughout the production process in the same way as its own products (in accordance with the requirements of this GMP+ standard).

7.11.2 Maintenance of the product

Relevant ISO 22000 / PAS 222 requirements	
ISO 22000	7.2
PAS 222	8.3; 16

7.11.3 Labelling and delivery

Relevant ISO 22000 / PAS 222 requirements	
ISO 22000	-
PAS 222	16; 20

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

When the participant is responsible for the transport he must provide the carrier with 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.

8 Measurement, analysis and improvement

8.1 General

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	8.1
PAS 222	-

8.2 Internal audit

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	8.4.1
PAS 222	-

The internal audit must be planned at a minimum audit frequency of 1x per 12 months.

8.3 Verification of the feed safety management system

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	8.4.2; 8.4.3
PAS 222	-

Verification with a minimum frequency of 1x per 12 months

8.4 Improvement

8.4.1 Continual improvement

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	8.5.1
PAS 222	-

8.4.2 Corrective action

Relevant ISO 22000 / PAS 222 requirements

ISO 22000	7.10.2
PAS 222	-

8.4.3 Preventive action

Relevant ISO 22000 / PAS 222 requirements	
ISO 22000	5.7; 7.2
PAS 222	

The participant must determine measures to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions must be appropriate to the effects of the potential problems.

A documented procedure must be established to record requirements for:
a. determining potential non-conformities and their causes;
b. evaluating the need for action to prevent non-conformities;
c. determining and implementing action needed;
d. records of the results of action taken (see 4.2.4), and;
e. reviewing preventive action taken.

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