



Quality and Safety System for Specialty Feed Ingredients

P-SP-01

SURVEILLANCE PROGRAMME

P-SP-01
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1. Introduction

In order to maintain credibility of the FAMI-QS certification process and to assure a homogenous interpretation and application of the FAMI-QS rules and requirements an integrity programme named '*Surveillance Programme for Certification Bodies*' has been initiated by FAMI-QS. It is designed to build confidence and trust in the certification process among all the interested parties.

The surveillance programme consists of two parts:

- **Part 1:** Office Audit - FAMI-QS conducts an assessment, at a given Certification Body's premises, to verify the FAMI-QS rules' implementation.
- **Part 2:** FAMI-QS carries out an assessment of a given Certification Body's performance, during its on-site audit when the auditor is performing the audit

The objectives of carrying out the surveillance programme are:

- To increase the Code of Practice's credibility;
- To improve its acceptance on a global basis;
- To confirm a homogenous interpretation and application of the applicable clauses;
- To confirm the compliance of the FAMI-QS Authorised Certification Bodies with the FAMI-QS Rules;
- To further investigate any incident and/or complaints;
- To provide input to the Accreditation Bodies' planning.

Ultimately, the process will further raise the level of awareness for feed safety and improve all of the associated Operators' level of compliance.

In the contracts with their clients, the CBs shall include a relevant reference to the on-site audit with the FAMI-QS auditor. A FAMI-QS Certified Operator shall be aware that they might be selected for the FAMI-QS Surveillance Programme.

The Surveillance Programme can also be initiated by the FAMI-QS team to investigate an incoming complaint regarding a FAMI-QS Certified Operator or an Authorised Certification Body.

2. Scope

The procedure is applicable to all the FAMI-QS Authorised Certification Bodies.

3. Selection Criteria for Certification Bodies

All the FAMI-QS Authorised Certification Bodies will be audited by the FAMI-QS Integrity Auditor, prior authorisation and within the programme's first year of implementation. The starting date is considered to be the publication date of this procedure.

The frequency for the implementation, of both Part 1 and Part 2, following the first-year audit, will be defined according to the following - non exhaustive - criteria:

- The number of CBs' critical locations (according definition in ISO/IEC 17011);

- A sudden increase or decrease in the number of FAMI-QS Certified Operators;
- A CB raises few or no NC's over a long time period;
- Crisis questioning about the certification's credibility;
- Product recalls;
- Complaints from customers of Certified Operators or of other interested parties;
- Concerns on the effectiveness of a given CB's certification process;
- Negative publicity;
- Unilateral intervention or negative feedback from regulators;
- Number of involved auditors per CB;
- A sudden change in qualified auditors;
- Number of involved operators and/or sites per CB;
- Number of transfers accepted;
- Number of overdue audits;
- Number of auditor-days delivered;
- Frequently too late delivery of the audit report or too late finalisation of the audit process;
- Extraordinary events;
- Importance of the feed (additive) product.

The FAMI-QS Quality Manager will define the Surveillance Programme annually, according to both the above-mentioned criteria and to a given Certification Body's performance, on the basis of the daily information exchange. The rationale behind the decisions made by the FAMI-QS Quality Manager shall be deemed to be internal, confidential, final and not subject to further debate.

3.1 Part 1 - Office Audit Approach

The Part 1 office audit is the audit which is conducted by a FAMI-QS Integrity Auditor (internal or external), either at the premises of the FAMI-QS Authorised Certification Body, or in one of its critical locations.

During the Part 1 audit, the auditor will access all internal procedures (limited to the FAMI-QS activity or what could have an effect on the FAMI-QS activity) according to the ISO 17021, the ISO/TS 22003, the FAMI-QS Rules for Certification Bodies and the FAMI-QS Certified Operator's records.

10% of the current certified Operators will be checked with minimum 10 files. Part of the documents that will be checked will be quotations and final invoices to the customer.

The office audit's date will be decided together with the Certification Body taking part in the programme.

The Office Audit could be combined with the internal audit programme of the Certification Body.

3.2 Part 1 - Office Audit Duration

Additional Man-day to the minimum man-days office audit					
Minimum Man-days - office audit	Number of Operating Countries	Number of Critical Locations	Number of FAMI-QS Auditors	Number of Certified Operators	Number of overdue audits
1	1-5: 0 6-10: 0.25 11-20: 0.5 21-30: 0.75 >30: 1	1-4: 0 5-10: 0.25	1-15: 0 16-30: 0.25 >30: 0.75	0-100: 0 101-150: 0.25 151-200: 0.50 > 200: 0.75	0-15: 0 16-30: 0.25 31-75: 0.50 > 75: 0.75

3.3 Part 2 - On-site

The selection of the FAMI-QS Certified Operator and / or CB's auditor, is done by the FAMI-QS Integrity Auditor who will accompany the CB's auditor and is made on a random basis, unless there are reasons for FAMI-QS to select a specific Operator or CB auditor.

In the event that a selected FAMI-QS Certified Operator refuses to accept the presence of a FAMI-QS Integrity Auditor, the Certification Body shall ensure that a meeting will be organised at the CB's premises, the day following the audit. In the meeting, the auditor conducting the audit shall be present, with all of the relevant audit evidences and audit findings. All the costs relating to the meeting, including the FAMI-QS Integrity Auditor's travel expenses, will be covered by the Certification Body. The CB can charge these costs to the FAMI-QS Certified Operator.

The on-site audits are only conducted by a FAMI-QS Integrity Auditor (internal or external). The aim is to assess a given auditor's performance and to evaluate the performance of the FAMI-QS system in place. The evaluation of the FAMI-QS System's performance in the audited Operator will be carried out by the FAMI-QS Integrity Auditor and will not be linked with any decision made by the Certification Body.

The Part 2 audit is only conducted during a scheduled audit and only during surveillance or re-certification.

Regarding the name of the selected Operator, FAMI-QS will inform the Certification Body with a minimum of three (3) months in advance. In turn, the Certification Body will need to confirm the date(s) as soon as possible; furthermore, it will need to send the audit plan to the FAMI-QS Integrity Auditor, at least fifteen (15) days before the audit.

FAMI-QS will send a confidential questionnaire to be answered by the selected Operator, five (5) days before the audit.

During the audit, the FAMI-QS Integrity Auditor shall only observe the audit. The audit shall be conducted in the language that has been agreed upon with the company. If clarifications will be

required, the FAMI-QS Integrity Auditor shall discuss them with the audit team, during the audit team meeting, either before the closing meeting or during the lunch break.

The FAMI-QS Integrity Auditor will not have any influence to the audit process or outcome of audit.

The result of the on-site audit might trigger a certain action on behalf of the Certification Body. Actions which have been taken after the on-site audit will be documented.

4. Results

4.1 Office Audit

The maximum level of confidence for the on-site audit is 10. Calculation of the level of confidence is the result of the office audit report, which has a confidence level of 1-5, multiplied by two (2). Required actions based on the results of the office audit are outlined in the table below:

Level of Confidence	Required Actions
01-02	<p>No confidence in the Certification Body's procedures and / or implementation. The FAMI-QS certification process is at high risk. FAMI-QS will notify the Accreditation Body (AB) responsible for the Certification Body in question, for further actions.</p> <p>The FAMI-QS Quality Manager will inform the AB that it intends to withdraw the license. The final decision shall be made by the AB of the CB in question.</p>
03-04	<p>Some confidence in the Certification Body's procedures and / or implementation. FAMI-QS will notify the Accreditation Body which is responsible for the Certification Body in question.</p> <p>FAMI-QS will monitor, based on the Integrity Programme, the CB's activities for a period of one (1) year, with at least (3) three additional audits.</p> <p>Cost of the monitoring: 500€/month</p> <p>The FAMI-QS Quality Manager will inform the AB that it intends to withdraw the license. The final decision shall be made by the AB of the CB in question.</p>
05-06	<p>Default confidence in the Certification Body's procedures and / or implementation.</p> <p>The requirements of the relevant Accreditation Standards and of the FAMI-QS Rules for Certification Bodies are partially covered. The Certification Body will need to close the relevant NCR, which will be revised and closed within three months from the office audit.</p>
07-08	<p>Good confidence in the Certification Body's procedures and / or implementation.</p> <p>The requirements of the relevant Accreditation Standards and of the FAMI-QS Rules for Certification Bodies are documented and there is sufficient evidence of implementation.</p>
09-10	<p>High level of confidence in the certification procedure and / or implementation.</p> <p>The requirements of the relevant Accreditation Standards and of the FAMI-QS Rules</p>

	for Certification Bodies are documented and there is good evidence of implementation.
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4.2 On-site Audit

For the on-site audit, the maximum level of confidence is 10. For 90%, the scope derives from the on-site audit. Calculation of the level of confidence is the result of the office audit report, which has a confidence level of 1 – 5, multiplied by two (2). The remaining 10% comes from the questionnaire that the Operator returns back to the FAMI-QS Integrity Auditor. Also multiplied by two (2).

Required actions based on the on-site audit's results are outlined in the table below:

Level of Confidence	Required Actions
01-02	<p>No confidence in the auditor's overall approach during the audit. Certification Body:</p> <ul style="list-style-type: none"> a. Shall organise an internal monitoring audit, with the auditor in question, within a reasonably short amount of time (max. 3 months and max. 1 FAMI-QS audit after the FAMI-QS integrity audit). b. Shall organise a training session, for all of the auditors in the region, with the participation of FAMI-QS. (the travel expenses, required for FAMI-QS to take part in the training, will be covered by the Certification Body in question). c. Make a root cause analysis about the performance of the auditors and size of deviation. d. Verification of effectiveness of the corrective actions taken. <p>Failure to implement the corrective actions will lead to the suspension of the key activities of the Certification Body in question, in the region where the on-site audit took place. In this case, an auditor should be sent from another location. The additional cost incurred to send an auditor from another location shall be covered by the Certification Body, given that the said cost will have arisen because of a discrepancy in the Operator's certification process.</p>
03-04	<p>Some confidence in the auditor's overall approach.</p> <p>Certification Body:</p> <ul style="list-style-type: none"> a. Shall organise a training session, for all of the auditors in the region, with the participation of FAMI-QS. (the travel expenses, required for FAMI-QS to take part in the training, will be covered by the Certification Body in question). b. Make a root cause analysis about the performance of the auditors and size of deviation. c. Verification of effectiveness of the corrective actions taken. <p>Failure to implement the corrective actions will lead to the suspension of the key activities of the Certification Body in question, in the region where the on-site audit took place. An auditor should be sent from another location. The additional cost incurred to send an auditor from another location shall be covered by the</p>

	Certification Body, given that the said cost will have arisen because of a discrepancy, in the Operator's certification process.
05-06	No reasons for concern: the auditor's approach covers the FAMI-QS code's requirements.
07-08	The auditor's performance and approach, during the FAMI-QS audits, creates added value to the FAMI-QS certified company.
09-10	The Certification Body concerned can be proud to have this auditor in their organisation. The auditor can be invited to join future FAMI-QS training sessions as a trainer. All travel expenses will be covered by FAMI-QS.

4.3 Access to the results

Each Certification Body will receive an audit report for the office and on-site audits.

At the end of the year, when the programme will have been completed, each CB will receive a benchmark chart (the performance of the CB and the average score of all the participating CBs).

The FAMI-QS Secretary General and the FAMI-QS Process Manager will have full access to the results.

The statistics on the programme's implementation will be communicated to the FAMI-QS Board of Directors; however, the names of the Certification Bodies and any other indication that could give an idea of who is behind the figures will not be disclosed.

The Accreditation Bodies may have access to the Surveillance Programme's reports, upon request, regarding the FAMI-QS Authorised Certification Bodies under their responsibility.

5. Confidentiality

Any exchange of information relating to the purpose of this programme will be kept strictly confidential and shall only be communicated between the involved parties (FAMI-QS, Certification Bodies, Accreditation Bodies). The information obtained during the Certification Body's surveillance programme and recorded in the report will be handled in a strictly confidential manner, both by FAMI-QS and by the FAMI-QS Integrity Auditor.

FAMI-QS and the FAMI-QS Integrity Auditor will not use the obtained information for any purposes, other than those established in the frame of the surveillance process.

The FAMI-QS Quality Manager will be responsible for safeguarding all confidential data.

6. Revision of the programme

The FAMI-QS Surveillance Programme (SP) is not a static programme. It will be revised according to both the implementation's progress and to the inputs received from the Accreditation Bodies, the Certification Bodies, the Certified Operators and the Competent Authorities.

The proposed revision will be discussed during the annual Certification Bodies meeting.