

# **EFISC.GTP**

# **Rules of Certification**

**Version 4.0 - 17.12.2017** 

**Effective from:** 

# Sectors covered by the EFISC.GTP certification scheme

The following sector specific sector documents have been developed by the respective sector organisations in cooperation with EFISC.GTP:

Starch Europe Sector reference document on the manufacturing of safe feed

ingredients from starch processing

FEDIOL Sector reference document on the manufacturing of safe feed

ingredients from oilseed crushing and vegetable oil refining

EBB Sector reference document on the manufacturing of safe feed

ingredients from biodiesel processing

COCERAL Sector reference document on the collection, transport, storage

and trading of safe feed/food ingredients (Good Trading Practices

(GTP))

The EFISC.GTP scheme is open to other feed/food business operators producing and/or handling feed/food ingredients by the development of a sector specific document.

The EFISC.GTP certification scheme is the result of the merge between the EFISC and GTP certification schemes as the outcome of the common vision on feed/food safety management certification to ensure a safe feed/food ingredient to its customers and facilitate trade

In this document feed/food are interchangeable depending of the scope

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## **SECTION 1: INTRODUCTION**

## 1.1 - General Introduction

### What is EFISC.GTP?

EFISC.GTP is a voluntary feed/food safety assurance scheme developed by Starch Europe (European starch industry), FEDIOL (European oil seed and protein meal industry), COCERAL (European association representing the trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agro supply), EBB (European biodiesel industry) and Euromalt (European malt industry) in order to establish a certifiable European Code to good practice for the collection, transport, storage, trading and industrial manufacturing of safe feed/food ingredients.

The EFISC.GTP Code, Rules of Certification and sector documents are managed by the EFISC.GTP Aisbl secretariat.

EFISC.GTP Aisbl provides the standards and framework for independent, approved third party certification of feed/food safety management systems based on ISO/IEC 17021-1:2015 and ISO/TS 22003:2013.

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

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

The EFISC.GTP logo and trademark have restricted use.

Participation is voluntary and based on objective criteria. EFISC.GTP Aisbl is not discriminatory to certification bodies and/or feed/food ingredients operators.

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

# 1.2 - EFISC.GTP Terms of Reference

- To respond to consumer concerns on feed/food safety in order to restore confidence.
- Encouraging adoption of commercially viable HACCP-based feed/food safety management schemes, which promote the safe production of feed/food ingredients 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.

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

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

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

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

EFISC.GTP documents might be translated into other languages and published on the EFISC.GTP Aisbl website. Once published, these official EFISC.GTP documents will be the only ones that may be used for EFISC.GTP 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.GTP feed/food ingredient safety assurance scheme

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

The EFISC.GTP scheme consists of the following documents:

- a) EFISC.GTP Code to good practice
- b) Sector specific documents (including Codes of good practice on specific subjects (for instance mycotoxins, dioxin))
- c) EFISC.GTP Rules of Certification

The sector specific documents are an integral part of the EFISC.GTP Code, developed by the responsible European feed/food ingredient sector organisations. The sector documents provide guidance on the products, hazards, processes, risk assessments and control measures. The sector documents and Codes of practice are approved by the respective European sector organisation and EFISC.GTP technical committee and Board. They are a component of the feed/food safety assurance system. The documents are available on the EFISC.GTP Aisbl website.

## 1.4 – EFISC.GTP governance

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

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

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

Members of the management unit, technical committee, EFISC.GTP Board and EFISC.GTP General Assembly are selected for their expertise and experience in feed/food ingredient safety.

## **EFISC.GTP Membership**

European feed/food sector organisations have the possibility to become a member of EFISC.GTP. For more information contact <a href="info@efisc.gtp.eu">info@efisc.gtp.eu</a>

## 1.5 - Scope of this normative document

This normative document explains the structure, rules and requirements of certification to EFISC.GTP standard 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.GTP 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.GTP Aisbl**

EFISC.GTP (AisbI) is the owner of the European Feed/food Ingredients Safety Code.

The rules and responsibilities of EFISC.GTP 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.GTP.

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 17021-1:2015 supplemented by ISO/TS 22003:2013 and the requirements as described in the EFISC.GTP 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 collecting, storing, transporting, trading or producing feed/food ingredients is entitled to obtain an EFISC.GTP certificate from an approved certification body provided the operator is in compliance with the requirements of the EFISC.GTP Code and its Annexes. The transport module cannot be certified as a stand-alone.

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.GTP.

### SECTION 2: EFISC.GTP AisbI RULES AND RESPONSIBILITIES

Through its secretariat, EFISC.GTP 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.GTP Aisbl website: www.EFISC.GTP.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.GTP Aisbl website.
- Updating periodically the EFISC.GTP Code and the Rules of Certification. All modifications will be notified to the licensed certification bodies and included in the EFISC.GTP 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.GTP Code and EFISC.GTP Rules of Certification will be decided by EFISC.GTP Aisbl on a case-by-case basis. The reference language versions of the EFISC.GTP Code and Certification Rules are the English versions, published on the EFISC.GTP 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.GTP Aisbl is responsible for granting, maintaining, suspending and withdrawing the allowance of certification bodies to issue EFISC.GTP certificates.

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

Certification of companies against EFISC.GTP 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.GTP certification shall apply to the EFISC.GTP Aisbl Board for the relevant scope, 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 17021-1:2015 (supplemented by ISO/TS 22003:2013)
- Fields of work in feed/food (reference document with the experience in feed/food)
- List of auditors, their qualification(s) and contact details (see §3.1.2)
- Certification procedure for EFISC.GTP

Apart from this, the certification body has to commit to include EFISC.GTP in the coverage of its ISO/IEC 17021-1:2015 (supplemented by ISO/TS 22003:2013)

accreditation within one year. This commitment shall be formalised by means of a letter addressed to the EFISC.GTP 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.GTP Aisbl.

As an integral part of their contractual agreement with EFISC.GTP Aisbl, licensed certification bodies will pay an annual license fee to EFISC.GTP 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 (coordination, reporting and fee obligations) and shall attend a full EFISC.GTP training session provided by EFISC.GTP Aisbl. Fully licensed status is achieved following endorsement of the contract by the certification body and EFISC.GTP Aisbl. Only licensed certification bodies are entitled to certify operators according to EFISC.GTP.

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

The certification body must notify EFISC.GTP 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.GTP Aisbl may decide to withdraw or suspend the approval from the Certification Body, following written notification.

# 2.2 - Verification and registration of auditors

EFISC.GTP 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.GTP requirements. Auditors are registered in the EFISC.GTP auditor registration database. Only after registration in the EFISC.GTP database he or she is authorised to perform EFISC.GTP 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.GTP Aisbl is responsible for the proper training, management and coordination of Certification Bodies.

## 2.4 - Verification of audit reports and certificates

EFISC.GTP Aisbl will verify the audit reports and EFISC.GTP certificates in order to monitor the audit results and ensure uniformity and consistency. EFISC.GTP confirms the good receipt of the documents to the certification body. Only after publication on the EFISC.GTP 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.GTP 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 a risk assessment of the number, complexity and size of the certification activities carried out by the certification bodies, EFISC.GTP will have in place a documented surveillance program. In the surveillance program process a representative of EFISC.GTP monitors the activities of the certification bodies and its associated auditor(s) on the occasion of a periodic assessment of a specific feed/food 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.GTP conducts an assessment at the certification body premises to verify the implementation of the quality management system and related EFISC.GTP requirements.

**Part 2: Witness Audit-** EFISC.GTP 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.GTP 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.GTP 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.GTP Aisbl, certification body, accreditation body and feed/food business operator). The information obtained during the surveillance of the certification body recorded in the report will be handled strictly confidential by EFISC.GTP Aisbl. EFISC.GTP Aisbl will not use it for purposes apart from those established in the frame of the surveillance process.

# 2.7 - Complaints

EFISC.GTP Aisbl will have a documented procedure in place for dealing with complaints of operators 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.GTP 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.GTP scheme.

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

- Participate in the coordination meetings organized by EFISC.GTP Aisbl. The objective of these meetings is to survey, reassess and train certification bodies. They take place, at least, once a year. EFISC.GTP 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/food ingredients sector followed by an examination.
- Report to EFISC.GTP Aisbl regarding auditor training programmes implemented (agenda, minutes, list of participants and results of the examination).
- Consult EFISC.GTP for the approval of new auditors and registration in the EFISC.GTP auditor registration system.
- Provide (under confidentiality) a copy of each certificate and audit report (Annex
   4) in English for verification and registration by EFISC.GTP before sending it to the operator.
- Report immediately to EFISC.GTP Aisbl any non-conformity identified in periodical auditing that leads to withdrawal of certification.
- Report to EFISC.GTP Aisbl about interpretation and implementation issues identified in carrying out the certification.
- Offer certification for EFISC.GTP on their website, including a link to the EFISC.GTP 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.GTP 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 17021-1:2015 and ISO/TS 22003:2013.
- Proven experience in the feed/food industry (already conducting HACCP based audits in the feed/food business, for example EFISC.GTP recognised schemes or official inspection of feed/food business operators.
- Within 1 year after the initial acceptance by EFISC.GTP Aisbl or within one year after EFISC.GTP is recognised as an accredited standard, the certification body must be accredited according to ISO/ IEC 17021-1:2015 (supplemented by ISO/TS 22003:2013) having EFISC.GTP included in the scope.
- Commitment to training and co-ordination obligations established by EFISC.GTP 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.GTP 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.GTP 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.GTP, and a documented sign of 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.GTP auditor database.
- The auditor shall:
- Qualify according to ISO/ IEC 17021-1:2015 and ISO/TS 22003:2013
- Are experienced in the feed/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/food safety management systems or equivalent).
- Post- secondary, field related education including food microbiology, feed/food processing fundamentals and chemistry including food analysis.
- Be able to apply relevant feed/food 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 feed/food industry audits in the last year) against EFISC.GTP or relevant feed/food scheme's recognised by EFISC.GTP (see Annex 3 EFISC.GTP Code) under the leadership of a qualified auditor.
- Have successfully completed training on:
  - Lead Assessor training based on ISO 19011:2011 and ISO/IEC 17021-1:2015 supplemented by ISO/TS 22003:2013 (minimum 5 day training)
  - Food safety management principles (e.g. ISO 22000:2005, prerequisite programmes (ISO/TS 22003:2013-2&6)
  - By the industry recognized HACCP training (minimum 2 day training)
  - European and National legislation applicable to feed/food safety
  - EFISC.GTP Code
  - EFISC.GTP Rules of Certification
  - The EFISC.GTP sector reference documents and have knowledge of the specific feed/food sector related risks (hazards, hazard assessment, hazard analysis, operational pre-requisite program (OPRP's), critical control points (CCP's), monitoring and 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.GTP feed/food 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 feed/food ingredient sector.

The auditor shall keep up to date with GMP, GHP, GTP, HACCP, PRP, feed/food safety and technological developments and have access to and be able to apply relevant laws and regulations, related ISO documents and the Codex Alimentarius.

The annual training of each auditor will incorporate a periodic examination, prepared by the certification body in cooperation with EFISC.GTP, 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.GTP scheme or EFISC.GTP 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.GTP may invite the auditors to participate on a special training session. The participation is required for all approved EFISC.GTP 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.GTP. Not providing the evidence will lead to the suspension and possible loss of the approval of the auditor.

In case EFISC.GTP 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.GTP certification. In coordination with the CB/ EFISC.GTP 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.

# 3.1.6 - 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.GTP 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 17011:2004.

The accreditation body shall be a member of the International Accreditation Forum and a signatory to the IAF ISO/IEC 17021-1:2015 (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 17021-1:2015 supplemented by ISO/TS 22003:2013 and the requirements as described in the EFISC.GTP scheme.

# 4.3 - Scope of accreditation

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

The EFISC.GTP code, rules of certification and sector documents.

The category as indicated in Annex A of ISO/TS 22003:2013.

#### 4.3 - Communication

The accreditation body will communicate with EFISC.GTP on the outcome and status of the accreditation process.

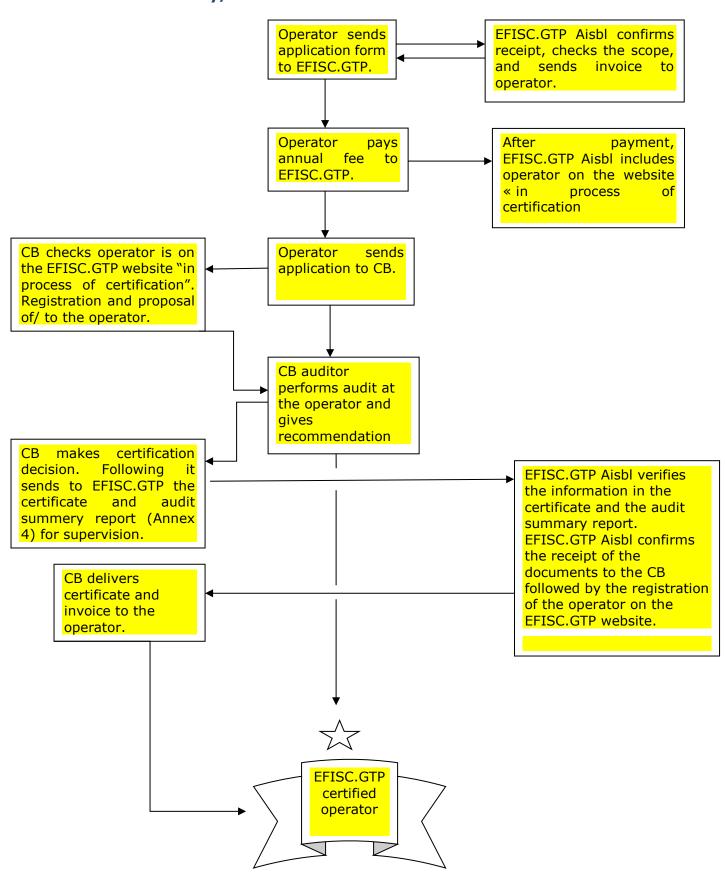
EFISC.GTP will share with the accreditation body the relevant findings of the surveillance programme (see  $\S$  2.5).

### **SECTION 5: OPERATOR'S RULES AND RESPONSIBILITIES**

The operator applying for certification agrees to the following:

- Any operator wishing to get EFISC.GTP certified will send an application letter to EFISC.GTP Aisbl. The application form is available as Annex 2 of this document. Upon receipt, EFISC.GTP 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.GTP 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.GTP listings on the EFISC.GTP Aisbl web site.
- Following, any operator wishing to get EFISC.GTP certified will contact a certification body listed in the public register of licensed certification bodies available on the EFISC.GTP 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.GTP 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.GTP Aisbl.
- The certificate holder is responsible for compliance of the process to the EFISC.GTP Code and 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.GTP



# **SECTION 7: Assessment of operators**

# 7.1 - Auditing

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

The certification body assesses the operator for compliance with the EFISC.GTP 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 the requirements of the EFISC.GTP certification scheme. All audits require inspection, assessment of the defined activity and of the feed/food safety management system of the specific operator. To make sure all aspects of the audit are covered auditors should make use of Annex 4 when seeking confirmation of the compliance of operators with EFISC.GTP.

A combined audit of EFISC.GTP with ISO 22000, FSSC 22000, BRC, IFS, GMP+, FCA, 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.GTP unannounced audit will take place without notice in addition to the annual announced audit in the three year certification cycle as described in ISO/IEC 17021-1:2015 and this document. The inspection will focus on GMP and GHP practices.

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

## a) Random (R) unannounced audit programme

The operator might receive one unannounced audit in the three year audit cycle. 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 FCA certified customers

The operator will receive one unannounced audit in the three year audit cycle. QS and FCA require feed ingredient 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 FCA 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 shall not take place in the period between two months before and two months after the annual audit. The unannounced audit will take place during normal working hours.

The operator may in principle not refuse the unannounced audit. However in an exceptional situation of a factory shut down or the absence of staff to accompany the auditor, the operator could refuse and postpone the unannounced audit. In such a situation the operator will provide a valid and documented motivation.

The unannounced audit time is minimum 4 hours, including reporting time (The reporting time is max. 25% of the 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 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 will be evaluated annually.

## 7.1.1 Multi-site certification

Multi-site certification is not permitted under the scope D (Animal Feed production)

Multi-site certification is permitted under the scope F (Distribution) and G (Provision of transport and storage services)

See reference ISO/TS 22003:2013 Table A.1

## 7.1.1.1 Requirements for multi-site certification under the scope F and G

The following requirements are meant to cover the certification of management systems in organisations with a network of sites spread out in a vast geographical area. They aim at ensuring that the audit provides adequate confidence that the operator complies with the scheme requirements while taking into account practical and economic considerations related to the specificities of certain operators such as collectors and storekeepers with numerous sites.

EFISC.GTP considers the EU internal market as one geographical area.

# 7.1.1.2 Scope and boundaries

These requirements apply to operators holding a multisite organisation, being a unique legal entity or not, where all sites shall have a legal or contractual link with the central

office of the operator and be subject to a common Feed/Food Safety Management System which is laid down, established, controlled and subject to surveillance and internal audits by the central office.

This means that the central office has rights to require that the sites implement corrective actions when needed in any site. This should be set out in a formal agreement between the central office and the sites.

## 7.1.1.3 General requirements

The operators in compliance with the scope of application of these multisite certification rules shall ascertain that:

- At least annually an audit for the central office for the FSMS (including PRP, OPRP, HACCP, other in line with the EFISC.GTP Code and relevant sector document) shall be performed
- All sites are of the same activity and are located within the same country or economic zone (EU internal market)
- All sites are operating under one centrally controlled and administered FSMS;
- An internal audit is carried out annually on each site;
- The certification body shall provide an audit report for each site

The use of multisite certification is possible for organisations with a central office and at least 20 additional sites based on the following combination of external and internal audits.

## A. External audits

On the basis of a sampling program, the certification body must randomly select the sites to be audited according to the following rules:

- For organisations with additional sites between 1-20 1/3 of the sites will be audited annually. All sites will be audited within the three year audit cycle.
- For organisations with more than 20 sites, the sampling shall be at the ratio of 1 site per 5 sites with a minimum of 20 within the three-year certification period.

The sampled sites to be audited during the certification period must be equally divided along the three years period. The selection of sites is of the responsibility of the Certification Body and must take into account the geographical criteria so as to reduce journeys from one site to the other, thus reducing costs for the operators.

After the audit, no sampled sites must be non-conforming. Audit findings of the sampled sites must be considered indicative of the entire system and correction must be implemented accordingly.

This does not preclude the obligation for the Certification Body to audit every 12 months the central office of the operator who has been granted a multisite certification.

Table: Examples of the number of sites to be audited within a three-year certification period when multisite is used

	Total number of sites											
	2- 20	21	22	23	24	25	26	27	28	29	30	31
Number of sites above 20	0	1	2	3	4	5	6	7	8	9	10	11
Additional number of sites to audit	0	1	1	1	1	1	2	2	2	2	2	3
Number of sites to be audited	2- 20	21	21	21	21	21	22	22	22	22	22	23

# 7.1.2 Audit planning

The certification audit shall be conducted in two stages at the premises of the operator. The audit consists out of a stage 1 and stage 2 audit as described in ISO/IEC 17021-1:2015 and ISO/TS 22003:2013. In the first stage the documentation of the FSMS is evaluated which includes the scope of the system, the operators feed/food safety policy, the management structure, HACCP and PRP programme. In the stage 2 audit the effectiveness of the FSMS 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:

- Infrastructure purchase and sales department, storage, transport 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 FSMS 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 FSMS 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 FSMS 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 FSMS, GMP, GHP, HACCP and PRP in compliance with the requirements in the EFISC.GTP Code and the relevant sector document.

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

When an organisation deploys workers in shifts and the products and/or processes are similar, the FTE number will be calculated based on employees on the main shift (including seasonal workers) plus feed/food safety related office workers.

When properly documented and justified, a reduction can be made for a less complex organisation measured by number of employees, size of the organisation and/or product volume or within categories having a basic audit time of less than 1.5 day audit time

A HACCP study corresponds to a hazard analysis for a family of products /services with similar hazards and similar production technology and, where relevant, similar storage technology.

If the scope of one specific operator covers more than one category, the audit time calculation shall be taken from the highest recommended basic audit time. Additional time is required for each HACCP study.

## **Initial audit:**

An initial audit takes place at the location of an applicant seeking certification against the EFISC.GTP Code. It should be carried out by checking the whole sections of the EFISC.GTP Code.

See table §7.1.4 Minimum initial audit and re-certification audit time for the relevant scope and time calculation

## **Surveillance audit:**

A surveillance audit is a periodical audit performed to ensure that an organization still meets EFISC.GTP 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.GTP 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 1 audit day

See table §7.1.4 Minimum initial audit and re-certification audit time for the relevant scope and time calculation

#### 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.GTP Code.

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

See table §7.1.4 Minimum initial audit and re-certification audit time for the relevant scope and time calculation

## **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/food safety incident
- 2. Follow up of the audit which is listed on the EFISC.GTP 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 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):

The audit time for each site is calculated in line with the table below.

# Basic calculation of minimum initial certification audit time (Ts)

# Ts = (D+H+FTE+S)

D=Basic audit time

H=Additional audit time

FTE=Number of employees involved in feed/food ingredients related activities S=Special (for instance fraud assessment)

# 7.1.4.1 Scope D Animal Feed Production

	Basic audit time (1 process lines/HACCP-	audit time Number of lines/HACCP- studies	Number of employees involved in feed ingredient related	in case of a combined audit with a valid	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*¹ department)	•	0.5 day per additional HACCP-study	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	the restriction that the audit duration of the combined audit equals to the minimum time for a single EFISC.GTP	Reduction of 50 % with the restriction that the audit duration of the combined audit equals to 50 % EFISC.GTP time + FC time. The minimum time for a combined audit cannot be less than 1 day
Main office ( purchase and/ or sales* department), including production site	,	0.5 day per additional HACCP-study		the restriction that the audit duration of the combined audit equals to the minimum time for a single EFISC.GTP audit(combined audit time minimum 2.0 day)	Reduction of 50 % with the restriction that the audit duration of the combined audit equals to 50 % EFISC.GTP time + FC time. The minimum time for a combined audit cannot be less than 2.0 day
Production site	,	0.5 day per additional HACCP-study		the restriction that the audit duration of the combined audit equals to the minimum time for a single EFISC.GTP 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.GTP time + FC time. The minimum time for a combined audit cannot be less than minimum 1,5 day

<sup>\*</sup>¹(Intercompany) purchasing and (intercompany) sales of EFISC.GTP certified feed/food ingredients

# **7.1.4.2 Scope F Distribution**

The audit time for each site is calculated in line with the table below.

	time (1 process lines/HACCP-	H Additional audit time Number of lines/HACCP- studies	FTE Number of employees involved in feed/food ingredient related activities (additional audit time)	version of GMP plus, Femas, Ovocom, QS for an identical	audit time in	For each additional site visited
Distribution, feed/food broking, trading		0.5 day per additional HACCP-study	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	restriction that the audit duration of the combined audit equals to the minimum time for a single EFISC.GTP audit(combined audit time minimum 1 day)	% with the restriction that	50% of minimum on- site audit time

# **7.1.4.2 Scope G Provision of storage and transport services**

The audit time for each site is calculated in line with the table below.

	time (1 process lines/HACCP-	Additional audit time Number of lines/HACCP- studies	Number of employees involved in feed/food ingredient related activities	version of GMP plus, Femas, Ovocom, QS for an identical	audit time in	For each additional site visited
Storage and transport		additional HACCP-study	50 to 79=1.0 80 to 199=1.5 200 to 499=2.0 500 to 899=2.5	with the restriction that the audit duration of the combined audit equals to the minimum time for a single EFISC.GTP audit (combined audit time	% with the restriction that	50% of minimum on- site audit time

# 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.

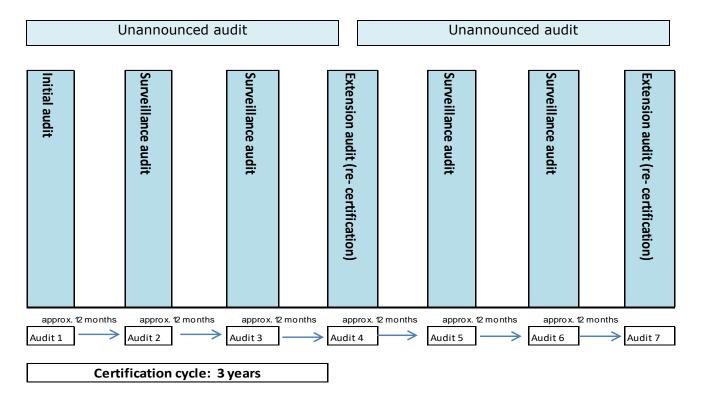
Re-certification is carried out at the end of a certification period (3 years) in order to assess whether the operator continues to meet the requirements of the Code.

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.GTP

The certification body will check compliance with the EFISC.GTP Code of Practice. For this purpose, auditors shall use the Annex 4.

In evaluating operators for compliance with EFISC.GTP, 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.GTP 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/food safety failure resulting in unsafe feed/food 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.GTP or a failure that may result in unsafe feed/food.
	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.GTP or poor evidence to demonstrate implementation.

# Non-conformities and their direct consequences

Non-conformity	Direct consequences
Critical	The auditor shall request (in writing):
	<ul> <li>Interruption of production.</li> <li>Blocking and/or recall of involved products.</li> <li>The operator to report the incident to the relevant authorities, as required by EU Regulation 178/2002.</li> <li>Closed upon evidence of correction through a partial audit</li> </ul>
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.GTP; 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 audit report form to indicate those elements of EFISC.GTP 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 renewa	al 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 reinstated 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 nonconformities 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 nonconformity. When 10 or more minor nonconformities are found the rules for a major non-conformity apply.	Action plan < 42 days after receipt list non- conformities Verification: next visit	

<sup>-\*</sup> after receipt list non- conformities (final audit day).

The suspension will be published in the register of certificates under "suspended" on the EFISC.GTP 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.GTP Aisbl to monitor audits and to ensure consistency, audit results must be supplied to EFISC.GTP Aisbl in a standard format in line with the reporting form (Annex4), to include the number of nonconformities per section (critical, major, etc.) of the previous and actual audit and a summary of observations and conclusions, including any unresolved issues, if identified,. The report of findings provided to EFISC.GTP 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.GTP 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.GTP 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.GTP Aisbl. This is the responsibility of the certification body. The responsibility for determining whether an operator is to be certified or not remains entirely to 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.GTP 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.GTP 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.GTP Aisbl with the following audit documentation as listed below for verification:

# **Initial Certification Audit/ Re-Certification Audit:**

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

### **Surveillance Audit:**

- 1 Audit Plan / Agenda
- 2. EFISC.GTP Audit Report (Annex 4)
- 3. Possible certificate modifications

# **SECTION 8: Incident management**

In the event that the operator experiences a public feed/food safety incident that requires a product recall, the organization shall immediately make the certification body and EFISC.GTP 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.GTP of the result from this assessment.

## **SECTION 9: Certificate**

Certification shall only take place where sufficient evidence to demonstrate compliance with EFISC.GTP 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.GTP Aisbl in a public register, available via the EFISC.GTP 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.GTP Aisbl register on the website (<u>www.EFISC.GTP.eu</u>).

# 9.2 - Expiring certificates

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

### 9.3 - Exclusions on certificates

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

# 9.4 - Use of logo

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

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

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

The EFISC.GTP 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.GTP name and/or logo need to be approved by EFISC.GTP Aisbl before publication.

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



### **SECTION 10: Related documents**

The currently valid documents include

- ISO/ IEC 17021:2015
- ISO/ TS 22003:2013
- ISO 19011:2011 Guidelines for the auditing of quality management and/ or environmental management systems
- ISO/ IEC 17000:2004 Conformity assessments- terminology and general principles
- EFISC.GTP Code
- EFISC.GTP Sector documents, including codes of practice

# SECTION 11: ANNEXES ANNEX 1: FEE SYSTEM

# **Certification Body**

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

For the year 2017- 2020 the license fee is fixed as follows

Scope D, G and F	2500 EUR
Scope G and F	2000 EUR

# **Operator**

The operator will pay for each location an annual fee to EFISC.GTP Aisbl of

Scope D	400
Scope G and F	350

Multisite certification, only for scope F and G:

Number of sites	1	2-10	11-39	40-79	>80
Main site	350				
Additional sites, linked to the main site, by site		50	40	30	20

## **ANNEX 2: APPLICATION LETTER FOR OPERATORS**

We herewith apply for EFISC.GTP 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 : O Fediol O Starch Europe	O EBB O COCERAL O Other

# **SITE(S) TO BE AUDITED**

Site 1	
Address (no PO box):	
City/Town:	Postal Code:
Country:	Website:
Telephone:	Fax:
Contact person 1:	Function:
Email:	Mobile phone
Contact person 2:	Function:
Email:	Mobile phone
Unannounced audit: O Mandatory	O Random
Scope:	

# 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  $\leqslant$  400 (scope D)/  $\leqslant$  350 plus fee multisite (scope G&F) per site and that our name is published on the EFISC.GTP Aisbl website.

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

Date:

Name and signature:

### **ANNEX 3: APPLICATION FOR APPROVAL OF CERTIFICATION BODIES**

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

Certifi	cation	<b>Body:</b>
---------	--------	--------------

Address:

# Coverage:

- Worldwide
- o EU 28
- o Country/ies (please mention it/them):

# **Contact person:**

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

We agree to send to EFISC.GTP Aisbl the following information:

- Copy of the appropriate accreditation according to ISO/IEC 17021-1:2015 supplemented by ISO/TS 22003:2013
- Letter of commitment that the certification body will have included EFISC.GTP in the coverage of their ISO/IEC 17021-1:2015 (supplemented by ISO/TS 22003:2013) accreditation within 1 year after approval date
- Proven experience as described in chapter 3.1.
- List of auditors, their curriculum vitae and qualifications according to section 3.
- Certification procedure for EFISC.GTP
- Contract (2 original signed copies)
- Commitment to training and co-ordination obligations established by EFISC.GTP.

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

Name:
Function:
Done in:
Date:
Signature:

# **ANNEX 4: MODEL OF AUDIT REPORT**

# EFISC.GTP Compliance report

OPERATOR:
Postal address:
Dossier no.:
SITE AUDITED:
Visiting address:
Company representative:
Job title:
Email:
Telephone:
Mobile:
Email:
SCOPE OF AUDIT
Sector:
Activity:
Which products:
# Employees feed/food ingredients (as applicable):
Audit combi with (FS)MS('s):
Number of HACCP studies:
Number of manufacturing processes:
Category ISO/TS 22003   D  G  G
CERTIFICATION RODY:

Name:

Lead auditor:

Other auditors and role:

Other attendees and role:

TYPE OF AUDIT:   Initial Verification	□ Surveillance	□ Renewal	
EFISC.GTP Code version:			
EFISC.GTP Rules of Certification:			
Sector document version:			
AUDIT DATE(S):			
Audit date(s):			
Duration of audit (contract/planning)	: h.		
Duration of audit (actual):	h.		
Report date:			

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

## **NON CONFORMITIES**

# Summary

EFISC.GTP 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 administratively within 72 days. Verification 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. Verification at the next audit.
- 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 administratively within 72 days. Verification 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/food safety management system and its compliance with the requirements of the EFISC.GTP Code.

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

+= assessed; OK -= assessed: non- conformity	Confo ce	rman	Remarks
Indicate:	Yes	No	
Number of non-conformities according to the auditor checklist			
Cr= Critical			
Ma= Major			
Mi= Minor			
	•	•	
Reference EFISC.GTP Code			

	Reference EFISC.GTP Code			
4.	Management system			
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			
12	Posourco			

4.2	Resource management		
	Summary		

4.2.1	Provision of resources	<u> </u>	1	T		
4.2.1	Provision of resources					
4.2.2						
4.2.2	Human resources					
4.2.2.1	Organisational chart					
4.2.2.2	Competency, awareness					
4.0.0.0	and education					
4.2.2.3	Personal hygiene					
4.2.3	Infrastructure and work environment					
	Summary					
		ī	Т		 	
4.2.3.1	Basic requirements					
4.2.3.2	Requirements for loading, storage,					
	production areas and					
	other feed/food related					
	facilities					
4.2.3.3	Equipment					
4.2.4	Control of monitoring and measuring devices					
4.2.5	Maintenance					
4.2.6	Cleaning, disinfection and sanitation					
4.2.7	Pest control					
4.2.8	Waste control					
4.2.9	Water, steam and air					
	supply					
4.3	Operational rules					
	Summary		1			
<u> </u>						

4.3.1	General			
4.3.1.1	Requirements for purchasing			
4.3.1.2	Incoming materials requirements			
4.3.1.3	Entry check program			
4.3.1.4	Gatekeeper protocol			
4.3.2	Handling of incoming material requirements			
4.3.3	Measures for prevention of cross contamination			
4.3.4	Measures for prevention of cross contamination			
4.3.5	Processing Aids and Technological Additives			
4.3.6	Rework			
4.3.7	Production and handling of feed/food ingredients			
4.3.8	Delivery of feed/food ingredients – labelling and accompanying documents			
4.3.9	The handling of non- certified feed/food and non-feed/food ingredients in collection, trade, storage and transport			
4.3.10	Storage			
	Summary			
4.3.10.1	Storage and transhipment			
4.3.11	Transport			

11	Managament system		
4.3.12	Sales		
4.3.12	Product and process development		
4.3.11.5	Water borne and rail transport		
4.3.11.4	Transport by road		
4.3.11.3	Transport operation bulk feed/food ingredients		
4.3.11.2	Transport operation packed feed/food ingredients		
4.3.11.1	General transport requirements		

4.4	Management system components			
4.4.1	Documentation requirements			
4.4.2	Traceability			
4.4.3	Inspection, sampling and analysis			
	Summary	 •		
	Assessed analysis			
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 – withdrawal and recall for safety reasons			
4.4.6	Internal audits			

4.5	Supplier and customer relationship		
4.5.1	Supplier relationship		
4.5.2	Customer relationship		
4.6	Feed/food Fraud Vulnerability		

5	Prerequisite programmes point 5.1 – 5.19 Food defence
	Summary

6	HACCPP System		
	Summary		
6.1	General introduction		
6.2	General requirements		
6.3	HACCP-team and team leader		
6.4	Incoming material and feed/food ingredients specifications		
6.5	Process information		
6.6	Hazard analysis		
6.7	Risk assessment		
6.8	Selection and assessment of control measures		
6.9	Establishing the operational prerequisite programmes (OPRP's)		

Assessment

6.10	Establishing the HACCP Plan		
6.11	Critical limits and monitoring		
6.12	Correction		
6.13	Validation of the feed/food safety management system		
6.14	Verification of the feed/food safety management system		



# Overview of non-conformities of previous audit

N.	EFISC.GTP Paragraph	Finding	Grade Cr/Ma/Mi	Action plan submitted (Y/N, date)	Required close-out date	Verification/ Proof	The NC is closed

### EFISC.GTP - Rules of Certification

# **Overview of non-conformities**

N.	EFISC.GTP Paragraph	Finding	Grade Cr/Ma/Mi	Action plan submitted (Y/N, date)	Required close- out date



# EFISC.GTP Non-conformity form

Operator:	Date:
Address/site:	Dossier no.:
City/country:	NC nr. of
Process/department:	EFISC.GTP 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: TEXT FOR CERTIFICATE**

Name [Name site] Name CB [Name CB]

Company Address CB [Address CB]

Name Site [Name site] [Location, country]

Adress Site [Address site]

[Location, country]

Certificate number [Certificate number]

This document serves to certify that [NAME SITE ] has implemented and maintains a Feed/Food Safety Management System including Good Manufacturing/Hygiene Practices (GMP, GHP) in compliance with the EFISC.GTP feed /food safety assurance Code version 4.0 and the Starch Europe/ FEDIOL/COCERAL/EBB/Euromalt/Other sector document version Y:

**Scope D** [Scope of certification: Production of X, Y, Z, including the (intercompany)purchasing of the incoming material, plant storage, transhipment, manufacturing, (intracompany)sales and transport of the feed ingredient (delete what is not applicable)]

**Scope G/F** [Scope of certification: Product handling of product group X,Y,Z, including collection, storage, trading and transport of feed/food ingredients (delete what is not applicable)]

Annex A of this certificate provide the locations covered under the multi-site certification (when applicable)

The compliance was determined in accordance with the EFISC.GTP Rules of Certification version 4.0.

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.GTP.eu

## Accreditation stamp

Annex A- The following sites are covered under this certificate (name, location, scope)



# Notes

