

# REGULATIONS FOR THE ISSUE AND MAINTENANCE OF CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEMS IN COMPLIANCE WITH THE UNI EN ISO 22000:2018 STANDARD AND THE FSSC22000 SCHEME VERSION 5.1

## 1. DESCRIPTION OF THE INSTITUTE

CERTIQUALITY S.r.l. is a Certification Institute that operates according to the general criteria defined by the standards of the UNI CEI EN ISO/IEC 17021 and ISO/TS 22003 series and, as an independent Body, provides requesting Organisations with services aimed at assessing and certifying the conformity of their Management Systems with the provisions of the reference standards.

For FSSC 22000 scheme certifications, Certiquality also acts in compliance with the requirements set out in the FSSC 22000 scheme by the FSSC 22000 Foundation (hereinafter "Foundation").

CERTIQUALITY S.r.l. does not offer any consultation service, either directly or through agency relationships with sub-contractors, to support Organisations setting up a Management System or prepare the relative documentation.

The legal nature of the Institute is described in its Articles of association.

The Institute's activities are financed by the application of Certification fees.

## 2. PURPOSE AND SCOPE

These Regulations define the relationships between CERTIQUALITY S.r.l. - hereinafter referred to as the "Institute" - and the Organisations requesting the Certification and

Registration of their Food Safety Management System.

The enforcement of these Regulations is supervised by the Committee for Safeguarding Impartiality, appointed by the Institute's Board of Directors, which include members from all parties interested in Certification.

The CERTIQUALITY Certificate is the document whereby the Institute certifies that the requesting Organisation employs a Management System compliant with a reference standard.

The UNI EN ISO 22000:2018 standard and the FSSC 22000 scheme define the requirements of a Food Safety Management System.

The ISO 22000:2018 standard is organised in accordance with the HLS - high level structure and it is based on the "risk based thinking" as well as the "process approach" principles, moreover it is applicable to all those organizations working in the food supply chain, independently from the dimensions and complexity. The Organization shall identify the boundaries and the applicability of the food safety management system in order to establish the relevant scope.

The scope shall specify the products and services, the processes and the production site/s included in the FSMS.

The scope shall include the activities, processes, products or services which may affect the food safety of final products.

The sectors where the ISO 22000:2018 standard is applicable are mentioned in the ISO/TS 22003:2013 standard.

The FSSC 22000 scheme provides a model of voluntary certification that can be applied to the whole food supply chain. It can cover the sectors of the supply chain where specific pre-requisite programmes (PRPs) have been developed and accepted. The sectors where the FSSC 22000 standard is applicable are mentioned in the ISO/TS 22003:2013 standard, with the limitations set out by the Foundation in the FSSC 22000 scheme version 5.1.

The FSSC 22000 scheme is based on the following standards and technical specifications:

- a) ISO 22000:2018 standard, requirements for the food safety management system;
- b) ISO 9001:2015 requirements applicable in the event that the specific 'FSSC 22000-Quality' scheme is required and applicable;
- c) Pre-requisite programme (PRPs) based on sector technical specifications (e.g. ISO/TS 22002-x; PAS xyz);
- d) Additional FSSC 22000 requirements included in the FSSC 22000 scheme;
- e) Decisions contained in the Board of Stakeholders list, periodically updated by the Board of Stakeholder of the FSSC 22000.

The FSSC 22000 scheme has been recognized by the Global Food Safety Organization (GFSI) since 2010.

NOTE: The specific requirements for the FSSC 22000 scheme additional to the provisions of the ISO 22000 standard are included in ANNEX 2 of these Regulations.

### 3. DEFINITIONS

The definitions provided in UNI EN ISO/IEC 17021, ISO/TS 22003, UNI EN ISO 22000 standards and in

the FSSC 22000 scheme as well as the following terms used in the text, shall apply.

#### 3.1 Organisation

Term used to indicate the Subject filling an application for Certification.

#### 3.2 Site

The whole area where the activities controlled by an Organisation are carried out, along with neighbouring and connected worksites or warehouses for raw materials, by-products, intermediate goods, finished goods and waste materials, and any facility and plant, fixed or otherwise, used to carry out the abovementioned activities.

#### 3.3 Food Safety Management System

Set of interrelated or interacting elements to establish policy and objectives and to achieve objectives, used to manage and organize a company with reference to food safety.

#### 3.4 Non-conformity

Minor non-conformity: lack with regards to a requirement of the management system that does not affect the ability to achieve the expected results.

Major non-conformity: lack with regards to a requirement of the management system that raises doubts about the ability of the system to achieve the expected food safety results or to effectively control the process.

### 4. GENERAL CONDITIONS

**4.1** The certification to the ISO 22000 standard and the certification to the FSSC 22000 scheme can be applied for by companies of the food industry that can be ascribed to one or more categories as defined by Annex A to the ISO/TS 22003 standard, with the limitations set out by the FSSC 22000 scheme, if any, included in annex 1 and 2 to these regulations.

**4.2** For the Certification procedure to be initiated by the Institute, the requesting Organisation must:

- have a Food Safety Management System that complies with the applicable requirements of the reference standard and with any specific prescription(s) defined for the types of product/process/service;
- describe the abovementioned System in specific documents (Management Manual, Procedure, etc.);
- accept the rules set forth by these Regulations, in the reference standards and the conditions communicated by the Institute.

**4.3** Acceptance of the application, issue and maintenance of the Certification are subject to the payment of the prescribed fees; failure to fulfil such obligations by the established deadline shall lead to the suspension or revocation of the Certificate, pursuant to the provisions set forth in Sections 8 and 9.

**4.4** The Organisation undertakes to keep its products and/or services complying with all applicable legal and compulsory requirements (such as directives, laws and regulations). It is the Institute's responsibility to verify on the basis of a sampling that is congruent with the audit time, that the Organisation is aware of, and capable of managing for all the compulsory aspects connected to the Food Safety Management System involved in certification.

#### **4.5 Amendments to the certification requirements**

Certification requirements may change as a result of:

- amendments to the reference standards;
- amendments to the issue conditions of the Certification.

In any case, by two months from the publication of the updates, the Institute notifies the certified Organisations and/or waiting to be certified and the auditors.

As far as updates applicable to the FSSC 22000 are concerned, Certiquality will inform all interested parties by 1 month from publication and, however, in accordance with the Foundation's provisions.

If it is not set forth by the Accreditation Body or by the standard, the Institute will define the date from which the changes will come into force and will define a reasonable period of time for the Organisations to adapt to the new requirements.

Organisations that do not wish to adjust their Food Safety Management System to the amendments of the reference standards or to the issue conditions of the Certification may waive their Certification by giving notice thereof to the Institute in accordance with the procedures set forth in Section 10 of these Regulations.

In the event of amendments to reference standards, the Institute reserves the right to verify the compliance of the Organisation's Food Safety Management System with the new provisions. All audit expenses are at the certified Organisation's expense.

**4.6** The Institute manages a list of the certified organisations, available on the website: [www.certiquality.it](http://www.certiquality.it). The Institute makes data public even in the case of suspension, revocation and waiver of certification if requested.

For the FSSC certification, the Institute also updates the Foundation Portal (see Annex 2 to these Regulations) with the details of the certified company.

Similar information is transmitted to the Bodies with which Certiquality has established acknowledgement agreements. The Organisation may also be included in the database of Accreditation Bodies. Such accreditation bodies may make the information on their website available to the signatories of relevant agreements with such bodies (e.g. chambers of commerce).

## 5. MANAGEMENT SYSTEM CERTIFICATION PROCEDURE

Before starting the actual certification procedure, an Organisation may request a preliminary inspection in order to evaluate its readiness for assessment, in relation to the requirements of reference standards. This visit is documented but is not considered for Certification audit purposes.

### 5.1 Request of certification offer/Certification application and acceptance of certification offer

Organisations that intend to obtain certification must request an offer by submitting an application and enclosing the required documentation.

The Institute proceeds with a formal examination of the documentation presented in order to verify the completeness and accuracy of the general information and to prepare and send the certification offer.

The signature and acceptance of the offer finalizes the contract between the parties.

The Organisation undertakes to respect and accept the provisions of the standards of reference for the certification, of these Regulations, and subsequent amendments, which are an integral part of the offer and it declares to know their content.

The Institute's regulations are available on the website: [www.certiquality.it](http://www.certiquality.it).

All the conditions governing the issue of Certification to national Organisations shall apply also to foreign Organisations, unless other specific provisions are defined by the Institute in international agreements.

In the case of bids, in accordance with the specific regulations set forth in the terms and conditions of the call for bids, procedures or documentation different from those referred to in these Regulations may be followed.

If during audits significant differences are found between the data provided by the company and the audit findings, Certiquality reserves the right to re-evaluate the offer.

Certification activities may not commence if the contract is not signed for acceptance by the Customer.

The certification is issued and maintained only in the presence of a valid certification contract.

### 5.2 Certification issue

Following the acceptance of the offer, the Institute agrees with the Organisation the period for conducting the audit.

Acceptance of the contract does not constitute either a direct or an indirect obligation to certify.

The Institute appoints the Audit Group and notifies the Organisation. The Organisation may, however, request in writing the replacement of one or more of the suggested members whenever there exist plausible reasons that are not directly related to the professionalism of the inspectors. Said reasons must be provided.

One member of the Group serves as Team Leader. The Audit Group may also be constituted by one member only for small and medium-sized Organisations.

**5.2.1** An essential condition for conducting the audit is the full operation of the Food Safety Management System with regards to the requirements of the reference standard and in particular the Organisation shall have carried out a full cycle of internal audits and at least one review shall have been carried out by the senior management.

The Organisation must ensure that:

- a) all the documents regarding the Food Safety System for which the Certification was requested and all the records relating to the application of the same Management System are available to the Auditors;
- b) auditors are assisted during audit;
- c) the access to the computer system is allowed, depending on the audit needs.

**5.2.2** The audit is aimed at verifying compliance with the requirements of the reference standard and with all the processes and activities in the certification scope.

The audit team starts the evaluation activities in both stages by holding an opening meeting with the senior management of the Organisation, during which the audit plan is explained.

### 5.2.3 Stage 1 and Stage 2

The first certification audit of the Food Safety Management System, both to the ISO 22000 standard and to the FSSC 22000 scheme shall be conducted in two stages: stage 1 and stage 2, that shall be carried out on-site and separately.

The certification audit in compliance with the FSSC 22000 scheme shall include the assessment of the requirements of the ISO 22000 standard and of the sector specific pre-requisite (PRPs) programme (technical specification of the ISO/TS 22000-x series other reference standard for PRPs) as well as the evaluation of the additional FSSC 22000 requirements, as per Annex 2.

The aim of the stage 1 audit is to acquire knowledge of the Food Safety Management System of the Organisation and of its preparedness to the stage 2 audit, in order to plan it.

If the organisation has implemented a combination of control measures externally developed, during the stage 1 audit the documentation included in the Food Safety

Management System is reviewed in order to determine if the combination of control measures is:

- adequate to the organisation,
- developed in compliance with the requirements of the ISO 22000 standard,
- kept up-to-date.

The availability of relevant authorizations is verified during the stage 1 audit, within the verification of the aspects related to legislative compliance.

The organisation is informed if the outcome of the stage 1 audit entails the need for postponing or cancelling the stage 2 audit.

The time interval between stage 1 audit and stage 2 audit cannot be more than 6 months. In the event of a longer time interval, the stage 1 audit is repeated.

The stage 2 audit schedules an inspection of production areas and it shall comprise a representative number of product lines, categories and sectors covered by the certification. The implementation of CCPs and operative PRPs is examined. The on-site audit covers all those areas which may affect food safety.

The verification of the manufacturing processes of the product and/or service covers at least 50% of the total audit duration. Such audit time does not include the verification of the activities connected with the development of the Food Safety Management System, training, control, audits, review and the improvement process.

Upon completion of the audit, the audit team meets to review the results and to process the collected data.

During the closing meeting and in the presence of the senior management of the organisation, the audit team describes the findings relating to the consistency of the Food Safety Management

System with the reference standard and it specifies the deviations detected, if any.

The Organization has then the opportunity to discuss with the audit team and clarify its position on what has been communicated.

Upon completion of each audit the auditor draws up a report with the summary of the audit results and he hands it over to the organisation, that signs it for acknowledgement and acceptance of its contents.

### Non-conformity

Upon completion of the audit, auditors analyse the nature and severity of the non-conformities detected and they discuss them with the company during the closing meeting.

Should non-conformities be detected, the Organisation shall submit to the Institute an implementation schedule detailing the corrective actions necessary to meet the requirements required for the certification issue.

Moreover, the Organisation shall have to demonstrate it has implemented and verified all the corrective actions or that it is specifically committed to attaining full compliance within a specific interval of time..

The management of findings for the certification in compliance with the FSSC 22000 scheme is described in Annex 2.

In any case, Certiquality may request the submission of documentation confirming the management of the corrective actions.

The Institute may conduct a supplementary, partial or full evaluation audit when there is no objective evidence of full conformity or when the implementation of corrective actions takes a

particularly long time (e.g. wait for obtaining authorizations or structural modifications).

The effectiveness of the corrective action plan implemented by the Organisation shall be assessed by the Institute during the subsequent audit.

**5.2.5** The documentation relating to the Food Safety Management System audit stages shall be submitted to the Technical Commission of the Institute responsible for issuing the Certification. On the basis of the audit outcome, the Technical Commission may request an additional inspection to annual audit aimed at the prompt verification of the critical points recorded.

**5.2.6** Special procedures for international cooperation with other bodies may be permitted from time to time, provided they are not in contrast with the provisions of these Regulations.

### 5.2.7 Multi-site organisations

A multi-site organisation is a company with a head office (that shouldn't necessarily be the company's headquarters) which plans, controls or manages some activities connected with the Food Safety Management System and a network of sites where such activities are totally or partially carried out.

A multi-site organisation can be certified in compliance with the ISO 22000 standard if it can demonstrate that:

- all sites work with a Food Safety Management System centrally monitored and managed;
- an internal audit has been conducted at each site in the year preceding certification;
- the results of the audit at each site have been considered as significant for the whole system and consequently corrections have been made.

A sampling of the sites to be audited is possible for those organisations which belong to A, B, E, F, G categories and have more than 20 operative sites with similar processes.

The audit is conducted by ensuring abidance by the following requirements:

- for organisations having 20 or less than 20 sites, all sites are audited;
- for organisations having more than 20 sites, 1 site out of 5 is sampled. The sites to be audited are randomly selected;
- the head office is audited at least once a year;
- a surveillance audit of a sample of sites randomly selected is carried out at least once a year;
- the results of audits carried out at the sampled sites are considered to be indicative for the whole system and as a consequence the organisation shall implement suitable corrective actions.

The requirements for the certification of multi-site organisations in compliance with the FSSC 22000 scheme are described in Annex 2.

**5.2.8** After issuing the Certification and paying all the due amount by the Organisation, the Institute issues the Certificate and transmits all the information regarding the certificate status to the national and international accreditation Bodies which collaborate or are recognized by the Institute, and to all parties requesting the same information, and it publishes the status of the Certification on its website.

For certifications in compliance with the FSSC 22000 scheme, the Institute updates the Foundation Portal in accordance with the provisions of Annex 2.

Certificates indicate 4 dates: date of first issue, date of resolution by the Technical Commission, three-year expiry date and current date of issue, which may coincide with the resolution date or be subsequent in the event of reprinting of or

publishing modifications to the certificate that do not involve resolution activities.

The certificate subject describes the certification scope and is formulated in accordance with the rules set forth by the reference standard of the certification.

### 5.3 Surveillance of certified organisation

The resolutions of Technical Commissions are promptly communicated to the Organisation. The month stated in the communication is the deadline by which the surveillance audit has to be carried out and has to be respected by the certified Organisations. Surveillance visits are scheduled annually for 12 months from the previous unless otherwise specified by the reference standard.

The first surveillance of the first three-year certification period shall be compulsorily carried out within one year from the last day of the certification audit.

Surveillance audits to the ISO 22000 standard are announced and carried out in one stage only. Surveillance audits to the FSSC 22000 scheme can be conducted in an unannounced way as set forth by Annex 2.

During surveillance audits it is verified the effectiveness of the Food Safety Management System, the conformity with the requirements of the ISO 22000 standard and, in the event of certification to the FSSC 22000 scheme, the compliance with the applicable PRPs and the FSSC 22000 additional requirements.

The activities, product lines, categories and sectors covered by the certification scope are sampled during the surveillance audit.

The sample is defined so as to be representative of the scheme implementation.

In exceptional circumstances, in order to comply with specific and justifiable business reasons

(carry out the surveillance audit on the same date of other audits related to the extension and/or renewal of the Certification or with audits related to the same Group, provided that there are justifiable organisational or logistics reasons, etc.) it may be possible to postpone the audit date by a maximum of 4 months provided it is performed within the calendar year of reference. The request for postponement must be submitted by the Organisation in writing to the Institute giving the reasons. The Institute reserves the right to decide whether to accept the request at its own discretion.

These months shall be recuperated during the subsequent audit in order not to reduce the regular audit intervals.

During the three-year period, the Organisation may request the audit to be postponed once only. Upon failure to comply with these requirements the Institute shall start the suspension course that may lead to the revocation of the certification.

During surveillance audits, Institute auditors must be allowed to verify that the conditions that have lead to the issue of the Certification have not changed, and in particular that there has been no change in the conditions that impact on the Food Safety Management System's ability to fulfil the necessary aims, in conformity with the reference standard.

### 5.3.1 Seasonal productions

If the productions in the certification scope are seasonal, Certiquality reserves the right to schedule audits so as to ensure verification of a representative number of production lines, categories and sectors covered by the certification.

### 5.4 Extraordinary audits

**5.4.1** If necessary, the Institute may decide to perform extraordinary unscheduled surveillance

audits, with a minimum of two working day's notice. For example: to assess the proper management of complaints received by the Institute; to assess the impact of organisational changes; in the event of requests made by Accreditation bodies (in this case, said bodies may take part in the audit); in the event of a clear or likely presence of a non-conformity.

In these cases, the Organisation cannot ask to replace the Institute auditors.

The cost of unscheduled audits shall have to be paid by the Organisation, both in the case of refusal to receive the auditors and in the case of "non conformity".

No expenses shall be charged if the unscheduled audits fail to reveal "non conformities".

### 5.5 Unannounced audits

Unannounced audits are specific for the FSSC 22000 scheme. The performance methods are described in Annex 2.

## 6. VALIDITY OF THE MANAGEMENT SYSTEM CERTIFICATION

The CERTIQUALITY Certification is periodically monitored, with a frequency of at least once a year, and comprises a full review of the Food Safety Management System every three years. The certificate issued indicates the three-year date of expiry.

The renewal audit shall be conducted with the purpose of assessing the continuous compliance with all requirements and to confirm the ongoing conformity and effectiveness of the Food Safety Management System with regards to the certification scope. The audit shall be planned so as to enable the company to manage findings, if any, and to Certiquality to deliberate within the certificate expiry.

Renewal audits are generally carried out in a single stage. In the event of significant changes to the Organisation or its Food Safety Management



System, the Institute reserves the right to plan for the performance of the renewal audit in two stages.

Certification maintenance is subordinate to the application of the provisions set forth in art. 12 of these Regulations

## 7. RIGHTS AND DUTIES OF THE CERTIFIED ORGANISATION

**7.1** After receiving the Certification, the Organisation can advertise the attainment of the same in the ways it deems most appropriate, provided that proper reference is always made to the scope and limitations of the Certification obtained according to the provisions set forth in REG 02 “Regulations for the use of certificates and identification marks”, keeping in mind that the logo for the ISO 22000 certification follows the general rules of use of management systems.

The FSSC 22000 logo and the ISO 22000 logo cannot be placed on the product (see specific requirements in Annex 2 to the FSSC).

Having ascertained the improper use of the Certification, the Institute shall take all measures to prevent its continuation and safeguard its interests.

**7.2** Certification is issued to the Organisation on the basis of the standard, and only for the activities certified and the operative units mentioned in the Certificate. It cannot be transferred to other units.

Organisations wishing to extend the scope shall submit an application to the Institute, that prepares an appropriate extension procedure.

The Institute must be notified of any changes related to identification and Organisational data or ownership, changes in corporate structure or slight changes in the description and editorial

aspects of the subject of Certification, and this may allow the maintenance of Certification, with issue of a new certificate. According to the extent of such changes, the Institute reserves the faculty to request further documentation or perform further audits on site, in order to verify that the changes do not affect the conformity of the Food Safety Management System.

### 7.3 Certified organisations undertake:

- to keep their structure in conformity with reference standard requirements;
- to accept, at their own expenses, the evaluation audits necessary to maintain the validity of the issued Certification;
- not to use their certification in such a way as to damage the reputation of the Institute and/or of the certification system, thus compromising the public’s trust in same;
- to cooperate with Certiquality in order to allow the performance of witness audits by the Accreditation Body and the FSSC 22000 Foundation;
- to allow, for audit purposes, the Institute's auditors, Experts or Observers as well as Accredia auditors and FSSC 22000 Foundation auditors to access its facilities and information system, assisting them during audits; should the Organisation refuse to admit Institute Observers or control and accreditation Bodies accompanying the Certiquality Auditors, the Institute may refuse certification issue, or alternatively suspend or revoke Certification. Furthermore Accredia may carry out control visits on the Organisation’s premises in the presence of the Certiquality Audit team: in such case Accredia inspectors may ask questions to the certified Organisation directly;
- to implement the corrective actions required to correct the reported deviations to its Food Safety Management System;
- to record all customers' complaints and the related corrective and preventive actions undertaken and make them available to the Institute and its auditors during surveillance audits ;

- to cease exhibiting or making any other use of the Certification documents (and, if applicable, of the Certiquality symbols or logos) immediately after the expiry, suspension, revocation, waiver and consequent withdrawal of the Certification; in the event of the certification scope being curtailed, all the relevant documents must be amended accordingly.

#### 7.4 Obligation to provide information

Organisations certified to the ISO 22000 standard or to the FSSC22000 scheme must inform Certiquality within 3 working days from the event, by fax/e-mail and subsequently by registered letter with return receipt or PEC about:

- any non-conforming situation recorded by monitoring Authorities, any suspension or revocation of authorisation, concessions, etc. relating to the production/distribution of products and/or services connected to the certification;
- any legal and/or administrative proceedings in progress, regarding the subject of certification, within the limits posed by law;
- public events concerning food safety (such as for example public recalls, calamities, food safety hotspots, etc.);
- changes to the company name, the contact address and the site subject to certification;
- changes to the organization (e.g. legal, commercial, organizational or ownership status) and management (e.g. managerial, decision-making or technical personnel);
- changes to the Food Safety Management System, to the scope and categories of products covered by the certified management system;
- any other changes making the information on the certificate inaccurate.

The Organisation shall keep the Institute informed of the developments of the aforesaid proceedings.

Supplementary obligations for the certification in compliance with the FSSC 22000 scheme are included in Annex 2.

As regards the above, Certiquality reserves the faculty to conduct appropriate and timely extraordinary audits and suspends, reduces or revokes certification when necessary, depending on the impacts on the Organisation's Food Safety Management System.

**7.5** In the event of certifications issued under accreditation, the Organisations undertake to familiarise themselves with and apply all the provisions of the Accredia Technical Regulations, which may be consulted on the website [www.accredia.it](http://www.accredia.it)

#### 8. CERTIFICATION SUSPENSION

In the event of problematic situations or deviations persisting after the term agreed for their correction shall entitle the Institute to suspend the Certification.

Examples of such severe deficiencies include the following cases:

- when surveillance reports major non conformity with relevant requisites, which does not imply a revocation;
- if the Organisation does not submit the evidence relating to the management of major non-conformities issued during audit within the prescribed timeframes;
- when the Organisation refuses to undergo periodical audit in accordance with the provisions set forth in Section 5.3.
- when the Organisation refuses to undergo additional or supplementary audits;
- if the Organisation fails to notify the Institute of significant amendments to its Food Safety Management System and/or its organisation;
- when an improper use of the Certification (symbols or logos) endures;
- in the event of any other failure to comply with the provisions of the certifying system, these Regulations and the procedures of the Institute.
- when Public Authority orders prejudice the implementation of the Food Safety Management System;

- if problems exist regarding the compulsory requirements of the product/service distributed or the Food Safety Management System in question;
- when the Organisation fails to notify the Institute pursuant to par. 7.4
- If payment of services already completed has not been made, with respect to any type of service performed by Certiquality, whether or not related to the certification; should the Organisation be in default more than once in the same three-year programme, certification will be immediately revoked.

The Organisation shall be notified of the Technical Commission's resolution by registered letter with return receipt, indicating the start date of validity, the duration, the prohibition to promote any activity related to the use of certification, including its utilization for taking part to calls for tenders, and the conditions for revoking the suspension.

The certified Organisation shall be responsible for undertaking prompt and adequate actions to correct any failure to comply with the Institute's provisions and for providing the Institute with formal notification of the proposed or implemented corrective actions.

Suspension shall only be repealed when the Institute has ascertained that satisfactory actions have been taken to ensure compliance with the certified requirements. The Institute reserves the faculty to perform an on-site audit before repealing the suspension.

In the event of failure to remove the causes that have led to the suspension within the deadline defined by the Institute, the Institute submits a revocation proposal to the resolution of the Technical Commission.

In exceptional cases, and only once during the same three-year certification period, the

Organisation may request for certification to be suspended for a maximum period of six months; such applications shall be assigned to Technical Commission resolution.

The additional requirements for the FSSC 22000 scheme are included in Annex 2.

## 9. CERTIFICATION REVOCATION

**9.1** The Food Safety Management System Certification may be revoked and, consequently, cancelled and withdrawn by the Institute's Technical Commission as a result of:

- failure to remove the causes that have led to the suspension of the Certification within the deadline defined by the Institute;
- when the cases indicated in paragraph 8 are of such a severe nature as to warrant immediate revocation;
- persistence of default beyond one month from receipt of the administrative suspension (cease and desist order) sent by the Institute by registered mail with return receipt;
- breach of laws or legally binding regulations regarding the products or processes that are the subject of certification.

The decision to revoke the Food Safety Management System's Certification shall be notified to the organisation by registered letter with return receipt.

**9.2** Following the revocation resolution, the Organisation undertakes to:

- return or destroy the original CERTIQUALITY;
- not to use any copies or reproductions thereof;
- remove from the letterhead, technical documents and advertising materials any and all references to or symbols of the CERTIQUALITY Certification;
- notify customers, particularly with reference to call for tenders, by the same means used to inform them of the attainment of the Certification.

**9.3** Following the revocation resolution, Certiquality shall delete the Organisation from the Registry of certified Organisations.

In the case of revocation due to administrative problems, the Organisation, which pays for its arrears within one month, may request reinstatement of the Certification.

The withdrawal of the Certification shall not entitle the Organisation to reimbursement of the amounts already paid of any kind and entails payment of a penalty, as set forth in Section 12.1.

The additional requirements for the FSSC 22000 scheme are included in Annex 2.

## 10. CERTIFICATION WAIVER

The Organisation may waive its Food Safety Management System Certification:

- a) at the end of the three-year period, by providing formal notice of its intention at least 3 months in advance;
- b) in the event of amendment of the reference standards, as set forth in Section 4.5 of these Regulations;
- c) in the event it disagrees with the reviews of these Regulations;
- d) in the event it disagrees with the amendments of the financial terms defined by the Institute;
- e) in the event of: cessation of activity or transfer of the Company branch, to which the Certification of the Food Safety Management System refers, to a different juridical subject, legal provisions, bankruptcy or winding up of the Organisation.

If the waiver originates from the transfer to a different juridical subject, the Contract shall continue to be valid until the end of the three-year period, subject to verification by the Institute of the maintenance of all the conditions that led to certification.

In cases b), c) and d), notification shall be sent by the Organisation no later than 1 month from the date in which the Institute has notified the amendments.

In cases b), c), d) and e), the waiver shall become effective from the date on which the Institute gives notification of its acknowledgement of the waiver, with contextual termination of certification validity.

In the event of waiver, the Organisation shall comply with the obligations set forth in Section 9.2.

In the event of waiver for reasons other than those listed above, the Organisation shall pay a compensation, as set forth in Section 12.1.

## 11. CONFIDENTIALITY

All records (documentation, letters and communications) relating to the activities connected with the Certification of the applicant Organisation's Food Safety Management System shall be regarded confidential and made available only in accordance with the provisions of the appropriate internal procedure.

All collaborators of the Institute who come into possession, while performing their work, with the aforementioned documents shall be obliged not to divulge them.

Access to and consultation of certification-related documents is reserved to those Institute functions, involved in the certification course, the certified Organisation and the accreditation and control Bodies.

Certiquality discloses information on certified Organisations with the written authorisation of same, except when information relating to the Organisation must be disclosed under legal obligations.

Certiquality operates in full respect of the current regulations about the processing of personal data. For any further information, please visit the company's website <https://www.certiquality.it/Trattamento-deidati-e-Privacy-Policy>.

## 12. CONTRACTUAL FINANCIAL CONDITIONS

### 12.1 Fees

The certification offers prepared by the Institute are based on the financial principles and criteria defined by the Board of Directors.

Contracts have three-year validity and renewal rules are defined in the specific contract signed by the parties.

As provided in Sections 9 and 10 of these Regulations, should the certificate be waived or withdrawn, the Organisation shall pay to the Institute, for the early termination of the practice, a compensation equal to 20% of the total contract price for the three-year term, provided, however, that such penalty shall be no less than 500 euros and no greater than 5000 euros.

All requests relating to the amendment of the audit schedule, made by the Organisation, may entail the payment of a supplementary fee, which shall be defined in accordance with the higher expenses incurred.

If the request is made in the 5 working days prior to the agreed date, the Institute reserves the right to charge a sum equal to 50% that envisaged for the audit.

Payment for any services performed by Certiquality shall be owed by the Organisation notwithstanding failure of the certification for reasons not attributable to Certiquality itself.

Furthermore, the company certified to the FSSC 22000 scheme shall annually pay for the administrative fee of the FSSC 22000 Foundation, for each certified site. The fee defined by the FSSC 22000 Foundation may vary periodically. The

variations are immediately notified to the certified organisations, as indicated in Annex 2.

### 12.2 PAYMENT TERMS

Fees for the activities carried out in connection with the Certification and its maintenance shall be paid to the Institute according to the instructions provided on the invoices issued from time to time. Failure to comply with the aforementioned obligations shall entitle the Institute to apply the provisions set forth in Sections 8 and 9 of these Regulations.

## 13. LIABILITY

The Organisation undertakes to guarantee the completeness and truthfulness of the documents and information made available to the Institute's appointed auditors.

Certiquality is expressly exonerated from all liability in the event of lacking or incomplete transmission of data or data that do not correspond to the company's actual situation.

Certiquality has the responsibility to verify that the Organisation's Food Safety Management System is able to effectively manage its compliance with laws and compulsory regulations in relation to the products and/or services provided, despite the fact that it does not assume any direct responsibility regarding the adequacy of the technical choices adopted for such reasons by the Organisation – which remains the only liable party – or the ascertainment of compliance with legal requisites.

The Certiquality Certification of a Food Safety Management System does not relieve the Organisation from the legal obligations originating from the supply of products, processes and services nor from the Organization's contractual obligations with its customers, with the exception of any Institute responsibility or guarantee obligation.

More specifically, the parties agree that the Institute shall not be responsible for defects of products, processes and services supplied by the Organization to third parties; in the cases referred to by the Legislative Decree no.206 dated 6/09/2005 (Consumer Code) and subsequent modifications and by the EEC Directive 85/374, disciplining the liability for damages caused by defective products and for systemic or occasional behaviour of the Organisation in violation of laws and/or Regulations.

The Institute shall not be liable for inadequacies or damages of any kind originating from the Organisation's activity or by its products, processes or services.

Certiquality shall not be liable for any potential error in any database of any accreditation and control body, including when such data shall have been transferred to third parties by any such body.

#### 14. APPEALS

Any Organisation with an interest may appeal against any of Certiquality's decisions.

Such appeal must be sent by registered letter to Certiquality within 30 days from the notification of such decision. Certiquality shall provide written confirmation of the receipt of such appeal.

Certiquality shall submit such appeal to a dedicated committee which shall render a reasoned decision within 30 days. Upon justification the appeals committee may render its decision within 60 days,

Upon denial of the appeal, the relevant decision becomes final; upon granting of the appeal, the relevant decision is quashed or revoked.

Expenses shall be paid by the losing party.

#### 15. APPLICABLE LAW AND DISPUTES

Any relationship between the Organisation and Certiquality is governed by the Italian law. The only competent court for disputes relating to the

application or interpretation of these Regulations shall be the Court of Milan.

#### 16.COMPLAINTS

Any person may submit communications/complaints regarding any behaviour of the Institute or the certified Organisations that may be regarded as not being in line with the reference standards.

Said communications/complaints must be made by letter or fax; telephone communications must subsequently be formalized in writing by the notifying party.

The Institute undertakes to keep the notifying party informed of the outcome of the complaint. Anonymous communications/complaints will not be considered by the Institute.

**ANNEX 1**

**ISO 22000 CERTIFICATION: APPLICABLE CATEGORIES BASED ON ISO/TS 22003:2013**

CLUSTER	CATEGORY		SUB-CATEGORY		EXAMPLES OF ACTIVITIES
Primary	A	Farming of animals	AI	Raising animals used for the production of meat/milk/eggs/honey	Raising animals (other than fish and seafood) used for the production of meat, eggs, milk or honey Growing, keeping, trapping and hunting (slaughtering at point of hunting) Associated farm packing and storage (NOTE 1)
			All	Raising fish and seafood	Raising fish and seafood used for meat production Growing, trapping and fishing (slaughtering at point of capture) Associated farm packing and storage.
	B	Farming of plants	BI	Farming of plants (other than grains and pulses)	Growing or harvesting of plants (other than grains and pulses): horticultural products - fruits, vegetables, spices, mushrooms, etc.; hydroponics for food. Associated farm packing and storage.
			BII	Farming of grains and pulses	Growing or harvesting of grains and pulses for food Associated farm packing and storage.
Production of food and animal feed	C	Food manufacturing	CI	Processing of perishable animal products	Production of animal products including fish and seafood, meat, eggs, dairy and fish products
			CII	Processing of perishable plant products	Production of plant products including fruits and fresh juices, vegetables, grains, nuts, and pulses
			CIII	Processing of perishable animal and plant products (mixed products)	Production of mixed animal and plant products including pizza, lasagne, sandwich, dumpling, ready-to-eat meals
			CIV	Processing of products stable at ambient temperature	Production of food products from any source that are stored and sold at ambient temperature, including canned foods, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, food-grade salt
	D	Animal feed production	DI	Animal feed production	Production of feed from a single or mixed food source, intended for food-producing animals
			DII	Pet food production	Production of feed from a single or mixed food source, intended for non-food producing animals
Catering	E	Catering		Preparation, storage and, where appropriate, delivery of food for consumption, at the place of preparation or at a satellite unit	
Distribution, transport and storage	F	Distribution	FI	Trade - wholesale	Provision of finished food products to a customer (retail outlets, shops, wholesalers)
			FII	Commercial intermediaries	Buying and selling food products on its own account or as an agent for others

					Associated packaging (NOTE 2)
	G	Transport and storage	GI	Transport and storage of perishable food and animal feed	Storage facilities and distribution vehicles for the storage and transport of perishable food and feed Associated packaging
			GII	Transport and storage of food and animal feed stable at ambient temperature	Storage facilities and distribution vehicles for the storage and transport of ambient stable food and feed Associated packaging
Ancillary services	H	Services (NOTE 3)			Provision of services related to the safe production of food, including water supply, pest control, cleaning services, waste disposal.
	I	Production of food packaging and packaging material			Production of food packaging material
	J	Equipment manufacturing			Production and development of food processing equipment and vending machines
Biochemicals	K	Production of (bio)chemicals			Production of additives, vitamins, minerals, bio-cultures (starters for cheese-making; bacterial cultures), flavourings, enzymes and processing aids Pesticides, drugs, fertilizers, cleaning agents

Clusters are defined and used in order to identify accreditation scopes.

NOTE 1: "Associated farm packing and storage" is a packaging without modifying and processing the product.

NOTE 2: "Associated packaging" is a packaging without modifying and processing the product.

NOTE 3: Within the "services" category, some of these services can be excluded from the scope of the Food Safety Management System; in order to define if they are included, a positive reply shall be given to one of the following questions:

- is the organisation/service capable of introducing a food hazard in the food chain?
- has the organisation/service provider a determining influence and authority in food-connected processes?



## ANNEX 2

### SPECIFIC SUPPLEMENTARY REQUIREMENTS FOR THE FSSC 22000 SCHEME VERSION 5.1

#### PURPOSE AND SCOPE

This Annex defines the specific requirements set forth by the FSSC 22000 scheme that can be applied to those Organisations wishing to achieve and register the Certification of their Food Safety Management System to the version 5.1 of the FSSC 22000 scheme.

The FSSC 22000 scheme:

- comprises:
  - a) the ISO 22000:2018 standard, requirements for the implementation of a Food Safety Management System;
  - b) the ISO 9001:2015 standard, applicable requirements if the specific 'FSSC 22000-Quality' scheme is applicable;
  - c) pre-requisite programme (PRPs) based on sector technical specifications (e.g. ISO/TS 22002-x; PAS xyz);
  - d) the additional FSSC 22000 requirements included in the FSSC 22000 scheme;
  - e) the decisions contained in the Board of Stakeholders list, periodically updated by the Board of Stakeholder of FSSC 22000;
  - f) legal and regulatory requirements.
- It is recognized by the Global Food Safety Initiative (hereinafter GFSI);
- It allows the integration with other standards concerning management systems such as quality, environment, health and safety etc.;
- It is governed by the non-profit FSSC 22000 Foundation and managed by an independent Committee of interested parties (Board of Stakeholders);
- It increases transparency along the whole food supply chain;

- It offers a 'Register of FSSC 22000 certified organisations' which is publicly accessible.

The sectors where the FSSC 22000 scheme is applicable are included in the ISO/TS 22003:2013 standard with the limitations set forth by the

Foundation in the FSSC 22000 scheme version 5.1.

#### 2. PRE-REQUISITE PROGRAMME

The scheme specifies the compulsory implementation of technical specifications that describe the pre-requisite programmes (PRPs) in detail, as indicated in clause 8.2 of the ISO 22000:2018 standard.

These PRP requirements are specified in the standards of the ISO / TS 22002-x series and/or in the BSI / PAS 221 standard.

#### 3. ADDITIONAL REQUIREMENTS

During audits to the FSSC 22000 scheme, Certiquality verifies the implementation, by the organisation, of the additional requirements as described in the document FSSC 22000 Scheme, version 5.1:

- Management of services and purchased materials.
- Product Labelling;
- Food Defence;
- Food Fraud Mitigation;
- Logo use;
- Management of allergens (Food Chain Categories C, E, FI, G, I e K);

- Environmental monitoring (Food Chain Categories C, I & K);
- Formulation of product (Food Chain Category D);
- Transport and Delivery (Food Chain Category FI);
- Storage and Warehousing (All Food Chain Categories);
- Hazard control and measures for preventing cross-contamination (Food Chain Categories C & I);
- PRP Verification (Food Chain Categories C, D, G, I & K);
- Product development (Food Chain Categories C, D, E, F, I & K);
- Health Status (Food Chain Category D);
- Requirements for organizations with multi-site certification (Food Chain Category A, E, FI & G).

#### 4. ACCREDITATION

Certiquality is accredited by Accredia, Italian accreditation Body, for the certification activities in compliance with the FSSC 22000 scheme. The accredited categories are shown on the up-to-date accreditation certificate available on the website [www.certiquality.it](http://www.certiquality.it).

#### 5. AMENDMENTS TO THE FSSC 22000 SCHEME

In the event of amendments to the scheme or publication of information notes related to the requirements of the FSSC 22000 scheme, Certiquality undertakes to send, within 1 month, specific notifications to the certified companies.

#### 6. UPGRADE AUDIT

In the event that the Foundation makes significant amendments to the requirements of

the FSSC 22000 scheme, Certiquality will conduct an 'Upgrade Audit' in accordance with the Foundation's provisions.

The amendments may entail the need for integrating the audit time with additional days. In this specific event, Certiquality informs the company about the contractual variations.

If established by the Foundation, following the positive outcome of the audit, including the correction of non-conformities, Certiquality issues an up-to-date version of the certificate.

#### 7. TRANSITION AUDIT

- 1) Transition audits are allowed starting from certifications to the ISO 22000 standard and from certifications in compliance with schemes recognized by GFSI with equivalent scopes.
- 2) Transition audits entail the start of a new certification cycle and they are carried out as stage 2 audits.  
A stage 1 audit may be carried out at Certiquality's discretion.
- 3) The certificate of compliance with the FSSC 22000 scheme, issued at the completion of the certification process, has a validity of 3 years.

#### 8. OBLIGATIONS

Organisations certified to the FSSC 22000 scheme must inform Certiquality within 3 working days from the event, by fax/e-mail and subsequently by registered letter with return receipt or PEC about:

- a) any significant changes which could have effects on the ability of the management

system to maintain compliance with the requirements of the FSSC 22000 scheme.

In the event of uncertainty about the relevance of the change, the Organisation shall inform Certiquality;

- b) serious events which may affect the Food Safety Management System or the 'FSSC 22000-Quality' system, the legality and/or integrity of the certification. Such events include legal proceedings, judicial proceedings, situations posing a threat to food safety, quality or the integrity of the certification as result of natural disasters or man-made disasters (for example, wars, strikes, terrorism, crime, floods, earthquakes, cybercrimes);
- c) public events concerning food safety (for example product recalls, calamities, health emergencies connected with food products);
- d) changes to the company name, the contact address and the organisation's site;
- e) changes to the organization (e.g. legal, commercial, organizational or ownership status) and management (e.g. managerial, decision-making or technical personnel);
- f) changes to the Food Safety Management System, to the scope and categories of products covered by the certified management system;
- g) any other changes making the information on the certificate inaccurate.

Certiquality will inform the Foundation in the event of a certified organisation recalling a product following the death and/or hospitalization of people or in the event of a product recall producing a significant dissemination of news in the media. The Foundation is notified within 3 days from the receipt of the information by the certified company.

By signing the contract, the Organisation accepts that:

- a) Certiquality shares information about the certification and auditing process with the FSSC 22000 Foundation, with GFSI, with the accreditation body Accredia as well as with the Competent Authorities;
- b) Certiquality publishes information regarding the certificate status in the Registry of certified companies in place on the website [www.certiquality.it](http://www.certiquality.it) and in the Foundation Portal;
- c) within the Integrity Program process, that Foundation's representatives are present during the audit, in order to verify the activity of Certiquality's auditors.

#### 9. SUSPENSION AND WITHDRAWAL OF THE CERTIFICATE AND REDUCTION OF THE CERTIFICATE SCOPE

- a) Certiquality shall immediately suspend the certification when a critical non-conformity is issued during the audit and/or when there is an evidence that the organisation is not able or not willing to demonstrate and maintain compliance with the requirements of the FSSC 22000 scheme.
- b) Certiquality withdraws the certification in the following cases:
  - when there are no conditions to repeal the certificate suspension within the maximum time of six months;
  - when the organisation ceases the activities in the scope of the certificate of conformity with the FSSC 22000 scheme,
  - in any other case when the integrity of the certification or of the audit process is seriously jeopardised.
- c) Certiquality reduces the certificate scope when there is an evidence that the organisation has a certificate whose scope exceeds the ability of the organisation to meet the requirements of the FSSC 22000 scheme.

Activities, processes, products or services cannot be excluded from the certification scope when such activities, processes, products or services may impact the food safety of finished products as defined in the certification scope.

#### **10. ACTIONS FOLLOWING THE SUSPENSION AND WITHDRAWAL OF THE CERTIFICATE AND REDUCTION OF THE CERTIFICATE SCOPE**

- 1) In the event of withdrawal or suspension of the certificate, the certification to the FSSC 22000 scheme ceases its validity. Within 3 days from the decision, Certiquality:
  - a) changes the certificate status in the Foundation Portal and in its registry of certified organisations and carries out any other action it may deem as appropriate;
  - b) inform the organisation in writing about the decision to suspend or withdraw the certificate;
  - c) inform the organisation about the most appropriate activities to inform its customers about the suspension or withdrawal of the certificate.
  
- 2) In the event of reduction of the certificate scope, the certification to the FSSC 22000 scheme remains valid only for the reduced scope, that is shown in the new certificate version. Within 3 days from the decision, Certiquality:
  - a) changes the certificate scope in the Foundation Portal and in its registry of certified organisations and carries out any other action it may deem as appropriate;
  - b) inform the organisation in writing about the modification of the certificate scope;
  - c) inform the organisation about the most appropriate activities to inform its

customers about the reduction of the certificate scope.

#### **11. EXTRAORDINARY EVENTS**

In case of extraordinary events which could temporarily prevent to carry out annual audits, Certiquality assesses the risk of maintaining the certification to ensure that the integrity of the certification itself is kept.

Certiquality informs the organisation of the risk assessment methods used and of the relevant results and planned actions.

In the event of a low risk, Certiquality can consider some alternative methods to verify the maintenance of the compliance of the Food Safety Management System of the Organisation.

Additional costs for the risk assessment process, if any, shall be paid for and notified to the Organisation.

If the annual surveillance cannot be carried out in the course of the year of competence, Certiquality may request a dispensation to the Foundation or suspend the certificate.

#### **12. AUDIT DURATION**

Certiquality, as accredited body, calculates the audit duration on the basis of the information contained in the application documents filled-in by the organisation and following the requirements of the ISO / IEC 17021-1 ed ISO / TS 22003 standards and of the FSSC 22000 scheme.

The audit duration is notified to the company together with the offer, the signing and

acceptance of which finalizes the contractual relationship between the parties.

During every annual audit, the minimum audit duration is always respected.

### 13. USE OF INFORMATION AND COMMUNICATION TECHNOLOGY

If the organisation intends to partly undergo a remote audit using information and communication technologies, Certiquality implements the requisites of the document IAF MD 4 - IAF MANDATORY DOCUMENT FOR THE USE OF INFORMATION AND COMMUNICATION TECHNOLOGY (ICT) FOR AUDITING/ASSESSMENT PURPOSES.

Information and communication technologies can be used in the following cases:

- a) interviews with personnel and review of the policies, procedures and records as part of the on-site audit;
- b) in case of use of the 'ICT Audit Approach' as described in Annex 9 to the FSSC 22000 scheme.

### 14. AUDIT PLANNING AND MANAGEMENT

- 1) The first certification audit of the Food Safety Management System is carried out on-site in two different stages: stage 1 and stage 2. The time interval between the two stages is 6 months. In the event of a longer time interval, the stage 1 audit shall be repeated.
- 2) At least one annual audit is planned to maintain the validity of the certificate or to ensure that the certification renewal is completed before the expiry of the certificate.
- 3) The annual audit is carried out at the organisation's site; it is a full audit conducted

so as to verify all the requirements of the FSSC 22000 scheme. Surveillance audits are carried out within the calendar year.

- 4) The audit is conducted on consecutive days for the duration established in the contractual agreements. In case of use of information and communication technologies, the requirements of the 'USE OF INFORMATION AND COMMUNICATION TECHNOLOGIES' section of these Regulations shall apply.
- 5) In the event of audits abroad, Certiquality agrees with the Organisation the language to be used. If necessary, the audit team can also include an interpreter. The expenses for the interpreter shall be paid by the company.
- 6) The three-year cycle of validity of the certification shall not be exceeded. Certiquality conducts audits by employing auditors qualified for the FSSC 22000 scheme and guaranteeing their replacement at least every two three-year certification cycles at the same certified site or after 6 years of consecutive presence at the certified site.

### 15. AUDIT PERIODICITY

The following audit periodicity shall be complied with.

- a) First surveillance: the first surveillance audit after certification is carried out within 12 months from the last day of the stage 2 audit.
- b) Renewal audit: the renewal audit is carried out at least 60 days before the certificate expiry.

### 16. SPECIAL AUDITS

Certiquality may conduct 'Special audits' in addition to, but not replacing, annual surveillance or renewal audits.

The 'Special audits' are documented and loaded in the Foundation Portal.

## 17. MULTIPLE ACTIVITIES MANAGED AT MORE THAN ONE SITE

### Head Office

Corporate positions relevant to certification, which are controlled by a Head Office, such as, by way of example, purchasing, approval of suppliers, quality assurance, are verified by interviewing the staff responsible for these functions, as described in the Food Safety Management System.

The functions at the head office are verified separately if they are not part of an audited site.

The audit of the head office is documented and shall be carried out before the on-site audit.

Audits at the sites that are in the certification scope and are controlled by a head office shall be completed within 12 months from the completion of the audit at the head office.

Every site receives:

- a) a separate audit;
- b) a separate report;
- c) a separate certificate.

The head office cannot receive its own separate certificate, but it is mentioned in the certificate of the site.

### Off-site activity

- 1) Where one manufacturing or service process is split across more than one physical address all locations may be covered in one audit provided that the different addresses are part of the same legal entity, under the same Food Safety Management System and that they are the sole receiver/customer of each other.

- 2) Storage facilities at another location shall also be included in the same audit provided they meet the above-mentioned requirements.
- 3) Each audited site is shown on the certificate issued to the site with information about the activities carried out.

## 18. MULTI-SITE CERTIFICATION

Multi-site certification and site sampling is only allowed for the following categories:

- 1) A – Animal Farming.
- 2) E – Catering.
- 3) FI – Retail/wholesale.
- 4) G – Storage and distribution.

A multi-site organisation can comprise different legal entities. Each legal entity shall have a contractual agreement with the central function and it shall be part of a single management system implemented, established and subject to continuous surveillance and internal audits by the above-mentioned central function.

The central function shall be audited at least annually and before the audits of the sampled sites. If necessary, a small number of the sample sites may be audited prior to the audit of the central function.

The certification of one organisation enables the issue of a group certificate.

The sites to be audited can be sampled, starting from the 21<sup>st</sup> site. The sampling is defined on the basis of the requirements of the ISO/TS 22003 standard and the FSSC 22000 scheme in their current versions.

New sites, to which certification shall be extended, have to be audited.

Once every 3 years, the annual audit shall be conducted fully unannounced. Said audit comprises the central functions and sites on the territory.

The central function shall take the responsibility for coordinating, handling and correcting the non-conformities detected at site level, in collaboration with the involved sites.

If the central function or one of the sites are not able to meet the requirements of the FSSC 22000 scheme, Certiquality does not issue the certification. In the event that the certification has been already issued, then Certiquality starts the suspension process of the whole certification.

Certiquality suspends a multi-site certification within 3 days from the finding of a critical non-conformity whether the audit has been completed or not.

If a major non-conformity is detected during an audit and the audit schedules a duration of more than 30 calendar days for its completion (audit at the central function and sites), the organisation shall submit to Certiquality a plan of corrective actions, including suitable temporary measures or the controls necessary to mitigate the risk until the non-conformity has been corrected.

## 19. UNANNOUNCED AUDITS

### Frequency

- 1) Certiquality carries out unannounced audits at least once in the three-year period of validity of the certification.

- 2) A certified organisation can voluntarily decide to replace all surveillance audits by unannounced audits. The organisation can also ask for receiving an unannounced renewal audit;
- 3) The certification audit (stage 1 and stage 2) cannot be replaced by an unannounced audit.

### Execution

- 1) The unannounced audit date is not communicated to the organisation and the audit plan is not sent to them in advance. The unannounced audit takes place during normal operational working hours, including the night shift, when required.
- 2) The Organisation shall inform Certiquality of black-out days, when it would have extreme difficulty in attending the audit or when production is idle.
- 3) The audit starts with an inspection of the production facilities commencing within 1 hour after the auditor has arrived on site. In case of multiple buildings at the same site the auditor shall, based on the risks, decide which buildings/facilities shall be inspected in which order;
- 4) The auditor assesses all the requirements of the FSSC 22000 scheme, including the production or service processes under way. Where parts of the audit plan cannot be audited, Certiquality schedules an announced follow-up audit to be carried out within 4 weeks from the completion of the unannounced audit. The fees of the follow-up audit shall be paid by the Organisation.
- 5) Certiquality defines which of the annual surveillance audits shall be chosen for the unannounced audit, taking into consideration the requirement that unannounced audits shall be conducted at least once every 3 years and adhering to the calendar year requirement.
- 6) If the Organisation refuses to receive the unannounced audit, Certiquality suspends

the certificate immediately. If the unannounced audit cannot be conducted within a six-month timeframe from the date of refusal, Certiquality withdraws the issued certificate.

- 7) The audit of a Head Office separate from the site is always announced.
- 8) Secondary sites, off-site storage, warehouses and distribution facilities are audited during the unannounced audit.

The audit fees will be charged to the Organisation also in the event that the auditors are prevented from entering the site and conducting the unannounced audit.

## 20. NON-CONFORMITY

The FSSC scheme schedules three levels of non-conformity:

- a) minor,
- b) major,
- c) critical.

### Minor non-conformity

A minor non-conformity is issued when the finding does not affect the capability of the Food Safety Management System to achieve the intended results. In this case:

- 1) the Organisation shall provide Certiquality with objective evidence of the correction, evidence of the root-cause analysis, of risks, and the proposed corrective action plan;
- 2) Certiquality reviews the corrective action plan and the evidences provided and approves it when acceptable.

The approval is completed within 28 days after the last day of the audit. Exceeding this timeframe will result in a suspension of the certificate;

- 3) The Organisation shall implement the corrective actions within the timeframes agreed with Certiquality;
- 4) Certiquality verifies the effectiveness of the corrective action plan, at the latest, during the next audit.

### Major non-conformity

A major non-conformity is issued when the finding affects the capability of the Food Safety Management System to achieve the intended results. In this case:

- 1) The Organisation shall provide Certiquality with objective evidence of the root-cause analysis, of risks, and evidences of an effective implementation.
- 2) Certiquality reviews the corrective action plan and it conducts a follow-up audit on-site to verify the implementation of corrective actions and to close the major non-conformity. In cases where documentary evidence is sufficient to close out the major non-conformity, Certiquality may decide to perform a documental audit. The follow-up audit shall be carried out within 28 calendar days from the audit completion.
- 3) The major non-conformity is closed by Certiquality within 28 calendar days from the audit completion. When the non-conformity cannot be closed within this timeframe, Certiquality suspends the certificate.
- 4) Where completion of corrective actions might take more time, the Organisation shall include in the corrective action plan any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented.

### Critical non-conformity

A critical non-conformity is issued when a direct food safety impact without appropriate action by the organisation is observed during the audit



or when legality and/or certification integrity are at stake. In this case:

- 1) Certiquality suspends the certificate within three working days from the issue of a critical non-conformity. Suspension is extended to a maximum period of 6 months.
- 2) The organisation shall provide Certiquality, within fourteen calendar days from the audit completion, with the evidence of the root cause analysis, of risks and propose a corrective action plan
- 3) In the period between six weeks to six months after the audit, Certiquality conducts a follow-up audit to verify the implementation of corrective actions and the closure of the major non-conformity. Certiquality carries out a full audit on-site having a minimum duration of one day. Following the follow-up audit with positive outcome, Certiquality restores the certificate and the audit cycle. The subsequent audit is scheduled by Certiquality according to the timeframe originally planned. The follow-up audit does not replace the annual audit.
- 4) If the Organisation is not able to effectively complete the corrective action plan within 6 months after the audit completion, then Certiquality withdraws the certificate.
- 5) In the event of a critical non-conformity issued during a certification audit, the audit is fully repeated.

## **21. AUDIT REPORT**

Certiquality provides a written report for each audit.

Certiquality provides the Organisation with a full audit report within two weeks from the date of decision of the certification.

The certified organization is the owner of an audit report, whilst the CB is responsible for the report data. Certiquality keeps the confidentiality of its contents.

In the event that information relating to the Organisation must be disclosed due to legal obligations, the Institute will inform the Organisation.

## **22. FSSC 22000 CERTIFICATE**

The certified organization is the certificate holder, not the owner. The CB is the data owner of the certificate data.

## **23. CERTIFICATE TRANSFER**

In the event of an Organisation requiring the transfer of the certificate to the FSSC 22000 scheme from another Certification Body, Certiquality implements the requirements of the document IAF MD 2:2017 Mandatory Document for the Transfer of Accredited Certification of Management Systems.

## **24. ANNUAL FEE**

The Organisations certified to the FSSC 22000 scheme shall pay an annual fee that Certiquality invoices on behalf of the Foundation, to which it transfers the full amount received.

The Foundation decides the amount of such fee annually.

## **25. USE OF THE FSSC 22000 LOGO**

The certified organisation can use the FSSC 22000 logo for promotional purposes on printed matters, websites and other promotional material.

The organisation which uses the FSSC 22000 logo shall comply with the following specifications:

The logo shall meet the following requirements:

Colour	Green	Grey
PMS	348 U	60% black
CMYK	82/25/76/7	0/0/0/60
RGB	33/132/85	135/136/138
#	218455	87888a

Use of the logo in black and white is permitted when all other text and images are in black and white.

In order to avoid the impression that Certiquality has certified a product, process or service provided by the FSSC22000 certified organization, it is not permitted to use the logo:

- a) on the product;
- b) on labelling;
- c) on packaging (primary, secondary or of any other type);
- d) in a manner that could give the impression that a product, process or service provided by the Organisation is certified.

## 26. PORTAL OF THE FSSC 22000 FOUNDATION

The status of the certificate of compliance with the FSSC 22000 scheme, issued to the Organisation, is published on the Foundation Portal.

For any type of audit, Certiquality loads the required data and documents in the Foundation Portal, within 28 calendar days from the certification decision and, however, not later than 2 months from the last day of audit.

When requested by the Organisation, Certiquality provides the access credentials to the Portal for the Organization Profile, Audit and Certification sections. Credentials are given to a person authorized by the Organisation.

## 27. INTEGRITY PROGRAM

FSSC has introduced a series of measures aimed at guaranteeing the correct implementation of the FSSC 22000 scheme, named “Integrity Program”.

The relevant activities of the Integrity Program are mainly aimed at verifying the activity of Certification Bodies and their auditors.

The Integrity Program may also involve a certified Organisation, that shall cooperate by allowing the performance of the audit by the FSSC 22000 auditors and by its delegates.

The areas of action of this programme are:

- 1) Surveillance audits carried out at Certiquality’s offices.
- 2) Remote, documental audits aimed at reviewing the audit documentation.
- 3) Surveillance audits carried out at the premises of certified organisations. These audits are announced with a short notice and they are aimed at verifying the assessment made by Certiquality.

**FSSC22000 CERTIFICATION: APPLICABLE (SUB)CATEGORIES BASED ON ISO/TS 22003:2013**

CATEGORY – Sub-category		EXAMPLES	APPLICABLE NORMATIVE DOCUMENTS
A	Farming	AI: Farming of animals for meat/milk/ eggs/honey	ISO 22000, ISO/TS 22002-3, FSSC 22000 Additional requirements
		AI: Farming of Fish and seafood	ISO 22000, ISO/TS 22002-3, FSSC 22000 Additional requirements
C	Food productions	CI: Processing of perishable animal products	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
		CI: Processing of perishable plant products	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
		CI: Processing of perishable animal and plant products (mixed products)	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
		CIV: Processing of ambient stable products	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements

D	Production of feed	DI: Production of feed	Production of single or multiple products, whether processed, semi-processed or raw, which are intended to be fed to food producing animals	ISO 22000:2018, ISO/TS 22002-6:2016, FSSC 22000 Additional requirements
		DIIa: Production of pet food (pet food for dogs and cats only)	Production of single or multiple products, whether processed, semi-processed or raw, which are intended to be fed to non-food producing animals being dogs and cats. Examples: Dry and wet pet food, treats, cooled, chilled, frozen and ambient stable.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements
		DIIb: Production of pet food (food for all other pets)	Production of single or multiple products, whether processed, semi-processed or raw, which are intended to be fed to non-food producing animals other than dogs and cats. Examples: Dry and wet pet food, treats, cooled, chilled, frozen and ambient stable.	ISO 22000:2018, ISO/TS 22002-6:2016, FSSC 22000 Additional requirements
E	Catering		Activities in restaurants, hotels, workplace cafeterias, handling foods at remote sites, transport and delivery directly to consumers. Activities for coffee shops, food trucks and event catering.	ISO 22000:2018, ISO/TS 22002-2:2013, FSSC 22000 Additional requirements
F	Retail /Wholesale		Activities: receipt, picking, storage, display of food products, dispatch, transport and delivery Examples: supermarkets; hypermarkets; convenience stores; cash and carry; mass/club stores, wholesalers selling to restaurants	ISO 22000:2018, BSI/PAS 221:2013, FSSC 22000 Additional requirements
G	GI	Provision of transport and storage services for perishable food and feed.	Transport and storage with cooling, chilling or frozen temperatures. Additional activities such as re-packing of packed product, freezing and thawing.	ISO 22000:2018, NEN/NTA 8069:2016, FSSC 22000 Additional requirements
	GII	Provision of transport and storage services for ambient stable food and feed.	Transport and storage. Additional activities such as repacking of packed product.	ISO 22000:2018, NEN/NTA 8069:2016, FSSC 22000 Additional requirements
I	Production of food packaging and packaging materials.		All manufacturing activities for plastic, carton, paper, metal, glass, wood and other materials to be used as packaging materials in the food/feed industry. Examples: bottles, boxes, jars, barrels, cork, cans; devices for closing packaging materials such as tape, plastic strips, or other when the manufacturer can prove that they belong	ISO 22000:2018, ISO/TS 22002-4:2013, FSSC 22000 Additional requirements

		to a food/ feed packaging material; Production of labels with direct food contact.	
<b>K</b>	Production of Bio-chemicals	Mixing, cooking, packing, distilling, drying, canning, sterilization for all products at ambient, chilled and frozen temperatures. Final products: e.g. food and feed additives, vitamins, minerals, bio-cultures, flavorings, enzymes and processing aids, gases as ingredients and/or packaging gas.	ISO 22000:2018, ISO/TS 22002-1:2009, FSSC 22000 Additional requirements