



Rules for Operators

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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).

The aim of this European Code of Practice is to ensure safety of Specialty Feed Ingredients and their Mixtures by:

- minimizing the risk, that adulterated feed additives, functional feed ingredients, premixtures, specialty complementary feed and specialty dietetic feed 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.

This Code shall apply to feed additives, functional feed ingredients, premixtures, specialty complementary feed and specialty dietetic feed operators at all stages from the first placing on the market including importation based on current EU legislation.

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 the quality and safety system for specialty feed ingredients and their mixtures. 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.

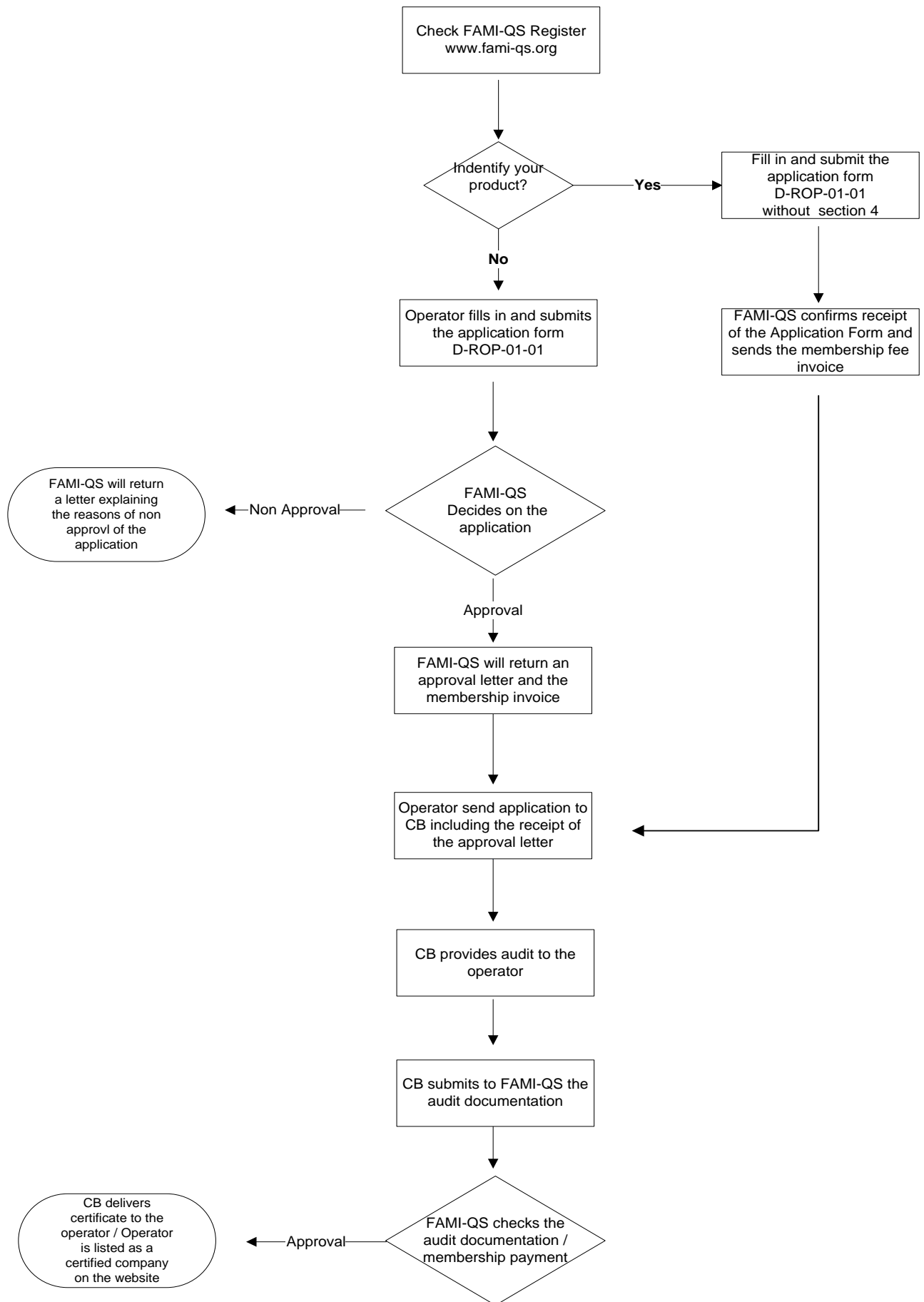
2. Application for certification and FAMI-QS associate membership

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, the FAMI-QS Quality Manager will return a letter of acceptance / rejection of the application. The acceptance / rejection of the application will be based on the products included in the application and their relevance to the FAMI-QS scope.

Once the application has been approved an for the associate membership fee and the FAMI-QS registration number will be sent to the accepted applicant operator.

A flowchart outlining the certification process is detailed below:



3. 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 flowchart above. A copy of the approval of the FAMI QS application must be sent by the operator to the certification body before the certification audit takes place. The certification body assesses the interested operator for compliance with FAMI-QS on the basis of initial certification, surveillance and re-certification audit.

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.

3.1 Audit 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 operator must verify that the scope of a subcontractors schemes are relevant and in alignment with the operators requirements.

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 must 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 of sections b) to f), Annex 1, FAMI-QS Guidance on Implementation.

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.

Surveillance audit:

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

Audit time for surveillance audits is set on $\frac{1}{3}$ of initial audit time. Depending on the previous audit results as well as the complexity of the product and/or processes the certification body 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 must 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. Depending on the previous audit results as well as the complexity of the product 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 for 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

3.2 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 less than 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.

3.3 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.

3.4 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, 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;
- 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.)

3.5 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:

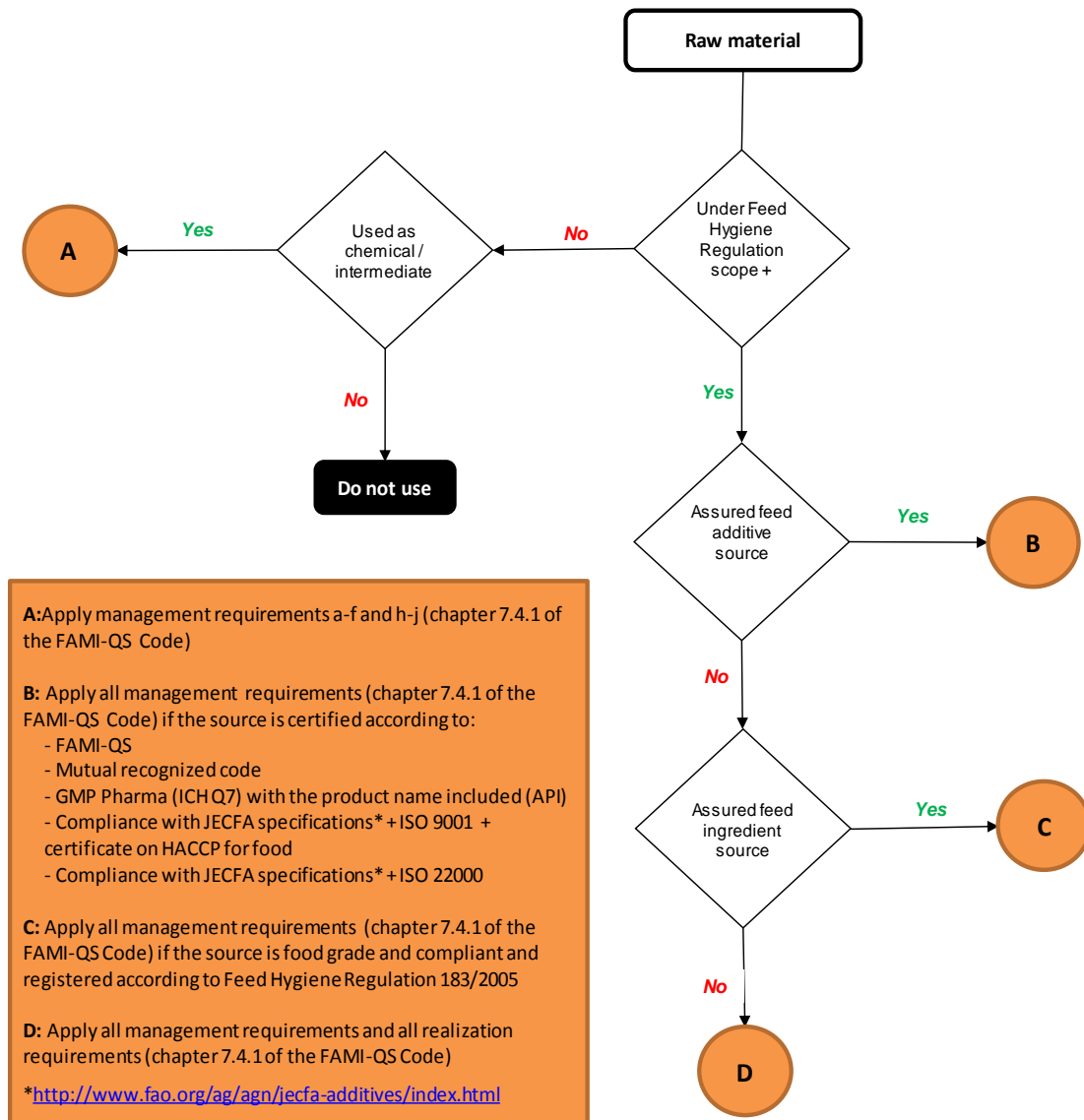
Non-conformity	Initial audit	Surveillance or Re-certification audit
Critical	Certification cannot be granted until the non-conformities have been closed.	<p>Certification will be temporarily suspended⁽¹⁾ and cannot be re-instated until the non-conformities have been closed.</p> <p>In case the non-conformities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

4. 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 shall 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.

5. 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 about the result of this assessment.

6 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.

7 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.

7.1 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.

8. Transparency

FAMI-QS is eligible to answer any questions concerning the products covered under the certificate.

9 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.