RULES FOR OPERATORS

VERSION 9 / Rev.0 — 2024-12-20

FAMIQS®

The Quality and Safety System
for Specialty Feed Ingredients

TABLE OF CONTENTS

1. SCOPE

This document defines the rules applicable for the provision of Feed Safety and Quality Management System against FAMI-QS Certification System. It also provides the necessary information to those reliant on the results of the FAMI-QS Certification about the way the third-party certification is conducted.

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

Feed Safety and Quality Management System certification against FAMI-QS Code of Practice attests that the production process is undertaken under hygienic conditions to minimize or 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 is a management system certification, not a product certification.

2. APPLICATION FOR CERTIFICATION

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.

- ***FAMI-QS Code of Practice Version 6 2018-10-02***
- ***FAMI-QS Feed Fraud Prevention and Defence Module Version 1.0 2019-09-02***
- ***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. Application for certification

Any Operator seeking FAMI-QS certification can send an application to FAMI-QS using the application form which is available on the FAMI-QS website. Before applying the Operator should determine if there is currently a recognized Certification Body in their region that can service their certification. If this is not obvious on review of the FAMI-QS Website the Operator should contact the FAMI-QS ASBL Secretariat.

The ten (10) steps outlining the certification process are detailed below:

STEP 1 The Operator should download a free copy of the FAMI-QS Code of Practice and the Rules for Operators (this document) and read the documents carefully.

STEP 2 The Operator should evaluate their readiness by performing an internal audit.

STEP 3 The Operator should identify its product(s) and fill in all the sections of the application form (e-form or word format available on https://fami-qs.org/scheme-documents/application-information) to register for FAMI-QS certification. 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**.

STEP 4 FAMI-QS Secretariat staff will evaluate the application and return an email stating if the application can be accepted or not. Once it has been approved, FAMI-QS will issue an invoice for the membership fee. The membership fee is paid on a yearly basis. Once it is paid, a letter of acceptance (approval letter) is sent to the Operator (a payment receipt is sent by email, upon request). The approval letter needs to be provided to the Certification Body.

STEP 5 The Operator should select a Certification Body from the FAMI-QS website list and contact them for a certification audit. The approval letter will be required for communication with the Certification Body.

STEP 6 The Certification Body provides an outline of the initial audit as follows:

Stage 1 - evaluation of the Feed Safety and Quality Management System, documentation, scope and preparedness for Stage 2.

Stage 2 - verification of the implementation of the Feed Safety and Quality Management System.

STEP 7 The audit is completed. Outcomes of the audit and any non-conformities are shared with the operator. The operator develops an action plan to address non-conformities and submits to the Certification Body. Assessment of the action plan and its implementation is undertaken by the Certification Body. Once complete, the Certification Body submits the audit documentation to FAMI-QS.

STEP 8 Revision of the audit documentation and its findings by the Certification Body, followed by the certification decision. The Certification Body delivers the certificate to the Operator.

STEP 9 FAMI-QS reviews the audit documentation and membership payment and validates the registration. After verification of the audit documentation, the Operator will be registered and listed on the FAMI-QS website as a FAMI-QS Certified Operator.

STEP 10 After the initial certification, an annual surveillance audit will apply. The certification is valid for three (3) years. After the cycle of three (3) years, a recertification audit will take place.

If there are no changes in the scope, company name or address, there would be no need to request a new approval letter. The previous one will remain valid.

Note: If an Operator is not listed on our website, we advise to check with your Certification Body if they have provided all the necessary documents to FAMI-QS. All questions related to this subject shall be submitted to FAMI-QS through audit@fami-qs.org.

2.3. Evaluation procedure of the application

As stated above, the Operator's application for Specialty Feed Ingredients requires a form to be filled in. This form has questions to be clearly answered by the Operator to evaluate if the ingredients produced/ traded are covered within the FAMI-QS scope. Guidance on how to fill up the application form can be obtained by sending an email to: *fffs_apply@fami-qs.org*.

Specialty feed ingredients shall be defined and labelled with clear application instructions according to the applicable animal feed legislation of the intended market. The regulatory status of the products will be the responsibility of the Operator. The products shall be legally produced in the country of origin and shall meet the regulatory requirements of the country of destination.

To get an application's approval, the product shall comply with the definition of Specialty Feed Ingredient. Any other result will lead to rejection of the application.

3. FAMI-QS MEMBERSHIP FEES

Once the application has been approved, FAMI-QS will make by return an invoice for membership fee. The membership fee invoice shall be paid within thirty (30) days from the issuing day. If the payment is delayed, a penalty fee will be imposed.

Membership fees conditions:

- **A fee is applied for each registered site within the FAMI-QS system.**
- **The amount of the membership fee is announced/published on the website.**
- **An invoice will be issued each calendar year following the application.**
- **If a FAMI-QS Certified Operator refuses to pay the membership fee, the company will be removed**

from the FAMI-QS website.

3.1. Other charges

If a FAMI-QS Certified Operator interrupts their membership and re-applies for FAMI-QS certification, an additional administrative fee will be charged and added to the annual membership fee. In addition, an administrative fee will be applied to process changes linked with the updates of the Approval letter, such as scope extension or other amendments. Only in the case of new sites registration, no administrative fee will be applied.

4. ASSESSMENT OF OPERATORS

Operators shall contact one of the FAMI-QS authorized Certification Bodies listed on the FAMI-QS website.

For application to the chosen Certification Body, the following information must be sent by the Operator to the Certification Body before the certification audit takes place:

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 on the market.

The Certification Body shall not exclude activities, processes, products or services from the scope of the audit when those activities/processes/products/services can have an impact on feed safety. These considerations shall be considered by the Certification Body in determining the audit program and audit plan.

The Certification Body assesses the Operators' compliance with FAMI-QS Code of Practice and Feed Fraud Prevention and Defence module during initial, surveillance and recertification audits.

In case of any unresolved disagreement between an Operator and an authorized Certification Body, circumstances should be reported in writing to the FAMI-QS Secretariat.

4.1. Auditing Time Calculation

4.1.1. INITIAL AUDITING TIME CALCULATION

TABLE 1: MODIFIED INITIAL AUDITING TIME CALCULATION TABLE (TABLE B.1 OF ISO 22003-1:2022)

	A	B	C	D
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 6 to 49 = 0.5 50 to 99 = 1.0 100 to 199 = 1.5 200 to 499 = 2.0 500 to 999 = 2.5 >1000 = 3.0
Category F	1.0			
Category K	2.0			

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 appointed 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.

5. AUDIT PLANNING

According to the requirements of ISO/IEC 17021-1:2015 and ISO 22003-1:2022, the FAMI-QS initial certification audit shall be conducted in two stages, Stage 1 and Stage 2.

Before Stage 1, the Operator shall provide the Certification Body (in written, electronic form or during a meeting between the Operator and the auditor) the documentation described in the previous chapter "Assessment of Operators".

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 the FAMI-QS maintains mutual recognition arrangements (see document *P-MS-003 – Recognised Standards*), the Certification Body shall audit the contracted manufacturer at least once within the certification cycle.

5.1. Initial Certification Audit

5.1.1. 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 determining 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, marketing materials *etc.*).

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 decision is made based on 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 auditing duration for an effective auditing at Stage 2.

g. The Feed Safety and Quality Management System complies with the requirements of the FAMI-QS Code of Practice, Process Documents and Feed Fraud Prevention and Defence module.

h. All processes that could have an impact on feed safety have been identified and included in the scope of the Feed Safety and Quality Management System.

i. The Operator's System collects the 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.

A 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 locations, natural disasters, 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. A Stage 1 might apply for the re-certification audit when major changes in the Operator's Feed Safety and Quality Management System have occurred.

5.1.2. STAGE 2

Stage 2 takes place at the location of an applicant who seeks certification against the FAMI-QS Code of Practice. All sections of the FAMI-QS Code of Practice and Feed Fraud Prevention and Defence module shall be verified.

The purpose of the Stage 2 is:

a. To confirm the implementation, including the effectiveness of the Operator's Feed Safety and Quality Management System to the requirements of the FAMI-QS Code of Practice and Feed Fraud Prevention and Defence module.

b. To verify that the information and evidence of conformity is achieved, for all the FAMI-QS Code of Practice and Feed Fraud Prevention and Defence module requirements.

c. To assess the capability of the Feed Safety and Quality Management System to perform key activities, such as production methods, controls, PRPs, HACCP plans and procedures, as well as the competency of the personnel involved in the feed/food safety functions, in conformity with the ISO standards.

d. To assess the Operator's Feed Safety and Quality Management System, in compliance with EU and local statutory, regulatory and contractual requirements.

e. To confirm that the Operator's Feed Safety and Quality Management System is effective in achieving the stated feed safety policies and objectives.

The selection of the executive and other personnel to be interviewed shall adequately cover every relevant functional area. If shiftwork is performed, an interview can be planned outside normal working hours.

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.

5.2. Subcontractor

The Operator's subcontractor(s), toll manufacturer(s), supplier(s) is subject to the same approval criteria as any other supplier of FAMI-QS Certified Operator.

If the subcontractor is not FAMI-QS certified or is not certified by any other mutual recognized standard, the

FAMI-QS Certified Operator shall evaluate the risk connected to the Operator's service and perform a full audit, to ensure that the subcontractor meets the FAMI-QS requirements. The FAMI-QS Certified Operator shall audit the establishment of the subcontractor against FAMI-QS requirements at least once within the FAMI-QS Certified Operator's certification cycle. A report shall be made available. The frequency of auditing the Operator shall be based on the risk associated with the Operator's service.

During the Operator's certification and surveillance audits, the auditor shall check the audit report of the subcontractor.

The Certification Body may also audit the subcontractor based on the evidence presented in the subcontractor audit report. On successful completion of the audit, a certificate will be granted to the Operator only.

If the subcontractor is certified according to FAMI-QS or to a mutually recognized standard, no additional FAMI-QS audit by the Operator is required if the applicable product falls under the scope of that certification.

6. MAINTAINING CERTIFICATION

6.1. Auditing Time Calculation for Surveillance audit and Re-certification

a. Surveillance Audit: the total 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.

6.2. Surveillance Audits

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.**

6.3. Recertification Audit

A recertification audit shall be conducted at least thirty (30) days prior to the expiry date of the certificate to allow for the certification decision prior to the expiry of the certificate.

A failure to perform the recertification 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 recertification 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 a Stage 2 shall be conducted to restore the certification.

7. SPECIAL AUDITS

7.1. Extension to the scope

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 within/in conjunction with a surveillance or re-certification audit.

7.2. Short Notice Audits

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 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.

7.3. Unannounced Audits

Certification Bodies shall include in the audit programme 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 (additional to surveillance audit).

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 Operator takes the necessary steps for granting access to the auditor in such events.

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

a. **in the first 6 months or the last six months of the certification cycle**

b. **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 upon between the Certification Body and the FAMI-QS Certified Operator and shall be part of the contract. The contract needs to 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 or

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 CCPs;**
- **Outsourced processes and evaluations of suppliers**
- **Inspection of the premises (internal – external);**
- **Observation if the employees perform their tasks according to the written procedures;**
- **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' evaluations;**
- **Purchase orders and specifications;**
- **Certificates of analysis (shall be checked per purchase order);**
- **Traceability; and**
- **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 FAM-QS Certified Operator, the certificate shall be suspended immediately. 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, so long as common topics have been checked and the food/feed chain category (D, K, FI, 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.

8. CLASSIFICATION OF NON-CONFORMITIES AND RECOMMENDATIONS

8.1. 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 significant 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 (3) minor nonconformities associated with the same requirement, or issues could demonstrate a systematic failure and thus constitute a major nonconformity.**

8.2. 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 and does not affect the capability of the management system to achieve the intended absolute results. More than three (3) minor non-conformities under the same clause shall be considered as major.

8.3. Consequences of non-conformities

TABLE 2: CONSEQUENCES OF NON-CONFORMITIES

TYPE	INITIAL AUDIT	SURVEILLANCE (including unannounced audits)	RE-CERTIFICATION AUDIT
Major	Certification cannot be granted. An action plan shall be submitted within seven (7) days after the audit. Non-conformities shall be closed within six (6) weeks after the audit	The action plan shall be presented to the Certification Body in fourteen (14) calendar days at the latest after the audit date. 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. 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.	Certification cannot be granted. An action plan shall be submitted within seven (7) days after the audit. Non-conformities shall be closed within six (6) weeks after the audit.
Minor	Certification cannot be granted until the non-conformities have been closed. An action plan shall be submitted within seven (7) days after the audit. Non-conformities shall be closed within six (6) weeks after the audit	Certification continues. The Certification Body shall indicate acceptability of the action plan within fourteen (14) calendar days of receipt of the action plan from the Operator. 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.	Certification continues. The Certification Body shall indicate acceptability of the action plan within fourteen (14) calendar days of receipt of 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 cannot be closed by then, it becomes a major non-conformity.

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. ASSESSMENT OF SUPPLIERS AND ASSURED SOURCES

Any raw material/traded product which enters the manufacturing process or trade of any product under the FAMI-QS scope shall be assessed according to chapter 8.6. of the FAMI-QS Code of Practice.

9.1. Audit guidelines for supplier audits

a. The frequency of the audits shall be at least every three (3) years.

b. The first audit shall be conducted no later than six (6) months after the first raw material delivery.

c. Audits shall be conducted by experienced employees (according to the Operator's procedures) or by a capable 3rd party auditor (according to the selection criteria established in Section 7 of the "Rules for Certification Bodies").

d. Relevant sections of the FAMI-QS Code of Practice shall be checked and audit reports, including follow-up procedures on actions, shall be available.

Note on the "experienced employees": An experienced employee is the employee that can demonstrate competences related to the following aspects:

- ***Knowing the importance of the quality of the raw material for the production process.***
- ***Understanding the principles of a Feed Safety and Quality Management System.***
- ***Knowing auditing techniques.***

It is the FAMI-QS external auditor's responsibility to check that the requirements set according to the FAMI-QS Code of Practice are met.

10. FEED SAFETY INCIDENT MANAGEMENT

If the FAMI-QS Certified Operator becomes aware or has reason to suspect a feed safety incident, or in the event of a product recall in relation to such incidents, the FAMI-QS Certified Operator shall immediately make the FAMI-QS ASBL Secretariat and the Certification Body aware of the situation.

Together with the FAMI-QS Certified Operator, the Certification Body in turn shall take appropriate action steps to assess the situation and any implications that there may be for the Operator's certificate.

The Certification Body shall inform FAMI-QS ABSL Secretariat of the result from this assessment and its further progress.

The FAMI-QS Certified Operator and the Certification Body shall follow the *P-CM-01 – Feed Safety Incident and Crisis Management Procedure for Operators and CBs.*

11.CERTIFICATE

11.1. Text on the certificate (minimum information):

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 OF PRACTICE (VERSION X, YYYY-MM-DD) and

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

ON THE FOLLOWING SITE/S[1] XXX

FAMI-QS SITE REGISTRATION: FAM-XXXX/XX

FOR ACTIVITY[2] OF SPECIALTY FEED INGREDIENTS FROM PROCESS[3]

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

FEED CHAIN CATEGORY[4] 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

(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.

(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 sold directly to the farm
- **FI:** when Operators trade their own products
- **FII:** when Operators trade products not produced by themselves

11.2. Certification Status Changes

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 about 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.

11.3. 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 website 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.

11.4. 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.

11.5. Global Invoicing Sites / Sales offices

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 table 3.

TABLE 3: AUDIT MAN-DAY CALCULATION INVOICING SITES/SALES OFFICES

	A	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 manufactured) by the Operator.**
- **All the production sites that deliver to the customers of their global invoicing sites/sales offices are FAMI-QS Certified (certification 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 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, and**
- **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 (products, customer requirements), and**
- **Overview of local complaints (if applicable).**

11.6. Transfer of Accredited/Non-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. 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. FAMI-QS Secretariat will communicate any open issues related to the transfer of the certificate. This could include open NCRs, failure to submit corrective actions, etc.

Note: Only the FAMI-QS Accredited/Authorized Branch of the Certification Body -and not the regional sales offices- can get in touch with the FAMI-QS Secretariat for pre-approval. The Certification Body shall contact the Secretariat once they have confirmed their ability to transfer the certificate. If the Certification Body cannot take over the certification, there is no need for confirmation.

11.6.1. 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 available 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 authorised FAMI-QS Certification Bodies shall notify FAMI-QS via email to 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 - IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems*.

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, if 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 audit reporting platform, and for this a dedicated pre-transfer review report/checklist has been created.

11.6.2. PRE-TRANSFER REVIEW

The pre-transfer review report is available on FAMI-QS report 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.

12. TRANSPARENCY

FAMI-QS is expected to answer any questions concerning the products covered under the certificate.

13. SURVEILLANCE PROGRAMME

The objective of the Surveillance Programme is to establish the level of confidence in the Certification Body's certification process by on-site and off-site observations. Details of the Surveillance Programme may be found in *P-SP-01 Surveillance Programme*.

Part of the Surveillance Programme could be undertaken at a FAMI-QS Certified Operator's site, and a representative of FAMI-QS could be present. The FAMI-QS representative is there to monitor the activities of the Certification Body and its associated auditor(s). The surveillance process is compulsory for all the authorized Certification Bodies. The results of the FAMI-QS surveillance program will always be communicated to the Accreditation Body related to the Certification Body.

14. SANCTIONS

In case of violations by FAMI-QS Certified Operator(s) and or any other requirement set out in the applicable Documents, FAMI-QS also has the right to impose, as its own option, one or more of the following sanctions:

- **A formal warning: the FAMI-QS Certified Operator shall provide its written feedback within seventy-two (72) hours after the sending of the formal warning,**
- **Special audit with a prior note of twenty-four (24) hours,**
- **Recommendation to the Certification Body for a suspension or withdrawal of the certificate, and/or**
- **Suspension from the FAMI-QS Certification system for a time period or for a lifetime.**

15. NOTIFICATION OF CHANGES

A FAMI-QS Certified Operator shall inform 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 on 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 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 FAMI-QS Certified Operator with a revised approval letter.

16.USE OF LOGO

The FAMI-QS name and logo may only be used by FAMI-QS Certified Operators that have obtained certification from a Certification Body recognized by FAMI QS ASBL. The right to use the FAMI-QS logo and/or name is exclusively granted by FAMI-QS ASBL 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 always constitute proof that the Operator is certified.

The FAMI-QS logo is available upon request made to FAMI-QS ASBL 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

FAMI QS®

The Quality and Safety System for
Specialty Feed Ingredients