



Rules for Certification Bodies

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1. Introduction

FAMI-QS certification is based on the FAMI-QS Code of Practice for Feed Additive and Premixture Operators (the '**Code**'). The only valid version of the Code is the English version, published on the FAMI-QS Asbl web site (www.fami-qs.org).

FAMI-QS certification 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 confined to 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 such activities as audit planning, assessment of documents, audit visit/s, reporting and certification.

A certification body may offer FAMI-QS certification alone or certification to other quality management systems in addition.

The certification body agrees to publication of its name and address on the official FAMI-QS listing of licensed certification bodies on the FAMI-QS web site. The terms 'FAMI-QS' and 'FAMI-QS Asbl' are used interchangeably in this document.

2. Assessment and recognition of certification bodies by FAMI-QS Asbl

Certification bodies wishing to obtain the licence to carry out FAMI-QS certification shall apply to the FAMI-QS Asbl Board, providing details for eligibility according to established selection criteria. The application form is available on the FAMI-QS website (<http://www.fami-qs.org/documents.htm>).

The certification body applies, submitting required enclosures:

1. Accreditation Certificates , ISO/IEC 17021 and ISO/TS 22003
2. Field of work in food and feed (reference document with the experience in food/feed)
3. List of auditors and their qualification (s), contact details, etc.
4. Certification procedure for FAMI-QS
5. Copy of the application to the accreditation body to include FAMI-QS under their current accreditation for system certification

The Board makes an approval/non-approval decision within 4 months, further to the recommendation by the Expert Panel. Decision is without appeal.

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 applicant certification body must agree to contractual provisions (co-ordination, reporting and fee obligations) and must attend a full training session of auditors 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 approved, the name and details of the recognised certification bodies are gathered by FAMI-QS Asbl in a public register that is available via the FAMI-QS Asbl homepage.

Approval of a certification body and its inclusion in the register is subject to the respect of the contractual agreement between FAMI-QS Asbl and the certification body.

In case of non-respect of contractual agreement, FAMI-QS Asbl may decide to withdraw recognition from the certification body, following written notification to the company.

As part of their contractual obligations, the recognised certification bodies 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 strictest confidence by FAMI-QS Asbl.

The certification body must notify FAMI-QS of any change to information given in the application or any change in circumstances relevant to requirements for certification bodies (set out below) within 8 weeks of the change having taken place.

3. Requirements for certification bodies

The certification body shall demonstrably comply with the following requirements by providing documentation at application. The certification body shall give consent to being audited by FAMI-QS and commit to continuous co-operation with FAMI-QS.

Applicant certification bodies should be able to demonstrate:

- Formal demonstration of their competence to carry out specific conformity assessment tasks by a third-party accreditation to provide certification to the FAMI-QS Code. The third-party is preferably an accreditation body that is signatory to the multilateral agreements of EA or IAF.
- Proven commitment to EA and/or IAF Mandatory Documents applicable for ISO/IEC 17021 and ISO/TS 22003. Proven commitment to ISO 19011:2002.
- Proven experience in the feed industry (already conducting HACCP based audits in the feed business, for example FAMI-QS mutually recognized schemes or official inspection of feed business operators).
- Commitment to training and co-ordination obligations established by FAMI-QS Asbl.
- Commitment to selection of competent and suitably trained auditors, and the ongoing training of auditors.
- The certification body 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 should demonstrably confirm this independence.

4. Requirements for auditors

The certification body shall have as a part of its own organization personnel having sufficient competence for managing the certification process for the specialty feed ingredients and their mixtures

The auditors must demonstrably comply with the following requirements (as shown on the table) by providing documentation through its Certification body:

Parameter	Auditor	Lead Auditor
Education	University Degree	Same as auditor
Knowledge	Food/feed microbiology, food safety, chemistry, animal nutrition , animal production, GMP, Feed Safety Management Systems	Same as auditor
Total work experience	4 years	Same as auditor
Work experience in Feed Safety 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	Same as auditor
Auditors training	Audit techniques based on ISO 19011, FAMI-QS Code	Same as auditor
Audit experience in Food / Feed Safety Management Systems	4 FAMI-QS or equivalent audits in training under the direction of an auditor competent as a audit team leader	10 complete FAMI-QS or equivalent audits and 4 as an auditor in training under the direction of an auditor competent as a team leader

- 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 should demonstrably confirm this independence.
- FAMI-QS may invite the auditors to participate on a special training session. The participation is required for all approved FAMI-QS auditors.

5. Requirements for decision makers

The audit documentation of initial certification, surveillance, re-certification and special audits shall be approved by a third party auditor “competence person”. The competence

person should not participate in the audit team. In case of initial certification or re-certification audit the review by the competence person must be done before the issuing of the certificate.

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

6. Assessment of operators

The certification body assesses the interested operator for compliance with FAMI-QS on the basis of initial, surveillance and re-certification audits.

FAMI-QS will confirm the operator's annual membership fee payment to the CBs during the review of the audit documentation. Once the certification body has submitted the agreed information to FAMI-QS that shows that the operator has been successfully audited and certified, and the membership fee has been paid by the operator, the name of the operator and the address of the certified sites will be listed on the FAMI-QS web site in the list of certified operators.

7. Auditing planning

Before the on-site audit for initial certification, the operator shall provide the auditor (in written or electronic form, or during a meeting between the operator and the auditor) with the following documentation:

- Approval letter from FAMI-QS
- List of products
- Information about production site (s) and/or subcontractor
- Organisational charts and process descriptions
- Quality manual (paper or electronic version)
- Any other information the auditor/operator may find useful/relevant

The selection of executive and other personnel to be interviewed should adequately cover every relevant functional area. If shift-work is performed, an interview sample can be planned outside regular working hours

Subcontractors are subject the same approval criteria as any supplier to a FAMIQS certified operator. If the subcontractor is not FAMI-QS certified the operator must perform a full audit to ensure the contractor meets the requirements of FAMI-QS. In case that the subcontractor is certified according to FAMI-QS or a mutual recognized standard no audit is required as long as the applicable product falls under the scope of that certification. During the operators' certification and surveillance audits, the contractor may also be inspected by the certification body to verify compliance with FAMIQS requirements. On successful completion of the audit, certificates will be granted to the operator only

The audit duration is determined by the certification body / audit team according to the following:

Initial audit:

An initial audit takes place at the location of an applicant seeking certification against the FAMI-QS Code. It should be carried out by checking the whole sections of the FAMI-QS Code.

Basic audit time	Additional audit time	Deductible audit time
Auditing the documentary quality system (main office): min 4 hours	Auditing 1 manufacturing process ⁽¹⁾ : min 6 hours	Any reduction of time for companies certified against other standards must be negotiated between the operator and the certification body. The reduction will never be > 50% of the initial calculation time.
	Auditing 2 manufacturing processes ⁽¹⁾ : min 9 hours	
	Auditing 3 manufacturing processes ⁽¹⁾ : min 12 hours	
	Auditing 4 manufacturing processes ⁽¹⁾ : min 15 hours	
	Auditing 5 manufacturing processes ⁽¹⁾ : min 18 hours	
	Auditing a storage/distribution activity (without any manufacturing process involved): min 2 hours	

⁽¹⁾ According to classification on sections b) to f), Annex 1, FAMI-QS Guidance on Implementation.

Surveillance audit:

A surveillance audit is a periodical audit performed to ensure that an organization still meets FAMI-QS requirements.

Audit time for surveillance audits is set on $\frac{1}{3}$ of the initial audit time as a minimum. Depending on the previous audit results as well as the complexity of the products and or processes the CB defines the audit time together with the operator. A minimum time of 4 hours shall be applied.

Re-certification audit:

A re-certification audit takes place at the end of a certification period. The audit must be planned in due time in order to avoid expiration of the certificate. It should be carried out by checking all sections of the FAMI-QS Code.

Audit time for re-certification visits is set on $\frac{2}{3}$ of initial audit time as a minimum. Depending on the previous audit results as well as the complexity of the products and or processes the certification body defines the audit time together with the operator. A minimum time of 4 hours shall be applied.

Special audits:

It may be necessary that an audit is conducted by the certification body at short notice, in the following cases:

1. If the operator is involved in an incident
2. Follow up of the which is listed on the FAMI-QS website under review

8. Frequency of audits and re-certification

Initial certification, re-certification and surveillance 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 Code.

1st Surveillance Audit: Approximately 12 months after the Initial Certification Audit

2nd Surveillance Audit: Approximately 24 months after the Initial Certification Audit

Re- Certification Audit:36 months after the Initial Certification Audit

Multi-site certification is permitted under consideration of IAF Mandatory Document for the Certification of Multiple Sites Based Sampling (IAF MD 1:2007) and in consultation with the certification body.

9. Evaluation of compliance with the FAMI-QS Code

The certification bodies will check compliance with each clause of the FAMI-QS Code of Practice. For this purpose, auditors may use the check listed provided by FAMI-QS.

The initial certification audit will take place in two stages, Stage 1 and Stage 2, according to the requirements of ISO /IEC 17021 and ISO/TS 22003.

9.1 Non-conformities

Prior to completion of the audit record and in preparation for final discussion between the operator and the auditor, the observations of the auditor are to be evaluated. In the course of this evaluation, any nonconformities detected are to be classified as follows:

Critical non-conformity

A critical non-conformity exists where 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 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 such that it contains an added poisonous or deleterious substance; e.g. pesticides are being used inconsistently with the labelled directions.

Major non-conformity

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.

Minor non-conformity

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

Examples could include:

- 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.

Recommendation

In addition to non-conformities, recommendations may be made by an auditor based on his observations, with a view to aiding the continuous improvement of the operator's feed safety management system.

When evaluating non-conformities and recommendations, the following points should be considered:

- the general presentation of the assessed area or company
- implemented HACCP principles for ongoing improvement of feed safety
- the motivation of the management and employees
- elimination of former nonconformities
- understanding of the system within the different corporate levels
- behaviour of participants (open-mindedness, honesty, etc.)

9.2 Consequences of nonconformities

Critical: In case of a critical non-conformity, the auditor shall request (in writing) that the operator reports it to the relevant authorities, as required by EU Regulation 178/2002. Critical non-conformities automatically trigger a full audit to be performed before closure.

Major: closed upon evidence of correction (sometimes triggering a partial audit).

Minor: closed by the acceptance of the action plan by the auditor.

Recommendation: no closure necessary.

Consequences and close-out:

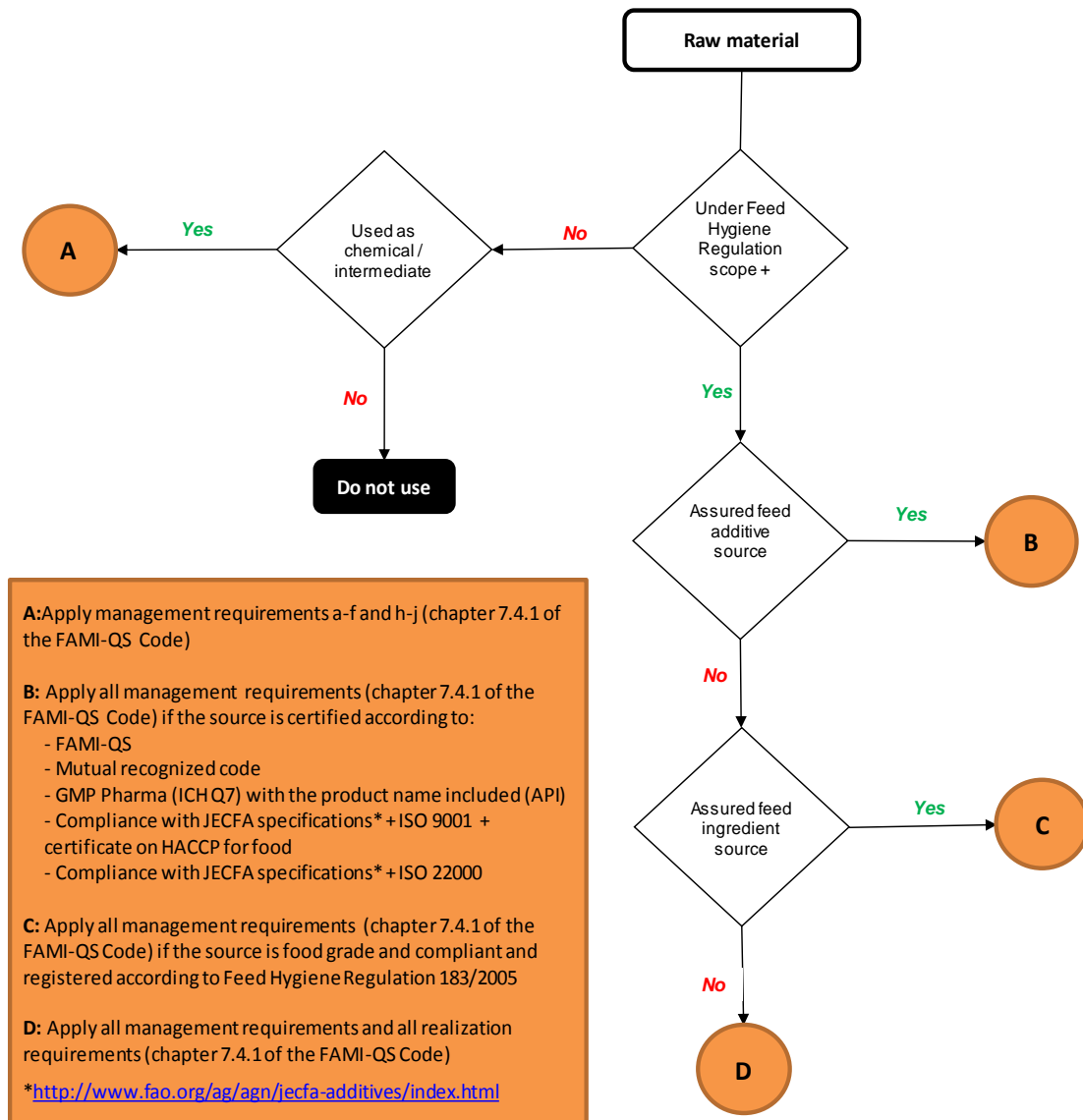
Non-conformity	Initial audit	Surveillance or Re-certification audit
<i>Critical</i>	Certification cannot be granted until the non-conformities have been closed.	<p>Certification will be temporarily suspended⁽¹⁾ and cannot be re-instated until the non-conformities have been closed.</p> <p>In case the non-conformities are not resolved within the maximum suspension period of 72 calendar days, the certificate will be withdrawn.</p>
<i>Major</i>	Certification cannot be granted until the non-conformities have been closed.	<p>Certification continues.</p> <p>The action plan must be presented to the certification body the latest 14 calendar days after the audit date.</p> <p>Evidence that non-conformities have been closed will be checked 28 days after the presentation of the action plan at the latest. In case a non-conformity is not resolved and closed by then, it becomes a critical non-conformity.</p>
<i>Minor</i>	Certification cannot be granted until the non-conformities have been closed	<p>Certification continues.</p> <p>An agreement on the action plan must be taken between the certification body and the operator; deadline for this agreement is 28 calendar days after the certification body has received the action plan from the operator.</p> <p>Evidence that non-conformities have been closed will be checked by the auditor during the next audit at the latest. In case non-conformity is not resolved and closed by then, it becomes a major non-conformity.</p>

⁽¹⁾ The suspension will be published in the "register of certificates under review" on the FAMI-QS website (<http://www.fami-qs.org/certifiedcompanies.htm>)

10 Assessment of suppliers and assured sources

This assessment shall be done 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 list of requirements (management requirements, realization requirements or other) will be different. Decision shall be made according to the following chart:



It is the FAMI-QS auditor's responsibility to check that the requirements set according to the previous flowchart and chapter 7.4.1 of the FAMI-QS Code are met. Failure from the operator to demonstrate compliance would constitute a critical non-conformity and consequently certification would be denied, or would result in withdrawal of a FAMI-QS certificate already issued to the operator.

Audit guidelines:

- In case realization requirements are requested, an audit at the supplier's location shall take place.
- The frequency of the audits shall be at least every 3 years.
- The first audit shall be executed no later than 6 months after the first delivery.
- Audits have to be executed by experienced employees (according to the operator's procedures) or by a capable 3rd party auditors (according to the selection criteria established in chapter 4 of the document "Rules for certification bodies".)
- According to the FAMI-QS requirements
 - Reports must be available including follow-up procedures on actions.

11 Incident management

In the event that the organisation becomes aware of a feed safety incident, or in the event of a product recall in relation to such incidents, the organization shall immediately make the certification body and FAMI-QS aware of the situation. The certification body in turn shall take appropriate steps to assess the situation, and any implications for the operator's certificate, and shall take appropriate action. The certification body shall inform FAMI-QS of the result from this assessment.

12 Certificate

A certificate shall be granted where sufficient evidence to demonstrate compliance with the Code exists. The decision to issue a certificate remains with the certification body. A certificate is valid for a period of 3 years.

12.1 Text of the certificate

<u>Operator's Name</u>	
has implemented and maintains a Feed Safety Management System including Good Manufacturing Practice (GMP) in compliance with:	
<u>FAMI-QS Code (Version x, yyyy-mm-dd)</u>	
on the following sites:	
<u>XXX</u>	
for	
<u>Activity¹⁾</u>	
<u>Scope²⁾</u>	
This certificate is valid until: yyyy-mm-dd	
Signature from the certification body:	Place, Date* yyyy-mm-dd

FAMI-QS Registration Number: xxx

For the validity of this certificate please check www.fami-qs.org

* issue of the certificate

Activity1)

e.g. placing on the market

Scope2)

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

12.2 Withdrawal of certificates

The withdrawal of a certificate remains the responsibility of the certification body. Once withdrawal is confirmed, the name of the operator will be removed from the FAMI-QS register on the website (<http://www.fami-qs/certifiedcompanies.htm>). Valid Certificates can be found on the FAMI-QS website.

12.3 Expiring certificates

When the validity date of the certificate has expired, the name of the company will still remain on the FAMI-QS register on the website (<http://www.fami-qs/certifiedcompanies.htm>) 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 register.

12.4 Exclusions on certificates

It is the obligation of the FAMI-QS certified operator not to mislead stakeholders and authorities regarding the scope of their certification.

13 Evaluation of compliance with the FAMI-QS Code

The certification body will check compliance with each clause of the FAMI-QS Code of Practice. For this purpose, auditors may use the check list provided by FAMI-QS.

The initial certification audit will take place in two stages, Stage 1 and Stage 2, according to the requirements of ISO /IEC 17021 and ISO/TS 22003.

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

- review of the implementation of corrective actions for previous non-conformities and their effectiveness
- presentation of any organisational changes
- evaluation of process descriptions/documented procedures for conformity with the standard requirements
- evaluation of practical implementation of the Code

The commitment of top management is estimated on the strength of its understanding of 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, top management. Any non-conformities established are to be discussed with top management and the management representative. The same applies to the agreement of the corrective action.

Documents consulted for audit purposes, including during interviews, should be identified in the audit record. Clearly identified document samples and any additional remarks are recorded to serve as a basis for evaluation of the operator by the auditor following the interviews. Only one audit record is needed when the audit is performed jointly by two or more auditors in a team.

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 concerned 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). There is ultimately only one audit record for each assessment.

If the auditors wish to see confidential documents such as formulas or special job processes they must have the approval of the management representative. Such documents are, however, not normally consulted.

13.1 Audit summary report

A draft of the audit summary report should be discussed with the operator and the final audit report sent to the operator within 6 weeks of the audit..

The report of findings provided to FAMI-QS Asbl shall be of sufficient detail to enable an understanding of the basis for the certification decision and should include the areas covered by the assessment, the positive and negative observations made and a summary of non-conformities. In case any uncertainties exist regarding the quality of the audit and corresponding certification, the FAMI-QS Quality Manager is entitled to initiate independent parallel audits.

A format of the audit report is available on the FAMI-QS website. Certification bodies are free to use the standard format provided by FAMI-QS or another one, but the summary

audit report requires at minimum the information requested in the checklist. Submitting the checklist itself is not mandatory.

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 FAMI-QS Asbl and to the operator, and that the report will be treated in strictest confidence. The contract between the certification body and the operator should include a clause specifying that this summary report is sent confidentially to FAMI-QS Asbl. This is the responsibility of the certification body. Responsibility for determining whether an operator will be certified remains entirely with the certification body.

The information obtained during the audit and that is recorded in the audit report will remain strictly confidential and will be made available only to representatives of the certification body and FAMI-QS Asbl. Any information used for statistical evaluation shall be formulated without any relation to the operator involved.

In case of any unresolved disagreement between an operator and a recognised certification body, circumstances should be reported in writing by the operator to FAMI-QS Asbl for consideration by the FAMI-QS Board.

13.2 Audit documentation

Certification bodies should provide to FAMI-QS Asbl with the following audit documentation as listed below:

Initial Certification Audit/ Re-Certification Audit:

1. Audit Plan /Agenda
2. FAMI-QS Audit Summary Report
3. Signed Certificate

Surveillance Audit :

1. Audit Plan / Agenda
2. FAMI-QS Audit Summary Report

14 Training and coordination with FAMI-QS Asbl

In addition to supervision by the National Accreditation Councils, FAMI-QS Asbl supervises the competent, uniform and complete realisation of audits through statistical and random evaluation of audit reports and annual harmonisation meetings for certification bodies.

Each certification body is required to ensure that every auditor undergoes at least 2 days ongoing relevant technical training/development per year in order to sustain professional development and knowledge of developments in quality assurance and 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 training of auditors remains the responsibility of certification bodies.

As an integral part of their contractual agreement with FAMI-QS Asbl, the recognised certification bodies compulsorily must:

- participate in the annual meeting of the Recognised Certification Bodies platform
- report to the supervisory Board regarding auditor training programmes implemented, at the latest 10 working days before the above mentioned annual meeting
- provide (under confidentiality) a copy of each audit summary report in English
- provide bi-annual statistical report of audits carried out and certifications granted
- report immediately to the supervisory Board any non-conformity identified in periodical auditing, that leads to withdrawal of certification
- report to the supervisory Board about interpretation and implementation issues identified in carrying out the certification.

15 Surveillance Program

In the surveillance program 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 in the office. The surveillance process is compulsory for all the authorized certification bodies. The surveillance process is considered beneficial to all stakeholders.

The surveillance program may consist 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 the Certification Body performance during their on-site audit, with prior agreement of the operator.

The FAMI-QS Asbl in co-operation with the certification body will determine where and when a specific surveillance program will be carried out and which part shall be applied.

The following criteria are typical – but not limited – of the selection process:

- Past and present experience with the certification body
- Accreditation status of the certification body
- Number of involved auditors
- Number of involved operators and/or sites
- Application of the product
- Exposure of the production process to risks

15.1 Confidentiality

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, Surveyor and Feed Business Operator). The information obtained during the surveillance of the certification body and that is recorded in the report will be handled

strictly confidential by the Surveyor and FAMI-QS. FAMI-QS and the Surveyor will not use it for purposes apart from those established in the frame of the surveillance process.

16 FAMI-QS certified companies

The certification body should maintain a list with the FAMI-QS certified operators or publish the companies on their internet website. The name of the operator, the scope, the validity of the certificate and the country should appear on this list or on the internet website.