

# RULES FOR OPERATORS

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## 1. Scope

FAMI-QS certification is based on the FAMI-QS Code of Practice. The only valid version of the Code is the English version, published on the FAMI-QS Asbl website.

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

- minimizing the risk, that adulterated Specialty Feed Ingredients enter the feed chain;
- enabling an Operator to implement the objectives of the feed hygiene regulation 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 Operators at all stages from the first placing on the market, including imports. FAMI-QS Code covers the following activities: Production and Trade.

Feed Safety and Quality Management System certification against FAMI-QS Code does attest that the production process is taking place under hygiene conditions in order to minimize and possibly eliminate the risks pertaining to the Feed/Food Chain.

FAMI-QS requires an operator to meet all applicable feed-safety-related statutory and regulatory requirements through its management system both in the country of production and in the country of destination. In case that in the country of or production and/ or destination there are no applicable feed-safety related statutory and regulatory requirements, the EU Feed Safety requirements shall be applied.

Certification of a Feed Safety and Quality Management System according to FAMI-QS Code is a management system certification, not a product certification.

For the current scope of FAMI-QS certification, please consult the FAMI-QS Code of Practice, Chapter 2.

# 2. Application for certification

Any Operator willing to be FAMI-QS certified can send an application to FAMI-QS using the application form which is available on the FAMI-QS website.

The ten (10) steps outlining the certification process are detailed below:

**STEP 1** The Operator should download a free copy of the FAMI-QS Code and the Rules of Operators and read the documents carefully.

**STEP 2** The Operator should evaluate their readiness and perform an internal audit.

**STEP 3** The Operator should identify its product(s) and fill in all the sections of the application form (e-form or word format available on <a href="http://www.fami-qs.org/apply">http://www.fami-qs.org/apply</a>) in order to register for FAMI-QS Certification.

**STEP 4** FAMI-QS will evaluate the application and return an email stating if the application can be accepted or not. Once it has been approved, FAMI-QS will issue an invoice for membership fee. The membership fee is paid on a yearly basis. Once it is paid, a letter of acceptance (Approval Letter) is sent to the Operator. A payment receipt is sent by email, upon request. The approval letter needs to be provided to the auditor.



**STEP 5** The Operator should select a Certification Body (CB) from the FAMI-QS website list and contact them for the audit. The approval letter will be required for the communication with the CB.

**STEP 6** The CB provides the initial audit as follows:

Stage 1 - evaluation of the Feed Safety and Quality Management System, documentation, scope and preparedness;

Stage 2 - verification of the implementation of the Feed Safety and Quality Management System.

**STEP 7** Outcomes of the audit and possible action plan for the non-conformities.

Assessment of the action plan and its implementation by the Certification Body.

The CB submits the audit documentation to FAMI-QS.

**STEP 8** Revision of the audit documentation and its findings by the Certification Body, followed by the certification decision. The CB delivers the certificate to your company.

**STEP 9** FAMI-QS reviews the audit documentation and membership payment and gives its validation for registration. After verification of the audit documentation, the Operator will be registered and listed on the FAMI-QS website as a certified Operator.

**Step 10** After the initial certification, an annual surveillance audit will apply. The certification is valid for 3 years. After the cycle of 3 years, a recertification audit will take place.

If there are no changes in the scope, company name or address, there is no need to request a new approval letter. The previous one remains valid.

Note: In the event that your company is not listed on our website, we advise you to check with your Certification Body if they have provided all the necessary documents to FAMI-QS. All questions related to this subject shall be submitted exclusively to <a href="mailto:audit@fami-qs.org">audit@fami-qs.org</a>.

## 2.1. Evaluation procedure of the application

As stated above, the Operator's application for Specialty Feed Ingredients requires a form to be filled in. This form has questions to be clearly answered by the Operator in order to evaluate if the ingredients produced/ traded are covered within the FAMI-QS scope.

Specialty feed ingredients shall be defined and labelled with clear application instructions according to the applicable animal feed legislation of the intended market. The regulatory status of the products will be under the responsibility of the Operator. The products shall be legally produced in the country of origin and shall meet the regulatory requirements of the country of destination.

To get an application's approval, the product shall comply with the definition of Specialty Feed Ingredient. Any other result will lead to the rejection of the application.

# 3. FAMI-QS Membership Fees

Once the application has been approved, FAMI-QS will return an invoice for membership fee. The membership fee invoice shall be paid within 30 days from the issuing day.

Membership fees conditions:

- A fee is applied for each registered site within the FAMI-QS system.
- The amount of the membership fee is announced on the website.



- An invoice will be issued each calendar year following the application.
- In the event that a FAMI-QS certified Operator refuses to pay the membership fee, the company will be removed from the FAMI-QS website.

# 3.1. Other charges

In the event that a FAMI-QS certified Operator interrupts their membership and re-applies for FAMI-QS certification, an additional administrative fee will be charged and added to the yearly membership fee.

In addition, an administrative fee will be applied to process changes linked with the updates of the Approval letter, such as scope extension or other amendments. Only in case of new sites registration, no administrative fee will be applied.

# 4. Assessment of Operators

Operators shall contact one of the FAMI-QS authorised Certification Bodies listed in the FAMI-QS website.

For the application, the following information must be sent by the Operator to the Certification Body before the certification audit takes place:

- a) Approval letter from FAMI-QS;
- b) Licence documents appropriate for the operations of the Operator;
- c) List of products coming from the processes covered in the FAMI-QS Scope. If, during the audit, auditors identify products that fall under FAMI-QS scope and are not part of the list, they shall immediately inform the Operator that all products shall be part of the audit.
- d) List of ingredients purchased from non-assured suppliers (processing aids/intermediates are excluded);
- e) Information about production site(s);
- f) Externally provided services (contract manufactures, warehouses);
- g) Audit report from the subcontractor(s) (toll manufacturer(s), supplier(s), if applicable;
- h) Countries where the products are placed.

The CB shall not exclude activities, processes, products or services from the scope of the audit when those activities/processes/products/services can have an impact on the feed safety. These considerations shall be taken into account in the audit programme and audit plan.

The Certification Body assesses the Operators' compliance with FAMI-QS, on the basis of initial, surveillance and recertification audits.

In case of any unresolved disagreement between an Operator and an authorised Certification Body, circumstances should be reported in writing by the Operator to FAMI-QS Asbl for consideration by the FAMI-QS Board.



## 4.1. Auditing Time Calculation

## 4.1.1. Initial Auditing Time Calculation

Table 1: Initial Auditing Time Calculation Table.

| Α  | В   | С  | D  | E   | F   |
|--|---|--|--|---|---|
| Basic audit time                             | Number<br>of<br>additional<br>days for<br>each<br>additional<br>process | Number of<br>audit days in<br>the absence<br>of a relevant<br>certified<br>system. | Additional auditing time dedicated to the auditing of the files for those feed ingredients purchased from non-assured sources. | Number of audit days<br>per number of<br>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<br>20 to 49 = 0.5<br>50 to 79 = 1.0<br>80 to 199 = 1.5<br>200 to 499 = 2.0<br>500 to 899 = 2,5<br>900 to 1 299 = 3,0<br>1 300 to 1 699 = 3,5<br>1 700 to 2 999 = 4,0<br>3 000 to 5 000 = 4,5<br>> 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 a maximum of 10% can be given based on the previous experience of the Certification Body with the Operator. For integrated audits: IAF MD 11 shall be applied for the auditing time reduction.

#### 4.1.2. Auditing Time Calculation for Surveillance audit and Re-Certification

- a) **Surveillance Audit:** the total minimum surveillance audit time should be one-third of the initial certification audit time, with a minimum of eight hours.
- b) **Re-Certification Audit:** the total minimum time should be two-thirds of the initial certification audit time, with a minimum of eight hours.



# 5. Audit planning

According to the requirements of ISO/IEC 17021-1:2015 and ISO/TS 22003, the FAMI-QS initial certification audit shall be conducted in two stages, stage 1 and stage 2.

Before the stage 1 audit for initial certification, the Operator shall provide the Certification Body (in written, electronic form or during a meeting between the Operator and the auditor) the documentation described in the previous chapter "Assessment of Operators".

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 (see document P-MS-003), the CB shall consider to audit the contracted manufacturer at least once within the certification cycle.

#### 5.1.Initial Certification Audit

#### 5.1.1. Stage 1

Planning shall ensure that the objectives of stage 1 can be met and the client shall be informed of any "on site" activities during stage 1. Stage 1 does not require a formal audit plan.

The objective of the stage 1 audit is to provide a focus for planning the stage 2 audit. This shall be achieved by gaining an understanding of the Feed Safety and Quality Management System, in the context of the Operator's feed safety hazard identification, analysis, HACCP plan and PRPs, policy and objectives, and in particular according to the Operator's level of preparation for the audit by reviewing the extent to which:

- a) The Feed Safety and Quality Management System is aligned with the requirements in the FAMI-QS Code.
- b) The Operator has identified PRPs that are appropriate to the business.
- c) Evaluating the audit report on audits carried out at the supplier premises (if applicable).
- d) Evaluating the audit report on audits carried out at the subcontractors' facilities (if applicable).
- e) The Feed Safety and Quality Management System includes adequate processes and methods for the identification and assessment of the Operator's feed safety hazards as well as the subsequent selection and categorization of control measures according to the FAMI-QS code.
- f) The Operator complies with the relevant feed legislation.
- g) The Operator's System collects the relevant statutory and regulatory requirements, related to the production in the country of origin and the placing of the specialty feed ingredients in the country of destination.
- h) The Feed Safety and Quality Management System is designed to achieve the Operator's feed safety policy.
- The Feed Safety and Quality Management System implementation programme allows to proceed to stage 2 of the audit.
- j) The validation, verification and improvement programmes are conformed to the requirements of the FAMI-QS Code
- k) The Feed Safety and Quality Management System documentation is in place and its requirements are internally and externally communicated (relevant suppliers, customers, other interested parties, *etc.*).
- Additional documentation needs to be reviewed /or which knowledge needs to be obtained in advance.

In exceptional circumstances, a part of stage 1 can take place off-site and shall be fully justified. The evidence demonstrating that stage 1 objectives are fully achieved shall be provided. Exceptional circumstances can include very remote location.



The findings in Stage 1 shall be documented and communicated to the client. The findings of Stage 1 do not include Non Conformities.

The interval between stage 1 and stage 2 shall not be longer than 6 months. Stage 1 shall be repeated if a longer interval is needed.

A stage 1 audit is required for the initial certification audit.

A stage 1 audit might apply for the re-certification audit when major changes in the Operator's Feed Safety and Quality Management System have occurred.

#### 5.1.1. Stage 2

A stage 2 audit takes place at the location of an applicant who seeks certification against the FAMI-QS Code. All sections of the FAMI-QS code shall be verified.

The stage 2 audit takes place at the Operator's site. The purpose of the stage 2 audit is:

- a) To confirm the implementation, including the effectiveness of the Operator's Feed Safety and Quality Management System to the requirements of the FAMI-QS Code.
- b) To verify that the information and evidence of conformity is achieved, for all of the FAMI-QS Code's requirements.
- c) To assess the capability of the Feed Safety and Quality Management System to perform key activities, such as production methods, controls, PRPs, HACCP plans and procedures, as well as the competency of the personnel involved in the feed/food safety functions, in conformity with the ISO standards.
- d) To assess the Operator's Feed Safety and Quality Management System, in compliance with EU and local statutory, regulatory and contractual requirements.
- e) To confirm that the Operator's Feed Safety and Quality Management System is effective in achieving the stated feed safety policies and objectives.

The selection of the executive and other personnel to be interviewed shall adequately cover every relevant functional area. If shift-work is performed, an interview can be planned outside normal working hours.

Any part of the Feed Safety and Quality Management System that is audited during the stage 1 audit and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during the stage 2 audit. However, the certification body shall ensure that the already audited parts of the Feed Safety and Quality Management System continue to conform to the certification requirements. In this case, the audit report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

#### 5.2.Subcontractor

The Operator's subcontractor(s) (toll manufacturer(s), supplier(s)...) is subject to the same approval criteria as any other supplier of FAMI-QS certified Operator.

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.

# 6. Maintaining certification

#### 6.1. Surveillance Audits

Frequency of the surveillance audits:

- a) 1st Surveillance Audit: within 12 months after the Initial Certification Audit.
- b) **2<sup>nd</sup> Surveillance Audit:** approximately 24 months after the Initial Certification Audit.

CB shall report to FAMI-QS Secretariat the annual surveillance activities (Company name, site, Auditor(s), audit dates.

#### 6.2. Recertification Audit

A failure to perform the re-certification audit before the expiration of the certificate results in the interruption of the certification cycle. In this case, the wording "certified since" cannot be included on the certificate.

If a re-certification is conducted after the expiry of a certificate, a Stage 1 and Stage 2 Audit shall be carried out.

# 7. Special Audits

## 7.1. Extension to the scope

In response to an application for the extension of the scope of a certification that has already been granted, the Certification Body shall undertake a review of the application and determine any audit activities that may be deemed necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance or re-certification audit.

#### 7.2. Short Notice Audits

It might be necessary for the Certification Body to conduct an audit of a certified Operator at short notice (up to 72 hours' notice), in order to:

- investigate a complaint, or
- in response to a feed safety incident or crisis at the Operator's site or
- as a follow-up on suspended certificate(s).



#### In such cases:

- a) The Certification Body shall inform the certified Operator(s) in advance and describe the conditions under which this/these short notice visit(s) will be conducted.
- b) The Certification Body shall notify FAMI-QS about the result of the audit.

In case of an incident, the P-CM-001 Feed Incident Management Procedure for Operators and Certification Bodies current version shall be applied.

#### 7.3. 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 FAM-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/F SSC 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).

## 8. Classification of non-conformities and recommendations

## 8.1. Major non-conformities

A major non-conformity is a non-conformity that affects the capability of the Feed Safety and Quality Management System to achieve the intended results or a complete failure to implement the requirements of the code.

Non-conformities could be classified as major in the following circumstances:

- if there is a significant documented evidence that there is no effective process control in place, or that products or services do not meet the specified requirements;
- a number of minor nonconformities associated with the same requirement or issues could demonstrate a systematic failure and thus constitute a major nonconformity.

#### 8.2. Minor non-conformities

A minor non-conformity exists when a requirement of the FAMI-QS Code has been addressed but there is insufficient evidence to demonstrate that it has been properly controlled or implemented and does not affect the capability of the management system to achieve the intended results.

More than 2 or 3 minor non-conformities under the same clause shall be considered as major.

## 8.3. Consequences of non-conformities

Table 2: Consequences of non-conformities.

| Non-       | Initial audit  | Surveillance  | Re-certification audit  |
|------------|--|---|---|
| conformity |  |   |   |
| Major      | granted. Action plan shall be submitted within 7 days after 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. |



| Non-<br>conformity | Initial audit           | Surveillance                                    | Re-certification audit                          |
|--------------------|-------------------------|---|---|
| Minor              | Certification cannot be |   | Certification continues.                        |
|                    | _                       | An agreement on the action plan shall be        | An agreement on the action plan shall be        |
|                    | conformities have been  | reached between the Certification Body and the  | reached between the Certification Body and the  |
|                    | closed.                 | Operator. The deadline for this agreement is 14 | Operator. The deadline for this agreement is 14 |
|                    | •                       | calendar days after the Certification Body has  | calendar days after the Certification Body has  |
|                    | submitted within 7 days | received the action plan from the Operator.     | received the action plan from the Operator.     |
|                    | after audit. Non-       | Evidence that non-conformities have been        | Evidence that non-conformities have been        |
|                    | conformities have to be | closed will be checked by the auditor, at the   | closed will be checked by the auditor, at the   |
|                    | closed within 6 weeks   | latest during the following audit. If the non-  | latest during the following audit. If the non-  |
|                    | after the audit         | conformity is not solved and closed by then, it | conformity is not solved and closed by then, it |
|                    |                         | becomes a major non-conformity.                 | becomes a major non-conformity.                 |

The auditor shall confirm that he has reviewed, accepted and verified the effectiveness of corrective actions.

# 9. Assessment of suppliers and assured sources

Any raw material / traded product which enter the manufacturing process or trade of any product under the FAMI-QS scope shall be assessed according to chapter 8.6. of the FAMI-QS Code.

## 9.1. Audit guidelines for supplier audits

- a) The frequency of the audits shall be at least every 3 years.
- b) The first audit shall be executed no later than 6 months after the first raw material delivery.
- c) Audits have to be executed by experienced employees (according to the Operator's procedures) or by a capable 3<sup>rd</sup> party auditor (according to the selection criteria established in the "Rules for Certification Bodies").
- d) Relevant sections of the FAMI-QS Code shall be checked and audit reports, including follow-up procedures on actions, shall be available.

**Note on the "experienced employees":** An experienced employee is the employee that can demonstrate competences related to the following aspects:

- Knowing the importance of the quality of the raw material for the production process.
- Understanding the principles of a Feed Safety and Quality Management System.
- Knowing auditing techniques
- Have been for at least three years within the Operator.

It is the FAMI-QS external auditor's responsibility to check that the requirements set according to the FAMI-QS Code are met.

# 10. Feed Safety Incident Management

In the event that the Operator becomes aware or has reasons to suspect a feed safety incident, or in the event of a product recall in relation to such incidents, the Operator shall immediately make the FAMI-QS Process Manager and the Certification Body aware of the situation.



Together with the Operator, the Certification Body in turn shall take appropriate action steps to assess the situation and any implications that there may be for the Operator's certificate. The Certification Body shall inform FAMI-QS of the result from this assessment and its further progress.

The Operator and the Certification Body shall follow the "Feed Safety Incident and Crisis Management Procedure for Operators and CBs" (P-CM-01).

## 11. Certificate

#### 11.1. Text of the certificate

Text on the certificate (minimum information):

| Operator's Name as 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 <u>www.fami-qs.org</u>  |  |
|   |  |

- 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).

<sup>(1)</sup> For Operators running multiple manufacturing processes at different sites it is sufficient to issue one certificate listing all the sites.

<sup>&</sup>lt;sup>(2)</sup> Activity means: **Production** and/ or **Trading**. The term placing on the market may also be used but the activity production or trade shall be specified, e.g. *placing on the market (trade and/ or production)*. Any other term like design and development, warehousing, transportation is not allowed.



- 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 (see categories below in (4)).
  - 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.

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.

(3) Production Process: The Certification Body shall identify and clearly state the process from which the ingredients are resulting from: **Bioprocess – Chemical – Mixing – Formulating – Mining – Extraction** 

(4) Classification of feed chain categories applicable to FAMI-QS (ISO/TS 22003:2013 – Annex A):

DI: for products fed directly to the animal and/or delivered to the farm

K: products not given directly to the animals and/or not sold directly to the farm

FI: when Operators trade their own products

FII: when Operators trade products not produced by themselves

#### 11.2. Withdrawal of certificates

The withdrawal of a certificate remains the responsibility of the Certification Body. Once a withdrawal is confirmed, the name of the Operator will be removed from the FAMI-QS "Certified Companies register" on the website.

Certified Operators holding valid certificates are listed on the FAMI-QS website.

A note of a withdrawn certificate will be e-mailed to all of the FAMI-QS certified companies and also uploaded on our section *Notification* of FAMI-QS website.

## 11.3. Suspended Certificates

The suspension of a certificate remains the responsibility of the Certification Body. CBs shall maintain a register of the suspended certificates. The minimum information that shall be included in the register is:

- a) Name of the company.
- b) Certificate number.
- c) Reason of the suspension.
- d) Suspension period.
- e) Condition for termination of the suspension.

The CB shall make FAMI-QS immediately aware about the suspension of a certificate. The name of the Operator will be removed from the section certified companies on the FAMI-QS website during the period of the suspension.

A list of suspended FAMI-QS certificates will be maintained on line. Suspension cannot exceed three months. Following that period, a FAMI-QS certified company will be removed from our website. Initial audit shall be applied if the feed business operator wishes to restore its FAMI-QS certificate.



#### 11.4. Exclusions on certificates

It is an obligation of the FAMI-QS certified Operators not to mislead stakeholders and authorities regarding the scope of their certification, validity of the certificate and site(s).

## 11.5. Invoicing Address/ Registration Address

The responsibility for placing products on the market relies in the invoicing address. Therefore, this address must be included under the Operator's Certificate.

In the event that the invoicing address is a PO box or no activity is taking place at the location, the address can be included on the certificate after a desk review of the legal documents (business registration, registration with the feed authorities, where applicable) performed by the auditor. This is not applicable when the invoicing address is holding responsibilities for warehousing, transportation, etc.

All the traceability and recall procedures are under the responsibility of the invoicing address. In this case, employees of the invoicing address shall be involved in the audit for the relevant parts.

## 11.6. Transfer of Accredited/Non Accredited FAMI-QS Certificates

For the transfer of accredited FAMI-QS certificates IAF MD2:2007 Mandatory Document for the Transfer of Accredited Certification of Management Systems shall be applied.

The CB responsible for the transfer shall contact FAMI-QS Secretariat prior to the transfer for pre-approval of the transfer. FAMI-QS Secretariat will communicate any open issues if related to the transfer of the certificate (if applicable).

# 12. Transparency

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

# 13. Surveillance Programme

The objective of the surveillance programme is to establish the level of confidence in the CB's certification process by on-site and off-site observations.

In the surveillance programme process, a representative of FAMI-QS monitors the activities of the Certification Bodies and its associated auditor(s) on the occasion of an assessment of a specific feed business Operator on site and / or at the Certification Body's premises. The surveillance process is compulsory for all of the authorized Certification Bodies.

The surveillance process is considered beneficial to all stakeholders.

The surveillance programme consists of two parts:



**Part 1:** Office Audit - FAMI-QS conducts an assessment, at the Certification Body premises, to verify the implementation of the FAMI-QS rules.

**Part 2:** FAMI-QS conducts an assessment of a Certification Body's performance, during its on-site audit, with prior agreement of the Operator.

The CBs shall include in the contracts with their clients a relevant reference, for the on-site audit with the participation of the FAMI-QS auditor. A FAMI-QS certified Operator shall be aware that it might be selected for the FAMI-QS Surveillance Programme.

FAMI-QS may also initiate the Surveillance Programme in case of an Operator's complaint.

A copy of the Surveillance Programme audit report will also be made available to the Certification Body's local accreditation body.

Any exchange of information related to the purpose of the surveillance activities will be kept strictly confidential and shall only be communicated between the parties involved (FAMI-QS, Certification Body)

A National Accreditation Body could have access to the Surveillance Programme report after a request.

The information obtained during the surveillance of the Certification Body, which is recorded in the report, will be handled in a strictly confidential manner by FAMI-QS. FAMI-QS will not use it for purposes apart from those established in the frame of the surveillance process.

#### 14. Sanctions

In case of a violation by the Certified Operator any other requirement set out in the applicable Documents, FAMI-QS has the right to impose, at its own option, one or more of the following sanctions:

- A formal warning: the certified organization shall provide its written feedback within 72 hours after the sending of the formal warning.
- Special audit with a prior note of 24 hours
- Recommendation to the Certification Body for a suspension or withdrawal of the certificate
- Suspension from the FAMI-QS Certification system or a time period or for lifetime

# 15. Notification of Changes

A FAMI-QS certified Operator shall inform the Certification Body and FAMI-QS without delay, for the following changes:

- a) The legal, commercial, organizational status or ownership.
- b) Operator and management changes
- c) Contact address and sites.
- d) Changes on the current certified scope.
- e) Major changes to the management system and processes.
- f) Issues related to the safety of the product.



g) Any other issue which may affect the capability of the Feed Safety and Quality Management System.

For changes regarding a, b, c, d, the FAMI-QS certified Operator needs to use the FAMI-QS Changes Notification form (D-ROP-01-03).

# 16. Use of logo

The FAMI-QS name and logo may only be used by Operators that have obtained certification from a Certification Body recognized 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.

Certification Body will verify during the on-site audit the appropriate use of the logo.