



TS 1.1 Prerequisite programme

TS 1.1 *Final Draft*

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Welcome

This Feed Certification Scheme document helps you to provide feed safety worldwide. By meeting the requirements set by GMP+ International together with our GMP+ Community, we aim to help you get the feed certification you need. Please read the information in this document carefully.

Let's make this work together!

1. Infrastructure

GMP+ certified companies must carry out all their activities in a local environment where feed must be protected from potentially hazardous substances. Feed must never contain unacceptable levels of potentially hazardous substances. If the local environment presents risks for feed safety, certified companies must show that those risks are controlled through a detailed risk assessment.

Helpful tip:

It can help to think about sites near your company locations which could potentially have a negative impact on feed safety. For example, nearby contaminated sites and waste sites, could form a risk.

1.1. Regulating access

Certified companies must clearly define and document the boundaries of all company locations. Access to all areas and facilities must be managed. Access must be authorised and controlled depending on the level of risk to feed safety.

Non-employees must only be given access to areas under the supervision of, or with permission from, an authorised person.

If it is not feasible to control access to the production plant, certified companies must set up control measures to prevent contamination.

Helpful tip:

Think carefully about how you plan and set up control measures and authorisation for all the areas and facilities which could pose a risk of contamination. This also includes all the places where feed is stored or located, including loading compartments.

1.2. Facilities and Equipment

Facilities, equipment and areas where feed is handled must be designed, constructed, maintained and managed to ensure that the safety of raw materials and feed is protected at all times. Both malicious and unintentional contamination of feed must be prevented.

Facilities

Facilities (including roofs, ceilings, overhead fixtures and drainage facilities for sewer, waste, rain and meltwater, for example) must be designed and constructed such that:

- a) accumulation of dirt is prevented;
- b) condensation and undesired (growth of) mould is prevented;
- c) cross-contamination of undesirable substances and substances with negative impact on animal health, human health or the environment is prevented;
- d) cleaning, disinfection and maintenance can be carried out;
- e) birds, pests and other animals have the least possible chance of getting in;
- f) areas or storage units for non-feed products are physically separated from areas or storage units for feed products.
- g) water and mud are not able to enter the facility.

Facilities must be provided with suitable natural or artificial lighting to ensure that cleaning, control and other activities which play a role in feed safety can be carried out effectively.

Veterinary medicinal products must be kept in a separate and secured room. Waste and toxic materials must be stored physically separately from feed.

Helpful tip:

Toxic materials can, for example, be cleaning and sanitising agents, water treatment products, non-food grade grease and stock protection agents.

Equipment

All equipment must be fit for the purpose for which it is used. Equipment must be designed and constructed in such a way that:

- h) it can be cleaned, disinfected and maintained to avoid the contamination of feed;
- i) the dosage capacity matches the quantity of product to be dosed. The following must be clearly stated and retained as documented information:
 1. the minimum and maximum weight permissible for the weighing equipment or dosage equipment;
 2. the accuracy of the weighing or dosage equipment.

Measuring equipment on process installations

Measuring equipment on process installations must be designed and constructed in such a way that:

- j) the required product temperatures can be reached and maintained during a certain time period in order to ensure feed safety. The time period and temperature must be registered;
- k) humidity, air flow and other process parameters which may have a negative impact on feed safety are controlled and retained as documented information.

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2. Maintenance

All areas and equipment intended for use must have an implemented maintenance programme. These maintenance programmes must be retained as documented information. All areas and equipment must be properly and regularly kept in good condition in accordance with that maintenance programme.

Certified companies must establish the requirements and conditions to ensure safe and hygienic operations during maintenance activities and in maintenance areas. The minimum requirements of the maintenance programme are that:

- a) All inspection, measuring, dosing and test equipment used in the manufacture of feed must be calibrated at least every 12 months.
- b) Equipment used for the weighing/dosage of premixtures, feed additives and veterinary medicinal products is:
 1. calibrated at least every six months according to a method established by the supplier of the equipment;
 2. appropriate for the range of weights or volumes to be weighed or dosed, and their accuracy must be checked regularly. This includes dosage equipment for preservatives which are used, for example, during silage-making.

All installed measurement equipment must be:

- c) calibrated or verified at specified intervals or prior to use in accordance with measurement standards which are derived from international or national measurement standards. If such standards do not exist
 1. the basis used for the calibration or verification must be retained as documented information; and
 2. inspections must be in accordance with standardised checklists;
- d) identified so that the calibration status can be determined;
- e) secured against tampering, or other alteration which would make the measurement result invalid;
- f) protected against damage and deterioration during handling, maintenance and storage.

The maintenance activities and findings must be retained as documented information,

Helpful tip:

It is useful to make sure that your maintenance programme contains a plan for all of the following aspects of your company location(s):

- 1) the areas where feed is handled ;
- 2) equipment and (internal) transport systems;
- 3) means of transport;

- 4) cleaning installations;
- 5) personnel involved (own personnel or personnel from third parties);
- 6) frequencies;
- 7) other aspects which may be specific to your company.

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3. Personal hygiene

3.1. Personnel and Visitors

Anybody who works in, or enters into, areas where feed is handled must wear clothing and protective equipment wherever contamination of feed by humans is identified as a risk based on a risk assessment. The protective clothing and equipment must not pose a feed safety threat and must be maintained in a hygienic condition.

Certified companies must establish and implement rules with respect to eating, drinking and smoking if this could have a negative impact on feed safety. This must be clearly indicated to personnel (including from third parties) and visitors. Eating, drinking and smoking must only be allowed in designated areas.

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4. Utilities

4.1. Air movement

Air used for conveying, drying or cooling must not have a negative impact on feed safety. Certified companies must evaluate the risk of the air becoming a vector for pathogens and take control measures if necessary.

4.2. Water and Steam

All forms of water (including steam) that come into direct contact with feed contact surfaces, or are included in feed, must not have a negative impact on feed safety. The use of water and its safety must be based on risk assessment.

Certified companies must ensure that the use of processing aids, such as anti-corrosion agents, do not introduce a feed safety hazard.

Water supply installations must be manufactured from inert materials.

4.3. Drying and Ventilating

The methods for drying and ventilation must be fit for purpose. If certified companies use fuels for drying feed, they must ensure that the fuel (and its combustion gases) used for the drying process does not have a negative impact on feed safety. The fuel must never come into contact with the feed.

Indirect drying

Certified companies must ensure that the combustion gases of the fuel used for indirect drying do not come into contact with the feed. A risk assessment of the indirect drying process must be retained as documented information.

Direct drying

A risk assessment of the fuels used for direct drying must be retained as documented information. See GMP+ TS 1.4 *Forbidden Products and Fuels* for more information.

Other methods

Certified companies must ensure feed safety if other methods are used for drying and ventilation. A hazard analysis of these methods must be retained as documented information.

Helpful tip:

More information about the drying processes can be found on the GMP+ International Portal (visit the [Website](#) -> click on [Portal](#) -> enter login -> click on items Tools -> Feed Support Products -> Fact sheets – [drying processes](#)).

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5. Pest control

Everything which is possible and effective must be done to keep pests, birds and pets away from the areas of a location where feed is produced, processed, stored and/or transported.

Pest control must be planned, carried out and documented. Acceptable and permitted pest control methods and resources must be used which also take into consideration the safety of personnel and feed safety.

Certified companies must draw up, document and implement a programme for controlling and combatting pests. Documented information of the control activities must show that there is compliance with the requirements.

Personnel must be assigned to manage the pest control programme and/or deal with qualified contractors at the location by all certified companies. Those personnel must be appropriately qualified and trained and comply with legal provisions to carry out any treatment required.

Waste must be managed in a manner that prevents the attraction and harbouring of pests.

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6. Waste management

Systems must be in place such that waste is identified, collected, removed and disposed of to prevent contamination of feed.

If waste contains hazardous concentrations of contaminants or other hazards, it must be removed in a proper fashion.

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7. Cleaning and Sanitising

Certified companies must ensure that cleaning and sanitising standards are adhered to. Exposure to pests and pathogens must be minimised. The accumulation of dust, dirt (including leakage) and feed remains must be avoided as much as possible.

In order to maintain feed safety at all times, certified companies must establish cleaning and sanitising programmes to maintain hygienic conditions. These cleaning and sanitising programmes must be retained as documented information.

Cleaning and sanitising programmes must include:

- a) responsibilities;
- b) methods;
- c) cleaning and sanitising agents;
- d) frequency;
- e) times of the cleaning;
- f) places where waste is collected and stored.

Cleaning and sanitising programmes must be monitored, verified and where appropriate validated for their suitability and effectiveness. An authorised person must carry out inspections of the cleaning and sanitising and documented information of all inspections must be kept.

Cleaning and sanitising agents and other chemicals must be fit for purpose. If they form a risk for feed safety, they must be stored separately in clearly identified areas. The residues of cleaning and sanitising agents must have no negative impact on feed safety. Machinery or components which come into contact with dry feed must be carefully dried after wet cleaning, before they are used again.

8. Prevention of cross-contamination

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

Carry-over of critical feed additives or veterinary medicinal products must be prevented or controlled by one or more of the following control measures:

- a) use of dedicated lines;
- b) cleaning;
- c) line changeover practices;
- d) product sequencing
- e) any other (combination of) validated control measure(s).

To support this, the carry-over of the production and equipment must be measured.

See GMP+ GMP+ TS 1.11 *Control of residues* for the requirements regarding the control of residues of a number of feed additives and veterinary medicinal products.

The production order used for production and transport lines must be retained as documented information. The production order relates to the whole production process (from receiving raw materials up to and including delivery of the feed).

9. Incoming Products & Services and Sales

9.1. Verification of incoming Products and/or Services

Verification of incoming products

Certified companies must establish, implement, maintain and update criteria for receiving incoming products and services. The results of entry checks must be retained as documented information.

Each incoming delivery must be verified on the basis of its specifications. The products must comply with the specifications. During the entry check, all incoming products must be released before they can be stored and/or further processed.

In case of doubt, the specifications must be verified. The received products must not be accepted if they do not comply with the specifications. See R 1.0 *Feed Safety Management Systems Requirements* § 8.7.2.3 how to deal with non-conforming products.

Verification of incoming loading compartments

Certified companies must also verify if the transport complies with the agreed requirements. This verification must be carried out by a loading inspector. The inspector must at least include the following elements in the entry check:

- a) verification that the transporter has the correct GMP+ certification;
- b) compliance with the requirements with respect to the loading sequence. See TS 1.9 *Transport activities, Annex: Transport sequence, cleaning regimes and release procedure*;
- c) previous loads and implementation of the required cleaning regimes.

For all received sea transport, short sea shipping, inland waterway transports or rail transport the Loading Compartment Inspection (LCI) reports must be available or retrievable.

If the result of the above-mentioned verification is positive, then the loading compartments are approved for the transport of feed.

If the result of the above-mentioned verification is negative, then the loading compartments are not approved for the transport of feed. If the certified company itself is responsible for (organizing) the transport, the certified company must take action(s) to ensure the loading compartment complies at least with the above-mentioned elements before loading.

If a third party is responsible for (organizing) the transport, the certified company must inform this third party of the negative result of the verification and obtain written confirmation of this from the third party before loading. Documented information of the correspondence in question must be kept.

9.2. Sale and Contract

Feed specifications must be agreed upon between certified companies and the customer and confirmed in a contract. Certified companies must ensure that all feed supplied meets the agreed specifications.

The sale of feed must be retained as documented information.

Helpful tip:

For the requirements for feed specifications that are related to feed safety: see R 1.0 *Feed Safety Management Systems Requirements* § 8.5.1.1.

10. Traceability system

Certified companies must retain the following as documented information for all products and services:

- a) name and address details of suppliers and customers;
- b) date of delivery;
- c) type of product or service;
- d) product quantity / number of products;
- e) batch number if applicable. This can also be designated as a manufacturer's batch number or a reference number;
- f) the date of empty report of silos, if applicable;
- g) transport/ distribution details such as the identification and code of the loading compartments (both GMP+ and non-GMP+ loading compartments). (if the certified company is responsible for transport);
- h) if applicable: copies of any accompanying documents, warranty statements, certificates etc. in accordance with the arrangements made with the instructing party.

Certified companies must determine whether the documentation of additional details is necessary.

Helpful tip:

All certified companies that carry out feed related activities are obliged to retain the above-mentioned documented information. This includes, for example, production companies responsible for the storage and transport of feed, but also certified companies that provide storage or transport as services for third parties.

The frequency of empty report of silos is important in the case of a recall. Any recall will be larger in size if the period of time between two silo empty reports will be longer.

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