



GMP+ B1 Production, Trade and Services



Art.	Description	Possible items for attention	Freq.	Interpretation Category 1	Interpretation Category 2	Interpretation Category 3
02 NORMATIVE REFERENCES						
2.1	GMP+ documents					
2.1	Does the company comply with the requirements specified in the A documents?	See A1, A2, A3 and A4	3			
2.2	Legal compliance					
2.2	Does the participant comply with community legislation, national legislation and good manufacturing practice?		3			
2.3	Has the participant implemented the duty to report a positive Salmonella analysis in the correct way?	# It only applies to deliveries to Dutch poultry farmers. # a positive Salmonella analysis must be classified. # Reporting to the poultry farmer and the Feed Safety Database - monitoring of a positive result and the classification must have taken place. # Corrective measures must be communicated to and harmonised with the poultry farmer.	3	# The company repeatedly takes no action with respect to a positive Salmonella result.	# A positive result from a larger series has been forgotten (carelessness). # The report has been made to the poultry farmer but the details have not been sent to the Feed Safety Database - monitoring # The positive result has been reported but the classification has not been done. # The reporting has not taken place within 6 hours of receipt. # No suitable corrective measures have been taken.	
2.4	Does the participant comply with the PDV Regulation on Medicated Feed 2003?	# This only applies to Dutch companies.	3			
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04 FEED SAFETY SYSTEM						
4.1	Requirements for the feed safety system					

4.1	Does the feed safety system which has been set up meet the requirements of this GMP+ standard?	# At a single location there are multiple companies within the framework of GMP+, see A1. # Quality assurance of storage in accordance with the requirements in GMP+ BA10. # Written notification if the handled feeds are non-GMP-certified.	3		Part of the process excluded without reason.	Not all non-GMP activities are fully described.
4.2	Documentation					
4.2.1	Is the feed safety system documented and does it cover the required sections?	Required sections: # Documented statement of management involvement. # Manual # Required GMP+ procedures. # Required GMP+ records. # Documents for effective planning, implementation and control of the production process. # Required permits, records and certificates under the animal feed legislation (for example registration within the framework of the animal feed hygiene regulation) # Gatekeeper feed additives: GMP+ requirements are guaranteed through a contract with the original producer. # Gatekeeper feed additives: HACCP dossier complies with GMP+ BA10.	3		Not in accordance with the norm in essential areas.	No full or correct representation of what happens in practice.
4.2.2	Does the manual include the required sections?	Required sections: # Scope, including any details (Gatekeeper function and products are described) and exclusions. # Minimum required GMP+ procedures or a reference. # Description of the interactions between processes. # Structure of the documentation.	3		Not in accordance with the norm in essential areas.	No full or correct representation of what happens in practice.
4.2.3	Is there a documented procedure for control of the feed safety system?		3		Necessary modifications not implemented or not fully implemented and the situation in practice is behind current developments in the company or the regulations.	Necessary modifications not implemented or not fully implemented but the situation in practice corresponds to the regulations.

4.2.4	Have relevant records been established, maintained and stored?	Storage period for records is at least three years.	3		# There is a backlog (> 2 months) in the relevant records. # Records arising from the feed safety system are not stored for the required period of time.	# Relevant records have been overlooked or are out of date (< 2 months). # No up-to-date description of the archiving of relevant records. # Relevant records are not easily accessible.
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05 MANAGEMENT RESPONSIBILITY						
5.1	Management commitment					
5.1	Is management demonstrably involved in the development and the implementation of the feed safety system?		3		No management involvement.	Incomplete or no up-to-date management statement.
5.2	Feed safety policy					
5.2	Does management ensure that the feed safety policy complies with the required sections?		3			
5.3	Planning					
5.3.1	Have objectives been established with respect to the safe production of animal feeds?		3			
5.3.2	Does management ensure that the feed safety system is implemented and maintained correctly and that its working and cohesion is always retained?		3			
5.4	Responsibility, authority and communication on feed safety					
5.4.1	Are responsibilities and authority established and recorded by way of an organisational chart and made known in writing within the organisation?	This applies in particular to the HACCP team and to the other functions which influence feed safety.	3			
5.4.2	Has a HACCP team been established with sufficient expertise from various different disciplines?		3	No operational HACCP team.	# Poorly functioning HACCP team. # Insufficient / no meeting.	# Meeting of HACCP team not minuted properly. # Not all departments represented. # Function of adviser not established.

5.4.3	Has a management representative been appointed?	Responsibilities and authority of the management representative: # Establishment, implementation and maintenance of the feed safety system. # Report results to the directors # Promote awareness within the organisation.	3		Not functioning in practice.	Not formally established but functioning in practice.
5.4.4	Has it been established what resources are required and are they available?		3			
5.4.5	Have suitable methods of internal communication been established within the organisation?		3		No demonstrable meeting structure with respect to the feed safety system.	# Frequency of meeting structure not established. # No demonstrable provision of information with respect to changes to the feed safety system.
5.5	Management review					
5.5.1	Has management assessed and established the effectiveness of the feed safety system at least once per year?		3			
5.5.2	Does the management statement include the required information?		3			
5.5.3	Does the result of the management statement meet the requirements set?		3			
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06 PREREQUISITES PROGRAMME						
6.1	General					
6.1	Has a reason been given for the exclusion of the prerequisites?	# The additional prerequisites have been worked out and implemented.	3			
6.2	Personnel					

6.2.1	Are personnel competent and do they have the necessary qualifications for carrying out the work involved in the package of tasks and has this been recorded and communicated?	# Rules must also have been established with respect to eating, drinking and smoking in production areas. # Gatekeeper feed additives: official responsible for the HACCP dossier complies with GMP+ BA10.	3		# Tasks and responsibilities with respect to the processing of feed additives, feed medicines and/or hygienic working have not been made clear to the employees. # Personnel do not understand the procedures.	No suitable record of the training requirements of employees.
6.2.2	Has there been a determination of the skills required by the personnel for carrying out the work and is this maintained and recorded?		3		Principle of HACCP is not known to the personnel.	Lack of relevant refresher training.
6.3	Infrastructure					
6.3	Has the infrastructure been determined, made available and maintained to comply with the feed requirements?		3			
6.3.1	Does the environment and the production buildings present no danger to the production of feed materials?		3			
6.3.2.1	Does the facilities meet the requirements of this GMP+ standard?	In this section there are various requirements with which the facilities must comply.	3		# The facilities are such that unintentional mixing and microbiological contamination are not prevented. # Influence on traceability.	
6.3.2.2	Do the production areas meet the requirements of this GMP+ standard?	# In this section there are various requirements with which the production areas must comply. # Record keeping of silo / tank empty reporting	3		Influence on feed safety.	
6.3.2.3	Do the recipients and the installations comply with the requirements of this GMP+ standard?	# Mixing installations, dryer / drying installations, measurement facilities # Weighing / dosage equipment is calibrated: 2x / year: equipment for premixes, feed additives and feed medicines. 1x / year: equipment for feed materials. # The monitoring and measurement installations are registered and checked for validity.	3		# Influence on feed safety. # Monitoring and measurement do not correspond to the requirements. Calibration not carried out. # Records have a backlog of more than two months.	# No complete updated documentation of calibration without safety being at risk. # Records have a backlog of less than two months.

6.3.2.4	Do the other facilities meet the requirements of this standard.	# Processing aids # Packaging material # Water or steam	3		# No hazard analysis carried out for processing aids.	
6.4	Work environment					
6.4.1	Are the production areas and equipment used for the production and/or mixing checked properly and regularly in accordance with written procedures and recorded?		3		Structural non-compliance with the established procedure.	Incidental non-compliance with the established procedure.
6.4.2	Have cleaning programmes been introduced and is there registration?	# Responsibilities, methods, frequency and times of the cleaning must be stated. # The residues of cleaning and disinfecting agents must be kept as small as possible.	3		Hygienic operation unsatisfactory.	
6.4.3	Is use made of effective programmes for the control of pest or harmful organisms and is this recorded?	Pest control must be carried out by qualified persons.	3		Insufficiently effective measures taken to exclude vermin.	Demonstrability and implementation not up-to-date.
6.4.4	Is waste and material which is not suitable for feed stored and identified separately?	# Hazardous concentrations of feed medicines and contaminants must be removed properly. # Participant must make clear how waste and its removal are controlled.	3	Real risk that waste and material which is not suitable for animal feed becomes mixed with animal feed.	Products which are not suitable for delivery are not identified.	
6.5	Identification and traceability					
6.5	Are the products traceable in all stages of production, processing and distribution?	# The required information available within 4 hours unless the authorities demand a faster time. # Minimum required records: Name & Address, date of delivery, type of product / service, product quantity, batch number. # Retention samples. # See GMP+ BA13.	3		Insufficient records for tracking & tracing.	Difficult to trace.
6.6	EWS and Recall					

6.6	Have written procedures been adopted for EWS and recall?	# After establishment of a recall procedure, a recall simulation should be carried out within 3 months. # Thereafter a recall simulation every year including the recording of experiences # If there is a potential hazard which can not be controlled by the participant in question and which may also cause damage to others then the participant is obliged to inform GMP+ International. # Working in accordance with GMP+ BA5.	3	# The company omits to keep GMP+ International informed directly.		
6.7	Production					
6.7.1	Has the production been carried out under planned and controlled circumstances?	If forbidden feed materials are processed or traded is there a direct report to GMP+ International.	3	# The standard for undesirable substances is breached, with a direct hazard for humans, animals and/or the environment, where no adequate improvement measures have been taken. # Forbidden feed material processed or traded.	# The standard for undesirable substances is breached, without direct hazard for humans, animals and/or the environment, where no adequate improvement measures have been taken. # No measures established and implemented to prevent recontamination.	
6.7.1.1	In the event of direct drying does the participant select, on the basis of a risk assessment, only fuels which do not compromise the safety of the animal feed?	No use of prohibited fuels as specified in GMP+ BA3.	3	# Use of prohibited fuels (GMP+ BA3)	# Use of fuel not based on a risk assessment.	
6.7.1.2	Have technical and organisational measures been taken to avoid cross-contamination and faults as much as possible with respect to the dosage of (raw) materials and are there records of this?		3			
6.7.1.3	Have feed materials, feed additives and feed medicines been mixed uniformly in the feed?		3	# Incorrect processing of feed additives or feed medicines (structural)	# Incorrect processing of feed additives or feed medicines (incidental)	

6.7.1.4	Have the conditions been matched with respect to pelleting / expansion / extrusion to the stability of the processed feed additives and feed medicines?	# It is obligatory to include a Salmonella-killing step in production where poultry feeds are involved. See GMP+ BA4.	3	# Incorrect processing of feed additives or feed medicines (structural)	# Incorrect processing of feed additives or feed medicines (incidental)	
6.7.1.5	Does a carry-over inspection take place and is account taken of the production sequence?	# See GMP+ BA1. # Implementation in accordance with GMP+ International testing procedure. See GMP+ BA4.	3		# No carry-over test carried out on critical lines. # Insufficient foundation with respect to flush charge (including medicines). # No foundation for residue norms.	# No correct carry-over test carried out.
6.7.1.6	Are internal return flows brought back into the charge / run from which they came or can it be derived from the records where they are stored with a determination of which return products may be included in which products?		3			# Traceability of return flows insufficient.
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07 PROCESS CONTROL						
7.1	Planning of the realisation of a safe feed					
7.1	Does the participant ensure the introduction, implementation and maintenance of permanent, written procedures based on the HACCP principles?		3			
7.2	Requirements for the feed					

7.2.1	Have requirements for the feed been determined by the participant?	# Are these requirements specified and has the associated use been determined. # Does the specification comply with the correct composition of the product in relation to type of animal and the latest date of feeding in GMP+ BA1 and GMP+ BA3. # In the event of production of a feed material there should be a risk assessment present for this method of production in the Feed Safety Database (FSD).	3	Not in possession of required legal certificates, records or permits.	No action taken as a result of analysis results which are outside the tolerances.	Not all norms are recorded, complete, applied or analysed.
7.2.2	Have these feed requirements been reviewed before an animal feed is delivered and are there records of this?	# Is there a determination on delivery of whether products comply with the product norms in GMP+ BA1. # On delivery do the product requirements comply with the negative list in GMP+ BA3. # Are specific requirements checked by the company in the end product. # Assessment of whether a new product complies with the legislation and regulations.	3			
7.2.3	Are there specifications (end product) per animal feed (group)?	Is this specification and use available to the customer on delivery	3	No specifications.	Some specifications are missing.	Specification is not up-to-date / incomplete.
7.2.4	Have procedures been established and implemented for communication with the customer?	Complaints registration	3			
7.3	Process information					
7.3	Have all flow diagrams and layouts been verified by the HACCP team?		3		# No demonstrable verification carried out. # No verification carried out after changes.	
7.3.1	Do the flow diagrams follow all the steps and are they accurately laid down?		3		Essential process steps are missing.	Incomplete description of the current production process.

7.3.2	Does the diagram shows the whole infrastructure of the establishment?		3		# No record on the diagram. # Not indicated where cross-contamination is possible.	
7.4	Hazards analysis					
7.4	Have all the potential hazards which may have an negative effect on feed safety been systematically identified and assessed by the HACCP team?		3	No hazards analysis.	Not all hazards specified	
7.4.1	Has the HACCP team established an acceptable level for each hazard?	# Established levels must at least comply with statutory norms and norms laid down in GMP+ BA1. # Based on the generic risk assessment from the Feed Safety Database (FSD) (if applicable)	3			
7.4.2	Have risk estimates been carried out and documented for each identified hazard?		3	# No risk estimation carried out.	# Not all risk assessment hazards identified. # No reasoning recorded.	
7.5	Establishment of critical control points (CCPs)					
7.5.1	Has the HACCP team established, recorded and implemented control measures for each established risk?		3		# Control measures not recorded.	
7.5.2	Has the HACCP team established, for each control measure, whether this control measure is the last measure in the process of controlling this risk in question?	# CCPs should be supported. # Specific measures should be monitored, validated and verified.	3			
7.6	Standards					
7.6	Have parameters and norms been established per CCP?	There must be compliance with the established feed norms and the residue norms for (critical) feed additives and feed medicines. See GMP+ BA1.	3	# Non-compliance with the residue norms for critical feed additives and feed medicines.	One of the elements has not been correctly evaluated.	
7.7	Monitoring and measuring					

7.7.1	Has a monitoring plan been drawn up in writing and has it been implemented?	# This plan applies to the processed materials up to and including the produced feeds. # Is the reasoning for the monitoring programme available and is it demonstrably based on the product norms GMP+ BA1 en GMP+ BA3. # Is there a check on whether products comply with the product specifications and the minimum product requirements in GMP+ BA1 en GMP+ BA3# Are proper measures taken in the event of deviation from the product specifications. # In the event of the minimum requirements in GMP+ BA1 en GMP+ BA3 being exceeded is the product removed from use and are proper records of this maintained. # This plan must at least comply with the inspections established in this GMP+ FSA scheme. # Laboratory must comply with the requirements of the GMP+ FSA scheme. See GMP+ BA10.	3	Analyses are carried out by an uncertified laboratory.	# No records of controls and inspections at the required points. (backlog of more than two months). # Deviating numbers of mandatory samples to be taken, sample testing and carry-over testing. # No full insight into whether the laboratory has certification for all analyses.	# Records of controls and inspections have a backlog of less than two months. # Analysis schedule not correct / up to date. No description of the method of sampling. # No check on storage life of premixes and feed additives.
7.7.2.	Has there been a check that the established residue norms for feed additives and feed medicines are not exceeded?	Must take place at least after measurement of carry-over.	3			
7.8	Corrective actions					
7.8	Have the non-conformities (in the animal feed or process) with respect to this GMP+ standard been established and controlled?		3		No procedure available or applied.	The procedure is incomplete.
7.9	Validation of the HACCP plan					
7.9	Has the HACCP system been validated by an independent validation team?	# If it is impossible to put together an independent validation team then this must be explained.	3			
7.10	Purchasing					

7.10.1	Do purchased products and services comply with the specified purchasing requirements, has a written procedure been established in which suppliers are assessed and records are kept?	See GMP+ BA10.	3	# Use of and purchasing from uncertified suppliers (products and services). # Absence of a risk assessment for a feed material.	# Suppliers not assessed. # No procedure available or applied. # Suppliers with an expired GMP+ certificate	Suppliers insufficiently assessed.
7.10.1.1	Does the participant comply with the additional requirements for the purchase of feed additives under gatekeeper conditions?	See GMP+ BA10.	3			
7.10.1.2	Does the participant comply with the additional requirements for the purchase of grains, seeds and legumes from uncertified origin?	See GMP+ BA10.	3			
7.10.1.3	Does the participant comply with the additional requirements for the purchase of palm oil from uncertified origin?	See GMP+ BA10.	3			
7.10.2	Have the purchasing data for a product or service to be bought been described in which the suitability of specified purchasing requirements is guaranteed?	Purchasing requirements must be based on the requirements which are set on the end product.	3		No specifications.	Specifications incomplete
7.10.3	Is there an entry inspection on purchased products and services?	# Feed medicines must be received and processed in accordance with the applicable statutory provisions. # Gatekeeper feed additives: product is in the original packaging. # Does the transport meet the requirements set (minimum check on the GMP+ certification of the carrier, compliance with loading sequence, prior loads and implementation of necessary cleaning regimes). # LCI report is demonstrable	3	Structural contravention of the statutory rules with respect to the use of feed medicines.	# Contravention of the statutory rules with respect to the use of feed medicines in feeds. # No proper entry check or sampling of delivered feed materials. # No purchasing requirements or specifications check on supplied products. # No / insufficient check on whether vets complete certificates correctly.	
7.11	Production					
7.11.2	Is the property of the client controlled, handled, assessed and secured in the same way as own products?		3			

7.11.3	Does the feed continue to comply with the requirements set during internal handling and delivery to the intended destination?		3		# No or insufficient labels # No product information made available to the cattle farmer for the maintenance of the hygiene of the feed. # Feed labels do not comply with the requirements.	
7.11.4	Before starting loading (of transport on the instructions of the customer) is there an assessment of whether the loading compartment is clean, free of remains of loads and of the odour of previous loads and is there feedback to the customer if there are deviations?	# The mandatory statutory information must be provided on delivery to the customer. # If during a check, deviations are observed with respect to the loading compartment then the judgement of the customer should be recorded.	3			
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08 MEASUREMENT, ANALYSIS AND IMPROVEMENT						
8.1	General					
8.1	Have the necessary monitoring, measurement, analysis and improvement processes been planned and implemented?		3			
8.2	Internal audits					
8.2	Are internal audits carried out and registered at least 1x / 12 months?		3		# Essential parts / departments were not audited. # Insufficient depth / insufficient reporting on findings, improvement measures in the internal audit. # Internal audit was more than a year ago	# Improvement measures from the internal audit are not demonstrably monitored / followed up.
8.3	Verification of the feed safety system					
8.3	Does verification of the feed safety system take place and is there a record of this?	# Gatekeeper feed additives: audit at the producer by or on behalf of the client. # Verification of the HACCP system.	3			
8.4	Improvement					
8.4.1	Is the effectiveness of the feed safety system continuously improved?		3			

8.4.2	Are measures taken to resolve the sources of non-conformities (corrective measures) and has this been laid down in a procedure?	GMP+ BA4.	3		Insufficient action taken: no testing carried out, no records or monitoring. # No action taken following a positive result.	Insufficient testing records or monitoring carried out. # Not reporting analysis results with respect to mandatory monitoring to the the Feed Safety Database - monitoring.
8.4.3	Are measures taken to resolve the sources of possible future non-conformities (preventive measures) and has this been laid down in a procedure?		3			