



GMP⁺-Certification Scheme Animal Feed Sector 2006

Minimum Requirements for Traceability

Appendix 8

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1. INTRODUCTION

Various GMP⁺ standards requires that the applicant must identify the product in a suitable fashion throughout the whole production process in accordance with the requirements specified in this appendix.

2. CONDITIONS

The terms and definitions for traceability in the animal feed sector apply to this document as included in Appendix 1.

An applicant in the GMP⁺ Certification Scheme should at least take into consideration the guidelines for registration with respect to traceability as included in Appendices II and III. A record should be made in each business situation of which process steps apply and consequently which record requirements are applicable.

The summaries A and B below will serve as a guide.

Applicable to all the specified registration requirements is that, for verification, the records must be kept for three years unless a longer period of time is required by legislation.

The applicant should, in accordance with a previously agreed procedure, take and keep sufficient¹ samples of feed materials, feed additives and other ingredients. In addition, if applicable, sufficient samples will be taken and kept of each batch produced or, in the case of continuous production, of each particular production component (max. the day's production).

These samples must be sealed and labelled in such a way that they are easily identifiable. They must be stored in such a way that any change to the composition or any deterioration of the sample is prevented. They must be kept for 6 months.

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

¹ See the requirements in the appendices for this

SUMMARY A: PROCESSES RELATING TO TRADE, STORAGE AND TRANSHIPMENT AND TRANSPORT.

See Appendix II for minimum requirements.

A. Processes	Compound feed	Premixes	Feed materials		Additives	Storage and transhipment	Transport
			Dry products	Wet by-products			
A1. Purchase by shipping agent	n/a	n/a	X	n/a	n/a	n/a	n/a
A2. Laying in	n/a	n/a	X	n/a	n/a	n/a	n/a
A3. Transport	n/a	n/a	X	n/a	n/a	n/a	n/a
A4. Purchase (for example by importer)	X	X	X	X	X	n/a	n/a
A5. Transhipment	X	X	X	n/a	X	X	n/a
A6. Interim storage	X	X	X	X	X	X	n/a
A7.1 Transport by vehicular traffic	X	X	X	X	X	n/a	X
A7.2 Transport by inland waterway	X	X	X	X	n/a	n/a	X
A8. The whole business process	X	X	X	X	X	n/a	n/a

SUMMARY B: PROCESSES RELATING TO TRADE AND PRODUCTION

See Appendix III for minimum requirements.

B. Processes	Trade and production of compound feeds	Trade and production of premixes	Trade and production of feed materials		Trade and production of additives
			Dry products	Wet by-products ²	
B Reception of raw materials	X	X	X	n/a	X
B2. Storage of raw materials	X	X	X	n/a	X
B3. Weighing and dosage	X	X	n/a	n/a	X
B4. Grinding and mixing	X	X	n/a	n/a	X
B5. Conditioning and pelleting	X	n/a ³	n/a	n/a	n/a ³
B6. Expansion	X	n/a ³	n/a	n/a	n/a ³
B7. Crumbing, coating and sieving	X	n/a ³	n/a	n/a	n/a ³
B8. Bagging	X	X	X	n/a	X
B9. Storage of finished product	X	X	X	X	X
B10. Distribution	X	X	X	X	X
B11. The whole business process	X	X	X	X	X

² The traceability minimum requirements for the production of wet by-products apply from the manufacturer (the silo for shipment of the product).

³ If other products are added to the (end) product during the production process between the grinding / mixing process and the bagging, then these products should be recorded with the added dosage with a link to the production date and the production run.

APPENDIX I: TERMS AND DEFINITIONS

Term	Definition
Traceability	Traceability provides insight into the location of the goods at a particular moment. The traceability system (or the tracking & tracing system) creates a set of historical data using established identification so that it is possible to follow products, semi-manufactured products and end products. <i>Tracking</i> is the determination of the location of a given batch at a period of time to be determined. <i>Tracing</i> is the determination of the history of raw materials, semi-manufactured and end products during their passage through the chain.
Article number	The article number is the general number which a company uses for a product which complies with certain specifications which were defined in advance by the company (for example a type of grain with certain specifications). The article number provides general information on a certain product. Specific information about that product is linked to a batch number.
Batch number	The batch number links specific information on a particular product to the batch in question. This is more specific than the general information from the type of raw material or the article number. An article number gives access to, for example, the information that it is a maize product with a particular feed value while the batch number also provides information on the size of a particular batch and what, for example, the quality aspects are for the batch in question.
Production run number	The production run number is a number which is created before the start of the production of a batch of compound feed. The use of feed materials and raw materials is linked to the production run number. A particular recipe is also linked to the production run number and the physical progress through the compound feed factory is recorded.
Contamination	Unintentional unavoidable contact of ingredients coming from other batches feed material in a specific batch of feed material.
Segregation	The setting up and organisation of physically separated product flows throughout the whole animal feed chain.
Recall	A recall regulates the calling back of a specified quantity of product. This refers to the process of informing customers and the organisation of the recall action for the products.
Recall in first instance	The recall in the first instance regulates the recall or blocking of a specific batch in which a problem has occurred. This may be as a result of a complaint from the customer or of an inspection of feed materials and/or end products.
Recall in the second instance	The recall in the second instance regulates the recall of a specific amount of product in which a particular problem has occurred. The amount is determined using downstream tracing after upstream tracing.

Downstream tracing	Downstream tracing: The determination of the history of the product from feed material via semi-manufactured products to end products. This process is used in the event of late signalling of problems in feed materials or semi-manufactured products, to determine in which batches of end products the problems may occur. Using downstream tracing, the size of the recall in the second instance can be determined.
Upstream tracing	Upstream tracing: the determination of the history of the specific product from end product via semi-manufactured products to feed materials. This process is specifically used to trace the source of a problem following a complaint from the market or deviations found during the inspection of semi-manufactured products or end products and is used to trace the source of the problem or faulty product. Downstream Tracing: the determination of the location of the products which have already been manufactured . This is used later for the recall of faulty products.
C&F	Costs and freight. This means that the seller has to pay the costs and freight for bringing the goods to the destination port specified but the risk of loss or damage to the goods and also that of any extra costs due to any events which may occur after the goods are loaded on board ship pass from the seller to the buyer when the goods pass the ship's rail in the shipping port.
FOB	Free on Board. This means that the seller has fulfilled his delivery obligation when the goods pass the ship's rail in the specified shipping port. This means that from that point the buyer bears all costs and risks of loss or damage to the goods.
Ship broker	The ship's broker takes care as the representative of the shipping company both of the loading of the ships and the receiving of cargoes.
Ship owner	The carrier involved in the operation of a means of transport (sea-going vessels) and everything associated with that.
Lighter	Vessel with a shallow draught intended for the recovery and transport of the cargo from large sea-going ships to smaller ships or to the quay.
Shipping agent	A company which takes care of the purchase, shipping, transport and sale of batches of product in the country of origin.
Importer	The company which brings the goods from abroad and hands in the foreign goods for clearance into the EU.
Factor	The representative who, on behalf of the importer, promotes the interests of the goods brought by ship (checks on quantity and quality) and takes care of further shipment and/or storage.
Bill of Lading	The document which represents the batch. The person who has possession of the bill of lading is the owner of the product. The captain signs the document and thereby shows that he has received the goods to transport them to a specified destination and to hand them over to an appointed person. It also describes under which conditions the delivery will take place. The bill of lading is also the agreement between the captain and the loader. There are bills of lading in the name of the company or the person to whom the goods must be delivered. There are also bills of lading to order where there is the right to transfer the goods to someone else for endorsement.
Storage plan	The plan which is drawn up to be able to store a mixed cargo properly in the ship. An indication is given of, among other things, hold numbers and types of raw material.
Organoleptic check	Assessment by way of sight, smell, touch and taste.

APPENDIX II: MINIMUM REQUIREMENTS FOR TRACEABILITY IN TRADING, STORAGE AND TRANSHIPMENT AND TRANSPORT

The following actions should be carried out by the company and/or the following information should be recorded by the company.

A1. Purchase of feed materials by the shipping agent in loading port
- Record of the quantity and type of feed material
- Record of the name and address data for the supplier (name, address, place and telephone)
- Record of the purchasing contract number for the batch
- Record of the date and place of shipment
- Demonstrable separation of suspect batches of feed material and a record of all deviations observed before shipping
- The registration of the combination of batch data for the purchased batch of feed material. The combination of batch data is unique for that batch.
- Record of the results of organoleptic checking of all purchased feed material
- The taking of samples of all batches of feed materials which should be kept sealed, labelled and administered in the administrative system.
- The period of time for which the samples are to be kept is at least 6 months.
A2. Laying in of feed materials in loading port
- The allocation of a unique code to a batch of feed material in the storage location (hold number). The combination of batch data is unique for that batch.
- Record of a change to the hold number for a batch of feed material
- The allocation of a unique code to all production resources
- Records of checks on agreement between loading specifications and purchasing specifications;
- Record of embarkation date and bill of lading date
- Record of the storage and transport sequences (to prevent contamination)
- Record of the route from unloading to embarkation
- Record of reporting empty routes and means of transport at least 1 x per week
- Record of complications during laying in
A3. Transport by seagoing ship
- Registration of name and address details of the transport operator
- Record of a change to the hold number for a batch of feed material
- Record of the planned and actual port of unloading
- Record of the owner of the batch of feed materials
- Registration and copies of all original bills of lading
- Record of complications during laying in or transport (captain's logbook)

A4. Purchase of feed materials (for example by the importer)
- Record of the quantity and type of feed material
- Record of the name and address data for the supplier (name, address, place and telephone) and the production location
- Record of the purchasing contract number for the batch (if applicable)
- Record of the date and place of transport/shipment
- Demonstrable separation of suspect batches of feed material and a record of all deviations observed before transport or shipping
- The registration of the combination of batch data for the purchased batch of feed material. The combination of batch data is unique for that batch.
- Record of the results of organoleptic checking of all purchased feed materials (at least in the event of deviations)
- The taking of samples from all batches of feed materials which should be kept sealed, labelled and administered in the lab system.
- The period of time for which the samples are to be kept is at least 6 months.
A5. Transshipment of feed materials
- The allocation of a unique code to a batch of feed material in the lighter or silo. The combination of batch data is unique for that batch.
- Record of a change to the storage location for a batch of feed material
- The allocation of a unique code to all production resources
- Record of the loading and transport sequences (to prevent contamination)
- Record of the route from unloading to embarkation / storage in silo / tank
- Record of reporting empty routes and means of transport (at least 1 x per week)
A6. Interim storage of feed materials
- The allocation of a unique code to every storage location and silo / tank.
- The allocation of a unique code to a batch of feed material for the storage location or silo / tank. The combination of batch data is unique for that batch.
- Record of the pumping over or turnover of feed material to other silos
- Record of the storage and transport sequences (to prevent contamination)
- Record of complications (= deviations) during storage
- Record of date of silo reported empty in the event of a change of product
A7.1 Transport by vehicle
- Registration of name and address details of the carrier
- The allocation of a unique batch of feed material to a delivery address and in the event of delivery to a livestock farmer the mandatory registration of the UBN number(s) of the livestock farmer or comparable unique company numbers in other countries than the Netherlands.
- The allocation of a unique batch of feed material to the licence number plate of the truck

A7.2 Transport by inland waterway
- Registration of name and address details of the carrier
- The allocation of a unique code to a batch of feed material in the storage location or boat. The combination of batch data is unique for that batch.
- Record of a change to the storage location of a batch
- The allocation of a unique batch of feed material to a delivery address
A8. The whole trade in feed materials
- The authorisations and responsibilities should be recorded in accordance with the GMP ⁺ regulations
- At the moment that a safety problem is observed in a feed material the clients for that feed material are informed immediately. In addition this is reported to the EWS (early warning system) centre of the Product Board Animal Feed. The reporting point will, if desirable, take care of subsequent communication to the parties in the chain. ⁴
- The necessary information – from customer to the data for the batch of raw materials delivered – should be available within 4 hours (recall 1st instance) ⁵
- The necessary information – from batch of raw material to problem identification to the underlying batches of raw materials – should be available within 12 hours (recall 2nd instance)
- The retrieved data should be handed over in writing (on paper) or in digital form within the time limit set
- The size of a recall in 1st instance is done on the basis of the recall of the product on the basis of the unique batch identification and data If applicable on the basis of FIFO delivery from the product silo / tank with a safety margin of 30%. A lower margin should be set by the company on the basis of its own research.
- The size of a recall in 2 nd instance is done on the basis of the recall of all products with the same unique batch identification or batch data If applicable on the basis of FIFO delivery from the product silos / tanks with a safety margin of 30%. A lower margin should be set by the company on the basis of its own research.

⁴ Guidelines for a recall protocol will be drawn up by the Product Board Animal Feed for the method of working in the event of a recall (Appendix 7).

⁵ Unless national legislation requires that the information must be available sooner.

APPENDIX III: MINIMUM REQUIREMENTS FOR TRACEABILITY IN THE PRODUCTION OF COMPOUND FEEDS, PREMIXES, FEED MATERIALS AND ADDITIVES

B1. Reception of products (macro and micro components) at the manufacturer
- Record of the quantity and type of incoming product
- Record of actual delivery date of product. If there is a planned delivery date then a correction should be made for the actual delivery date if this is different (authorisation needed).
- Record of the time of delivery (if more than one batch of the same product will be delivered per day)
- Record of the name and address data for the supplier (name, address, place and telephone)
- Record of the purchase contract number
- Record of the method of transport (ship, road transport, rail)
- Record of the control data for the delivery slip with the weighing result
- Record of the control data for the delivery specifications with the purchasing specifications
- Demonstrable separation of suspect batches of products and a record of all deviations observed
- Registration of the name and address details of the carrier
- Record of received external returns, record of the type (type of animal) and the amount of feed
- The allocation of an internal batch number to the received batch of product or the combination of the batch data of a batch of product (supplier, quantity, type, delivery date and time) make the batch identification unique.
- Record of the date of the silo or tank empty measurement (minimum 1 per 3 months).
- (If this is not feasible in practice then a company may in certain situations use a lower frequency of silo empty reporting. The reasons for this should be given. The company should realise that any recall will be larger in size because the period of time between two silo empty reports will be longer.
- The taking of samples from <i>critical</i> ⁶ products which in the lab system should be kept properly, labelled and administered.
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- Record of the results of organoleptic checking of all received products
- The period of time for which the samples are to be kept is at least 6 months.
B2. Storage of products (macro and micro components) at manufacturer
- The allocation of a unique code to every storage silo and storage tank.
- The allocation of the batch number of the product or the uniquely identified batch of product to the storage silo or storage tank (for example raw material batch number x is stored in silo A).
- The linking of the unique batch data in an external return to the storage silo or storage tank.
- Record of the pumping over or turnover of product to other silos / tanks.
- Record of the storage and transport sequences (to prevent contamination)
- Record of observed complications (= deviations) during storage

⁶ To be based on a company risk analysis

B3. Weighing and dosage
- The allocation of an article number per (end) product per production date before the start of the (daily) production
- Record of dosage/weighing of products from silo / tank numbers (source) for particular production on a date (link to article number or production run number)
- Record of date and time of dosage and weighing
- Record of the allocation of product use (which ones and the amount from which silo / tank numbers) and production destination (article number or production run number)
- Record of actual dosage (in comparison to planned dosage on the basis of the formula/recipe)
B4. Grinding and mixing
- The allocation of an article number to a grinding line (number) by the daily production date
- Record of dosage of the addition of other products and the mixing in of internal return flows (what, from which silo / tank and the quantity)
B5. Conditioning and pelletising
- The allocation of an article number to a press line (number) by the daily production date
- Record of allocated dosage of the addition of other products and the mixing in of internal return flows (what, from which silo / tank and the quantity)
B6. Expansion
- The allocation of an article number to a production line (number) by daily production date
- Record of allocated dosage of the addition of other products and the mixing in of internal return flows (what, from which silo / tank and the quantity)
B7. Crumbling, coating and sieving
- The allocation of an article number to a production line (number) by production date
- Record of allocated dosage of the addition of other products and the mixing in of internal return flows (what, from which silo / tank and the quantity)
B8. Bagging of finished product
- Record of silo / tank number by packaging line
- The labelling of the end product with article number and bagging date and/or specification of use-by date

B9. Storage of finished product
- Record of article number / production date by finished product silo / tank (number)
- Record of date of silo / tank empty report (minimum 1x per 3 months) ⁷ . (If this is not feasible in practice then a company may in certain situations use a lower frequency of silo empty reporting. The reasons for this should be given. The company should realise that any recall will be larger in size because the period of time between two silo empty reports will be longer.
- Samples should be taken from each batch or, in the event of continuous production, from each production segment (max. the daily production) . These samples should be kept for at least 6 months and labelled such that a link can be made to the production date.
B10. Distribution
- Record of the name and address details of the carrier
- The recording of a loading silo number to customer number / delivery address with the mandatory registration of the UBN number(s) of the livestock farmer or comparable unique company number in countries other than the Netherlands.
- The recording of a loading silo / tank number to the licence number of the truck
B11. The manufacturer's whole business process
- The authorisations and responsibilities should be recorded in accordance with the GMP ⁺ regulations
- At the moment that a safety problem is observed in a feed material the clients for that feed material are informed immediately. In addition this is reported to the EWS (early warning system) centre of the Product Board Animal Feed. The reporting point will, if desirable, take care of subsequent communication to the parties in the chain. ⁸
- The necessary information – from customer to article number / production date – should be available within 4 hours (recall 1st instance) ⁵
- The necessary information – from customer to article number / production date to raw materials to article number / production date – should be available within 24 hours (recall 2nd instance)
- The retrieved data should be handed over in writing (on paper) or in digital form within the time limit set
- The size of the 1st instance recall is based on the recall of the product based on article number / production date on the basis of FIFO delivery from the finished product silo with the safety margin set for this of 30%. A lower margin should be set by the company on the basis of its own research.

⁷ For wet by-products from a continuous production process the date of silo empty reporting must be recorded. The time of silo empty reporting depends on the production process.

⁸ Guidelines for a recall protocol will be drawn up by the Product Board Animal Feed for the method of working in the event of a recall (Appendix 7).

B11. The manufacturer's whole business process

- The size of a 2nd instance recall is based on the recall of all article numbers with raw materials from the faulty article number / production date. This is done on the basis of FIFO for raw materials from the raw materials silos with the safety margin set for this purpose of 30%. A lower margin should be set by the company on the basis of its own research.