

Rules for Certification Bodies

Version 6 / 2011-05-13

Rules for Certification bodies

Table of contents

1. Introduction	3
2. Assessment and recognition by FAMI-QS Asbl of certification bodies.....	3
3. Requirements for certification bodies	4
4. Requirements for auditors	4
5. Requirements for Decision Makers	5
6. Assessment of operators	6
7. Auditing Planning.....	6
8. Frequency of audits and re-certification	7
9. Evaluation of compliance with the FAMI-QS Code	8
10. Assessment of suppliers and assured sources	10
11. Incident Management	11
12. Certificate.....	11
12.1 Text of the certificate	11
12.2 Withdraw Certificate.....	12
12.3 Expiring Certificates	12
13. Evaluation Compliance with the FAMI-QS Code	12
13.1 Audit Summary report.....	13
13.2 Audit Documentation	13
14. Training and coordination with FAMI-QS Asbl	14
15. Surveillance Program	14
16. FAMI-QS Certified Companies	15
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 the list or internet.	15
Introduction.....	1
1. Assessment and recognition by FAMI-QS Asbl of certification bodies.....	1
2. Requirements for certification bodies	2
3. Requirements for auditors	3
4. Assessment of operators.....	3
4.1. Evaluation of compliance with the FAMI-QS Code.....	3
4.2. Final discussion and conclusion	4
4.3. Audit report.....	4
5. Training and coordination with FAMI-QS Asbl.....	4
Annex	6

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](#) ~~appropriately 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.

~~This document should be implemented as a complementary process to the document "Rules for Operators".~~

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

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](#)

~~(accreditation certificate, fields of work, list of auditors and their qualification/s, contact details, etc). Apart from this, the certification body has to commit to include FAMI-QS in the coverage of its accreditation within one year. This commitment shall be formalised by means of a letter addressed to the FAMI-QS Board.~~

The Board makes an approval/non-approval decision within 4 months, further to 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 to FAMI-QS an annual fee . 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 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, available via the FAMI-QS Asbl homepage.

~~Recognition of a certification body~~ Approval of a certification body and 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 they are appointing for conducting 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 ~~must shall~~ demonstrably comply with the following requirements by providing documentation at application. The certification body ~~must 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. ISO 19011:2002 and IAF Guidance on ISO/IEC Guide 65 and/or the IAF Mandatory Documents applicable for ISO/IEC 17021.~~
- 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, wW~~ 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:

<u>Parameter</u>	<u>Auditor</u>	<u>Audit Team Leader</u>
<u>Education /</u>	<u>University Degree</u>	<u>Same as auditor</u>
<u>Knowledge</u>	<u>Food/feed microbiology, food safety, chemistry,</u>	<u>Same as auditor</u>

<u>Parameter</u>	<u>Auditor</u>	<u>Audit Team Leader</u>
	<u>animal nutrition, animal production, GMP, Feed Safety Management Systems</u>	
<u>Total work experience</u>	<u>4 years</u>	<u>Same as auditor</u>
<u>Work Experience in Feed Safety Systems</u>	<u>At least 2 years of the total 4 years</u>	<u>Same as auditor</u>
<u>Feed Safety Training</u>	<u>HACCP principles, hazard assessment, hazard analysis, food/feed safety management principles including PRPs</u>	<u>HACCP principles, hazard assessment, hazard analysis, food/feed safety management principles including PRPs</u>
<u>Auditors Training</u>	<u>Audit technics based on ISO 19011, FAMI-QS Code</u>	<u>Same as auditor</u>
<u>Audit Experience in Food / Feed Safety Management Systems</u>	<u>4 FAMI-QS or equivalent audits in training under the direction of an auditor competent as a audit team leader</u>	<u>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</u>

- Qualification according to ISO 19011:2002
- Proven experience in the feed (already conducting HACCP based audits in the feed business, for example FAMI-QS mutually recognized schemes or official inspection of feed business operators). A minimum of 20 audits or 3 years of experience is required.
- Lead auditor training according to ISO 19011:2002
- Specifically and regularly trained by the Certification body on the FAMIQS code
- 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 the approved FAMI-QS auditors.

5. Requirements for Decision Makers

The audit documentation of initial certification, surveillance, re-certification, 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 must be done before the issuing of the certificate.

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

5.6. 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 annual membership fee payment to the CBs during the review of the audit documentation. The Certification body is not allowed to issue the certificate until the payment of the annual member fee has been done. For that reason, the auditor will ask the operator to show the payment receipt as a proof of it.

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 certified operator the name of the operator and the address of the certified sites will then be listed on the FAMI-QS web site in the list of certified companies.

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 production site (s) and/or subcontractor
- Organisational chart and processes description
- Quality manual (paper or electronic version)
- Any other information the auditor/operator may find useful/relevant

The organisational chart should clearly display each unit of the operator.

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

Subcontractors are subject to the same approval criteria as any supplier to a FAMI-QS certified operator. If the subcontractor is not FAMI-QS certified the operator shall perform a full audit to ensure the subcontractor meets the requirements of FAMI-QS. In case that a subcontractor is certified according to FAMI-QS or a mutual recognized standard no audit is required. During the operators' certification and surveillance audits, the subcontractor may also be inspected by the certification body to verify compliance with FAMI-QS 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 an applicant seeking certification against the FAMI-QS Code. It should be carried out by checking the whole sections of the FAMI-QS Code.

<u>Basic audit time</u>	<u>Additional audit time</u>	<u>Deductible audit time</u>
<u>Auditing the documentary quality system (main office): min 4 hours</u>	<u>Auditing 1 manufacturing process⁽¹⁾: min 6 hours</u>	<u>Any reduction of time for companies certified against other standards shall be negotiated between the</u>
	<u>Auditing 2 manufacturing processes⁽¹⁾: min 9 hours</u>	

Auditing 3 manufacturing processes ⁽¹⁾ : min 12 hours	operator and the certification body
Auditing 4 manufacturing processes ⁽¹⁾ : min 15 hours	The reduction will never be > 50% of the initial calculation time.
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 periodic audit performed to ensure that an organization still meets FAMI-QS requirements.

Audit time for surveillance visits is set on $\frac{1}{3}$ 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 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 the whole 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 CB defines the audit time together with the operator. A minimum time of 4 hours shall be applied.

Special audits:

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

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

8. Frequency of audits and re-certification

Certification, re-certification and surveillance audits may be combined with audits of other management systems. The frequency of surveillance audits 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.

6.9. Evaluation of compliance with the FAMI-QS Code

The Certification body will check compliance ~~of the operator's quality management system and HACCP system with each clause of the FAMI-QS Code of Practice. For this purpose, auditors may use the checklist provided in Annex with each clause of FAMI-QS Code~~

9.1 Non Conformities

Prior to completion of the audit record and in preparation for final discussion between the operator and 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; or
- 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/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 or a recall procedure.
- Failure to establish 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 it has been properly controlled or implemented.

Examples could include:

- Adequate cleaning is clearly taking place but records to evidence this are not available.
- The HACCP plan is obviously effective but a documenter review has not taken place in the last year.

Recommendation

In addition to non-conformities, recommendations may be made by an auditor based on their observations, with a view to aiding the continuous improvement of the operator’s quality 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 report it to the relevant authorities, as required by EU Regulation 178/2002. Critical nonconformities 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:

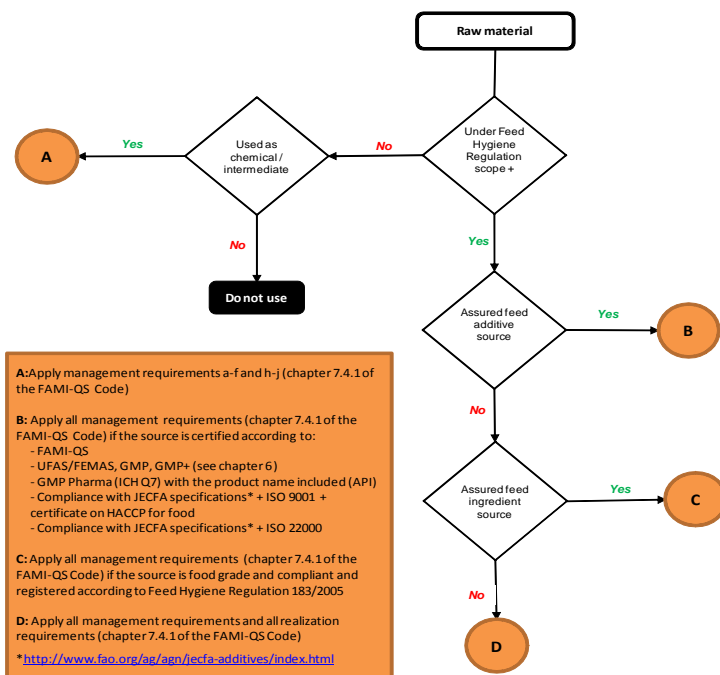
<u>Non-conformity</u>	<u>Initial audit</u>	<u>Surveillance or Re-certification audit</u>
<u>Critical</u>	<u>Certification cannot be granted until the non-conformities have been closed out.</u>	<u>Certification will be temporarily suspended⁽¹⁾ and cannot be re-instated until the non-conformities have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

⁽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 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, and audit at the supplier's location shall take place.
- The frequency of the audits shall be every 3 years.
- The first audit has to be executed no later than 6 months after the first delivery.
- Audits have to be executed by experienced employees (according companies procedures) or capable 3rd party auditor (according to the selection criteria established in chapter 4 of the document "Rules for certification bodies".)
- According to the FAMI-QS requirements (checklist in Annex of the document "Rules for certification bodies" as a tool for auditing)
- Reports shall be available and follow-up procedures on actions.

11. Incident Management

In the event that the organization becomes aware of legal proceedings with respect to product safety or legality, or in the event of a product recall, the organization shall immediately make the CB and FAMI-QS aware of the situation. The CB in turn shall take appropriate steps to assess the situation and any implications for the certification, and shall take any appropriate action. CB shall inform FAMI-QS for the result assessment of the situation.

12. Certificate

Certification shall only take place where sufficient evidence to demonstrate compliance with the Code exists. The decision to deliver the certificate remains on the certification body. A certificate is valid for a period of 3 years.

12.1 Text of the certificate

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

FAMI-QS Registration Number: xxx

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

* issue of the certificate

12.2 Withdraw Certificate

The withdrawal of the certificate remains the responsibility of the certification body. Once withdrawal is confirmed, the name of the company 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 further 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 on the website.

13. Evaluation Compliance with the FAMI-QS Code

The certification Body will check compliance of the operator with each clause of 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.

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/documentated 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 quality 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.

~~4.1. Final discussion and conclusion~~

~~Non conformities and corrective actions to be taken are documented in the action plan, and must be signed by the lead auditor and the management representative. The management representative receives the original copy of the action plan and makes a copy for the auditor.~~

13.1 Audit Summary report

A draft of the audit report should be discussed with the operator and the final audit report sent to the operator within 6 weeks of the audit. ~~To enable FAMI-QS to monitor audits and to ensure consistency, audit results must be supplied to FAMI-QS in a standard format, to include the number of non-conformities per section (critical, major, etc.) and a summary of observations and conclusions.~~

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 audit and corresponding certification, the Quality Manager is entitled to initiate independent parallel audits.

A format of audit report is enclosed to this document (see Annex). Certification bodies are free to use the standard format provided by FAMI-QS or another one, but the summary audit report has to include at least the information requested in Annex (with the exception of the questionnaire, which is not mandatory).

Audit reports provided to operators in the local language (not English) ~~must~~ 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 is to be certified or not remains entirely with 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 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 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](#)

7.14. 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 CBs and its associated auditor(s) on the occasion of an assessment of 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 as 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 on 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 will be applied.

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

- Past and present experience with the CB
- Accreditation status of the CB
- Number of involved auditors
- Number of involved operators and/or sites
- Importance of the feed additive product
- Exposure of the production process to risks

Any exchange of information related to the purpose of this project 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 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 the list or internet.

Annex

MODEL OF AUDIT REPORT

Updated according to the new Code and Regulations

OPERATOR:

Postal address:

SITE(s) AUDITED:

Visiting address(es):

Other areas visited:

Contact person:

Job Title:

Email:

Telephone:

Fax:

Employees feed additives:

Other Quality Systems in place:

Annual FAMI-QS fee paid on: (date)

CERTIFICATION BODY:

Name:

Lead auditor:

Other auditors:

TYPE OF AUDIT : Initial Surveillance Re-certification

FAMI-QS code version:

Duration of audit:

AUDIT DATE(S):

Report date:

Scope of certification

According to the Annex I of the Regulation (EC) N° 1831/2003, the scope of the certification is (mark with a cross):

1. Category: 'technological additives'

Functional groups

- 1. a) preservatives
- 2. b) antioxidants
- 3. c) emulsifiers
- 4. d) stabilisers
- 5. e) thickeners
- 6. f) gelling agents
- 7. g) binders
- 8. h) substances for control of radionuclide contamination
- 9. i) anticaking agents;
- 10. j) acidity regulators
- 11. k) silage additives
- 12. l) denaturants
- 13. (m) substances for reduction of the contamination of feed by mycotoxins: substances that can suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action.

Formatted: Bulleted + Level: 1 + Aligned at: 1.88 cm + Tab after: 2.52 cm + Indent at: 2.52 cm

2. Category: 'sensory additives'

Functional groups

- 8. a) colourants
 - substances that add or restore colour in feedingstuffs
 - substances which, when fed to animals, add colours to food of animal origin
 - substances which favourably affect the colour of ornamental fish or birds
- 9. b) flavouring compounds.

Formatted: Bulleted + Level: 1 + Aligned at: 1.88 cm + Tab after: 2.52 cm + Indent at: 2.52 cm

Formatted: Bulleted + Level: 3 + Aligned at: 3.17 cm + Tab after: 3.49 cm + Indent at: 3.49 cm

Formatted: Bulleted + Level: 1 + Aligned at: 1.88 cm + Tab after: 2.52 cm + Indent at: 2.52 cm

3. Category 'nutritional additives'

Functional groups

- a) vitamins, pro-vitamins and chemically well-defined substances having similar effect
- b) compounds of trace elements
- c) amino acids, their salts and analogues
- d) urea and its derivatives

Formatted: Bulleted + Level: 1 + Aligned at: 1.88 cm + Tab after: 2.52 cm + Indent at: 2.52 cm

Formatted: Indent: Left: 1.25 cm, Bulleted + Level: 1 + Aligned at: 1.88 cm + Tab after: 2.52 cm + Indent at: 2.52 cm

4. Category 'zootechnical additives'

Functional groups

- 1. a) digestibility enhancers
- 2. b) gut flora stabilisers;
- 3. c) substances which favourably affect the environment
- 4. d) other zootechnical additives

Formatted: Bulleted + Level: 1 + Aligned at: 1.88 cm + Tab after: 2.52 cm + Indent at: 2.52 cm

5. Premixtures

General assessment

General comments on the management system applied by the operator and assessment of its effectiveness in terms of compliance with the requirements of the FAMI-QS Code.

–SCOPE:

–What was looked at:

–What was found:

–MANAGEMENT SYSTEM:

–What was looked at:

–What was found:

–MANAGEMENT RESPONSIBILITY:

–What was looked at:

–What was found:

–RESOURCE MANAGEMENT:

–What was looked at:

–What was found:

–PRODUCT REALISATION:

–What was looked at:

–What was found:

–SYSTEM REVIEW:

–What was looked at:

–What was found:

–CONTROL OF NONCONFORMING PRODUCTS:

–What was looked at:

–What was found:

–STATISTIC TECHNIQUES:

–What was looked at:

–What was found:

Non-conformities and recommendations

Summary

FAMI-QS Section	Grade			
	Critical	Major	Minor	Recomm.
2- Scope				
4- Management system				
5- Management responsibility				
6- Resource management				
7- Product realisation				
8- System review				
9- Control of nonconforming products				
10- Statistic techniques				
Total amount				

~~Details of non-conformities/recommendations and corrective actions~~

N.	FAMI-QS-Section	Finding	Date of finding	Grade	Corrective action	Done (date)

Questionnaire

4.0	List other standards the operator may comply with:	Remark:		
		Yes	No	Remark
4.1	Is there a documented MS in place?			
	Does the MS include regulatory, safety and customer requirements?			
	Does the MS cover all the operator's activities?			
	Are there other activities that conflict with the feed safety requirements?			
4.2	Can employees commitment to feed safety and quality be demonstrated?			
	Are HACCP principles applied?			
	Is an effective change control system implemented?			
	Is there a system in place to inform Management in case of threats to product quality and feed safety?			
	Is there a system in place to ensure management is kept up dated on all relevant legislation, feed and food safety issues and other relevant guidelines?			
4.3	Does a written quality and safety policy exist?			
	Is there a Quality Manual in place?			
	Are documented procedures and records available?			
	Is the scope of the MS defined?			
	Are quality procedures established as part of the MS?			
	Do quality procedures cover the prerequisite program in support of the HACCP program?			
	Are HACCP procedures sufficient to ensure feed safety?			
	Are specifications and testing procedures for incoming materials and finished products documented?			
	Are master formulae and operating instructions for each product or group of products in place?			
	Are Processing records for each batch of product available?			
	Are Standard Operating Procedures (SOPs) for all activities under the scope of the MS documented?			
	Are documents unambiguous and include title, nature and purpose?			
	Are documents approved, signed and dated by appropriate authorised Persons?			

	Are documents kept up to date?			
5.1	Can Management commitment to feed safety and quality be demonstrated?			
5.2	Does the quality and safety policy specify the operator's objectives including regulatory and customer requirements?			
	Is the policy adequately communicated?			
	Does the operator have the basic resources necessary to fulfil the stated objectives?			
	Are the Management and HACCP systems documented, reviewed, updated and communicated to key staff?			
5.3	Is a suitably qualified HACCP team leader appointed?			
	Is the scope of the HACCP system clearly defined?			
	Do job descriptions exist for each individual or group of individuals?			
	Is there a system in place to identify and correct problems within the management and HACCP systems?			
	Is a suitably qualified person appointed to ensure compliance with regulatory requirements?			
	Is an organisational chart available?			
5.4	Is a management representative with responsibility for quality and safety appointed?			
	Does the management representative report to top management?			
	Do responsibilities include promotion of awareness of customer requirements?			
5.5	Is a documented procedure in place for management to review the suitability and effectiveness of the MS and HACCP?			
	Are records of this review available?			
	Is the review conducted periodically and predefined intervals?			
	Are conclusions drawn and actions taken documented as part of the review?			
	All actions communicated to key personnel within the organisation?			
6.1	An organisational chart exists and is updated?			
	Appropriate persons have been assigned responsibilities to comply with external requirements?			
	The design is appropriate?			
6.2	The staff is sufficient and skilled to comply with expected tasks and requirements?			
	Job descriptions are available and updated?			
6.2.1	Necessary competence are available in disciplines concerning:			

	<ul style="list-style-type: none"> — Feed safety — HACCP — Hygiene — Quality — Health and safety — Environment 				←	Formatted: Bulleted + Level: 1 + Aligned at: 0 cm + Tab after: 0.63 cm + Indent at: 0.63 cm
	Level of competence is documented and maintained?					
	Is there a sufficient level on personel hygiene facilities and personel hygiene?					
6.3	The facility is designed to facilitate a good environment as described in 6.3.2.1?					
	The facility is designed to, if necessary, make it easy to clean					
	The facility is suitable to minimize feed safety risks					
	Necessary utilities are available e.g. <ul style="list-style-type: none"> — Potable water or other water quality — Steam — Pressured air — Heating system — Extraction units — Other relevant utility system 				←	Formatted: Bulleted + Level: 1 + Aligned at: 0 cm + Tab after: 0.63 cm + Indent at: 0.63 cm
6.4	A formal calibration system is in place?					
	This includes items to be calibrated?					
	Appropriate calibration intervals are defined					
	Calibration results are documented?					
	A formal preventive maintenance system exists?					
	Appropriate maintenance intervals are defined?					
	Maintenance work is documented?					
	Maintenance work does not interfere with product safety?					
6.5	A formal cleaning program exists covering: <ul style="list-style-type: none"> — Daily house-keeping — Periodic deep cleaning — Cleaning after maintenance 				←	Formatted: Bulleted + Level: 1 + Aligned at: 0 cm + Tab after: 0.63 cm + Indent at: 0.63 cm
	The program defines responsibility?					
	Post evaluation is covered?					

	Cleaning records are filled in currently?			
	Procedures on cleaning of equipment exist and they support hygiene and feed safety?			
	Employees are trained in cleaning procedures and the training is documented?			
6.6	A formal (documented) preventive pest control system is in place?			
	The responsibility: Inhouse or contracted?			
	Ensure that relevant preventive measures are taken, re: <ul style="list-style-type: none"> — Rodents, outside and inside — Insects, flying and crawling — Birds — Other relevant pests 			
	Ensure a map or schematics of preventive measures showing the locations exist and are updated?			
	Pest activities are documented?			
	Applied pesticides/chemicals are suitable for the purpose (Product Data Sheet)?			
	Ensure legality of the pesticide/chemicals?			
	The plant is maintained reasonably clear of infestation?			
6.7	Waste materials are properly identified to avoid mix up with production materials?			
	Waste is handled properly to avoid risks for workers or environment, both internally and externally?			
7.1.1	A system to identify external requirement is implemented?			
	The external requirement are communicated and complied with?			
	Requirements and compliance are documented?			
	Requirements specified by customers are controlled and implemented?			
7.1.2	Procedures are in place to comply with identified requirements?			
7.1.3	Relevant product information is in place?			
	The information is communicated to the customer?			
	Information provided by customers are received and implemented?			
7.2	A HACCP program is developed and maintained?			
	A multidisciplinary team is announced?			
	A competent teamleader is appointed?			
	Adequate training of the HACCP team members is supplied?			
	An adequate prerequisite quality program exists?			
	A HACCP analysis is performed and documented?			

Formatted: Bulleted + Level: 1 +
 Aligned at: 0 cm + Tab after: 0.63 cm
 + Indent at: 0.63 cm

	<ul style="list-style-type: none"> — The Critical Control Points (CCPs) are identified — Critical limits are specified — Monitoring is provided — A deviation procedure is established and implemented — Verification procedures are established and implemented — All procedures and records are archived 				←	Formatted: Bulleted + Level: 1 + Aligned at: 0 cm + Tab after: 0.63 cm + Indent at: 0.63 cm
	Possible biological, physical and chemical hazards are considered					
7.3.1	Development plans are issued prior to relevant phases of the development process?					
	The development plan considers risks related to safety?					
	HACCP is considered?					
7.3.2	A formal change control procedure exists?					
	Changes are approved before implementation?					
	Changes are controlled and documented?					
	Changes implemented are reviewed, verified and archived?					
	Safety, quality and regulatory requirements are covered by the change control procedure?					
7.4.1	New suppliers are covered by an approval process?					
	Approved suppliers are documented, reviewed, re-evaluated and the documentation is up to date?					
	The review is done periodically at a predetermined interval?					
	Purchased incoming material has an agreed specification?					
	Specifications comply with feed safety topics and legislative requirements?					
7.4.2	A written procedure on handling of incoming materials exist?					
	Incoming materials are registered uniquely and include? <ul style="list-style-type: none"> — Suppliers name and lot/batch number — Operators lot/batch number — Name of material — Quantity and date of receipt — Possibly expire date 				←	Formatted: Bulleted + Level: 1 + Aligned at: 0 cm + Tab after: 0.63 cm + Indent at: 0.63 cm
	Incoming bulk materials are stored according to adequate separation procedures?					
	Materials are inspected before, during and after unloading?					
	The inspection includes contamination, pest infestation and documentation of findings?					
	Non-conformities are recorded?					

	Records of inspection results are documented and archived?			
	Incoming materials are released before use?			
	Documentation is maintained in case a product is returned to the supplier?			
7.5.1	Production areas are accessible to authorized personnel only?			
	Production is run according to formal production planning?			
	The production plan is distributed to relevant persons?			
	Production records are kept to prove compliance with master formula?			
	Cross-contamination is prevented or controlled?			
	Each product has a specification, unique name and/or code?			
	Each product has a predefined label?			
	Finished products are clearly marked and identified?			
	Each product has a predefined packaging instruction?			
	The packaging process is controlled to avoid contamination and mix-up?			
	Deliveries are inspected prior to dispatch?			
	The inspection is documented?			
	Non-conforming products are segregated and stored in a manner to prevent failures?			
	Storage facilities are operated in a manner to prevent failures during handling?			
	Storage facilities are suitable to purpose, e.g. cleanliness, ventilation, dry and temperature controlled?			
	A defined stock rotation system is in place, e.g. FIFO?			
	Outdated stock is controlled and segregated			
	Loose bulk materials are controlled and segregated from other loose bulk material?			
7.5.2	A written verification procedure is in place?			
	Verification data demonstrates that all production processes achieve planned results?			
	Verification data demonstrates that carry-over is controlled?			
7.5.3	A traceability system is in place, including tracing back from the final product through quality control data and batch records to the raw materials used and the suppliers?			
	Deliveries can be traced to customers, including customer name, date, batch and amount?			
7.5.4	A stability program is defined and on-going?			
	Product environment is controlled during storage to preserve conformance with quality and safety requirements?			
7.6.1	Agreements with subcontractors are documented			

	Selection of transporters takes into consideration their ability to fulfill the operators requirements as certified by this code?			
	Transporters are controlled, evaluated and meet expected quality and safety requirements?			
	Requirements in this code are applied by the operator also to transports arranged by the buyer?			
7.5.2	Procedures are in place to ensure product integrity during transport?			
	Packaging provides adequate protection for the raw material or finished goods?			
7.5.3	Procedures are in place to control all relevant risks found in the operators HACCP?			
	If cleaning is required the cleaning certificates shall include all relevant information needed to evaluate if the supplied container is suitable for loading?			
	Procedures are in place to safeguard against unwanted or forbidden contaminants?			
8.1	Does a formal review system exist?			
	Does the system include collection of data?			
	Does the system include analysis of the data?			
	Does the system include a conclusion?			
	Does the system include actions for improvement originating from the conclusion?			
	Are time scales for improvements defined and maintained?			
8.2	Is a scheduled audit program in place?			
	Are internal audits carried out?			
	Are the scope of audits defined?			
	Are feed safety issues included in the scope?			
	Are the frequency of audits defined?			
	Are auditors suitably trained?			
	Are audits and non-conformities reported and documented?			
	Are reports distributed to key staff?			
	Are formal follow-up's reported?			
	Are corrected non-conformities verified?			
9.1	Does a formal system exist on how to handle non-conforming products?			
	Does the procedure cover	Product identification?		
		Documentation of non-conformities?		
		Evaluation of root causes?		
		Documentation of corrective actions		

		and verification steps?			
		Segregation, handling and assessment of non-conforming product including: Rejected Materials? Accepted Materials with restrictions? Justification of potential alternative use within feed safety requirements?			
		Is staff aware of these procedures?			
		Is clear marking of non-conforming product in place or another means of control?			
		Are records of non-conformities maintained?			
9.2		Does a formal customer complaint handling system exist?			
		Is responsibility for controlling complaints defined?			
		Does the system include sufficient customer and product information?			
	Are the complaints evaluated according to:	Cause?			
		Seriousness?			
		Customer?			
		Other relevant topics?			
		Are complaint topics used to prevent reoccurrence?			
		Are the related corrective actions carried through?			
		Is feedback given to the customer?			
9.3		Does a formal recall procedure exist?			
		Is responsibility assigned to an appropriate person?			
		Is the recall process adequately described?			
		Does the recall procedure include handling, reassessment and/or disposal of recalled product?			
		Are effective corrective and preventative actions implemented?			
		Are recalls recorded?			
		Is the recall procedure tested regularly?			
		Are the test recalls documented?			
		Are the outcomes of the test recalls evaluated?			
9.4		Does a crisis management procedure exist?			
		Is responsibility for notifying customers and regulatory authorities defined?			
		Is responsibility for conducting a product recall defined?			
10		Are statistical techniques applied?			
		Has the use of statistical techniques been evaluated and defined?			

	Is an overview of each statistical technique available?			
	are the suitability of techniques documented?			
	Does the operator possess the necessary statistical competencies?			