



RULES FOR CERTIFICATION BODIES

VERSION 8 / REV.3 – 2018-10-12



The Quality and Safety System
for Specialty Feed Ingredients

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I 1. SCOPE

This document defines the rules applicable for the audit of a Feed Safety and Quality Management System compliant with the requirements given in the FAMI-QS Code. It also provides the necessary information and confidence to customers about the way certification of their suppliers is granted.

Certification of Feed Safety and Quality Management System is a third-party conformity assessment activity (as described in ISO/IEC 17000:2004, 5.5), and bodies performing this activity are third-party Certification Bodies (CBs).

FAMI-QS Certification is a Feed Safety and Quality Management System certification (including Good Manufacturing Practices) for the sector of Specialty Feed Ingredients.

The requirements for FAMI-QS Authorised Certification Bodies can be used as a criteria document for the accreditation or peer assessment of Certification Bodies, which seek to be recognized as competent to certify that a Feed Safety and Quality Management System complies with the FAMI-QS Code.

Feed Safety and Quality Management System certification against FAMI-QS Code attests that the production process is taken place under hygiene conditions, in order to minimize and possibly eliminate the risks pertaining to the Feed/Food Chain. FAMI-QS requires an Operator to meet all applicable feed-safety-related statutory and regulatory requirements through its management system, both in the country of production and in the country of destination.

Certification of a Feed Safety and Quality Management System according to FAMI-QS Code is a management system certification, not a product certification.

2. ASSESSMENT AND RECOGNITION OF A CERTIFICATION BODY

2.1. Required documents

Certification Bodies that wish to obtain a licence to carry out FAMI-QS certification shall apply to the FAMI-QS SPRL Secretariat, providing details for eligibility according to the established selection criteria.

CBs shall be accredited against ISO/IEC 17021-1:2015 and ISO/TS 22003:2013 prior to the submission of their application to FAMI-QS. CB can be a non-governmental or a governmental body, with or without regulatory authority.

The application form is available on the FAMI-QS website (<http://www.fami-qs.org/certificationbodies> under application form for CBs).

In order to apply, the Certification Bodies shall submit the documentation outlined below:

- **Accreditation Certificates** ISO /IEC 17021-1:2015 and ISO/TS22003:2013;
- **Copy of the application** to any IAF signatory Accreditation Body to include FAMI-QS under their current accreditation for management system certification;
- **Proof of working** in the feed sector (reference documents showing experience in feed);
- **Marketing plan** for the development of FAMI-QS Certification within their organisation.

The Certification Bodies shall not have undertaken any consultancy and/or training activities within the company to be audited, over a period of two years prior to the audit and shall be able to demonstrate this impartiality.

Key activities like:

- **Maintenance** of the Quality System;
- **Development** of certification procedure for FAMI-QS;
- **Training** and qualification of staff;
- **Contract review** and planning of certification activities;
- **Assignment** of audit teams;
- **Certification** decisions;
- **Issuance** of the certificate

can take place in one or in several locations, but need to be under the supervision of the FAMI-QS Scheme Manager.

2.2. Approval Process

After sending the application form, the duration of the approval process may vary depending on the readiness of the Certification Body. Following the initial approval of the application by FAMI-QS, the Certification Body shall apply for FAMI-QS Accreditation to its Accreditation Body (AB). Accreditation Body shall be IAF MLA Signatory Management system certification - ISO/IEC 17021-1.

Step 1 Evaluation of the documents (see point 2.1).

Step 2 Feedback by FAMI-QS based on the submitted documents.

Step 3 Office Assessment: FAMI-QS will conduct an office assessment prior to the final approval. The costs of the office assessment (travel, auditors' man-day etc.) will be shared between FAMI-QS and the Certification Body.

Step 4 Submission of an application to an approved AB.

Step 5 Auditors' Training: FAMI-QS approved trainer will deliver a training to the potential FAMI-QS auditors recommended by the Certification Body.

Step 6 Approval: The Certification Body has completed the accreditation process and is allowed to issue accredited FAMI-QS certificates. In the event that all the above steps are completed and the accreditation process is finalised at a later stage, FAMI-QS can grant a temporary approval for a maximum of three years without accreditation.

All information obtained before, during or after assessment, including the fact that a particular Certification Body has applied for recognition, or that an application has been deferred or rejected, will be treated as highly confidential by FAMI-QS.

2.3. Fees

See section <http://fami-qs.org/certification-bodies.html> on FAMI-QS website.

3. TERMS AND DEFINITIONS

For the purpose of this document, the terms and definitions given in FAMI-QS Code, ISO/IEC 17000, ISO/IEC 17021-1:2015 and ISO/TS 22003:2013 shall apply.

4. PRINCIPLES

The principles of ISO/IEC 17021-1:2015, Clause 4, are the basis for the subsequent specific performance and descriptive requirements for FAMI-QS Authorised Certification Bodies.

I 5. GENERAL REQUIREMENTS

5.1. Legal and contractual matters

5.1.1. LEGAL RESPONSIBILITY

The requirements of ISO/IEC 17021-1:2015 § 5.1.1 are applied.

5.1.2. CERTIFICATION AGREEMENT

The requirements of ISO/IEC 17021-1:2015 clause 5.1.2 are applied. The certification agreement shall also include: the presence of the Accreditation Assessor and the FAMI-QS Integrity Auditor, the requirements for Crisis Management and the conditions for the provision of the unannounced audits.

5.1.3. RESPONSIBILITY FOR CERTIFICATION DECISIONS

The requirements of ISO/IEC 17021-1:2015 § 5.1.3 shall apply.

5.2. Management of impartiality

The requirements of ISO/IEC 17021-1:2015 § 5.2 shall apply.

Consultancy shall not be provided by either the Certification Body or any part of the same legal entity. Certification Body shall collect information related to the provider (name of the organisation and name of the individual consultant) of the consultancy services to their client. This information shall be documented and available upon request of FAMI-QS or an AB.

Certification Bodies are allowed to assign the same auditor to the same Operator, only for three (3) consecutive years. After this period, the auditor can only perform an audit again to that Operator when a three (3) years' break take place.

An exception to the above mentioned can be given, in case the auditor is part of an audit team and this is well justified. An impartiality assessment shall be performed prior to the release of the auditor in question. This impartiality assessment shall be per audit and a confirmation of the Impartiality Committee is required.

I 6. STRUCTURAL REQUIREMENTS

The requirements of ISO/IEC 17021-1:2015 § 6, apply.

I 7. RESOURCE REQUIREMENTS

7.1. Competence of personnel

7.1.1. GENERAL CONSIDERATIONS

The requirements of ISO/IEC 17021-1:2015 § 7.1.1 shall apply.

The Certification Bodies shall have sufficient, competent personnel for managing and supporting the provision of the FAMI-QS certification services.

7.1.2. DETERMINATION OF COMPETENCE CRITERIA

The requirements of ISO/IEC 17021-1:2015, § 7.1.2, shall apply.

The Certification Body shall have processes in place to ensure that personnel have appropriate knowledge and skills relevant to the FAMI-QS Certification. The Certification Bodies shall take into consideration the geographic areas in which they operate.

The competence criteria included on the Table I below shall form the basis for the criteria developed for each category. IAF MD 20 Generic Competence for AB Assessors: Application to ISO/IEC 17011, could be also used as a form of guidance to complement the competence requirements per function.

Table I: Competence requirements per function. (next page)

TABLE 1 : COMPETENCE REQUIREMENTS PER FUNCTION.

COMPETENCE (KNOWLEDGE AND SKILLS)	FUNCTIONS				
	Application Review	Audit Team Selection	Audit planning activities	Auditing Activities	Certification Decision
Ability to understand the content of FAMI-QS Approval Letter	X	X		X	
Ability to apply the application review requirements of ISO/IEC 17021 and those of FAMI-QS requirements for CBs and CB procedures, including: - Integrated Management System Audits according to IAF MD 11:2013 - FAMI-QS audit duration requirements and their application;	X	X	X	X	X
Ability to understand the impartiality assessment		X	X		
Ability to identify the below, in relevance to the FAMI-QS Process: - PRP; - feed safety hazards; - legal requirements;	X		X	X	X
Ability to determine if there are: - specific cultural and social customs related to the production process and geographic areas to be assessed; - specific factors required to audit the FAMI-QS Code.	X	X	X	X	X
Ability to identify the competence required for the audit team, in accordance with this table and the Certification Body's procedures.		X			
Ability to understand the content of FAMI-QS Approval Letter	X	X		X	X
Ability to apply the application review requirements of ISO/IEC 17021 and those of FAMI-QS requirements for CBs and CB procedures, including: - Integrated Management System Audits according to IAF MD 11:2013 - FAMI-QS audit duration requirements and their application;	X	X	X	X	X
Ability to develop an audit plan that ensures: - that the audit team members audit the processes that they are technically competent to audit; - that the audit time is optimized; - that the specific FAMI-QS requirements are met			X	X	
Ability to identify: - microbiological hazards; - chemical hazards; - physical hazards; - feed safety labelling requirements; - feed safety regulations that are relevant to the FAMI-QS scope Ability to evaluate the organisation's capacity to identify and meet applicable (country of production/country of destination) feed safety regulations.				X	
Knowledge of the sector of activity (by type of process) and the associated risks in relation to the place of the Operator in the food chain				X	X

Examples of personal behaviours that are important for the personnel involved in FAMI-QS certification activities are described below:

- a.** Ethical, i.e. fair, truthful, sincere, honest and discreet;
- b.** Open-minded, i.e. willing to consider alternative ideas or points of view;
- c.** Diplomatic, i.e. tactful in dealing with people;
- d.** Collaborative, i.e. effectively interacting with others;
- e.** Observant, i.e. actively aware of physical surroundings and activities;
- f.** Perceptive, i.e. instinctively aware of and able to understand situations;
- g.** Versatile, i.e. adjusts readily to different situations;
- h.** Tenacious, i.e. persistent and focused on achieving objectives;
- i.** Decisive, i.e. reaches timely conclusions based on logical reasoning and analysis;
- j.** Self-reliant, i.e. acts and functions independently;
- k.** Professional, i.e. exhibiting a courteous, conscientious and generally business-like demeanour in
- l.** The workplace;
- m.** Morally courageous, i.e. willing to act responsibly and ethically even though these actions may not
- n.** Always be popular and may sometimes result in disagreement or confrontation;
- o.** Organised, i.e. exhibiting sound time management, prioritization, planning, and efficiency.

Determination of behaviour is situational and weaknesses may only become apparent in a specific context. The Certification Body should take appropriate action for any identified weakness that could adversely affect the certification activity.

Note: Qualification(s) and experience can be used as part of the criteria; however, competence is not based on these alone, as it is important to ensure that a person can demonstrate the ability to apply the specific knowledge and skills that one would expect a person to have after completing a qualification or having a certain amount of industry experience.

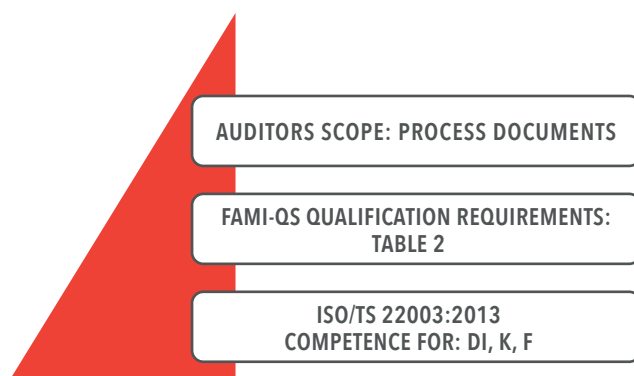
7.1.3. EVALUATION PROCESSES

The requirements of ISO/IEC 17021-1:2015, §7.1.3 shall apply.

7.1.4. OTHER CONSIDERATIONS

The requirements of ISO/IEC 17021-1:2015, § 7.1.4 shall apply.

FIGURE 1: SUMMARY OF THE COMPETENCE REQUIREMENTS.



7.2. Personnel involved in the certification activities

The requirements of ISO/IEC 17021-1:2015, § 7.2 shall apply.

The Certification Bodies shall have, within their operations, a sufficient number of auditors, including audit team leaders, and technical experts to cover all of its activities related to FAMI-QS and to handle the volume of audit.

7.2.1. APPROVAL OF THE AUDITORS

The final approval of the FAMI-QS Auditors will be done for the following scopes: Bioprocess, Chemical, Extraction, Formulation, Mining and Mixing. The validity of the approval will be four (4) years.

Step 1 Define competence requirements as defined in Table 1. The competence shall be defined for the following Feed Chain Categories/ Subcategories: DI, K and F. Competence requirements are maintained at the level of the Chain Categories/ Subcategories and not for each approved scope.

Step 2 Auditor shall meet the qualification requirements defined on the Table 2.

Step 3 Auditor shall demonstrate knowledge on one or more FAMI-QS Process Documents (Bioprocess, Chemical, Extraction, Formulation, Mining and Mixing).

Step 4 Auditor shall attend a FAMI-QS training, organised by FAMI-QS or provided internally by the CB (based on the FAMI-QS Training).

Step 5 CB will arrange a monitoring on-site audit prior to the approval of the auditor. The monitoring can be performed in a relevant feed standard which covers one of the FAMI-QS Processes.

Step 6 CB notifies FAMI-QS Secretariat for the approval of an auditor. The notification shall contain the following:

- Full Name;
- E-mail address;
- Country where the auditor is based;
- Scopes (Bioprocess, Chemical, Extraction, Formulation, Mining and Mixing).

Step 7 FAMI-QS Secretariat, in return, will confirm the registration of the auditor and inform the CB regarding the registration number and validity period via a confirmation e-mail for the registration of the auditor.

TABLE 2 : QUALIFICATION REQUIREMENTS.

PARAMETER	AUDITOR	LEAD AUDITOR
Education	Post-secondary education (e.g. biology, chemistry, food engineering, pharmacy, agricultural engineering, nutritionist, zootechnology).	Same as auditor
Knowledge	Food/feed microbiology, food safety, chemistry, animal nutrition, animal production, animal health, Feed GMP, Feed and Food HACCP.	Same as auditor
Total work experience in Management Systems	4 years	Same as auditor
Work experience in Feed/Food Safety Management Systems	At least 2 years of the total 4 years.	Same as auditor
Feed safety training	HACCP principles, hazard assessment, hazard analysis, food/feed safety management principles including PRPs, FAMI-QS Code.	Same as auditor
Auditor's training	Follow the FAMI-QS Auditors' Training.	Same as auditor
Audit experience in Feed/Food Safety Management Systems	Six (6) feed/food SMS Audits in the last 3 years.	3 Complete FeSM Audits
Audit experience per scope	At least one (1) Feed Audit in the scope relevant	-

7.2.1.1. AUDITORS' SCOPES

- **FAM-PD-01:** Bioprocess
- **FAM-PD-02:** Chemical
- **FAM-PD-03:** Extraction
- **FAM-PD-04:** Formulation
- **FAM-PD-05:** Mining
- **FAM-PD-06:** Mixing

7.2.1.2. AUDITORS' SCOPE EXTENSION

In case that a CB would like to extend the auditing FAMI-QS Scope to a currently approved auditor, the auditor shall demonstrate a knowledge in the relevant FAMI-QS Process Document and at least two Feed Audits or one (1) year work experience in the scope relevant to the extension process. The validity of the auditor will remain unchangeable.

7.2.2. MAINTENANCE OF THE AUDITORS' NOMINATIONS

For the maintenance of the auditors' nomination the following conditions shall be applied:

- a. Attend the annual training organised by FAMI-QS (train the trainer option possible).
- b. Maintenance of the scope: 2 FAMI-QS Audits in each approved process within the validity period.
- c. The Certification Body shall monitor each FAMI-QS auditor. The documented monitoring process for auditors shall include a combination of on-site evaluation, review of audit reports and feedback from clients or from the market. Each FAMI-QS Auditor shall undergo at least one monitoring during his/her validity period.

If no audit experience can be shown for a period of four (4) years per scope, action shall be taken for the scope reduction of an auditor.

The maintenance of the auditor's nomination is a responsibility of the Certification Body.

7.3. Use of individual external auditors and external technical advisors

The requirements of ISO/IEC 17021-1:2015, § 7.3 shall apply.

7.4. Personnel records

The requirements of ISO/IEC 17021-1:2015, § 7.4 shall apply.

7.5. Outsourcing

The requirements of ISO/IEC 17021-1:2015, § 7.5 shall apply.

I 8. INFORMATION REQUIREMENTS

8.1. Public Information

The requirements of ISO/IEC 17021-1:2015, § 8.1, shall apply.

8.2. Certification Documents

The requirements of ISO/IEC 17021-1:2015, § 8.2, shall apply.

8.3. Certificate

8.3.1. TEXT ON THE CERTIFICATE

Text on the certificate (minimum information):

<p>OPERATOR'S NAME</p> <p>has implemented and maintains a Feed Safety and Quality Management System including Good Manufacturing Practice (GMP) in compliance with:</p> <p>FAMI-QS CODE (VERSION X, YYYY-MM-DD), ON THE FOLLOWING SITE/S⁽¹⁾ XXX</p> <p>FAMI-QS SITE REGISTRATION: FAM-XXXX/XX</p> <p>FOR ACTIVITY⁽²⁾ OF SPECIALTY FEED INGREDIENTS FROM PROCESS⁽³⁾</p> <p>FEED CHAIN CATEGORY⁽⁴⁾ DI, K, FI, FII</p> <p>THE OPERATOR IMPLEMENTS MEASURES FOR FEED FRAUD / FEED DEFENSE ACCORDING TO THE FAMI-QS SUPPLY CHAIN INTEGRITY MODULE V XX</p> <p>THIS CERTIFICATE IS VALID UNTIL: YYYY-MM-DD</p> <p>Signature of the Certification Body: _____</p> <p style="text-align: right;">PLACE, DATE YYYY-MM-DD</p> <p style="text-align: center;">For the validity of this certificate please check www.FAMI-QS.org</p>

⁽¹⁾ For Operators running multiple manufacturing processes at different sites it is sufficient to issue one certificate listing all the sites.

⁽²⁾ Activity means: **Production** and/ or **Trading**. The term placing on the market may also be used but the activity production or trade shall be specified, e.g. placing on the market (trade and/ or production). Any other term like design and development, warehousing, transportation is not allowed.

- **Placing on the market (TRADE)** – Applicable for traders who place specialty feed ingredients on the market purchased from suppliers certified with one of the mutually recognized standards (see document P-MS-003).

- **Placing on the market (PRODUCTION)** – Applicable for Operators who place specialty feed ingredients on the market purchased as feed from suppliers that are not certified with one of the mutual recognized standards and for food grade specialty feed ingredients, food ingredients and pharma grade specialty feed ingredients. The purchasing has to fulfil the requirements of the FAMI-QS Code. The HACCP plan at the level of the trading office shall consider all the hazards related to the production (level of the producer).

- Traders that place on the market products under their own label are considered producers. In case the subcontractor is not certified against one of the standards with which the FAMI-QS maintains mutual recognition arrangements, the CB shall consider to audit the contracted manufacturer, at least once within the certification cycle. *NOTE: In this case, the activity is production but the feed chain category is FI (see categories below in (4)).*

Example 1: If a trader does repackaging for FAMI-QS, this is considered production since the trader shall manage additional risk/ hazards.

Example 2: In case the Operator has a pharma grade ingredient and want to sell as feed grade ingredient, this is also considered as production activity. Here, the Operator shall ensure that the pharma grade ingredient is compliant with the feed grade requirements.

These activities are not traditional production activities, but the auditor shall approach them as production. From the perspective of ISO/TS 22003:2013 these activities fall under Scope F.

⁽³⁾ Production Process: The Certification Body shall identify and clearly state the process from which the ingredients are resulting from: **Bioprocess – Chemical – Mixing – Formulating – Mining – Extraction**

⁽⁴⁾ Classification of feed chain categories applicable to FAMI-QS (ISO/TS 22003:2013 – Annex A):

- **DI**: for products fed directly to the animal and/or delivered to the farm
- **K**: products not given directly to the animals and/or not sold directly to the farm
- **FI**: when Operators trade their own products
- **FII**: when Operators trade products not produced by themselves

8.3.2. WITHDRAWAL OF CERTIFICATES

The withdrawal of a certificate remains the responsibility of the Certification Body. Once a withdrawal is confirmed, the name of the Operator will be removed from the FAMI-QS “Certified Companies Register” on the website.

Certified companies holding valid certificates are listed on the FAMI-QS website.

A note of a withdrawn certificate will be e-mailed to all FAMI-QS certified companies and also uploaded on our section Notification of the FAMI-QS website.

8.3.3. SUSPENDED CERTIFICATES

The suspension of a certificate remains the responsibility of the Certification Body. CBs shall maintain a register of the suspended certificates. The minimum information that shall be included in the register is:

- a. Name of the company;
- b. Certificate number;
- c. Reason of the suspension;
- d. Suspension period;
- e. Conditions for termination of the suspension.

The CB shall make FAMI-QS immediately aware about the suspension of a certificate. The name of the Operator will be removed from the section certified companies on the FAMI-QS website during the period of the suspension.

A list of suspended FAMI-QS certificates will be maintained on line. Suspension cannot exceed three months. Following that period, a FAMI-QS certified company will be removed from the FAMI-QS website. Initial audit shall be applied if the Operator wishes to restore its FAMI-QS certificate.

8.3.4. EXCLUSIONS ON CERTIFICATES

It is an obligation of the FAMI-QS certified Operators not to mislead stakeholders and authorities regarding the scope of their certification, validity of the certificate and site(s).

8.3.5. INVOICING ADDRESS/ REGISTRATION ADDRESS

The responsibility for placing products on the market relies in the invoicing address. Therefore, this address must be included under the Operator's Certificate

In the event that the invoicing address is a PO box or no activity is taking place at the location, the address can be included on the certificate after a desk review of the legal documents (business registration, registration with the feed authorities, where applicable) performed by the auditor. This is not applicable when the invoicing address is holding responsibilities for warehousing, transportation, etc.

All the traceability and recall procedures are under the responsibility of the invoicing address. In this case, employees of the invoicing address shall be involved in the audit for the relevant parts.

8.3.6. TRANSFER OF ACCREDITED FAMI-QS CERTIFICATES

For the transfer of accredited FAMI-QS certificates, IAF MD2:2017 Mandatory Document for the Transfer of Accredited Certification of Management Systems shall be applied.

The Certification Body responsible for the transfer shall contact FAMI-QS Secretariat prior to the transfer for pre-approval. FAMI-QS Secretariat will communicate any open issues related to the transfer of the certificate (if applicable).

8.4. Reference to certification and use of marks

The requirements of ISO/IEC 17021-1:2015, § 8.3, shall apply.

The Certification Bodies need to confirm that the FAMI-QS logo is used by the certified company according to the FAMI-QS requirements. A statement on the correct use of the FAMI-QS logo shall be included in the audit report's "General Assessment" section.

The FAMI-QS name and logo may only be used by Operators that have obtained certification from a Certification Body recognized by FAMI-QS. The right to use the FAMI-QS logo and/or name is exclusively granted by FAMI-QS and can be withdrawn at any moment in the event of non-compliance with certification requirements.

Certified Operators may display the FAMI-QS logo for the period of validity of their certificate. Use or display of the FAMI-QS logo does not constitute proof that the Operator is certified.

The FAMI-QS logo is available upon request made to the FAMI-QS Secretariat and/or to the relevant CB. It may be used only in its original colours and proportions. Guidelines are displayed on the FAMI-QS Website.

The FAMI-QS name and logo shall not be used on products, packaging, labels, means of transport, but may be used on certificates, advertisements and brochures.

8.5. Confidentiality

The requirements of ISO/IEC 17021-1:2015, § 8.4 shall apply.

8.6. Information exchange between Certification Body and its clients

8.6.1. INFORMATION ON THE CERTIFICATION ACTIVITY AND REQUIREMENTS

The requirements of ISO/IEC 17021-1:2015, § 8.5.1 shall apply.

8.6.2. NOTICE OF CHANGES BY CERTIFICATION BODY

The requirements of ISO/IEC 17021-1:2015, 8.5.2 shall apply.

The Certification Bodies shall have a procedure in place to notify the FAMI-QS certified Operators of the FAMI-QS specific requirements and any changes related to the certification procedure.

8.6.3. NOTICE OF CHANGES BY A CERTIFIED CLIENT

The Certification Bodies shall ensure that the FAMI-QS certified Operator informs the Certification Body and FAMI-QS without delay, of the following changes:

- a.** Legal, commercial, organisational status or ownership;
- b.** Operator and management changes;
- c.** Contact address and sites;
- d.** Changes to the current certified scope;
- e.** Major changes to the management system and processes;
- f.** Issues related to the safety of the product;
- g.** Any other issue which may affect the capability of the Feed Safety and Quality Management System.

For changes regarding a, b, c, d, a revision of the approval letter is required.

I 9. PROCESS REQUIREMENTS

9.1. Pre-Certification Activities

9.1.1. APPLICATION

The requirements of ISO/IEC 17021-1:2015, § 9.1.1 shall apply.
For the application, the following information, in addition to ISO/IEC 17021-1:2015, Clause 9.1.1, is required:

- a. Approval letter from FAMI-QS;
- b. Licence documents appropriate for the operations of the Operator;
- c. List of products coming from the processes covered in the FAMI-QS Scope. If, during the audit, auditors identify products that fall under FAMI-QS scope and are not part of the list, they shall immediately inform the Operator that all products shall be part of the audit.
- d. List of ingredients purchased from non-assured suppliers (processing aids/intermediates are excluded);
- e. Information about production site(s);
- f. Externally provided services (contract manufactures, warehouses);
- g. Audit report from the subcontractor(s) (toll manufacturer(s), supplier(s), if applicable);
- h. Countries where the products are placed.

The CB shall not exclude activities, processes, products or services from the scope of the audit when those activities/processes/products or services can have an impact on the feed safety. These considerations shall be taken into account in the audit programme and audit plan.

9.1.2. APPLICATION REVIEW

The requirements of ISO/IEC 17021-1:2015, § 9.1.2 shall apply.

9.1.3. AUDIT PROGRAMME

The requirements of ISO/IEC 17021-1:2015, § 9.1.3 shall apply.

9.1.4. DETERMINING AUDIT TIME

The requirements of ISO/IEC 17021-1:2015, § 9.1.4, shall apply.
The requirements of Annex B.1 ISO/TS 22003:2013, shall apply.

TABLE 3 : INITIAL AUDITING TIME CALCULATION TABLE.

A	B	C	D	E	F
Basic audit time	Number of additional days for each additional process	Number of audit days in the absence of a relevant certified system.	Additional auditing time dedicated to the auditing of the files for those feed ingredients purchased from non-assured sources.	Number of audit days per number of employees.	For each additional site under the same Feed Safety and Quality Management System, operating a similar manufacturing process.
Scope K, DI 1.5 for one process. Scope F 1.0	0.5	0.25	01-05 ingredients 0.25 06-10 Ingredients 0.5 11-15 ingredients 0.75 More than 15 ingredients 1.00	1 to 19 = 0 20 to 49 = 0.5 50 to 79 = 1.0 80 to 199 = 1.5 200 to 499 = 2.0 500 to 899 = 2,5 900 to 1 299 = 3,0 1 300 to 1 699 = 3,5 1 700 to 2 999 = 4,0 3 000 to 5 000 = 4,5 > 5 000 = 5,0	50% of the minimum on site audit time.

A: Basic audit time: In case of trading scope F, the basic audit time only covers one process from which the total number of final product(s) are derived.

B: Additional auditing time for additional manufacturing processes: For traders of the scope F, the additional time covers the total number of additional processes.

C: In order to avoid duplication where another relevant management system (ISO 9001, GMP+, FSSC 22000, ISO 22000) is in place and when certified by the same Certification Body, column C is not applicable. Auditors shall have full access to the audit reports of those audits.

D: Additional auditing time dedicated to the auditing of the files for those feed ingredients entering the production process and/or trading which are coming from non-assured sources.

E: Additional auditing time according to the number of employees (FTE) under the FAMI-QS System.

F: For each additional site operating under centrally controlled and administrated FAMI-QS System, 50% of the minimum on-site audit time shall be considered: $(A+B+C+D+E)*0.5$

The initial certification auditing time includes the auditing time for Stage 1 and Stage 2 audit. However, it does not include the time for preparation of the audit nor for writing the audit report.

Auditing Time shall be approved by the FAMI-QS Scheme Manager or a competent FAMI-QS employee of the Certification Body. For Certification Bodies with more than one location offering FAMI-QS Certification services, auditing time calculation shall be released by the Certification Body's location/ branch authorised by FAMI-QS. Formal appointment is required. Auditing time calculation shall be recorded and must be traceable. A reduction of maximum of 10% can be given based on the previous experience of the Certification Body with the Operator. For integrated audits: IAF MD II shall be applied for the auditing time reduction.

9.1.5. AUDITING TIME CALCULATION FOR SURVEILLANCE AUDIT AND RE-CERTIFICATION

- a. Surveillance Audit: the total minimum surveillance audit time shall be one-third of the initial certification audit time, with a minimum of eight hours.
- b. Re-Certification Audit: the total minimum time shall be two-thirds of the initial certification audit time, with a minimum of eight hours.

The initial surveillance and re-certification auditing time does not include the time for preparation of the audit nor for writing the audit report.

9.1.6. MULTISITE SAMPLING

The requirements of ISO/IEC 17021-1:2015, § 9.1.5 shall apply.
The requirements of ISO/TS 22003:2013, § 9.1.5.2 shall apply.

9.1.7. MULTIPLE MANAGEMENT SYSTEMS STANDARDS

The requirements of ISO/IEC 17021-1:2015, § 9.1.6, apply. The IAF MD 11:2013 and IAF MD 1:2018 should be considered.

9.2. Planning audits

The requirements of ISO/IEC 17021-1:2015, § 9.2, shall apply.

Traders that place on the market products under their own label, are considered producers. Production in this case is done by a subcontractor. In case the subcontractor is not certified against one of the standards with which FAMI-QS maintains mutual recognition arrangements (see document P-MS-003), the CB shall consider auditing the contracted manufacturer, at least once within the certification cycle.

9.3. Initial certification

9.3.1. INITIAL CERTIFICATION AUDIT

The requirements of ISO/IEC 17021-1:2015, § 9.3.1 shall apply.

9.3.1.1. GENERAL

The initial certification audit of a Feed Safety and Quality Management System shall be conducted in two stages: stage 1 and stage 2.

9.3.1.2. STAGE 1

Planning shall ensure that the objectives of stage 1 can be met and the client shall be informed of any "on site" activities during stage 1. Stage 1 does not require a formal audit plan.

The objective of the stage 1 audit is to provide a focus for planning the stage 2 audit. This shall be achieved by gaining an understanding of the Feed Safety and Quality Management System, in the context of the Operator's feed safety hazard identification, analysis, HACCP plan and PRPs, policy and objectives, and in particular according to the Operator's level of preparation for the audit by reviewing the extent to which:

- a. The Feed Safety and Quality Management System is aligned with the requirements in the FAMI-QS Code.
- b. The Operator has identified PRPs that are appropriate to the business.
- c. Audit report on audits carried out at the supplier premises is available (if applicable).
- d. Audit report on audits carried out at the subcontractors' facilities is available (if applicable).
- e. The Feed Safety and Quality Management System includes adequate processes and methods for the identification and assessment of the Operator's feed safety hazards as well as the subsequent selection and categorization of control measures according to the FAMI-QS code.
- f. The Operator complies with the relevant feed legislation.
- g. The Operator's System collects the relevant statutory and regulatory requirements, related to the production in the country of origin and the placing of the specialty feed ingredients in the country of destination.
- h. The Feed Safety and Quality Management System is designed to achieve the Operator's feed safety policy.
- i. The Feed Safety and Quality Management System implementation programme allows to proceed to stage 2 of the audit.
- j. The validation, verification and improvement programmes are conform to the requirements of the FAMI-QS Code.
- k. The Feed Safety and Quality Management System documentation is in place and its requirements are internally and externally communicated (relevant suppliers, customers, other interested parties, etc.).
- l. Additional documentation that needs to be reviewed /or which knowledge needs to be obtained in advance.
- m. In exceptional circumstances, a part of stage 1 can take place off-site and shall be fully justified. The evidence demonstrating that stage 1 objectives are fully achieved shall be provided. Exceptional circumstances can include very remote location.

In case the client is already certified to a Feed Safety and Quality Management System by the same Certification Body, stage 1 can be skipped.

The interval between stage 1 and stage 2 shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed.

9.3.1.3. STAGE 2

The requirements of ISO/IEC 17021-1:2015, § 9.3.1.3 shall apply.

Any part of the Feed Safety and Quality Management System that is audited during the stage 1 audit and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during the stage 2 audit.

However, the Certification Body shall ensure that the already audited parts of the Feed Safety and Quality Management System continue to conform to the certification requirements.

In this case, the audit report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

9.4. Conducting audits

The requirements of ISO/IEC 17021-1:2015, § 9.4 shall apply.

9.4.1. GENERAL

The requirements of ISO/IEC 17021-1:2015, § 9.4.1 shall apply.

9.4.2. CONDUCTING THE OPENING MEETING

The requirements of ISO/IEC 17021-1:2015, § 9.4.2 shall apply.

9.4.3. COMMUNICATION DURING THE AUDIT

The requirements of ISO/IEC 17021-1:2015, § 9.4.3 shall apply.

9.4.4. OBTAINING AND VERIFYING INFORMATION

The requirements of ISO/IEC 17021-1:2015, § 9.4.4 shall apply.

9.4.5. IDENTIFYING AND RECORDING AUDIT FINDINGS

The requirements of ISO/IEC 17021-1:2015, § 9.4.5 shall apply.

9.4.5.1. CLASSIFICATION OF NON-CONFORMITIES AND RECOMMENDATIONS

a. Major non-conformities

A major non-conformity is a non-conformity that affects the capability of the Feed Safety and Quality Management System to achieve the intended results or a complete failure to implement the requirements of the code.

Non-conformities could be classified as major in the following circumstances:

- if there is a significant documented evidence that there is no effective process control in place, or that products or services do not meet the specified requirements;
- a number of minor nonconformities associated with the same requirement or issues could demonstrate a systematic failure and thus constitute a major nonconformity.

b. Minor non-conformities

A minor non-conformity exists when a requirement of the FAMI-QS Code has been addressed but there is insufficient evidence to demonstrate that it has been properly controlled or implemented, but does not affect the capability of the management system to achieve the intended results. More than 2 or 3 minor non-conformities under the same clause shall be considered as major.

9.4.5.2. CONSEQUENCES OF NON-CONFORMITIES

TABLE 4 : CONSEQUENCES OF NON-CONFORMITIES.

NON-CONFORMITY	INITIAL AUDIT	SURVEILLANCE	RE-CERTIFICATION AUDIT
Major	Certification cannot be granted. Action plan shall be submitted within 7 days after audit. Non-conformities have to be closed within 6 weeks after the audit	The action plan shall be presented to the Certification Body, in 14 calendar days at the latest after the audit date. Evidence that non-conformities have been closed will be checked 28 days after the presentation of the action plan at the latest. In case that the aforementioned time frame is not sufficient, further coordination with FAMI-QS is required. If a non-conformity is not resolved, then the certification is suspended and a special audit shall be applied for the closing of the major NCR.	Certification cannot be granted. Action plan shall be submitted within 7 days after audit. Non-conformities have to be closed within 6 weeks after the audit.
Minor	Certification cannot be granted until the non-conformities have been closed. Action plan shall be submitted within 7 days after audit. Non-conformities have to be closed within 6 weeks after the audit	Certification continues. An agreement on the action plan shall be reached between the Certification Body and the Operator. The deadline for this agreement is 14 calendar days after the Certification Body has received the action plan from the Operator. Evidence that non-conformities have been closed will be checked by the auditor, at the latest during the following audit. If the non-conformity is not solved and closed by then, it becomes a major non-conformity.	Certification continues. An agreement on the action plan shall be reached between the Certification Body and the Operator. The deadline for this agreement is 14 calendar days after the Certification Body has received the action plan from the Operator. Evidence that non-conformities have been closed will be checked by the auditor, at the latest during the following audit. If the non-conformity is not solved and closed by then, it becomes a major non-conformity.

The auditor shall confirm that he/she reviewed, accepted and verified the effectiveness of corrective actions as described in ISO/IEC 17021-1:2015, § 9.4.10.

9.4.6. PREPARING AUDIT CONCLUSIONS

The requirements of ISO/IEC 17021-1:2015, § 9.4.6 shall apply.

9.4.7. CONDUCTING THE CLOSING MEETING

The requirements of ISO/IEC 17021-1:2015, § 9.4.7 shall apply.

9.4.8. AUDIT REPORT

The requirements of ISO/IEC 17021-1:2015, § 9.4.8 shall apply.

In the event that an audit evidence indicates that the audit findings lead to the identification of a non-conformity, this shall be clearly mentioned in the relevant chapter of the audit report. The report shall include a disclaimer statement to indicate that the audit is based on a sampling of the available information and that consequently, there will always be an element of uncertainty present in the auditing evidence, which may be reflected in the audit findings. Those relying or acting upon the audit results and conclusions shall be aware of this uncertainty.

Audit reports provided to Operators in the local language (not English) shall include a statement that a summary report in English and the non-conformities will be sent to FAMI-QS and to the Operator, and that the report will be treated in strictest confidentiality.

9.4.8.1. SUBMISSION OF AUDIT DOCUMENTATION TO FAMI-QS

Audit documentation (including documentation related to unannounced audits) shall be provided exclusively through the FAMI-QS audit documentation platform.

9.5. Certification Decision

The requirements of ISO/IEC 17021-1:2015, 9.5 shall apply.

9.5.1. REQUIREMENTS FOR PERSON OR COMMITTEES THAT MAKE THE CERTIFICATION DECISION

The audit documentation of initial certification, surveillance, re-certification and special audits shall be approved by “competent person(s)” of the CB.

The competent person(s) shall not participate in the audit team. In the case of an initial certification or re-certification audit, the review by the competent person(s) shall be carried out before issuing the certificate.

The competent person shall be able to demonstrate compliance with the same requirements as the FAMI-QS auditor.

The decision maker is not required to have or to maintain audit experience.

9.6. Maintaining certification

9.6.1. GENERAL

The requirements of ISO/IEC 17021-1:2015, § 9.6.1 shall apply.

9.6.2. SURVEILLANCE ACTIVITIES

The requirements of ISO/IEC 17021-1:2015, § 9.6.2.1 shall apply.

9.6.2.1. SURVEILLANCE AUDITS

The requirements of ISO/IEC 17021-1:2015, § 9.6.2.1 shall apply.

Frequency of the surveillance audits:

- a. **1st Surveillance Audit: within 12 months after the Initial Certification Audit.**
- b. **2nd Surveillance Audit: approximately 24 months after the Initial Certification Audit.**

CB shall report to FAMI-QS Secretariat the annual surveillance activities (Company name, site, Auditor(s), audit dates).

9.6.2.2. RECERTIFICATION AUDIT

The requirements of ISO/IEC 17021-1:2011, § 9.6.3.2 shall apply.

A failure to perform the re-certification audit before the expiration of the certificate results in the interruption of the certification cycle. In this case, the wording “certified since” cannot be included on the certificate.

If a re-certification is conducted after the expiry of a certificate, a Stage 1 and Stage 2 Audit shall be carried out.

9.6.3. SPECIAL AUDITS

9.6.3.1. EXTENSION TO THE SCOPE

The requirements of ISO/IEC 17021-1:2015, § 9.6.4.1 shall apply.

In response to an application for the extension of the scope of a certification that has already been granted, the Certification Body shall undertake a review of the application and determine any audit activities that may be deemed necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance or re-certification audit.

9.6.3.2. SHORT-NOTICE AUDITS

The requirements of ISO/IEC 17021-1:2015, § 9.6.4.2, shall apply.

The conditions for the provision of short notice audits shall be agreed between the Certification Body and the FAMI-QS Operator and shall be part of the certification agreement.

It might be necessary for the Certification Body to conduct an audit of a certified Operator at short notice (up to 72 hours' notice), in order to:

- investigate a complaint, or
- in response to a feed safety incident or crisis at the Operator's site or
- as a follow-up on suspended certificate(s).

In such cases:

- a. The Certification Body shall inform the certified Operator(s) in advance and describe the conditions under which this/these short notice visit(s) will be conducted.
- b. The Certification Body shall notify FAMI-QS about the result of the audit.

In case of an incident, the P-CM-001 Feed Incident Management Procedure for Operators and Certification Bodies current version shall be applied.

A short notice audit, could be initiated upon FAMI-QS request. Cost of the audits will be covered by the FAMI-QS Certified Operator.

9.6.3.3. UNANNOUNCED AUDITS

Certification Bodies shall include in their internal audit program for each FAMI-QS Certified Operator, an unannounced audit. The unannounced audits are applicable to both producers and traders. Participation in the unannounced audit program is mandatory.

Frequency: once per certification cycle.

Duration: 0.5 man-days minimum. The unannounced audits can be done by any approved Feed/Food Auditor.

Notification to the FAMI-QS Certified Operator: No notice in advance. Certification Body shall ensure the Operator takes the necessary steps for granting access to the auditor in such events.

| Note: Operators should follow a similar procedure as for the unannounced audits performed by the authorities.

The conditions for the provision of the unannounced audits shall be agreed on between the Certification Body and the FAMI-QS certified Operator and shall be part of the contract. The contract needs to ensure that one unannounced audit is undertaken after the initial certification audit and within each 3-year period thereafter.

Operators shall inform the Certification Body regarding any scheduled maintenance closure of the company.

There are a number of topics that should be covered during an unannounced audit for production and trading activities.

1) Topics covered during an unannounced audit for production activity

The auditor should cover all or a combination of the below areas:

- Monitoring of CCP;
- Inspection of the premises (internal – external);
- Observation if the employees perform their tasks according to the written procedure;
- Crisis Management.

2) Topics covered during an unannounced audit for trading activity

The auditor should cover all or a combination of the below areas:

- Suppliers' evaluation;
- Purchase orders and specs;
- Certificates of analysis (shall be checked per purchase order);
- Traceability;
- Crisis management.

In the event that the certified Operator refuses to participate in the unannounced audit, as defined in the contract between the CB and the FAMI-QS Operator, the certificate shall be suspended immediately, and the CB shall withdraw the certificate, if the unannounced audit is not conducted within a six-month timeframe.

For Integrated Management Systems both for Feed and Food (FAMI-QS/FSSC 22000), the unannounced audit performed for FSSC 22000 could be also considered for FAMI-QS, as long as common topics have been checked. In this case, the auditor shall also be a FAMI-QS approved auditor. The FAMI-QS and FSSC 22000 certificates shall be issued by the same Certification Body.

Topics checked during the unannounced audit might be skipped during the subsequent audit, only in the case that the audit has been performed by a FAMI-QS approved auditor (excluding production areas).

9.7. Complaints

The requirements of ISO/IEC 17021-1:2011, § 9.8 shall apply.

9.8. Client records

The requirements of ISO/IEC 17021-1:2015, § 9.9 shall apply.

10. MANAGEMENT SYSTEM REQUIREMENTS FOR CERTIFICATION BODIES

The requirements of ISO/IEC 17021-1:2015, § 10 shall apply.

11. ADDITIONAL APPLICABLE PROCEDURES

11.1. Extraordinary Events or Circumstances

IAF ID 3:2011 Informative Document for Management of Extraordinary Events or Circumstances affecting ABs, CBs and Certified Operators should be considered.

Certification Body shall inform FAMI-QS about the extraordinary events or circumstances where a FAMI-QS Operator may be involved and when scheduled surveillance audits or recertification cannot be conducted.

11.2. Integrity programme

All FAMI-QS authorised CBs may undergo an assessment additional to the accreditation, as defined in P-SP-01 Surveillance Programme. The results of the FAMI-QS Integrity audit will always be communicated to the Accreditation Body related to the CB.



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