



GMP B3 (2007) Trade, Collection and Storage & Transhipment of Feeds

Art.	Description	Possible items for attention	Frequency	Interpretation Cat. 1	Interpretation Cat. 2	Interpretation Cat. 3
01 SUBJECT MATTER AND AREA APPLICABILITY						
1.1	General					
1.1	Does the company comply with the requirements specified in the A documents?	See A1, A2, A3 and A4 documents	3			
02 NORMATIVE REFERENCES						
2.0	Legislation					
2.0	Does the participant comply with community legislation and national legislation?		3			
2.1	Has the participant implemented the duty to report a positive Salmonella analysis in the correct way?	<ul style="list-style-type: none"> # It only applies to deliveries to Dutch poultry farmers. # a positive Salmonella analysis must be classified. # Reporting to the poultry farmer and the DOS (Database of Undesirable Substances) of a positive result and the classification must have taken place within 6 hours of receipt. # Corrective measures must be communicated to and harmonised with the poultry farmer. 	3	<ul style="list-style-type: none"> # The company repeatedly takes no action with respect to a positive Salmonella result. 	<ul style="list-style-type: none"> # 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 DOS. # 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. 	
2.2	Does the participant comply with the GMP+ International Regulation on Medicated Feed 2003?		3			
04 FEED SAFETY SYSTEM						
4.1	Management: Responsibility and involvement					
4.1	Is management demonstrably involved in the development and the implementation of the feed safety system?	<ul style="list-style-type: none"> # Raising awareness of the importance of feed safety, compliance with the requirements of the customer and compliance with the feed legislation. # Compose HACCP team # Making resources available # Management review at least 1x/12 months 	3		<ul style="list-style-type: none"> # No management involvement. # No demonstrable meeting structure with respect to the feed safety system. 	<ul style="list-style-type: none"> # No demonstrable provision of information with respect to changes to the feed safety system.
4.2	HACCP team					



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4.2	Has a HACCP team been established with sufficient expertise from various different disciplines and has a HACCP plan been drawn up?	<ul style="list-style-type: none"> # Draw up prerequisites # Carry out hazards analysis in accordance with guidelines in Annex 1 # Established hazards levels must at least comply the legal and GMP+ norms. # Hazard levels are based on the generic risk assessment in the Database of Feed Materials Risk Assessments (DRV) (if applicable). 	3	<ul style="list-style-type: none"> # No operational HACCP team # No risk assessment carried out. 	<ul style="list-style-type: none"> # Poorly functioning HACCP team; insufficient or no discussion. # Not all risk assessment hazards identified. # No demonstrable verification carried out, also not after changes. # Essential process steps are missing. # Reasoning / control measures not recorded 	<ul style="list-style-type: none"> # Meeting of HACCP team not minuted properly. # Not all departments represented. # Function of adviser not established. # Incomplete description of the current process.
4.3	The feed safety system					
4.3.1	Has the scope of the feed safety system, including any particularities or exclusions, been established and recorded?	<ul style="list-style-type: none"> # Gatekeeper function and products are described # Contracting out of work in accordance with Appendix 10. # 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.
4.3.2	Does the structure of the feed safety system specifically relate to the organisation of the participant?		3			
4.4	Documentation and registration					
4.4.1	Does the manual include the required sections?	<ul style="list-style-type: none"> # Description of the scope, required permits, reg. and cert. under the feed legislation, required GMP+ procedures, instructions and records. # HACCP documentation # Required GMP+ procedures, instructions and records. # Gatekeeper feed additives: contract with the original producer; HACCP dossier complies with the Appendix. 10 # Gatekeeper untreated agricultural products: risk assessments products + contract with grower. 	3		Not in accordance with the norm in essential areas.	No full or correct representation of what happens in practice.



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4.4.2	Are documents and record details checked and kept and maintained properly.	Storage period for records is at least three years.	3		# Necessary modifications not implemented or not fully and the situation in practice is behind current developments in the company or the regulations. # There is a backlog (> 2 months) in the relevant records. # Records arising from the feed safety system are not kept for the required period of time.	# Necessary modifications not implemented or not fully but the situation in practice corresponds to the regulations. # Relevant records have been overlooked or are out of date (< 2 months). # No up-to-date description of the method of archiving. # Relevant records are not easily accessible.
4.5	Identification and traceability / sampling					
4.5.1	Are there suitable measures by which the effective traceability of animal feeds is guaranteed?	Participant must comply with the requirements of Appendix 8.	3		Insufficient records for tracking & tracing.	Difficult to trace.
4.5.2	Are sufficient samples taken from the incoming and/or outgoing feeds?	Procedure for taking and retaining samples.	3			
4.6	Complaints					
4.6	Is there a documented procedure for handling customer complaints?	Complaints registration	3			

05 PREREQUISITES

5.1	Personnel					
5.1.1	Are all personnel aware of their responsibility for feed safety?		3			
5.1.2	Are personnel expert 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?	# This applies in particular to the HACCP team and to the other functions which influence feed safety. # Rules must also have been established with respect to protective clothing, eating, drinking and smoking in production areas. # Feed additives gatekeeper official responsible for the HACCP dossier complies with Appendix 10.	3		# Personnel do not understand the procedures. # Principle of HACCP is not known to the personnel.	# No suitable record of the training courses, experience etc. of employees. # Lack of relevant refresher training.
5.2	Infrastructure					
5.2.1	Does the environment and the production buildings present no danger to the production of feed materials?	In this section there are various requirements with which the environment and production areas must comply.	3			
5.2.2	Has an access regulation been established for the production areas?		3			
5.2.3	Is there hygienic working with the transport systems and processing installations and are they suitable for their purpose?		3		Influence on feed safety.	



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5.2.4	Do the production areas meet the requirements of this GMP+ standard?		3		The production area is such that unintentional mixing and microbiological contamination are not prevented. Influence on feed safety.	
5.2.5	Have technical and organisational measures been taken to prevent cross-contamination and errors as much as possible?		3		# Influence on feed safety. # Influence on traceability.	
5.2.6	Are production areas for reception, loading and unloading designed such that birds and other animals have the least possible chance of getting in?		3		Insufficiently effective measures taken to prevent vermin.	
5.2.7	Has water or steam been used during cleaning or in the processing of feeds safe for animals.	Use of processing aids.	3			
5.3	Maintenance and hygiene management					
5.3.1	Are the production areas and installations properly and regularly maintained in accordance with the written procedures and is this registered?		3		Structural non-compliance with the established procedure.	Incidental non-compliance with the established procedure.
5.3.2	Have cleaning programmes been drawn up 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.	
5.3.3	Is use made of effective programmes for the control of vermin or harmful organisms and is this recorded?	# Acceptable methods and resources. # Waiting times are taken into consideration (for example during fumigation)	3		Insufficiently effective measures taken to prevent vermin.	Demonstrability and implementation not up-to-date.
5.3.4	Is waste and material which is not suitable for feed stored and identified separately?		3	Real risk that waste and material which is not suitable for feed becomes mixed with feed.	Products which are not suitable for delivery are not identified.	
5.3.5	Do glass and breakable materials form a hazard for the feeds?		3			

06 TRADE IN FEEDS

6.1 Determination of requirements and communication with customers



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6.1	Have the requirements of the customer with respect to feed safety been understood, specified and complied with?	<ul style="list-style-type: none"> # Legal requirements: Appendix 12. # Additional requirement with respect to feed safety # Is there a determination of whether products comply on delivery with the product norms in Appendix 1. # Do the feed materials used comply with the minimum requirements in Appendix 2. # Do the product requirements on delivery comply with the negative list Appendix 3. # Mandatory monitoring in accordance with Appendix 4. # On the purchase/sale of a feed material there should be a risk assessment present for this product in the Database of Feed Materials Risk Assessments (DRV). 	3	<ul style="list-style-type: none"> # Not in possession of required legal certificates, records or permits. # Absence of a risk assessment for a feed material. 		Not all norms are recorded, complete, applied or analysed.
6.2	Specification and labelling					
6.2.1	Are there specifications (end product) per animal feed (group)?	# Does the specification comply with the correct composition of the product in relation to type of animal and the latest date of feeding in Appendices 1 and 3.	3	No specifications.	Some specifications are missing.	Specification is not up-to-date / complete.
6.2.2	Is the necessary information issued to the customer on delivery?	<ul style="list-style-type: none"> # Is the specification and use available to the customer on delivery. # The mandatory statutory information must be provided on delivery to the customer. 	3		<ul style="list-style-type: none"> # No or insufficient labels. # No product information made available to the cattle farmer for the maintenance of the hygiene of the feed. # Single feed labels do not comply with the requirements. 	
6.3	Selection of suppliers					
6.3	Does the selection and assessment of suppliers take place in accordance with the requirements of this GMP standard?	<ul style="list-style-type: none"> # See Appendix 10: App. 1 Additional requirement GTP code, App. 3 Additional requirements for the purchasing of untreated agricultural products # European suppliers certified /registered in accordance with EG 183/2005. # Suppliers of other products and services assessed on the basis of analysis based on HACCP principles. 	3	Use of and purchasing from uncertified suppliers (products and services).	<ul style="list-style-type: none"> # Suppliers not assessed. # Not demonstrable that no Loading Category 1 products were carried (for example during the hiring of loading compartments). 	Suppliers insufficiently assessed.
6.4	Purchase / sale					
6.4	Are the purchase and sale of feeds must be clearly recorded?		3			
6.5	Verification of the purchased product					



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6.5	Are the inspection activities established and implemented to verify that the purchased feeds are in accordance with the specified requirements?		3		# No proper entry check or sampling of delivered feed materials. # No purchasing requirements or specifications check on supplied products.	
6.6	Documentation					
6.6	Is there a documented procedure for the whole trading process?	# Specifications are documented # Maintenance of documents and communication of changes.	3			
07 CONTROL OF OPERATIONAL ACTIVITIES						
7.1	General					
7.1	Are all the stages in the process planned and monitored to ensure that the feed remains in accordance with the documented specifications and the documented parameters for critical steps?	# Control based on the formal HACCP principles, see Annex 1.	3		No action taken as a result of analysis results which are outside the tolerances.	Not all norms are analysed.
7.2	Verification of incoming feeds					
7.2	Is each incoming delivery of feed verified in accordance with an established procedure?	# 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, oil leaks). # In the event of doubt are the specifications verified using analyses.	3		No proper entry check or sampling of delivered feed materials.	
7.3	Cleaning / sieving					
7.3	Is the presence of contaminants such as glass, wood or earth in the feeds limited as much as possible?	Sieving: - sieve maintenance plan, - person responsible for checks, - random sample visual inspection of the sieved batches	3			
7.4	Drying and ventilating					
7.4	Are the correct methods used for the drying and ventilation of feeds?	# The fuels used during direct drying comply with Annex 2. # Responsible person checks the moisture content after drying or ventilation. # Implemented maintenance plan for dryers and ventilators.	3	Use of prohibited fuels	Use of fuel not based on a risk assessment	
7.5	Storage					



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7.5	Are the in-house storage and transhipment activities of the participant controlled using his own feed safety system in accordance with the requirements of this standard?	<ul style="list-style-type: none"> # Cross-contamination / mixing is avoided. # Check on storage moulds. # Use of legally permitted stock protection agents (Appendix 12) is documented in accordance with the instructions. # Storage and transhipment activities are contracted out in accordance with the requirements of this standard. 	3			
7.6	Simple treatment of feeds					
7.6	Do the machines / tools for simple treatment comply with the requirements?	<ul style="list-style-type: none"> # Machines / tools are suitable for purpose, correctly set adjusted, thoroughly maintained and cleaned. # Clear instructions for the personnel. 	3		<ul style="list-style-type: none"> # Structural non-compliance with the established procedure. # Hygienic operation unsatisfactory. 	Incidental non-compliance with the established procedure.
7.7	Packaging					
7.7	Is the packaging suitable for the purpose?		3			
7.8	Transport					
7.8.1	Does transport lead to undesired contamination of the feed?		3		Unintentional mixing and microbiological contamination can not be prevented.	
7.8.2.1	Is road transport carried out in accordance with the certification requirements of this standard?	<ul style="list-style-type: none"> # Is there minimally worked in accordance with the requirements of Appendix 14. # Transport of packaged products is exempted from certification. 	3			
7.8.2.2	Before starting with loading, is there an assessment of whether the loading compartment is clean, free of load residues and the odour of previous loads?	<ul style="list-style-type: none"> # Visual checks of the loading category are recorded. # If during a check, deviations are observed with respect to the loading compartment then the judgement of the customer should be recorded. 	3	Participant does not establish the product category and the cleaning regime.	No record of visual inspection.	Records are present but incomplete.
7.8.2.3	Are the transport activities carried out correctly?	<ul style="list-style-type: none"> # No mixing during transport. # Loading compartments are covered. # Canvas for covering is clean and dry if necessary. 	3		Unintentional mixing and microbiological contamination can not be prevented.	
7.8.2.4	Is there a visual check of load residues after the unloading of the loading compartment?		3			
7.8.2.5	After the transport is there cleaning and/or disinfection in accordance with Appendix 14, does the cleaning programme comply with the statutory and supplementary requirements and are they validated?	Has a control programme been established and implemented for the assessment of cleaning and disinfectant methods?	3	<ul style="list-style-type: none"> # No cleaning procedure available or is not applied when necessary. # No release by competent authority / inspection body after a prohibited load and before the transport of animal feeds. 	<ul style="list-style-type: none"> # The cleaning procedure is incomplete or is not adhered to properly. # Use of disinfectant after transport of LR2 is not demonstrable. # No validation of the effectiveness of cleaning. 	Validation of the effectiveness of cleaning is not carried out properly.



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7.8.2.6	Does registration take place of the transports, of the cleaning between consecutive bulk transports and of the inspections?	Registration per bulk loading compartment. # No prohibited loads carried. # Records are present of at least three previous loads, the associated cleaning regimes and the results of visual inspections after cleaning. Exceptions are the previous loads which do not form a potential hazard. # The statutory records should be available (including the waybill)	3	Incidentally no or incomplete records of transport sequence and cleaning without direct consequences for feed safety and subsequent links	Incidentally no or incomplete records of transport sequence and cleaning without direct consequences for feed safety and subsequent links	Difficult to trace.
7.8.3	Does the non-certified transport to other GMP B3 companies meet the requirements?	# Before LCI delivery: registration per loading compartment of at least 3 previous loads, cleaning regimes used, result of visual inspections prior to the loading and after the cleaning. # Function of loading inspector is specified in the quality system. Suitability for the position is demonstrable.	3	LCI not carried out	Loading taking place in advance of the LCI.	
7.8.4	Is transport by inland waterway, sea or train carried out in accordance with the certification requirements of this standard?	# Transport to a GMP B1 company: Affreightment of inland waterways in Europe is GMP B4.2-certified; carriers within Europe are GMP B4.3 certified; affreightment of sea transport is GMP B4.4 certified; affreightment of rail transport is GMP B4.5 certified. # Transport to other companies: LCI by an inspection agency at EN 17020 level or a company loading inspector. The shipper may not undertake his own LCI.	3	LCI not carried out	# Affreightment party does not contract out the LCI to an external CO. # Loading taking place in advance of the LCI.	

08 VERIFICATION AND MONITORING

8.1	Monitoring					
8.1	Has a monitoring plan been drawn up and implemented?	Different parts of the monitoring plan are specified in this section.	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 samples to be taken for Salmonella and sample testing. # No full insight into whether the laboratory has certification for all analyses.	# Not all norms are established, complete, applied or analysed. # 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.
8.2	Corrective actions, recall and early warning					



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8.2.1	Are measures taken to resolve the sources of non-conformities (corrective measures) and has this been laid down in a procedure?		3		# No action taken as a result of analysis results which are outside the tolerances. # No examination carried out.	# Insufficient examination, registration or monitoring carried out. # Not reporting analysis results with respect to Salmonella testing to the Database of Undesirable Substances.(DOS).
8.2.2	Has a written recall procedure been established and implemented?	# Recall procedure complies with the Appendix 7. # Destination of the recalled feeds is described.	3			
8.2.3	Is there a procedure with respect to the Early Warning System and is the Product Board Animal Feed informed of potential danger to others?	# 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 the Product Board Animal Feed. # Working in accordance with Appendix 5.	3	The company omits to keep the Product Board Animal Feed informed directly.		
8.3	Verification and improvement of the system					
8.3.1	Are internal audits carried out at least once per 12 months?	Gatekeeper feed additives: audit at the producer by or on behalf of the client, at least 1x per 3 years.	3		Essential sections / departments were not audited. # Insufficient depth / insufficient reporting on findings, improvement measures in the internal audit. # Internal audit was carried out more than a year ago.	# Improvement measures from the internal audit are not demonstrably monitored / followed up.
8.3.2	Is the effectiveness of the feed safety system continuously improved?	# Documented procedure. # Corrective actions # Preventive measures.	3			