Audit Checklist

FAMI-QS CODE VERSION 6	
Operator:	
FAMI-QS Registration Number:	
Date of Audit:	
Auditor:	

		Yes	No	Remark
4	**Management System**			
4.1	Understanding the Operator and its context			
a	Are external and internal risks determined and documented?			
b	Are external and internal risks reviewed to ensure continual relevance?			
c	Are external and internal risks communicated internally?			
4.2	Understanding the needs and expectations of interested parties			
a	Are interested parties determined and documented?			
b	Are the requirements of the interested parties documented?			
c	Are the interested parties reviewed to ensure continual relevance?			
d	Are there any records demonstrating that interested parties were reviewed?			
4.3	Feed Safety and Quality Management System and its Processes			
a	Is there a documented Feed Safety and Quality Management System in place?			
Has the Operator determined:				
b	the processes needed for the Feed Safety and Quality Management System?			
c	the inputs required and the outputs expected from these processes?			
d	the sequence and interaction of these processes?			
e	the criteria, methods including measurements and related performance indicators needed to ensure the effective operation, and control of these processes?			

		Yes	No	Remark
f	the resources needed and how they are ensured?			
g	the risks and opportunities in accordance with the requirements, and planned and implemented the appropriate actions to address them?			
h	the methods for monitoring, measuring, as appropriate, evaluating processes and, if needed, changes to processes to ensure that they achieve the intended results?			
i	the opportunities for improvement of the processes and the Feed Safety and Quality Management System?			
j	assigned responsibilities and authorities for the processes?			
4.4	Feed Safety and Quality Management System Documentation			
a	Is there a Feed Safety and Quality Manual in place?			
b	Is there a documented Feed Safety and Quality Policy?			
c	Are documented quality procedures and records available?			
d	Are specifications and testing procedures for incoming materials and finished products documented?			
e	Are process records for each batch of product available?			
f	Are Standard Operating Procedures (SOPs) for all activities under the scope of the Feed Safety and Quality Management System documented?			
g	Are documents unambiguous and include title, nature and purpose?			
h	Are documents approved, signed and dated by appropriate authorised persons?			
i	Are documents legible, controlled and kept up to date?			
j	Are documents available and suitable for use?			
k	Are documents adequately protected?			
4.5	Determining the scope of the Feed Safety and Quality Management System			
a	Are the boundaries and applicability of the Feed Safety and Quality Management System determined and documented?			
b	Are the process, products and production sites specified and documented?			
c	Are there any exclusions to the scope, and if so, is there justification?			
4.6	Feed Safety and Quality Policy			
a	Is the Feed Safety and Quality Policy suitable for the purpose of the operation and scope?			
b	Does it include a commitment to provide safe specialty feed ingredients?			

		Yes	No	Remark
c	Does it include a commitment to satisfy applicable regulatory requirements?			
d	Does it include a commitment towards continuous improvement of the Feed Safety and Quality Management System?			
e	Does it include a commitment to take the necessary actions for preventing fraud/adulteration?			
f	Does it provide a framework for setting and reviewing feed safety and quality objectives?			
g	Is it communicated at all levels within the organisation?			
h	Is it reviewed at planned intervals (at least yearly)?			
5	**Leadership**			
5.1	Leadership commitment			
Has top management demonstrated leadership and commitment by:				
a	establishing Feed Safety and Quality Policy and objectives?			
b	allocating resources needed for Feed Safety and Quality Management System?			
c	ensuring achievement of intended results of Feed Safety and Quality Management System?			
d	promoting continual improvement?			
e	supporting other management roles within the organisation to do the same?			
f	communicating effectively the Feed Safety and Quality Policy?			
5.2	Responsibilities			
Has top management defined:				
a	responsibilities and authority for all personnel within the Feed Safety and Quality Management System?			
b	an organisational chart for the organisation?			
c	a qualified HACCP team leader?			
d	a system in place to identify and correct problems with regard to the Feed Safety and Quality Management System?			
6	**Planning**			
6.1	Actions to address risks and opportunities			
a	Are risks and opportunities determined as a result of internal and external risks and interested parties?			
b	Does the organisation plan actions needed to address risks and opportunities?			
Do the actions include development and implementation of:				
c	Good Manufacturing Practices?			

		Yes	No	Remark
d	HACCP plan and reviews?			
e	emergency preparedness and response plan?			
6.2	**Feed safety and quality objectives and planning to achieve them**			
Has the organisation established Feed Safety and Quality objectives that are:				
a	consistent with Feed Safety and Quality Policy?			
b	measurable?			
c	considered regulatory and contractual requirements?			
d	monitored?			
e	communicated?			
f	updated?			
g	Is documented information available for monitoring efforts?			
6.3	**Planning of changes**			
Has the organisation proceeded in a planned and systemic manner by:				
a	identifying the purpose of the change and their consequence?			
b	considering the integrity of the Feed Safety and Quality Management System?			
c	allocating resources?			
d	allocating responsibilities?			
7	**Good Manufacturing Practices**			
7.1	**Establishment**			
a	Is the establishment designed and maintained to eliminate or minimise feed safety hazards?			
b	Is the establishment designed and maintained to prevent contamination from surroundings?			
c	Are the establishment boundaries defined and documented?			
d	Is access to the establishment and bulk receiving lines controlled?			
e	Is there an assessment of feed safety hazards originating from potential acts of sabotage, vandalism or terrorism?			
7.1.1	**Local site environment**			
a	Are potential sources of contamination from the local site environment identified and assessed?			
b	Are measures taken to protect against potential sources of contamination?			
c	Is vegetation tended, removed or otherwise managed?			
7.1.2	**Layout and workspace**			

		Yes	No	Remark
a	Are production areas designed, constructed and maintained to prevent and control feed safety hazards?			
b	Are testing areas and laboratories designed and operated to prevent contamination?			
c	Does the layout permit adequate cleaning and/or disinfection?			
7.1.3	Internal structures and fittings			
a	Are structural materials cleanable and resistant to the cleaning system applied?			
b	Is standing water prevented and/or removed?			
c	Are openings properly managed?			
d	Are ceilings and overhead fixtures designed to prevent hazards?			
e	Are ventilation systems and devices adequate to prevent hazards?			
7.2	Equipment			
a	Is equipment designed and located to permit access for operation, cleaning and maintenance?			
7.3	Storage			
a	Is a storage management system in place?			
b	Are control measures adequate and documented for storage activities?			
c	Are storage conditions appropriate for the intended use of the material?			
d	Is a defective or customer returned products area identified?			
e	Is the dispatch area secured from material theft, uncontrolled access and contamination?			
7.4	Utilities			
7.4.1	Water supply			
a	Does water supply comply with specified water quality and safety requirements?			
7.4.2	Ventilation			
a	Are production and storage areas well ventilated?			
7.4.3	Compressed air and other gases			
a	Do air and gases come into direct contact with feed suitable for use?			
b	Are compressor oils of appropriate technical grade (e.g. food)?			
7.4.4	Lighting			
a	Is lighting of sufficient intensity to ensure optimum cleaning?			
b	Are light fixtures designed to prevent contamination? Are lights shatterproof?			

		Yes	No	Remark
c	Is a glass/brittle registry in place?			
7.5	**Waste disposal**			
7.5.1	**Waste control**			
a	Are waste containers clearly marked?			
b	Are waste containers located in designated area?			
c	Are removal frequencies managed?			
d	Are materials such as veterinary drugs or contaminants disposed of in an appropriate way?			
7.5.2	**Drains and drainage**			
a	Are drains designed and maintained to prevent contamination?			
7.6	**Equipment suitability**			
7.6.1	**Measuring devices**			
a	Are measuring and dosing devices identified?			
b	Is monitoring and measurement carried out in a manner consistent with documented procedures?			
c	Is there a formal calibration system in place?			
d	In case of external calibration, is the laboratory accredited against ISO/IEC 17025 or equivalent?			
e	In case of internal calibration, are reference materials certified?			
7.6.2	**Maintenance**			
a	Is there a documented preventive maintenance programme in place?			
b	Are maintenance activities recorded?			
c	Is there a procedure for the release of equipment under maintenance?			
7.7	**Measures for prevention of cross-contamination**			
a	Is there a programme in place to prevent, control and detect potential cross-contamination?			
b	Are risk assessments available to support procedures?			
c	Is the effectiveness of procedures verified and documented?			
7.8	**Cleaning**			
a	Is there a documented cleaning and sanitising programme in place?			
Does the programme specify:				
b	areas, items of equipment and tools?			
c	training of cleaning staff?			
d	responsibilities?			

		Yes	No	Remark
e	cleaning/sanitising agents?			
f	method and frequency?			
g	monitoring and verification?			
h	Are cleaning records filled in and verified?			
7.9	Pest control			
a	Is there a documented preventive pest control system in place?			
Is the preventive pest control programme:				
b	maintained under the Operator's control?			
c	Does it take into account periodic reviews including physical inspections and frequency determined by risk assessment?			
d	clearly defined and does it reflect the activities of the site?			
e	reviewed for effectiveness?			
f	Does it assure the qualification of the external pest controller?			
g	Does the hazard analysis consider the risk due to infestation and use of pesticides?			
h	Are the results of the pest control regularly reviewed and actions taken?			
i	Is a map of pest control devices maintained?			
j	Is staff trained for application of pesticide?			
k	Are records of pesticide use kept?			
7.10	Personnel hygiene			
a	Are requirements for personal hygiene and behaviour established and documented?			
b	Are visitors and subcontractors informed about hygiene and health requirements?			
7.10.1	Personal behaviour and cleanliness			
Does the documented procedure cover:				
a	permissibility of eating, drinking, gum chewing and tobacco use in designated areas?			
b	control measures to avoid hazards by personal belongings such as jewellery?			
c	staff hygiene, sanitary facilities and toilets maintenance?			
d	the availability of separate lockers?			
e	instructions on unacceptable behaviour such as sneezing or coughing?			
7.10.2	Clothing and protective equipment			
a	Is appropriate workwear provided to staff?			

		Yes	No	Remark
b	Is clothing maintained in hygienic conditions?			
c	Is a dress code defined for visitors and subcontractors?			
7.10.3	Health status			
a	Is a written procedure regarding medical care available?			
7.11	Transport			
a	Is transport certified against FAMI-QS Recognised Standards (P-MS-003)?			
If not certified against FAMI-QS Recognised Standards, are the following requirements applied:				
b	Are agreements with transporters documented?			
c	Are requirements communicated to the transporters?			
d	Are transporters controlled and evaluated?			
e	In case transport is arranged by the buyer, are the requirements in the code applied?			
f	Is the transport company documenting and maintaining evidence of education and training of driving personnel?			
g	Are procedures in place to ensure product integrity during transport?			
h	Does the transport company ensure that containers are fit for use?			
i	Are there documented records of cleaning of feed contact containers?			
j	Are deliveries traceable including previous load information, container identification and cleaning operations?			
7.12	Feed packaging information and customer communication			
a	Is the intended use and content communicated to customers?			
b	Are there procedures in place detailing the correct labelling of products?			
c	Is the label fulfilling the legal requirements of the country of the destination?			
7.13	Competence and training			
a	Is the competency of the staff involved in feed safety and quality determined?			
b	Is the staff trained in feed safety and quality?			
c	Is there documented information of competence?			
7.14	Awareness			
a	Is the staff aware of the contribution to the effectiveness of the Feed Safety and Quality Management System?			
b	Is the staff aware of the implications of not conforming to the Feed Safety and Quality Management System requirements?			

		Yes	No	Remark
7.15	Communication			
a	Are internal and external communication points established?			
7.16	Complaint handling system			
a	Does a formal customer complaint handling system exist?			
Does the complaint handling system:				
b	allocate responsibility for controlling and adequate follow up?			
c	allow tracking of each complaint?			
d	record customer name, product name and identification code?			
e	record reason of complaint?			
f	identify if other customers are affected?			
g	Are corrective actions carried out in a timely and effective manner?			
h	Are complaint topics used to avoid recurrence and implement ongoing improvement?			
7.16.1	Feed Safety Incident Communication (Crisis Management)			
a	Is the crisis management procedure documented?			
b	Does it meet the requirements of the FAMI-QS Feed Safety Incident Procedure (P-CM-001)?			
c	Are responsibilities defined for notifying customers and regulatory authorities?			
d	Are responsibilities defined for conducting a product recall within the operation?			
e	Are tests of Feed Safety Incident Communication conducted at regular intervals?			
7.16.2	Recall procedures			
a	Does a documented recall programme exist?			
b	Are responsibilities assigned?			
c	Are recalls documented?			
d	Are effective corrective and preventive actions implemented?			
e	Is the recall programme evaluated at least annually?			
f	Is the test recall documented?			
g	Are the outcomes of the test recalls evaluated?			
8.	Operation			
8.1	Operation planning and control			
a	Are there adequate actions in place to ensure effective planning, implementation and control of the processes?			
b	Is there a method to ensure establishment of criteria for the processes?			

		Yes	No	Remark
c	Is there a method to ensure implementation of control of processes according to the criteria?			
d	Is there a method to ensure retention of documented information to show process effectiveness?			
e	Are the consequences of unintended changes reviewed and actions taken to mitigate any adverse effects?			
8.2	Determination of requirements for products			
a	Is there a process in place to determine the statutory and regulatory requirements?			
b	Is there a process in place to determine the requirements specified by the customer including delivery and post-delivery?			
c	Is there a process in place to determine the requirements not stated by the customer but necessary for specified and intended use?			
d	Is there a process for communication of information with customers?			
e	Is there a process in place to review requirements prior to Operator's commitment to supply products?			
8.3	Design and development			
a	Is evidence available that the organisation plans and controls the design and development of products and services, considering the nature, duration and complexity of the design activities?			
8.3.1	Design and development planning			
Is the following determined during design and development planning:				
a	the nature, duration and complexity of the design and development activities?			
b	the requirements that specify particular process stages, including reviews?			
c	the required design and development verification and validation?			
d	the responsibilities and authorities involved?			
e	the need to control interfaces between individuals and parties?			
f	the need for involvement of customer and user groups?			
g	Is documented information maintained to demonstrate that the design and development requirements have been met?			
8.3.2	Design and development inputs			
Are inputs relating to product requirements determined and documented information maintained relating to:				
a	requirements essential for the specific type of products and services, including functional and performance requirements?			
b	applicable statutory and regulatory requirements?			

		Yes	No	Remark
c	standards and codes of practice?			
d	internal and external resources?			
e	the potential consequences of failure?			
f	the level of control expected by customers and other interested parties?			
g	the potential consequences of failure?			
h	the potential consequences of failure?			
i	Is there evidence available to indicate that inputs are reviewed for adequacy?			
j	Is there evidence available to indicate that requirements are complete and unambiguous?			
8.3.3	Design and development controls			
Are there controls in place to ensure:				
a	the results to be achieved are clearly defined?			
b	reviews are conducted as planned?			
c	verification activities that input requirements are met?			
d	validation is conducted to ensure that resulting products are capable of meeting the requirements for the specified intended use?			
8.3.4	Design and development outputs			
Are there controls in place to ensure:				
a	input requirements have been met?			
b	outputs are adequate for the subsequent processes for the provision of products and services?			
c	identification of monitoring and measuring requirements, and acceptable criteria?			
d	designed products are fit for intended purpose and their safe and proper use?			
e	Is documented information maintained from the design and development process?			
8.4	Change control			
a	Are changes in the development process reviewed, controlled and approved before implementation?			
b	Is documented information on results of changes and any necessary actions maintained?			
8.5	Control of externally provided products and services			
a	Are external production and service operations carried out under controlled supervision?			

		Yes	No	Remark
b	Is documented communication on applicable requirements available?			
c	Are documented criteria established for the evaluation, selection and monitoring of performance of external providers?			
d	Is documented evaluation and results available?			
8.5.1	Type and extent of control of external provision – Contract Manufacturers			
a	If the Operator is not competent to carry out the process and choose to outsource it, are there adequate controls in place?			
b	In case the contract manufacturer is not FAMI-QS certified or certified by any other recognised standard (P-MS-003), has the Operator evaluated the risks and performed an audit?			
c	Is the audit report available?			
d	Does the audit report content meet the requirements of the FAMI-QS Code?			
e	Is the auditor sufficiently trained (knowledge of FAMI-QS Code, auditing techniques, and the scope of external provider)?			
8.6	Purchased materials			
8.6.1	Selection and management of suppliers			
a	Is there a documented process for the selection, approval and monitoring of suppliers?			
b	Is origin, transport, storage, processing and handling included in the selection and approval process?			
c	Is an approved supplier list maintained including status as assured and non-assured sources?			
d	Are the assured and non-assured sources compliant with FAMI-QS Recognised Standards (P-MS-003)?			
e	Are suppliers subject to periodical review at intervals based on risk assessment?			
Are the following documented for each raw material:				
f	specification?			
g	product description?			
h	method of production?			
i	analytical characteristics?			
j	undesirable substances?			
k	evaluation of supplier?			
l	process to qualify supplier in emergency situation?			
m	Is a documented audit programme available for non-assured sources?			
n	Are all non-assured sources audited against the FAMI-QS requirements?			

		Yes	No	Remark
8.6.2	Verification of incoming materials			
a	Is each batch registered by means of a batch number, full name of product, date of receipt, quantity received and expiry date?			
b	Are written procedures available for checking and approving incoming materials?			
c	Are retention samples taken and stored?			
d	In case of rejection due to non-compliance, is there documented evidence of disposal, destination and return to supplier?			
8.7	HACCP Programme			
a	Is the applicable FAMI-QS Process document(s) being followed?			
b	Is a HACCP programme established, implemented and maintained?			
Is there documented information on:				
c	each identified CCP?			
d	feed safety hazards controlled at CCP?			
e	control measures?			
f	monitoring procedure?			
g	corrective actions to be taken if critical limits are exceeded?			
h	list of responsibilities?			
i	records of monitoring?			
j	following process changes or updates to feed safety hazards?			
k	Is the HACCP programme re-evaluated at least every 3 years?			
8.7.1	Determination of critical limits for critical control points and monitoring			
a	Are critical limits established in a way to ensure that the identifiable acceptable level of feed safety hazards is not exceeded?			
b	Are critical limits measurable and able to demonstrate rationale by scientific or documented information?			
Are procedures, instructions and records available for:				
c	measurements and observations?			
d	monitoring devices?			
e	calibration methods?			
f	monitoring frequency?			
g	monitoring results?			
h	responsibilities?			
i	Is training given to responsible persons?			

		Yes	No	Remark
j	Is the monitoring procedure able to determine when critical limits have been exceeded in time for the product to be isolated, before it is used or consumed?			
8.7.2	HACCP team leader			
a	Is a HACCP team leader appointed?			
b	Is there documented information on training to HACCP team members?			
c	Is there documented information on reporting to top management?			
8.8	Control of Production			
Is there evidence of controlled conditions for:				
a	availability of information that describes the characteristics of the finished product?			
b	a written specification?			
c	a unique name or code for each product?			
d	details of packaging and labelling?			
e	traceability of each product unit?			
f	production carried out according to written procedures?			
g	inspection of all finished products?			
h	retention sample for the minimum shelf life of product?			
8.8.1	Identification and traceability			
a	Are process outputs identified by suitable means through product realisation?			
b	Is documentation information retained to maintain traceability?			
c	Is the traceability system verifiable and monitored?			
8.8.2	Preservation of product			
Are production preservation methods established for:				
a	production?			
b	identification?			
c	handling?			
d	packaging?			
e	storage?			
f	protection?			
8.8.3	Post-delivery activities			
a	Does the Operator meet the requirements for post-delivery activities?			
Are the following taken under consideration:				

		Yes	No	Remark
b	risks associated?			
c	nature, use and intended lifetime of product?			
d	customer feedback?			
e	statutory and regulatory requirements?			
f	storage?			
8.8.4	Release of products			
a	Are there planned arrangements in place to ensure achievement of the product requirements?			
b	Is documented information maintained as evidence of conformity with the acceptable criteria?			
c	Are there controls in place to ensure that release of the product to the customer does not proceed until all planned arrangements are satisfactorily completed?			
d	Is there documented information identifying the person authorising the release?			
8.8.5	Control of nonconforming process outputs and products			
a	Are process outputs and products that do not conform to the requirements, identified and controlled to prevent unintended use or delivery?			
b	Is there a documented procedure for dealing with products which do not comply?			
Does the procedure include:				
c	identification of product and batch code?			
d	documentation of any nonconformity, corrective action and verification step?			
e	evaluation of cause of non-conformity?			
f	segregation of affected batch?			
g	provision for disposal, reprocess or rework?			
h	verification of conformity to the requirements after correction?			
i	informing the customer and obtaining authorisation for release?			
j	Is responsibility for review and disposal of the nonconforming product defined?			
k	Is documented information of actions taken on nonconforming process outputs and products maintained?			
8.8.5.1	Rework			
a	Is rework considered within the HACCP programme?			
b	Does rework management include criteria and conditions for acceptance, storage, identification, traceability and processing?			
9	Performance evaluation			

		Yes	No	Remark
9.1	Monitoring			
Has the Operator determined:				
a	what needs to be monitored and measured?			
b	the methods for monitoring, measurement, analysis, evaluation and verification?			
c	when the monitoring and measuring must be performed?			
d	when the results must be analysed?			
e	Is documented information retained as evidence of the results?			
9.2	Internal audit			
a	Are internal audits conducted at planned intervals?			
Does the internal audit activity determine whether the Feed Safety and Quality Management System:				
b	conforms to the Operator's own requirements?			
c	conforms to the FAMI-QS Code requirements?			
d	conforms to regulatory and other defined requirements?			
e	is effectively implemented and maintained?			
Does the Operator have a documented audit programme that includes:				
f	frequency?			
g	methods?			
h	responsibilities?			
i	planning requirements?			
j	scope & criteria?			
k	reporting?			
l	Are auditors trained and competent to conduct audits?			
m	Is evidence available to confirm that internal auditors do not audit their own work?			
n	Are corrective actions scheduled and verified?			
o	Is documented information retained as evidence of implementation of audit programme and audit results?			
9.3	Management review			
a	Does top management review the Feed Safety and Quality Management System at planned intervals to ensure its continuing suitability, adequacy and effectiveness?			
b	Are records of the review maintained?			
Does the review take into consideration:				
c	the status of actions from previous management reviews?			
d	changes in external and internal risks?			

		Yes	No	Remark
e	the need to update or change the Feed Safety and Quality Management System?			
f	recalls?			
g	nonconformities?			
h	customer complaints?			
i	corrective actions?			
j	monitoring and measurements results?			
k	audit results?			
l	opportunities for continual improvement?			
m	the need to update the Feed Safety and Quality Policy?			
n	Do the results of the management review include decision and actions related to continuing improvement opportunities and any need for changes to the Feed Safety and Quality Management System?			
o	Are decisions needed to change any aspects of the Feed Safety and Quality Management System communicated to key staff?			
p	Is documented information retained as evidence of results of management reviews?			
10.	**Improvement**			
10.1	**Nonconformity and corrective action**			
In the presence of nonconformity, does the Operator:				
a	react to the nonconformity?			
b	evaluate the need for action to eliminate the cause?			
c	implement any action needed?			
d	document any actions?			
e	communicate the solution?			
f	review the effectiveness of the corrective action?			
10.2	**Continuing improvement**			
a	Is the organisation continuously improving the suitability, adequacy and effectiveness of the Feed Safety and Quality Management System?			
b	Is there documented evidence of continuing improvement activities?			