

 Technical Specifications

TS1.10 - Operational activities

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1. Operational activities

The requirements in this document are **in addition** to those set out in the R1.0 *Feed Safety Management Systems Requirements*.

1.1. Control of production

Production must be planned, scheduled and controlled.

All process controls relevant to the safety of the feed being produced must be demonstrably effective and managed in accordance with the requirements for risk assessment as explained in the document R1.0 *Feed Safety Management Systems Requirements* § 8.5.

During internal processing and delivery to the proposed destination, the GMP+ certified company must ensure that feed always complies with the set requirements. This must include all the relevant requirements on:

- a. identification,
- b. handling,
- c. packaging,
- d. storage,
- e. and protection.

Feed production procedures must include corrections and corrective actions to be taken in the event of critical process parameters being breached.

If a breakdown -- or other unforeseen circumstances -- results in the production of feed that does not meet the required specifications, the resulting products must be treated in accordance with the Nonconforming Product procedures. See document R1.0 *Feed Safety Management Systems Requirements* § 8.7. and § 10.1..

Where production processes contain a 'killing step' that is critical to realise the acceptable level of microorganisms in feed, the certified company must ensure that controls are in place to prevent feed becoming cross-contaminated with pathogens at subsequent process steps. The certified company must therefore include in its risk assessment areas where condensation may occur, or where material is allowed to bypass the 'kill step' and is added at a later step in the production process of finished goods.

1.2. Processing aids

The certified company must ensure that the use of processing aids does not have a negative impact on feed safety. A risk assessment must demonstrate that the unintentional but technically unavoidable presence of residues of processing aids -- or their derivatives -- in the end product have no negative impact on animal health, human health or the environment and no impact at all on the end product.

1.3. Dosage

The certified company must ensure that all products (such as feed materials, feed additives and veterinary medicinal products) are processed in the correct dosage and in the intended feed.

Premixtures with coccidiostatica and histomonostatica and veterinary medicinal products must be added to the main flow of the compound feed as close as possible to -- or in -- the mixer, but after the milling process.

Dosing systems must be calibrated by a competent person and the calibration findings must be updated and kept as documented information.

1.4. Mixing and Homogeneity

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

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

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

Note: Dry mixtures, containing critical feed additives and / or veterinary medicinal products, must comply with the conditions regarding homogeneity established in the document TS1.11 *Control of residues & homogeneity of critical feed additives and veterinary medicinal products*.

 **Helpful tip:**

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

 **Helpful tip:**

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

 **Helpful tip:**

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

1.5. Pelletising, Expansion and Extruding

In pelletising / expansion / extrusion the production conditions must take into account the stability of the processed feed additives and veterinary medicinal products involved. The certified company must validate and verify the effectiveness of the processing step, including the processing instructions provided by the supplier.

1.6. Packaging

Packaging material used (including reusable packaging material) must be fit for purpose. Packaging material must not have a negative impact on feed safety.

The certified company must establish the reusability of the packaging and applicable cleaning regime based on a risk assessment. Reusable packaging must be strong, easy to clean and, if necessary, suitable for disinfection.

In the case of reusable packaging material recovered from livestock farms, the certified company must ensure-- based on a risk assessment -- that the packaging is still fit for purpose.

1.7. Cleaning, Sieving, Filtering

Feed must be as much as possible free from contaminants such as wood, earth, packaging materials or other foreign bodies. Whenever a certified company decides to clean (remove objects or substances from) a feed, correct cleaning methods must be used.

The cleaning itself must be validated and verified. Material which is separated from the primary product flow by way of sieves, filters or graders can be reprocessed or collected for addition to feed if the risk assessment concludes that it is safe.

+ Helpful tip:

'Foreign bodies' means things which should not be present in feed such as glass, plastic, broken lightbulbs, metal, and other materials which may have accidentally got into the feed.

+ Helpful tip:

Individual batches can be cleaned if the nature of the contamination permits this. Batches can be sieved or filtered to remove substances or foreign bodies which do not belong in the product. It's useful to remember that the correct operation of the sieve is important as is keeping a good maintenance plan for the sieve.

1.8. Returns

Return management

Returns (internal and external) must be managed in such a way that feed safety is not negatively impacted and traceability is maintained. Return management must include criteria and conditions for acceptance, storage, identification, traceability and processing.

Products returned from distribution must be assessed on feed safety hazards and handled accordingly.

The approval and use of returns must be assessed within the HACCP plan. Returns that are not approved must be considered as nonconforming products and be handled accordingly. See document R1.0 *Feed Safety Management Systems Requirements* § 8.7.2.3..

Helpful tip:

Certified companies should always ensure that return management does not compromise the GMP+ Feed Certification scheme, other applicable feed legislation (for example about the use of coccidiostats, antibiotics, animal proteins, veterinary medical products in feed) or other regulations.

Helpful tip:

Here are a couple of examples of return products: nonconforming products; and the first quantities of a batch or dust from filters in the pneumatic systems of an installation.

Rework management

When returns are reworked, the quantity, type and conditions must be specified. All process steps and methods of addition must be defined.

There must be instructions which explain which return products may be included in which feed, and in what percentages this may take place.

Rework must be identified and retained as documented information to maintain traceability and to make it possible to derive how much returned product has been processed and in which batch (for each feed type).

When rework activities involve removing a product from filled or wrapped packages, controls must be in place for the removal and segregation of packaging materials to avoid contamination of the product.

1.9. Storage

1.9.1. Control of storage as Property and as a Service for third parties

The certified company must control all storage activities for which it is responsible to ensure that feed remains in accordance with the specifications and the established parameters for Critical Control Points. This must be based on risk assessment. This applies to storage for both packaged and unpackaged feed.

Control measures for the storage must be adequate and retained as documented information.

To avoid confusion, (cross-)contamination or degradation of the quality, all products on a premises must be transported (internally) and stored in such a way they are -- and remain -- easily identifiable.

GMP+ assured feed stored on a premises must be segregated from other products during all stages, unless the hazard analysis demonstrates that non-separated storage does not have a negative impact on the safety of GMP+ assured feed. The certified company 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 used by qualified people (people who have permission to use the stock protection agent).

The certified company must retain as documented information which stock protection agent is used, when it is used, and for which feed. It is then important that the prescribed waiting times are respected.

 **Helpful tip:**

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

 **Helpful tip:**

One of the key factors for storage is temperature. Where applicable, temperatures should be kept as low as possible and show as little variation as possible in order to prevent condensation, decay and spoiling. You can often detect the presence of (storage) moulds by observing discolouration or noticing a musty smell. Other key factors for storage are ventilation and isolation.

1.9.2. Additional requirements for storage as a service

When storage is provided as a service for third parties, the certified company must comply with the following additional requirements:

- a. The service provider must make clear to the customer or owner of the feed:
 1. what service is being guaranteeing;
 2. their mutual responsibilities;
 3. additional requirements from the customer or owner of the feed (as long as they do not interfere with the GMP+ Feed Certification scheme).
- b. the service provider must retain all internal product movements as documented information;
- c. the service provider must receive information from the customer or owner of the feed about the nature of the product and product characteristics. This is in order to be able to carry out a correct hazard analysis, take proper control measures and monitoring to ensure proper storage. In the event of doubt, the service provider must take action to get this information;
- d. customers or owners of feed do not have to be assessed, they are not suppliers. All other suppliers of products or services such as cleaning agents or laboratories need to be assessed as described in the document R1.0 *Feed Safety Management Systems Requirements* § 7.1.5. and § 9.3.2..

Helpful tip:

When providing storage you do not need to obtain information about production and drying processes. This is the responsibility of the customer or owner of the feed.

1.10. Separation

The certified company must ensure that the non - GMP+ assured activities, processes, products or services do not have a negative impact on safety of the GMP+ assured feed. This must be supported by a HACCP analysis as described in R1.0 *Feed Safety Management Systems Requirements* § 8., and ensured by the FSMS.

Helpful tip:

Please keep in mind that when excluding a part from certification, it is vital to implement control measures that ensure a separation between the activities, processes, products or services that are subject to GMP+ certification and those that are excluded from certification.

Physical separation can be an effective control measure. Think of separate production lines, separate production areas and equipment. Organizational separation is also possible.

Remember that the control measures are demonstrably effective in all cases.



Risk Management tools

That was a lot of information to digest and one might ask, what is the next step? Luckily we can offer support for the GMP+ Community when doing this. We provide support by means of various tools and guidances but as each company has a shared responsibility to feed safety, and therefor tailor-made solutions cannot be offered. However, we do help by explaining requirements and provide background information about the requirements.

We have developed various supporting materials for the GMP+ Community. These include various tools, ranging from Frequently Asked Questions (FAQ) lists to webinars and events.

Risk management tools (RMT)

Risk management tools (RMT) provides valuable and up-to-date information about potentially high-risk feed. The products vary from flow charts of production processes including the risks (Risk Assessments) and studies on undesirable substances (fact sheets).

Where to find more about the GMP+ International Risk Management tools?

Fact sheets

More information: [GMP+ Platform](#)

Product list

More information: [Product List](#)

Risk Assessments

More information: [GMP+ Platform](#)

GMP+ Monitoring database

More information: [GMP+ Monitoring database](#)

Support documents

More information: [Support documents](#)

We enable every company in the feed chain to take responsibility for safe and sustainable feed.

GMP+ International

Braillelaan 9

2289 CL Rijswijk

The Netherlands

t. +31 (0)70 – 307 41 20 (Office)

+31 (0)70 – 307 41 44 (Help Desk)

e. info@gmpplus.org

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