



GMP B2 (2010) Production of Feed Ingredients

Art.	Description	Possible items for attention	Frequency	Interpretation Cat. 1	Interpretation Cat. 2	Interpretation Cat. 3
01 INTRODUCTION						
1.3	Scope and application of this standard					
1.3	Do the activities fall under the scope of this standard?	# Production van feed ingredients.	3			
02 NORMATIVE REFERENCES						
2.1	GMP+ documents					
2.1	Does the company comply with the requirements specified in the A documents?		3			
2.2	Legal compliance					
2.2	Does the participant comply with the relevant legal requirements both of the country in which the feed ingredients were produced and the countries in which they will be put onto the market?	# Certification by / registration with competent authority.	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?	# Raising awareness of the importance of feed safety, compliance with the requirements of the customer and compliance with the feed legislation. # Assemble the HACCP team. # Make sufficient resources available. # Management review at least 1x/12 months.	3		# No demonstrable management review carried out.	# No (quality) objectives laid down.
4.2	HACCP-Team					
4.2	Has a HACCP team been established with sufficient expertise from various different disciplines?	# Carry out hazards analysis in accordance with guidelines in chapter 6. # Should consist of personnel from all the relevant business activities and positions and at least one member will have demonstrable experience and knowledge of HACCP.	3	# No operational HACCP team.	# Poorly functioning HACCP team; no minutes from the HACCP team meeting.	# Lack of reasons for the frequency of HACCP team meetings. # Not all departments represented. # Function of advisor not established (if use is made of this).
4.3	The feed safety system					
4.3	Has the scope of the feed safety system, including any particularities or exclusions, been established and recorded?	# The scope must in any event include all feed ingredients and all activities which relate to this. # The participant must also describe all activities and/or products which do not relate to feed.	3		# A section of the process is excluded with a reason.	# Not all non-GMP activities are fully described.
4.4	Documentation and registration					



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4.4.1	Does the manual include the required sections?	# Description of the scope. # HACCP documentation # Required GMP+ procedures, instructions and records.	3		# Not in accordance with the norm in essential areas.	# No full or correct representation of what happens in practice.
4.4.2	Are documents and record details checked and kept and maintained properly?	# Documentation must be reviewed at least every year by a competent person. # Documentation must always be available to and understandable by the personnel who have to carry out the requirements of the procedure. # Retention period for records is at least three years.	3		# Necessary modifications not implemented or not fully and the situation in practice is behind the current situation in the company or the regulations. # There is a backlog (> 2 months) in the relevant records. # Records 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.

05 PREREQUISITE PROGRAMMES

5.0	Prerequisite programme					
5.0	Does the participant have an effective prerequisites programme?	# Reason for excluded prerequisites. # The additional prerequisites have been worked out and implemented.	3			
5.1	Personnel					
5.1.1	Are all personnel aware of their responsibility for feed safety?	# Organisational chart. # Descriptions of the qualifications and the responsibilities of supervisory personnel. # Rules with respect to the wearing of protective clothing, eating, drinking and smoking in the production and storage areas are laid down.	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.	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 present a hazard to feed ingredients?	# If the environment does present risks the the participant must show by way of an analysis that the risks are satisfactorily controlled.	3			
5.2.2.1	Do the production buildings present a hazard for feed ingredients?	# Production area and plant fit for production and storage.	3			



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5.2.2.2	Are there sufficient areas for the reception and loading and unloading of feed ingredients and for potentially harmful products?	# Contamination should be avoided by creating good conditions. # The intrusion of rainwater and contaminated water should be prevented during loading, unloading and storage	3			
5.2.2.3	Are there sufficient areas for the storage of feed ingredients and for potentially harmful products?	# Suitable floors, walls and ceilings.	3			
5.2.2.4	Is all the equipment which will be used for the production of feed ingredients suitable for their purpose?	# In this section there are various requirements with which the equipment must comply.	3			
5.2.3	Has an access regulation been established for the production areas?		3			
5.2.4.1	Have technical and organisational measures been taken to prevent cross-contamination and errors as much as possible?	# Residue norms in GMP+ Appendix 1 and the carry-over test in accordance with Appendix 4 (if applicable)	3			
5.2.4.2	Has the participant evaluated the risk of the airflow which can possibly act as a means of transport for pathogens and taken the necessary precautions?		3			
5.2.4.3	Is water or steam been used during cleaning or in the processing of feeds ingredients safe for animals?	# Quality of the water.	3			
5.2.4.4	Has the participant carried out a risk assessment of the use of processing aids to show that there is no harmful effect to humans, animals or the environment?	# Effects of residues of processing aids on the ready feed ingredients.	3			
5.2.4.5	Is the packaging suitable for the feed ingredient in question and for the chosen method of delivery and transportation?		3			
5.3	Maintenance and hygiene management					
5.3.1	Has the participant drawn up and implemented a (documented) programme of planned maintenance for all the relevant areas and equipment?	# Also agreements with external companies in relation to hygiene and safety.	3		# Structural non-compliance with the established procedure.	# Incidental non-compliance with the established procedure.
5.3.2	Is all the inspection, measurement and testing equipment which is used calibrated at intervals of a maximum of 12 months?	# Dosage equipment for technical aids and processing aids.	3			
5.3.3	Are the production, storage and transport facilities cleaned in such a way that the safety of the feed ingredients can be maintained?	# Is the chosen cleaning method effective? # An authorised person must carry out the inspections with respect to the status of the cleaning and maintain a record of this.	3		# Hygienic operation unsatisfactory	



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5.3.4	Is use made of effective programmes for the control of vermin or harmful organisms and is this recorded?	# Permitted methods and means. # Employees must have permission in accordance with national legislation to carry out pest control operations. # Waiting times are taken into consideration (for example during fumigation)	3		# Insufficiently effective measures taken to deal with vermin.	# Demonstrability and implementation not up-to-date.
5.3.5	Is waste 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.	
5.3.6	Are glass and breakable materials a hazard for the feed ingredients?		3			
5.4	Identification and traceability / sampling					
5.4.1	Are there suitable measures by which the effective traceability of animal feeds is guaranteed?	# Register with relevant details of the purchase, production and sale by which products can be recalled immediately, specifically and accurately. # Details must be available within 4 hours (or less if the competent authority demands this)	3		# Insufficient records for tracking & tracing.	# Difficult to trace.
5.4.2	Are sufficient samples taken from the incoming and/or outgoing feeds?	# Sampling and storage in accordance with GMP+ Appendix 13. # The samples must be sealed and/or not openable and must be clearly identifiable.	3			
5.5	EWS and Recall					
5.5	Is there a procedure available with respect to EWS and has a recall-procedure been established and implemented?	# 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 (procedure according to GMP+ Appendix 5). # A recall simulation must be carried out at least once per year.	3	# The company omits to keep the competent authority and GMP+ International informed immediately.		

06 HACCP

6.1	Planning of the realisation of safe feed					
6.1	Has the participant ensured that one or more written procedures on the basis of HACCP principles have been introduced, implemented and maintained?	# HACCP plan	3			
6.2	Description of products and processes					
6.2.1	Has the participant determined and specified all the (safety) requirements with respect to the feed ingredients to be produced?	# Legal provisions and relevant GMP+ requirements. # Customer requirements. # If the participant produces a feed material then it should be included in the DRV database with an identical production method.	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.



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6.2.2	Has the participant also specified the raw materials and other products which are used during production?	# This also applies to services.	3			
6.2.3	Has the HACCP team drawn up a description of the production process in the form of flow diagrams?	# Waste flows and contracted out process steps should also be included in the flow diagram.	3			
6.3	Hazards analysis					
6.3.1	Has the HACCP team identified and documented all the potential hazards?	# This also applies to the processes in the prior links such as raw materials and additives.	3	# No hazards analysis.	# Not all hazards specified.	
6.3.2	Has the HACCP team carried out a risk assessment for each identified hazard?		3	# No risk estimation carried out.	# Not all risk assessment hazards identified. # No reasoning recorded.	
6.4	Establishing control measures and CCPs (critical control points)					
6.4.1	Has the HACCP team laid down and implemented control measures for controlling all risks which can have a negative effect on feed safety?	# More than one control measure may be necessary to control a risk and more than one risk may be controlled by a single control measure.	3			
6.4.2	Has the HACCP team assessed whether the control measures form the last measure in the process for the controlling of the risk?	# The motivation for the CCP must be laid down.	3		# The lacking of a motivation for a CCP # Not all significant CCPs have been identified	
6.5	Establishing critical limits					
6.5	Has the HACCP team determined for each CCP which parameters must be measured, analysed or observed and which product norms apply to these parameters?	# See GMP+ Appendix 1	3			
6.6	Monitoring					



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6.6	Has a monitoring plan been drawn up in writing and has it been implemented?	<p># Is the reasoning for the monitoring programme available and is it demonstrably based on the product norms from GMP+ Appendices 1 and 3.</p> <p># Is there a check on whether products comply with the product specifications and the minimum product requirements in appendices 1 and 3.</p> <p># Are proper measures taken in the event of deviation.</p> <p># In the event of the minimum requirements in GMP+ Appendices 1 and 3 being exceeded is the product removed from use and are proper records of this maintained. Duty to report in the event of Salmonella contamination.</p> <p># This plan must at least comply with the inspections established in this GMP+ certification scheme.</p> <p># Laboratory must comply with the requirements of the GMP+ certification scheme. See GMP+ Appendix B10 for the requirements with respect to the use of an external laboratory.</p>	3	# Analyses are carried out by an uncertified laboratory.	<p># No records of controls and inspections at the required points (backlog of more than two months).</p> <p># Non-standard number of sample tests.</p> <p># No full insight into whether the laboratory complies with GMP+ certification for all analyses.</p>	<p># Records of controls and inspections have a backlog of less than two months</p> <p># No description of the method of sampling</p>
6.7	Corrective actions					
6.7	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.
6.8	Validation and verification					
6.8.1	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			
6.8.2	Has the participant verified the HACCP system?		3			
07 CONTROL OF OPERATIONAL AC						
7.1	Purchase					
7.1.1	Does the participant have a (documented) procedure which ensures that the purchase of raw materials, services and feed ingredients is in accordance with the requirements and conditions of GMP+ ?	<p># Supplier is at the moment of delivery either GMP+ or equivalent certified (see GMP+ Appendix 10)</p> <p># Risk assessment (on the basis of HACCP) must be carried out prior to the purchase of raw materials or services.</p> <p># Each feed material which is purchased must be included in the DRV database.</p>	3			
7.1.2	Does the participant have a (documented) procedure for the yearly assessment of his suppliers?		3			



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7.2	Verification of received products					
7.2	Is each incoming delivery of feed verified in accordance with an established procedure?	# Does transport comply with the requirements set (prior loads, cleaning, 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	Storage					
7.3.1	Are the in-house storage and transshipment activities of the participant controlled using his own feed safety system in accordance with the requirements of this standard?	# Cross-contamination / mixing is avoided. # Use of legally permitted stock protection agents. Documentation present. # Storage and transshipment activities are contracted out in accordance with the requirements of this standard.	3			
7.3.2	Are all products which are produced or stored by the participant but which are not intended for use as a feed kept separate from the feed ingredients and identified as such?		3			
7.4	Production					
7.4.1	Are all activities carried out in accordance with the standard?		3			
7.4.2	Has the participant drawn up a documented procedure which describes what to do about raw materials and feed ingredients which do not comply with the specifications?		3			
7.5	Sales & contracts					
7.5	Are the specifications for the feed ingredients laid down in a contract between the participant and the buyer?		3			
7.6	Labelling and delivery requirements					
7.6	Is the necessary information issued to the customer on delivery?	# Is this specification and use available to the customer on delivery. # On delivery the legally prescribed information must be issued to the customer. # 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+ appendices 1 and 3.	3	No specifications.	# No or insufficient labels. # No product information made available to the livestock farmer for the maintenance of the hygiene of the feed. # Feed labels do not comply with the requirements. # Some specifications are missing.	Specification is not up-to-date / complete.
7.7	Transport					
7.7.1	Has the participant taken sufficient measures to prevent undesired contamination during transport?		3		Unintentional mixing and microbiological contamination can not be prevented.	



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7.7.2.1	Is road transport carried out in accordance with the requirements of this standard?	# Is there minimally worked in accordance with the requirements of Appendix 14.	3			
7.7.2.2	Before loading, is there an assessment of whether the loading compartment is clean, free of load residues and the odour of previous loads?	# 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.
7.7.2.3	Are the transport activities carried out correctly?	# No mixing during transport. # Loading compartments are covered. # Canvas for covering is clean and dry if necessary.	3			
7.7.2.4	Is there a visual check of load residues after the unloading of the loading compartment?		3			
7.7.2.5	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	# 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.	# 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.
7.7.2.6	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 available of at least three previous loads, the associated cleaning regimes and the results of visual inspections after cleaning (if applicable)	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.
7.7.3	Is road transport on the orders of service providers carried out in accordance with the requirements of this standard?		3			
7.7.4	Is road transport carried out by third parties in accordance with the requirements of this standard?	# The documentation of three prior loads (for bulk loads) must be reviewed by a competent person before the product is loaded.	3			
7.7.5	Is transport by inland waterway, sea or train carried out in accordance with the requirements of this standard?	# Transport to a GMP B1 company: Freight brokerage of inland waterways in Europe is GMP B4.2-certified; carriers within Europe are GMP B4.3 certified; freight brokerage of sea transport is GMP B4.4 certified; freight brokerage 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	# Freight party does not contract out the LCI to an external CO. # Loading taking place in advance of the LCI.	

08 VERIFICATION AND IMPROVEMENT



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8.1	Complaints					
8.1	Is there a documented procedure for handling customer complaints?	# Complaints registration	3			
8.2	Internal audit					
8.2	Are internal audits carried out at least once per 12 months?		3		# Essential sections / departments were not audited. # Insufficient depth / insufficient reporting on findings, improvement measures not demonstrable. # Internal audit was carried out more than a 12 months ago.	# Improvement measures from the internal audit are not demonstrably monitored / followed up.
8.3	Management review and improvements					
8.3	Is there a regular assessment of whether the feed safety system can be improved?	# Documented procedure. # Corrective actions # Preventive measures.	3			