

Rules for Certification Bodies

Version 7 / 2013-03-08



TABLE OF CONTENTS

0.	Introduction	4
1.	Assessment and recognition of Certification Bodies by FAMI-QS Asbl	4
2.	Requirements for auditors	6
2.1	Nomination of auditors	6
2.1.1	Responsibilities of Lead Auditor / Auditor	7
2.1.1.1	<i>Responsibilities of the Lead Auditor</i>	7
2.1.1.2	<i>Responsibilities of the Auditor</i>	8
2.2	Maintenance of auditor nominations.....	8
2.3	Auditors nomination renewal	8
3	Assessment of Operators	9
3.1	Auditing Time Calculation	9
3.1.1	Initial Auditing Time Calculation.....	9
3.1.2	Auditing Time Calculation for Surveillance audit and Re-Certification	10
4	Audit planning	10
4.1	Initial Certification Audit	11
4.1.1	Stage 1 Audit approach	11
4.1.2	Stage 2.....	12
4.2	Subcontractor.....	12
4.3	FAMI-QS Logo	13
4.3.1	Use of Logo.....	13
5	Special audits.....	13
5.1	Extension to the scope	13
5.2	Investigation of an complaint and/or an incident	14
6	Frequency of audits and re-certification	14
7	Classification of non-conformities and recommendations	14
7.1	Critical non-conformities	14
7.2	Major non-conformities	15
7.3	Minor non-conformities	15
7.4	Opportunity for improvements (recommendations)	15
7.5	Consequences of non-conformities	16
8	Requirements for decision maker	16
9	Assessment of raw materials / traded product / suppliers	17
10	Feed Safety Incident Management.....	19
11	Certification decision and certificate	20
11.1	Text of the certificate	20
11.2	Withdrawal of certificates.....	21

11.3	Suspended Certificates.....	21
11.4	Expired certificates.....	21
12	Exclusions on certificates	21
13	Evaluation of compliance with the FAMI-QS Code.....	22
14	Audit.....	22
14.1	Audit summary report	22
14.2	Audit documentation	23
14.2.1	<i>Initial Certification Audit/ Re-Certification Audit</i>	24
14.2.2	<i>Surveillance Audit:</i>	24
15	Contractual requirements and training of Certification Bodies / Auditors	24
16	Certification Instructions	25
17	Surveillance Programme	25
18	FAMI-QS Certified Companies	26
19	Notification of Changes.....	26
20	Additional Applicable Procedures	26

0. Introduction

These rules address the requirements for Certification Bodies (CBs), their personnel and the way they shall perform assessments and certifications. This document is the only applicable document for the CB.

FAMI-QS certification is based on the FAMI-QS Code of Practice. The only valid version of the Code is the English version, published on the FAMI-QS Asbl website (www.fami-qs.org).

FAMI-QS Certification is a Feed Safety Management System certification (including Good Manufacturing Practices) for the sector of Specialty Feed Ingredients and their Mixtures. The aim of FAMI-QS certification is Feed Safety Management and it shall not be confused with a Quality Management System.

FAMI-QS certification as a Feed Safety Management System is open to any ISO/IEC 17021 and ISO/TS 22003 accredited Certification Body established worldwide, on the basis that the body is a legal entity and will be restricted to the declared scopes, activities and locations.

The Certification Body is responsible for the complete execution of the assessment of an Operator seeking FAMI-QS certification, including activities such as audit planning, assessment of documents, audit visit/s, reporting and certification.

The terms 'FAMI-QS' and 'FAMI-QS Asbl' are used interchangeably in this document.

1. Assessment and recognition of Certification Bodies by FAMI-QS Asbl

Certification Bodies that wish to obtain a licence to carry out FAMI-QS certification shall apply to the FAMI-QS Asbl Board, providing details for eligibility according to the established selection criteria. The application form is available on the FAMI-QS website (<http://www.fami-qs.org/certificationbodies> under application form for CBs).

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

- a. Copy of the application to any EA and/or IAF signatory accreditation body to include FAMI-QS under their current accreditation for management system certification.
- b. Accreditation Certificates ISO /IEC 17021 and ISO/TS22003.
- c. Proof of working in the feed and food sector (reference documents showing experience in feed/food).
- d. List of potential auditors and their qualification, including contact details *etc.*
- e. Certification procedure for FAMI-QS.
- f. List of the Certification Body's critical locations

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

The FAMI-QS Board decides on approval/non-approval within 4 months following the recommendation of the FAMI-QS Quality Manager. The decision is without appeal.

Note on Critical Location

Critical locations are those locations at which the Certification Body performs key-activities for FAMI-QS certification.

FAMI-QS considers the following as key activities:

- 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.
- Issue of the certificate.

The above key activities can take place in one or in several locations.

As an integral part of their contractual agreement with FAMI-QS Asbl, the recognised Certification Bodies will pay an annual fee to FAMI-QS. Fees between Operators and Certification Bodies are at the discretion of both parties.

Upon approval, the applying Certification Body shall agree to contractual provisions (co-ordination, reporting and fee obligations) and shall attend a full auditor training session provided by FAMI-QS.

Fully licensed status is achieved following endorsement of the contract by the Certification Body and FAMI-QS. Only contracted Certification Bodies are entitled to certify Operators according to FAMI-QS.

No Certification Body is allowed to grant a FAMI-QS certificate without a licence from FAMI-QS Asbl. Only FAMI-QS certificates issued by recognised Certification Bodies will be recognised by FAMI-QS Asbl.

Once a Certification Body has been approved, its name and contact details are published by FAMI-QS Asbl, in a public register that is available via the FAMI-QS Asbl website.

Approval of a Certification Body and its presence in the register is subject to the respect of the contractual agreement between FAMI-QS Asbl and the Certification Body.

In case of violation of contractual agreements, FAMI-QS Asbl may decide to withdraw recognition from the Certification Body, following a written notification to the Certification Body.

As part of their contractual obligations, the recognised Certification Bodies shall inform FAMI-QS Asbl of the name and details of the auditors appointed to conduct FAMI-QS audits.

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 in the strictest confidence by FAMI-QS Asbl.

The Certification Body shall notify FAMI-QS of any changes in the information provided in the application or of any changes in circumstances that are relevant to the requirements for Certification Bodies, within 8 weeks of the changes having taken place.

2. Requirements for auditors

2.1 Nomination of auditors

The Certification Body shall have, within its Operator, personnel with sufficient competence for managing the process for certification of schemes covering specialty feed ingredients and their mixtures.

The auditors shall demonstrate compliance with the following requirements (as shown on the table) by providing documentation through its Certification Body:

Parameter	Auditor	Lead Auditor
Education	post-secondary education (biology, chemistry, food engineering, pharmacy, agricultural engineering).	Same as auditor.
Knowledge	Food/feed microbiology, food safety, chemistry, animal nutrition, animal production, GMP, HACCP, Feed Safety Management Systems.	Same as auditor
Total work experience	4 years within the sector of feed/food.	Same as auditor.
Work experience in Feed Safety Management Systems	At least 2 years of the total 4 years.	Same as auditor.
Feed safety training	HACCP principles, hazard assessment, hazard analysis, food/feed safety management principles including PRPs, FAMI-QS Code, annual FAMI-QS meeting of the Recognised CB Platform.	Same as auditor.
Auditors training	Audit techniques based on ISO 19011, FAMI-QS Code.	Same as auditor.
Audit experience in Feed/Food Safety Management Systems	12 feed/food SMS Audits in the last 3 years. 4 out of 12 shall be FAMI-QS audits or audits of equivalent schemes Equivalent schemes: GMP, GMP+, UFAS/FEMAS, ISO 22000 scope L, ISO 22000 scope F, and ISO 9001 (scope 03, 12, 13) +HACCP, ISO 9001 (scope 13) +HACCP.	Five complete FAMI-QS audits or audits of equivalent schemes in the role of an audit team leader, under the Direction and guidance of an auditor who is competent as an audit team leader.

- a. A formal procedure for the auditors' approval shall be in place.
- b. Before the final nomination of the auditor the Certification Body shall communicate the potential auditor(s) to FAMI-QS.
- c. FAMI-QS will provide feedback to the CB on the qualifications of the auditor(s). The final decision on the approval of the auditor(s) rests with the CB.
- d. The auditor may not, within a period of two years prior to the audit, have undertaken any consultancy and/or training activities with the company to be audited, and shall confirm this independence.
- e. Upon the approval of the auditor, FAMI-QS will issue a certification card and post it to the auditor. The nomination of the auditor remains valid for 4 years.

Terms of use for the auditor's certification card

- The "*auditor certification card*" remains the property of FAMI-QS Asbl.
- The card is provided by FAMI-QS Asbl free of charge.
- The card is strictly personal.
- The Certification Body shall ensure that, in case an auditor's nomination is suspended or withdrawn during the period of the validity of the card, it will collect the card and return it to FAMI-QS Asbl.
- The card renewal is a responsibility that rests with FAMI-QS, according to the information that is provided in "*auditors nomination renewal*", as described in chapter 2.3.

FAMI-QS may invite auditors to participate in a training session. The participation is required for all approved FAMI-QS auditors.

2.1.1 Responsibilities of Lead Auditor / Auditor

The Certification Body shall make aware the Lead Auditor and Auditor about their responsibilities under FAMI-QS certification.

2.1.1.1 Responsibilities of the Lead Auditor

- a. Assist with the application review.
- b. Assist with the audit team selection.
- c. Assist with the audit planning activities.
- d. Conduct document review.
- e. Conduct Stage 1 and Stage 2 audits.
- f. Conduct the opening and closing meeting for the initial certification audit.
- g. Conduct surveillance audit and re-certification audit.
- h. Prepare and submit the audit report.
- i. Decide on certification (the lead auditor shall not be member of the audit team).

2.1.1.2 Responsibilities of the Auditor

- a. Assist with the application review.
- b. Assist with the audit team selection.
- c. Assist with the audit planning activities for surveillance and re-certification audit.
- d. Assist with the audit planning activities re-certification audit (only if the auditor was part of the audit team for the initial certification audit).
- e. Conduct document review for surveillance and re-certification audits.
- f. Conduct Stage 1 and Stage 2 audits as member of the audit team.
- g. Conduct the opening and closing meeting for surveillance audit when a lead auditor is not part of the audit team.
- h. Conduct the re-certification audit, only if the auditor was member of the audit team of the initial certification audit.
- i. Prepare and submit the audit report.
- j. Decide on certification (the auditor shall not be member of the audit team).

2.2 Maintenance of auditor nominations

In order to maintain his or her nomination as an auditor for four years, he or she needs to fulfil at least one of the following conditions annually:

- a. Take part in two FAMI-QS audits as a Technical Expert, an Auditor or a Lead Auditor and attend a two day long FAMI-QS training, organized either by the Certification Body or by FAMI-QS Asbl.
- b. Take part in two GMP+ FSA GMP+B1, GMP+ B2(2010) or GMP+ B3(2007) audits, as a Technical Expert , an Auditor or a Lead Auditor and attend a two day long FAMI-QS training, organized either by the Certification Body or by FAMI-QS Asbl.
- c. Take part in in four ISO 22000 audits with scope L or F and/or ISO 9001 scope 03, 12, 13 as an Auditor or a Lead Auditor and attend a two day long FAMI-QS training, organized either by the Certification Body or by FAMI-QS Asbl.

The number of required audits can be reduced by one, if a seminar/conference/training relevant to the FAMI-QS scope (other than one provided by the Certification Body or by FAMI-QS) has been attended.

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

2.3 Auditors nomination renewal

Prior to the expiration of an auditor's nomination, the Certification Body shall submit the following information (auditor renewal data sheet) to FAMI-QS:

- a. Audits conducted during the nomination period. (FAMI-QS, GMP+, ISO 22000 scope L and F, ISO 9001 scope 03, 12, 13).
- b. FAMI-QS training attended during the nomination period.
- c. Conferences, seminars, training sessions attended during the nomination period.

3 Assessment of Operators

The Certification Body assesses the Operators' compliance with FAMI-QS, on the basis of initial, surveillance and re-certification audits.

3.1 Auditing Time Calculation

3.1.1 Initial Auditing Time Calculation

A	B	C	D ⁽⁴⁾	E ⁽⁴⁾	F
Basic audit time					
For producers: 1 manufacturing process ⁽¹⁾ For traders: 1 product category ⁽²⁾	For producers: For each additional manufacturing process ⁽¹⁾ For traders: For the total number of additional product categories ⁽²⁾	For producers and traders: For the total number of assured / non-assured sources ⁽³⁾	In absence of certified relevant management system	Number of employees	For each additional site visited, operating similar manufacturing processes
1.5 day	0.5 day	Assured: 0-50: 0 day 51-100: 0.25 >100: 0.5 Non-assured: 0-30: 0 day 31-60: 0.5 61-100: 0.75 >100: 1	0.25 day	1 to 19 = 0 day 20 to 49 = 0.5 50 to 79 = 1.0 80 to 199 = 1.5 200 to 499 = 2.0	50 % of minimum on site audit time

⁽¹⁾ According to the processes described in Guidance – Annex 1: standard fermentation process – mining process – standard processes for the manufacture of premixtures – Chemical processes – Extraction process.

⁽²⁾ According to the Scope Description document P-SCD-01, products category are defined as the following: Feed additives (FA) with the following 5 categories, Technological – Sensory – Nutritional –

Zootechnical – Coccidiostats and Histomonostats – Functional Feed Ingredients (FFI) – Specialty Complementary Feed (SCD) and Specialty Complementary Dietetic Feed (SCDF).

⁽³⁾ According to chapter 9 “Assessment of raw materials / suppliers” of the Rules for CBs resp. for Operators.

⁽⁴⁾ Columns D and E are not applicable if a certified management system, e.g. ISO 9001, is already in place

Legend of the table for auditing time calculation

A: Basic audit time for producers or traders of specialty feed ingredients and their mixtures.

B: Additional auditing time for additional manufacturing processes or total additional traded product categories

C: Additional auditing time based on the total number of assured/non-assured sources.

D: Additional auditing time in absence of relevant certified systems.

E: Additional auditing time in absence of relevant certified systems according to the number of employees.

F: Auditing time reduction for additional sites operating similar manufacturing processes.

Note to the auditing time calculation

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

3.1.2 Auditing Time Calculation for Surveillance audit and Re-Certification

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

4 Audit planning

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

Before the stage 1 audit for initial certification, the Operator shall provide the Certification Body (in written, electronic form or during a meeting between the Operator and the auditor) with the following documentation:

- a. Approval letter from FAMI-QS.
- b. List of products under the FAMI-QS scope.
- c. List of assured and non-assured sources / traded products.
- d. Information about production site(s).

- e. Audit report from the subcontractor(s) (toll manufacturer(s), supplier(s)...- if applicable, section 9 step D).
- f. Information about subcontractor(s) covered under the Feed Safety Management System of the Operator.
- g. Relevant organisational charts and process descriptions
- h. Feed Safety Manual
- i. Any other information the auditor/Operator may find useful /or relevant

Note to the list of products

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 feed business Operator that all products shall be part of the audit. Special attention shall be given to products which are already authorized as feed additives.

4.1 Initial Certification Audit

4.1.1 Stage 1 Audit approach

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

- a. The Feed SMS is aligned with the requirements in the FAMI-QS Code.
- b. The Operator has identified PRPs that are appropriate to the business.
- c. Evaluate the audit report on audits carried out at the supplier premises (if applicable).
- d. Evaluate the audit report on audits carried out at the subcontractor (if applicable).
- e. The Feed SMS includes adequate processes and methods for the identification and assessment of the Operator's feed safety hazards as well as the subsequent selection and categorization of control measures according to the FAMI-QS code.
- f. The Operator complies with the relevant feed legislation.
- g. The Feed SMS is designed to achieve the Operator's feed safety policy.
- h. The Feed SMS implementation programme allows to proceed to stage 2 of the audit.
- i. The validation, verification and improvement programmes are conformed to the requirements of the FAMI-QS Code
- j. The Feed SMS documentation is in place and its requirements are internally and externally communicated (relevant suppliers, customers, other interested parties *etc.*).
- k. Additional documentation needs to be reviewed /or which knowledge needs to be obtained in advance.

It is the responsibility of the Certification Body to decide if Stage 1 will take place on the premises of the CB or of the client. Justification of the decision is required.

The findings in Stage 1 shall be documented and communicated to the client. The findings of Stage 1 do not include Non Conformities.

The stage 2 audit shall be conducted within six months after the date of Stage 1. In case that the stage 2 is not conducted within six months, the stage 1 audit must be repeated.

A stage 1 audit is required for the initial certification audit.

A stage 1 audit might apply for the re-certification audit when major changes in the Operator's Feed Safety Management system have occurred.

4.1.2 Stage 2

A stage 2 audit takes place at the location of an applicant who seeks certification against the FAMI-QS Code. All sections of the FAMI-QS code shall be verified.

The stage 2 audit takes place at the Operator's site. The purpose of the stage 2 audit is:

- a. To confirm the implementation, including the effectiveness of the Operator's Feed Safety Management System to the requirements of the FAMI-QS Code.
- b. To verify that the information and evidence of conformity is achieved, for all of the FAMI-QS Code's requirements.
- c. To assess the capability of the Feed Safety 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 Management System, in compliance with EU and local statutory, regulatory and contractual requirements.
- e. To confirm that the Operator's Feed Safety 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 shift-work is performed, an interview can be planned outside normal working hours.

4.2 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 Operator shall evaluate the risk connected to the Operator's

service and, if relevant, perform a full audit, in order to ensure that the subcontractor meets the FAMI-QS requirements. Thus, the Operator shall audit the establishment of the subcontractor against FAMI-QS requirements. A report shall be made available.

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.

4.3 FAMI-QS Logo

The Certification Body needs to confirm that the FAMI-QS logo is used by the certified company according to the FAMI-QS requirements (Rules for Operators). A statement on the correct use of the FAMI-QS logo shall be included in the audit report's "*General Assessment*" section.

4.3.1 Use of Logo

The FAMI-QS name and logo may only be used by Operators that have obtained certification from a Certification Body recognised 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.

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 FAMI-QS Asbl and/or to the relevant Certification Body. It may be used only in its original colours and proportions.

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

5 Special audits

5.1 Extension to the scope

In response to an application (changes notification form D-ROP-01-03) for the extension of the scope of a certification that has already been granted, the Certification Body shall undertake a review of the application and determine any audit activities that may be deemed necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance or re-certification audit.

5.2 Investigation of an complaint and/or an incident

It may be necessary for the Certification Body to conduct audit of certified Operator at short notice, in order to investigate a complaint or in response to a feed safety incident or crisis at the Operator's site or as a follow-up on suspended certificate(s). In such cases:

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

6 Frequency of audits and re-certification

Initial certification, surveillance and re-certification audits may be combined with audits of other management systems. The frequency of surveillance audits for single site certification will never be below one audit per year.

Re-certification is carried out at the end of a certification period (3 years), in order to assess whether the Operator continues to meet the requirements of the FAMI-QS Code.

- a. **1st Surveillance Audit:** within 12 months after the Initial Certification Audit.
- b. **2nd Surveillance Audit:** approximately 24 months after the Initial Certification Audit.
- c. **Re-Certification Audit:** 36 months after the Initial Certification Audit. A re-certification audit takes place prior to end of a certification period. The audit shall be planned in due time, in order to avoid expiration of the certificate.

Note on the re-certification audit

- A failure to perform the re-certification audit before the expiration of the certificate results in the interruption of the certification cycle. In this case, the wording "*certified since*" cannot be included on the certificate.
- If a re-certification is conducted after the expiry of a certificate, a Stage 1 and Stage 2 Audit shall be carried out.

7 Classification of non-conformities and recommendations

7.1 Critical non-conformities

A critical non-conformity exists when the auditor observes a regulatory violation or a feed safety failure which requires that the Operator:

- a. Immediately interrupts production.
- b. Holds products in quarantine.
- c. Discontinues shipping to customers.
- d. Recalls the product.

Examples could include:

- Violations of European and/or national legislation.

- Direct observation of products being produced, packed or held in a manner which poses a clear threat to animal and/or human health, *e.g.* safety of raw material or/product cannot be assured.
- Discovery of records showing that products are being or have been produced in a manner which poses a clear threat to animal and/or human health.
- The product is adulterated because it contains an added poisonous or deleterious substance; *e.g.* melamine.

7.2 Major non-conformities

A major non-conformity is a complete failure to implement a requirement of the Code.

Examples could include:

- Failure to implement HACCP principles.
- Failure to implement a recall procedure.
- An imminent feed/food safety hazard exists.
- Failure to implement the raw material assessment according to the chapter 9 “Assessment of raw materials / supplier” of the Rules for CBs resp. for Operators.

7.3 Minor non-conformities

A minor non-conformity exists when a requirement of the FAMI-QS Code has been addressed but there is insufficient evidence to demonstrate that it has been properly controlled or implemented.

Examples could include:

- Failure to prove, that in connection with the FAMI-QS Feed Safety Incident and Crisis Management Procedure, the required notification form and progress report has been sent to FAMI-QS.
- Adequate cleaning is clearly taking place but records of evidence are not available.
- The HACCP plan is obviously effective but a documented review has not taken place in the last year.

7.4 Opportunity for improvements (recommendations)

In addition to non-conformities, opportunities for improvements may be made by an auditor according to his observations, with a view to help the continuous improvement of the Operator’s Feed Safety Management System.

The basic requirement to identify and to record improvement opportunities is that the requirements of the FAMI-QS Code have been fulfilled but there are still areas for potential improvement of system effectiveness and efficiency.

Opportunity for Improvement will be checked during the following regular audit.

7.5 Consequences of non-conformities

Non-conformity	Initial audit	Surveillance or Re-certification audit
Critical	Certification cannot be granted until the non-conformities have been closed.	Certification will be temporarily suspended and cannot be re-instated until the non-conformities have been closed. In case the non-conformities are not resolved within the maximum suspension period of 72 calendar days, the certificate will be withdrawn.
Major	Certification cannot be granted until the non-conformities have been closed.	Certification continues. The action plan shall be presented to the Certification Body, at the latest 14 calendar days after the audit date. Evidence that non-conformities have been closed will be checked 28 days after the presentation of the action plan at the latest. If a non-conformity is not resolved and closed by then, it becomes a critical non-conformity.
Minor	Certification cannot be granted until the non-conformities have been closed.	Certification continues. An agreement on the action plan shall be reached between the Certification Body and the Operator. The deadline for this agreement is 28 calendar days after the Certification Body has received the action plan from the Operator. Evidence that non-conformities have been closed will be checked by the auditor, at the latest during the following audit. If the non-conformity is not solved and closed by then, it becomes a major non-conformity.

The auditor shall confirm that he has reviewed, accepted and verified the effectiveness of corrective actions.

8 Requirements for decision maker

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

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

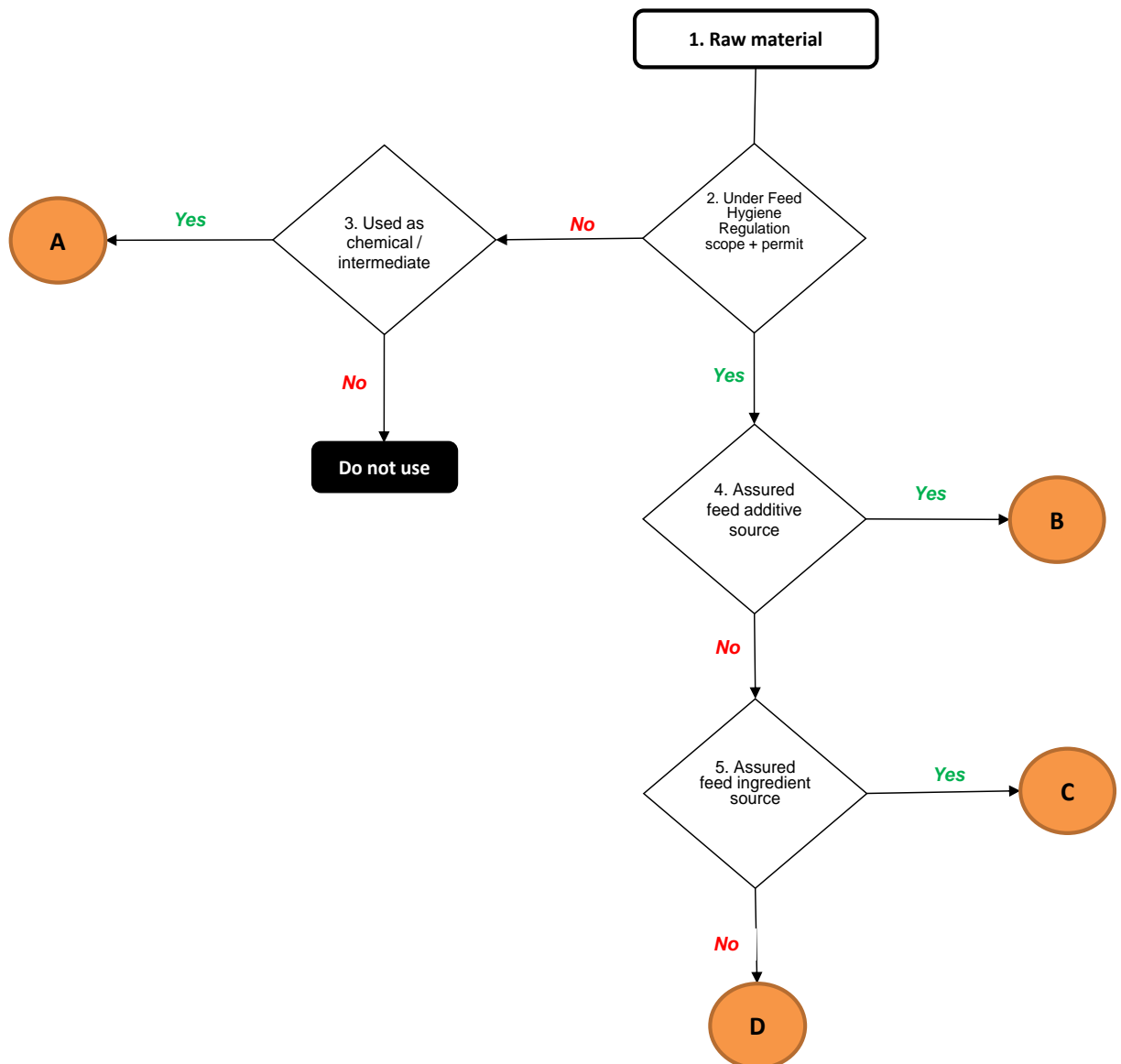
The competence person shall be able to demonstrate compliance with the same requirements as the FAMI-QS auditor.

9 Assessment of raw materials / traded product / suppliers

Any raw material / traded product which enter the manufacturing process or trade of any product under the FAMI-QS scope shall be assessed according to chapter 7.4.1 of the FAMI-QS Code.

Depending on the nature of the product and the certification status of the supplier, the requirements ensuring that the raw material is assured for its intended use will be different.

The decision shall be made according to the following chart and table:



Step	Action
1	Define all of the raw materials that enter the production process of all products under the FAMI-QS scope.
2	Is the raw material regulated according to 183/2005? If yes, go to step 4 If no, go to step 3
3	Is the raw material used as a chemical / intermediate? If yes, go to A If no, don't use the raw material
A	Apply the management requirements from a to f and from h to j of chapter 7.4.1 of the FAMI-QS Code <i>e.g. solvents</i>
4	<ul style="list-style-type: none"> • Is the supplier certified according to FAMI-QS? If yes, go to B • Is the supplier certified according to a mutual recognized code? If yes, go to B The relevant Codes are published on the FAMI-QS website. • Is the supplier certified according to GMP Pharma with the product name included (API)? If yes, go to B • Is the supplier certified according to ISO 9001 and does he have a documented HACCP programme (food or feed) in place, for the production of the raw material? If yes, go to B • Is the supplier certified according to ISO 22000? Is the raw material also compliant with a JECFA (Joint FAO/WHO Expert Committee on Food Additives) specification? If yes, go to B <p>If none of the above mentioned requirements can be met, go to step 5.</p>
B	Apply the management requirements from a to j of chapter 7.4.1 of the FAMI-QS Code. <i>e.g. ethoxyquin, antioxidants</i>
5	Is the raw material of food grade quality? If yes, go to step C If no, go to step D
C	Apply the management requirements from a to j of chapter 7.4.1 of the FAMI-QS Code. <i>e.g. gelatine, sugar</i>
D	Apply both, the management requirements from a to j and the realization requirements from k to l of chapter 7.4.1 of the FAMI-QS Code. Perform also an audit at the supplier's production location.

Note for Brazilian Operators

FAMI-QS recognizes Brazilian Operators certified under “*Sindirações Level 2 domestic programme*” as an assured source for the ingredients which are not covered by the FAMI-QS scope.

Audit guidelines for supplier audits:

- a. The frequency of the audits shall be at least every 3 years.
- b. The first audit shall be executed no later than 6 months after the first raw material delivery.
- c. Audits have to be executed by experienced employees (according to the Operator’s procedures) or by a capable 3rd party auditor (according to the selection criteria established in the “*Rules for Certification Bodies*”).
- d. Relevant sections of the FAMI-QS Code 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 Management System.
- Knowing auditing techniques
- Have been for at least three years within the Operator.

It is the FAMI-QS external auditor's responsibility to check that the requirements set according to the previous flowchart and chapters 7.4.1 of the FAMI-QS Code are met.

10 Feed Safety Incident Management

In the event that the Operator becomes aware or has reasons to suspect a feed safety incident, or in the event of a product recall in relation to such incidents, the Operator shall immediately make the FAMI-QS Process Manager and the Certification Body aware of the situation.

Together with the 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 of the result from this assessment and its further progress.

The Operator and the Certification Body shall follow the “*Feed Safety Incident and Crisis Management Procedure for Operators and CBs*” (P-CM-01).

11 Certification decision and certificate

The information provided by the audit team to the Certification Body, for the certification decision, shall include, as a minimum:

- a. the audit report,
- b. comments on the non-conformities and, where applicable, the corrective actions taken by the client,
- c. recommendation from the auditor on whether or not to grant the certification, together with any conditions or observations.

If sufficient evidence to demonstrate compliance with the Code exists, a certificate shall be granted. The decision to issue a certificate remains the Certification Body's responsibility. A certificate is valid for a period of 3 years.

11.1 Text of the certificate

Operator's Name

has implemented and maintains a Feed Safety Management System including
Good Manufacturing Practice (GMP) in compliance with:
FAMI-QS Code (Version x, yyyy-mm-dd)
on the following site/s⁽¹⁾ :
XXX
for
Activity⁽²⁾
Scope⁽³⁾

This certificate is valid until: yyyy-mm-dd

Signature of the Certification Body: Place, Date yyyy-mm-dd

FAMI-QS Registration Number: FAM-xxxx

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.

⁽²⁾ Activity means: design and development - production - trading - placing on the market.

⁽³⁾ Scope:

- Feed Additives: The categories and functional groups of additives shall be indicated as they appear in Annex I of Regulation (EC) 1831/2003.

The below listed categories will appear on the certificate only as a category name:

- Functional Feed Ingredient
- Premixtures
- Specialty Complementary Feed
- Specialty Complementary Dietetic Feed

11.2 Withdrawal of certificates

The withdrawal of a certificate remains the responsibility of the Certification Body. Once a withdrawal is confirmed, the name of the Operator will be removed from the FAMI-QS “*Certified Companies register*” on the website: <http://www.fami-qs.org/certifiedcompanies>.

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

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

11.3 Suspended Certificates

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

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

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

11.4 Expired certificates

Once the validity date of the certificate has expired, the name of the company will still remain on the “*Certified Companies register*” on the FAMI-QS website <http://www.fami-qs.org/certifiedcompanies> for a period of one month. If, after this period, a renewed certificate has not been submitted to FAMI-QS Asbl, the name of the company will be removed from the FAMI-QS “*Certified Companies register*” which is published on the FAMI-QS website.

12 Exclusions on certificates

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

13 Evaluation of compliance with the FAMI-QS Code

The Certification Body will check the compliance with each clause of the FAMI-QS Code of Practice. For this purpose, auditors may use the checklist provided by FAMI-QS (also on FAMI-QS website, <http://www.fami-qs.org/code>).

In evaluating Operators for compliance with the Code, auditors shall use an audit schedule which includes:

- a. Review of the implementation of corrective actions for previous non-conformities and their effectiveness.
- b. Presentation of any organisational changes.
- c. Evaluation of process descriptions/documented procedures for conformity with the standard requirements.
- d. Evaluation of practical implementation of the Code.

The top management's commitment is estimated according to the strength of its understanding of both the Feed Safety Management System in place and of the FAMI-QS Code. The level of understanding of the system is determined in the course of a presentation by, and discussion with, the top management. Any non-conformity shall be discussed with the top management and the management representative. The same applies to the agreement on the corrective actions.

Documents consulted for audit purposes, including those reviewed during interviews, shall be identified in the audit record. Clearly identified document samples and any additional remarks are recorded to serve as a basis for the auditor's evaluation of the Operator, after the interviews.

Where auditors operate separately during an audit, each auditor shall keep his own audit record. Evaluation is undertaken on completion of separate stages or, where non-conformities are established, immediately after the assessment of the management element carried out by both auditors jointly. At the end of the assessment, the Lead Auditor receives the sections of the audit record completed by the co-auditor(s).

If the auditors wish to see confidential documents such as formulas or special job processes, they shall obtain the management representative's approval. Such documents are, however, not normally consulted.

14 Audit

14.1 Audit summary report

The report shall be based on the relevant guidance provided in ISO 17021, ISO 17022, ISO/TS 22003 and ISO 19011.

The report on the findings submitted to FAMI-QS Asbl shall be detailed enough to enable an understanding of the basis for the certification decision; it shall include the areas covered by the assessment, the opportunities for improvements and a summary of the non-conformities.

The audit report shall contain the audit evidence and audit findings summarizing the conformities with the requirements addressed by the FAMI-QS Code.

In the event that an audit evidence indicates that the audit findings lead to the identification of a non-conformity, this shall clearly be mentioned in the relevant chapter of the audit report.

Note on the Audit Evidence

The audit evidence shall be kept with audit documentation. If the audit is conducted by two or more auditors, the Certification Body shall be in a position to trace from which auditor the audit evidence comes from.

Audit evidence can be shown on the auditors' notes.

The report shall include a disclaimer statement to indicate that the auditing is based on a sampling of the available information and that consequently, there will always be an element of uncertainty present in the auditing evidence, which may be reflected in the audit findings. Those relying or acting upon the audit results and conclusions shall be aware of this uncertainty.

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

The Certification Body is responsible for:

- a. The contract between the Certification Body and the Operator which shall include a clause specifying that the summary report is sent confidentially to FAMI-QS Asbl.
- b. The decision to grant or not a certificate to an Operator is taken by the Certification Body.

The information obtained during the audit and recorded in the audit report will remain strictly confidential and will be made available only to representatives of the Certification Body and of FAMI-QS Asbl. Any information used for statistical evaluations shall be formulated without indicating any relation to the Operator involved.

In cases of unresolved disagreement between an Operator and a recognised Certification Body, the occurred circumstances shall be reported in writing by the Operator to FAMI-QS Asbl, in order to be evaluated by the FAMI-QS Quality Manager.

14.2 Audit documentation

Certification Bodies shall provide FAMI-QS with the following audit documentation:

14.2.1 Initial Certification Audit/ Re-Certification Audit

- a. Audit Plan /Agenda.
- b. FAMI-QS Audit Summary.Report
- c. Non-Conformities List.
- d. Signed Certificate.

14.2.2 Surveillance Audit

- a. Audit Plan / Agenda.
- b. FAMI-QS Audit Summary Report.
- c. Non-Conformities List

15 Contractual requirements and training of Certification Bodies / Auditors

In addition to the supervision carried out by the National Accreditation Councils, FAMI-QS supervises the competent, uniform and complete realisation of audits, both through statistical and random evaluations of audit reports and with annual harmonisation meetings for Certification Bodies.

Each Certification Body is required to ensure that every auditor undergoes at least 2 days of on-going relevant technical training/development per year, in order to both achieve professional development and also be aware of the developments occurring in quality assurance, as well as of the legal obligations relating to the animal feed sector.

FAMI-QS Asbl assures the co-ordination and general training of the recognised Certification Bodies, through annual meetings of the Recognised Certification Bodies Platform. The Certification Bodies are responsible for the auditors training.

As an integral part of their contractual agreement with FAMI-QS Asbl, the recognised Certification Bodies are obliged to:

- a. Participate in the annual meeting of the Recognised Certification Bodies Platform.
- b. Provide (under confidentiality) a copy of each audit summary report in English and issue the certificate.
- c. Report immediately to the FAMI-QS Quality Manager any non-conformity identified in periodical auditing, that leads to withdrawal of certification.
- d. Report immediately any feed safety incident/crisis situation to the FAMI-QS Process Manager. Report any crisis updates, including corrective actions taken and the final decision on the certification status of the involved Operator.

16 Certification Instructions

In an event that CBs are required to take certain actions that are not described in the current Rules, the FAMI-QS Quality Manager 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:

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

17 Surveillance Programme

The objective of the surveillance programme is to establish the level of confidence in the CB's certification process by on-site and off-site observations.

In the surveillance programme process, a representative of FAMI-QS monitors the activities of the Certification Bodies and its associated auditor(s) on the occasion of an assessment of a specific feed business Operator on site and / or at the Certification Body's premises. The surveillance process is compulsory for all of the authorized Certification Bodies. The surveillance process is considered beneficial to all stakeholders.

The surveillance programme consists of two parts:

Part 1: Office Audit - FAMI-QS conducts an assessment, at the Certification Body premises, to verify the implementation of the FAMI-QS rules.

Part 2: FAMI-QS conducts an assessment of a Certification Body's performance, during its on-site audit, with prior agreement of the Operator.

The CBs shall include in the contracts with their clients a relevant reference, for the on-site audit with the participation of the FAMI-QS auditor. A FAMI-QS certified Operator shall be aware that it might be selected for the FAMI-QS Surveillance Programme.

FAMI-QS may also initiate the Surveillance Programme in case of an Operator's complaint.

A copy of the Surveillance Programme audit report will also be made available to the Certification Body's local accreditation body.

Any exchange of information related to the purpose of the surveillance activities will be kept strictly confidential and shall only be communicated between the parties involved (FAMI-QS, Certification Body)

A National Accreditation Body could have access to the Surveillance Programme report after a request.

The information obtained during the surveillance of the Certification Body, which is recorded in the report, will be handled in a strictly confidential manner by FAMI-QS. FAMI-QS will not use it for purposes apart from those established in the frame of the surveillance process.

18 FAMI-QS Certified Companies

The Certification Body shall maintain a list with the FAMI-QS certified Operators or publish the certified companies on its internet website. The name of the Operators, the scope, the validity of the certificate and the country shall appear in the list or on the website.

19 Notification of Changes

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.

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

- a. The legal, commercial, organizational status or ownership.
- b. Operator and management changes
- c. Contact 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 Management System.

For changes regarding a, b, c, d, the FAMI-QS certified Operator needs to use the FAMI-QS Changes Notification form.

20 Additional Applicable Procedures

[1] P-CM-001 Feed Safety Incident and Crisis Management Procedure for Operators and CBs.

[2] P-SP-01 Surveillance Programme.