

EFISC Rules of Certification



Changes in the document are highlighted

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SECTION 1: INTRODUCTION

1.1 – General Introduction

What is EFISC?

EFISC is a voluntary feed safety assurance scheme developed by Starch Europe (European starch industry), [FEDIOL](#) (European oil seed and protein meal industry) and EBB (European Biodiesel Board) in order to establish a certifiable European Code to good practice for the industrial manufacturing of safe feed materials.

The EFISC Code and Rules of Certification are managed by the EFISC Aisbl secretariat.

EFISC Aisbl provides the standards and framework for independent, approved third party certification of feed materials processes based on ISO/IEC 17021 and ISO/TS 22003.

EFISC is a feed materials operator standard. The objective of EFISC certification is to form part of the verification of Good Practices along the whole production chain.

EFISC is a business-to-business tool and is therefore not directly visible to the final feed products.

The EFISC logo and trademark have restricted use. Participation is voluntary and based on objective criteria. EFISC Aisbl is not discriminatory to certification bodies and/or feed materials operators.

The terms 'EFISC and 'EFISC Aisbl' are used interchangeably in this document.



1.2 – EFISC Terms of Reference

- To respond to consumer concerns on food and feed safety in order to restore confidence Encouraging adoption of commercially viable HACCP-based feed safety management schemes, which promote the safe production of feed materials within Europe and worldwide.
- Promoting the best use of sector specific knowledge and experience in PRP and HACCP implementation.
- Providing guidance for continuous improvement by corrective measures.
- Establish a harmonised, single, recognised framework for independent third party verification.
- Communication and consulting openly with all actor groups. (Compound feed manufacturers, certification bodies and key partners).

EFISC, the European Feed Ingredients Safety Certification, is a set of normative documents, setting out the requirements for applicants participating in the EFISC certification.

The EFISC Aisbl certification program is one mean of providing assurance that an operator has implemented EFISC in line with its policy and in a uniform way.

The only valid versions of EFISC and its certification rules are the English versions, published on the EFISC Aisbl web site (www.efisc.eu).

The English language edition of this and other normative EFISC documents are the original editions.

EFISC documents might be translated into other languages and published on the EFISC Aisbl website. Once published, these official EFISC documents will be the only ones that may be used for EFISC certification in that language. Translated documents will be identified as having normative status after a thorough translation review. Until the translations reach the normative status, the sentence “please refer to the English version in case of doubt” will be written on each sheet of the translated documents, in the respective language.

Accreditation may be sought and obtained by certification bodies in other languages only against documents with normative status recognised in this way.

1.3 - Structure of the EFISC feed material safety assurance scheme

This document is referred to as the EFISC Rules of Certification. It is part of the EFISC feed safety assurance scheme.

The EFISC scheme consists of the following documents:

- a) EFISC Code to good practice
- b) Sector specific documents (including sector codes of practice)
- c) EFISC Rules of Certification

The sector specific documents are an integral part of the EFISC Code, developed by the responsible European feed material producing sector organisations. The sector documents provide guidance on the products, hazards, processes, risk assessments and control measures. The sector documents are approved by the respective European sector organisation and EFISC. Codes of practice referred to in the sector documents are a component of the feed safety assurance system.



The documents are available on the EFISC Aisbl website (www.efisc.eu). Sector codes of practice are available on the website of the sector organisation.

1.4 - EFISC governance

The EFISC feed safety assurance scheme is governed by the EFISC Aisbl, a non-profit organisation, based in Brussels, Belgium. The EFISC Aisbl consists of a daily management unit, a technical committee, the EFISC Board of Directors and the EFISC General Assembly.

The daily management unit manages the scheme, its development, communication and promotion with the stakeholders involved.

The EFISC technical committee reviews and updates the EFISC documents in order to meet the legal requirements, developments in good practice and technological developments. This process happens in dialogue with the feed safety working groups of the relevant European sector organisations and the licensed certification bodies.

The EFISC Board instructs the daily management unit and technical committee and reviews and approves the work done.

Members of the management unit, technical committee, EFISC Board and EFISC GA are selected for their expertise and experience in feed material safety.

1.5 - Scope of this normative document

This normative document explains the structure, rules and requirements of certification to EFISC and the procedures that should be followed to obtain and maintain certification. In order to address the different interests of groups of users, the document has a sectioned structure. Every interested party has to identify to which group of users it belongs first, and after refer to its correspondent section.

The sectioned structure identifies four actor groups of users: EFISC Aisbl, certification bodies', accreditation bodies and operators. As there is a large interaction between the four actor groups, all users shall take notice of all of the sections mentioned below.

Group 1 – EFISC Aisbl

EFISC (Aisbl) is the owner of the European Feed Ingredients Safety Code.

The rules and responsibilities of EFISC are described in SECTION 2 of this document.

Group 2 – CERTIFICATION BODIES

A certification body is an independent third party that assesses and certifies that the operator meets the requirements of EFISC.

The rules and responsibilities of certification bodies are described in SECTION 3 of this document.

Group 3- ACCREDITATION BODIES

The accreditation body is an independent national body that assesses and certifies that the certification body meets the requirements of the ISO standard ISO/ IEC 17021 supplemented by ISO/ TC 22003 and the requirements as described in the EFISC rules of certification. Therefore it assures users of the competence and impartiality of the certification body.

The rules and responsibilities of accreditation bodies are described in SECTION 4 of this document.

Group 4 - OPERATORS

Any operator that is producing feed materials on an industrial scale is entitled to obtain an EFISC certificate from an approved certification body provided the operator is in compliance with the requirements of the EFISC Code and its Annexes.

Any operator is included in the scope, provided he bears the responsibility for first placing on the market.

The rules and responsibilities of operators are described in SECTION 5 of this document.

Section 5 provides a flowchart which shows, simplified, the lines of communication between the operator, certification body and EFISC.

SECTION 2: EFISC Aisbl RULES AND RESPONSIBILITIES

Through its secretariat, EFISC Aisbl will be in charge of:

- Maintaining a public register with an updated list of the approved certification bodies. The only valid register is available on the EFISC Aisbl website: www.efisc.eu
- Maintaining a public register with an updated list of the certified operators, with indication of the scope of certification. The only valid register is available on the EFISC Aisbl website.
- Updating periodically the EFISC Code and the Rules of Certification. All modifications will be notified to the licensed certification bodies and included in the EFISC Aisbl homepage information. As an aid to users, each revision of these documents will be published with the areas of significant change highlighted. A reasonable transition period for the implementation of changes to the EFISC Code and EFISC Rules of Certification will be decided by EFISC Aisbl on a case-by-case basis. The reference language versions of the EFISC Code and Certification Rules are the English versions, published on the EFISC Aisbl web site.
- Assessment and approval of Certification Bodies (See §2.1).
- Verification and registration of the auditors (See §2.2 & §3.1.2).
- Training, managing and coordinating Certification Bodies (See §2.2).
- Verification of audit reports and certificates (See §2.4).
- Implementation of the surveillance program (See §2.5).
- Dealing with complaints (See§2.6).

2.1 – Assessment and approval of Certification Bodies

EFISC Aisbl is responsible for granting, maintaining, suspending and withdrawing the allowance of certification bodies to issue EFISC certificates.

No certification body is allowed to grant an EFISC certificate without licence from EFISC Aisbl. Only EFISC certificates issued by contracted certification bodies will be valid.

Certification of companies against EFISC is open to any appropriately accredited certification body (see 3.1.1) established on the basis that the body is a legal entity and will be confined to declared scopes, activities and locations.

Certification bodies wishing to obtain the licence to carry out EFISC certification shall apply to the EFISC Aisbl Board, providing details for eligibility according to established selection criteria. The application form is available in Annex 3. The certification body applies, submitting required enclosures:

- Accreditation certificate ISO/ IEC 17021 (supplemented by ISO/TS 22003)
- Fields of work in food and feed (Reference document with the experience in food and feed)
- List of auditors, their qualification(s) and contact details (see §3.1.2)
- Certification procedure for EFISC

Apart from this, the certification body has to commit to include EFISC in the coverage of its ISO/IEC 17021 (supplemented by ISO/TS 22003) accreditation within one year or within one year after EFISC is recognised as an accredited standard. This commitment shall be formalised by means of a letter addressed to the EFISC Aisbl Board. The certification body shall ensure that the accreditation body selected for the assessment will fulfil the requirements as described in chapter 4.

The Board makes a(n) approval/non-approval decision within 4 months, further to recommendation by the Expert Panel. Decision is without appeal.

All information obtained before, during or after assessment, including the fact that a particular certification body has applied for approval, or that an application has been deferred or rejected, will be treated in strictest confidence by EFISC Aisbl.

As an integral part of their contractual agreement with EFISC Aisbl, licensed certification bodies will pay an annual license fee to EFISC Aisbl. Fees between operators and certification bodies are at the discretion of both parties. See Annex 1 for more information.

Upon approval, the applicant certification body shall agree to contractual provisions (co-ordination, reporting and fee obligations) and shall attend a full EFISC training session provided by EFISC Aisbl. Fully licensed status is achieved following endorsement of the contract by the certification body and EFISC Aisbl. Only licensed certification bodies are entitled to certify operators according to EFISC.

Once approved, the name and details of the approved Certification Bodies are gathered by EFISC Aisbl in a public register, available via the EFISC Aisbl homepage. Approval of a Certification Body and inclusion in the register is subject to the respect of the contractual agreement between the Certification Body and EFISC Aisbl. Certification Bodies agree to publication of its name and contact details on the official list of approved Certification Bodies on the EFISC Aisbl web site. It is understood that the only official register of EFISC Certification Bodies and certified operators is the one managed by EFISC Aisbl.

The certification body must notify EFISC Aisbl of any change to information given in the application or any change in circumstances relevant to requirements for certification bodies (set out below) within 8 weeks of the change having taken place.

In case of non-respect of contractual agreement, EFISC Aisbl may decide to withdraw or suspend the approval from the Certification Body, following written notification.

2.2 - Verification and registration of auditors

EFISC Aisbl will verify the qualifications of all auditors in order to monitor the qualifications, experience, training and audit activities of the auditors in order to strive for a harmonised, solid verification of the EFISC requirements. Auditors are registered in the EFISC auditor registration database. Only after registration in the EFISC database he or she is authorised to perform EFISC audits.

See §3.1.2 Auditor qualifications and §3.1.3 Retention of approval of the auditor.

2.3 – Training, management and coordination of Certification Bodies

EFISC Aisbl is responsible for the proper training, management and coordination of Certification Bodies.

2.4 - Verification of audit reports and certificates

EFISC Aisbl will verify the audit reports and EFISC certificates in order to monitor the audit results and ensure uniformity and consistency. EFISC confirms the good receipt of the documents to the certification body. Only after publication on the EFISC website the certificate can be delivered to the operator by the certification body. See § 2.5 surveillance programme, § 5.0 communication chart and §6.1.7 audit report.

2.5 - Surveillance Program

In addition to supervision by the national accreditation body, EFISC Aisbl verifies the competent, uniform and complete realisation of audits through statistical and random evaluation of audit reports and annual harmonisation meetings for certification bodies.

Based on the risk assessment of the number, complexity and size of the certification activities carried out by the certification bodies EFISC will have in place a documented surveillance program. In the surveillance program process a representative of EFISC monitors the activities of the certification bodies and its associated auditor(s) on the occasion of an periodic assessment of a specific feed business operator on site and in the office. The surveillance process is compulsory for all certification bodies. The surveillance process is considered beneficial to all stakeholders.

The surveillance program contains of the following elements:

Part 1: Office Audit- EFISC conducts an assessment at the certification body premises to verify the implementation of the quality management system and related EFISC requirements.

Part 2: Witness Audit- EFISC conducts an assessment of the certification body/ auditor performance during their on-site audit, with prior agreement of the operator.

Part 3: Parallel audit- EFISC conducts an assessment of the certification body/ auditor performance based on the auditor checklist and audit report, with prior agreement of the operator. The verification of the CB audit will be done within 6 weeks after the regular audit.

The EFISC Aisbl in co-operation with the certification body will determine where and when a specific surveillance program will be carried out and which part shall be applied. The following criteria are typical – but not limited – of the selection process:

- Past and present experience with the certification body
- Accreditation status of the certification body
- Number of involved auditors
- Number of involved operators and/or sites
- Application of the product
- Exposure of the production process to risks

The outcome of the assessment will be communicated and discussed with the certification body. If needed measures for improvement will be taken.

Furthermore the outcome of the audit will be communicated with the relevant accreditation body in agreement with the certification body

2.6 - Confidentiality



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 (EFISC Aisbl, certification body, accreditation body and feed business operator). The information obtained during the surveillance of the certification body recorded in the report will be handled strictly confidential by EFISC Aisbl. EFISC Aisbl will not use it for purposes apart from those established in the frame of the surveillance process.

2.7 - Complaints

EFISC Aisbl will have a documented procedure in place for dealing with complaints of manufacturers and certification bodies, including requirements for investigation, complaint management documentation and resolution of the complaint.

SECTION 3: CERTIFICATION BODIES' RULES AND RESPONSIBILITIES

Certification bodies are responsible for the complete execution of the assessment of an operator seeking EFISC certification, including such activities as audit planning, assessment of documents, audit visits, reporting and certification. The certification body shall take all steps required to evaluate the conformance of the operator with the requirements of the EFISC scheme.

As an integral part of their contractual agreement with EFISC Aisbl, the recognised certification bodies compulsorily must:

- Participate in the coordination meetings organized by EFISC Aisbl. The objective of these meetings is to survey, reassess and train certification bodies. They take place, at least, once a year. EFISC Aisbl is responsible of the preparation of the training materials, which can be afterwards used by the approved Certification Bodies for the training of auditors.
- Provide every auditor at least 2 days ongoing relevant technical training/development per year in order to sustain professional development and knowledge of developments in quality assurance and legal obligations relating to the animal feed materials sector followed by an examination.
- Report to EFISC Aisbl regarding auditor training programmes implemented (agenda, minutes, list of participants and results of the examination).
- Consult EFISC for the approval of new auditors and registration in the EFISC auditor registration system.
- Provide (under confidentiality) a copy of each certificate and audit report (Annex 4) in English for verification and registration by EFISC before sending it to the manufacturer.
- Provide a half yearly statistical report of audits carried out by auditor and certifications granted.
- Report immediately to EFISC Aisbl any non-conformity identified in periodical auditing that leads to withdrawal of certification.
- Report to EFISC Aisbl about interpretation and implementation issues identified in carrying out the certification.
- Offer certification for EFISC on their website, including a link to the EFISC Aisbl website.
- Have in place a clearly defined and publically available appeals, complaint and dispute procedure.

3.1 - Approval of Certification Bodies

The process of assessment and approval of certification bodies must be followed as described in §2.1.

3.1.1 - Requirements for Certification Bodies

The certification body must demonstrably comply with the following requirements by providing documentation at application (see annex 3).

Applicant certification bodies should be able to demonstrate:

- Formal demonstration of their competence to carry out specific conformity assessments tasks by a third party accreditation to provide certification to the EFISC code. The third party is an accreditation body that is signatory to the Multilateral Recognition

Arrangement (MLA) of the European Accreditation Body (EA), and the International Accreditation Forum (IAF)

- Proven commitment to EA and / or IAF Mandatory Documents applicable for ISO/ IEC 17021 and ISO/ TS 22003.
- Proven experience in the feed industry (already conducting HACCP based audits in the feed business, for example EFISC recognised schemes or official inspection of feed business operators.
- Within 1 year after the initial acceptance by EFISC Aisbl or within one year after EFISC is recognised as an accredited standard, the certification body must be accredited according to ISO/ IEC 17021 (supplemented by ISO/TS 22003) having EFISC included in the scope.
- Commitment to training and co-ordination obligations established by EFISC Aisbl (See § 2.2).
- Commitment to selection of competent and suitably trained auditors, and the ongoing training of auditors. Materials for the training of auditors shall be available through EFISC Aisbl.
- Commitment to monitor the quality of reports compiled by each auditor and take suitable action when reports do not meet the scheme requirement.
- The certification body may not, within a period of two years prior to the audit, have undertaken any consultancy and/or dedicated training activities with the operator's site to be audited, and should demonstrably confirm this independence.

3.1.2 - Requirements for the certification body quality management system

The certification body shall operate an effective and documented quality management system, containing all necessary procedures for compliance, available and used by all relevant staff of the certification body. As a minimum it shall contain:

- The legal status of the certification.
- The quality policy statement.
- The organisational structure and a description of the related jobs and responsibilities.
- A list of the relevant personnel, their qualifications, training received and job description.
- The description of the audit, evaluation and certification process.
- The management review and policy procedures.
- Procedures in relation to documentation control.
- A list of all subcontractors and the procedure for their assessment and management.
- Procedures for actions related to non-conformities and the evaluation of the corrective actions.
- Procedures for conducting internal audits, their evaluation and corrective actions following.



3.1.3 - Requirements for auditors

Auditors are either employed or sub-contracted by the certification bodies.

3.1.3.1 Initial approval of the auditor

Certification bodies shall ensure that all auditors, including contractors:

- Are approved by the certification body before they are allowed to carry out EFISC audits without supervision. In order to gain approval, auditors will follow an initial training program, covering the requirements below, followed by an examination, prepared by the certification body in cooperation with EFISC, and a documented sign off by the supervisor.
 - The certification body shall provide the name, details and qualifications of the auditors and evidence that the requirements are met.
 - The auditor will be registered in the EFISC auditor database.
 - The auditor shall:
 - Qualify according to ISO/ IEC 17021 and ISO/TS 22003
 - Are experienced in the feed and/or food sector (at least 5 years of full time work experience in the areas of processing, technology, raw materials and/or products of which 2 years in quality assurance with feed or food safety management systems or equivalent).
 - Post- secondary, field related education including food microbiology, feed and food processing fundamentals and chemistry including food analysis.
 - Be able to apply relevant feed legislation.
 - Demonstrate competence and understanding in the implementation of management systems, HACCP and PRP programmes.
 - New auditors shall for a first qualification be assessed on their performance in a combination of minimum 10 audit days or 5 on site audits at different organisations (complete and satisfactory food and/or feed industry audits in the last year) against EFISC or relevant feed scheme's recognised by EFISC (see Annex 3 EFISC Code) under the leadership of a qualified auditor.
- Have successfully completed training on:
 - Lead Assessor training based on ISO 19011 and ISO/IEC 17021 supplemented by ISO/TS 22003 (minimum 5 day training)
 - Food safety management principles (e.g. ISO 22000, prerequisite programmes (PAS 222:2011))
 - By the industry recognized HACCP training (minimum 2 day training)
 - European and National legislation applicable to feed safety
 - EFISC Code
 - EFISC Rules of Certification
 - The EFISC sector reference documents and have knowledge of the specific feed sector related risks (hazards, hazard assessment, hazard analysis, critical control points (CCP's), monitoring, risk management).

3.1.3.2 Annual training, audit experience and evaluation

- In order to maintain the approval the auditor shall be regularly trained by the certification body on the EFISC feed safety assurance scheme. A special focus will be given to the different sector documents and their risk assessments. (At least 2 days ongoing relevant technical training/development per year).

The training program shall sustain professional development and knowledge of developments in quality assurance and legal obligations relating to the animal feed sector.

The auditor shall keep up to date with GMP, HACCP, PRP, feed safety and technological developments and have access to and be able to apply relevant laws and regulations.

- The annual training of each auditor will incorporate an periodic examination, prepared by the certification body in cooperation with EFISC, of his knowledge and skills and the ability to apply these. Each product category will be included in the examination. The exam will be followed by a sign off of the satisfactory completion of the training programme by the appointed competent supervisor. The outcome will be documented.

If an auditor does not pass the examination (score below 59 %), he or she is obliged to a re-examination within six months.

If an auditor passes the exam with a score between 60-79% the approval is valid for a two year period.

If an auditor passes the exam with a score between 80- 100% the approval is valid for a 3 year period.

- In order to maintain the audit experience the auditor shall perform at least 5 external audits at different organisations of the EFISC scheme or EFISC recognised feed schemes annually.

3.1.3.3 Additional requirements for the auditor

- Have not, within a period of two years prior to the audit, undertaken any consultancy and/or training activities with the operator's site to be audited. They shall demonstrably confirm this independence.
- Undersign non-disclosure forms regarding all information obtained, willing or unwilling, during audits or related to audits.
- EFISC may invite the auditors to participate on a special training session. The participation is required for all approved EFISC auditors.

3.1.4 - Retention of approval of the auditor

In order to maintain the approval as auditor the requirements under 3.1.3 have to stay fulfilled and documented. Evidence shall be provided annually by the CB to EFISC. Not providing the evidence will lead to the suspension and possible loss of the approval of the auditor.

In case EFISC and/ or the certification body has reasons to question the performance of an auditor this can lead to a temporary suspension of the auditor to perform EFISC certification. In coordination with the CB/ EFISC an evaluation will take place and the necessary corrective action taken in order to ensure the qualification of the auditor. If the auditor fails the following examination it results in a loss of the approval.

3.1.5 - Information requirements

The certification body should maintain a list with the EFISC certified operators or publish the companies on their internet website. The name of the operator, the scope, the validity of the certificate and the country should appear on this list or on the internet website.

3.1.6 - Appeals and complaints

The certification body shall have arrangements for appeals and complaints.

3.1.7 - Conflicts of interest

The certification body shall require all staff involved in the certification process to sign a contract or agreement which clearly commits them to:

- Complying with the rules of the organization, with particular reference to confidentiality and independence from commercial or personal interests.
- Declaring any issues in relation to personal conflicts of interests.

SECTION 4: ACCREDITATION BODIES RULES AND RESPONSIBILITIES

4.1 - Accreditation requirements

The accreditation body is responsible for the assessment and accreditation of the certification body that wishes to apply for accreditation in conformance with the EFISC scheme.

The accreditation body performing the assessment shall operate to a high standard of competence and ensure a consistent and harmonised application of the relevant standards. The accreditation body shall meet and act conform the requirements of ISO/ IEC 17011.

The accreditation body shall be a member of the International Accreditation Forum and a signatory to the IAF ISO/IEC 17021 (QMS/EMS) Multilateral Recognition Arrangement.

Furthermore the accreditation body shall act in compliance with the GFSI requirements on the application of ISO/IEC 17011:2004.

4.2 - Accreditation Criteria

As described under 3.1.1 requirements, the certification body shall operate a certification system that meets the requirements of the ISO standard ISO/ IEC 17021 supplemented by ISO/ TC 22003 and the requirements as described in the EFISC scheme.

4.3 - Scope of accreditation

The scope of accreditation shall be indicated on the accreditation certificate and provide the reference to:

The EFISC code, rules of certification and sector documents

The category as indicated in Annex A of ISO/ TS 22003

4.3 - Communication

The accreditation body will communicate with EFISC on the outcome and status of the accreditation process. [↪](#)

EFISC will share with the accreditation body the relevant findings of the surveillance programme (see § 2.5).

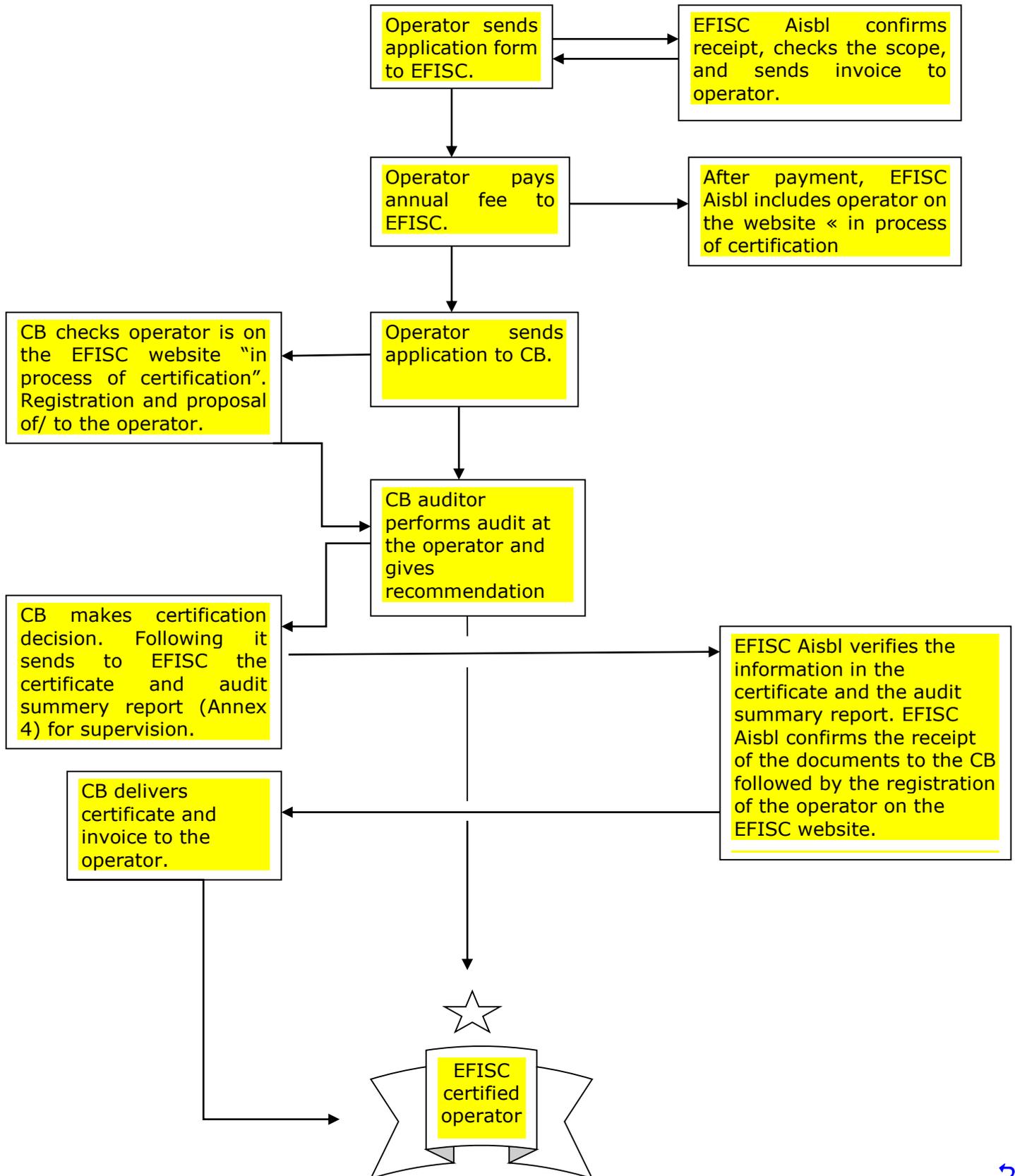
SECTION 5: OPERATOR'S RULES AND RESPONSIBILITIES

The operator applying for certification agrees to the following:

- Any operator wishing to get EFISC certified will send an application letter to EFISC Aisbl. The application form is available as Annex 2 of this document. Upon receipt, EFISC Aisbl will return an invoice with details of payment of the annual fee (See Annex 1). Once the payment is done the operator will appear in the EFISC Aisbl website as a company in the process of being audited/ certified.
- A certified operator or an operator in the process of being certified agrees to publication of its name and address on the official EFISC listings on the EFISC Aisbl web site.
- Following, any operator wishing to get EFISC certified will contact a certification body listed in the public register of licensed certification bodies available on the EFISC Aisbl website. The registration process must be finalised before the first certification body inspection/audit.
- The process of audit and certification to be followed by the operators is described in section 6.
- The operator should then be audited without any critical non-conformities within a period of 12 months; otherwise EFISC Aisbl will remove the operator from the website. If within the 12 months after sending the application form the name and/or contact details of the applicant have changed, this should be communicated to EFISC Aisbl.
- The certificate holder is responsible for compliance of the production process to EFISC and the EFISC Rules of Certification.
- Operators who are sanctioned by a responsible certification body cannot change that certification body until that certification body (the "outgoing" certification body) closes out the corresponding non-conformance, or until the sanction penalty period is over.
- Registered operators are responsible for communicating data updates to certification bodies according to the internal procedures of each certification body.



SECTION 6: Communication flowchart certification process operator/ certification body/ EFISC



SECTION 7: Assessment of operators

7.1 - Auditing

A certification body may offer EFISC certification alone or in combination with other food or feed safety management systems (see Annex 3 EFISC Code for recognised schemes)

The certification body assesses the operator for compliance with the EFISC code on the basis of initial-, surveillance- and re-certification audits. In addition an unannounced audit programme is in place.

a) Initial- , surveillance and recertification audit

All 3 types of audits, as mentioned above, are part of the certification system. They should be such to give confidence that certified operators comply and continue to comply with EFISC. All audits require inspection, assessment of the production and of the feed safety management system of the specific operator. To make sure all aspects of the audit are covered, a checklist has been developed (annex 5) that takes into consideration the various elements of the code and auditors should make use of it when seeking confirmation of the compliance of operators with EFISC.

A combined audit of EFISC with ISO 22000, FSSC 22000, BRC, IFS, GMP+, OVOCOM, QS, FEMAS, is possible in order to avoid overlapping, repetitive, audits. See table 7.1.4 for the applicable minimum audit time.

b) Unannounced audit programme

The EFISC unannounced audit will take place in addition to the annual announced audit in the three year certification cycle as described in ISO 17021 and this document.

All EFISC certified operators will participate in the unannounced audit programme. However there are two options.

a) Random (R) unannounced audit programme

The Certification Body will randomly select around 5 % of the certified operator(s) annually and implement the necessary unannounced audits (5% in addition to operators participating in the mandatory unannounced audit programme).

b) Mandatory (M) unannounced audit programme for suppliers to QS and OVOCOM certified customers

QS and OVOCOM require feed material producers to have one unannounced audit in the three years as a pre-condition in order to be eligible to deliver into the scheme. The EFISC certified operator delivering into the QS and OVOCOM scheme will arrange as such with the certification body. The certification body will inform EFISC on the participation of the operator in the mandatory unannounced audit programme.

The participation of the operator in the in the unannounced audit programme will be indicated in the EFISC certification database (R or M).

The unannounced audit will take place in the period two months after and before the annual audit. The audit will focus on GMP and GHP practices. The unannounced audit will take place during normal working hours.

The unannounced audit time is minimum 4 hours, including reporting time (The reporting time is max. 25% of the time).

The operator will be informed by the certification body two working days in advance in order to organise entrance and guidance through the facility. The starting time will be agreed on. The CB will provide the personal information on the auditor arriving for the audit to the operator. In a situation where more traveling time is required and/or visa applications, the two days can be extended to the minimum workable time.

The operator can indicate up to 15 days in the year that the audit cannot take place. The days should be used when the site is not in production because of planned maintenance. The operator may in principle not refuse the unannounced audit. In case of refusal the operator will provide a valid motivation.

The outcome of the unannounced audit will be handled in accordance with the requirements described in Section 7 and especially §7.1.10 Follow-up of nonconformities and their closure.

The EFISC unannounced audit (random or mandatory) will be covered in the contractual arrangement between the operator and the Certification Body. The cost for the unannounced audit and possible follow-up in case of non-conformities will be paid by the operator.

The participation of the operator in the unannounced audit programme (R or M) will be indicated on the public EFISC database for certified operators.

The effectiveness of the unannounced audit programme programme will be evaluated annually.

7.1.1 Multi-site certification

Multi-site certification is not permitted.

7.1.2 Audit planning

The certification audit shall be conducted in two stages at the premises of the manufacturer. The audit consists out of a stage 1 and stage 2 audit as described in ISO/IEC 17021 and ISO/TS 22003. In the first stage the documentation of the feed safety management system is evaluated which includes the scope of the system, the manufacturers feed safety policy, the management structure, HACCP and PRP programme. In the stage 2 audit the effectiveness of the feed safety management system is evaluated.

Audit planning should be based on the current organisational chart of the operator to be certified. The organisational chart should clearly display each unit of the operator, and the scope of the audit must then be determined according to defined units. Important influencing factors are:

- Production location including purchase and sales department or production location
- The range of goods and services.
- The variety of processes and grade of automation.
- Combined certification
- Requirements devolving from statutory regulations.
- Sophistication of the system.



The operator shall provide on request of the certification body the following documentation:

- Organisational chart and short process descriptions
- List of products
- Information about the production site, and / or subcontractors
- The Feed Safety Management System Manual on site during the audit (paper or electronic version).
- List of applicable regulations
- Any other information the auditor/operator may find useful/relevant.

The selection of executive and other personnel to be interviewed should adequately cover every relevant functional area.

For the surveillance or re-certification audit, the operator shall provide the certification body with the following documentation:

- Changes in organisation.
- Changes in Feed safety Management System Manual.
- Changes in list of applicable regulatory texts.
- Changes in scope (products/ processes), possible mergers/de-mergers, etc.
- Any other information the operator/auditor may find useful/relevant.

The operator shall notify the certifying body immediately of any changes in legal form or scope that affect the validity of the issued certificate. The certification body decides on the necessity of and additional audit to assure ongoing validity of the certification and/or the certificate issued. Records should be available on this.

7.1.3 Determination of audit time

Audit duration is dependent on the number of parallel processes to be audited at the same location within the scope of the feed safety management system to be certified. One audit day is 8 hours. Auditor time stated does not include reporting. Reporting time is to be agreed between the operator and the CB. Typically reporting time is 0.5 day per site but can vary depending of the size, complexity and audit combinations.

Initial certification, re-certification, surveillance audits and unannounced audits may be combined with audits of other management systems.

The defined audit time will ensure the effectiveness and depth of the assessment of the feed safety management system, GMP, HACCP and PRP in compliance with the requirements in the EFISC Code.

Depending of the complexity of the products and or processes and the number of FTE (full time equivalents)/ employees involved in feed material related activities as well as the possible previous audit results the certification body defines the audit time together with the operator.

Initial audit:

An initial audit takes place at the location of an applicant seeking certification against the EFISC Code. It should be carried out by checking the whole sections of the EFISC Code. [↗](#)

Surveillance audit:

A surveillance audit is a periodical audit performed to ensure that an organization still meets EFISC requirements. Depending on the previous audit results as well as the complexity of the products and or processes the CB defines the audit time together with the operator. The auditor ensures to address all EFISC requirements during the total of the two surveillance audits. Typical audit time for surveillance visits is set on 75 % of the initial audit time with a minimum of 0.75 audit day on site.

Re- certification audit:

A re- certification audit takes place at the end of a certification period. The audit must be planned in due time in order to avoid expiration of the certificate. It should be carried out by checking all sections of the EFISC Code.

Audit time for renewal of the certificate is identical to an initial audit.

Special audits:

It may be necessary that an audit is conducted by the certification body at short notice, in the following cases:

1. If the operator is involved in an feed safety incident
2. Follow up of the audit which is listed on the EFISC website under review

It is the responsibility of the Certifying Body to increase the audit time if the complexity of processes or the auditee's organisation calls for this.

Unannounced audits

Typical audit duration for an unannounced audit is 4 hours, including reporting.

The operator will be informed by the certification body 48 hours in advance in order to organise entrance and guidance through the facility. The starting time will be agreed on. The CB will provide the personal information on the auditor arriving for the audit to the operator

The operator can indicate up to 15 days in the year that the audit cannot take place. The days should be used when the site is not in production. The unannounced audit will take place during week days .

7.1.4 Minimum initial audit and re-certification audit time (in audit days/ one day= 8 hours):

	D Basic audit time (2 process lines/HACCP-study)	H Additional audit time Number of lines/HACCP-studies	FTE Number of employees involved in feed material related activities (additional audit time)	Deductible audit time in case of a combined audit with a valid version of GMP plus, Femas, Ovocom, QS for the scope production of feed materials	Deductible audit time in case of a combined audit with a valid version of ISO 22000, FSSC 22000, BRC, IFS
Main office (purchase and/or sales department), including production site	1,5	0.5 day per additional HACCP-study / main processing line	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	Reduction of 75% with the restriction that the audit duration of the combined audit equals to the minimum time for a single EFISC audit (combined audit time minimum 1.5 day)	Reduction of 50 % with the restriction that the audit duration of the combined audit equals to 50 % EFISC time + FC time. The minimum time for a combined audit cannot be less than 1.5 day
Production site	1 day	0.5 day per additional HACCP-study / main processing line		Reduction of 75% with the restriction that the audit duration of the combined audit equals to the minimum time for a single EFISC audit (combined audit time minimum 1 day)	Reduction of 50 % with the restriction that the audit duration of the combined audit equals to 50 % EFISC time + FC time. The minimum time for a combined audit cannot be less than minimum 1 day.

Basic calculation of minimum initial certification audit time (Ts)

$$Ts = (D+H+FTE)$$

7.1.5 Frequency of audits and re-certification

Each site of the operator will be audited at a frequency as indicated in the graph below. Re-certification is carried out at the end of a certification period (3 years) in order to assess whether the operator continues to fully meet the requirements of the Code.

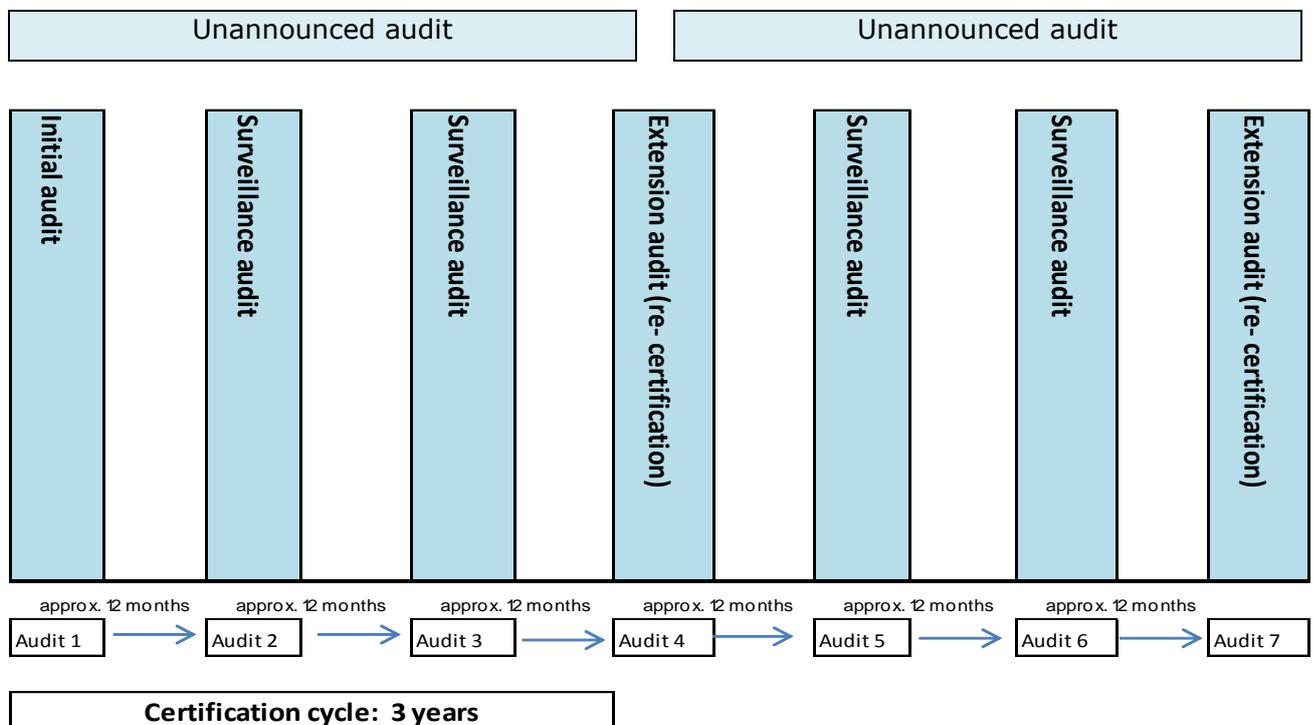
The frequency of surveillance audits for certification will never be below one audit per year. Re-certification is carried out at the end of a certification period (3 years) in order to assess whether the operator continues to meet the requirements of the Code.

1st Surveillance Audit: The date of the audit following initial certification shall not be more than 12 months from the last day of the stage 2 audit.

2nd Surveillance Audit: The date of the audit following initial certification shall not be more than 24 months from the last day of the stage 2 audit.

Re-Certification Audit: The date of the audit following initial certification shall not be more than 36 months from the last day of the stage 2 audit.

The unannounced audit takes place once in the three years' certification cycle.



7.1.6 Use of auditors

Once the certification cycle of three years is finalised a new auditor has to be deployed by the certification body for the starting of the new cycle. In a situation where alternative auditor is not available an exception can be made and the period can be extended for one extra audit cycle maximum.

7.1.7 Evaluation of compliance with EFISC

The certification body will check compliance with the EFISC Code of Practice. For this purpose, auditors shall use the auditor checklist provided by EFISC (See Annex 5).

In evaluating operators for compliance with EFISC, auditors should use an audit planning which includes:

- Review of the implementation of corrective actions for previous nonconformities and their effectiveness.
- Review of any organisational changes.
- Evaluation of process descriptions/documented procedures for conformity with the requirements of the Code (not compulsory during surveillance audits).
- Evaluation of practical implementation of the Code

Any non- conformity established is to be discussed with senior management and/or the management representative present during the audit. The same applies to the agreement on the corrective action.

Documents and other positive evidence consulted for audit purposes, including interviews, should be identified in the audit record. Clearly identified document samples and any additional remarks are recorded to serve as a basis for evaluation of the operator by the auditor following the interviews. Only one audit record is needed when the audit is performed jointly by two or more auditors in a team. Where auditors operate separately during an audit, each auditor shall keep his own audit record. Evaluation is undertaken on completion of separate stages or, where nonconformities are established, immediately after the assessment of the management element concerned by both auditors jointly. At the end of the assessment, the lead auditor receives the sections of the audit record completed by the co-auditor/s. There is ultimately only one audit record for each assessment.

If the auditors wish to assess confidential documents such as formulas or special job processes they must have the written approval of a management representative. The auditor shall inquire during the opening meeting for the presence of such documents and the need to assess them. If approval is not given and no other evidence of compliance is available, this will lead to a major or critical non-conformity regarding the EFISC applicable requirements.

7.1.8 Nonconformities

Prior to completion of the audit record and in preparation to the feedback to the operator, the observations of the auditor are to be evaluated. In the course of this evaluation, nonconformities encountered are to be classified as follows:

Classification Non-conformities and their causes

Classification	Cause
Critical	A regulatory violation, feed safety failure resulting in unsafe feed and/or complete unwillingness to cooperate in the audit. A major non-conformity of an audit that has been not addressed within the appropriate time
Major	A complete failure to implement a requirement of EFISC or a failure that may result in unsafe feed. A minor non-conformity of a previous audit that has been not addressed in the appropriate time
Minor	A partial failure to implement a requirement of EFISC or poor evidence to demonstrate implementation.

Non-conformities and their direct consequences

Non-conformity	Direct consequences
Critical	The auditor shall request (in writing): <ul style="list-style-type: none"> • Interruption of production. • Blocking and/or recall of involved products. • The operator to report the incident to the relevant authorities, as required by EU Regulation 178/2002. Closed upon evidence of correction through a partial audit
Major	Closed upon evidence of correction (administrative or partial audit).
Minor	Closed by the acceptance of the action plan by the auditor.

A readable copy of any non-conformity form shall be discussed with the operator and handed over to him.

7.1.9 Final discussion and conclusion

The result of assessment may be the conclusion that the management system:

- a) Fulfils the requirements of EFISC; or
- b) Has one or more nonconformities.

The auditor will present the list of non-conformities, if any. The management representative is entitled to comment on the results of the audit. The goal is to reach agreement about the weaknesses and strengths of the implemented safety management system and if there are any nonconformities, their scale and the corrective actions to be taken.

The list of nonconformities must be signed by the lead auditor and the management representative. The management representative receives the original copy of the list and makes a copy for the auditor.

This also serves as the basis for determining the work involved in the next assessment. The result shall be agreed with senior management during the final discussion and the details of the agreement reached shall be recorded in the report.

The lead auditor prepares the presentation for the final discussion in line with the observations and agreements reached. The following points should be considered:

- Complete record of participants present.
- Presentation of the assessment results. Indication that the certification bodies Certification Board takes the final decision on the award of the certificate.
- Explanation of weaknesses and strengths.
- Explanation of further steps (follow-up assessment, if applicable).
- Fixing a date for next assessment.
- Closing remarks by the co-auditor, if desired.
- Closing remarks by the management representative.
- Exchange of views, if desired.

The lead auditor should use the questionnaire within Annex 5 to indicate those elements of EFISC which were applicable and audited.

In the case of non-conformities the management shall prepare an action plan, analyse the cause and describe the specific correction and corrective actions to be taken to eliminate detected non conformities, within a defined time (See table 6.1.6) and communicate the action plan to the certification body. The certification body shall review the action plan to see if this is acceptable.

The certification body will verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of non-conformities shall be recorded.



7.1.10 Follow-up of nonconformities and their closure

The consequences of nonconformities are outlined below:

Non-conformity	Initial or renewal audit		Surveillance audit	
	Consequence	Close-out*	Consequence	Close-out *
Critical	Certification denied until the non-conformities have been closed	Action plan < 14 days Verification < 72 days	Certificate suspended and cannot be re-instated until the non-conformities have been closed. In case the non-conformities are not resolved within the maximum suspension period of 72 calendar days, the certificate will be withdrawn	Action plan < 14 days Verification < 72 days
Major	Certification denied until the non-conformities have been closed	Action plan < 42 days Verification < 72 days	Certification continues. Evidence that non-conformities have been closed will be checked within 72 days. In case a non-conformity is not resolved and closed by then, it becomes a critical non-conformity	Action plan < 42 days Verification < 72 days
Minor	Certification granted when less than 10 minors. When 10 or more minor non-conformities verification are found the rules for a major non-conformity apply.	Action plan < 42 days When less than 10 minors verification at the next visit.	Certification continues when less than 10 minors. An agreement on the action plan must be taken between the operator and the CB. Evidence that non-conformities have been closed will be checked by the auditor during the next visit at the latest. In case a non-conformity is not resolved and closed by then it becomes a major non-conformity. When 10 or more minor non-conformities are found the rules for a major non-conformity apply.	Action plan < 42 days after receipt list non-conformities Verification: next visit

-* after receipt list non-conformities

Verification of the action plan can consist, in the case of a major non-conformity, of an administrative approval or an "on site" verification depending on the evaluation of the auditor. In case of a critical non-conformity "on site" verification is mandatory.

The suspension will be published in the register of certificates under "suspended" on the EFISC website and in the "news" section.

7.1.11 Audit report

The final audit report will be sent to the operator within 6 weeks after the audit. To enable EFISC Aisbl to monitor audits and to ensure consistency, audit results must be supplied to EFISC Aisbl



in a standard format in line with the reporting form , to include the number of nonconformities per section (critical, major, etc.) and a summary of observations and conclusions, including any unresolved issues, if identified,. The report of findings provided to EFISC Aisbl shall be of sufficient detail to enable an understanding of the basis for the certification decision and should include the areas covered by the assessment, the positive and negative observations made and a summary of nonconformities. In case any uncertainty exists regarding the quality of audit and corresponding certification, EFISC Aisbl is entitled to initiate independent parallel audits.

A format of audit report is enclosed to this document (see Annex 4).

Audit reports provided to operators must include a statement advising the operator that a summary report in English will be sent to EFISC Aisbl, and that the report will be treated in strictest confidence. The contract between the certification body and the operator should include a clause specifying that this summary report is sent confidentially to EFISC Aisbl. This is the responsibility of the certification body. The responsibility for determining whether an operator is to be certified or not remains entirely with the certification body.

The information obtained during the audit and recorded in the audit report will remain strictly confidential and will be made available only to representatives of the certification body, the operator and EFISC Aisbl. Any information used for statistical evaluation shall be formulated without any relation to the operator involved.

In case of any dispute between an operator and an approved certification body, circumstances should be reported in writing by the operator to EFISC Aisbl for consideration, parallel to addressing the standard procedures of the certification body regarding complaints and/or appeals.

7.1.12 Audit documentation

Certification bodies should provide to EFISC Aisbl with the following audit documentation as listed below for verification:

Initial Certification Audit/ Re-Certification Audit:

1. Audit Plan /Agenda
2. EFISC Audit Report (Annex 4)
3. Signed Certificate

Surveillance Audit :

- 1 Audit Plan / Agenda
2. EFISC Audit Report (Annex 4)

SECTION 8: Incident management

In the event that the manufacturer experiences a public feed safety incident that requires a product recall, the organization shall immediately make the certification body and EFISC aware of the situation. The certification body in turn shall perform a short notice audit to assess the situation, and any implications for the operator's certificate, and shall take appropriate action. The certification body shall inform EFISC of the result from this assessment.

SECTION 9: Certificate

Certification shall only take place where sufficient evidence to demonstrate compliance with EFISC exists. A certificate is valid for a period of 3 years.

A certification body may issue certificates on the basis of an assessment carried out by another body provided that the agreement with the subcontracted body or personnel requires it to comply with all the relevant requirements.

The decision on certification, continuation of certification and/or application of sanctions is taken by the CB's Certification Board, based on the findings and recommendation of the auditor. The certification body shall ensure that the Certification Board that make the certification or recertification decisions are different from those who carried out the audits. The Certification Board consist of technical reviewer and the certification manager. The technical reviewer is a designated, competent officer within the certification body different from the one(s) who carried out the evaluation. This officer shall comply with the requirements as auditor.

The certificate has to be issued according to the template provided in annex 6.

The names and addresses of certified companies and the valid certificate are gathered by EFISC Aisbl in a public register, available via the EFISC Aisbl homepage.

9.1 - Withdrawal of certificates

The withdrawal of the certificate remains the responsibility of the certification body. Once withdrawal is confirmed, the name of the company will be removed from the EFISC Aisbl register on the website (www.efisc.eu).

9.2 - Expiring certificates

When the validity date of the certificate has expired, the name of the company will still remain on the EFISC register on the website (www.efisc.eu) for a further period of one month. If, after this period, a renewed certificate has not been submitted to EFISC Aisbl, the name of the company will be removed from the EFISC register on the website.

9.3 - Exclusions on certificates

It is the obligation of the EFISC certified operator not to mislead stakeholders and authorities regarding the scope of their certification.

9.4 - Use of logo

EFISC certified operators might display the EFISC logo on the finished product specification for the period of validity of their certificate.

EFISC name and logo may only be used by operators that have obtained certification from a certification body approved by EFISC Aisbl. The right to use the EFISC logo and/or name is exclusively granted by EFISC Aisbl, and can be withdrawn at any moment in the event of non-compliance with certification requirements.

The use or display of the EFISC logo does not constitute proof that the operator is certified. For the validity of the certificate check the certification database on the EFISC website.

The EFISC name and logo shall not be used for promotion activities on products, packaging, labels, means of transport, but can be used for advertisements and brochures.

Press releases with "EFISC name and/or logo need to be approved by EFISC Aisbl before publication.

The EFISC logo is available upon request made to EFISC Aisbl. It may be used only in its original colours and proportions.



SECTION 10: Related documents

The currently valid documents include

- ISO/ IEC 17021
- ISO/ TS 22003
- ISO 19011- Guidelines for the auditing of quality management and/ or environmental management systems
- ISO/ IEC 17000 Conformity assessments- terminology and general principles
- EFISC Code
- EFISC Sector documents, including codes of practice



SECTION 11: ANNEXES

ANNEX 1: FEE SYSTEM

Certification Body

As an integral part of their agreement with EFISC Aisbl the certification body will pay to EFISC an annual license fee.

For the year 2015- 2018 the license fee is fixed at EUR 2500,-

Operator

The operator will pay an annual fee of EUR 400,- to EFISC Aisbl

Membership

European sector organisations have the possibility to become a member of EFISC. For more information contact info@efisc.eu

ANNEX 2: APPLICATION LETTER FOR OPERATORS

We herewith apply for EFISC Certification and request to be registered in the system.

OPERATOR

Company name:	
VAT Number:	
Address:	
City/Town:	Postal Code:
Country:	Website:
Telephone:	Fax:
Contact person:	Function:
Email:	Mobile phone:
Member of : <input type="checkbox"/> Fediol <input type="checkbox"/> Starch Europe <input type="checkbox"/> EBB	

SITE(S) TO BE AUDITED

Site 1	
Address (no PO box):	
City/Town:	Postal Code:
Country:	Website:
Telephone:	Fax:
Contact person 1:	Function:
Email:	
Contact person 2:	Function:
Email:	

Name of the CERTIFICATION BODY:

For **additional sites**, please provide the same information requested as for site 1.

We agree to be charged with an annual fee of € 400 per site and that our name is published on the EFISC Aisbl website.

We confirm that we have read and understood the EFISC Rules of certification.

Date:

Name and signature:



ANNEX 3: APPLICATION FOR APPROVAL OF CERTIFICATION BODIES

We herewith apply as approved certification body of EFISC Aisbl and request to be licensed to provide EFISC certification.

Certification Body:

Address:

Coverage:

- **Worldwide**
- **EU 27**
- **Country/ies (please mention it/them):**

Contact person:

Contact details (email, telephone, mobile, fax, website):

We agree to send to EFISC Aisbl the following information:

- Copy of the appropriate accreditation according to ISO/IEC 17021 supplemented by ISO/TS 22003
- Letter of commitment that the certification body will have included EFISC in the coverage of their ISO/IEC 17021 (supplemented by ISO/TS 22003) accreditation within 1 year after approval date (Provisioning EFISC is evaluated by the European Accreditation Body).
- Proven experience as described in chapter 3.1.
- List of auditors, their curriculum vitae and qualifications according to section 3.
- Certification procedure for EFISC
- Contract (2 original signed copies)
- Commitment to training and co-ordination obligations established by EFISC.

After examination of this documentation, EFISC will make an approval/non-approval decision within 4 months.

Name:

Function:

Done in:

Date:

Signature:



ANNEX 4: MODEL OF AUDIT REPORT

EFISC Compliance report

OPERATOR:

Postal address:

Dossier no.:

SITE AUDITED:

Visiting address:

Company representative:

Job Title:

Email:

Telephone:

Fax:

Mobile:

Employees feed materials:

Audit combi with (FS)MS('s):

SCOPE OF AUDIT

Sector:

Activity:

Which products:

CERTIFICATION BODY:

Name:

Lead auditor:

Other auditors:

TYPE OF AUDIT : <input type="checkbox"/> Initial	<input type="checkbox"/> Surveillance	<input type="checkbox"/> Renewal	<input type="checkbox"/>
Verification			

EFISC version:

Duration of audit (contract/planning): h.

Duration of audit (actual): h.

AUDIT DATE(S):

Report date:

Note: A summary report in English will be sent to EFISC Aisbl; this report will be treated in strictest confidence.

NON CONFORMITIES

Summary

EFISC Section	Critical	Major	Minor
Management responsibility			
Management system components			
Prerequisite programs			
HACCP plan			
Total			

Consequences and follow-up

Initial or renewal audit

- Critical- Certification is denied. The operator shall draw up an action plan within 14 days after the receipt of the list with non- conformities. Its implementation will be verified on site within 72 days.
- Major- Certification is denied. The operator shall draw up an action plan within 42 days after receipt of the list with non- conformities. Its implementation will be verified administratively (where valid) or on site within 72 days.
- Minor- Certification is granted. The operator shall draw up an action plan within 42 days after the receipt of the list with non- conformities. Its implementation will be verified during the next regular visit.
- Certification is granted. No further action of the operator is required.

Surveillance audit

- Critical- Certification is suspended. The operator shall draw up an action plan within 14 days after the receipt of the list with non- conformities. Its implementation will be verified on site within 72 days.
- Major- The operator shall draw up an action plan within 42 days after the receipt of the list with non- conformities. Its implementation will be verified administratively (where valid) or on site within 72 days.
- Minor- The operator shall draw up an action plan within 42 days after the receipt of the list with non- conformities. Its implementation will be verified during the next regular visit.
- No further action of the operator is required.



GENERAL ASSESSMENT

General conclusions on the implementation and effectiveness of the feed safety management system and its compliance with the requirements of the EFISC Code.

- Information on assessment by item.
- The number of the item refers to the applicable sections of the EFISC Code.
- For each item shall be referred to the requirements on management, PRP and HACCP in the EFISC Code and the relevant sector document, applicable EU and national legislation and customer requirements.

+= assessed; OK -= assessed: non- conformity Indicate: Number of non-conformities according to the auditor checklist Cr= Critical Ma= Major Mi= Minor	Conformance		Remarks
	Yes	No	

	Reference EFISC Code			
4.1	Management responsibility			
	Summary			
4.1.1	Management commitment, responsibility and policy			
4.1.2	HACCP team leader: responsibility, authority and communication			
4.1.3	Management review			
4.2	Resource management			

	Summary			
4.2.1	Provision of resources			
4.2.2	Human resources			
4.2.2.1	Organisational chart			
4.2.2.2	Competency, awareness and education			
4.2.2.3	Personal hygiene			
4.2.3	Infrastructure and work environment			
	Summary			
4.2.3.1	Basic requirements			
4.2.3.2	Requirements for loading, storage, production areas and other feed related facilities			
4.2.3.3	Equipment			

4.2.4	Control of monitoring and measuring devices			
4.2.5	Maintenance			
4.2.6	Cleaning and sanitation			
4.2.7	Pest control			
4.2.8	Waste control			
4.3	Operational rules			
	Summary			
4.3.1	General			
4.3.2	Incoming requirements material			
	Summary			

4.3.2.1	Processing aids and additives for production of feed materials			
4.3.2.2	Gatekeeper protocol			
4.3.3	Handling of incoming material			
4.3.4	Measures for the prevention of cross contamination			
4.3.5	Measures for the prevention of contamination			
4.3.6	Rework			
4.3.7	Production of feed materials			
4.3.8	Finished feed materials			
4.3.9	Storage			
4.3.10	Transport			
4.3.11	Product and process development			
4.4	Management system components			



	Summary			
4.4.1	Documentation requirements			
4.4.2	Traceability			
4.4.3	Inspection, sampling and analysis			
	Summary			
4.4.3.1	Sampling			
4.4.3.2	Frequency of analysis			
4.4.3.3	Laboratory and methods			
4.4.4	Control of non-conforming product			
4.4.5	Crisis management			
4.4.6	Internal audits			
4.5	Supplier and customer relationship			
	Summary			



4.5.1	Supplier relationship			
4.5.2	Customer relationship			
5	Pre Requisite Program Point 5.1- 5.19			
	Summary			
6	HACCP system			
	Summary			
6.2	General requirements			
6.3	HACCP team and team leader			
6.4	Incoming material and finished product specifications			
6.5	Process information			
6.6	Hazard analysis			
6.7	Risk assessment			



6.8	CCP determination			
6.9	Critical limit and monitoring			
6.10	Correction			
6.11	Validation of the feed safety management system			
6.12	Verification of the feed safety management system			



EFISC Non-conformity form

Operator:	Date:
Address/site:	Dossier no.:
City/country:	NC nr. of
Process/department:	EFISC paragraph:
Operator's representative:	Lead auditor:
Details of the non-conformity:	
Initials lead auditor:	Initials operator's representative (seen):
Non-conformity close-out details:	
Close-out date:	Initials lead auditor:

ANNEX 5: CHECKLIST FOR AUDITORS

Please find the Excel version of the EFISC audit checklist version 3.0 on the EFISC website under "Documents".

Note: this checklist is used on site and completed by hand of the auditor. The checklist is an aid; text of the EFISC Code is leading.

ANNEX 6: TEXT FOR CERTIFICATE

Name Company	[Name site]	Name CB	[Name CB]
Name Site	[Name site]	Address CB	[Address CB]
Address Site	[Address site]		[Location, country]
Certificate number	[Location, country]		
	[Certificate number]		



This document serves to certify that [NAME SITE] has implemented and maintains a Feed Safety Management System including Good Manufacturing Practice (GMP) in compliance with the European Feed Ingredients Safety Certification (EFISC) version X and the Starch Europe/ FEDIOL/EBB sector document version Y:

[Scope of certification: Production of X, Y, Z, including the purchasing of the raw material, plant storage, transshipment, manufacturing, sales and transport of the feed material (delete what is not applicable)]

The compliance was determined in accordance with the EFISC Rules of Certification version X.

This certificate is valid from [DATE] until [DATE]

First issued at [DATE}

Authorized by: [NAME AND FUNCTION CERTIFICATION MANAGER CB]

For the validity of this certificate please check www.efisc.eu

