



# RULES FOR CERTIFICATION BODIES

VERSION 9 / REV.0 — 2024-12-20



The Quality and Safety System  
for Specialty Feed Ingredients

# TABLE OF CONTENTS

<b>1. SCOPE.....</b>	<b>5</b>
<b>2. ASSESSMENT AND RECOGNITION OF A CERTIFICATION BODY..</b>	<b>6</b>
2.1. Required documents .....	6
2.2. Approval Process .....	7
2.3. Fees.....	8
<b>3. TERMS AND DEFINITIONS .....</b>	<b>8</b>
<b>4. PRINCIPLES .....</b>	<b>8</b>
<b>5. GENERAL REQUIREMENTS .....</b>	<b>8</b>
5.1. Legal and contractual matters.....	8
5.1.1. LEGAL RESPONSIBILITY .....	8
5.1.2. CERTIFICATION AGREEMENT .....	8
5.1.3. RESPONSIBILITY FOR CERTIFICATION DECISIONS .....	8
5.2. Management of impartiality.....	8
<b>6. STRUCTURAL REQUIREMENTS .....</b>	<b>9</b>
<b>7. RESOURCE REQUIREMENTS .....</b>	<b>9</b>
7.1. Competence of personnel .....	9
7.1.1. GENERAL CONSIDERATIONS .....	9
7.1.2. DETERMINATION OF COMPETENCE CRITERIA .....	9
7.1.3. EVALUATION PROCESSES.....	12
7.2. Personnel involved in the certification activities.....	13
7.2.1. APPROVAL OF THE AUDITORS .....	13
7.2.1.1. AUDITORS' SCOPES.....	14
7.2.1.2. AUDITORS' SCOPE EXTENSION.....	14
7.2.2. MAINTENANCE OF THE AUDITORS' NOMINATIONS .....	15
7.3. Use of individual external auditors and external technical advisors	15
7.4. Personnel records.....	15

7.5. Outsourcing.....	15
<b>8. INFORMATION REQUIREMENTS .....</b>	<b>15</b>
8.1. Public Information .....	15
8.2. Certification Documents .....	16
8.2.1. CERTIFICATE .....	16
8.2.1.1. TEXT ON THE CERTIFICATE .....	16
8.2.2. CERTIFICATION STATUS CHANGE.....	17
8.2.3. EXCLUSIONS ON CERTIFICATES .....	17
8.2.4. INVOICING ADDRESS .....	17
8.2.5. TRANSFER OF ACCREDITED FAMI-QS CERTIFICATES .....	17
8.2.5.1. ELIGIBILITY OF A CERTIFICATE FOR TRANSFER.....	18
8.2.5.2. PRE-TRANSFER REVIEW .....	18
8.3. Reference to certification and use of marks .....	19
8.4. Confidentiality.....	19
8.5. Information exchange between the Certification Body and its clients..	19
8.5.1. INFORMATION ON THE CERTIFICATION ACTIVITY AND REQUIREMENTS	19
8.5.2. NOTICE OF CHANGES BY THE CERTIFICATION BODY .....	19
8.5.3. NOTICE OF CHANGES BY A CERTIFIED OPERATOR .....	19
<b>9. PROCESS REQUIREMENTS.....</b>	<b>20</b>
9.1. Pre-Certification Activities .....	20
9.1.1. APPLICATION .....	20
9.1.2. APPLICATION REVIEW .....	20
9.1.3. AUDIT PROGRAMME.....	20
9.1.4. DETERMINING AUDIT TIME .....	21
9.1.5. AUDITING TIME CALCULATION FOR GLOBAL INVOICING SITES/SALES OFFICES	21
9.1.6. AUDITING TIME CALCULATION FOR SURVEILLANCE AUDIT AND RE- CERTIFICATION .....	23
9.1.7. MULTISITE SAMPLING .....	23
9.1.8. MULTIPLE MANAGEMENT SYSTEMS STANDARDS .....	23
9.2. Planning audits .....	23
9.3. Initial certification .....	23
9.3.1. INITIAL CERTIFICATION AUDIT .....	23
9.3.1.1. GENERAL .....	23
9.3.1.2. STAGE 1.....	23
9.3.1.3. STAGE 2 .....	24
9.4. Conducting audits .....	25

9.4.1.	GENERAL .....	25
9.4.2.	CONDUCTING THE OPENING MEETING .....	25
9.4.3.	COMMUNICATION DURING THE AUDIT .....	25
9.4.4.	OBTAINING AND VERIFYING INFORMATION .....	25
9.4.5.	IDENTIFYING AND RECORDING AUDIT FINDINGS .....	25
9.4.5.1.	CLASSIFICATION OF NON-CONFORMITIES AND RECOMMENDATIONS .....	25
9.4.6.	PREPARING AUDIT CONCLUSIONS .....	26
9.4.7.	CONDUCTING THE CLOSING MEETING .....	26
9.4.8.	AUDIT REPORT .....	27
9.4.8.1.	SUBMISSION OF AUDIT DOCUMENTATION TO FAMI-QS .....	27
<b>9.5.</b>	<b>Certification Decision .....</b>	<b>27</b>
9.5.1.	REQUIREMENTS FOR PERSON OR COMMITTEES THAT MAKE THE CERTIFICATION DECISION .....	27
<b>9.6.</b>	<b>Maintaining certification .....</b>	<b>27</b>
9.6.1.	GENERAL .....	27
9.6.2.	SURVEILLANCE ACTIVITIES .....	27
9.6.2.1.	SURVEILLANCE AUDIT .....	27
9.6.3.	RECERTIFICATION .....	28
9.6.4.	SPECIAL AUDITS .....	28
9.6.4.1.	EXTENSION TO THE SCOPE .....	28
9.6.4.2.	SHORT-NOTICE AUDITS .....	28
9.6.4.3.	UNANNOUNCED AUDITS .....	29
<b>9.7.</b>	<b>Complaints .....</b>	<b>30</b>
<b>9.8.</b>	<b>Client records .....</b>	<b>30</b>
<b>10.</b>	<b>MANAGEMENT SYSTEM REQUIREMENTS FOR CERTIFICATION BODIES .....</b>	<b>30</b>
<b>11.</b>	<b>ADDITIONAL APPLICABLE PROCEDURES .....</b>	<b>31</b>
11.1.	Extraordinary Events or Circumstances .....	31
11.2.	Integrity programme .....	31
11.3.	Certification Instructions .....	31

# | 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 17000:2020, 4.5), and bodies performing this activity are third-party Certification Bodies.

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 Authorized Certification Bodies can be used as a criteria document for the accreditation 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 of Practice.

Feed Safety and Quality Management System certification against the FAMI-QS Code attests that the production process takes place under hygienic conditions to minimize and 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, in the country where the feed business operator is registered. The specialty feed ingredients traded by the operator shall be legally produced in the country of origin and meet the regulatory requirements of the country of destination.

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

## 2. ASSESSMENT AND RECOGNITION OF A CERTIFICATION BODY

### 2.1. Normative references

The following documents are referred to in the text in such a way that all or some of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- *ISO/IEC 17021-1:2015, Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*
- *ISO 22003-1, Food Safety – Part 1: Requirements for bodies providing audit and certification of food safety management systems*
- *IAF MD 2:2023 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems*
- *IAF MD 4:2023 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes*
- *IAF MD 11:2023 IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems*

### 2.2. Required documents

A Certification Body that wishes to obtain a license to carry out FAMI-QS certification shall apply to the FAMI-QS ASBL Secretariat, providing details for eligibility according to the established selection criteria.

The Certification Body shall be accredited against ISO/IEC 17021-1:2015 and ISO 22003-1:2022 prior to the submission of their application to FAMI-QS. The Certification Body can be a non-governmental or a governmental body, with or without regulatory authority.

The application form is available on the FAMI-QS website (<https://fami-qs.org/certified-organisations/certification-bodies>) under application form for Certification Bodies).

To apply, the Certification Body shall submit the documentation outlined below:

- **Accreditation Certificate(s) for ISO /IEC 17021-1:2015 and ISO 22003-1:2022;**
- **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 organization.**

The Certification Body shall not have provided any consultancy and/or training activities to 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.

## 2.3. Approval Process

Upon receipt of the application form, the duration of the approval process may vary depending on the Certification Body's readiness.

**Step 1** Review of the Application and confirmation of Certification Body's eligibility for FAMI-QS Certification Services.

### **Step 2** Training Requirement

At least one member from each certification function (application, audit review) involved in FAMI-QS Certification Services must attend dedicated trainings organized by FAMI-QS, related to FAMI-QS Rules for Certification Bodies.

FAMI-QS will provide the applicant Certification Body with on-site training on the FAMI-QS Code of Practice and Feed Fraud Prevention and Defense Module at the Certification Body facilities (with the cost shared between the applicant Certification Body and FAMI-QS). All auditors listed on the application must attend the FAMI-QS-provided training on the FAMI-QS Code of Practice and Feed Fraud Prevention and Defense Module.

### **Step 3** Office Assessment

FAMI-QS will conduct an office assessment. The costs of the office assessment (including travel and auditors' man-days) will be shared between the applicant Certification Body and FAMI-QS.

### **Step 4** Provisional Approval

Upon completing the office assessment, provisional approval will be granted to the applicant Certification Body for three (3) years. The Certification Body must sign the contractual arrangement, and the provisional approval period will be listed on our website. During this provisional approval period, the Certification Body shall issue non-accredited certificates.

The Certification Body must complete its accreditation against FAMI-QS prior to the end of the provisional approval. The Certification Body shall apply for FAMI-QS Accreditation to its national Accreditation Body. The Accreditation Body must be an IAF MLA Signatory for main scope of Management System Certification - ISO/IEC 17021-1, and sub-scope of FAMI-QS, and recognized by FAMI-QS ASBL to conduct accreditation activities according to FAMI-QS requirements.

### **Step 5** Final Approval

Final approval is granted upon the completion of the accreditation process.

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.

## 2.4. 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 of Practice, ISO/IEC 17000:2020, ISO/IEC 17021-1:2015 and ISO 22003-1:2022 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 Authorized Certification Bodies.

# 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 § 5.1.2 are applied.

The certification agreement shall also include the:

- **presence of the Accreditation Assessor and the FAMI-QS Integrity Auditor,**
- **requirements for Crisis Management,**
- **conditions for the provision of the unannounced audits, and**
- **transfer of the certificates as described in the § 8.2.5 of FAMI-QS Rules for Certification Bodies**

### 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 organization 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 Accreditation Body.



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 of that Operator after a three (3) year break away.

An exemption to the above can be given, where 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.

## 6. STRUCTURAL REQUIREMENTS

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

## 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 Body 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 and Annex A, 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 in **Table 1** below shall form the basis for the criteria developed for each food chain category.

*NOTE: This table is an adaption of the requirements in ISO 22003-1, specific to the FAMI-QS scheme. Generic competencies 4-10 and 14-19 of Annex C of ISO 22003-1 have been removed, as these are covered in the ISO/IEC 17021-1 Annex A. Auditors are still required to demonstrate those competencies.*

**TABLE 1: COMPETENCE REQUIREMENTS PER FUNCTION.**

Competence (knowledge and skills)	Certification Functions		
	Conducting the application review*	Auditing and leading the audit team	Reviewing audit reports and making certification decisions
Ability to understand the content of FAMI-QS Approval Letter	X	X	X
Ability to apply the application review requirements of ISO/IEC 17021-1, ISO 22003-1 and those of FAMI-QS requirements for Certification Bodies procedures, including: <ol style="list-style-type: none"> <li>1. Integrated Management System Audits according to IAF MD 11</li> <li>2. Categorizing the Operator with the appropriate FAMI-QS Processes (as described Section 2 of the FAMI-QS Code of Practice), feed chain activities (Production and/or Trade) and feed chain categories (D, K, F).</li> <li>3. FAMI-QS audit duration requirements and their application.</li> </ol>	X	X	X
Ability to identify the below, in relevance to the FAMI-QS Process: <ul style="list-style-type: none"> <li>- GMPs;</li> <li>- feed safety hazards;</li> <li>- legal requirements.</li> </ul>	X	X	X
Ability to determine if there are: <ol style="list-style-type: none"> <li>1. specific cultural and social customs related to the production process and geographic areas to be assessed;</li> <li>2. specific factors required to audit the management system, product or process.</li> </ol>	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	X	X
Ability to conduct and manage an audit to achieve the audit objectives within the agreed time frame.  For the team leader, the ability to facilitate meetings for the effective exchange of information and the ability to make assignments or re-assignments where necessary to ensure: <ol style="list-style-type: none"> <li>1. that the audit team members audit the processes that they are technically competent to audit;</li> <li>2. that the audit time is optimized;</li> <li>3. that the specific FAMI-QS requirements are met.</li> </ol>		X	

Competence (knowledge and skills)	Certification Functions		
	Conducting the application review*	Auditing and leading the audit team	Reviewing audit reports and making certification decisions
Ability to identify: <ul style="list-style-type: none"> <li>- microbiological hazards;</li> <li>- chemical hazards;</li> <li>- physical hazards;</li> <li>- feed safety labelling requirements;</li> <li>- CP for Fraud and Defence;</li> <li>- supply chain mapping that are relevant to the FAMI-QS scope.</li> </ul>		X	
Ability to evaluate the organization’s capacity to identify and meet applicable feed safety regulations (for country of production and country of destination), including the Certification Body’s procedure for the handling of issues related to the statutory and regulatory requirements.	X	X	X
Ability to apply the principles of feed safety, HACCP, hazard assessment and hazard analysis in the feed chain (sub)category. Ability to apply FAMI-QS requirements in relation to: <ol style="list-style-type: none"> <li>1. outsourced processes;</li> <li>2. feed defence;</li> <li>3. feed fraud.</li> </ol>		X	X
Ability to apply feed chain (sub)category practices and vocabulary in relation to: <ol style="list-style-type: none"> <li>1. feed chain relationships;</li> <li>2. best practice with respect to PRPs and control measures;</li> <li>3. common feed chain processes (within the scope of the scheme);</li> <li>4. production technologies and processing terms;</li> <li>5. common equipment;</li> <li>6. facility design;</li> <li>7. packaging types and attributes;</li> <li>8. microbiological terms and names;</li> <li>9. chemical terms and names;</li> <li>10. good laboratory practices;</li> <li>11. local terminology.</li> </ol>		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 feed chain.		X	X

\* to determine audit team competence required, to select the audit team members, and to determine the audit time.

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 demeanor in the workplace;
- l. Morally courageous, i.e. willing to act responsibly and ethically even though these actions may not always be popular and may sometimes result in disagreement or confrontation;
- m. Organized, 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**

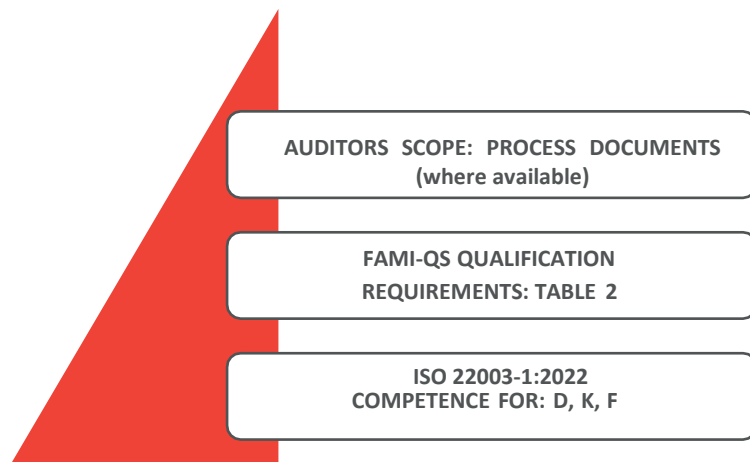
ISO/IEC 17021-1:2015 and ISO 22003-1:2022 §7.1.3, shall apply.

Where the evaluation of auditors includes an on-site evaluation, the evaluator shall have the competencies of a lead auditor.

### **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 approval of the FAMI-QS Auditors will be undertaken for the following scopes: Bioprocess, Chemical, Extraction, Mining, Mixing, Trade and Fraud and Defense. The validity of the approval will be four (4) years.

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

**Step 2** Auditors shall meet the qualification requirements defined on the **Table 2**.

**Step 3** Auditors shall have completed the FAMI-QS Certification System Version 6 training, organised by FAMI-QS or provided internally by the Certification Body (based on the FAMI-QS Training materials).

**Step 4** Auditors shall demonstrate knowledge on one or more FAMI-QS Process Documents (Bioprocess, Chemical, Extraction, Mining and Mixing) and on the FAMI-QS Feed Fraud Prevention and Defence Module.

**Step 5:** The Certification Body shall conduct an on-site evaluation of the auditor during the approval site audit as part of the auditor approval process. The evaluation can be performed in a relevant feed standard that covers one of the FAMI-QS Processes.

**Step 6** The Certification Body notifies the FAMI-QS Secretariat regarding the approval of an auditor. The notification shall contain the following:

- Auditor’s full Name;
- e-mail address;
- country where the auditor is based;

- **scopes (Bioprocess, Chemical, Extraction, Mining, Mixing, Trade, and Fraud and Defence).**

**Step 7:** In return, the FAMI-QS Secretariat will confirm the auditor's registration and inform the Certification Body regarding the registration number and validity period via a confirmation e-mail.

**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	Four (4) years	Same as auditor
Work experience in Feed/Food Safety Management Systems	At least two (2) years of the total four (4) years.	Same as auditor
Feed safety training	HACCP principles, hazard assessment, hazard analysis, feed safety management principles including PRPs, FAMI-QS Code of Practice.	Same as auditor
Auditor's training	Follow the FAMI-QS Certification System Training.	Same as auditor
Audit experience in Feed/Food Safety Quality Management Systems	Six (6) feed/food Safety QMS Audits in the last three (3) years.	Three (3) Complete FeSQMS Audits
Audit experience per scope	At least one (1) Feed Audit in the relevant scope	Same as auditor

#### 7.2.1.1. AUDITORS' SCOPES

- **FAM-PD-01: Bioprocess**
- **FAM-PD-02: Chemical**
- **FAM-PD-03: Extraction**
- **FAM-PD-05: Mining**
- **FAM-PD-06: Mixing**
- **FAM-AD-07: Trade**
- **FAM-MD-01: FFPD**

#### 7.2.1.2. AUDITORS' SCOPE EXTENSION

If a Certification Body would like to extend the auditing FAMI-QS Scope of a currently approved auditor, the auditor shall demonstrate knowledge in the relevant FAMI-QS Process Document (where available) and have completed at least one (1) Feed Audits or one (1) year work experience in the scope relevant to the extension process. The validity of the auditor will remain unchanged.

A witness audit of a FAMI-QS Code of Practice audit, within the requested scope, is required prior to the final confirmation of the extension. The witness audit may be undertaken remotely.

The Certification Body notifies the FAMI-QS Secretariat regarding the Certification Body's approval of an auditor's scope extension. The FAMI-QS Secretariat shall confirm the maintenance on the auditor's scope and inform the Certification Body via e-mail.

### **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 organized by FAMI-QS.
- b.** Maintenance of the scope: Two (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 (1) 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 to reduce the scope of the auditor. The Certification Body shall inform the FAMI-QS Secretariat of any reduction in the scope of an auditor.

The maintenance of the auditor's approval and documentation records of the monitoring activities are the 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.

# **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.

### 8.2.1. CERTIFICATE

#### 8.2.1.1. TEXT ON THE CERTIFICATE

In addition to the requirements of ISO/IEC 17021-1:2015 § 8.2.2, the text on the certificate shall include the following minimum information:

**OPERATOR'S NAME**

has implemented and maintains a Feed Safety and Quality Management System including Good Manufacturing Practice (GMP) in compliance with:

FAMI-QS CODE **(VERSION X, YYYY-MM-DD)** and

FEED FRAUD PREVENTION AND DEFENSE MODULE **(VERSION X, YYYY-MM-DD)**

ON THE FOLLOWING SITE/S<sup>(1)</sup> **XXX**

FAMI-QS SITE REGISTRATION: FAM-**XXXX/XX**

FOR **ACTIVITY** <sup>(2)</sup> OF SPECIALTY FEED INGREDIENTS FROM **PROCESS** <sup>(3)</sup>

(IN COMPLIANCE WITH THE FAMI-QS PD-XX)

FEED CHAIN CATEGORY<sup>(4)</sup> **D, K, FI, FII**

THIS CERTIFICATE IS VALID UNTIL: **YYYY-MM-DD**

Signature of the Certification Body: \_\_\_\_\_ **PLACE, DATE YYYY-MM-DD**

For the validity of this certificate please check [www.FAMI-QS.org](http://www.FAMI-QS.org)

**(1)** For Operators running multiple manufacturing processes at different sites it is sufficient to issue one certificate listing all the sites, when the scope and the validity period are the same. Separate certificates can be provided to sites as long as the main certificate is referenced on the site certificate, and the certificate is not misleading or suggests that the site holds its own certification.

**(2)** Activity means: **Production** and/ or **Trading**. No other term is allowed.

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

**(4)** Classification of feed chain categories applicable to FAMI-QS (ISO 22003-1:2022 Annex A):



- D:** 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.

### 8.2.2. CERTIFICATION STATUS CHANGE

The suspension or withdrawal of a certificate remains the responsibility of the Certification Body. With regards to the Suspended status, the maximum period cannot exceed three months. Following that period, if appropriate actions have not been taken by the operator, the Operator's certificate will be withdrawn by the Certification Body. At a minimum, a Stage 2 shall be conducted if the feed business Operator wishes to restore its FAMI-QS certificate.

### 8.2.3. EXCLUSIONS ON CERTIFICATES

FAMI-QS Certified Operators are obligated not to mislead stakeholders and authorities regarding the scope of their certification, validity of the certificate and site(s). The provision of concise and coherent information by FAMI-QS Certified Operators with regards to their activities is fundamental for FAMI-QS. Misleading the supply chain and stakeholders by providing inaccurate information with regards to the scope of certification, claims, or activities of the operator cannot be accepted.

Certification Bodies shall ensure that all the communication of a FAMI-QS Certified Operator provided through marketing material, product specification and websites is not misleading, and is aligned with their certified activities.

Certification bodies shall review the websites of each of their FAMI-QS Certified Operators and ensure that the information published is consistent, coherent, transparent and aligned with the activities of FAMI-QS Certified Operators.

### 8.2.4. INVOICING ADDRESS

The site related to the invoicing address must be included on the FAMI-QS Certified Operator's certificate, as this is the site responsible for placing products in the market. In the event that the invoicing address is a PO box or no activity is taking place at the site, 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) is performed by the auditor.

All traceability and recall procedures shall be 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.

### 8.2.5. TRANSFER OF ACCREDITED FAMI-QS CERTIFICATES

For the transfer of accredited FAMI-QS certificates, *IAF MD2:2023 Mandatory Document for the Transfer of Accredited Certification of Management Systems* shall be applied.

The receiving Certification Body shall contact FAMI-QS Secretariat prior to the transfer for pre-approval. The FAMI-QS Secretariat will communicate any open issues related to the transfer of the certificate (if applicable) and provide the Certification Body with the transfer approval. This could include open non-conformities, failure to submit corrective actions, etc.

*Note: Only the FAMI-QS Accredited/Authorized Branch and not the regional sales offices can get in touch with the FAMI-QS Secretariat for pre-approval. Please get in touch with the FAMI-QS Secretariat once you have confirmed that you can perform the transfer. In the event that the Certification Body cannot take over the certification, there is no need for confirmation.*

### 8.2.5.1. ELIGIBILITY OF A CERTIFICATE FOR TRANSFER

For the receiving Certification Body to accept the transfer of the certification, it shall ensure that the necessary resources (FAMI-QS auditor) are sufficient to provide the service to the organization, without impacting the planning of the current FAMI-QS Certification. Once the auditors' capacity has been confirmed and documented, the next step will be the confirmation of the eligibility of the certification for transfer.

In the event of a change, addition or removal of local resources, the authorized FAMI-QS Certification Bodies shall notify FAMI-QS via email to [fffs\\_info@fami-qs.org](mailto:fffs_info@fami-qs.org).

Only valid FAMI-QS certificates shall be transferred. A FAMI-QS Certificate which is known to be suspended shall not be accepted for transfer. To confirm the validity of the certificate, please consult the FAMI-QS list of certified operators at: <https://fami-qs.org/certified-organisations>.

If the certificate is eligible for transfer, then the transfer of the certification shall be completed prior to the date of when the next surveillance is due or prior to the expiry of the certificate.

The issuing Certification Body **shall not suspend or withdraw the organization's** certification following the notification that the organization is transferring to the accepting Certification Body if the client continues to satisfy the requirements of certification.

Certification Bodies shall include in their certification agreement with their client a clear provision on how they will handle the transfer both as an issuing and receiving Certification Body. The conditions under which the issuing Certification Body can suspend or withdraw the FAMI-QS Certificate shall be stated and aligned with the provision of IAF MD2:2023.

The issuing Certification Body shall withdraw the certificate upon completion of the transfer or when the requirements of the certification are not fulfilled.

*NOTE: For example, a certificate is due for a surveillance audit in May 2023. The organization informs the issuing Certification Body in February 2023 that they will transfer their certificate to a new Certification Body. In this case, as long as the requirements of the certification are fulfilled, the Certification Body shall maintain the certificate until the date of when the next audit activity is due. In this example, by May 2023.*

The transfer of the certificate shall be managed exclusively through the FAMI-QS reporting platform, and for this a dedicated pre-transfer review report/checklist has been created.

### 8.2.5.2. PRE-TRANSFER REVIEW

The pre-transfer review report is available on the FAMI-QS reporting platform under the audit type dropdown list. For the creation of the pre-transfer review report, the workflow/process is the same as the publication of a certificate.

Before submitting it for validation, the accepting Certification Body shall create:

1. the audit folder by choosing the pre-transfer report and then
2. the certificate using the same validity period.

As a minimum, the pre-transfer report shall include the evidence as described on §2.2.4 of IAF MD 2:2023.

Upon completion of the transfer, the accepting Certification Body shall inform the issuing Certification Body about the completion. The issuing Certification Body will then unlock the certificate and change the status to withdrawn. This will allow us to avoid the double listing of the FAMI-QS Certified Operator.

## 8.3. Reference to certification and use of marks

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

During the onsite audit the Certification Bodies shall confirm that the FAMI-QS logo is used by the FAMI-QS Certified Operator 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.

FAMI-QS 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 Certification Body. 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, certificates of analysis, means of transport, but may be used on certificates, advertisements and brochures.

## 8.4. Confidentiality

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

## 8.5. Information exchange between the Certification Body and its clients

### 8.5.1. INFORMATION ON THE CERTIFICATION ACTIVITY AND REQUIREMENTS

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

### 8.5.2. NOTICE OF CHANGES BY THE CERTIFICATION BODY

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

The Certification Body 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.

### 8.5.3. NOTICE OF CHANGES BY A CERTIFIED OPERATOR

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, organizational status or ownership;
- b. Operator and management changes;
- c. Contact details, 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.

*NOTE: For changes regarding a, b, c and d, the FAMI-QS Certified Operator needs to provide a marked-up approval letter for review and acceptance by the FAMI-QS ASBL Secretariat. The Secretariat will then provide the Operator with a revised approval letter.*

## 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, § 9.1.1, is required:

- a. Approval letter exclusively issued by the FAMI-QS ASBL Secretariat;
- b. Legal feed business operations documents e.g. registration with competent authorities, tax authorities etc;
- c. List of products coming from the processes covered in the FAMI-QS Scope. For products coming from bioprocess this information will include the name and number of the strain, and the microorganism used in the process. **This applies to producers and traders.** The listing shall be in the following format: **ingredient, microorganism/strain, deposition number.** 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). Service providers suppliers or services that have an impact on feed safety, such as contract manufacturers, toll manufacturers, evaluation control, equipment, packaging materials, uniform cleaning, facility cleaning services must be included in the Operator's identification and evaluation of externally provided sources;
- g. Audit report or risk assessment from the subcontractor(s), toll manufacturer(s), supplier(s), if applicable;
- h. Countries where the products are placed.

The Certification Body 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 considered by the Certification Body in determining 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.

The Certification Body shall include confirmation of the Audit Program and the effectiveness of the auditing time calculation as part of the certification decision.

Confirmation that the elements of the auditing time calculation remain unchanged is required e.g. changes on the number of assured non-assured sources, processes, number of employees.

**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 22003-1:2022, shall apply.

**TABLE 3: MODIFIED INITIAL AUDITING TIME CALCULATION TABLE (Table B.1 of ISO 22003-1:2022)**

	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>
Feed Chain Category	Basic site audit duration in audit days	Number of audit days for each additional HACCP study (process)	Additional auditing time for auditing of the files for feed ingredients purchased from non-assured sources.	Additional number of audit days based on full-time equivalent employees (FTE)
Category D	1.0	0.5	01-05 ingredients 0.25 06-10 Ingredients 0.50 11-15 ingredients 0.75 >15 ingredients 1.00	1 to 5 = 0.0
Category F	1.0			6 to 49 = 0.5
Category K	2.0			50 to 99 = 1.0
				100 to 199 = 1.5
				200 to 499 = 2.0
				500 to 999 = 2.5
				>1000 = 3.0

Additional notes:

**A:** Basic audit time: in all cases Feed Fraud Prevention and Defence Module is included. In the 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:** 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.

**D:** Additional auditing time according to the number of full-time equivalent employees (FTE) under the FAMI-QS System.

The initial certification auditing time includes the auditing time for Stage 1 and Stage 2. However, it does not include the time for preparation of the audit nor for writing the audit report. The Certification Body shall decide how the time will be split between Stage 1 and Stage 2.

Auditing Time shall be approved by the FAMI-QS Scheme Manager or a competent 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 authorized by FAMI-QS. Formal appointment is required. Auditing time calculation shall be recorded and must be traceable. A maximum reduction of 10% can be given based on previous experience of the Certification Body with the Operator. For audits of integrated management systems IAF MD 11 shall be applied for the auditing time reduction.

**9.1.5. Auditing time calculation for Global Invoicing Sites / Sales offices**

This process is added on to the initial auditing time calculation for the inclusion of site(s) that do not hold any product responsibility.

If an Operator would like to include the network of their global invoicing sites/sales offices, the auditing time calculation should be adjusted accordingly and as it is shown on the table.

	<b>A</b>	<b>B</b>
Feed Chain Category	HQ Auditing Time	Time for each additional site (invoicing site / sales office)
Category F	1.0	1h 15min

The following conditions should also be in place:

- **The global invoicing sites /sales offices trade only products that are produced or sold (contract manufacture) by the Operator.**
- **All the production sites that deliver to the customers of their global invoicing sites/sales offices are FAMI-QS Certified (certified with mutual recognised standards excluded).**
- **The invoicing site / sales office does not hold any warehousing, transport, repacking, sampling and release responsibilities.**
- **The Operator has a multisite structure with a centralised FAMI-QS Management System.**
- **The audit is conducted remotely in the case of the invoicing sites/ sales offices with the audit team to be located at the HQ.**
- **The audit cycle is three (3) years (each site must be audited at least once over the certification cycle).**

At the **HQ**, the following elements are checked by the Certification Body:

- **Verification of the scope of audit (product, sites/offices, processes),**
- **Verification of FAMI-QS-Approval Letter,**
- **Verification of actual and draft certificate(s),**
- **Leadership and Policy,**
- **Management Review,**
- **Control of externally provided products and services,**
- **Purchased /produced materials,**
- **Communication,**
- **Roles and Responsibilities.**

**For each site/office**, it is necessary to check:

- **Local organization, roles and responsibilities (e.g. most senior management responsible person, recall manager),**
- **Interfaces, requirements and general issues with local authorities (registrations, permits, inspections),**
- **Overview of feed business customers (feed products, customer requirements),**
- **Overview of local complaints (if applicable).**

### 9.1.6. 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 (8) hours.
- b. Re-Certification Audit: the total minimum time shall be two-thirds of the initial certification audit time, with a minimum of eight (8) 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.

### 9.1.7. MULTISITE SAMPLING

The requirements of ISO/IEC 17021-1:2015, § 9.1.5 shall apply. The requirements of ISO 22003-1:2022, § 9.1.5 shall also apply.

### 9.1.8. MULTIPLE MANAGEMENT SYSTEMS STANDARDS

The requirements of ISO/IEC 17021-1:2015, § 9.1.6, apply. The IAF MD 11:2023 and IAF MD1:2023 should be considered.

## 9.2. Planning audits

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

Traders that place products on the market 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 Certification Body 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 Stage 1 is to provide a focus for planning Stage 2. 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 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 of Practice.
- b. Any publicly available information corresponds to the actual operations of the feed business organization (e.g.

website).

- c. The Operator has identified PRPs that are appropriate to the business.
- d. Audit report/risk assessment on audits carried out at the supplier premises is available (if applicable), the effectiveness of the report (s), and on whether additional actions are required prior to Stage 2.
- e. Audit report on audits carried out at the subcontractors' facilities is available (if applicable), the effectiveness of the report (s) and whether an audit is required at the premises of the subcontractor(s).
- f. Review appropriateness of the audit duration for an effective audit during Stage 2.
- g. The Feed Safety and Quality Management System comply with the requirements of the FAMI-QS Code, Process Documents and Feed Fraud Prevention and Defence module.
- h. All processes that have an impact on feed safety have identified and included in the scope of the Feed Safety and Quality Management System.
- i. The Operator's System collects the relevant statutory and regulatory requirements relevant to its operations.
- j. The Feed Safety and Quality Management System is designed to achieve the Operator's feed safety policy.
- k. The Feed Safety and Quality Management System implementation programme allows to proceed to Stage 2 of the audit.
- l. 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.).
- m. Additional documentation that needs to be reviewed /or which knowledge needs to be obtained in advance.

Stage 1 is required for the initial certification audit and shall be carried out onsite at the Operator's premises to achieve the objectives of the audit.

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 or events can include very remote location, a natural disaster, a pandemic, a short seasonal production and other special circumstances.

The findings in Stage 1 shall be documented and communicated to the client. The findings of Stage 1 do not include non-conformities reporting but advice to address issues where they arise.

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. If the Operator is already certified to a Feed Safety and Quality Management System by the same Certification Body, Stage 1 is not mandatory.

### 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 Stage 1 and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during Stage 2. 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 Stage 1.



## 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

The definition for Major non-conformity is included in ISO/IEC 17021-1 at Clause 3.12. 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 FAMI-QS Code of Practice.

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

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

##### b. Minor non-conformities

The definition for Minor non-conformity is included in ISO/IEC 17021-1 at Clause 3.13. A minor non-conformity exists when a requirement of the FAMI-QS Code of Practice 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 three (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.**

TYPE	INITIAL AUDIT	SURVEILLANCE (including unannounced audits)	RE-CERTIFICATION AUDIT
<b>Major</b>	<p>Certification cannot be granted. An action plan shall be submitted within seven (7) days after the audit.</p> <p>Non-conformities shall be closed within six (6) weeks after the audit</p>	<p>The action plan shall be presented to the Certification Body in fourteen (14) calendar days at the latest after the audit date.</p> <p>Evidence that non-conformities have been closed will be checked twenty-eight (28) days after the presentation of the action plan at the latest. In case the time frame is not sufficient, further coordination with FAMI-QS is required.</p> <p>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 non-conformity.</p>	<p>Certification cannot be granted.</p> <p>An action plan shall be submitted within seven (7) days after the audit.</p> <p>Non-conformities shall be closed within six (6) weeks after the audit.</p>
<b>Minor</b>	<p>Certification cannot be granted until the non-conformities have been closed.</p> <p>An action plan shall be submitted within seven (7) days after the audit.</p> <p>Non-conformities shall be closed within six (6) weeks after the audit</p>	<p>Certification continues.</p> <p>The Certification Body shall indicate acceptability of the action plan within fourteen (14) calendar days of receipt of the action plan from the Operator.</p> <p>Evidence that non-conformities have been closed will be verified by the auditor, at the latest, during the following audit. If the non-conformity cannot be closed by then, it becomes a major non-conformity.</p>	<p>Certification continues.</p> <p>The Certification Body shall indicate acceptability of the action plan within fourteen (14) calendar days of receipt of the action plan from the Operator.</p> <p>Evidence that non-conformities have been closed will be checked by the auditor, at the latest, during the following audit. If the non-conformity cannot be closed by then, it becomes a major non-conformity.</p>

The auditor shall confirm that he/she/they has/have reviewed, accepted and verified the effectiveness of corrective actions as described in ISO/IEC 17021-1:2015, § 9.4.10. Additionally, all non-conformities (major and minor) need to be closed on the FAMI-QS reporting platform.

**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.

If audit evidence indicates that the audit findings lead to the identification of a non-conformity, this shall be clearly mentioned in the relevant section 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 need to be aware of this uncertainty.

The Certification Body shall upload each report onto the FAMI-QS audit documentation platform.

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 FAMI-QS Certified 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 Certification Body shall ensure that the person(s) who review the audit reports of initial, surveillance, re-certification and special audits and make the certification decision has appropriate competence. The decision maker(s) shall be able to demonstrate compliance with the same requirements as the FAMI-QS auditor and be approved by the Certification Body.

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

The competent person(s) assigned by the Certification Body to make the certification decision 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.

## **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 shall apply.

##### **9.6.2.1. SURVEILLANCE AUDIT**

The requirements of ISO/IEC 17021-1:2015, § 9.6.2.2 shall apply.

Frequency of the surveillance audits:

- a. 1st Surveillance Audit: within twelve (12) months after the end date of the Initial Certification Audit.
- b. 2nd Surveillance Audit: approximately twenty-four (24) months after the end date of the Initial Certification Audit.

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

### 9.6.3. RECERTIFICATION

The requirements of ISO/IEC 17021-1:2011, § 9.6.3 shall apply, with the following modifications.

The Certification Body shall conduct a recertification audit at least thirty (30) days prior to the expiry date of the certificate to allow time for the certification decision prior to the expiry of the certificate.

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 within six (6) months after the expiry of a certificate, at least a Stage 2 shall be conducted. If the certification expiry is more than six (6) months, a Stage 1 and Stage 2 shall be conducted to restore the certification.

### 9.6.4. SPECIAL AUDITS

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

Special audits can be conducted remotely only if the objectives of the audit can be achieved in a fully remote setting. Where remote special audits are conducted, they shall be conducted in accordance with the requirements in this document and the requirements of *IAF MD 4 - IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes*. The justification for using a remote audit shall be recorded by the Certification Body.

#### 9.6.4.1. 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 the extension may be granted. This may be conducted in conjunction with a surveillance or recertification audit.

#### 9.6.4.2. 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 Certified Operator and shall be part of the certification agreement.

It might be necessary for the Certification Body to conduct an audit of a FAMI-QS Certified Operator at short notice (up to seventy-two (72) hours' notice) 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 FAMI-QS 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 the result of the audit.

In case of an incident, the *P-CM-01 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. The cost of the audits will be covered by the FAMI-QS Certified Operator.

#### 9.6.4.3. UNANNOUNCED AUDITS

Certification Bodies shall include an unannounced audit in their audit program for each FAMI-QS Certified Operator. 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. The Certification Body shall ensure the FAMI-QS Certified Operator takes the necessary steps for granting access to the auditor in such events.

**Restrictions on scheduling unannounced audits:** Unannounced audits shall not be:

- **in the first 6 months or the last six months of the certification cycle**
- **adjacent to a surveillance audit.**

*Note: Operators should follow a similar procedure as for 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 shall include that a minimum of one (1) unannounced audit is undertaken after the initial certification audit and within each 3-year period thereafter as an additional audit, on top of surveillances audits.

FAMI-QS Certified Operators shall inform the Certification Body regarding any scheduled maintenance closure of the company.

#### 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;**
- **Outsourced processes and evaluations of suppliers;**
- **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.**

If the FAMI-QS Certified Operator refuses to participate in the unannounced audit, as defined in the contract between the Certification Body and the FAMI-QS Certified Operator, the certificate shall be suspended immediately, and the Certification Body 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, if common topics have been checked and the food/feed chain category (D, K, FI or FII) is the same. In this case, the auditor shall also be a FAMI-QS approved auditor for the same food/feed chain category. The FAMI-QS and FSSC 22000 certificates shall be issued by the same Certification Body and for the same food/feed chain category.

#### **9.6.5. SUSPENDING, WITHDRAWING OR REDUCING THE SCOPE OF CERTIFICATION**

The suspension or the withdrawal of a certificate remains the responsibility of the Certification Body.

Once a withdrawal is confirmed, the certification body shall immediately inform FAMI-QS ASBL Secretariat, about the status change, the reason of withdrawal and submit the certificate under “withdrawn” status. The certificate remains visible on FAMI-QS website as withdrawn. Automatically, a notification is sent to the members that have subscribed to receive the status changes.

With regards to the suspended status, the certification body shall make FAMI-QS immediately aware of the suspension of the certificate and the reason of the suspension. Also in this case, the certificate remains visible on FAMI-QS website as suspended, and a notification is sent to the subscribed members.

The maximum period of the suspension cannot exceed three months. Following that period, if appropriate actions have not been taken by the operator, the Operator’s certificate will be withdrawn by the Certification Body. At a minimum, a Stage 2 shall be conducted if the feed business Operator wishes to restore its FAMI-QS certificate.

### **9.7. Complaints**

The requirements of ISO/IEC 17021-1:2015, § 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 Accreditation Bodies, Certification Bodies 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. Surveillance Programme

All FAMI-QS authorized Certification Bodies may undergo an assessment additional to the accreditation, as defined in *P-SP-01 Surveillance Programme*. The results of the FAMI-QS surveillance programme audit will always be communicated to the Accreditation Body related to the Certification Body.

## 11.3. Certification Instructions

In an event that Certification Bodies are required to take certain actions that are not described in the current Rules, the FAMI-QS Scheme Management Director will issue Certification Instructions. FAMI-QS will define all the actions that need to be implemented by the Certification Body.

The following events (non-exhaustive list) might trigger the issuing of a Certification Instruction:

- **Changes in legislation.**
- **Changes in international standards.**
- **Lessons learned following an incident or a crisis.**
- **Results of the Surveillance Programme.**
- **A need for a specific interpretation of the FAMI-QS Code or the Rules for Operators and/or the Rules for Certification Bodies.**



The Quality and Safety System for  
Specialty Feed Ingredients