

## Note for FAMI-QS Feed Business Operators

Since the publication of the revised FAMI-QS Certification System on the 1<sup>st</sup> of October 2017, we have received numerous comments for further clarification on the requirements covered in the Code, Rules and Transition Document. Consequently, these FAMI-QS documents were subject to some technical changes that will be emphasised in this *Note for FAMI-QS Feed Business Operators*.

**Please note that this document is only for information purposes. Feed Business Operators are kindly requested to always refer to the complete documents available on our website.**

### 1. Transition

An update on the application dates and requirements took place.

- a) 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).**
- b) Certification Bodies can only proceed with the provision of FAMI-QS Certification under version 6 after 1 April 2019.
- c) 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.
- d) New applicants wanting to become FAMI-QS certified have to do it under version 5.1 until 1 April 2019.

### 2. FAMI-QS Code

Final document: Version 6 REV 4 - 2018-07-16

Some clarifications on the FAMI-QS Code of practice are highlighted in the table below. This table can also be found on the FAMI-QS Version 6 Transition Requirements document (P-MS-002/ REV. 3 2018-10-12).

*Table 1: FAMI-QS Code Version 6 Structure.*

<p><b>Chapter 4</b> <b>Understanding the context of the Operator</b></p>	<ul style="list-style-type: none"> <li>• Operational environment</li> <li>• Expectations of the chain (interested parties)</li> <li>• 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</li> <li>• 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</li> </ul>
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	<p>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.</p> <p>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 integrated management system can combine the actions.</p> <p>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>
<p><b>Chapter 5 Leadership</b></p>	<ul style="list-style-type: none"> <li>• Management responsibility</li> <li>• Organisation’s management have to demonstrate that they are actively involved in the management and operation of the management system</li> <li>• The Feed Safety and Quality Management System needs to be fully integrated into the business processes</li> </ul>
<p><b>Chapter 6 Planning</b></p>	<ul style="list-style-type: none"> <li>• Related to the Feed Safety Management System</li> <li>• Actions to address risks and opportunities</li> <li>• Feed safety and Quality objectives and planning to achieve them</li> </ul>
<p><b>Chapter 7 Good Manufacturing Practices</b></p>	<ul style="list-style-type: none"> <li>• Aligned with the requirements of ISO/TS 22002 Part 6 - Feed PRPs</li> <li>• Aligned with the requirements of FSMA CGMP Animal Food</li> <li>• 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.</li> <li>• Clarification on § 8.5.1. <i>Type and extent of control of external provision – Contract Manufacturers:</i></li> </ul> <p>&gt;&gt; TRADING ACTIVITIES:</p> <ul style="list-style-type: none"> <li>- <b>Placing on the market (TRADE)</b> – 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).</li> <li>- <b>Placing on the market (PRODUCTION)</b> – 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).</li> <li>- <b>Traders that place on the market products under their own label are considered producers.</b> 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 FIL.</li> </ul>

	<ul style="list-style-type: none"> <li>• Example 1: If a trader does repackaging for FAMI-QS, this is considered production since the trader shall manage additional risk/ hazards.</li> <li>• 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.</li> </ul> <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>
<b>Chapter 8 Operations</b>	<ul style="list-style-type: none"> <li>• The heart of the management system (the business). This chapter shall be combined with the Process documents relevant to the Operator</li> </ul>
<b>Chapter 9 Performance Evaluation</b>	<ul style="list-style-type: none"> <li>• Actions to address risks and opportunities</li> <li>• Feed safety and Quality objectives and planning to achieve them</li> </ul>
<b>Chapter 10 Improvement</b>	<ul style="list-style-type: none"> <li>• Requirements for managing nonconformities</li> <li>• Requirements for continuous improvement</li> </ul>

### 3. Rules for the Operators – Main adjustments

Final document: P-ROP-01 Version 8 REV 2 - 2018-10-12

This *Note for FAMI-QS Feed Business Operators* covers the main changes of the revised rules since the day of their publication. However, it is important to reinforce that the Operators are requested to read again the document to be sure that all requirements are understood and applied. The following updates were carried out:

#### 3.1. Update on Auditing Time Calculation Table

Table 2: Initial Auditing Time Calculation Table

A	B	C	D	E	F
Basic audit time	Number of additional days for each additional process	Number of audit days in the absence of a relevant certified system.	Additional auditing time dedicated to the auditing of the files for those feed ingredients purchased from non-assured sources.	Number of audit days per number of employees.	For each additional site under the same Feed Safety and Quality Management System, operating a similar manufacturing process.
Scope K, DI 1.5 for one process. Scope F 1.0	0.5	0.25	01-05 ingredients 0.25 06-10 Ingredients 0.5 11-15 ingredients 0.75 More than 15 ingredients 1.00	1 to 19 = 0 20 to 49 = 0.5 50 to 79 = 1.0 80 to 199 = 1.5 200 to 499 = 2.0 500 to 899 = 2,5 900 to 1 299 = 3,0 1 300 to 1 699 = 3,5 1 700 to 2 999 = 4,0 3 000 to 5 000 = 4,5 > 5 000 = 5,0	50% of the minimum on site audit time.

**A:** Basic audit time: In case of trading scope F, the basic audit time only covers one process from which the total number of final product(s) are derived.

**B:** Additional auditing time for additional manufacturing processes: For traders of the scope F, the additional time covers the total number of additional processes.

**C:** In order to avoid duplication where another relevant management system (ISO 9001, GMP+, FSSC 22000, ISO 22000) is in place and when certified by the same Certification Body, column C is not applicable. Auditors shall have full access to the audit reports of those audits.

**D:** Additional auditing time dedicated to the auditing of the files for those feed ingredients entering the production process and/or trading which are coming from non-assured sources.

**E:** Additional auditing time according to the number of employees (FTE) under the FAMI-QS System.

**F:** For each additional site operating under centrally controlled and administrated FAMI-QS System, 50% of the minimum on-site audit time shall be considered:  $(A+B+C+D+E)*0.5$

A reduction of maximum of 10% can be given based on the previous experience of the Certification Body with the organization. For Integrated audits a reduction up to 20% can be given (IAF MD 11).

*Note on Integrated Management System (IMS):* A single management system managing multiple aspects of organisational performance to meet the requirements of more than one management standard, at a given level of integration. Integration relates to the management system being able to integrate documentation, appropriate management system elements and responsibilities in relation to two or more sets of audit criteria/standards. A management system may range from a combined system adding separate management systems for each set of audit criteria/standard, to an Integrated Management System, sharing in single system documentation, management system elements, and responsibilities.

### 3.2. Subcontractor

If the subcontractor is not FAMI-QS certified or is not certified by any other mutual recognized standard, the Operator shall evaluate the risk connected to the Operator's service and perform a full audit, in order to ensure that the subcontractor meets the FAMI-QS requirements. The Operator shall audit the establishment of the subcontractor against FAMI-QS requirements at least once within the certification cycle. A report shall be made available.

During the Operator's certification and surveillance audits, the auditor shall check the audit report of the subcontractor. The Certification Body may also audit the subcontractor based on the evidence presented in the subcontractor audit report. On successful completion of the audit, a certificate will be granted to the Operator only.

If the subcontractor is certified according to FAMI-QS or to a mutually recognized standard, no additional FAMI-QS audit by the Operator is required as long as the applicable product falls under the scope of that certification.

### 3.3. Unannounced Audits

Certification Bodies shall include in their internal audit programme an unannounced audit, for each FAMI-QS certified Operator. The unannounced audits are applicable to both producers and traders. Participation in the unannounced audit program is mandatory.

- **Frequency:** once per certification cycle.
- **Duration:** 0.5 man-days minimum. The unannounced audits can be done by any approved Feed/Food Auditor.

- **Notification to the FAMI-QS Certified Operator:** No notice in advance. Certification Body shall ensure the Operator takes the necessary steps for granting access to the auditor in such events.  
*Note: Operators should follow a similar procedure as for the unannounced audits performed by the authorities.*

The conditions for the provision of the unannounced audits shall be agreed on between the Certification Body and the FAMI-QS certified Operator and shall be part of the contract. The contract needs to ensure that one unannounced audit is undertaken after the initial certification audit and within each 3-year period thereafter.

Operators shall inform the Certification Body regarding any scheduled maintenance closure of the company.

There are a number of topics that should be covered during an unannounced audit for production and trading activities.

#### **(i) Topics covered during an unannounced audit for production activity**

The auditor should cover all or a combination of the below areas:

- Monitoring of CCP;
- Inspection of the premises (internal – external);
- Observation if the employees perform their tasks according to the written procedure;
- Crisis Management.

#### **(ii) Topics covered during an unannounced audit for trading activity**

The auditor should cover all or a combination of the below areas:

- Suppliers' evaluation;
- Purchase orders and specifications;
- Certificates of analysis (shall be checked per purchase order);
- Traceability;
- Crisis management.

In the event that the certified Operator refuses to participate in the unannounced audit, as defined in the contract between the CB and the FAMI-QS Operator, the certificate shall be suspended immediately, and the CB shall withdraw the certificate, if the unannounced audit is not conducted within a six-month timeframe.

For Integrated Management Systems both for Feed and Food (FAMI-QS/FSSC 22000), the unannounced audit performed for FSSC 22000 could be also considered for FAMI-QS, as long as common topics have been checked. In this case, the auditor shall also be a FAMI-QS approved auditor. The FAMI-QS and FSSC 22000 certificates shall be issued by the same Certification Body.

Topics checked during the unannounced audit might be skipped during the subsequent audit, only in the case that the audit has been performed by a FAMI-QS approved auditor (excluding production areas).

### 3.4. Consequences of non-conformities

Table 3: Consequences of non-conformities.

Non-conformity	Initial audit	Surveillance	Re-certification audit
<b>Major</b>	Certification cannot be granted. Action plan shall be submitted within 7 days after audit. Non-conformities have to be closed within 6 weeks after the audit	The action plan shall be presented to the Certification Body, in 14 calendar days at the latest after the audit date. Evidence that non-conformities have been closed will be checked 28 days after the presentation of the action plan at the latest. In case that the aforementioned time frame is not sufficient, further coordination with FAMI-QS is required. If a non-conformity is not resolved, then the certification is suspended and a special audit shall be applied for the closing of the major NCR.	Certification cannot be granted. Action plan shall be submitted within 7 days after audit. Non-conformities have to be closed within 6 weeks after the audit.
<b>Minor</b>	Certification cannot be granted until the non-conformities have been closed. Action plan shall be submitted within 7 days after audit. Non-conformities have to be closed within 6 weeks after the audit	Certification continues. An agreement on the action plan shall be reached between the Certification Body and the Operator. The deadline for this agreement is 14 calendar days after the Certification Body has received the action plan from the Operator. Evidence that non-conformities have been closed will be checked by the auditor, at the latest during the following audit. If the non-conformity is not solved and closed by then, it becomes a major non-conformity.	Certification continues. An agreement on the action plan shall be reached between the Certification Body and the Operator. The deadline for this agreement is 14 calendar days after the Certification Body has received the action plan from the Operator. Evidence that non-conformities have been closed will be checked by the auditor, at the latest during the following audit. If the non-conformity is not solved and closed by then, it becomes a major non-conformity.

### 3.5. Text of the certificate

Operator's Name

*has implemented and maintains a Feed Safety and Quality Management System including Good Manufacturing Practice (GMP) in compliance with:*  
*FAMI-QS Code (Version x, yyyy-mm-dd)*

on the following site/s<sup>(1)</sup> XXX

FAMI-QS Site Registration: FAM-xxxx/xx

for Activity<sup>(2)</sup> of Specialty Feed Ingredients  
From Process<sup>(3)</sup>

Feed Chain Category<sup>(4)</sup> DI, K, FI, FII

The Operator implements measures for feed fraud / feed defense according to the FAMI-QS Supply Chain Integrity Module V XX

This certificate is valid until: yyyy-mm-dd

Signature of the Certification Body: \_\_\_\_\_ Place, Date yyyy-mm-dd

*For the validity of this certificate please check [www.fami-qs.org](http://www.fami-qs.org)*

## 4. Recognised standards

Final document: P-MS-003, Version 1 / Revision 6 - 2018-10-12

**Note: The Recognised standards document is subject to more frequent updates. On our website, we always upload the updated version.**

### 4.1.1. Feed grade

Suppliers that are certified with one of the following mutually recognised standards are considered as assured sources:

- a) FAMI-QS
- b) GMP+ International
- c) Feed Chain Alliance (OVOCOM)
- d) UFAS/FEMAS
- e) QS Qualität und Sicherheit GmbH – for Europe
- f) Sincirações Level 2 – Sincirações Level 2 certified Operator is recognised as an assured source only for the supply of feed ingredients to FAMI-QS certified Operators in Brazil. Sincirações Level 2 certified Operator is not considered as an assured source when the FAMI-QS certified Operator is based outside Brazil.

The specialty feed ingredients concerned shall be part of the certificate of the recognized standard. FAMI-QS certified companies shall ensure that the ingredient is also covered under the certificate. This can be checked through a statement by the supplier.

### 4.1.2. Food Grade - food additive

If the ingredient is a food additive, suppliers fulfilling the following requirements are considered as assured sources:

- a) ISO 22000 certified + self-declaration of compliance with the JECFA (joint FAO/WHO expert committee on food additives) specification
  - b) FSSC 22000 certified + self-declaration of compliance with the JECFA (joint FAO/WHO expert committee on food additives) specification
  - c) ISO 9001 + documented HACCP programme in place + self-declaration of compliance with the JECFA (joint FAO/WHO expert committee on food additives) specification
- NOTE on c): This will be accepted until 1st October 2021.

### 4.1.3. Food grade ingredient

If the ingredient is food grade, suppliers that are certified with one of the following standards are considered as assured sources:

- a) ISO 22000
  - b) FSSC 22000
  - c) ISO 9001 + documented HACCP programme in place
- NOTE on c): This will be accepted until 1st October 2021.

#### 4.1.4. Pharma grade

If the ingredient is pharma grade, suppliers fulfilling the following requirement are considered as assured sources:

- a) Certification according to Pharma GMP, with the product name included (API) in it.
- b) Certification (EXCiPACT) or 3rd party confirmation for excipients.

For further information on the documents, please contact us at [revision@fami-qs.org](mailto:revision@fami-qs.org) (only to FAMI-QS Certified Feed Business Operators).