



FAMI-QS VERSION 6

TRANSITION

REQUIREMENTS

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1. Introduction

This document defines the transition from FAMI-QS Code Version 5.1 to FAMI-QS Code Version 6 and identifies activities which should be considered by all relevant interested parties.

The revision introduces significant changes and it was published on 02 October 2017.

The most noticeable change in the FAMI-QS Certification System is the new structure of the FAMI-QS Code and the Scope adaptation for global understanding.

2. FAMI-QS Code Version 6

FAMI-QS Code Version 6 now follows the same overall structure as other ISO management system standards (known as the High-Level Structure, ISO/IEC Directives, Part 1 Consolidated ISO Supplement — Procedures specific to ISO), making it easier for anyone using multiple management systems (MS). The majority of FAMI-QS Certified Operators maintains more than one MS (ISO 9001, ISO 2200, FSSC 22000, etc.).

Another major difference is the focus on risk-based thinking and process approach. While this has always been a part of the FAMI-QS Code, the new version better clarifies this approach.

FAMI-QS Code Version 6 has two pillars: quality and feed safety. The requirements of the FAMI-QS Code Version 5.1 have been re-organised in order to meet the ISO High Level Structure. In some cases, the requirements have been addressed in a more detailed way. This will on one hand, allow Operators to get more guidance for the implementation of specific requirements and, on the other hand, avoid misinterpretation.

What is essentially required from an Operator, is to be able to understand the operational environment of its activities, the impact of this operational environment on feed safety, and an in-depth knowledge of its operational processes and the outputs of the latter.

Table 1: FAMI-QS Code Version 6 Structure.

<p>Chapter 4 Understanding the context of the Operator</p>	<ul style="list-style-type: none"> • Operational environment • Expectations of the chain (interested parties) • Requires an organisation to determine the internal and external issues and requirements that can impact the planning of the Feed Safety and Quality Management System • Clarification on § 4.6 Quality and Safety Policy e) (...) actions for preventing fraud/ adulteration: actions shall be aligned with the requirements addressed in the Supply Chain Integrity Programme. FAMI-QS is currently working on the development of the Supply Chain Integrity Module, which is a module that will provide requirements for defining actions against fraud and defence. The module will be mandatory for all FAMI-QS certified Operators. The expected date for the completion of this module is March 2019. A transition period will be given for compliance with the module. In the meantime, FAMI-QS certified Operators shall initiate the internal discussions on feed fraud and feed defense issues. Feed fraud and feed defense issues shall be approached in combination with clauses § 4.1, § 4.2 § 6.1§ 6.2 of the FAMI-QS Code version 6. During the audit the Operator shall be able to demonstrate to the auditor their action plan to approach feed fraud and feed defense. The action plan (not specific actions) shall cover the supply chain and the internal processes carried by the Operator. Companies certified with FSSC 22000 and operate under a integrate management system can combine the actions. Please note that if there are no initial actions, as defined above, a NCR will be raised at the Feed Safety and Quality Policy.
<p>Chapter 5</p>	<ul style="list-style-type: none"> • Management responsibility

<p>Leadership</p>	<ul style="list-style-type: none"> • Organisation’s management have to demonstrate that they are actively involved in the management and operation of the management system • The Feed Safety and Quality Management System needs to be fully integrated into the business processes
<p>Chapter 6 Planning</p>	<ul style="list-style-type: none"> • Related to the Feed Safety Management System • Actions to address risks and opportunities • Feed safety and Quality objectives and planning to achieve them
<p>Chapter 7 Good Manufacturing Practices</p>	<ul style="list-style-type: none"> • Aligned with the requirements of ISO/TS 22002 Part 6 - Feed PRPs • Aligned with the requirements of FSMA CGMP Animal Food • Clarification on § 7.11 Transportation: FAMI-QS does not certify transport activities. However being transportation an important process which affects feed safety, the Code defines the requirements that a FAMI-QS Operator shall request from their transport company. The FAMI-QS Operator is exempted from these requirements when using a transporter certified against one of the FAMI-QS recognised standards for transport: AIC or GMP+ International. • Clarification on § 8.5.1. <i>Type and extent of control of external provision – Contract Manufacturers:</i> <p>>> TRADING ACTIVITIES:</p> <ul style="list-style-type: none"> - Placing on the market (TRADE) – Applicable for traders who place specialty feed ingredients on the market purchased from suppliers certified with one of the mutually recognized standards (see document P-MS-003). - Placing on the market (PRODUCTION) – Applicable for Operators who place specialty feed ingredients on the market purchased as feed from suppliers that are not certified with one of the mutual recognized standards and for food grade specialty feed ingredients, food ingredients and pharma grade specialty feed ingredients. The purchasing has to fulfil the requirements of the FAMI-QS Code. The HACCP plan at the level of the trading office shall consider all the hazards related to the production (level of the producer). - Traders that place on the market products under their own label are considered producers. In case the subcontractor is not certified against one of the standards with which the FAMI-QS maintains mutual recognition arrangements, the CB shall consider to audit the contracted manufacturer, at least once within the certification cycle. NOTE: In this case, the activity is production but the feed chain category is FII. <ul style="list-style-type: none"> • Example 1: If a trader does repackaging for FAMI-QS, this is considered production since the trader shall manage additional risk/ hazards. • Example 2: In case the Operator has a pharma grade ingredient and want to sell as feed grade ingredient, this is also considered as production activity. Here, the Operator shall ensure that the pharma grade ingredient is compliant with the feed grade requirements. <p>These activities are not traditional production activities, but the auditor shall approach them as production. From the perspective of ISO/TS 22003:2013 these activities fall under Scope F.</p>
<p>Chapter 8 Operations</p>	<ul style="list-style-type: none"> • The heart of the management system (the business). This chapter shall be combined with the Process documents relevant to the Operator
<p>Chapter 9 Performance Evaluation</p>	<ul style="list-style-type: none"> • Actions to address risks and opportunities • Feed safety and Quality objectives and planning to achieve them
<p>Chapter 10 Improvement</p>	<ul style="list-style-type: none"> • Requirements for managing nonconformities • Requirements for continuous improvement

Due to significant changes in the code, a track changes document outlining the modifications to the structure and rephrasing of the requirements will not be provided. All the interested parties are kindly asked to read the code and the process document(s) relevant to their operations very carefully.

Relevant interested parties are:

- i) Organisations certified against FAMI-QS
- ii) Accreditation Bodies (ABs)
- iii) Certification Bodies (CBs).

2.1. FAMI-QS Scope

The clear Management System approach of the FAMI-QS Code shall be reflected also in the FAMI-QS scope description. The rephrasing of our scope definition for international implementation will not change the range of ingredients eligible to be FAMI-QS certified. Instead, it will classify those ingredients by the process they result from.

The new title of the scope will be *Specialty Feed Ingredients*. A specialty feed ingredient is defined as any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animals/ animal products and animal performance. The scope includes production and trade of single ingredients coming out of the following production processes or their combination: Chemical, Bioprocessing, Mining, Extraction, Mixing and Formulating.

The management system approach allows FAMI-QS to use its industry's knowledge more efficiently, identifying risk per process, rather than per product. This will greatly improve the current production process and encourage better knowledge exchange at global level. Moreover, it will contribute to create a fair playing field.

Specific per process hazard assessments were developed, with the view of providing specific guidelines for managing the hazards associated with each process. The so called *Process Documents* will act as an add-on to the FAMI-QS Code. These will be auditable documents established for each process described in Chapter 2 of the FAMI-QS Code.

3. Transition

The transition period will be three (3) years starting from the publication date of the FAMI-QS Code Version 6, which happened on 02 October 2017. **The transition period will be until 01 October 2020.**

FAMI-QS Secretariat will not accept any application under Version 5.1 as from 01 October 2019.

3.1. Validity of the FAMI-QS Certificates Version 5.1

FAMI-QS Certificates Version 5.1 will no longer be valid after 01 October 2020.

The expiry date of certifications based on FAMI-QS Version 5.1, issued during the transition period, needs to correspond to the end of the three-year transition period on 01 October 2020.

3.2 Application dates

1. FAMI-QS applications under version 6 will open in March 2019. Current FAMI-QS certified Operators under version 5.1 that have a valid approval letter don't need to request a new document. New approval letters will only be issued in case of changes in the scope, company address, company name or new site(s).

2. Certification Bodies can only proceed with the provision of FAMI-QS Certification under version 6 after 1 April 2019.

3. The transition to Version 6 will be a recertification audit. A new auditing time calculation is required. Certification bodies shall provide a justification in the event that Stage 1 audit will not be applicable. In addition, Certification bodies shall ensure that a new contract covering the provisions stated on the FAMI-QS Rules for Certification Bodies Version 8 applicable to the Operators are included. The new certificate will be issued with a validity of three (3) years (new certification cycle). The wording “*certified since*” can be maintained.

4. New applicants wanting to become FAMI-QS certified have to do it under version 5.1 until 1 April 2019.

4. Specific Requirements

4.1. FAMI-QS Certified Operators

Operators certified under FAMI-QS Version 5.1 shall take the following actions:

- a) Read the FAMI-QS Code Version 6 very carefully. Due to significant changes in the code, a track changes document outlining the modifications to the structure and rephrasing of the requirements will not be provided.
- b) Identify and integrate in your system the Process Documents applicable to your operations. Traders will need to consider all the process documents applicable to the products they trade (how those products are produced).
- c) Reflect on actions for preventing fraud/ adulteration, risks and opportunities.
- d) Develop an implementation plan.
- e) Provide appropriate training and raise awareness amongst all parties that have an impact on the effectiveness of the Feed Safety Management System, within your organisation.
- f) Update the existing Feed Safety Management System to meet the revised requirements and provide verification of its effectiveness.
- g) Liaise with their Certification Body for transition arrangements.
- h) When the Certification Body confirms that they are ready to offer FAMI-QS Certification under Version 6, you shall proceed with the new application for FAMI-QS, in order to obtain an updated approval letter. The approval for transition to Version 6 will be provided without any additional charges.

4.2. Certification Bodies

Certification Bodies shall take the following actions:

- a) Read and implement the Rules for Certification Bodies Version 8.
- b) Ensure that all the auditors have undergone the initial training under the FAMI-QS Version 6. At least one auditor from each Certification Body shall attend the training provided by FAMI-QS. Then a Certification Body can organise an internal training. The agenda and participants list shall be submitted to FAMI-QS.
- c) Ensure that all the personnel involved in the FAMI-QS Certification process meets the requirements of FAMI-QS Rules for Certification Bodies Version 8.
- d) Communicate with existing FAMI-QS Certified Operators, sharing guidance on the transition process and arrangements for transition.

- e) Communicate to the existing FAMI-QS Certified Operators all the relevant information regarding the validity of their certificates.
- f) Provide a written action plan for the transition to your Accreditation Body and FAMI-QS.
- g) In order for you to be able to proceed with the provision of FAMI-QS certification services under Version 6, it is required the inclusion of the FAMI-QS Version 6 under your accreditation certificate. CBs can issue a temporarily a non-accredited certificate until the accreditation process is finalised. A special audit on behalf of FAMI-QS is required. Upon the completion of the accreditation process, the CBs shall transfer the non-accredited certificates issued to accredited certificates.
- h) Confirm to your clients the date for the launch of the transition of the FAMI-QS Certificates Version 5.1 to Version 6 and the date from when you will start accepting applications under FAMI-QS Version 6.

4.3. Accreditation Bodies

This only applies to Accreditation Bodies that already provide FAMI-QS Accreditation Services.

Accreditation Bodies shall continue their scheduled accreditation activities related to Version 5.1, as per their internal schedule.

For the transition to the FAMI-QS Version 6, Accreditation Bodies shall perform a desktop review or an office audit to ensure that the Certification Body is ready to provide FAMI-QS Certification Services against FAMI-QS Code Version 6.

Certification Bodies will provide to the Accreditation Bodies the following information:

- FAMI-QS Certification procedure;
- List of auditors and their approval scopes;
- Action plan for the transition.

A witness audit is not required for the update of the Accreditation Certificate (unless the Accreditation Body decides otherwise).