

EFISC Rules of Certification



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TABLE OF CONTENTS

SECTION 1: INTRODUCTION	4
1.1 – General Introduction	4
1.2 – EFISC Terms of Reference	5
1.3 – Scope of this normative document	5
SECTION 2: EFISC RULES AND RESPONSIBILITIES	7
2.1 – Assessment and recognition of Certification Bodies	7
2.2 – Training, management and coordination of Certification Bodies	8
SECTION 3: CERTIFICATION BODY'S RULES AND RESPONSIBILITIES	9
3.1- Approval of Certification Bodies	9
3.1.1- Requirements for Certification Bodies	9
3.1.2- Requirements for auditors	10
SECTION 4: OPERATOR'S RULES AND RESPONSIBILITIES	11
SECTION 5: FLOWCHART COMMUNICATION CERTIFICATIONPROCESS	12
SECTION 6: ASSESSMENT OF OPERATORS	
6.1- Auditing	13
6.1.1- Audit planning	13
6.1.2- Frequency of audits and re-certification	15
6.1.3- Evaluation of compliance with the EFISC Code	16
6.1.4- Nonconformities	17
6.1.5- Final discussion and conclusion	18
6.1.6- Closure of nonconformities	19
6.1.7- Audit report	19
6.2- Certificate	20
6.2.1- Withdrawal of certificate	20
6.2.2- Expiring Certificates	20
6.2.3- Exclusion of Certificates	20
6.2.4- Use of logo	20

ANNEXES:

Annex 1: Fee system	21
Annex 2: Application letter for operators	22
Annex 3: Application letter for Certification Bodies	23
Annex 4: Model of audit report	24
Annex 5: Checklist for auditors	29
Annex 6: Model of certificate	37

SECTION 1: INTRODUCTION

1.1 – General Introduction

What is EFISC?

EFISC is a voluntary feed materials safety standard developed by the [AAF](#) (starch industry) and [FEDIOL](#) (oil seed and protein meal industry) in order to establish a European Code to good practice for the industrial manufacturing of safe feed materials, in the framework of EFIP.

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 EN 45011 or ISO/IEC Guide 65.

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.

What is EFIP?

[European Feed Ingredients Platform](#), EFIP is a joint project initiated by all of the major European associations or federations representing the sectors that supply feed materials to the EU market. EFIP is an organisation that sets out a voluntary standard for the certification of feed materials around the globe.

1.2 – EFISC Terms of Reference

- To respond to consumer concerns on food and feed safety in order to restore confidence in the feed chain.
- Encouraging adoption of commercially viable HACCP-based schemes, which promote the safe production of feed materials within Europe and worldwide.
- Developing a framework for benchmarking existing assurance schemes and standards including traceability.
- Providing guidance for continuous improvement by corrective measures.
- Good manufacturing production.
- Establish a single, recognised framework for independent verification.
- Communication and consulting openly with all actor groups. (EFIP members, 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- 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 three actor groups of users: EFISC Aisbl, Certification Bodies and operators. As there is a large interaction between the three 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 - 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 of the EU area.

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

Section 5 provides a flowchart which shows the lines of communication for certification between the three actor groups.

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.

- Assessing and approving Certification Bodies according to chapter 2.1
- Training, managing and coordinating Certification Bodies according to chapter 2.2

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. EFISC Aisbl is also responsible for the training and coordination of certification bodies.

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, fields of work, list of auditors and their qualification(s), contact details, etc.).

Apart from this, the certification body has to commit to include EFISC in the coverage of its EN 45011 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 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 – Training, management and coordination of Certification Bodies

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

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

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.
- Report to EFISC Aisbl regarding auditor training programmes implemented (agenda, minutes and list of participants).
- Consult EFISC Aisbl after auditing a manufacturer of feed materials with the results and draft certificate for control by EFISC Aisbl before sending it to the manufacturer.
- Provide (under confidentiality) a copy of each certificate and audit summary report in English.
- Provide a half yearly statistical report of audits carried out 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.

3.1- Approval of Certification Bodies

The process of assessment and approval of Certification Bodies must be followed as described in chapter 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:

- Accreditation according to EN 45011 including coverage for EFISC. Only applications from certification bodies which are accredited by a member of the IAF Multilateral Agreement (MLA) for a certification system with a relevant area of operations in feed and/or food industry will be taken into consideration. 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 EN 45011 having EFISC included in the scope.
- Commitment to training and co-ordination obligations established by EFISC Aisbl (see chapter 2.2).

- Commitment to selection of competent and suitably trained auditors, and the ongoing training of auditors. Materials for the training and examination 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 auditors

Certification bodies shall ensure that all auditors, including contractors:

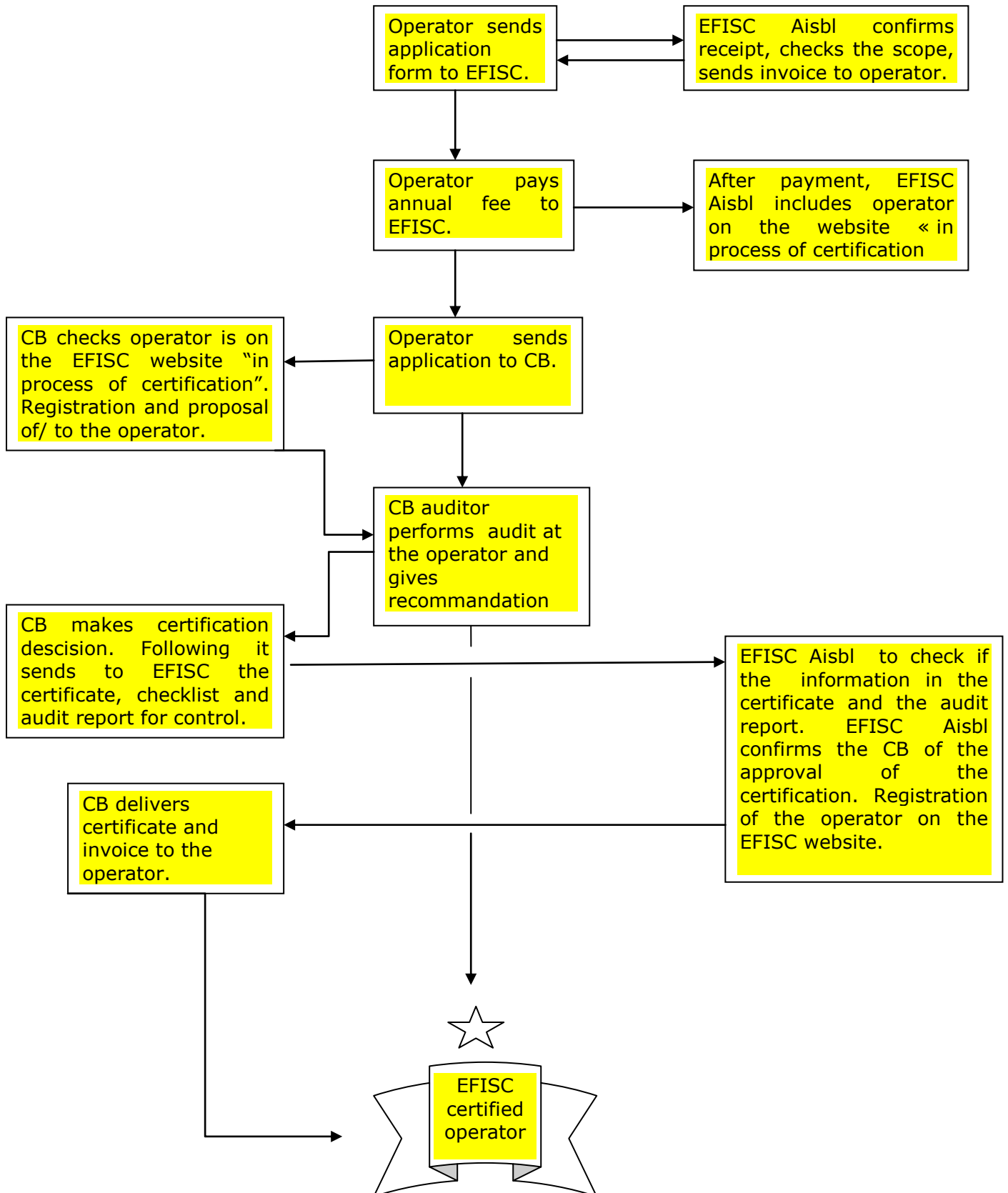
- Are approved before they are allowed to carry out EFISC audits without supervision. In order to gain approval, auditors must meet all of the requirements shown below. The certification body shall provide evidence to EFISC Aisbl that the requirements of the appointed auditors are met. Name, details and qualifications of the auditors are provided to EFISC Aisbl as part of the contractual agreement with the CB.
- Qualify according to ISO 45011 and ISO 19011:2002.
- Are experienced in the feed and/or food sector (at least 3 years).
- Have audit experience (minimum 10 complete and satisfactory food and/or feed industry audits) against relevant scheme's.
- Have successfully completed Lead Assessor training and recognized training in HACCP.
- Understand the feed sector reference documents and have knowledge of the feed sector related risks.
- Are specifically and regularly trained by the Certification Body on the EFISC code (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 sector).
- 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.

SECTION 4: 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 of these certification rules.
- 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 informed to EFISC Aisbl.
- The certificate holder (individual operator or operator group for group certification) 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.

5.0 Communication flowchart certification process Operator/ Certification Body/ EFISC



6.0 Assessment of operators

6.1- Auditing

A certification body may offer EFISC certification alone or in combination with other food or feed safety management systems

The certification body assesses the operator for compliance with the EFISC code on the basis of initial-, surveillance- and re-certification audits.

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 all the elements of the code and auditors should make use of it when seeking confirmation of the compliance of operators with EFISC.

Combined audit of EFISC with ISO 22000, FSSC, BRC or IFS, whose scope includes the production of feed materials, is possible in order to avoid unnecessarily repetitive audits. In order to assist the auditor the EFISC audit checklist contains a benchmarking against these schemes. The result of the benchmarking exercise is reflected in the audit checklist. In the EFISC audit report the total outcome and evaluations of the combined schemes must be documented together with the relevant actions and timeframe.

Combined audit of EFISC with GMP plus, Femas, Ovocom and QS, with the scope the manufacturing of single feed materials, is possible in order to avoid unnecessarily repetitive audits. In the EFISC audit report the total outcome and evaluations of the combined schemes must be documented together with the relevant actions and timeframe.

6.1.1 Audit planning

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:

- Main office including production or production location
- The structure of the unit to be certified including the number of locations (plants, branches, sales departments, etc.).
- The range of goods and services.
- The variety of processes and grade of automation.
- Similarities in structure of quality management systems in the case of groups.
- 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.
- Copy of the Feed Safety Management System Manual and the result of the latest Management Review.
- List of applicable regulations.

- Any other information the auditor/operator may find useful/relevant.

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. The operator shall inform the customer in case he is delivering products from a process that is outside of the scope of the EFISC certificate. Records should be available on this.

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 typically 0.5 day per site.

Initial audit and renewal audit:

	Basic audit time (1 process line/HACCP-study)	Additional audit time Number of lines/HACCP-studies	Deductible audit time in case of a combined audit with version of GMP plus, Femas, Ovocom, QS (scope production feed materials)	Deductible audit time in case of a combined audit with ISO 22000, FSSC, BRC or IFS (scope production feed materials)
Main office including production	1,5	0.5 day per additional HACCP-study / main processing line	-75% (minimum 1.5 day)	-30% (minimum 1.5 day)
Production site	1 day	0.5 day per additional HACCP-study / main processing line	-75% (minimum 1 day)	-30% (minimum 1 day)

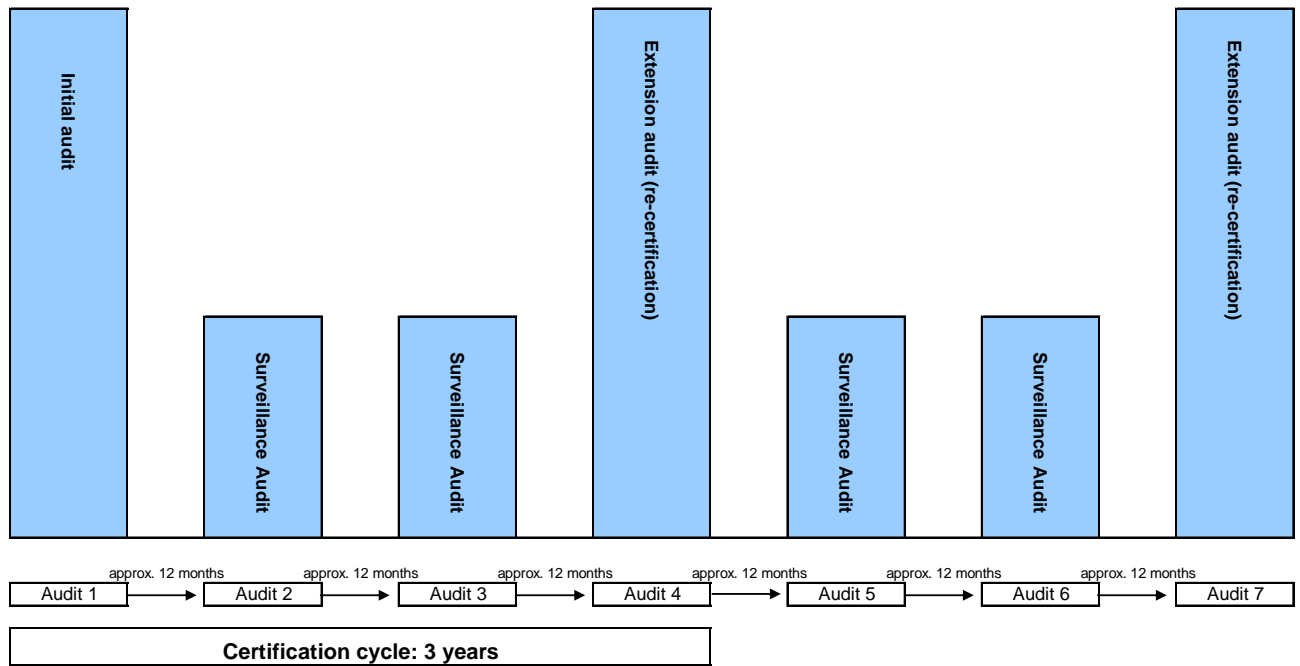
Surveillance audit:

Audit time for surveillance visits is set on 75 % of the initial audit time with a minimum of 0.75 audit day on site. Reporting time is typically 0.5 day per site.

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.

6.1.2 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.



6.1.3 Evaluation of compliance with EFISC

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).

Any nonconformity 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 non-conformities regarding the EFISC applicable requirements.

6.1.4 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.
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.
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.
Major	None
Minor	None

Recommendations

In addition to non-conformities, recommendations may be made by an auditor based on observations, with a view to aiding the continuous improvement of the operator's feed safety management system.

For making recommendations, the following points should be considered:

- The general presentation of the assessed area or company.
- Implemented HACCP principles for ongoing improvement of feed safety.
- The motivation of the management and employees.
- Elimination of former nonconformities.
- Understanding of the system within the different corporate levels.

6.1.5 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 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 aim should be to document corrective actions directly following the audit.

Nonconformities and corrective actions to be taken are documented in the action plan, and must be signed by the lead auditor and the management representative. The management representative receives the original copy of the action plan 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 body's 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.

6.1.6 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	Action plan < 14 days Verification < 28 days	Certificate suspended	Action plan < 7 days Verification < 14 days
Major	Certification denied	Action plan < 28 days Verification < 56 days	None	Action plan < 14 days Verification < 28 days
Minor	Certification granted (< 10 minors)	Action plan < 28 days Verification: next visit	None	Action plan < 28 days Verification: next visit

Recommendation: no closure necessary.

A critical or major nonconformity which has not been closed prevents the granting of an EFISC certificate (whereas a recommendation does not).

6.1.7 Audit report

A readable copy of any non-conformity form shall be discussed with the operator and handed over to him. 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, to include the number of nonconformities per section (critical, major, etc.) and a summary of observations and conclusions. 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.

6.2 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 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 certificate may also list more than one site from the same company.

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

6.2.1 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)

6.2.2 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.

6.2.3 Exclusions on certificates

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

6.2.4 Use of logo

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.

Certified operators may display the EFISC logo for the period of validity of their certificate. Use or display of the EFISC logo does not constitute proof that the operator is certified.

The EFISC logo is available upon request made to EFISC Aisbl and/or to the relevant certification body. It may be used only in its original colours and proportions.

The EFISC name and logo shall not be used on products, packaging, labels, means of transport, but may be used on certificates, advertisements and brochures.

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

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 2010 the license fee is fixed at EUR 1250,-

For the year 2011- 2015 the license fee is fixed at EUR 2500,-

Operator

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

Memberschip

Operators 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:	
Member of : <input type="checkbox"/> Fediol <input type="checkbox"/> AAF	

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 EN 45011.
- Letter of commitment that the certification body will have included EFISC in the coverage of their EN 45011 accreditation within 1 year after approval date (Provisioning EFISC is recognized as an accredited standard).
- Proven experience as described in chapter 3.1.
- List of auditors, their curriculum vitae and qualifications according to section 3.
- 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:

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

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.

Management responsibility:

Your text here.

Management system components:

Your text here.

Prerequisite programs:

Your text here.

HACCP plan:

Your text here.

NON CONFORMITIES AND RECOMMENDATIONS

Summary

EFISC Section	Grade			
	Critical	Major	Minor	Recomm.
3.1.1 Management responsibility				
3.1.2 Management system components				
3.2 Prerequisite programs				
3.3 HACCP plan				
Total				

Recommendation and follow-up

Initial or renewal audit

- Certification is denied. The Operator shall draw up an action plan within 14 days after the audit date. Its implementation will be verified on site within 28 days.
- Certification is denied. The Operator shall draw up an action plan within 14 days after the audit date. Its implementation will be verified administratively (where valid) or on site within 56 days.
- Certification is granted. The Operator shall draw up an action plan within 14 days after the audit date. Its implementation will be verified during the next regular visit.
- Certification is granted. No further action of the Operator is required.

Surveillance audit

- Certification is suspended. The Operator shall draw up an action plan within 7 days after the audit date. Its implementation will be verified on site within 14 days.
- The Operator shall draw up an action plan within 14 days after the audit date. Its implementation will be verified administratively (where valid) or on site within 28 days.
- The Operator shall draw up an action plan within 14 days after the audit date. Its implementation will be verified during the next regular visit.
- No further action of the Operator is required.

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 on the EFISC website under "Documents".

Note: this checklist is used on site and completed by hand of the auditor. Both sheets "general information" and the "assessment sheet" have to be completed. This checklist is part of the audit package and is handed in after the audit. The checklist is an aid; text of the EFISC Code is leading.

Annex 5 - EFISC checklist for the auditor



NOTES

Indicate EFISC audit or, in case of a combined audit, indicate the implemented FSMS: ISO22000 ,FSSC (ISO22000 & Pas220), BRC or IFS	1. <u>Enter the type of audit</u> : EFISC, ISO 22000, FSSC, BRC or IFS certification in the yellow field. 2. If a standard is chosen, <u>select 'Y' in the list under the yellow header</u> that appears below in order to select the appropriate checklist
Initial audit/ Renewal audit/ Surveillance audit. At the initial audit and renewal audit all questions have to be controlled. For the surveillance audit the auditor decides which elements needs to be verified during one of the two surveillance audits depending on the previous findings. All requirements are verified during the two surveillance audits Questions are to be used as guidance for the audit. The Code to good practice is the leading document. In case of a combined audit the audit results of the food safety management system have to be combined with the outcome of the EFISC audit. Always make sure that feed safety issues are included and addressed in the operators FSMS.	Scoring methodology Conform= Green= G Minor= Y= Yellow Major= Orange= O Critical= Red= R Critical- a regulatory violation, feed safety failure resulting in unsafe feed and/ or complete unwillingness to cooperate in the audit. Minor- a partial failure to implement a requirement of EFISC or poor evidence to demonstrate implementation 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 not been addressed.

EFISC

OVERALL AUDIT RESULT	SECTION SCORES TOTAL
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See table 6.1.6 RoC page 18	Number of minors=Y	1
	Number of major=O	0
	Number of critical=R	0
	Number of conform=G	1

			EFISC	ISO 22000	FSSC	BRC	IFS			
Chapter	Section (grey=PRP)	Writing						Remarks	SCORE per section	
1. Management responsibility (code chapter 4.1)	1	Management commitment, responsibility and policy	Has the management put a feed safety system in place? Is the management involved in the implementation and development?	Y	Y	Y	Y	Y	Here you can put your findings and observations in text	G
	2		Are the policies and objectives in line with the EFISC Code , statutory and regulatory demands?	Y	Y	Y	Y	Y		Y
	3		Is the scope of the HACCP system defined by defining product categories, sites/ lines?	Y	Y	Y	Y	Y		
	4		Are the outsourced activities identified and controlled?	Y	Y	Y	Y	N		
	5	HACCP team leader; responsibility, authority and communication	Does the HACCP team leader has clear responsibilities and adequate authorities	Y	N	N	N	Y		
	6		Is adequate communication to the HACCP team leader established?	Y	N	N	Y	N		
	7		Are adequate resources made available by the higher management for maintaining the feed safety system	Y	N	N	N	N		
	8	Management review	Is the annual management review report available?	Y	N	N	N	N		
2. Resource management (code chapter 4.2)	1	Human resources, organisational chart, competency, awareness and education	An organisational chart exist and is updated?	Y	Y	Y	N	N		
	2		Are the job descriptions available and updated?	Y	N	N	N	N		
	3		Necessary competences are available in disciplines concerning feed safety, HACCP and GHP	Y	Y	Y	Y	Y		
	4		The awareness of personnel on feed safety and their role is evident?	Y	Y	Y	Y	Y		
			Is a documented training program in place on the relevant process and production requirements, hygiene and feed safety?	Y	Y	Y	Y	Y		

Chapter	Section (grey=PRP)	Writing						Remarks	SCORE per section
	5	Is all personal monitoring (critical) control points trained in monitoring and corrective actions?	Y	Y	Y	Y	Y		
	6	Personal hygiene, sanitary facilities, clothing, jewellery policy, eating and drinking on site	Y	Y	N	N	N		
	7	Proper clothing, suitable for the type of product being manufactured, is available and worn in manufacturing areas? Also for visitors?	Y	Y	N	N	N		
	8	Clear procedure for no smoking and eating and drinking on site are given?	Y	Y	N	N	N		
	9	Infrastructure and work environment, maintenance, cross contamination, cleaning	Y	Y	Y	Y	Y		
	10	Does the facility location, design and construction provide for effective maintenance, clean ability and hazard controls?	Y	Y	N	N	N		
	11	Are premises and rooms designed to prevent cross contamination?	Y	Y	Y	Y	Y		
	12	Are water, steam and air of suitable quality?	Y	Y	Y	Y	Y		
	13	Is the equipment placed away from walls to allow for easy access for cleaning and to avoid pest?	Y	Y	N	N	N		
	14	Are the drainage facilities designed, constructed and maintained to avoid the risk of contamination?	Y	Y	N	N	N		
	15	Is the equipment suitable for the production of feed materials?	Y	Y	N	N	N		
	16	Control of monitoring and measuring devices, documentation	Y	N	N	N	N		
	17	Is the relevant measuring equipment calibrated/verified?	Y	N	N	N	N		
	18	Are the records of calibration results present?	Y	Y	Y	Y	Y		
	19	Maintenance, lubricants	Y	Y	N	N	N		
	20	Are the lubricants used food grade where applicable?	Y	Y	N	N	N		
	21	Cleaning and sanitation	Y	Y	N	N	N		
	22	A formal, documented, cleaning program exist and is in place?	Y	Y	N	N	N		
	23	Procedures on the cleaning of equipment exist and are implemented, supporting hygiene and feed safety?	Y	Y	N	N	N		
	24	Employees are trained in the different cleaning procedures and the training is documented?	Y	Y	Y	N	N		
	25	Cleaning equipment is clean and suitable for use in feed materials production environment?	Y	Y	Y	Y	Y		
	26	Pest control	Y	Y	N	N	N		
	27	A formal preventive pest control system is in place for the production, including the factory environment? Frequency of inspection shall be defined and documented. The findings are recorded.	Y	Y	N	N	N		
	28	Applied pesticides are / chemicals and tools are suitable for the purpose and legally approved?	Y	Y	N	Y	Y		
	29	Waste control	Y	Y	Y	Y	Y		
	30	The plant is maintained reasonable clear of infestation?	Y	Y	Y	Y	Y		
		Is waste disposed in a way to avoid contamination. Disposal should happen on a regular base to avoid waste accumulation.	Y	Y	N	N	N		
		Are the waste materials properly identified and separated to avoid mix- up with production materials?	Y	Y	N	N	N		

Chapter	Section (grey=PRP)	Writing						Remarks	SCORE per section
3. Operational Rules (Code chapter 4.3)	1	Incoming materials requirements	Is purchasing information available for the raw material to be purchased including requirements for the approval of the product	Y	N	N	N	N	
	2		Is a receipt, registration and storage procedure in place?	Y	N	N	N	N	
	3		Is a documented program in place to inspect the incoming materials against feed safety criteria?	Y	N	N	N	N	
	4		Are the samples properly stored and sampled?	Y	Y	Y	Y	Y	
	5		Non conformities are recorded and reported to the responsible unit?	Y	Y	N	N	N	
	6	Measures for the prevention of cross contamination	Is a program in place to prevent, control and detect physical, chemical and microbiological contamination?	Y	Y	N	N	N	
	7	Rework, handling	Is rework handled in a way to ensure that feed safety, traceability and regulatory compliance are maintained?	Y	Y	N	N	N	
	8	Production of feed materials	Production is running according to formal production planning?	Y	Y	Y	Y	Y	
	9		Are work instructions available?	Y	Y	Y	Y	Y	
	10		Written procedures are available aiming at defining, controlling and monitoring the critical points in the manufacturing process?	Y	Y	Y	N	N	
	11		Production areas are accessible to authorised personnel only?	Y	Y	N	N	Y	
	12	Finished feed materials	Each product has a specification, unique name and/ or code?	Y	N	N	N	N	
	13		Each batch has a unique identifier?	Y	Y	Y	Y	N	
	14		Finished product is inspected prior to dispatch to ensure it meets its specification?	Y	Y	Y	N	N	
	15		Is a retention sample taken for each batch and kept for the duration of the shelflife of the feed material	Y	Y	Y	Y	Y	
	16		In case of non conforming products these are segregated and recorded?	Y	N	N	N	N	
	17	Storage	Storage areas are suitable for their purpose and managed in a way to prevent the risk of cross contamination? Are the finished products clearly identified?	Y	Y	N	N	N	
	18		Is the product environment controlled during storage to preserve conformance with safety requirements?	Y	Y	N	N	N	
	19	Transport	Is the transport offered suitable for feed materials?	Y	Y	Y	Y	Y	
	20		Are the requirements for the transporter documented and communicated by the operator?	Y	Y	Y	Y	Y	
Management System Components (Code chapter 4.4)	1	Documentation requirements	Is the feed safety management system manual present and up to date?	Y	N	N	Y	N	
	2		Is there a documented procedure in place on document and record control?	Y	N	N	N	N	
	3		The archiving time of records exceeds the expiry date of products produced plus one year?	Y	Y	Y	Y	Y	
	4		Are records up to date, legible, readily identifiable and retrievable?	Y	N	N	N	N	

Chapter	Section (grey=PRP)	Writing						Remarks	SCORE per section
	5	Traceability	Are the direct suppliers of all raw materials traceable?	Y	N	N	N	N	
	6		Are the direct customers of all finished products traceable?	Y	N	N	N	N	
	7		Are the record regarding traceability maintained and readily available?	Y	Y	Y	N	N	
	8		Validity of traceability procedures is verified by documented test at least once a year?	Y	Y	Y	N	Y	
	9	Inspection, sampling and analysis	Are documented procedures on sampling in place and implemented?	Y	Y	Y	Y	Y	
	10		Sampling and analysis are valid, suitable for its purpose and in line with legal requirements?	Y	Y	Y	Y	Y	
	11		Reliability of outsourced analysis demonstrable eg. By ISO 17025 accreditation?	Y	Y	Y	N	N	
	12	Control of non conforming products	Is a documented procedure in place for the management of non- conforming materials?	Y	N	N	Y	Y	
	13	Crises management, withdrawal and recall for safety reasons	Does a crisis management procedure exist and is it implemented?	Y	N	N	N	N	
	14		A recall procedure is in place and its validity is verified by a documented procedure at least once a year?	Y	N	N	N	Y	
	15	Internal audits	Are internal audits implemented covering the implementation and maintenance of the FSMS as well as the compliance with regulatory and other defined requirements?	Y	N	N	N	N	
	16		Is a documented audit procedure in place?	Y	N	N	N	N	
	17		Are the findings of the internal audits followed up and implemented?	Y	N	N	N	N	
Supplier and customer relationship (Code chapter 4.5)	1	Supplier relationship	Is an adequate communication with suppliers demonstrable?	Y	N	N	N	N	
	2	Customer relationship	Is an adequate communication with customers demonstrable?	Y	N	N	N	N	
	3		Contract review demonstrable including communication with the HACCP team leader on feed safety aspects?	Y	N	N	N	N	
	4		Management of customer complaint in a documented procedure?	Y	Y	Y	N	Y	
Prerequisite programme (Code chapter 5)	1	Construction and lay-out of the building, lay-out of premises and workspace, utilities, waste disposal, equipment, cleaning and maintenance, management of incoming materials, measures for the prevention of contamination, cleaning and sanitation, pest control, personal hygiene, personal facilities, rework, product recall, storage	Is a documented and effective prerequisite program in place?	Y	Y	Y	Y	Y	
	2		Is the relevant legislation/ references/ branch codes incorporated in the PRP program?	Y	Y	Y	Y	Y	
HACCP System (Code chapter 6)	1	General Requirements	Is a documented and implemented HACCP system in place?	Y	N	N	N	N	
	2		Does the HACCP system covers the full scope from the incoming raw materials till the transfer of legal ownership?	Y	Y	Y	Y	Y	
	3		Are outsourced activities included in the scope and HACCP system?	Y	Y	Y	Y	Y	

Chapter	Section (grey=PRP)	Writing						Remarks	SCORE per section
	4	HACCP team and team leader	Does the HACCP team has a thorough knowledge of the HACCP principles, process and equipment, products rawmaterials and their hazards, the legal requirements?	Y	N	N	N	N	
	5	Incoming materials and finished product specifications	Is the composition of the HACCP team and competence of members documented?	Y	N	N	N	Y	
	6		Planning and minutes of HACCP team meetings are available?	Y	Y	Y	Y	Y	
	7		Are all incoming materials and feed materials covered by the HACCP system?	Y	Y	Y	Y	N	
	8		Product specifications are available?	Y	Y	Y	Y	Y	
	9	Process information	Are all processes documented in flow diagrams?	Y	Y	Y	Y	Y	
	10		Do the flow diagrams represent the actual situation?	Y	Y	Y	Y	Y	
	11		Is the on site validation of process information by the HACCP team demonstrable	Y	Y	Y	Y	Y	
	12	Hazard analysis	Documented hazard analysis covering all incoming materials and all processes within the scope?	Y	Y	Y	Y	Y	
	13		The hazard analysis show the nature of the hazard and its cause?	Y	Y	Y	Y	Y	
	14	Risk assessment	All hazards controlled by PRP or control measures in the FSMS?	Y	Y	Y	Y	Y	
	15		Riskassessment using severity and likely hood? Consistent categorisation of significant and non- significant risk?	Y	N	N	N	N	
	16	CCP determination	Is a hazard evaluation carried out by a structural method , motivated and documented?	Y	Y	Y	Y	Y	
	17	Critical limits and monitoring	Critical limits for all CCP's are validated?	Y	Y	Y	Y	Y	
	18		Monitoring of CCP's signals exceeding of critical limits and represents the continuous state?	Y	Y	Y	Y	Y	
	19		Indirect monitoring is validated and/ or operators competence is demonstrable?	Y	Y	Y	Y	Y	
	20	Correction	Corrective actions on exceeding limits are defined by product?	Y	Y	Y	Y	Y	
	21		Control of all CCP's is implemented in procedure	Y	Y	Y	Y	Y	
	22		Monitoring reports are available? Overview of all CCP's and their control is available?	Y	Y	Y	Y	Y	
	23	Validation	Validation of the HACCP system?	Y	Y	Y	Y	Y	
	24	Verification of the feed safety management system	Annual verification of the FSMS demonstrable and documented? The output of verification includes conclusions on implementation, effectiveness and validity of the FSMS?	Y	Y	Y	Y	Y	

ANNEX 6: TEXT FOR CERTIFICATE

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



This document serves to certify that the following animal feed materials production process(es) of [NAME SITE] is/are considered to be in compliance with the European Feed Ingredients Safety Certification (EFISC):

[Scope of certification]

The compliance of this/these production process(es) of animal feed materials was determined in accordance with the EFISC Rules of Certification.

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

First issued at [DATE}

Authorized by: [NAME AND FUNCTION CERTIFICATION MANAGER CB]