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 of 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.

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 Authorized 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 it 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 authorized Certification Body.

2 Scope

The procedure is applicable to all of 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, 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;
- A sudden increase 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;
- Number of involved operators and/or sites;
- 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 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 the relevant internal procedures (limited to FAMI-QS activity) according to the ISO 17021, the ISO/TS 22003, FAMI-QS Rules for Certification Bodies and 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.

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

3.2 Part 1 - Office Audit Duration

<table>
<thead>
<tr>
<th>Minimum Man-days - office audit</th>
<th>Number of operating Countries</th>
<th>Number of Critical Locations</th>
<th>Number of Auditors</th>
<th>Number of Certified Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1-5: 0</td>
<td>1-4: 0</td>
<td>1-30: 0</td>
<td>0-100: 0</td>
</tr>
<tr>
<td></td>
<td>6-10: 0.25</td>
<td>5-10: 0.25</td>
<td>31-60: 0.25</td>
<td>101-150: 0.25</td>
</tr>
<tr>
<td></td>
<td>11-20: 0.5</td>
<td></td>
<td>&gt;60: 0.75</td>
<td>151-200: 0.50</td>
</tr>
<tr>
<td></td>
<td>21-30: 0.75</td>
<td></td>
<td></td>
<td>&gt; 200: 0.75</td>
</tr>
<tr>
<td></td>
<td>&gt;30: 1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.3 Part 2 - On-site

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

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 organized 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 of the costs related 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 internal FAMI-QS Integrity Auditors. 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 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 result of the on-site audit might trigger certain action on behalf of the Certification Body.

4 Results

4.1 Office Audit

The maximum level of confidence for the on-site audit is 10. Required actions based on the results of the on-site audit are outlined in the table below:

<table>
<thead>
<tr>
<th>Level of Confidence</th>
<th>Required Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-02</td>
<td>No confidence in the Certification Body’s procedures. 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. 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.</td>
</tr>
<tr>
<td>03-04</td>
<td>Some confidence in the Certification Body’s procedures. FAMI-QS will notify the Accreditation Body which is responsible for the Certification Body in question. FAMI-QS will monitor the CB’s activities for a period of one (1) year, with at least (3) three additional audits. Cost of the monitoring: 500€/month 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.</td>
</tr>
<tr>
<td>05-06</td>
<td>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</td>
</tr>
</tbody>
</table>


close the relevant NCR, which will be revised and closed within three months from the on-site audit.

07-08 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.

09-10 High level of confidence in the certification procedure.

4.2 On-site Audit

For the on-site audit, the maximum level of confidence is 10. For 90%, the scope is derived from the on-site audit and, for the remaining 10%, from the questionnaire that the Operator returns back to the FAMI-QS Integrity Auditor.

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

<table>
<thead>
<tr>
<th>Level of Confidence</th>
<th>Required Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-02</td>
<td>No confidence in the auditor’s overall approach during the audit. Certification Body:</td>
</tr>
<tr>
<td></td>
<td>a. Shall organize an internal monitoring audit, with the auditor in question, within a reasonably short amount of time (max. 3 months after the FAMI-QS integrity audit).</td>
</tr>
<tr>
<td></td>
<td>b. Shall organize 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).</td>
</tr>
<tr>
<td></td>
<td>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 said cost will have arisen because of a discrepancy, in the Operator’s certification process.</td>
</tr>
<tr>
<td>03-04</td>
<td>Some confidence in the auditor’s overall approach. Certification Body:</td>
</tr>
<tr>
<td></td>
<td>a. Shall organize 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).</td>
</tr>
<tr>
<td></td>
<td>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 Certification Body, given that said cost will have arisen because of a discrepancy, in the Operator’s certification process.</td>
</tr>
<tr>
<td>05-06</td>
<td>No reasons for concern: the auditor’s approach covers the FAMI-QS code’s requirements.</td>
</tr>
</tbody>
</table>
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 concerned Certification Body can be proud to have this auditor in its organization. The auditor will 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 of 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 FAMI-QS authorized Certification Bodies under their responsibility.
5 Confidentiality

Any exchange of information related 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.