



# **GMP+ Feed Certification scheme**

В

Module: Feed Safety Assurance

# GMP+B3

Previous B3(2007)
Trade, collection and storage & transshipment

3

Version: 1st of April 2016

**EN** 

© GMP+ International B.V.

All rights reserved. The information in this publication may be consulted on the screen, downloaded and printed as long as this is done for your own, non-commercial use. For other desired uses, prior written permission should be obtained from the GMP+ International B.V.

GMP+ International info@gmpplus.org www.gmpplus.org

# History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implemen- tation date
0.0 / 09-2010	Previous versions can be found in History		01-01-2011
0.1 / 09.2010	Trevious versions can be lound in <u>riistory</u>		01-07-2011
0.1 / 09-2011	-		01-01-2012
0.1 / 09-2011	-		01-01-2013
0.2 / 11-2012	-		01-03-2013
1.0 / 06-2014	Editorial changes:	Entire	01-03-2015
1.0 7 00 2014	All editorial changes are listed in a <u>factsheet</u>	Document	01 01 2010
	Chapter 2 has been updated. Emphasized is that GMP+ FSA requires the implementation of a management system to assure the feed safety, as defined in applicable legislation and GMP+ FSA standards	2	01-01-2015
	The requirements regarding the notification of contamination in feed towards customers and in the framework of the EWS has been updated.	5.5	01-01-2015
	Requirements for specification of the status of the feed product or service to be purchased has been updated.	7.1.2.1	01-10-2015
	Deleting a part of the chapter 7.3.1 and the entire chapter 7.3.2 and replacing them by reference to GMP+ B4.	7.3.1 7.3.2	01-01-2018
2.0 / 11-2015	Following the editorial changes in B1, B2 dated 1-6-2015	Entire Document	01-06-2015
	Requirements for specification of the status of the feed product or service to be purchased has been amended.	7.1.2.1	01-04-2016
	The FSP list is not applicable for feed for non-food producing animals.	6.3.1	01-04-2016
	References to GMP+ B4.1, B4.2, B4.4. and B4.5 are deleted as these standards are abolished per 31-12-2015.	7.3.3	01-04-2016

# **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.

# **INDEX**

1	INTRODUCTION	5
	1.1 GENERAL	5
	1.2 STRUCTURE OF THE GMP+ FEED CERTIFICATION SCHEME	5
	1.3 SCOPE AND APPLICATION OF THIS STANDARD	6
	1.4 THE STRUCTURE OF THIS STANDARD	9
	1.5 EXCLUSION OF REQUIREMENTS	10
2	FEED SAFETY MANAGEMENT SYSTEM OBJECTIVE	11
3	TERMS AND DEFINITIONS	11
4	FEED SAFETY MANAGEMENT SYSTEM	12
	4.1 MANAGEMENT RESPONSIBILITY	12
	4.2 PERSON RESPONSIBLE FOR QUALITY	12
	4.3 REQUIREMENTS FOR THE FEED SAFETY SYSTEM	13
	4.4 DOCUMENTATION AND REGISTRATION	15
	4.4.1 Documentation and Quality Manual	15
	4.4.2 Administration of documentation and data	15
5	PREREQUISITES PROGRAMME	17
	5.1 PERSONNEL	17
	5.1.1 General	17
	5.1.2 Competency and training	18
	5.2 Infrastructure	
	5.2.1 Environment	
	5.2.2 Production areas and equipment	
	5.2.3 Access control	
	5.2.4 Other requirements	
	5.3 MAINTENANCE AND HYGIENE	
	5.3.1 Maintenance	
	5.3.2 Maintenance of measuring equipment	
	5.3.3 Cleaning5.3.4 Prevention and control of pest	
	5.3.5 Waste management	
	5.3.6 Glass and breakable materials	
	5.4 IDENTIFICATION AND TRACEABILITY / SAMPLING	
	5.4.1 Identification and traceability	
	5.4.2 Sampling	
	5.5 EWS AND RECALL	
6	HACCP	29
	6.1 PLANNING OF THE REALIZATION OF SAFE FEED	20
	6.2 HACCP TEAM	
	6.3 DESCRIPTION OF PRODUCTS AND PROCESSES	
	6.3.1 Determination of requirements	
	6.3.2 Specification of feeds	
	6.3.3 Description of the process	
	6.4 HAZARDS ANALYSIS	
	6.4.1 Identification of hazards	
	6.4.2 Risk estimation	
	6.5 ESTABLISHMENT OF CONTROL MEASURES AND CCPs (CRITICAL CONTROL POINTS)	34
	6.5.1 The establishment of specific control measures	

Version: 1st of April 2016

6.5.2	Determine the critical control points (CCPs)	34
6.6	DETERMINATION OF STANDARDS	34
6.7	Monitoring	34
6.8	CORRECTIVE ACTIONS	36
6.9	VALIDATION AND VERIFICATION	36
6.9.1	Validation	36
6.9.2	Verification	37
7 CON	TROL OF OPERATIONAL ACTIVITIES	38
7.1	TRADE IN FEEDS	
7.1.1	General	38
7.1.2		
7.1.3		
7.1.4	Verification of the purchased product	40
7.1.5		41
7.1.6	Sale and contracts	41
7.1.7	Labelling and delivery	42
7.2	STORAGE	42
7.2.1		
7.2.2		43
7.2.3	<b>5</b> 1	
7.2.4	Cleaning / sieving / filtering	45
7.2.5	, 5 9	45
7.2.6		_
7.2.7		
7.2.8	Storage as a service for third parties	48
7.3	Transport	49
7.3.1	General	49
7.3.2		
7.3.3	Road transport carried out by a subcontractor	50
7.3.4	Transport via inland waterway, by sea and by train	50
7.3.5	Transport for which third parties are responsible	52
8 VER	FICATION AND IMPROVEMENT	53
8.1	COMPLAINTS	53
8.2	INTERNAL AUDIT	53
	ASSESSMENT OF THE MANAGEMENT SYSTEM AND IMPROVEMENTS	
ANNEX 1	: FUELS	55

# 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).

<u>GMP+ Feed Safety Assurance</u> 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 <u>GMP+ Feed Responsibility Assurance module</u>, 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.

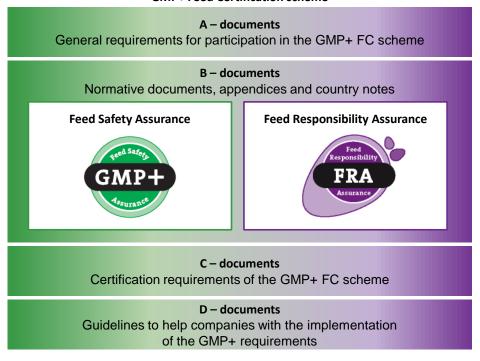
Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. Certification bodies are able to carry out GMP+ certification independently.

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:

**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+ B3 *Trade, collection and storage & transshipment* and is part of the GMP+ FSA module.

#### 1.3 Scope and application of this standard

This standard contains the requirements for a feed safety management system for the quality assurance of:

 <u>Trade in feed.</u> This includes trading in all types of feed (compound feed, premixtures, feed additives and feed materials) and varies from internationallyoriented trading in, for example, feed materials or feed additives, through to the trading of crude feeds and other straight feeds (usually to be supplied to livestock farmers).

# Guidance:

If the trader also physically receives and stores feeds then he must be certified for these activities. See below at 2. Storage and transshipment of feeds.

2. Storage and transshipment of feeds. Activities can be certified within this scope which are normally carried out by a storage & transshipment company. This includes, on the one hand, (basic) activities such as intake, cleaning, drying, the actual storage, ventilation and delivery. Specific requirements for these steps are included in a number of separate sections.
Storage & transshipment companies sometimes also carry out other activities

within the framework of 'good storage practice'. These must of course be controlled on the basis of HACCP principles. Use is not made of many separate sections for this but of a single section with requirements.

GMP+ B3 Trade, collection and storage & transshipment

#### Guidance:

An important question is which activities are included within the scope 'Storage & transshipment of feed'. Within GMP+, in addition to the 'basic activities' specified above, the scope Storage & Transshipment also includes the activities related to the processes specified below:

- Conservation and silage / acidification for longer storage life
- Chopping of crude feeds
- Packaging of crude feeds in bales
- Crushing or breaking of grains, seeds or legumes including any subsequent packaging of these products
- Dehulling
- Addition of water to, for example, molasses during storage
- Mixing of two equal feed materials for standardization or to increase the batch size. (Note: Mixing of undesirable substances for dilution purposes is prohibit-
- Bulking of feeds (such as dumping bagged goods into a bulk wagon or loading compartment, filling in barrels/IBC containers, from IBC containers to loading compartments, etc.)

Not included in Storage & Transshipment are:

- Mixing of feed materials and/or feed additives for, for example, compound feed or premix (such as the mixing of fats);
- Production of a feed material as a by-product of food production These activities are designated as production. Other GMP+ standards apply to this.

# Guidance:

In this standard, use is often made of the words 'storage' and 'storing'. Where relevant, this should be taken to mean 'storage & transshipment' or 'storing & transhipping' respectively.

Collection or the collecting trade can be described as the purchase, storing or selling on of primarily vegetable primary products such as grains, oil seeds, crops or legumes containing protein, tuber and root crops. A collector (usually) purchases directly from the growers. A collector should be certified for the scope Trade in addition to being certified for the scope Storage & Transshipment. It is permitted also to include the designation Collection on the certificate. Please refer to the certification requirements in question.

Storage and transshipment activities may be carried out by for example a trader for his own products. In addition, a company which stores and/or tranships feeds as a service for third parties may also apply this standard. In such a case the responsibilities are then different. See also section 7.2.8.

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

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 for a third party.

GMP+ B3 Trade, collection and storage & transshipment

If a participant carries out activities involving 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.

A company can also trade and store products for use in another sector such as food or fuel. It is not a problem with respect to quality assurance if a single control system is used which as a minimum complies with the requirements of this standard.

However, a company should realise that the focus in this standard lies on controlling the specified activities for the feed sector. Other sectors may set other (statutory) requirements. A company must specify the additions itself and show that there is compliance with them. In addition, the exclusion of GMP+ requirements is not possible other than in accordance with that which is laid down in section 1.5.

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 various risks and the associated control measures are. A participant may include these control measures in prerequisite programmes or carry them out as a specific measure to control a particular critical point. This standard also requires inspections and checks.

The participant remains responsible at all times for the safety of the feeds and activities and for the checks on compliance with the requirements which he carries out himself. Compliance with the requirements of this standard and being certified accordingly allows the participant to demonstrate the safety and quality of his services or feeds to third parties.

Irrespective of the obligations arising from this standard, the participant must only market feeds which are healthy, sound and of normal trading quality. There must, in all cases, be compliance with the statutory requirements.

The participant will not introduce any feeds to the market which represent a danger to the health of humans or animals or for the environment. The participant must also avoid introducing feed into the market in a way which could be in any way misleading.

# Guidance:

In this standard the word 'feed' is often used. This includes:

- a. compound feeds,
- b. premixtures,
- c. feed materials, and
- d. feed additives.

Version: 1st of April 2016

See also GMP+ A2 Definitions and Abbreviations for the definitions.

Account should be taken of this when reading and applying this standard. If requirements only relate to feed materials, for example, then this term will be used as such.

GMP+ B3 Trade, collection and storage & transshipment

**GMP+** International

#### The structure of this standard

The feed safety management system requirements have been placed in Chapter 4. Chapter 5 contains the requirements for a number of prerequisite programmes. These programmes are essential for establishing a basic level of hygiene. Chapter 6 provides the minimum HACCP requirements.

Additional requirements for the control of a number of operation activities are included in Chapter 7. Finally, the conditions and requirements for verification and improvement are to be found in Chapter 8.

#### Guidance

Guidance has been included for a number of requirements in this standard. This guidance is in a separate light green box starting with the word 'Guidance'. The guidance does not include mandatory 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 to clearly distinguish between the guidance boxes and the mandatory requirements, the guidance boxes will preferably make no use of the word 'must'. This is, by the way, not always the case. Where the word 'must' or 'should' is nevertheless used it must read as guidance relating to the requirements set.

Note: Please note: In contrast to the green boxes, the white boxes do contain conditions. These conditions must be regarded as details of the conditions above these boxes.

The structure of this standard corresponds to that of a number of other GMP+ standards. The requirements in a number of general chapters are the same with respect to content as those in this standard although they are not described in such detail in all standards. This depends on the scope of the standard. Because every standard is written for a specific target group, some of the wording used to describe the requirements in these general chapters may differ a little. This has been done to increase the link to the target group as much as possible.

#### Guidance

The general chapters are chapters 4, 5, 6 and 8.

The structure of GMP+ B3 Trade, Collection and Storage & Transshipment is, for example, identical to that of GMP+ B2 Production of Feed Ingredients. The GMP+ B2 standard is intended for producers.

The words 'production' and 'to produce' therefore occur regularly in this standard. The GMP+ B3 Trade, Collection and Storage & Transshipment standard is intended for collectors, storage companies and traders. The words 'production' and 'to produce' are avoided as much as possible in this standard and words such as 'trade', 'storage' and 'collection' occur much more frequently.

A company which, for example, produces a feed material and also trades in feed materials (meaning feed materials which are produced by third parties) can apply both standards in combination. A combined application is quite simple to achieve because of the identical structures and because a number of chapters are identical with respect to content. The company should be alert to completeness in the application of a second standard or should check whether any extra measures are necessary for the second activity.

GMP+ B3 Trade, collection and storage & transshipment

Version: 1st of April 2016

<u>GMP+ Appendices</u> (designated as GMP+ BAxx), to which there are also references, are separate GMP+ documents within the B series which are not attached to this standard. If there is a reference 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 services which do not comply with feed safety as laid down in the GMP+ Feed Safety Assurance 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 too small.

#### Guidance

The above must not be read in contradiction with the possibility to trade non-GMP+ feed. This is possible if the relevant requirements are met. See paragraph 4.3.

Companies sometimes have trouble implementing certain requirements. A common remark is that this particularly applies to small companies and especially with respect to some 'management system requirements' such as the management statement, document management, internal audit, management review, etc. A deliberation choice was made in this standard to make all the requirements mandatory for smaller companies as well and not to exclude any of these requirements in principle. This might have suggested that quality assurance was at a lower level in smaller companies.

In addition, the GMP+ FSA module assumes the control of risks through the application of HACCP principles. The management system required is therefore supportive and serves to ensure that the risks are properly controlled on a continuous basis. It does not matter whether these risks occur at smaller or larger companies, they must always be controlled at the level desired by GMP+. A simple company structure and a clear, simple and transparent business process may mean that the management system requirements are implemented in a different way.

The auditor also has a certain freedom to assess in which the basic principle is and continues to be that the system used is able to control the risks.

A number of guidance boxes in this standard provide suggestions for how a small company can meet a particular requirement. Also, as an aid, a number of examples of the implementation of requirements in this standard are provided in GMP+D2.6 'Guidance documents for specific GMP+ application'". The participant is free to use these (modified if necessary in accordance with his own situation).

GMP+ B3 Trade, collection and storage & transshipment

# 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+appendix, 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 a 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.gmpplus.org)

# 3 Terms and definitions

See GMP+ A2 Definitions and Abbreviations for definitions.

# 4 FEED SAFETY MANAGEMENT SYSTEM

### 4.1 Management responsibility

Management must be aware of its responsibility for feed safety. Feed is part of the food chain.

# Management must:

- a. Make the organisation aware of the importance of feed safety and of compliance with both the requirements of this GMP+ standard, the obligations of the feed legislation and the requirements of the customer.
- b. Record specific policy objectives with respect to feed safety in writing in a statement of policy.
- c. Demonstrate its responsibility and involvement in the development and introduction of the feed safety management system to achieve safe feed.
- d. Put together a HACCP team.
- e. Ensure that resources and manpower are available. Management must itself determine what resources are necessary for the guaranteeing of safe feed and ensure that these resources are also available. There must at least be compliance with the requirements of this standard.
- f. Assess at least once per 12 months whether the feed safety management system is still suitable and effective. See section 8.3 for details of such a management assessment.

#### Guidance

Feed safety is mostly expressed in standards for undesirable substances. See the relevant legislation and GMP+ BA1 Specific feed safety limits.

For more information on customer requirements refer also to section 6.2.

By resources is meant, among other things, the infrastructure (buildings, work areas and facilities), personnel and other means which are required for a suitable feed safety system. See chapter 5 for this subject.

#### 4.2 Person responsible for quality

Top management will appoint a person who, irrespective of other responsibilities, will have the responsibility and authority:

- a. to establish a feed safety management system and to implement it and maintain it in accordance with this standard, and
- b. to report to top management on the results of the feed safety management system and any need for improvement, and
- c. to ensure that the awareness of feed safety is promoted throughout the whole organisation.

# 4.3 Requirements for the feed safety system

The participant must establish, document, implement and maintain a feed safety management system in accordance with the requirements of this standard. The feed safety management system must be modified in accordance with changing legislation and in accordance with other developments related to safety. The feed safety management system must ensure that all activities which may have an influence on the safety of feeds are thoroughly defined, implemented and complied with in the organisation.

The participant must determine and document the scope of the feed safety management system by establishing which feeds, activities and locations are covered within the scope of the system. The scope must in any event include all feeds and all activities related to the feeds for which the participant is responsible. In addition, the participant must lay down the objectives for the improvement in feed safety.

The participant shall determine:

- a. The part of the chain for which the participant is responsible. This begins where the responsibility for the previous link (the supplier) ends and ends where the responsibility for the following link in the feed chain begins.
- b. Feeds (in specifications) which are collected, stored and/or traded.
- c. Activities relating to the collection, storage and/or trading of feeds. This includes activities which are outsourced to third parties.
- d. Relevant locations. These include those locations where the relevant administrative work is carried out.

If a participant decides to contract out an activity which possibly has an influence on feed safety then the participant must ensure that this activity is also carried out in accordance with the requirements of this GMP+ standard. In some cases certification is required. See GMP+ BA10 *Minimum Requirements for Purchasing*.

The participant must also describe all other relevant activities and/or products which are not related to feed. The participant must ensure that these activities can not exert any negative influence on the safety of the feeds.

It is possible to trade non-GMP+ certified feed on the condition that:

- This non-GMP+ certified feed is processed, stored and/or transported separately and that this has absolutely no influence on the safety of GMP+ certified feed.
- b The participant will in his records make a clear and demonstrable distinction between the GMP+ certified feed and the non-GMP+ certified feed.
- c There is compliance with the labelling requirements for the non-GMP+ certified feed.

In addition to GMP+ certified storage, it is possible to have non-GMP+ certified storage of feed or storage of non-feed. The conditions for this are the following:

- a This non-GMP+ certified storage is separate from the GMP+ certified storage so that this has absolutely no influence on the safety of the GMP+ certified storage. This must be supported with a hazards analysis.
- b The participant determines, also on the basis of a hazards analysis, whether the use of common transport facilities forms a risk to the safety of the GMP+ certified storage.

GMP+ B3 Trade, collection and storage & transshipment

Version: 1st of April 2016

- A major point for attention is possible contamination as a result of carry-over. Where necessary the participant must establish the degree of carry-over and take proper control measures.
- The participant will in his records make a clear and demonstrable distinction between the GMP+ certified storage and non-GMP+ certified storage. The status of products ('feed' or 'non-feed' and also 'GMP+ certified' or 'non-GMP+ certified') must be clear.

The participant must control the above with his feed safety system.

#### Guidance

The scope of the feed safety management system contains the following elements, among others:

- a The selection of suppliers and the purchase of raw materials and feeds
- b All transport and storage activities for which the participant is responsible
- All other process steps which are purchased or controlled by the participant such as planning, purchasing, (interim) storage, internal transport, sales and packaging.

The structure of the feed safety management system relates specifically to the organisation of the participant and contains, in any event, a statement of the quality policy and the quality objectives (see section 4.4), the requirements and the procedures for maintaining the safety of the feeds.

The description of all activities may result in the participant having to apply a second or perhaps a third standard in addition to this standard. The participant can also decide to apply the GMP+ B1 Production, Trade and Services instead of a number of sub-standards. In the event of any doubt it is advisable to consult the certification body and the website of GMP+ International also provides more information (www.gmpplus.org).

Not all products and services to be purchased have to be GMP+ certified. For this see purchasing requirements in GMP+ BA10 Minimum Requirements for Purchasing.

Activities and/or products which are not related to feed are, for example, storage of fuels or paint, agricultural vehicles, wood, etc.

A trader may also trade in non-GMP+ feeds as long as he is sure that they are and remain clearly identified and separated from GMP+ certified feeds. The idea behind this is that a customer who wants GMP+ feeds also gets them. Likewise, a storage company can also store GMP+ feeds in addition to non-GMP+ feeds. Here too the requirement for (physical) separation applies such as in a separate part of the site, separate silo's or separate sheds. Ensure by way of the feed safety management system that any mixing or interchange is excluded. In the event of the use of common pipelines or other transport systems, an assessment should be made of whether there is a risk of undesired mixing or contamination such as a result of carry-over and measures should be taken if necessary to control this.

#### 4.4 Documentation and registration

# 4.4.1 <u>Documentation and Quality Manual</u>

The participant must draw up and implement procedures and instructions which include the requirements of this standard.

The documentation of the feed safety management system must in any event contain the following elements or must refer to them:

- a. Quality policy including the objectives for feed safety
- b. Description of the scope of the feed safety management system as required in chapter 4.3
- c. All relevant permits, registrations and certificates in accordance with national and international legislation
- d. HACCP documentation
- e. All the procedures, instructions, registration forms and suchlike which are required for this standard and/or which are necessary for the feed safety management system.
- f. All details relating to process, handling, audits and inspections and all other reports which are required for this standard. This register must be set up and maintained as evidence of compliance with the requirements and of the effective operation of the feed safety system.

These documents, instructions, forms, etc. must have a clear structure.

#### Guidance:

Relevant permits, registrations or certificates may, for example, include the statutory permits for collection, storage & transshipment, trade or export.

Procedures etc. may be part of a structured and/or certified feed safety management system (for example ISO-9001 or HACCP). In addition, these procedures may be part of a national regulation or a sector or company regulation in which comparable control is ensured. These same procedures may of course be used as far as they are required in this GMP+ standard.

The layout and structure of the quality documentation which is necessary and which is required in this standard such as (documented) procedures, instructions, forms, documenting of data, etc. may be harmonised with the nature of the activities to be assured, the size of the company and the level of training and expertise of the employees.

#### 4.4.2 Administration of documentation and data

The documents and data must be controlled. They must be archived and retained in the correct fashion.

This means that the documentation:

- a. Must be kept up to date
- b. Must be approved and assessed at least every year by the authorised person. In this assessment attention must in any event be paid to any changes to the legislation and/or changes to the GMP+ FSA scheme
- c. Must always be available and must be understandable to the members of the staff who have to implement the requirements of the procedure

d. Must be amended if changes have taken place which have a direct effect on the activities of the participant.

The participant must ensure that all documentation and data:

- a. Is retained for a period of at least 3 years unless a longer retention period is prescribed by law.
- b. Are kept such that any deterioration in the condition or damage to the documentation and data is prevented.
- c. Are stored in such a way that they can be retrieved in full and with ease.
- d. Are fully legible.

#### Guidance:

Documentation may also be made available, administered and archived in digital form.

The aim is for the participant to show that procedures have been implemented which guarantee continual agreement with (amended) legal provisions and any other information which is relevant to the feeds collected, stored and/or traded by the participant.

Information relating to safety aspects which influence business operations must be effectively transferred to the personnel responsible for the relevant work. Changes to practice or procedures which are necessary due to new information must be implemented effectively.

Where documents are part of a manual, the participant may decide, for example, only to sign the table of contents with the current version numbers of the individual documents.

The annual assessment of the documentation may be part of the internal audit. See section 8.2.

# 5 Prerequisites programme

In order to be able to apply the HACCP principles successfully, the participant must establish and apply a general basic prerequisites programme for various parts of the business operation in accordance with this chapter. If this is not sufficient then the participant must detail and implement additional prerequisites. The participant may implement additional prerequisites. The participant may exclude prerequisites as long as reasons are given.

# Guidance

HACCP: There is a manual available to assist companies in the identification, evaluation and control of hazards which relate to food and feed safety. This manual is available on the website of GMP+ International (www.gmpplus.org).

A prerequisites programme establishes the necessary environmental and hygiene conditions by which the collection, storage and/or trading of feeds can be properly controlled. See Codex Alimentarius.

The prerequisites programme is part of the HACCP plan and is subsequently included in the internal audit planning which is determined as part of the HACCP plan.

A trader who trades in feeds but does not obtain them physically can skip a number of sections (5.2 and 5.3) in this chapter because these relate to physical handling within the framework of collection or storage. The relevant sections for a trader are 5.1, 5.4 and 5.5. See also the following table.

Section	Trade	Storage
5.1 Personnel	Χ	X
5.2 Infrastructure		Χ
5.3 Maintenance and Hygiene		Χ
5.4 Identification and traceability	Χ	Χ
5.5 EWS and Recall	Χ	Χ

#### 5.1 Personnel

# 5.1.1 General

All employees must be aware of their responsibility for feed safety.

#### There must be:

- a. an organization chart, and/or
- b. a description of the tasks of individual employees (or a task description for a group of employees in the same job) and proof of the qualifications of the employees (even if these are temporary employees).

This is only necessary for relevant functions within the framework of feed safety.

All relevant employees must be demonstrably aware of their tasks, responsibilities and authority with respect to the maintenance of feed safety. This information must be modified if considerable changes occur.

Protective clothing must be worn wherever contamination of feed by personnel is identified as a risk by the risk assessment study. All clothing and equipment must be kept in proper hygienic condition.

Clear rules must be established with respect to eating, drinking and smoking if this can have a negative effect on the quality of feeds. This must be clearly indicated to both employees and visitors (including personnel from third parties). If necessary there must be separate facilities available.

In addition, the participant must demonstrably ensure that (technical) personnel from third parties are instructed that during work at the premises these activities may not have a negative effect on feed safety. The participant must ensure that the area in question is satisfactorily cleared up and cleaned before work is resumed.

#### Guidance

Providing If task descriptions give provide sufficient insight into the company organisation, then it is not necessary to include an organizational chart in the personnel dossier.

By task descriptions is primarily meant the description of the tasks which can influence feed safety. Making aware of tasks can, for example, mean the provision of instructions on the work to be carried out.

Examples of qualifications might be education or training, diplomas and a list of professional experience.

The demonstrable instruction of (technical) personnel from third parties may also be important with respect to insurance matters in the event of a claim.

# 5.1.2 Competency and training

Employees who carry out activities which may have an influence on feed safety must be competent to carry out those activities. Their level of competence will depend on their relevant education, training courses and experience. The participant must have sufficient personnel with the skills and qualifications necessary for the collection, storage and trading of safe feed.

#### The participant must:

Version: 1st of April 2016

- a. Establish the skills required by employees for their work and which may play a role in feed safety. This also applies to the HACCP team.
- b. Offer training or take other measures to meet these needs.
- c. Maintain personnel dossiers of training courses, education, skills and experience.

The above also applies to temporary personnel.

#### 5.2 Infrastructure

#### 5.2.1 Environment

The collection and storage of feeds must be carried out in an environment in which contamination by potentially hazardous substances cannot lead to unsafe feed.

If an environment entails a risk to feed safety then the participant must demonstrate by way of a hazard analysis that the hazards are satisfactorily controlled.

#### Guidance

In buildings where feeds are stored, external influences may clearly not form a hazard to feed safety. These include contaminated soil, proximity to rubbish dumps, waste incinerators, etc. The participant can use a hazard analysis to determine whether the environment entails a danger to feed safety.

#### 5.2.2 Production areas and equipment

#### 5.2.2.1 General

The production areas and equipment must be designed, constructed and maintained such that the safety of the feeds is guaranteed at all times. Attention must be paid to the prevention of negligent and unintentional contamination of feeds.

Building must where necessary be designed and constructed so that:

- a. accumulation of dirt is prevented
- condensation and undesired growth of mould is restricted as much as possible
- falling dust particles and feed remains from plant or equipment is limited as much as possible
- d. cleaning, disinfection and maintenance can be carried out properly
- e. the chance of birds and other animals penetrating is minimised
- f. third parties are not able to enter the buildings without reason.

The production areas must ensure that:

- a. the chance of errors is limited as much as possible and other harmful effects on the safety of the feeds is prevented as much as possible
- b. there is no confusion of the various feeds, the feeds are properly identified and no improper use of the feeds can take place
- c. proper physical and organisational separation is applied and maintained of products which are intended for use as, on the one hand, feeds and, on the other hand, may have a harmful effect on the health of humans, animals or on the environment.

This separation is intended as a safety measure so that feeds cannot come into contact with, or can be mixed with, other products.

The production areas must be provided with suitable natural or artificial lighting to ensure that cleaning, control and other activities which play a role in the safety of feeds can be carried out effectively.

The roofs and ceilings must be designed, constructed and maintained such that the accumulation of dirt is prevented and the quantity of condensation, mould growth and falling dust is minimised to prevent any harmful influence on the safety of the feed.

Sewer, waste, rain and melt water must be removed in such a way that the plant and the safety of the feeds cannot be subjected to any harmful effects.

Contaminants resulting, for example, from leaks must be avoided as much as possible and must be resolved as quickly as possible.

The drainage facilities must be fit for purpose. These must be designed and constructed with a view to avoiding any risk of the feed being contaminated.

#### Guidance

Examples of products which can have a harmful effect on the health of humans and animals and also on the environment are artificial fertiliser, seed decontaminants, fuel, lubricants, cleaning agents and disinfectants, glass, crop protection agents, waste.

A physical and organisational separation of products to prevent the mixing of feeds which can have a harmful effect on the health of humans, animals and on the environment can be achieved by the participant as he sees fit on the basis of a hazard analysis.

#### 5.2.2.2 Production areas for reception, loading and unloading

There must be suitable areas for the reception and the loading and unloading of feeds and of potentially hazardous products (such as cleaning agents, lubricants, fuels and suchlike).

During the reception or loading and unloading of goods, the participant must do everything which is reasonably possible to avoid the risk of contamination and that, for example, bad weather cannot have an influence on the feeds to be loaded

# <u>Guidance</u>

Transshipment facilities must be constructed in a way that the quality and safety of the feeds is guaranteed at all times. This must preferably be guaranteed by use of closed transshipment equipment (no open transshipment). If this is not possible, sufficient control measures must be taken to avoid contamination. An exception to this is the unloading and loading of seagoing vessels, short sea shipping, motorised and inland waterway vessels and barges or lighters. The unloading takes place using a crane, a conveyor belt or a pneumatic unloading system and the loading takes place using a crane or pipe loading system. The direct loading or unloading process is for technical and nautical reasons not possible in a closed system. In order also to guarantee the safety and quality of the feed material in this form of transport, special measures may have to be taken.

#### These include:

- a. preventing the penetration of rain water and contamination by dirty water as much as possible during loading and unloading. This is usually not a problem in a closed system. Rain can give problems during loading and unloading in the open air. In that case consideration must be given on the basis of a realistic hazards analysis to stopping the loading or unloading process or to continuing but possibly applying special measures. In each case the participant must ensure that the quality of the feed is not negatively influenced by this.
- b. If steam is used for the unloading of liquid feeds (such as molasses) in order to empty the means of transport then ensure that this steam is of such a quality that contamination with undesirable substances is prevented.
- c. Ensure during the unloading of liquid feeds that no undesirable crosscontamination with other feeds or products can occur due to the use of pipelines.

### 5.2.2.3 Production areas for storage

Proper separation must be achieved for production areas for the storage of feeds and potentially hazardous products (for example cleaning materials, lubricants, fuel and suchlike).

Make sure in storage areas that mud, snow and other potential sources of contamination which can be transferred by vehicles do not come in contact with the stored feeds. Rainwater must also be prevented from penetrating the storage area.

There must be sufficient hardened surface at the entrance to the storage area (for example a concrete floor) so that water and mud cannot penetrate the storage area.

Ensure for the external storage of grass or maize silage or wrapped bales that they are properly covered so that mould is prevented. The storage location must be (brush) clean and tidy. Waste and toxic materials (including crop protection agents, cleaning agents, pesticides, fertilisers, etc.) must be stored separately from the product. The location must be clearly separated from machinery stores and workshop.

#### 5.2.2.4 Equipment

All equipment which is used during collection or storage must be fit for purpose.

Equipment which comes into contact with feeds must be designed and constructed where necessary in such a way that it can be properly cleaned, disinfected and maintained to prevent contamination of the feeds.

Sieves, filters and graders which are identified as critical points must be checked regularly to ensure that they are suitable and effective.

The participant must calibrate his equipment regularly to make sure that the measured values are correct. This must be done in accordance with a schedule. The results must be recorded.

#### Guidance

This includes magnets and/or metal detectors which may be used in the plant to control risks. These should, of course, function properly.

All weighing and measurement equipment which might be used must, of course, also be suitable for the range of weights or volumes which might be weighed or measured. There should also be a regular check that the equipment is still accurate.

This includes dosage equipment for preservatives which are used, for example, during silage. The dosage capacity should agree with the quantity of product to be spread. The participant must know:

- a. The minimum and maximum weight which is permitted for the weighing equipment or dosage equipment.
- The accuracy of the weighing or dosage equipment.

If the participant makes use of silo's then a proper assurance system for the prevention of errors must be used when filling these silo's.

### 5.2.3 Access control

The regulation of access to production areas must established. Anyone who is not an employee may only be given access to the production areas under the supervision or if he has permission for unaccompanied access from a person authorised to do this.

#### 5.2.4 Other requirements

Technical or organisational measures must be taken to prevent or minimise *cross-contamination*.

#### Guidance

This includes feed which is treated to remove any contaminants being kept separate from feed which has not yet been treated or from another product.

If the participant uses air, water or steam, then a hazard analysis must establish whether there are risks associated with this and they must be controlled.

This also applies if the participant makes any use of *processing aids* or (technological) additives Use may only be made of legally-permitted processing aids and technological additives.

#### **Guidance**

Version: 1st of April 2016

When using water and/or steam remember the processing aids such as anticorrosion agents.

When silaging products where the sugar level is too low, the silage is too wet or too dry then the additives to retard heating may be added to the silage (sugars, salt, micro-organisms, ureum). Only silage agents which are legally permitted may be used. The participant can ensure this by, for example, having the supplier make a statement or by only purchasing the silage agent from a GMP+ participant.

GMP+ B3 Trade, collection and storage & transshipment

The packaging of the feed must be suitable for the type of feed in question and for the chosen means of transport or delivery. The packaging must be designed for the protection of the feed during normal storage, treatment and delivery conditions.

Reusable packaging should be sufficiently sturdy, easy to clean and, if necessary, should be able to be disinfected. The participant should establish a cleaning regime on the basis of a hazard analysis.

If applicable, special attention should be paid to the recovery from livestock farms of pallets and other reusable packaging material.

# 5.3 Maintenance and hygiene

#### 5.3.1 Maintenance

A maintenance plan must be drawn up and applied for all relevant areas and plant or equipment. This is to ensure safe and hygienic working.

The documents in which the maintenance activities are recorded must show that there is compliance with the requirements and conditions.

The participant must record the maintenance which is carried out on all equipment which is critical within the framework of the collection and storage of feeds.

# Guidance

The following elements may be included when drawing up the maintenance programme:

- a. (production) areas and production halls
- b. Equipment and (internal) transport systems.
- c. Personnel involved (own personnel or hired personnel)
- d. Frequencies

Maintenance activities may not form any risk at all for feed safety.

Also remember the maintenance of means of transport for which the participant is responsible.

# 5.3.2 Maintenance of measuring equipment

The participant will ensure that any use of measuring equipment does not have a negative effect on feed safety.

# <u>Guidance</u>

When maintaining measurement equipment, remember its calibration.

#### 5.3.3 Cleaning

The participant must ensure that in all relevant phases of the collection and storage of feeds the standards for cleaning are adhered to such that exposure to pest and pathogens is minimised.

A cleaning programme must be drawn up and the participant must ensure that the collection and storage facilities are cleaned in such a way that this is sufficient to maintain the safety of the feed at all times.

Cleaning and disinfection programmes must be checked for suitability and effectiveness. An authorised person must carry out the inspections of the status of the cleaning and a register will be maintained of all these inspections.

Cleaning and disinfection agents and other chemicals which are used for hygienic purposes must, if applicable, be stored separately in clearly identified areas. This is to avoid the risk of unintentional contamination or contamination due to negligence.

Machines or components and also storage areas which come into contact with dry feeds must be dried after wet cleaning or must be dry before they are used again.

### Guidance

During cleaning the dirt and remains which might form a source of contamination are removed. The required cleaning methods and materials depend on the nature of the company and this may include disinfection and hygiene treatment. Only cleaning and disinfection agents may be used which are permitted to be in contact with feeds. These will be used in accordance with the user instructions of the manufacturer and in accordance with the associated requirements and conditions in the product safety data. If cleaning and disinfection agents come into contact with feeds then the participant must ensure that the control systems always ensure correct and effective levels of dilution. The participant can make use of the information in the user instructions for the cleaning agent or disinfectant used.

The cleaning programme should include at least the following elements:

- a. Production areas
- b. Equipment and (internal) transport systems
- c. Involved jobs / employees
- d. When is cleaning carried out (in which situations?) When is the decision to clean?
- e. Method of cleaning
- f. The cleaning agents. These should be recorded and be fit for purpose.

Cleaning activities should not form any risk at all to feed safety. Ensure that remains of cleaning and disinfection agents do not remain behind unnecessarily on or in the cleaned equipment or areas

If transport is involved then remember the cleaning of the means of transport.

# 5.3.4 Prevention and control of pest

The participant must do everything which is reasonably possible to keep birds, pets and pest away from the production areas and to prevent their presence. The participant must take measures to prevent pest getting into the company sites or buildings. The participant must draw up, document and implement a programme for the control and combating of pest.

Employees must, if applicable, comply with legal provisions if they carry out pest control operations.

Activities within the framework of pest control must be planned, carried out and recorded. The documents in which the control activities are recorded must show that the requirements and conditions are complied with.

#### Guidance

#### Remember:

- a. Buildings are kept in good condition by repairs and maintenance to prevent the penetration of pest.
- b. Potential breeding places should be prevented.
- c. Doors are closed where possible and close properly. Pest cannot penetrate when they are closed.
- d. Holes, waste pipes and pits and other places where pest can get in should be closed off whenever possible. If closing off is not possible then screens or metal sieve covers are used to minimise the possibility of pest.
- e. If possible, animals will be kept out of the production areas and also outside the surrounding storage locations and production areas. If the presence of birds or other animals is unavoidable then procedures will be set up to protect the feeds from potential contamination.
- f. In cases where the shooting of pest is permitted and is part of the pest control programme, then no lead or other toxic ammunition will be used.
- g. All bait will be fixed in location unless this is not possible for a special reason.
- h. Open bait boxes and individual bait products will not be set up in areas where their use or presence may form a hazard to raw materials or feeds.

Procedures for pest control will be established and will ensure that materials which are intended for the killing or prevention of pest cannot contaminate feeds. Pest control registers include the following:

- a. Details of all the means in use together with the associated safety data for the product;
- b. Qualifications (if legally required) of the personnel involved in activities relating to pest control. In some countries the legislator requires that employees who are involved have diplomas if they carry out pest control operations
- c. Maps showing the locations of bait boxes and the type of bait products
- d. Details of corrective actions which have been implemented.
- e. The carrying out of the pest control programme must be recorded as such by the participant that it is clear to everyone that the programme was correctly carried out:

# 5.3.5 Waste management

All substances which are considered to be waste must be visually marked as such and protected in such a way that any chance of errors or improper use is eliminated.

The waste must be collected and stored in separate bins or buckets. These must be easily recognizable as such and must be closed to prevent pest.

# 5.3.6 Glass and breakable materials

The participant must ensure that glass and breakable materials do not form any hazard to the feeds. Every reasonable effort must be made to minimise the risk of glass breakage and to ensure that the feeds are not contaminated if glass breakage should unfortunately occur.

#### 5.4 Identification and traceability / sampling

# 5.4.1 Identification and traceability

Feeds must be traceable in all stages of collection, storage, trade and transport so that, where applicable, they can immediately be withdrawn from the market specifically and precisely and/or the customers can be properly informed. The participant must, for this purpose, set up and describe an internal traceability procedure.

The participant must take suitable measures to ensure that the products can be traced effectively during each of the stages referred to above for which the participant is responsible. The participant must maintain a register for this purpose with respect to purchase, production and delivery which can be used effectively to trace products from reception to delivery.

The participant must have the necessary information available within 4 hours unless the competent authorities have established a shorter period of time.

See D 2.4 Guideline for Traceability for more information about setting up a internal traceability procedure.

The participant must record at least the following details of all products and services:

- a. the name and address details of the suppliers and customers
- b. delivery date
- c. type of product or service
- d. number of products
- e. batch number if applicable.
- f. transport/ distribution details (if the participant is responsible for transport)

The participant must also establish whether it is necessary to record other details.

During the sale of individual bagged goods it is sufficient to have a clear designation for the traceability of the bags.

# Guidance

The feed legislation requires that feeds and all other products intended for processing in a feed or of which it could be expected that they would be processed in a feed must be traceable in every step of the production process. If necessary the products can in this way immediately be taken out of circulation and/or the customers can be correctly and specifically informed.

The batch number can also be designated using the batch number of the manufacturer, a reference number, an own batch number or other number.

If the participant stores feeds as a service then he should consider suppliers and customers as the originators.

GMP+ B3 Trade, collection and storage & transshipment

**GMP+** International

# 5.4.2 Sampling

In addition, within the framework of traceability, sufficient samples will be taken of incoming feeds and (if applicable) processing aids and/or outgoing feeds. This must take place in accordance with a procedure established in advance by the participant.

#### These samples must:

- a. Be packed such that adulteration is not possible.
- b. Be provided with labels such that samples can easily be identified.
- c. Be stored in such a way that any change to the composition or any deterioration of the samples is excluded.
- d. Be kept available for the competent authorities for a period which has been matched to the use for which the feeds were put on the market.

Refer to GMP+ BA13 Minimum Requirements for Sampling.

The participant may enter into agreements with third parties (for example the manufacturer or supplier) on the taking and storing of samples according to the above requirements with the above purpose. In that case the participant must have a written agreement with that third party.

#### Guidance

In the GMP+ FSA module all participants who process, produce or import physical products are obliged to take samples. For all other companies (such as traders), the obligation for taking samples depends on the interpretation of the feed legislation by the competent authorities.

A trader does not therefore have to retain a sample of all sold feeds himself as long as he has the assurance that, for example, his customer has a sample which is available for the competent authority in the event of an emergency.

#### 5.5 EWS and Recall

The participant has a procedure for the (early) signalling and handling of signals which indicate that the safety of a feed might not match the statutory standards or the standards laid down in the GMP+ FSA module and which might lead to damage to subsequent links in the chain. Signals will be assessed on this basis.

When a feed is discovered which does not comply with:

- a. the statutory provisions with respect to safety, or
- b. usual trading quality, or
- c. the requirements of the GMP+ certification scheme,

then the participant will undertake the following actions:

- a. inform the customers:
  - 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 as soon as possible, and
- b. immediately block the animal feed or have it blocked, and
- c. recall the feed and make sure that it stays outside the feed and livestock farming sectors.

An exception to this is if the participant can demonstrate that the nonconformity is without harmful consequences for the health of animals or humans. The requirement remains that the statutory standards may not be 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. A recall simulation must be carried out within 3 months of the establishment of the recall procedure. The recall simulation must then be repeated every 12 months. The experience gained during this recall simulation must be recorded.

#### Guidance

A guideline has been published on the website of GMP+ International with information about recalls and how a recall procedure can be set up and implemented.

The depth and scope of the annual recall simulation may vary and may, for example, depend on changes made to the company organisation or the way the business is run.

As part of the recall-procedure a list should be drawn up and maintained of all the relevant contact persons including those contact persons at the competent authority who must be alerted in the following circumstances:

- a. In the case of a serious risk to safety
- b. If statutory limits have been exceeded and a warning or report is mandatory under national legislation in such cases

Parts of the recall procedure are, for example:

- a. The identification of non-standard batches or loads of feed including the consequences for other feeds, batches, loads or raw materials.
- b. Ensuring that, in the event of a recall of a non-feed product, the recall of a feed product is considered and, if necessary, carried out
- c. The identification of the loads or batches involved.
- d. Management of recalled feeds including separation from other products.
- e. The documenting of the destination of any recalled products.

GMP+ B3 Trade, collection and storage & transshipment

Version: 1st of April 2016

# 6 HACCP

# 6.1 Planning of the realization of safe feed

The participant must ensure that one or more written procedures on the basis of HACCP principles have been introduced, implemented and maintained.

The following principles are involved:

- a. carry out a hazard analysis
- b. determine the critical control points (CCPs)
- c. establish standards for the CCPs
- d. draw up and implement a monitoring plan for the CCPs
- e. define corrective actions
- f. validate and verify the HACCP plan
- g. document and register the HACCP plan

In order to apply these principles successfully, the participant must comply with a number of requirements including:

- a Put together a HACCP team (section 6.2)
- b Describe products and processes including the use (section 6.3)
- c Draw up and implement a prerequisites programme (Chapter 5).

#### <u>Guidance</u>

See GMP+ D2.1 'Guideline HACCP GMP+' on the website of GMP+ International for a description of a plan for the application of the HACCP principles.

The result of the application of HACCP principles can be recorded in a so-called HACCP plan. A HACCP plan is a document which is drawn up in accordance with the HACCP principles. This ensures that significant hazards for food and feed safety in the sector of the feed chain are controlled.

#### 6.2 HACCP team

Version: 1st of April 2016

The participant must put together a HACCP team to draw up a HACCP system. This team must draw up an effective HACCP plan.

The HACCP team must consist of personnel from all the relevant business activities and positions within the company and at least one member must have demonstrable knowledge and/or experience of the application of the HACCP principles.

The HACCP team must carry out a hazards analysis which is intended to identify and monitor risks which might have a negative effect on the safety of the feeds.

The HACCP team must have sufficient expertise in various disciplines or must be able to make use of expertise for the carrying out of the hazards analysis and the drawing up and maintenance of the required feed safety system.

The names of the members of the HACCP team must be included in the HACCP documentation.

GMP+ B3 Trade, collection and storage & transshipment

It is acceptable for individual employees to fulfil various roles within the HACCP team. The participant can also make use of external persons or consult external sources on the condition that the team can function effectively.

# Guidance

A HACCP plan is a document which is drawn up in accordance with the HACCP principles and which ensures that significant hazards to food and feed safety are controlled.

A reasonable effort is expected of the participant to ensure that a HACCP team is put together with members from various parts of the company. If it is not possible for a participant to put together a full team then the team may also, for example, consist of the participant himself assisted by an external consultancy firm.

# 6.3 Description of products and processes

#### 6.3.1 <u>Determination of requirements</u>

The participant must determine all requirements with respect to feeds including storage and/or transport:

- Statutory requirements with respect to feeds and their collection, storage and transport, and
- b. all additional requirements related to feed safety or which are necessary for the specified or intended use if this is known

Communication with customers must in any event be clear with respect to:

- a the requirements of the customer with respect to the safety of feeds and/or
- other special customer requirements. If the customer participates in a certain feed safety programme then the participant must ensure that he (the participant) understands and complies with the specific requirements of the programme such as the specific conditions under which the storage or transport must take place.

Every type of *feed material* which is purchased or received must be included (together with a generic risk assessment) in the Feed Support Products (the FSP). If the participant purchases or receives a *feed material*:

- a for which no risk assessment has been included in the Feed Support Products of GMP+ International, or
- b which uses a production method which does not agree with one of the risk assessments already included in the Feed Support Products of GMP+ International.

then the participant must ensure in advance that a (part of the) risk assessment is included in the FSP. The above does not apply to feed materials which are only traded for pet food feed for non-food producing animals.

#### Guidance

Version: 1st of April 2016

See for the relevant requirements in the context of the GMP+ Feed Safety Assurance (FSA) module:

a. GMP+ BA1 Specific feed safety limits,

- b. GMP+ BA3 Minimum Requirements for the Negative List,
- c. GMP+ BA4 Minimum requirements for inspections and Analysis
- d. GMP+ BA10 Minimum Requirements for Purchasing.

Consult the website of GMP+ International for the procedure with respect to sending in a risk assessment for publication in the Feed Support Products.

A generic risk assessment for a feed additive does not have to be included in the Feed Support Products of GMP+ International.

# 6.3.2 Specification of feeds

The participant must determine and specify all (safety) requirements with respect to feeds. There must be a description on the basis of the above requirements for each feed.

The scope of the this specification must stretch from the products used during production up to and including distribution.

If the requirements are amended then the participant must ensure that the relevant specification is modified and the relevant personnel are aware of the changes. This specification must be kept up to date.

The specifications must include, where applicable, at least the following:

- a Characteristics of the feed
  - 1. General details (name, coding, origin, method of creation/production, etc.)
  - 2. Composition (chemical, physical, microbiological)
  - 3. Raw materials and auxiliary substances used (including feed additives and processing aids where applicable)
  - 4. Product standards or requirements (feed legislation; agreements with customers) and tolerances. Under the GMP+ Feed Safety Assurance module the feeds must at least comply with the relevant product standards which are laid down in GMP+ BA1 Specific feed safety limits.
  - 5. Other features (including storage, packaging).
- b. Characteristics for use
  - 1. Intended use
  - 2. Processing/handling instructions
  - 3. Dosage instructions
  - 4. Storage conditions
  - 5. Storage life
  - Conditions and agreements with respect to transport and the place of delivery
  - 7. The statutory notices as indicated on the packaging or in the accompanying documents.

#### Guidance

The GMP+ FSA module is aimed at feed safety assurance. A specification will in any event contain information on the safety aspects. End product specifications offer an initial indication of possible hazards. In addition to the ingredients which are used (raw materials, feed additives, processing aids), other elements are also specified which can have an influence on the safety of nutrition and the feed. This may involve chemical, physical or microbiological characteristics (such as contaminating or undesirable substances) or the desired conditions for collection, storage or transport.

Account is taken of the requirements and standards in the various appendices of the GMP+ standard and, if necessary, these will be included in the specification.

Note: Not all components can always be specified in full. This applies particularly to the components specified in b).

It may be decided for reasons of effectiveness to form feed groups. It is then important that:

- a. Specific differences between the individual feeds to be produced are examined critically
- b. The storage conditions are equivalent
- c. No major aspects relating to product safety are forgotten.

The dosage instructions mean the instructions intended for direct feeding to animals and also the instructions for handling of processing in, for example, compound feeds.

When drawing up the product specifications for primary products, the participant may make use of external sources such as sector specifications. This specification should then be checked for correctness and completeness and modified where necessary.

A trader may make use of the specifications drawn up by the manufacturer. See also GMP+ D2.5 'A guide for the supplier assessment'.

# 6.3.3 <u>Description of the process</u>

The HACCP team must draw up a description of the process in the form of flow charts and a map (if relevant) which enables the organisation to identify and assess hazards.

The flowcharts and the map must be verified by the HACCP team and must be kept up to date.

The flowcharts must at least comply with the following requirements:

- a. They must show all the separate steps in the process from purchasing to delivery. These include all the activities which are outsourced and a description of all the products used including auxiliary substances, customer returns and waste which is created during the process.
- b. They must be clear and accurate and offer sufficient detailed for establishing any possible hazards

The infrastructure of the company as a whole is shown in a map which includes the following:

- a. the company units, storage area and personnel facilities
- b. the areas or rooms where cross-contamination or incidental contact is possible between lubricants and coolants, untreated and treated feeds, packaging, pallets and suchlike.

#### Guidance

See the HACCP manual on the website of GMP+ International for a summary of useful symbols with which a process can be described schematically.

The drawing of a map is only relevant if the participant physically receives and stores feeds.

# 6.4 Hazards analysis

# 6.4.1 <u>Identification of hazards</u>

The HACCP team must identify and document all potential hazards which could have a negative effect on feed safety.

The hazard identification is based on:

- a. Raw materials and auxiliary substances
- b. The specification of the feed
- c. The set-up of the company and the resources used
- d. The flow chart drawn up
- e. The map drawn up
- f. Experience, expertise, research and other sources of information (internal/external)
- g. The generic risk assessment which is included in the Feed Safety Database (if applicable).

For each hazard the HACCP team also registers an acceptable level for presence in the feed where at least compliance is achieved with the statutory standards and the standards in the GMP+ FSA module. See GMP+ BA1Specific feed safety limits.

# 6.4.2 Risk estimation

The HACCP team carries out a risk estimation for each identified hazard. This is done systematically. The purpose is to establish whether a hazard is of such a nature that elimination or reduction to an acceptable level is essential for the processing and/or handling safe animal feed.

#### 6.5 Establishment of control measures and CCPs (critical control points)

# 6.5.1 The establishment of specific control measures.

The HACCP team must record and implement the measures for controlling all risks for which it has been established on the basis of the hazard analysis that they might have a negative effect on feed safety.

More than one control measure may be necessary to control a risk and more than one risk may be controlled by a single control measure.

### 6.5.2 Determine the critical control points (CCPs)

The HACCP team must then assess whether this control measure forms the last measure in the process for the controlling of the risk. If this is the case then it is a CCP (critical control point). The reason for the presence of a critical control point (CCP) must be recorded.

#### 6.6 Determination of standards

To determine whether a specific control measure works effectively the HACCP team will determine the following for each critical control point (CCP):

- a. which parameters must be measured, analysed or observed, and
- which product standards (action and rejection limits) apply for these parameters.

When determining the product standards (action and rejection limits) the provisions of the relevant feed legislation and the product standards in the GMP+ FSA module (in GMP+ BA1 *Specific feed safety limits*) must be complied with. These product standards must always be considered to be (contractual) obligations.

# **Guidance**

During the determination of critical limits or product standards, the participant makes use of the provisions in chapter 6.3.

#### 6.7 Monitoring

A monitoring plan which particularly includes the control of critical control points in the process must be drawn up, recorded and implemented.

The plan will contain all planned measurements, analyses and observations of characteristics which indicate that the critical control points are controlled. This applies to incoming and outgoing feeds.

The monitoring plan must in any event be in accordance with the requirements laid down in the GMP+ FSA module (see GMP+ BA4 *Minimum Requirements for Inspections and Analysis*). The participant must show the reasoning for the structure of the monitoring plan.

The results of this monitoring must be recorded.

The monitoring plan includes:

- a. The procedures for and the frequency of the sampling
- b. The (analysis) methods and equipment used. These methods must be suitable for achieving the planned results
- c. The laboratories which are chosen for the analyses in question
- d. The frequencies of the analyses, checks and inspections
- e. Compliance with the specifications and the usage if there is no compliance with the specification
- f. All planned inspections and checks and analyses
- g. The instructions for the carrying out of inspections and checks
- h. The personnel who are responsible for carrying out the monitoring activities
- i. The personnel who are responsible for assessing the results of the monitoring plan
- j. The personnel who are responsible for releasing the feed

The participant must ensure correct identification and storage of the samples (during the period which applies to these kinds of samples) within the framework of the monitoring plan. See also GMP+ BA13 *Minimum Requirements for Sampling*.

Within the framework of the feed safety management system, the participant must preferably have the analyses in question carried out by a laboratory approved for this under the GMP+ FSA module. See GMP+ BA10 *Minimum Requirements for Purchasing*. The laboratory must also be accredited for the analysis which is carried out.

#### <u>Guidance</u>

The above does not of course mean that a participant must have his own laboratory. He can also ensure that he can make use of the services of an external laboratory.

Next to GMP+ B10 certified companies also ISO 17025-laboratories are approved under the GMP+ FSA module. It is important to determine that the analysis in question is actually carried out under the accreditation.

Preferably: If it is not reasonably possible to make use of a laboratory with ISO-17025 accreditation for the analysis in question then a participant can also make use of an

- a. ISO-17025 laboratory which is accredited for other analyses
- b. ISO-9001(2008)-certified laboratory.

If a laboratory does not comply with the above then it is in any event important that the laboratory produces results in a reliable fashion and that an independent third party has formed a positive conclusion with respect to this.

Monitoring is not just the analysis of feeds for contamination. Monitoring also includes, for example, the checking of the expiration date on bagged goods.

It is possible for a groups of companies to set up a joint monitoring programme. The requirements for this can be found in GMP+ BA4 *Minimum Requirements for Inspections and Analysis*.

The participant may enter into agreements with his supplier or customer about monitoring. This should be recorded in a contract.

The results of analyses carried out within the framework of another quality programme (for example that of a supplier) may also be used as long as they conform to the requirements in this section and GMP+ BA4 Minimum Requirements for Inspections and Analysis.

#### 6.8 Corrective actions

The participant must ensure that all deviations from the requirements in this standard are recorded and checked in order to prevent improper use or unauthorised delivery of feeds. These inspections and the associated authorisation for dealing with nonconformity must be laid down in a procedure.

The participant must deal with nonconformities with respect to a feed in one of the following ways and must have demonstrable proof of this available:

- a by taking measures to resolve the observed nonconformity
- b by permitting the use, release or acceptance with approval of an authorized government body
- by taking measures to exclude the original intended use or the original application. If products are no longer suitable for use as feed then they must be given a use which is in accordance with the provisions of the applicable legislation

If the nonconformity is resolved then this must be verified again to show that there is now compliance with all the requirements.

# **Guidance**

Remember to maintain details and/or to keep demonstrable proof of the type of nonconformity and the measures which were subsequently taken (also including any approvals obtained)

This inspection serves for the identification, documentation, evaluation, separation (if this is practically feasible) and removal of the feeds which do not comply and as a report to the interested parties both internally and externally.

#### 6.9 Validation and verification

#### 6.9.1 Validation

Before a start can be made on the implementation of the HACCP plan, the participant must validate that the chosen control measures will be effective in controlling the risks. If the validation shows that the chosen control measures are not effective then the participant must take additional measures.

The validation may be carried out by (members of) the HACCP team. Independent persons must also be involved in the validation unless this is not reasonably possible. The participant must then explain this (see guidance).

The persons involved in the validation and the activities which they carry out must be clearly laid down.

#### Guidance

The purpose of validation is independently to determine <u>in advance</u> that the hazards which have been determined by the HACCP team are complete and correct and that they will be effectively controlled using the HACCP plan.

A reasonable effort is expected of the participant to ensure that there is an independent assessment by the HACCP team. This might include the use of a consultant, an employee, an employee of another company with similar activities or someone else who is able to ask critical questions with respect to the HACCP plan such as a customer. If a participant is unable to obtain an independent person for the validation then he may carry out a non-independent validation. This validation is then carried out by the HACCP team itself.

The collection and assessment of objective data (such as analyses) can provide a lot of insight into the effective functioning of the HACCP plan. See section 8.3 for this.

## 6.9.2 Verification

Once the HACCP plan has been drawn up then periodic (at least yearly) verification of (elements of) the system must take place. Verification is the use of supplementary information to verify whether the system is still effective and whether it functions as intended. Verification is carried out and documented by the HACCP team. See also section 8.3

# Guidance

Verification is the use of additional information to check if the system is still effective and whether it is being used as intended.

The verification of the HACCP plan is often carried out as part of a general review of the management system. Other requirements for a complete assessment have for these reasons been laid down in section 8.3 'Assessment of the management system and improvements'.

More information about verification of the HACCP plan can be found in the HACCP manual which is located on the website of GMP+ International.

# 7 CONTROL OF OPERATIONAL ACTIVITIES

#### Guidance:

The following table shows the sections which include the various requirements

Section	Trade	Storage and transshipment	Transport*
7.1	X		
7.2		X	
7.3			Χ

<sup>\*</sup> If the participant is not responsible for the transport (for example because the customer comes and picks up the feeds himself) there are still some requirements with respect to correct delivery. See section 7.3.5 for this.

#### 7.1 Trade in feeds

#### 7.1.1 General

The participant must ensure that the trade in feeds is in accordance with the conditions and requirements of GMP+. The trade in feeds must be administered clearly and straightforwardly.

A procedure must be drawn up for the whole trading process. Specifications must be part of the purchase documents and contracts.

# Guidance:

The trading process itself is an important process which must be controlled in a proper fashion to be able to assure the safety of the feeds. On the one hand the trader is engaged with customers who have (specific) requirements with respect to the feeds and, on the other hand, with suppliers who can supply feeds.

**Note:** If a trader is also responsible for storage then also refer to section 7.2.

# 7.1.2 Purchasing

#### 7.1.2.1 General

The participant must ensure that purchased feeds and any other products and services comply with the specified purchasing requirements.

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. Specify as such in the contract or another official document. This specification is –of course- not applicable when an accepted gatekeeper option for purchasing is applied. See for this GMP+ BA10 Minimum requirements for Purchasing. The participant must select and assess (potential) suppliers and choose suppliers who are able to provide feeds and/or services which comply with the specified requirements.

At least the following requirements must be met with respect to the above by the participant:

a. Prior to the purchase of products or services, the participant must carry out a hazard analysis based on HACCP principles. On the basis of this hazards analysis and also the quality assurance which is carried out by the supplier, the participant must select a supplier and establish his entry check accordingly.

If the participant purchases feeds or specific services then the participant must also ensure that these feeds or services:

- b. come from suppliers who are GMP+ certified at the moment of delivery, or
- c. come from suppliers who are certified on the basis of a standard which is approved in the GMP+ FSA module,
- d. certain feeds and services can also be purchased without one of the above certificates (an uncertified supplier). Separate requirements have been laid down for this.

See GMP+ BA10 *Minimum Requirements for Purchasing* for more details on which feeds and services this covers and for more details of what is possible.

#### Guidance

The specified purchasing requirements are based on the requirements which are set for the feed to be produced (end product, see section 6.2).

Within the framework of the GMP+ FSA module, certification is possible for the following services: transport, storage & transshipment and laboratory services (under the associated GMP+ standard). If a participant purchases one of these services then the participant must ensure that these services are certified for GMP+ or for another standard which is accepted as being equivalent. For this see GMP+ BA10 Minimum Requirements for Purchasing:

- a there are currently still a number of special exceptions for the contracting out of storage and transport particularly for companies outside the Netherlands. See section 7.3 for the transport or GMP+ BA10 'Minimum Requirements for Purchasing' for the storage.
- b the contracting out of processes such as drying or packaging can only be done to certified companies which are approved under GMP+. For this see GMP+ BA10 Minimum Requirements for Purchasing.
- c if a participant purchases other types of services such as the cleaning of silo's, pest control, maintenance of equipment and suchlike then a certificate is not necessary. There has then 'only' to be compliance with the requirements specified in d) (see the box for guidance).

Other products are, for example, processing aids or cleaning and disinfectant agents. Other services include silo cleaning or pest control. This refers, of course, to products or services which may influence the safety of feeds.

### 7.1.2.2 Purchasing within the framework of collection

In the previous section general requirements were set for purchasing by a trading company. These requirements also apply in full to collection in the event of, for example, purchasing from another collector, a trading company or from a certified grower.

For direct purchase from a non-certified grower, a number of special purchasing options have been established. For this see GMP+ BA10 *Minimum Requirements for Purchasing*, appendix 3 Annex 4.

#### Guidance:

GMP+ is based on a closed chain which means that all the companies in the chain are GMP+ certified or are certified in accordance with another approved standard. The GMP+ chain begins with cultivation. The grower should therefore be GMP+ certified. In practice, however, many growers take part in special cultivation quality programmes which are nationally oriented. It is not possible to arrange compatibility or approval for each of these programmes. It is for this reason that GMP+ has separate purchasing rules for the purchase of feed materials from non-GMP+ certified growers in a so-called Gatekeeper's protocol.

# 7.1.3 Assessment of suppliers

#### 7.1.3.1 General

The participant must assess all suppliers each year. Criteria must be established for selection, assessment, approval and evaluation.

In addition, growers may be assessed as a group. The participant will explain the group classification.

### Guidance:

For this subject refer to GMP+D 2.5 'A guide for the supplier assessment'. This document is available on the website of GMP+ International.

The collector often has many suppliers (growers). An assessment cannot be fully completed for each individual grower. The hazard analysis which is carried out can then apply to, for example, a group of 'identical' growers.

Many other kinds of practical possibilities are conceivable for making agreements with growers. It is important that a grower is informed of the rules which he must follow. See also section 7.2.2. for the entry check requirements.

### 7.1.4 Verification of the purchased product

The participant must establish and implement inspection activities to verify that the purchased feeds are in accordance with the specified requirements. If applicable, these inspections may also be carried out by inspection companies. Refer to section 7.1.5 for handling non-standard feeds.

If the participant actually receives the feeds at his own site then see section 7.2 for the verification of the incoming product.

### 7.1.5 Non-standard products

The participant must draw up a procedure which regulates what is done with feeds which do not meet the specifications.

This procedure must include the following elements:

- a identification of the batches or loads in question
- documentation for the management and maintenance of the non-standard products
- c assessment of the cause of the non-conformity
- d separation of the batches or loads in question
- e communication with the parties involved
- f preventive or corrective actions to prevent reoccurrence of the nonconformity.

The responsibility for the inspection and removal of non-conformant feeds must be defined. Every case of nonconformity must be documented along with the decisions taken with respect to the actions to be undertaken. These must be taken by competent personnel.

Non-conformant feeds must be handled in one of the following ways:

- a remove as waste or for use as biomass
- b treat so that it becomes suitable for use as feed
- c accept with concessions (if agreed in writing with the customer)
- d sell as a different quality (if the product meets the specifications for the other quality).

Requirements for the treatment of feeds which do not comply so that they are suitable as feed must be documented. In cases of deviations all feeds must be assessed again after the treatment in order to ensure that the batch involved now complies with the specified requirements.

The approval and treatment (for example with respect to rejected quality or customer returns) must be considered within the framework of the HACCP plan. The quality (specifications) of customer returns must be known. The participant must have information which shows whether mixing or cross-contamination has taken place at the external company. A procedure must be laid down for the recalling of external return flows. The feeds which cannot be approved must be considered to be waste and demonstrably removed in the correct fashion.

Feeds which do not fully comply with the customer specifications may only be delivered to the customer if the customer has been made aware of the problem and has confirmed to the participant in writing that this delivery will be accepted.

### 7.1.6 Sale and contracts

Specifications for feed must be agreed between the participant and the buyer and confirmed in a contract. The participant must ensure that all feeds are supplied in accordance with the agreed specifications.

The sale of feeds must be maintained clearly.

# Guidance

The specification of feeds relates to safety requirements: See also Section 6.3.2.

If the drawing up of a contract with the buyer is not usual (for example in the event of direct delivery to the livestock farmer) then it is also possible to attach the specifications to the invoice.

### 7.1.7 <u>Labelling and delivery</u>

On delivery the batch must be accompanied by the legally-required product information. The documentation with respect to delivery must be clear.

The participant must ensure that the labelling and the delivery of the feeds which he delivers are in accordance with the applicable legal requirements.

See GMP+ BA6 *Minimum requirements for labelling & delivery* for additional requirements regarding trading non-GMP+ certified feeds and additional labelling requirements.

# 7.2 Storage

# 7.2.1 General

All the stages in the process must be planned and monitored to ensure that the feed remains in accordance with the specifications and the established parameters for critical control points. This must be based on a HACCP hazard analysis. There must be proper registration.

All process control points which are relevant for the safety of the feeds which are processed, collected, stored, etc., must be demonstrably and effectively controlled in accordance with the formal HACCP principles.

Special attention must be paid to the stages which are not discussed in detail in the following chapters. Proper control measures must be implemented. Procedures must prescribe corrective actions in cases where critical process parameters are exceeded. These procedures must be based on a HACCP hazard analysis.

There must be sufficient suitable checks (for example of storage life) during the activities such as during reception, loading, storage and the processing phases.

A qualified person must be made responsible for the storage activities.

If changes are made to the storage process then the participant must examine the procedure and implement the necessary changes.

# 7.2.2 <u>Verification of incoming products ('entry check')</u>

There must be a procedure for the acceptance of incoming products. This procedure must prescribe criteria for the proper acceptance and release of feeds including criteria for the approval of transport.

The procedure must be based on a completed hazard analysis. The carrying out of entry checks must be recorded. For the requirements with respect to sampling see section 5.4.

The products must comply with the specifications. The check on compliance with the specifications is an important point. The participant must also check whether the transport complies with the agreed requirements

(As a minimum a check on: the correct GMP+ certification of the carrier, compliance with the requirements with respect to loading sequence, previous loads and implementation of the necessary cleaning regimes). The LCI reports for all received sea transport, short sea shipping, inland waterway transports or rail transport should be available or retrievable.

In the case of doubt the specifications must be verified by way of analyses. The frequency of this may differ for the various parameters. In addition, batches from 'new' suppliers must be checked at a higher intensity.

The products may not be accepted if they do not comply with the purchasing specifications unless they are treated to ensure that the batch does comply with the specifications.

# Guidance:

Inspection points may be:

- a The colour
- b The physical form
- c The odour
- d Contamination by insects, dirt or other items which do not belong in the product and which should not be mixed into feeds
- e Damp / mould
- f Abnormal damage
- g Agreement with the specification
- h Is the means of transport clean and in order? Does the transport comply with the agreements and requirements set (prior loads, cleaning)?

A collector often has many suppliers (growers). It is a big job to check every delivery from every grower (100%) and it is possibly not necessary. The requirements demand that the entry check should be based on the risks. A hazard analysis can provide information with which the intensity and the size of the checks could be established.

## 7.2.3 Storage & transshipment

The participant must control all storage & transshipment of bagged goods and also bulk. This applies for storage & transshipment at both own sites and at hired locations.

Measures for the control of storage must be satisfactory.

Feeds must be transported (internally) and stored in such a way they are and remain easily identifiable. This is to avoid confusion, cross-contamination and degradation of the quality.

All products which are stored in the same building by the participant but which are not intended for use as feed must be clearly kept separate from the feeds and identified as such during every phase of production, packaging, storage, consignment and delivery unless the hazards analysis specifically establishes that non-separated storage entails no risk to the feed.

Where applicable temperatures must be kept as low as possible and show as little variation as possible to prevent condensation and decay. The presence of (storage) moulds is characterised by colour deviations and a musty odour. The participant must check the batch for the absence of storage moulds (for example through sensory perception).

The participant may only use stock protection agents if:

- a they are approved by the competent authorities, and
- b they are in accordance with the user instructions, and
- c they are applied by qualified persons.

The participant must document which agent is used, when it is used and for which feeds. It is then important that the prescribed waiting times are taken into consideration.

If silo's or tanks are used for storage then the participant must maintain a record of the silo or tank empty reports (minimum 1x per 3 months). (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 must be given. The company must realise that any recall will be larger in size because the period of time between two silo empty reports will be longer.

Storage can also be outsourced to a company which is also certified for GMP+ or which has another certificate which is accepted within the GMP+ FSA module. In some specific situations, storage can also be outsourced to a non-certified company. See GMP+ *BA10 Minimum requirements for Purchasing* for storage certificates which are approved and for more details.

#### Guidance:

Stock protection agents are, for example, acids or preservation agents and pest control agents. The purpose of stock protection agents is to protect the feed during storage so that storage does not have any negative effects on the feed.

Decay is influenced by the duration, temperature and relative moisture content during storage. In storage conditions which are too damp and/or too hot there is a risk of decay through microbes, fungus and the creation of mycotoxins. The correct conditions must be controlled.

If the participant also stores other products (non-feeds or products with a non-feed use) then, in principle, the requirement for separate storage applies unless a hazard analysis shows that 'common' storage cannot have a harmful effect on the feed. Non-separate storage may, for example, not be necessary if foodstuffs are stored in the same area.

### 7.2.4 Cleaning / sieving / filtering

The presence of contaminants such as glass, wood earth or packaging materials in the feeds must be limited as much as possible. In such cases a feed must be cleaned so that it complies with the specifications again. The participant must use satisfactory cleaning methods for this.

The cleaning equipment and the cleaning itself must be checked.

If separated material (material which is separated from the primary product flow by way of sieves, filters or graders) is reprocessed or collected for addition to feed then the hazard analysis must take into consideration the potential risks which could arise from such practices. The process diagram must provide insight into possible reprocessing (internal returns). Material which is designated as waste must be removed in the correct way.

#### Guidance:

Batches can be cleaned if the nature of the contamination permits this. Batches can be sieved or filtered to remove substances which do not belong with the product. The correct operation of the sieve is important as is a good maintenance plan for the sieve.

Check, for example, that the sieve is clean. If this is not the case then, prior to the sieving process, the sieve must first be cleaned. A random sample visual inspection of the sieved batches to check on the presence of substances which do not belong to the product must be remembered.

# 7.2.5 Drying and ventilating

The correct methods for drying and ventilation must be used for the drying of the feeds or the control of the moisture level and the temperature of the feeds.

In principle, only those fuels are acceptable which are specified in Annex 1, part A. All other fuels are not permitted unless it can be shown by way of a hazard analysis that there is no risk to the safety of feeds. In addition, the fuels specified in Annex 1, part B are not permitted in any case.

There are, of course, other methods to counter decay. If the participant uses these then he must ensure that this results in proper conservation.

#### Guidance:

For some feeds (such as grains and straw) the moisture content is important. Moisture (in combination with a high temperature) can quickly lead to the growth of undesirable (micro)biological organisms, biological decay and overheating.

A low moisture content and a low temperature prevent decay in particular. The moisture content can be reduced by way of drying, ventilation or a combination of these.

### <u>Drying</u>

The drying of grain should preferably be done indirectly. Direct drying may also be possible depending on the product. In that case the quality of the fuel and the maintenance of the burners is of great importance. The possible hazards of contamination with undesirable substances such as dioxin or PAHs from the fuel must be controlled. The risks of the fuel must be mapped out using a HACCP analysis. Control measures must be specified and must be checked regularly.

Feeds can also already be dried elsewhere. In this case the participant should receive information from his supplier about the drying method. On the basis of this information and additional (visual) checking or analysis the participant should assess whether the feeds have been sufficiently dried in a suitable manner.

#### Ventilation

In addition to drying (using hot air) it may be decided to use forced ventilation (using cold air).

#### Checking

The moisture content will be checked by the participant after drying or ventilation. This check of the moisture content must show whether the selected drying method was sufficient effective to bring down the level of moisture. The drying process may only be stopped if the moisture content has dropped below the desired percentage.

Proper operation of dryers and ventilators is assured by correct implementation of the maintenance plan.

More information about the drying processes can be found on the homepage of the Portal of GMP+ International under Knowledge/Library – drying processes.

### 7.2.6 Other activities

Version: 1st of April 2016

Any other activities which are carried out before, during or after storage must also be controlled on the basis of the HACCP principles. The participant must specify and control any risks and check on this (monitoring).

The relevant details must be recorded.

#### Guidance:

For a description of other activities see section 1.3.

### 7.2.7 Non-standard feeds

#### Guidance:

N.B. This section is the same as 7.1.5.

The participant must draw up a procedure which regulates what is done with feeds which do not meet the specifications.

This procedure must include the following elements:

- a Identification of the batches or loads
- b Documentation for the management and maintenance of the non-standard products
- c Assessment of the cause of the non-conformity
- d Separation of the batches or loads in question
- e Communication with the parties involved
- f Preventive or corrective actions to prevent reoccurrence of the nonconformity.

The responsibility for the inspection and removal of non-conformant feeds must be defined. Every case of nonconformity must be documented along with the decisions taken with respect to the actions to be undertaken. These must be taken by competent personnel.

Non-conformant feeds must be handled in one of the following ways:

- a remove as waste or for use as biomass
- b treat so that it becomes suitable for use as feed
- c accept with concessions (if agreed in writing with the customer)
- d sell as a different quality (if the product meets the specifications for the other quality).

Requirements for the treatment of feeds which do not comply so that they are suitable as feed must be documented. In cases of deviations all feeds must be assessed again after the treatment in order to ensure that the batch involved now complies with the specified requirements.

The approval and treatment (for example with respect to rejected quality or customer returns) must be considered within the framework of the HACCP plan. The quality (specifications) of customer returns must be known. The participant must have information which shows whether mixing or cross-contamination has taken place at the external company. A procedure must be laid down for the recalling of external return flows. The feeds which cannot be approved must be considered to be waste and demonstrably removed in the correct fashion.

Feeds which do not fully comply with the customer specifications may only be delivered to the customer if the customer has been made aware of the problem and has confirmed to the participant in writing that this delivery will be accepted.

### 7.2.8 Storage as a service for third parties

#### Guidance

The service provider is not the owner of the feeds. Certain requirements of this standard should in that case be implemented differently or may even lapse entirely. The responsibility of the service provider is always limited to the correct implementation of the storage & transshipment service. He should comply with the relevant GMP+ requirements.

The responsibility for the feeds complying with other GMP+ requirements (such as product standards and purchasing) lies with the client or owner.

The basic principle is that the responsibilities must at all times be demonstrable and verifiable. As a service provider the participant has, when applying this standard, a special obligation to make clear what he is guaranteeing.

In the event of doubt he must take action to obtain clarity from or provide to his originator about responsibilities.

The participant must comply with all the relevant requirements in this standard with respect to storage & transshipment.

The participant must also comply with the additional requirements as agreed with the originator (as long as they are not in contravention to the requirements specified in this standard). In any event the participant must agree with the originator that sufficient information is provided with respect to the nature of the product and of the specific product characteristics, to assure a proper storage.

#### Guidance

Sufficient Information: Think also of information regarding traceability and identification. Proper storage includes avoidance of contamination and decline of quality.

The following requirements for storage & transshipment are not or only to a very limited extent applicable or must be applied with a different focus or applied to various responsibilities which the service provider and the originator or owner have with respect to the feeds and have agreed on (see above):

- a. the GMP+ appendices (chapter 2 and the various sections in which there is a reference to these GMP+ appendices).
- b. Traceability: Traceability means mainly internal traceability. A system must be established for this in which all the relevant internal product movements are properly recorded (section 5.4).
- c. in the event of irregularities in the feeds this will be reported to the originator (section 5.5/7.2.7). If legislation requires it then an irregularity must also be reported to the competent authority. The requirements for recall and the recall simulation apply if one is the owner of the product.
- d. If the participant stores feeds for third parties then he must receive a specification for the feeds from his client which enables him to carry out a correct hazards analysis and to take proper control measures relating to storage (section 6.3).
- e. The monitoring is focused on establishing that the control measures which are taken work properly for storage & transshipment (section 6.7). The standards used for this (section 6.6) may be different to those specified in GMP+ BA1 Specific feed safety limits.

GMP+ B3 Trade, collection and storage & transshipment

Version: 1st of April 2016

- f. Originators do not have to be assessed (section 7.1.3). For the suppliers of a storage & transshipment company this might include laboratories or suppliers of cleaning agents. Originators (customers) are not suppliers.
- g. In the event of doubt about products which are offered by originator there will be discussions with them (section 7.1.4)
- h. Data about production and about drying does not need to be available. This is the responsibility of the originator (section 7.2.5).
- i. If silo's or tanks are used for storage, the participant must maintain a report of the silo or tank empty reports (minimum 1x per 3 months). (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 must be given. The company must realise that any recall will be larger in size because the period of time between two silo empty reports will be longer).

This summary is not exhaustive. There may possibly be other requirements which must be otherwise applied within the framework of storage as a service than is normally the case of storage as property.

### 7.3 Transport

### 7.3.1 General

All transport of feed (by sea, by inland waterway shipping, by road transport, by rail, in containers or by way of some other transport system), irrespective of whether this carried out within the control of the participant or is outsourced must be controlled in the correct way specifically with respect to hygiene and potential contamination. Loads which are transported together with raw materials and feeds may not adversely affect the safety of the raw materials or feeds.

The participant may be responsible for the transport of feeds to buyers who work in accordance with a different quality assurance programme (other than GMP+). The participant must in that case ensure that in addition to the relevant transport requirements of this standard that there is also compliance with the specific demands and requirements of that programme.

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

# Guidance

For the transport of feeds in general, the loading compartments must, before loading, be completely empty, clean, dry and free of remains and odours from previous loads in order to prevent contamination of the load or carry-over. This means:

- a Free of possible 'agri-bulk unfriendly elements' such as remains of previous loads and/or cleaning activities
- b Free of pest in the broadest sense of the word. (insects, mammals, dead or alive).

See also the requirements for transport by inland waterway shipping, sea or rail in section 7.3.4. Actually, for the participant who is responsible for these forms of transport, these requirements mean that he must additionally apply another standard

If the participant is not responsible for the transport of his feeds then the relevant requirements in section 7.3.5 still apply.

## 7.3.2 Own road transport

The own road transport of feed ingredients must meet the requirements in the GMP+ B4 Transport and be certified as such.

# 7.3.3 Road transport carried out by a subcontractor

Road transport to a GMP+ certified company must be carried out by a carrier with a GMP+ B4.1 or B4 road transport certificate or by a carrier with a certificate which has been approved as equivalent. For this see GMP+ BA10 *Minimum Requirements for Purchasing*.

In addition it is also possible to make use of non-certified carriers for road transport. In this case the participant must apply the requirements from GMP+ BA10 *Minimum Requirements for Purchasing*, Annex 9.

## Transport of packaged feed

If a participant makes use of an external carrier for the transport of packaged feed then this external carrier and / or fright 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 raw materials or feed ingredients must take place in a clean and dry loading compartment.

#### Sealed loading units

Version: 1st of April 2016

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:

- 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.

#### 7.3.4 Transport via inland waterway, by sea and by train

*Inland waterways transport:* If the affreightment of inland waterways transport takes place on the responsibility of the participant, he must be GMP+ B4.2 /B4 certified. If a third party is responsible, then this third party must be GMP+ B4.2 /B4 certified.

GMP+ B3 Trade, collection and storage & transshipment

For the activities below no certification for GMP+ B4.2/B4 is required, but the participant must demonstrably comply with corresponding sections of GMP+ B4.2/B4. The participant must guarantee these activities in the feed safety system.

Giving the order for affreightment: demonstrable compliance with GMP+

B4.2 section 7.12.1 or GMP+ B4 section 7.2.1 and 7.2.2 and guaranteed activity in the feed safety management

system.

Approval of the ship before loading: demonstrable compliance with GMP+

B4.2 section 7.12.1 or GMP+ B4 section 7.2.1 and 7.2.2 and guaranteed activity in the feed safety management

system.

Giving the order for LCI: demonstrable compliance with GMP+

B4.2 sections 7.12.4 to 7.12.6 or GMP+ B4 sections 7.2.3 to 7.2.5 and guaranteed activity in the feed safety

management system.

The hold (= the actual means of transport in an inland waterway vessel) must always be certified for GMP+ B4.3.

Seagoing transport and transport by rail: Transport by sea and by rail must take place in accordance with the requirements of, respectively, GMP+ B4.4/ B4

Transport (Road & rail transport and affreightment). Affreightment of Sea Transport or GMP+ B4.5 / B4 Affreightment of Rail Transport. The originator for sea transport or for transport by rail must be certified for this.

In the event of transport via inland waterway, sea transport and transport per rail, an inspection should take place to check the cleanliness of the loading compartments (LCI = Loading Compartment Inspection) before loading is started. The loading process should also be controlled to be able to guarantee feed safety.

The participant who himself acts as the affreightment party cannot carry out an LCI. The inspection must be carried out by an inspection agency at EN 17020 level which is specialized in, and is accredited for, feed / grains or liquid agri-bulk and operates internationally on the basis of a certified quality system such as ISO 9001 or equivalent

If the participant does not act as the affreightment party, he can carry out the inspection by himself. This can be done by a loading inspector from the company. The 'load inspector' is a function specified in the quality system of the company and must be performed by an employee who - on the basis of training and experience - has the knowledge and skill to assess loading compartments on their suitability for use with feed ingredients.

In the event of the transport of GMP+-assured feed ingredients and non-GMP+-assured feed ingredients there must be a strict physical separation of these feed ingredients.

### 7.3.5 Transport for which third parties are responsible

If a third party is responsible for road transport then the participant must take reasonable precautions to prevent potential hazards.

If feeds must be loaded into a vehicle which has been arranged by a third party then the participant must check that the proposed means of transport is suitable for the feed to be transported and cleaned.

If the participant is instructed by a customer to load a batch in a means of transport which is not considered by the participant to be suitable then the participant must inform the buyer of this and obtain written confirmation from the customer before loading. Copies of the correspondence in question must be kept.

#### Guidance

A hazard analysis can provide information with which the intensity and the size of the checks could be established.

If use is made of an loading facility at which nobody is physically present to inspect the loading compartment for transport, the participant can make do with a written confirmation from the customer that loading may be done without a visual inspection.

# 8 Verification and improvement

# 8.1 Complaints

The participant must document his procedure for handling complaints. This procedure must in any event describe the registration of relevant aspects of the complaint and the associated measures taken.

A procedure for recording and handling complaints must at least consist of:

- a. The registration of the complaint
- b. the examination of the source of complaint
- c. registration of the measures taken as a result of the complaint
- d. registration of communication with the customers in question.

#### 8.2 Internal audit

The participant must have a procedure for the internal audit.

This procedure means that the participant draws up and implements a programme of planned audits to check that the feed safety management system functions properly and that it is also effective. During this internal audit, the following must be assessed in any event:

- a. compliance with the requirements and conditions of this standard
- compliance with the requirements and conditions of the participant's HACCP plan
- c. compliance with the participant's procedures
- compliance with the legal provisions with respect to the safety and quality of feeds

The programme must ensure that all relevant activities are audited at least once per year (= every 12 months).

All personnel carrying out internal audits must be competent for this by training or education (internal or external), or experience.

The results of the internal audit must be formally reported to the people with the responsibility for the area which is covered within the audit. All the aspects must be documented where the company operations or activities are not in compliance with the operational requirements. Such nonconformities must be corrected. The audit report must be signed by a person authorised to do so when the nonconformities are resolved.

#### Guidance

The checklist which is available on the website of GMP+ International (www.gmpplus.org) can be used during the internal audit.

The internal audit reporting may also be administered digitally.

### 8.3 Assessment of the management system and improvements

The participant must establish, collect and analyse suitable data at least once per year:

- a. in order to show that the feed safety management system is suitable and effective, and
- b. to assess whether improvement in the effectiveness of the feed safety management system is possible.

A procedure must be drawn up for this.

Verification of (elements of) the HACCP plan is part of this assessment.

The result of the analysis partly forms the input for the management review (see section 4.1)

The input for such an assessment must in any event contain:

- a. Verification of the prerequisites programme
- b. The results of the monitoring plan and the analysis of products
- c. Verification of the hazards analysis.
- d. Evaluation of the level of knowledge of the personnel
- e. The results of the supplier assessment
- f. Analyses of complaints (from customers)
- g. The implementation of legislation and regulations
- h. The results of internal and external audits
- i. Changes which have an influence on the feed safety system.

The assessment will in any event contain information on:

- a. The extent to which the feed safety management system can be applied
- b. The possibilities and chances of improving the feed safety system.

Also, a participant who operates as a service provider, must during the internal audit verify whether there is compliance with any additional requirements from the originator.

#### Guidance

More information about verification of the HACCP plan can be found in the HACCP manual.

# Annex 1: fuels

# Part A: Permitted fuels

#### Permitted are:

# 1. Fuels in gaseous form:

Natural Gas (NG or CNG - "(Compressed) Natural Gas")

# 2. Liquid Natural Gas ("LNG - Liquid Natural Gas"):

- Biogas ("Land Fill Gas")
- Liquid petroleum gas (LPG or refinery gas)

# 3. Fuels in liquid form:

- Petrol
- Light fuel oil
- Diesel oil
- Heavy fuel oil if in accordance with the legal standards (these are not uniform within Europe).

# 4. Fossil fuels in solid form:

- Thermal coal
- Metallurgical coal
- Antracite
- Coal products for domestic use including briquettes..

### 5. Biological fuels:

Non-fossil products of animal or vegetable origin such as straw, (clean)
wood chips, coconut husks and cacao shells, bagasse. In some areas (including Brazil) 'wood fuel' is grown on a large scale and is used in agriculture.

These types of fuel can be considered as vegetable / fibres / wood with respect to structure and composition. If these fuels are clean and dry then the risk is relatively low.

Vegetable and animal fats

\_\_\_\_\_

# Part B: Not-permitted fuels

See GMP+ BA3 *Minimum requirements Negative List*, chapter 5, for forbidden fuels.