

FAMI-QS Certification Rules Version 5



European Feed Additives and PreMixtures Quality System

Version 4 (old)

- Requirements for:
 - Certification Bodies, Auditors, Operators
- FAMI-QS membership
- Audit rules
- Certificate
- Logo
- Mutual recognition

Concerns

- Too large a document
 - > 30 pages
- Too many topics not relevant to operators
 - Requirements for auditors etc
- Some topics in need of clarification
 - Source assurance, audit time, nonconformities etc
- Operators are not reading the document
 - Not obvious what applies to them

New Certification Rules

- Issued in 2 separate documents
 - **Rules for Operators**
 - **Rules for CBs**
- For CBs both documents apply!
- Clarify exactly what operators resp. CBs need to do
- Clarify any topics not fully explained
- Include topics raised by CBs to first draft

Major changes: Rules for Operators

Section

2.1: Subcontractor approval

2.1: Auditing time

2.2: Multisite rules

2.5: Consequences & closure of Non-Conformities

3: Source assurance

4: Crisis management

5.1/5.2/5.3: Text of certificates, withdrawal and expiring certificates

Subcontractor approval

- Subcontractors are subject to the same approval criteria as any other supplier
- FAMI-QS certification of subcontractors is preferable to ensure production of safe products
- Alternatives can be used but an onsite audit, at least by the operator, must take place to verify compliance with FAMI-QS requirements

Audit time

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 shall 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	

Audit time for **surveillance** visits is set **on $\frac{1}{3}$ of initial audit time**. A minimum time of 4 hours shall be applied.

Audit time for **re-certification** visits is set on **$\frac{2}{3}$ of initial audit time**. A minimum time of 4 hours shall be applied.

Multisite rules

- According to IAF MD 1:2007
IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling
- Communication of audit program to FAMI-QS

Consequences & closure of NCs

- New rules on evaluation of NCs established
- Consequences of NCs on certification now depend on type of audit and type of NC
 - certification granted/denied/suspended
 - initial, re-certification, surveillance
 - critical, major, minor

Decision matrix (I)

Non-conformity	Initial audit	Surveillance or Re-certification audit
<i>Critical</i>	Certification cannot be granted until the non-conformities have been closed out.	Certification will be temporarily suspended ⁽¹⁾ and cannot be reinstated until the non-conformities have been closed out. In case the non-conformities are not resolved within the maximum suspension period of 72 calendar days, certification will be withdrawn.

Decision matrix (II)

Non-conformity	Initial audit	Surveillance or Re-certification audit
Major	Certification cannot be granted until the non-conformities have been closed out.	Certification continues. The action plan shall be presented to the certification body the latest 14 calendar days after the audit date. 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.

Decision matrix (III)

Non-conformity	Initial audit	Surveillance or Re-certification audit
Minor	<p>Certification can be granted after receipt of the action plan.</p> <p>An agreement on the action plan shall 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 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.</p>	<p>Certification continues.</p> <p>An agreement on the action plan shall 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 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.</p>

Source assurance

- Incoming material must be from certified and from a recognised source, but alternatives can be used
- Decision tree helps operators to appropriate measures depending on nature of incoming material
- Measures are set out in chapter 7.4.1 of the Code
- Audit at the supplier's location performed by operator or CB as final measure for not assured materials

Crisis management

- Legislative compliance in the Code
- Further details in the Guidance
- Rules for operators define required actions and responsibilities
- Operator-side:
 - notification of the CB when crisis occurs
 - written feed-back to CB as follow-up
- CB-side:
 - follow-up during next audit

Certificates

Withdrawal

- Remains the responsibility of the CB
- As a consequence the name of the company will be removed from the FAMI-QS website

Expired certificates

- Must be renewed and submitted to FAMI-QS within 1 month after the expiring date
- If not, the name of the company will be removed from the FAMI-QS website

New FAMI-QS logo



- Version 5 of FAMI-QS documents will be implemented with new styled logo
- May be used in its original colours and proportions on certificates, advertisements and brochures

Major changes: Rules for CBs

- Requirements for accreditation
- References (ISO/IEC etc) updated
- Requirements for auditors better defined
 - proven experience in feed sector
 - min. 20 audits or 3 years experience
- New functional group added to category « technological additives »
- Checklist is updated

For all



Annexes on the website

- List of fees
- Application forms