



*GMP+ Feed Safety Assurance scheme*

## **Trade, Collection and Storage & Transhipment**

**B**

### **GMP+ B3 (2007)**

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# 1 Introduction

## 1.1 General

The GMP+ Feed Safety Assurance scheme (GMP+ FSA) has been developed since 1992. It was managed from 1992 up until 2009 by the Product Board Animal Feed, The Hague, The Netherlands. Since 2010, this scheme is managed by GMP+ International.

It is a scheme for assuring feed safety in all the links in the feed chain. It is also an international scheme, applicable worldwide.

The establishment and development of the scheme was primarily the result of demand from the subsequent links in the animal production chain for better control of feed safety. Another contributory factor was the damage caused by more and less serious contamination incidents.

In the initial phase the demand arose for better differentiation in an increasingly saturated European sales market for animal products. Since 1999, feed & food safety has been a top issue internationally both politically and commercially, because of serious incidents in the feed sector. Because of this, demonstrable assurance of feed safety has become a sales prerequisite.

The basic principle of the GMP+ FSA scheme is that the feed chain is part of the food production chain. Proper assurance of feed safety worldwide is a high priority. Companies must live up to their responsibilities and respond properly and convincingly to the needs of animal production. The GMP+ Feed Safety Assurance scheme is an aid to realise this.

## 1.2 Structure of the GMP+ Feed Safety Assurance Scheme

The documents within the GMP+ FSA scheme are subdivided into a number of series. A description follows of these:

<b>A</b> General (framework) documents	These documents contain the requirements for participation in the certification scheme for companies and certification bodies (framework regulation, the use of logo's, etc.). This series also includes a general list of definitions and abbreviations.
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**B**  
Normative documents.

These documents contain the international standards and additional country notes for use by companies with respect to the various feed products and production phases including cultivation and industrial production, treatment and processing, collection, trade, means of transport, storage and transshipment.

These documents are divided in several subgroups, with a code and a name

<b>Document</b>	<b>Code</b>	<b>Nname</b>
⇒ Standard	GMP+ Bxx	e.g. GMP+ B3(2007) <i>Trade, Collection and Storage &amp; Transshipment</i>
⇒ Appendix	GMP+ BAxx	
⇒ Country Note	GMP+ BCNxx	

**C**  
Certification requirements

These documents contain the Rules of Certification including those for the approval of certification bodies and auditors, the frequency of audits, minimum audit time, assessment criteria, checklists, etc. There is also an explanation of how the supervision by certification bodies is implemented and of how GMP+ International supervises the certification process.

**D**  
Interpretations and accompanying texts

In addition to the above-mentioned normative documents, there are also supporting documents in the D series including a list of frequently-asked questions, manuals and guidances with additional information.

All these documents are available through the website of GMP+ International ([www.gmpplus.org](http://www.gmpplus.org)).

The document in the present case is referred to as standard GMP+ B3(2007) *Trade, Collection and Storage & Transshipment* and is part of the GMP+ FSA scheme.

### 1.3 Scope and application of this standard

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

- a. Trade in feed. This trade varies from internationally-oriented activities (primarily trade in feeds which are delivered to the compound feed sector) to the trade in forage products and other simple feeds (which are mostly supplied to cattle

farmers). This refers to the trade in feeds such as hay, straw, green maize and silage and also sugar beet pulp, potato pulp, etc.

- b. Storage and/or transhipment activities for all types of feed. These activities can be carried out and guaranteed by the participant himself (for example the collecting trader). In addition, companies who store and/or tranship feeds as a service may apply this standard.
- c. Collection including any simple treatment or processing<sup>1</sup> of vegetable primary products such as grains, oil seeds, crops containing protein/legumes, tuber and root crops and also hay, straw and suchlike. NOTE: this applies of course in as far as these vegetable primary products have or are given the destination of feed.

Transport carried out for own products as part of or as a supplement to the above activities, can also be certified. See Section 7.8 for this.

Industrial production of compound feeds, premixes, feed materials and feed additives is not included in the scope of this standard. There are other standards available for these activities.

NOTE: In this standard the word 'feed' is usually used. It includes:

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

For further information and definitions refer to GMP+ A2 *Definitions and Abbreviations*. Account must be taken of the above when reading and applying this standard. If requirements only relate to feed materials, for example, then this term will be used as such.

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

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

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

The participant remains responsible at all times for the safety of the feed ingredients and activities associated with them, as well as for checking on compliance with

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<sup>1</sup> *By simple treatment or processing is meant a processing stage which only has an effect on the structure of the product. Examples of this are drying, cleaning, pressing, silage, making bales/packaging, chopping.*

the requirements. This must be done by the participant himself. By complying with the requirements of this standard and by being certified accordingly, the participant can demonstrate the safety and quality of his services or feed ingredients to third parties.

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

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

#### **1.4 The structure of this standard**

The feed safety system requirements are laid down 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 requirements for trade.

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.

GMP+ Appendices (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 feed ingredients or offering services which do not comply with feed safety as defined in the GMP+ FSA scheme.

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

## **2 Normative references**

### **2.1 GMP+ documents**

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

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

These documents can be found on the GMP+ International's website ([www.gmpplus.org](http://www.gmpplus.org))

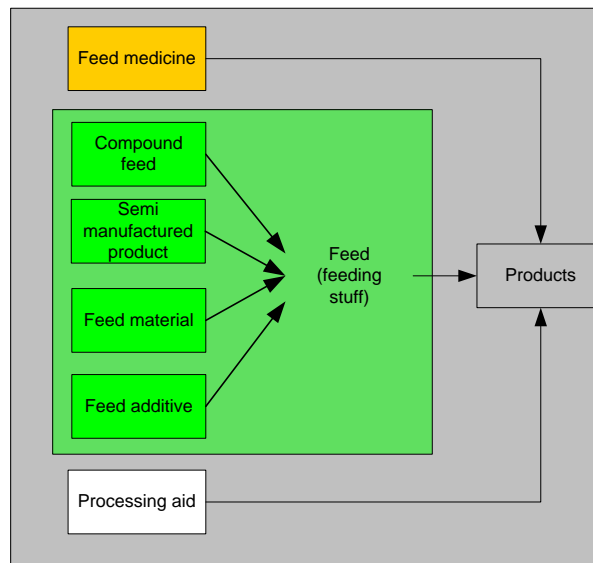
### **2.2 Legal compliance**

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

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

### 3 Terms and definitions

The relationship is shown in the following diagram between the various sorts of feed and some other products which are used in the processing of feed. For definitions of these (and other definitions) refer to GMP+ A2 *Definitions and Abbreviations* ([www.gmpplus.org](http://www.gmpplus.org)).



## 4 Requirements for the feed safety system

### 4.1 Management: responsibility and involvement

Management must be aware of its responsibility for the safety of the feed ('fit for the animal and for the consumer of animal products'). Feed is part of the food production chain.

Management must:

- d. Make the organisation aware of the importance of feed safety and of compliance with both the requirements of the customer and the obligations of the feed legislation.
- e. Demonstrate its responsibility and involvement in the development and introduction of the feed safety system to achieve safe feed.
- f. Establish a HACCP team:
- g. Ensure that resources are available. The participant himself must determine what resources are necessary for the realisation of safe feed and ensure that these resources are also available. 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.
- h. Assess at least once per 12 months whether the feed safety system is still suitable and effective.  
The input for such a management review must in any event contain information on:
  1. the results of the control plan and other verification elements of the HACCP system;
  2. the results of the supplier evaluation;
  3. the results of internal and external audits;
  4. feedback / complaints from customers;
  5. changes to, for example, the feed legislation which may have an influence on the feed safety system.

This review must in any event contain information of:

- a. the extent to which the feed safety system must or can be modified;
- b. the possibilities and chances of improving the feed safety system.

This management review must be documented and archived.

### 4.2 HACCP team

The HACCP team must carry out a hazards analysis with the object of identifying and controlling risks which could have a negative effect on feed safety. See Annex 1 for the requirements for the carrying out of a HACCP hazards analysis. A feed safety system must also be set up in support of risk control.

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.

As explained in section 1.3, this standard describes as carefully as possible the requirements with respect to various risks and the associated control measures for some activities and feeds. These control measures may be part of a prerequisite programme or be established as a specific measure to control a particular critical point.

The HACCP team must draw up a description of the process in the form of flow charts and a lay-out which enables the organisation to identify and analyse hazards. The following items are indicated in this lay-out:

- a. the routing of products and personnel;
- b. the areas where cross-contamination of and incidental contact with products, which are treated or which are finished, through raw materials, feed additives, lubricants, cooling agents, personnel, packaging, pallets and containers can not be excluded;
- c. the areas and facilities which are available to the personnel.

The HACCP team must also:

- a. determine whether the operational management of the company complies with the activities described in this standard;
- b. determine whether the risks are sufficiently controlled by this;
- c. carry out an additional hazards analysis (including the establishment of control measures) for process steps which are not (properly) described in this standard;
- d. specify all operations in control measures;
- e. implement all control measures;
- f. validate the specified control measures and modify them if necessary;
- g. document the previous steps (in descriptions, procedures, instructions, etc.)

Also see Annex 1 *HACCP guidelines* for this.

## **4.3 The feed safety system**

### **4.3.1 Scope**

The participant must determine and record the scope of the feed safety system. The scope must in any event include all feeds and all activities related to the feeds for which the participant is responsible.

The participant shall determine the following:

- 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. All feeds (in specifications) which are traded, stored, transhipped and/or processed.
- c. All activities related to feed (trade, storage, collection, treatment and transport) (in flow charts), including activities which are outsourced. With respect to transport the participant must at least include in the description the number and type of transport means, the types of loads which are transported and the cleaning method used. See also the sections containing transport requirements.
- d. All relevant locations whether these are the property of the company or not, including locations where administrative activities are carried out.

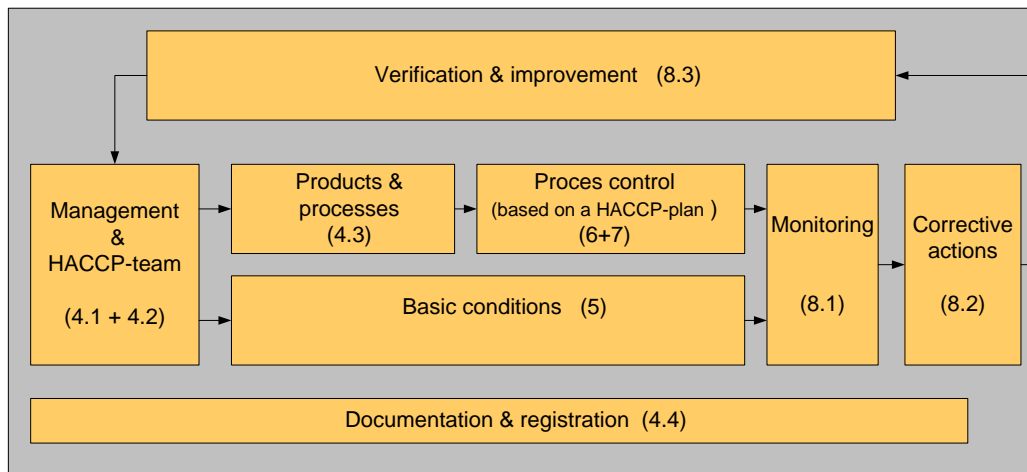
**NOTE:**

- a. A participant can exclude the trade in non-GMP+-certified feeds from the scope of the feed safety system. This exclusion is done on the condition that
  - 1. these non-GMP+-assured feeds are separately processed, produced, stored and/or transported and that they no influence whatsoever on the safety of feed which is covered by the feed safety system.
  - 2. The participant must in his records make a clear and demonstrable distinction between the GMP+-assured feed and the non-GMP+-assured feed.
  - 3. If a participant trades non-GMP+ certified feeds then their status must be reported in writing to the client. This applies in the event of delivery to GMP+-certified customers or customers who are certified in another certification scheme which has been declared to be equivalent to the GMP+ FSA scheme (see GMP+ BA10 *Minimum Requirements for Purchasing*). The sentence “The goods delivered do not have the GMP+ status as specified in the GMP+ Feed Safety Assurance scheme” (or: “The goods delivered are non-GMP+-certified”) must be specified in the sales contract. If there is no sales contract then this must be specified in some other written form by the time of delivery at the latest.
- b. If a participant decides to outsource a process which possibly has an influence on feed safety then the participant must ensure that this process is also carried out in accordance with the requirements of this GMP+ standard and is also certified as such. See GMP+ BA10 *Minimum Requirements for Purchasing*.
- c. The participant must also describe all other activities and/or products which are not feed related. The participant must ensure that these activities do not have a negative influence on the safety of the feeds.

#### 4.3.2 Structure

The structure of the feed safety system must relate specifically to the organisation of the participant and be aimed at continuous control of feed safety. This must be based on the HACCP principles. The minimum requirements for this feed safety system are described in this standard.

The following diagram provides an overview of the required system.



## 4.4 Documentation and registration

### 4.4.1 Manual

The participant must draw up a manual and maintain it. This manual must contain all the documents required for implementing the feed safety system as described in this standard or refer to it.

This required manual contains or refers to:

- a. Description of the scope of the feed safety system as required in section 4.3
- b. All relevant records or approvals in accordance with national and international legislation
- c. The HACCP documentation
- d. All procedures, instructions, registration forms, etc.
- e. All records of treatment, audits and inspections and all other records which are required under 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.

There must be a clear, unambiguous structure applied to these documents, instructions, forms, etc.

### 4.4.2 Checking of documentation and data

The documents and (registration) data must be controlled. They must be kept and maintained in the correct fashion.

The documentation must

- a. be approved, dated and signed by an authorised person and must be reviewed at least once per year for relevancy and currency;
- b. always be accessible and understandable to those members of the personnel who implemented the requirements of the procedure;
- c. be revised and updated if the process undergoes a relevant change so that it is always up to date.

Participants must ensure that:

- a. All documentation and (registration) details which are required under this standard are kept for a period of at least 3 years unless a longer retention period is prescribed by law.
- b. There are storage facilities for documentation and any degradation in the condition of or damage to the documentation is recorded.
- c. Documents and details are sorted and stored in such a way that the information is complete and easy to retrieve.

## 4.5 Identification and traceability / sampling

### 4.5.1 Identification and traceability

The participant must take suitable measures to ensure that the feeds produced can be traced effectively. To do this he must register the relevant data with respect to

purchasing and suppliers and sales and customers to be able to trace the feeds effectively.

#### 4.5.2 Sampling

In addition, within the framework of traceability sufficient samples must be taken from incoming and/or outgoing feeds. To do this a previously-determined procedure must be followed by the participant.

These samples must:

- a. be sealed and labelled in such a way that they are easily identifiable.
- b. be stored in such a way that any change to the composition or any deterioration of the sample is excluded.
- c. be kept available for the competent authorities for a period which has been matched to the use for which the feeds were placed on the market.

NOTE: within the framework of this GMP+ standard all participants who actually physically process or import samples must have samples taken. In all companies who apply this standard the obligation to take samples can be made dependent on the interpretation of the feed legislation by the competent authorities in question.

The participant may enter into written agreements with third parties on the taking and storing of samples. This may apply, for example, to traders.

#### 4.6 **Complaints**

Participants must document their procedure for handling complaints from customers. This procedure must in any event describe the registration of relevant aspects of the complaint and the measures taken.

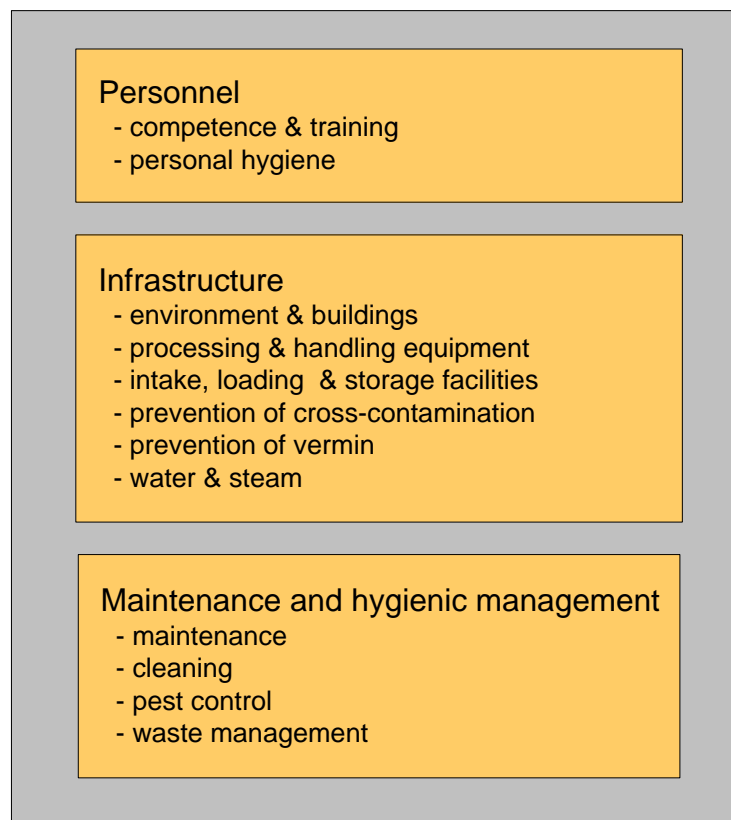
A procedure for recording and handling complaints must at least consist of:

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

## 5 Prerequisite programmes

In order to be able to guarantee safe feeds, the HACCP system must be founded on a sound basis: the so-called prerequisite programmes. These prerequisites and (hygiene) practices are considered to be a pre-condition for the implementation of an effective HACCP plan. Prerequisite programmes create the environmental and implementation conditions for the provision of safe feeds. This chapter describes the requirements for certain elements of the prerequisite programmes with respect to personnel, buildings, production areas and equipment and for maintenance and hygiene control.

NOTE: prerequisite programmes do not have to be limited to these elements; other aspects may also be considered to be prerequisites.



NOTE: As indicated in section 1.5, the requirements in section 5.1 are applicable to each company which applies this standard. The requirements in sections 5.2 and 5.3 may be excluded but only with a proper argument.

## 5.1 Personnel

### 5.1.1 General

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

There must be:

- a. an organisational chart
- b. a description of the qualifications (for example diplomas, summary of professional experience) and the responsibilities of supervisory personnel.

The personnel must be clearly informed in writing with respect to tasks, responsibilities and competences, especially in the case of changes. This is to be able to keep the desired feed safety under control.

### 5.1.2 Competency and training

Personnel who carry out work which may influence feed safety must be competent. Their level of competency is based on suitable courses, training, skills and experience. The participant must have sufficient personnel with the skills and qualifications which are required for the trading, treatment or processing of safe feeds.

The participant must:

- a. Establish the necessary skills which the personnel must have if they carry out work which influences feed safety. This also applies to the HACCP team
- b. Offer training or take other measures to meet these needs
- c. Maintain personnel records of courses, training, skills and experience.

Protective clothing must be worn if the hazards analysis shows that contamination of feeds may take place.

Clear rules must be established with respect to food, drink and smoking in the processing areas in which cross-contamination of feeds must be prevented.

The above also applies to temporary personnel.

The participant must also ensure that (technical) personnel from third parties are directed during work at the location such that maintenance and construction work do not have a negative effect on the safety of raw materials or feeds.

## 5.2 Infrastructure

### 5.2.1 Environment, building and production areas

The processing of and/or working with feeds must be carried out in an environment where it is not possible for the presence of potentially hazardous substances to lead to an unacceptable level of those substances in feeds.

Buildings where treatment takes place or where work is done on feeds may not be at or near to places which present a clear hazard for feed safety. This includes contaminated ground, proximity of rubbish tips and suchlike.

If an environment presents a risk to feed safety then the participant must show by way of a hazard analysis that the risks are sufficiently controlled. The production areas and the equipment must be designed, constructed and maintained such that the safety of feeds is guaranteed at all times and that contamination of the feeds is prevented. They must be designed and constructed such that, where necessary:

- a. accumulation of dirt is prevented;
- b. condensation, undesired mould and falling particles are limited
- c. cleaning, disinfection and maintenance can be carried out properly.

The production areas must be such that:

- a. the chance of errors is limited as much as possible and contamination, cross-contamination and any negative influence on the safety of feeds is prevented as much as possible
- b. There can be no confusion among the various feeds, the feeds are properly identified and no incorrect use of the feeds can take place
- c. That a strict and complete physical and organisational separation is imposed between the feed and products which must not be in feed<sup>2</sup>.

This separation is intended with respect to feed safety to prevent feeds coming into contact or being mixed with other products.

The production areas must be provided with proper natural and/or artificial lighting.

Sewer, waste, rain and melt water must be discharged in such a way that the equipment and the safety of the feeds is not influenced. Spilled feed and dust must be controlled to prevent pest.

Drainage facilities are suitable for the intended purpose. They must be designed and constructed in such a way that any risk of contamination of the feeds is prevented.

### 5.2.2 Access regulation

Access arrangements must be established for the production areas. Anyone who is not an employee may only be given access to the production areas under the supervision of or with the permission of an authorised person.

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<sup>2</sup> *Examples are fertiliser, fuel, cleaning and disinfectant agents, glass, crop protection agents, waste.*

### 5.2.3 Processing plants

All transport systems and processing plants must be kept sufficiently clean and hygienic so that they do not exert a negative influence on the feeds which come into contact with them.

All equipment (including sieves, filters, graders, weighing scales, measurement equipment and such like) which is used for the processing, storage and transportation of feeds must be suitable for their purpose.

### 5.2.4 Production areas

Proper production areas must be provided for, for example, reception, loading and unloading and the storage of feeds and potentially hazardous products (such as cleaning agents, lubricants, fuels, etc.).

During reception or loading and unloading the participant must do everything which is reasonably possible to create such conditions that the risk of contamination is avoided and that, for example, bad weather can not have an influence on the feeds to be loaded.

During loading, unloading and storage the penetration of rain water and contaminated water must be prevented.

In the case of a storage area care must be taken that mud, snow and other potential contaminants which may be transferred by vehicles are not able to exert any negative influence on the stored feeds.

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

Feeds must be stored such that these can be easily identified and that confusion with other products is prevented.

### 5.2.5 (Cross) Contamination

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

The processed feeds must be kept separate from the untreated feeds to prevent cross-contamination of the processed feed.

### 5.2.6 Prevention of pest

Production areas for reception, loading and unloading must be designed such that birds and other animals have the least possible chance of getting in.

### 5.2.7 Water and steam

The participant must be sure that the water or the steam which is used during the cleaning or in the processing of the feeds is safe for animals. The participant must ensure that the feeds are not contaminated by the use of water of poor quality.

Special attention must be paid to processing aids.

## 5.3 Maintenance and hygiene management

### 5.3.1 Maintenance

A (written) programme of planned maintenance must be drawn up and implemented for all production areas and equipment so that safe and hygienic operations are ensured.

Records of the maintenance activities must show that there is compliance with the requirements.

The maintenance programme must contain at least the following elements:

- a. (production) areas and production halls
- b. equipment and (internal) transport systems
- c. Personnel involved (own personnel or hired personnel)
- d. Frequencies
- e. Other aspects. Maintenance activities may not form any risk at all for feed safety

The participant must record the maintenance which is carried out on all equipment which is critical for the processing of and/or operations with feeds.

### 5.3.2 Cleaning

Dust, dirt and feed remains can form a major breeding ground for the growth of bacteria which can contaminate feeds. The accumulation of dirt, dust and feed remains must therefore be prevented as much as possible. A participant shall establish, implement and document all necessary measures that must ensure proper production hygiene.

Records of the cleaning activities must show that there is compliance with the requirements.

The cleaning programme must contain at least the following elements:

- a. (production) areas and production halls
- b. equipment and (internal) transport systems
- c. involved personnel
- d. frequency of cleaning
- e. the cleaning agents used must be recorded and must be suitable for purpose. In addition, these activities may not form any risk at all for feed safety remains of cleaning and disinfectant agents must be minimised

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

The participant must record the cleaning work which is carried out on all equipment which is critical for the processing of and/or operations with feeds.

### 5.3.3 Pest control

Everything which is reasonably possible must be done to keep birds, pets and pest away from the production areas and to prevent their presence. The participant must

take measures to counter pest and set up, implement and document a pest control programme.

Activities within the framework of pest control must be planned, carried out and recorded. Records of the control activities must show that there is compliance with the requirements.

The participant must describe which methods are used, the personnel involved, etc. In the implementation of pest control programmes acceptable methods and resources for pest control must be used.

The control must relate to all types of animals (birds, insects, mammals).

If the presence of, for example, birds is unavoidable then procedures must be set up to protect the feeds from potential contamination. The penetration of pest into buildings must be avoided as much as possible. Doors and windows must remain closed as much as possible.

The participant must record the pest control which is carried out on all areas and equipment which is critical for the processing of and/or operations with safe feeds.

#### 5.3.4 Waste management

All materials which are considered to be waste must be visually designated as such and protected in such way that the chance of errors or unintended use is eliminated.

The waste must be collected and stored in separate bins or containers. These must be easily identifiable and must be covered in the case of pest or insect waste.

#### 5.3.5 Glass and breakable materials

The participant must ensure that glass and breakable materials do not form any hazard to the feeds. All reasonable efforts must be made to minimise the risk of glass breakage and to ensure that no contamination of feeds can take place in the event of glass breakage.

## 6 Trade in animal feeds

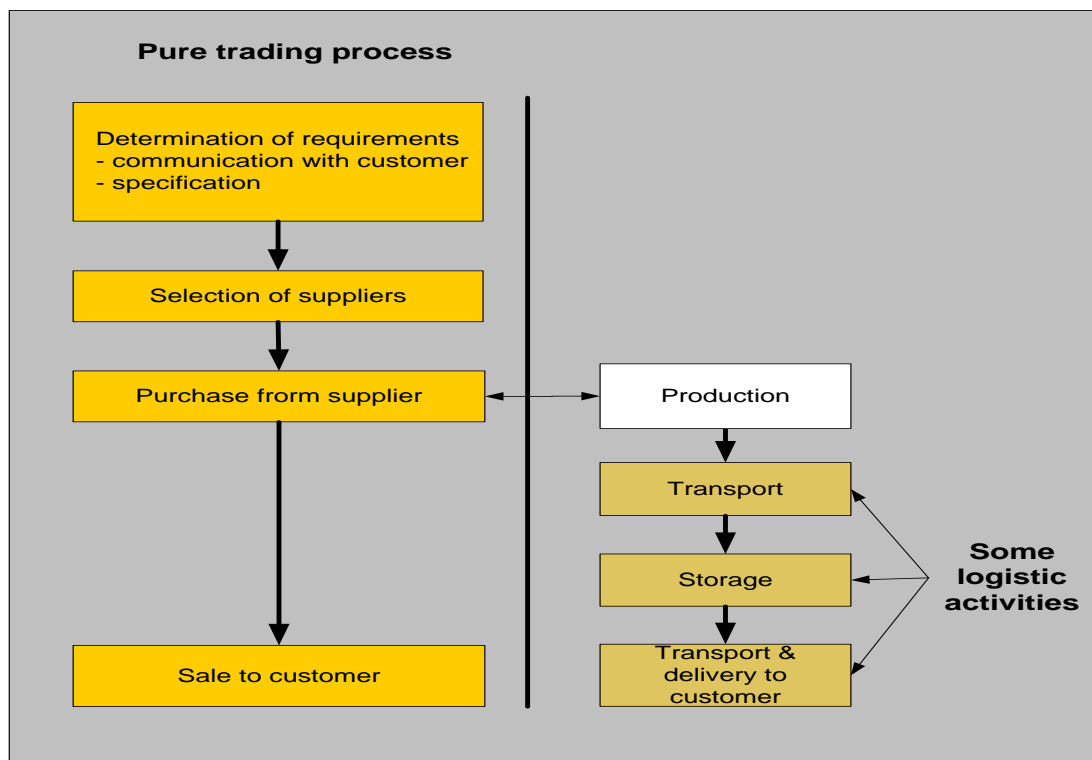
The trading process is an important process which must be controlled in a proper fashion to be able to assure the safety of the feeds. On the one hand the trader is engaged with customers who have (specific) requirements with respect to the feeds and, on the other hand, with suppliers who can supply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

A number of stages can be distinguished in the trading process:

- communication with the customer about his requirements
- determination of the requirements with respect to feeds including what is necessary for labelling and delivery documentation
- selection of suppliers
- the actual purchase of feeds
- registration

This chapter describes the requirements for the control of these trading activities.

NOTE: These stages also apply to a company which, in addition to the trading activities, also carries out the collection, storage and transport of feeds. These activities must also of course be controlled in the correct way. Refer for the requirements for the collection, storage and transport to the relevant sections of this standard.



## 6.1 Determination of requirements and communication with customers

The participant must enter into discussions with the customer and ensure that the requirements of the customer with respect to feed safety are understood, specified and complied with.

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

The communication with the customer must result in the determination of:

- a. the requirements of the customer with respect to the safety of feeds and/or
- b. 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.

The participant must also determine:

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

Refer for the relevant requirements in the context of the GMP+ Feed Safety Assurance Scheme:

- a. GMP+ BA1 *Product Standards*;
- b. GMP+ BA3 *Minimum Requirements Negative List*;
- c. GMP+ BA4 *Minimum Requirements for Sampling and Analysis*;
- d. GMP+ BA10 *Minimum Requirements for Purchasing*;

For each type of feed that is purchased or received a generic risk assessment must be included in the Feed Safety Database.

If no generic risk assessment is published for the feed material in question in the Feed Safety Database then the participant can only purchase or sell it within the framework of GMP+ after publication of this feed material in the database. For the procedure for the publication of a feed material in the Feed Safety Database see GMP+ International's website. ([www.gmpplus.org](http://www.gmpplus.org))

## 6.2 Specification and labelling

### 6.2.1 Specification of the animal feed

There must be a description on the basis of the above requirements for each feed to be purchased. The scope of the description of the feed must stretch from the products used during production up to and including distribution.

The specifications must include, where applicable<sup>3</sup> 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);
  4. Standards / requirements (feed legislation; agreements with customers) and tolerances. Under the GMP+ Feed Safety Assurance scheme the feeds must at least comply with the relevant product standards which are laid down in GMP+ BA1 *Product Standards* ;
  5. Other features (including storage, packaging).
- b. Characteristics for use:
  1. Intended use;
  2. Processing instructions;
  3. instructions for administering the products to animals;
  4. Storage conditions;
  5. Storage life;
  6. Conditions and agreements with respect to transport and the place of delivery;
  7. The legal notices as indicated on the packaging or in the accompanying documents. See the following section.

NOTE: 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 production and storage conditions are equivalent;
- c. No major aspects relating to product safety are forgotten.

### 6.2.2 Labelling and delivery requirements

The participant must provide his customer with the necessary information with respect to the feeds supplied so that his customer (the next link in the chain) can carry out his own proper hazard analysis.

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

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<sup>3</sup> Not all links in the chain can always specify all components. This applies particularly to the components specified in b).

The participant must ensure that the feeds which are supplied by him comply with the applicable requirements for both the country in which it was produced or treated and, if applicable, the country in which it is placed on the market.

### **6.3 Selection of suppliers**

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. All suppliers must also be reviewed every year. Criteria must be established for selection, assessment, approval and evaluation.

The participant must demonstrate that all suppliers meet the requirements.

The participant must only obtain and use feeds from suppliers who comply with the relevant legislation and regulations. In Europe, suppliers must be registered and/or certified in accordance with EC Regulation No. 183/2005.

Under the GMP+ Feed Safety Assurance scheme the following two prerequisites apply with respect to the supplier:

- a. The supplier is also GMP+-certified at the moment of delivery;
- b. The supplier is not GMP+ -certified but is certified under another approved certification scheme.

Specific purchasing requirements apply for some feeds and services. See also GMP+ BA10 *Minimum Requirements for Purchasing*.

Prior to the purchase of other products (other than feeds) or services<sup>4</sup> (other than storage and transshipment, transport or laboratory) the participant must carry out its own hazard assessment 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 modify his entry check accordingly.

### **6.4 Purchase / sale**

The participant must ensure that the purchasing of feeds and services is in accordance with the above requirements. The purchase and sale of feeds must be clearly recorded.

For the requirements in the field of storage and transshipment refer to the relevant sections of Chapter 7.

### **6.5 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.

If the participant actually receives the feeds at his own site then see Chapter 7.

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<sup>4</sup> Products are, for example, processing aids or cleaning and disinfectant agents. Services include silo cleaning or pest control. This refers, of course, to products or services which may influence the safety of feeds.

## **6.6 Documentation**

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

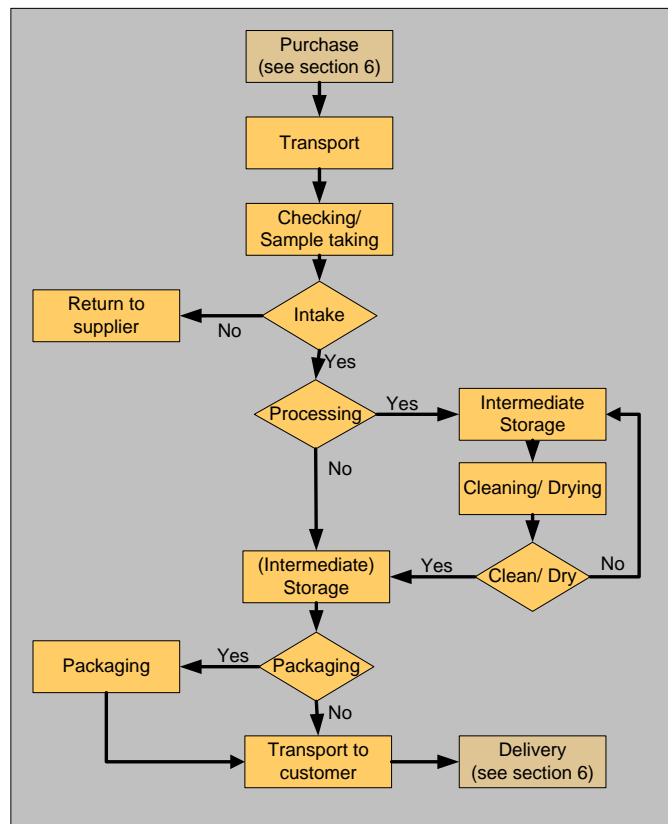
If the requirements are amended then the participant must ensure that the relevant documents are modified and the relevant personnel are aware of the changes to the requirements.

## 7 Control of operational activities

There are various stages to be distinguished in the process of collecting, storage and/or transport of feeds. See also the diagram below.

As explained in section 1.3, this standard describes as carefully as possible the requirements with respect to various risks and the associated control measures for some activities and feeds.

NOTE: the requirements for purchase and delivery are described in the chapter on trading.



### 7.1 General

All the stages in the process must be planned and monitored to ensure that the feed remains in accordance with the documented specifications and the documented parameters for critical steps. This must be based on a HACCP hazard analysis.

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. See also Annex 1 *HACCP Guidelines*.

Special attention must be paid to the stages which are discussed in detail in the following sections. Proper control measures must be implemented. Procedures must prescribe corrective measures in cases where critical process parameters are exceeded. These procedures must be based on a HACCP hazard analysis.

There must be sufficient suitable checks during the activities such as during reception, loading, storage and the processing phases.

A qualified person must be made responsible for production.

If changes are made to a product, process or a phase of the treatment, storage or delivery then the participant must examine the procedure and implement the necessary changes.

## **7.2 Verification of incoming feeds**

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

Each incoming delivery must be verified. During the entry check all incoming feeds must be released before they can be stored and/or further processed. For the requirements with respect to sampling see section 4.5.

The feeds must comply with the specifications. The check on compliance with the specifications is an important control point.

Inspection points may be:

- a. the colour;
- b. the physical form ;
- c. odour;
- d. contamination by insects, dirt or other items which do not belong in feeds;
- e. damp / mould;
- f. abnormal damage.

The participant must also check whether the transport complies with the agreed requirements (minimum check: whether the carrier is GMP+ certified or complies with the requirements with respect to the previous loads, the prescribed cleaning, oil leaks, etc.).

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

The feeds 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. See the following sections for this.

### 7.3 Cleaning / sieving

The presence of contaminants such as glass, wood or earth 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 make use of proper cleaning methods for this.

Batches can be cleaned if the type of contamination permits this. Batches may be sieved to remove (physical) contaminants. The correct operation of the sieve is a critical point and this must therefore be controlled by way of a good maintenance plan.

The responsible person must in addition also check in advance 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 physical contamination must be carried out by the person responsible for this.

### 7.4 Drying and ventilating

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 microbiological organisms, biological decay and overheating.

A low moisture content and a low temperature prevent decay. 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.

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

The moisture content can be reduced by way of drying, ventilation or a combination of these.

#### Drying

Drying must preferably be indirect. This prevents toxic components (such as dioxins and PAHs) from the combustion gases from getting into the feeds. Special attention must therefore be paid to possible contamination during (artificial) direct drying. The quality of the fuel is therefore important.

In principle, only those fuels are acceptable which are specified in Annex 2 *Fuels*, section 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 2 *Fuels*, section B are not permitted in any case.

Received feeds can also already be dried elsewhere. In this case the participant must make agreements with his supplier on the provision of information with respect to the drying method. On the basis of this information and additional (visual) checking or analysis the participant must assess whether the feeds have been sufficiently dried in a suitable manner.

### Ventilation

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

### Checking

The moisture content must be checked by the person responsible for this after drying or ventilation. This check of the moisture content must show whether the selected drying method was sufficient 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.

## **7.5 Storage**

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

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

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 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.

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.

Where applicable temperatures must be kept as low as possible to prevent condensation and decay. The presence of (storage) moulds is characterised by colour deviations and a musty odour. The person responsible must check the batch for the absence of moulds (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 responsible person 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.

Storage and transshipment may only be outsourced to a company which is GMP+ certified for this. See GMP+ BA10 Minimum Requirements for Purchasing. The

exceptions may be:

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

In these exceptional case, the participant must:

- a. have an inspection carried out before usage of the control on feed safety
- b. establish that the storage and transhipment company complies with all the applicable legal obligations relating to feed<sup>5</sup>.
- c. Lay down agreements in a contract on the relevant prerequisites (hygiene, T&T, etc.), control measures to be carried out and audits. This must offer guarantees to GMP+ equivalents with respect to the storage of the feeds.
- d. have periodic inspections carried out of compliance with the agreements made.

## 7.6 Simple treatment of feeds

By 'simple treatment' is meant treatment activities which are very easy to carry out. See the list of definitions in GMP+ A2 *Definitions and Abbreviations*.

These activities must be controlled on the basis of the HACCP principles.

The participant must:

- a. Use machines which are suitable and correctly adjusted for the operation to be carried out
- b. These machines must be thoroughly maintained and cleaned. In particular, contamination through prior use or lubricants must be prevented
- c. Clearly instruct the personnel in the achievement of the desired level of feed safety.

## 7.7 Packaging

The packaging of the feeds must be suitable for the kind of feed and the chosen method of delivery or transport. The packaging must be designed for the protection of the feed during normal storage, treatment and delivery conditions.

## 7.8 Transport

### 7.8.1 General requirements

Transport may not lead to undesired contamination of the feed. To control the risks of contamination of feeds during transport the participant must at least apply the relevant requirements and prescribed working methods from GMP+ BA14 *Minimum Requirements for Road Transport*.

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<sup>5</sup> For Europe, for example, there is a duty of registration under Reg. (EC) 183/2005.

## 7.8.2 Road transport

### 7.8.2.1 *General*

The road transport of feeds must comply with the relevant GMP+ requirements from this standard and GMP+ BA14 *Minimum Requirements for Road Transport* and be certified as such. The following options are possible for road transport of own<sup>6</sup> feeds.

Transport of own feeds	To	Certification in accordance with
By own means of transport	GMP+ B1, GMP+ B2, GMP+ B3 GMP+ B5	GMP+ B4.1 <i>Road Transport</i> or GMP+ B3 (= this standard), see section 7.8.2
By external carrier	GMP+ B1 GMP+ B5	GMP+ B4.1 <i>Road Transport</i>
By external carrier	GMP+ B2 GMP+ B3	GMP+ B4.1 <i>Road Transport</i> or GMP+ B3 (= this standard), see section 7.8.3 <sup>7</sup>

If the destination of road transport is a GMP+ B1-certified company and is carried out by an externally-engaged carrier then this carrier must be GMP+ B4.1 *Road Transport* certified or certified under a scheme which has been approved as an equivalent in the GMP+ Feed Safety Assurance scheme. An exception to this are those external carriers who are only used for the transportation of packaged products. The road transport of packaged feeds in own transport must be assured in an own feed safety system.

### 7.8.2.2 *Loading*

Before loading feeds a visual inspection must be carried out to determine whether the loading compartment is clean and, if necessary, dry. In addition, the outside of the vehicle, including the chassis, must be free of all visible remains of the previous load.

The driver must visually check the loading category of the feed during loading (see GMP+ BA14 *Minimum Requirements for Road Transport*). The results of this check must be recorded.

If participants are instructed by a buyer to load a batch in a means of transport which does not comply with the requirements then the participant must consult with the buyer for further instructions before loading. The results of this consultation must be demonstrable

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<sup>6</sup> *It is not possible to have transport for third parties certified under this standard. In that case the participant must be additionally certified in accordance with GMP+ standard GMP+ B4.1 Road Transport.*

<sup>7</sup> *This option is only permitted for transport which takes place entirely outside the Netherlands. Transport requirements are evaluated on this point to remove differences between the Netherlands and other countries.*

### 7.8.2.3 Transport

Feeds may (in combined transports) not become mixed together.

The participant must ensure that the loading compartments are covered during transport. Penetration of rainwater, contamination by the excrement of birds or other forms of contamination of the loading compartment must be prevented even if the loading compartment is empty. If the covering of loading compartments is not possible then the loading compartment must be wiped dry, if necessary after hosing clean, before another load is loaded. Tarpaulins to be used for covering loading compartments are to be clean before bulk loading and in the case of loading dry feeds they are also to be dry.

### 7.8.2.4 Unloading

After unloading the participant must visually check the loading compartment for remains of the load. If applicable the participant must remove the load remains as much as possible.

### 7.8.2.5 Cleaning

Cleaning and/or disinfection must take place before loading feeds. The participant must apply the relevant requirements and the working method as prescribed in *GMP+ BA14 Minimum Requirements for Road Transport*. After each cleaning, at least a visual inspection must be carried out.

Each cleaning programme drawn up for a certain loading compartment must be checked for effectiveness (validated). The participant must draw up a control programme which includes the minimum frequency for carrying out these checks. Then this cleaning programme can be used as the official cleaning method for each similarly constructed transport space.

### 7.8.2.6 Registration

There must be a record of the transported loads, the cleaning between successively transported loads and the inspections.

At least the following details must be maintained and available:

- a. The loads must be maintained by way of a journey sheet in the case of bulk transport for each loading compartment and the means of transport. The details of the last three loads must be available for checking unless it is specifically determined in the hazard check that the previous loads do not form a potential hazard. This may be the case, for example, if the same type of feed is always carried in the transport means.
- b. The legally-prescribed documentation including the way bill.
- c. The cleaning and disinfection measures carried out for each bulk transport compartment.
- d. The results of the cleaning and disinfection measures must be visually checked and recorded on the journey sheet.

### 7.8.3 Road transport

This option is only permitted for transport which takes place entirely outside the Netherlands. For transport from and to companies registered in the Netherlands the requirements apply in 7.8.2<sup>7</sup>.

For road transport to another GMP+ B3-certified company it is also permissible to engage a non-certified external carrier.

These external carriers must be properly instructed with respect to the relevant transport requirements. These must be checked by the participant (by way of an internal audit) and inspected.

The participant and/or the external carrier who has been engaged must provide the following during the transport of feeds:

- a. A journey sheet for each loading compartment with details of the previous loads
- b. Details for each loading compartment about the cleaning and disinfection procedures which are carried out
- c. Details of the cleaning inspection prior to the loading for the loading compartment
- d. Details of the inspections which are carried out per loading compartment.

If the result of the inspection is positive then the loading compartment is approved for the transportation of feeds. This inspection must be carried out by a loading inspector. A 'loading inspector' is a position which is specified in the quality system. This role is fulfilled by an employee who, on the basis of training and experience, has the knowledge and skills required for the inspection of a loading compartment for its suitability for the loading of feeds.

The receiving GMP+ B3-certified company must carry out an entry check on the incoming feed transport. The company must check:

- a. that the three previous loads were acceptable as prior loads for the transportation of feeds
- b. that proper cleaning has taken place
- c. that an inspection has been carried out before loading.

If the result of the entry check is positive then the feeds can be accepted.

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

#### a1) inland waterway transport to GMP+ B1 *Production, Trade and Services* certified companies

Affreightment by inland waterway must always be GMP+ B4.2 *Affreightment of Short Sea Shipping and Inland Waterway Transport* certified. This applies both when the participant carries out the affreightment himself and when the affreightment is carried out by third parties.

The carriage (= the actual transportation by inland waterway vessel) must be GMP+ B4.3 *Inland Waterways Transport* certified.

a2) Sea transport and rail transport to GMP+ B1-certified companies

Transport by sea or by rail must comply with the requirements of GMP+ B4.4 *Sea Transport Affreightment* and GMP+ B4.5 *Rail Transport Affreightment*. The principal for the sea transport or rail transport should be certified as such.

b) Inland waterway transport, sea transport and rail transport to GMP+-certified companies

This option is only permitted for transport which takes place entirely outside the Netherlands. For transport from and to companies registered in the Netherlands the requirements apply in a1 and a2 <sup>7</sup>.

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

The inspection and quality assurance may be carried out by:

- a. An inspection agency at EN 17020 level which specialises 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
- b. A loading inspector from a GMP+ B3(2007) *Trade, Collection and Storage & Transshipment* certified company which has purchased the transport or, at his request, the loading inspector of the supplier. The position of load inspector is a function specified in the quality system of the company and must be performed by an employee with the training and experience to assess loading compartments with expertise and know-how on their suitability for use with feeds.

The participant who himself acts as the shipping party must have the LCI carried out by an external audit organisation. The shipper may not undertake his own LCI.

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

## 8 Verification and improvement

### 8.1 Monitoring

In order to be able to verify whether the control measures have been effective, the critical points in the processes and the feeds are subjected to periodic inspections. A monitoring plan which particularly includes the checking of critical points in the process must be drawn up and implemented.

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 or a reference if use is made of an external laboratory (see below). These methods and equipment must be sufficient to achieve the desired results.
- c. The frequencies of the analyses, checks and inspections. The monitoring plan must in any event be in accordance with the inspections laid down in the GMP+ FSA Scheme (see GMP+ BA4 *Minimum Requirements for Sampling and Analysis*).
- d. Compliance with the specifications and the usage if there is no compliance with the specification.
- e. All planned inspections and checks and analyses.
- f. The instructions for the carrying out of inspections and checks.
- g. The personnel who are responsible for implementing the monitoring plan.
- h. The personnel who are responsible for assessing the results of the monitoring plan.
- i. The personnel who are responsible for releasing the feed.

Sampling must be carried out in accordance with GMP+ BA13 *Minimum Requirements for Sampling*.

The participant must ensure correct identification and storage for the correct period of the samples within the framework of the monitoring plan.

Each participant must, within the framework of the feed safety system, be able to have available a laboratory with sufficient personnel and equipment. A laboratory belonging to a company registered in the Netherlands must be GMP+ B10-certified<sup>7</sup>. The analysis work can also be carried out by an external laboratory if it meets the requirements. See GMP+ BA10 *Minimum Requirements for Purchasing* for further requirements.

### 8.2 Corrective actions, recall and early warning

#### 8.2.1 Corrective actions

The participant must ensure that deviations from the requirements in this standard are recorded and controlled in order to prevent unintentional use or delivery of feeds. A procedure must be laid down for this.

- A documented procedure must contain at least the following elements:
- a. Identification and separation of the batches involved A participant must ensure that the feeds which do not comply with the (legal) requirements are clearly identified and separated in such a way that the feeds can not be used either by accident or by inattentiveness.
  - b. The participant must handle deviations in one of the following ways:
    - 1 Take measures to resolve the deviations.
    - 2 Take measures to exclude the original intended use or the original application.  
Requirements for the reprocessing of feeds which do not comply must be documented. In cases of deviations all feeds must be assessed again after the implementation of the treatment in order to ensure that the batch involved now complies with the specified requirements.
  - c. Communication with the parties involved if this is necessary or desirable.
  - d. Assessment of the cause of the deviation.
  - e. Preventive or corrective actions to prevent reoccurrence of the deviation.
  - f. Documentation for the management and maintenance of the deviation with respect to feeds.

**NOTE:**

- a. Corrective actions are intended to resolve a deviation which is observed among feeds
- b. Corrective measures are intended to prevent deviations from reoccurring. See section 8.3.2

### 8.2.2 Recall

The participant must implement a system for rapid recall in the event that a feed is discovered which does not comply with:

- a. the legal requirements with respect to safety, or
- b. the merchantable quality, or
- c. the essential requirements of the GMP+ Feed Safety Assurance scheme

If the above must occur then the participant must take the following measures:

- a. immediately inform the customer, and
- b. immediately block the feeds or have them blocked, and
- c. recall the feeds and ensure that they remain outside the feed and livestock sector.

unless the participant can demonstrate that the deviation is without harmful consequences for the health of animals or humans and that the legal standards are not exceeded.

The participant must describe by way of written procedures what the destination is of the recalled feeds. Before these are put back into circulation they must be reassessed in accordance with a documented procedure.

### 8.2.3 Early warning

The participant has a documented procedure for warning at an early stage and for handling these signals which warn that the safety of feeds may not comply with the legal standards or the standards set in the GMP+ Feed Safety Assurance scheme and may lead to damage in subsequent links in the chain. The signals must be as-

essed on this basis and if necessary or desirable control measures must be taken to prevent or control the hazard which has been signalled.

In such cases the designated authority must be informed.

In the case of a potential hazard which can not be controlled by the participant in question and which can also cause damage to other parties then the participant must inform GMP+ International. This must be done in accordance with GMP+ BA5 *Minimum Requirements EWS*.

### **8.3 Verification and improvement of the system**

#### **8.3.1 Internal audit**

The participant must carry out an internal audit at planned times in order to be able to establish whether the feed safety system:

- a. conforms to the requirements of this GMP+ standard and to the standards of the feed safety system established by the participant, and
- b. is effectively implemented and maintained.

An annual audit programme (meaning a minimum audit frequency of once per 12 months) must be scheduled and implemented in which all aspects of the activities are covered.

Account shall be taken of the results of the previous audits. The audit criteria, scope, frequency and methods shall be established. The selection of the auditors and the implementation of the audits must ensure that the audits are objective and impartial. Auditors may not for example carry out an audit of their own work.

#### **8.3.2 Improvement**

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

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

A documented procedure must be established up for this.

This assessment must

- a. Contain details from relevant sources such as monitoring, internal/external audits, complaints, records, assessments;
- b. Offer information with respect to the possibilities for corrective and preventive measures to improve the effectiveness of the feed safety system.
- c. Be part of the management review (see section 4.1).

Corrective measures The participant must take action to resolve the causes of deviations and to prevent a repeat of the deviation. Corrective measures which are taken must be suitable with respect to the effects of the deviation in question.

Preventive measures The participant must take action to resolve the causes of potential deviations and to prevent the deviation. Preventive measures which are taken must be suitable with respect to the effects of the potential problems.

## Annex 1: HACCP guidelines

Each company must carry out its own HACCP hazards analysis especially for activities and/or feeds for which the requirements and conditions in this standard are insufficient. The results of this must be added to the HACCP plan. The following HACCP stages can be distinguished:

0. Preparatory stages:
  - 0.1 Put together a HACCP team:
  - 0.2 Draw up a specification for feeds
  - 0.3 Define the intended use
  - 0.4 Make flow charts including a map
  - 0.5 Confirmation of the above on site
  - 0.6 Implement a prerequisite programme
1. Carry out a hazards analysis (identification of hazards and risk estimation ('is the hazard a risk?'), in which the critical control points are also defined
2. The definition of control measures
3. The definition of target values ('product standards') and critical limits for critical control points
4. Define how monitoring of the critical control points must be done
5. Define corrective actions for critical control points
6. Verification of the HACCP system including validation
7. Documentation of the previous steps.

NOTE: This annex offers guidelines for the application of some preparatory steps and some HACCP principles. A full hazards analysis based on HACCP must be carried out. The stages and principles which are not described in detail in this annex must be carried out in accordance with the recognised HACCP principles such as they are, for example, described in the HACCP Manual.

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### 0. Preparatory stages:

- 0.1 Put together a HACCP team (see Section 4.2)
- 0.2 Draw up a specification for feeds (see Section 6.2)
- 0.3 Define the intended use (see Section 6.2)
- 0.4 Make process diagrams

### Specification of the process

The participant must describe the process including all process stages and process requirements including the use of process diagrams and additional explanations.

The process specification is different for each company. A floor plan of the production areas of a company can be useful when systematically mapping out the processes. The process specification includes the previous process steps (such as cultivation, harvesting, storage and transport) if the participant is not the primary producer.



**1. Carry out a hazards analysis (identification of hazards and risk estimation in which the critical control points are also defined)**

Identification of hazards

A HACCP team must identify and document all potential hazards which could have a negative effect on feed safety. A hazard can be described as a contaminant in feed which can have adverse consequences for the health of humans and animals. The hazard identification is based on:

- raw materials and auxiliary substances
- the specification of the feed
- the flow chart drawn up (process specification)
- experience, expertise, research and other sources of information (internal/external)
- the generic risk assessment which is included in the Feed Safety Database.

The participant categorises these hazards as chemical, physical or microbiological. This is done systematically for each process step in each process diagram and on every change in the process which can have a negative effect on feed safety. The prerequisite programmes are part of the hazards analyses.

Category	Description	Examples
Chemical hazards	Undesired chemical substances which occur in feeds either naturally, through contamination or through the use of auxiliary substances or which contaminate the product during treatment and/or handling.	Remains of pesticides, heavy metals, environmentally-unfriendly substances, mycotoxins, PCBs, dioxins, cleaning agents, lubricants, mineral oils, aids to treatment and/or handling, biological degradation products, minerals, acid remains and suchlike.
(Micro-)biological hazards	Undesired micro-organisms, toxins produced by these and carriers of animal illnesses which can penetrate or develop in the feed. Distinction among vegetative, toxigenic (toxin producing) and micro-organisms producing traces	Salmonella, enterobacteriaceae, fungi and moulds (as indicative organisms), bone meal from mammals (as carrier of BSE) and suchlike
Physical hazards	Foreign substances which may be able to penetrate into the feeds during storage, treatment and/or transport and which could be hazardous for the animals to be fed.	Glass, plastic, metal fragments, stone, bones, remains of packaging materials, asbestos and suchlike.

Hazards can occur if the feeds are contaminated with other substances via:

- specific conditions during cultivation, harvesting and storage when microbiological contaminants are created.
- The use of auxiliary substances such as pesticides, insecticides, fungicides, technological treatment agents which are used in, added to or come into contact with feeds

- Specific treatment stages if substances can be added to the feeds such as during steam heating or artificial drying

Attention must be particularly paid to the following (potential) hazards:

Source of hazard	Description / explanation
Direct artificial drying	Feeds come into contact with combustion gases. Depending on the quality of the fuel and the settings of the combustion plant, undesirable substances may be created with which feeds can be contaminated. These are substances such as DNMA (dinitroso-methylamines), poly-aromatic hydrocarbons, PCBs, dioxin, etc.
Steam injection	In the case of steam injection, the quality of the steam is important because this comes into direct contact with the feeds. The quality of the steam is determined by the quality of the water which is used in the boiler and the processing aids used such as anti-corrosion agents.
Technical and auxiliary aids	Examples of these are lubricants, acidity regulators, binding agents and conservatives. These aids can also contaminate feeds. The safety of these auxiliary substances is there an important item for attention. In cases where sanitary substances are used the participant must ensure that the control system ensures at all times that there is a correct and effective dosage.
Mycotoxins	Mycotoxins may occur during the cultivation of crops and during the storage and treatment of harvested feeds. Climate and storage conditions (moisture content and temperature) are especially important. It is necessary to determine if feeds are sensitive to mycotoxins and what the conditions are which are related to this.
Heavy metals and dioxin	These undesirable substances often occur in products such as minerals, trace elements and auxiliary substances which occur in nature (mines, quarries, etc.)

### Risk assessment

The HACCP team carries out an assessment for each identified hazard. 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. Each identified hazard must be assessed by the HACCP team using the CCP (*Critical Control Point*) decision tree including the estimate of whether the hazard is a risk ('chance x seriousness') or through an equivalent method. The CCP decision tree is used to determine whether a hazard must be controlled using a specific control measure (CCP), a general measure or another periodic measure.

The assessment is also based on practical experience, experimental data, literature, etc. The participant must document the data used and the conclusions.

The term 'risk' is determined by two elements, 'seriousness' and 'chance' of a potential hazard. The quality assurance for each risk category is characterised by a combination of control measures.

Seriousness is the consequence for the consumer and/or the target animal if they are exposed to this hazard. Seriousness is divided into three levels:

- High: fatal consequences, serious illness, irrecoverable injuries both immediately and in the longer term
- Medium: substantial injuries and/or illness, occurring both immediately and in the longer term
- Low: minor injuries and/or illness, not or hardly occurring or only in extremely high doses for a long period of time

The chance is the probability that the hazard must occur in the feed at the moment of consumption by humans and/or the target animal. The chance is based on measurements, observations or expectations in a company-specific situation and it is divided into three levels:

- Low: practically impossible or not probable
- Medium: can occur, has already occurred
- High: occurs regularly

Four risk levels can be determined using the hazards analysis. In the case of risk level 1, no measures are needed. IN risk level 2 periodic measures must be implemented (often activities which have to be carried out only once). Risk level 3 requires general control measures such as hygiene programmes, maintenance and calibration, purchasing procedures, etc.

Most of these have already been included in the prerequisite programmes required in chapter 5.

In the case of risk level 4 specific measures are required which are aimed at the actual situation.

The following model can be used:

Risk estimation model	Chance of occurrence (in feed; on use)		
	Low	Medium	High
Seriousness			
High	3	4	4
Medium	2	3	4
Low	1	2	3
	Low	Medium	High

### **The CCP decision tree**

The hazards analysis also determines if there is a CCP (*critical control point*). This is a point, step or procedure where it is of vital importance that specific control measures are applied to prevent or limit the hazard or to restrict and control it at an acceptable level.

The reason for the presence of a CCP must be recorded.



## 2. The definition of control measures

The HACCP team must determine, record and implement all the measures for controlling risks for which the team was established and on the basis of the hazard analysis in the previous section because these risks may have a negative effect on feed safety.

Control measures can be classified as specific or general control measures. 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.

### Specific control measures

Control measures which are related to CCPs must be classified as specific control measures. Specific control measures are actions or activities which are essential for controlling a significant risk. These are often monitored by physical or chemical parameters such as temperature, time, moisture level, pH and sensory parameters such as visual presence and composition.

The participant must monitor each specific control measure. In addition, the specific control measures contain corrective measures and these must be validated and verified.

### General control measures

Control measures which are not related to CCPs must be classified as general control measures.

General control measures are actions or activities which are often part of prerequisite programmes (purchasing, training of personnel, etc.). In general, the implementation of this type of measure ensures an acceptable level of control.

General control measures must be validated to show that they have the desired effect within the individual organisation. After validation, approval by the HACCP team takes place. The effectiveness of the control of the identified hazards by general control measures must be verified.

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## 3. The definition of target values ('product standards') and critical limits for critical control points

### 4. Define the critical control points are monitored

### 5. Define corrective actions for critical control points

### 6. Validate the HACCP system

The purpose of validation is to ensure that the hazards which were originally established by the HACCP team are completely and correctly mapped out. These must be effectively controlled by way of the proposed general and specific control measures, the monitoring plan and the corrective actions and measures (HACCP plan).

The members of the HACCP team can be members of the validation team but the validation team must also have independent members. These may be production workers who are not directly involved in the setting up of the HACCP plan. The composition of the validation team and the activities they carry out must be clearly laid down.

Validation is carried out by demonstrating that:

- The list of potential hazards which was drawn up is complete and is based on proper scientific data.
- The risk assessment which, with the help of a decision tree including the risk estimate ('chance x seriousness') from Appendix 15<sup>8</sup> or equivalent was set up is based on practical experience, experimental data, literature and suchlike
- The general and specific control measures are sufficient to control the hazards.
- The methods which are used for monitoring control measures are effective

Corrective measures must be sufficient and serve to prevent the release of an unsafe feed. It must be possible to demonstrate that the situation can be remedied immediately.

## 7. Verification of the HACCP system

See chapter 8.

## 8. Documentation of the previous steps.

The following table is useful for documenting the hazards analysis. Identified hazards (for each process stage) can be entered. The results of the follow-up steps in the HACCP procedure can also be entered here.

**Table 1: Overview of hazards analysis and control measures**

<b>Process: ..... No.</b>	<b>Process step</b>	<b>Hazard</b>	<b>Cat.</b>	<b>Chan ce.</b>	<b>Seri ous nes s</b>	<b>Risk</b>	<b>Risk reason- ing</b>	<b>Type of measures</b>	<b>Reference</b>

During identification of the hazards in each process step and working through the CCP decision tree, the risk analysis table can be filled in line for line. This shows on paper that the HACCP analysis has been carried out.

1. The hazards are identified per process stage in the process diagram and are entered in the table. In the table the columns *No.*, *Process step* and *Hazard description* are filled in per line.

<sup>8</sup> This appendix will be completely revised in 2007.

2. An indication is given per hazard of which of the three categories is applicable (M: micro-biological, C: chemical, P: physical). in column Cat.
3. The CCP decision tree is gone through per hazard and consists of a number of questions. The risk assessment is mentioned in question 2 of the decision tree. The chance, the seriousness and the risk category are completed in the appropriate columns in the table (columns *Chance*, *Seriousness* and *Risk*).
4. In the column Explanation there must always be a short explanation of the results for each hazard. This explanation is intended to support the choice which is made by the HACCP team. In addition this information can be used in later verification and can also be used by the HACCP team if its composition changes. The considerations then remain accessible and clear.
5. When the decision tree has been gone through, the (control) measures must be summed up in the column *Types of measures*.

As shown in the previous stages, target levels and critical limits, monitoring programmes and corrective actions must be drawn up for CCPs. To obtain a clear overview of the recognised CCPs a table can be used in which the target values, critical limits, monitoring and corrective actions are specified.

This table can also refer to the necessary procedures, instructions and registration forms (documentation).

**Table 2: Overview of monitoring and corrective actions**

Critical point	Action and rejection limits	Monitoring			Corrective actions		Documentation (Incl. validation CCPs)
		Method	Frequency	Responsible person	Description of action	Responsible person	
CCP 1							
CCP 2							
.....							
.....							
'Critical point 1'							
'Critical point 2'							

The hazard analysis often shows that general measures ('GMP+' measures; part of the prerequisite programmes) may also play a vital role in limiting the hazard (risk class 3 of the risk estimate). It is recommended that these types of risk are also included in the table. Indicate, where possible monitoring frequencies and corrective actions (this is dependent on the risk and must not be possible in all cases). Also indicate the necessary procedures, instructions, registration forms and other documents.

## Annex 2: Fuels

### Section 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”):**

- Bio gas (“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
- Anthracite
- 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 Brasil) '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

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### Part B: Not-permitted fuels

The following fuels are forbidden on the basis of scientific research into the drying processes:

1. **Petcoke:**

This is a residual product after distillation in the oil refinery. It is unsuitable as a fuel for direct dryers

2. **Lubricating oil, engine oil and hydraulic oil:**

These products are not intended for use as a fuel. Not as such and not as “waste oil”

3. **Recycling oils (used oils, etc.):**

These are often mixes of unknown origin and with an unknown composition. IN the past the deliberate mixing with flammable chemical residuals occurred regularly (including the TCR affair).

4. **Mixed urban waste, mixed industrial waste and dried purification sludge:**

These are and continue to be formally waste products (report "Refuse Derived Fuel; current practice and perspectives, 2003). Member states of the EU may only issue a licence in special cases and for specific purposes to use this as fuel. These waste materials may unintentionally have high levels of persistently contaminating substances. The use of these in a direct drier, because of the risks and also from the point of view of GMP+ and HACCP, may not be tolerated.

5. **Recycling products:**

This includes for example preserved wood and demolition wood, vegetable materials contaminated with preservation agents, insecticides or which are contaminated with oil or chemicals (for example sawdust).