

Rules for Operators

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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).

The aim of this European Code of Practice is to ensure safety of feed additives and premixtures by:

- minimizing the risk, that adulterated feed additives and premixtures enter the feed chain;
- enabling an operator to implement the objectives of the feed hygiene regulation (183/2005/EC); and
- providing measures to ensure that other applicable feed safety regulatory requirements are met.

Feed is considered unsafe for its intended use if it has adverse effect on human or animal health, or if the food derived from food-producing animals is unsafe for human consumption.

This Code shall apply to feed additives and premixture operators at all stages from the first placing on the market of feed additives and premixtures based on current EU legislation. Therefore it also applies to the placing on the market of feed additives and premixtures after import from third countries.

Compliance with FAMI-QS does not exonerate the operator from meeting the statutory or regulatory requirements in each country in which the operator is active. A tool for checking the regulatory status of feed additives is the Register of Feed Additives:

(http://europa.eu.int/comm/food/food/animalnutrition/feedadditives/registeradditives_en.htm)

FAMI-QS Asbl is an association that sets out certification of feed additives and premixtures around the globe. FAMI-QS certification verifies that any certified operator is in compliance with the FAMI-QS Code and Regulation (EC) 183/2008 laying down requirements on feed hygiene as verified by a FAMI-QS licensed and accredited certification body.

1. Application for certification and FAMI-QS associate membership

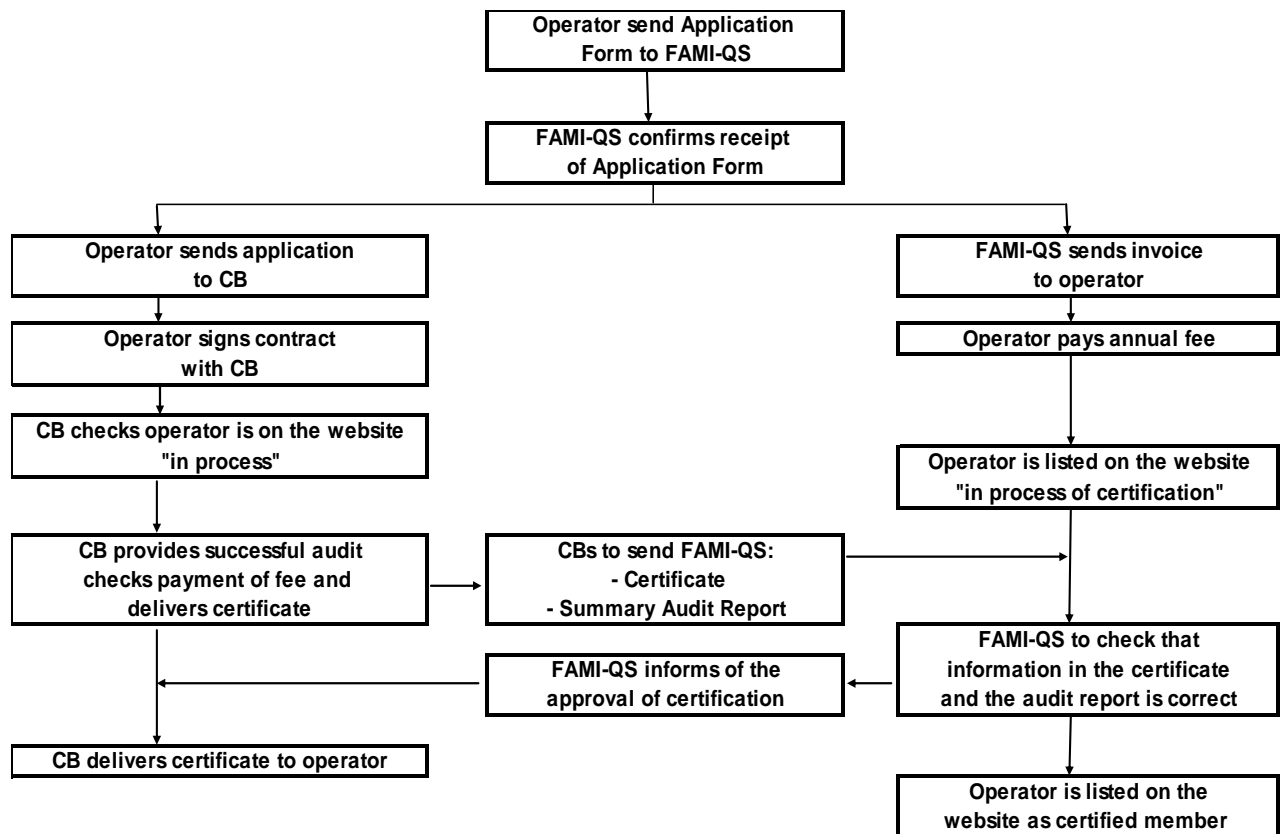
Any operator wishing to get FAMI-QS certified will send an application letter to FAMI-QS. The application form is available on the FAMI-QS website (<http://www.fami-qs.org/documents.htm>)

Upon receipt, FAMI-QS will return an invoice with details of payment of the associate membership fee. Schedule of annual fees is available on the FAMI-QS website.

Once the payment is done, a FAMI-QS receipt will be issued and sent to the operator, which will also appear in the FAMI-QS website as a company in the process of being audited/certified. The operator should then be audited without any critical non-conformities within a period of 12 months; otherwise FAMI-QS Asbl will remove the operator from the website.

If within the 12 months after sending the application form the name and/or contact details of the applicant have changed, this should be informed to FAMI-QS.

A flowchart outlining the certification process is detailed below:



2. Assessment of operators

Operators should contact one of the FAMI-QS licensed certification bodies as listed in the FAMI-QS website (<http://www.fami-qs.org/certificationbodies.htm>) as shown in the figure above. The certification body assesses the interested operator for compliance with FAMI-QS on the basis of initial certification audit.

2.1. Audit planning

Audit planning should be based on the current organisational chart of the operator to be certified. The organisational chart should clearly display each unit of the operator, and the scope of the audit shall then be determined according to defined units. Important influencing factors are:

- the structure of the unit to be certified including the number of locations (plants, branches, sales departments, etc.)
- the number of employees per organisational unit
- the number of employees having the same or similar duties (e.g. shift work)
- the range of goods and services
- the variety of processes and grade of automation
- similarities in structure of quality management systems in the case of groups
- current certification (ISO 9001:2008 or HACCP certification for example)
- requirements devolving from statutory regulations
- sophistication of the system

These factors may influence the number of interviews needed to achieve a representative survey of the organisation. 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. In larger organisations auditors should ensure that all functions of an area are encompassed by interviews. In the case of a number of departments which have the same function(s), one sample which shows a 'typical situation', may be sufficient. A 'typical situation' is one that represents all departments concerned. One example could correspond to different sales departments which organise their work in the same way.

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 contractor meets the requirements of FAMI-QS. During the operators' certification and surveillance audits, the contractor 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.

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:

- organisation chart
- quality manual (or electronic review)
- list of applicable regulatory texts
- any other information the auditor/operator may find useful/relevant

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 shall 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 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	

⁽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 1/3 of initial audit time. A minimum time of 4 hours shall be applied.

Re-certification audit:

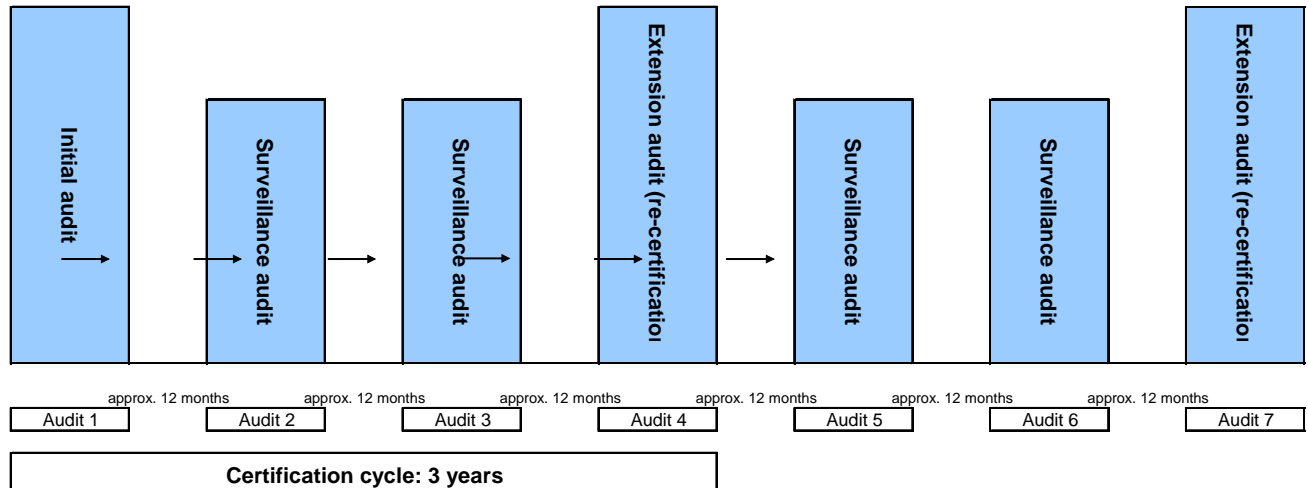
An re-certification audit takes place at the end of a certification period. It shall be carried out by checking the whole sections of the FAMI-QS Code.

Audit time for re-certification visits is set on 2/3 of initial audit time. A minimum time of 4 hours shall be applied.

It is the responsibility of the certification body to increase the audit time if the complexity of processes or the auditee's organisation calls for this.

2.2. 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.



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. The resulting program of audits agreed between the operator and the certification body shall be communicated to FAMI-QS.

In case of modification of the Code, certified companies shall comply with the modifications within 1 year, unless otherwise advised by FAMI-QS Asbl. All modifications to the Code will be notified to the approved certification bodies and included in the FAMI-QS Asbl homepage for information.

2.3. Evaluation of compliance with the FAMI-QS Code

The certification body will check compliance with each clause of the FAMI-QS Code of Practice.

2.4. 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 non-conformities 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 auditors based on their observations, with a view to aiding the continuous improvement of the operator’s compliance to FAMI-QS.

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.)

2.5. Consequences of non-conformities

Critical: 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.

Consequences and close-out:

Non-conformity	Initial audit	Surveillance or Re-certification audit
Critical	Certification cannot be granted until the non-conformities have been closed out.	Certification will be temporarily suspended ⁽¹⁾ and cannot be re-instated 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.

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

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

2.6. Final discussion and conclusion

The lead auditor prepares the presentation for the final discussion in line with the observations and agreements reached. The following points should be considered:

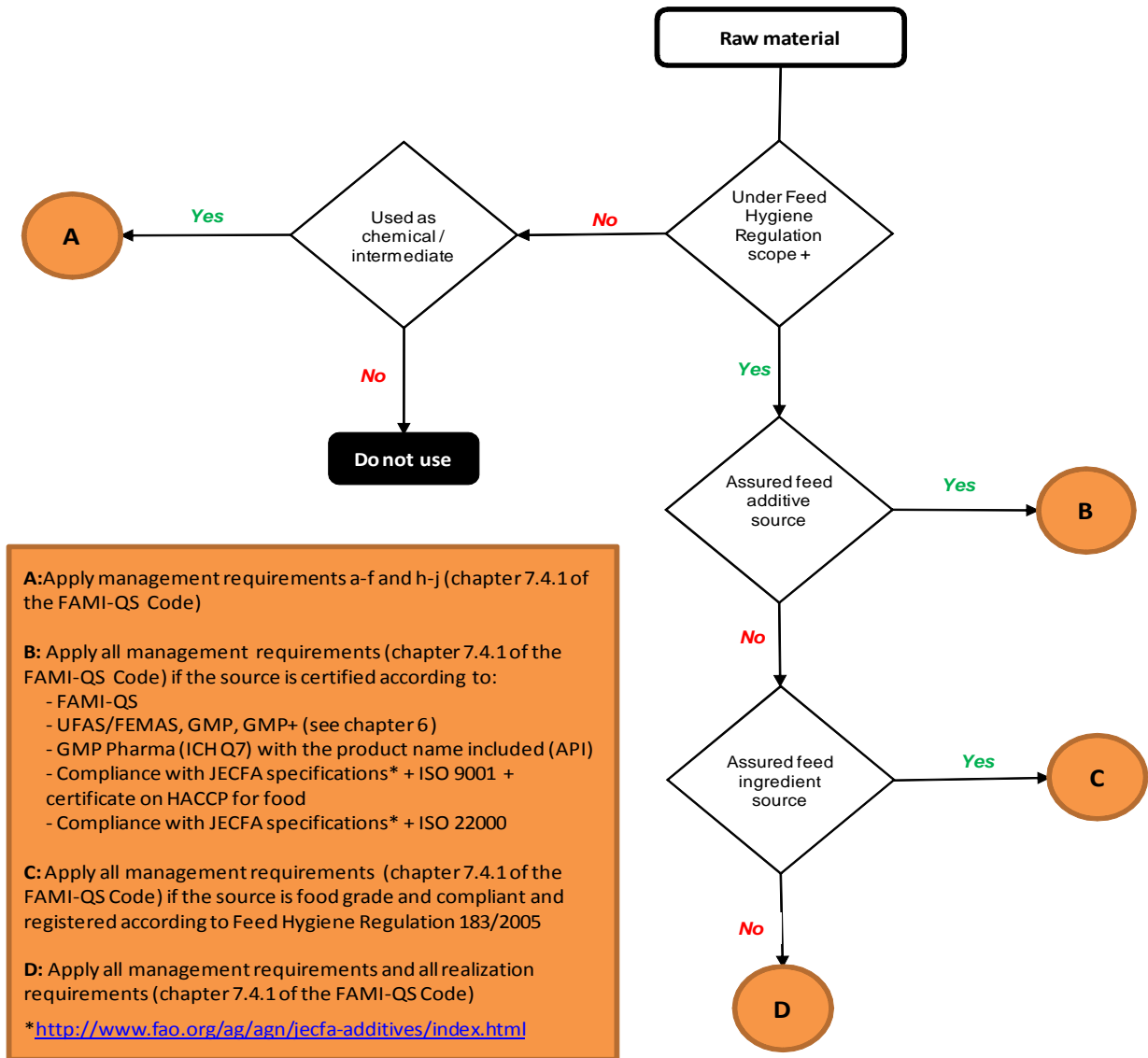
- Complete record of participants present
- Presentation of the assessment results. Indication that the certification body's management takes the final decision on the award of the certificate
- Explanation of further steps (follow-up assessment, if applicable)
- Fixing a date for next assessment
- Closing remarks by the co-auditor, if desired
- Closing remarks by the management representative
- Exchange of views, if desired

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.

3. 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.

4. Crisis management

Referring to Section 9.4 of the Code and Annex 9 of the Guidance, specific actions and responsibilities as defined on the table below are to be followed:

	Step 1: Crisis occurred	Step 2: Stabilization	Step 3: Evaluation and Follow-up
Operator	<p>Notify simultaneously external communication, at least</p> <ul style="list-style-type: none"> - local authorities - customers - FAMI-QS (contact persons from the website) - CB - Other relevant stakeholders <p>Implement actions to prevent further escalation of the crisis identified.</p> <ul style="list-style-type: none"> - Recall is started - assemble a crisis team - internal communication - put the product in quarantine - stop use of specific raw materials - stop production of products affected 	<p>Ensure that all information is available to identify root cause identification.</p> <p>Implement Corrective and Preventive Actions</p> <p>Keep customers and all stakeholders informed.</p>	<p>Verify Corrective and Preventive Actions</p> <p>Send written feed-back to:</p> <ul style="list-style-type: none"> - CB - FAMI-QS <p>Ensure feed-back to:</p> <ul style="list-style-type: none"> - Authorities - customers - internal info <p>Ensure that the entire case is recorded.</p>
FAMI-QS	<p>Notify</p> <ul style="list-style-type: none"> - Other branch associations 	<p>Statement on the FAMI-QS website</p> <p>Link to the official Rapid Alert System website</p> <p>Follow up on developments</p>	<p>Receive feed-back (the case is closed)</p>
Certification body	-	-	<p>Receive feed-back.</p> <p>Follow-up on next audit.</p> <p>Lessons learnt</p>

5. 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.

5.1. Text of the certificate

The Certification Body: (...)

hereby certifies that the company: (...)

has implemented and is in compliance with the FAMI-QS Code of Practice on the following site(s): (...)

for the placing on the market of feed additives belonging to the following category(ies) and functional group(s): (...)

Audits, documented in a report, have verified that the operator fulfils the requirements of this Code.

This certificate is valid until: (...)

The categories and functional groups of additives shall be indicated as they appear in Annex I of Regulation (EC) 1831/2003 on additives for use in animal nutrition and the Community Register of Feed Additives. Otherwise, the whole name of category and functional group can be replaced by the corresponding number of category and letter of functional group as they appear in these reference documents.

There are few cases when feed additives appear unclassified into categories or functional groups in the Community Register:

- Additives that are classified into a category but have not been given a functional group.
Alternatively, these products have been assigned a “subclassification”. In these cases, the category and the subclassification shall be indicated in the certificate.
- Additives that have been not classified neither into a category nor a functional group.
The mention “zootechnical enzymes” or “zootechnical microorganisms”, depending on the product, shall be indicated in the certificate.

In relation to premixtures, information about feed additive categories and the corresponding list is not relevant and should not be included on the certificate.

This text may be combined with other phrases in case of combined audits.

The certificate may also list more than one site from the same company.

The names and addresses of certified companies are gathered by FAMI-QS Asbl in a public register, available via the FAMI-QS Asbl homepage.

5.2. Withdrawal of certificates

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>)

5.3. 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.

5.4. 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.

5.5. 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.

6. Mutual recognition between FAMI-QS Asbl and other standards

FAMI-QS Asbl has established an agreement with other organizations which seal the mutual recognition between their schemes, pursuing similar safety aims.

These organizations, their standards and origin are:

Organization	Standard / system	Origin
AIC Services	UFAS and FEMAS (includes intermediate suppliers)	United Kingdom
OVOCOM	GMP	Belgium
PDV	GMP+	The Netherlands

The scope of the mutual recognition covers both additives and premixtures.

On the basis of this, certificates obtained in either of the schemes are fully equivalent and will allow the participant to buy from operators certified under the other scheme without any additional requirements. These systems do not require from each other's operators any other formality or step than the proof they are holding a valid certificate in order to consider them as "assured supplies".