1. Objective

This Certification Regulation refers to the certification procedures applied by BQC for the auditing and certification of Food Safety Management Systems in accordance with the **EN 22000** series, **ISO/TS 22003** or other relevant European or international standards or standard documents. The overall management and issuance of the certificate of compliance meets the requirements of the **ISO/IEC 17021-1:2015** standard, the Hellenic Accreditation System (E.SY.D.) as well as BQC General Certification Regulation.

2. Terms – Abbreviations – Definitions

The terms used in this Regulation are in accordance with the terms set forth in §2 of the BQC General Certification Regulation and with the **EN ISO 22000:2018, ISO/TS 22003:2013** and the **ISO/IEC 17000** standards.

Food Safety Management System FSMS: part of the management system that focuses on identifying, evaluating and controlling food safety-related risks

3. Certification Procedure

3.1 Application

Organizations wishing to certify their FSMS contact BQC and are informed that the full implementation of the FSMS under certification and the existence of corresponding records for at least two (2) months are required. Then, they fill in the information questionnaire **F050-1**, which is sent free of charge and serves as an application for certification.

3.2 Application Review

After the certification application is returned completed by the organization, it is forwarded to the Certification Department, who shall conduct a review of the application and additional information for the certification (fills-in **F050-10**), in order to calculate the necessary mandays for the audit and ensure that:

a) the information regarding the applicant organization and its management system is sufficient to conduct the audit,

b) the requirements for certification are clearly defined and documented,

c) any known differences in understanding between the applicant organization and BQC are resolved,

d) BQC has the capacity and ability to perform the certification activities,

e) the requested scope of certification, the facilities of the organization, the time needed to complete audits and other elements that affect the certification activities are taken into account (language, safety issues, risks to impartiality, etc.)

f) the FSMS under Certification is implemented for at least two (2) months.

In case BQC cannot undertake the certification, the reason is documented in the application review form **F050-10**, the organization is notified in writing and the process is discontinued.

If BQC can undertake the audit, a Quotation will be prepared by the General Manager of BQC, which is sent to the organization along with the BQC General Certification Regulation to be signed.

To determine the audit program and any later changes, the requirements as described in **F050-10,** where the minimum* time required to conduct the audit is determined, are taken into account. The duration of surveillance audits is usually the 1/3 of time required for the initial audit, with a minimum time of 1 audit day (or 0.5 audit day for categories A and B), while the time required for recertification audit is usually the 2/3 of the time that would be required, if the initial audit was conducted at that time, with a minimum time of 1 audit day (or 0.5 audit day for categories A and B).

**The minimum audit time is established for the audit of an FSMS which includes only one HACCP study. 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.*

Upon receiving the **F050-1** Form, BQC reviews, as mentioned before, the data submitted by the organization in order to determine, among other things, the time of audit for each of the audits of the

three-year certification cycle, justifying this decision. For the justification, the information of **Annex B** of **ISO/TS 22003** is used and the following points, between others, are taken into account:

- requirements of the relevant standard for FSMS,
- size and complexity of the organization,
- technological and regulatory framework,
- existence of subcontracting processes within the scope of the audited FSMS,
- results of previous audits,
- number of sites.

When the scope of application (and certification) of the audited FSMS covers more than one category, the audit-time calculation is based on the category with the highest recommended basic audit time by adding (where applicable) extra time for each additional HACCP study (e.g. minimum 0.5 audit day for each HACCP study).

Factors that may affect the duration of an audit:

Increase in audit time:

- Staff speaking in more than one language (requiring interpreter(s) or preventing individual auditors from working independently).
- Large number of different product types, different product lines, development of new products.
- Large number of Critical Control Points (CCPs) and Operational Prerequisite Programs (OPRPs).
- Complicated logistics involving more than one building or location where work is carried out.
- In-house laboratory testing / quality control.

Decrease in audit time:

- Combined audit for two or more Management Systems, where the organization's management system is integrated and structured to include shared responsibilities and processes for more than one standard.
- Organizations of low complexity (based on the number of employees, the size of the organization and/or the product volume). *It is only applicable to surveillance and recertification audits.*
- Organizations of categories where less than 1.5 audit days are required (i.e. all categories except for C, D and K). *It is only applicable to surveillance and recertification audits.*

Reduction of audit duration due to the existence of multiple Management Systems

If the organization's management system is integrated and structured to include common responsibilities and processes for more than one standard, then the required mandays are determined according to **IAF MD11:2023** and **F050-69** IMS mandays calculation. The number of mandays required totally for all management systems cannot be reduced, in any case, by more than 20% of the total mandays.

Multi-site sampling:

A multi-site organization is an organization that has a recognized central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) at which specific activities of the FSMS are designed, controlled or managed, as well as a network of facilities in which these activities are fully or partially conducted.

Examples, of possible multi-site organizations are:

- ✓ organizations operating with franchises
- ✓ a manufacturing company with one or more production sites and a network of sales offices
- ✓ service organizations with multiple sites offering a similar service
- ✓ organizations with multiple branches

BQC may audit the single FSMS of an organization with multiple facilities provided that the following apply:

- ✓ all sites are operating under one centrally controlled and administrated FSMS.
- ✓ an internal audit has been conducted on each site within one year prior to certification.
- ✓ audit findings of the individual sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

The use of multi-site sampling is only possible for categories A, B, E, F and G (according to Annex A of **ISO/TS 22003**) and for organizations with more than 20 sites operating similar processes within these categories. This applies to the initial certification, to surveillance and to recertification audits. The certification body shall justify its decision on sampling for multi-site certification.

When multi-site sampling is used to audit the management system of a client covering the same activity in different locations, BQC develops a sampling program to cover the all the files or fields, products and departments of the organization as well as all the requirements of the standard. The sampling program and the number of sites to be audited follow the methodology below:

- The use of multi-site sampling is only possible for organizations with more than 20 sites. For organizations with 20 sites or less, all sites shall be audited. The sampling for more than 20 sites shall be at the ratio of 1 site per 5 sites. All sites shall be randomly selected and, after the audit, all audited sites shall comply with the certification requirements / criteria.
- At least annually, an audit of the central office for the FSMS shall be performed by the certification body.
- At least annually, surveillance audits shall be performed by the certification body on the required number of sampled sites.
- Audit findings of the sampled sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

3.3 Audit team selection

After the signing of the cooperation agreement by the organization, the Certification Department of BQC, after taking into account the mandays and the overall abilities of the audit team required to conduct the audit, chooses the Audit Team or the Auditor (and Technical Expert, whenever required) to conduct the audit, so as:

- to be familiar with applicable legal regulations and BQC certification procedures.
- to be conversant with the relevant method and documents of audit.
- to have the appropriate technical knowledge of the specific activities for which certification is sought and of the relevant procedures of the organization.
- to have an adequate level of understanding, so as to conduct a reliable evaluation of the supplier's ability to provide products, processes and services on the organization's certification subject.
- be able to communicate effectively, both in writing and orally in the required language.
- be free from any interest, which may compel the team to deviate from an impartial or non-discriminatory manner of action, for example:
  - ➢ members of the audit team or their organization should not have provided consulting services to auditee.
  - ➢ members of the audit team or their organization should not have any previous or planned bond with the auditee.
  - ➢ members of the audit team must not have any relation to a competitive of the auditee.

3.4 Initial Contact with the Auditee

The lead auditor of the audit team communicates with the representative of the auditee.

Purpose:

- o Create communication channels with the auditee.
- o Authorization confirmation for the conduct of the audit.
- o Application for provision of the necessary documentation of the audited organization (as it is described in §3.5.1 of this Regulation).
- o Determination of health and safety rules during the onsite audit.
- o Determination for any arrangements for the onsite audit.
- o Agreement on the presence of observers and guides for the Audit Team.

The Lead Auditor develops an audit plan **F050-5** for each audit, which is the basis of the agreement for the conduct and scheduling of audit activities.

When informed of the composition of the audit team and the schedule, the audited organization has the right to request in writing within three (3) days upon receiving the audit plan and with proper justification, the replacement of a member or members of the audit team or a change of the audit date. In such cases the Certification Department re-assigns the Audit Team or the audit schedule and re-informs the audited organization.

If in the assigned audit team there is a technical expert, an interpreter or a trainee, they are not counted as auditors in the calculation of man-days.

If for any reason the organization is unable to follow the audit plan, the organization is obliged to inform the CB. In case that during the opening meeting the auditor realizes that the audit plan cannot be followed under the responsibility of the organization, the auditor shall postpone the audit.

3.5 Initial Certification Audit

The initial certification audit of a management system is conducted in two stages: stage 1 and stage 2.

3.5.1 Stage 1

During the first stage of the audit:

a) the documentation of the management system of the audited organization is reviewed. For this purpose, the audited organization shall send to BQC the basic documentation (HACCP study, flow charts of products/services, legal documents, list of procedures) for the FSMS that wishes to be certified.

b) the condition of the facilities and the location of the organization are evaluated and interviews with personnel are being conducted to determine its readiness for the second stage of the audit.

c) the condition and understanding of the client regarding the requirements of the standard are reviewed, particularly regarding the identification of key performance issues, processes, the objectives and functioning of the management system.

d) the necessary information regarding the scope of the management system, processes and facilities of the organization and the relevant regulatory and legislative conformity requirements is collected.

e) a focal point is provided for the planning of the 2nd stage of audit, having a sufficient understanding of the management system and the operations of the organization.

f) it is assessed whether internal audits and management reviews are planned and executed and how the level of implementation of the management system justifies if the organization is ready for the 2nd stage of audit.

g) the provision of resources for the 2nd stage of the audit is reviewed and details of the 2nd stage of audit are agreed with the organization.

The stage 1 of the audit is performed to provide a focus for planning the 2nd stage of audit by gaining an understanding of the organization's FSMS and the organization's state of preparedness for stage 2 by reviewing the extent to which:

a) the organization has identified PRP that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements),

b) the FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations),

c) relevant food safety legislation is implemented,

d) the FSMS is designed to achieve the organization's food safety policy,

e) the FSMS implementation justifies proceeding to the 2nd stage of audit,

f) the programs for validation of control measures, verification of activities and improvement and their compliance with the requirements of the related standard (e.g. ISO 22000),

g) the documentation of the FSMS in relation to the existence of communication channels both internally (within the organization) and externally (e.g. clients, suppliers, interested parties, etc.), and

h) there is any additional documentation which BQC needs to review and/or information which BQC needs to obtain in advance.

Where an organization has implemented an externally developed combination of control measures, during the 1st stage of audit, the documentation included in the FSMS shall be re-examined to determine if the combination of control measures:

- is suitable for the organization,
- was developed in compliance with the requirements of ISO 22000, and
- is kept up to date

For FSMS, stage 1 of audit shall be carried out at the client's premises in order to achieve the objectives stated above.

In exceptional circumstances (e.g. very remote location, short seasonal production) part of the 1st stage can be carried out off-site. The organization shall provide to BQC evidence demonstrating that the objectives of the 1st stage are fully achieved and BQC shall record any relevant documentation and decision.

The findings of the 1st stage are documented in the audit report and are communicated to the organization, including any points that could be recorded during the 2nd stage of audit as Non-Conformities.

When determining the interval between the 1st and 2nd stage, the organization's need to resolve any problematic points identified during the 1st stage is taken into account, as well as the severity of the findings.

3.5.2 Stage 2

The purpose of stage 2 of the audit is to assess the organization's management system and its effectiveness. The 2nd stage of the audit takes place at the premises of the organization and includes at least:

a) information and objective evidence regarding the conformity with all the requirements of the standard or other regulatory document of the applicable management system, as well as the organization's own policies, objectives and procedures;

b) monitoring, measuring, reporting and reviewing of significant objectives and targets;

c) the management system and the performance of the organization regarding the conformity with legal requirements;

d) the operational control of the processes of the organization;

e) the internal audit and management review;

f) top management responsibility and commitment to the policy and the achievement of objectives;

g) the relationships between regulatory requirements, policies, objectives and performance targets, any applicable legal requirements, responsibilities, personnel skills, operations, procedures, performance data and conclusions and findings of internal audits.

Note that if the audited organization has assigned to a subcontractor, part or the entirety of a process – included in the certification scope – it will be audited onsite by the audit team. This onsite audit can be avoided if the implementation and results of this process can be verified by reviewing the records and documents of the implemented Management System.

BQC does not exclude parts of processes, products or services deemed necessary to ensure food safety. The 2nd stage of audit shall be conducted in time, day or season in which the audited organization is in full operation.

Part of the initial certification audit may also be carried out using the remote audit method* using ICT means. This percentage will be determined on a case-by-case basis and may be increased if conditions and the subject (scope of certification) allow it. In any case, there will be a justification for this increase. The above will be allowed after sufficient justification and in accordance with the regulatory framework.

**Remote audit also means the audit of remote facilities of the organization using ICT means, even if*

the audit is carried out onsite at a facility of the organization.

3.5.3 Conclusions of Initial Certification Audit

The audit team analyzes all the information and objective evidence collected in both stages of the audit, reviews the findings of the audit and arrives at the conclusions of the audit.

3.5.4 Information for Granting of Initial Certification

The information provided by the audit team to the Certification Department of BQC to take the certification decision shall include, at least, the following:

a) the audit reports;

b) comments on non-conformities and, wherever possible, the corrective actions of the organization;

c) confirmation of the information provided during the review of the application;

d) confirmation that the purpose of the audit has been achieved;

e) a suggestion whether the organization shall be certified or not, along with together with any conditions or remarks.

The Lead Auditor, for each audit he/she undertakes, develops a three-year audit program for a complete certification cycle. The three-year audit program includes the activities that need to be documented in order that the implemented management system complies with the requirements of the relevant standard. Any non-conformities and observations recorded during the audit are also noted in the program.

The Certification Department of BQC, makes the certification decision based on the evaluation of the findings and conclusions of the audit and other relevant information (e.g. public information, comments about the audit report by the client).

When during the certification audit major non-conformities are identified, which are not resolved within six (6) months from the last day of the 2nd stage, then the 2nd stage of audit should be repeated before the certification decision is made.

3.6 Surveillance Activities

3.6.1 General

BQC conducts out annual surveillance audits to regularly review the organization's departments and operations covered by the purpose of the certified management system, and changes of the organization and its management system.

The surveillance activities include onsite audits to assess whether the organization's management system meets specific requirements, against the standard based on which the certification is granted.

Part of the surveillance audits may also be carried out using the remote audit method* using ICT means. This percentage will be determined on a case-by-case basis and may be increased if conditions and the subject (scope of certification) allow it. In any case, there will be a justification for this increase. The above will be allowed after sufficient justification and in accordance with the regulatory framework.

**Remote audit also means the audit of remote facilities of the organization using ICT means, even if the audit is carried out onsite at a facility of the organization.*

Other surveillance activities may be:

a) questions of BQC to the certified organization, regarding the certification,

b) review of any statements of the organization regarding its operations (e.g. promotional material, website),

c) requests to the client to provide documents and records (on paper or electronic form),

d) other means of monitoring the performance of the certified organization, and

e) FSMS compliance with new data (e.g. changes in legislation, standards, etc.).

Surveillance audits (1st and 2nd) take place before the expiry of the period of 12 and 24 months respectively, starting from the day of the certification decision.

3.6.2 Surveillance Audit

The surveillance audits are on-site audits, but not necessarily complete audits of the system. They are

designed in combination with other surveillance activities (see §3.6.1), so that BQC can maintain confidence that the certified management system continues to meet the requirements between recertification audits. The program of surveillance audits shall include, at least, the following:
a) changes in food safety policy,
b) the organization's ability to identify the applicable legal requirements,
c) the implementation and evaluation of compliance with legal and regulatory requirements,
d) the effectiveness of the management system regarding the achievement of the objectives,
e) the progress of pre-designed activities with regard to continuous improvement,
f) the continuous operational control,
g) the review of any changes,
h) the use of logos and / or other references to certification,
i) the audit of files for objections and complaints, where any inability of compliance or failure to meet the certification requirements is recorded along with the actions of the audited organization to investigate the effectiveness of the FSMS, the procedures it implements, and the appropriate corrective measures it takes,
j) maintenance and update of system elements such as internal audits, management review and corrective actions,
k) the review of the actions performed for non-conformities identified during the previous audit.

The audit report shall include, at the very least, the above, as well as information on the resolution of non-conformities previously recorded and any significant changes observed since the previous audit.

3.7 Recertification Activities

3.7.1 General

The recertification audit is carried out before the expiration of the certificate of conformity unless the termination of Certification is requested by the organization in writing at least 3 months before the expiry of the certificate of conformity.

If, under the responsibility of the organization, the recertification audit is conducted after the expiration date of the certificate (without documented justification), the audit is considered an audit of initial certification and the rules described in §3.5 are followed.

3.7.2 Planning of Recertification Audit

A recertification audit is designed and conducted to assess the ongoing satisfaction of all the requirements of the relevant standard of the management system or another regulatory document. The purpose of the recertification audit is the confirmation of the continuous compliance and effectiveness of the management system as a whole, as well as the continuing relevance and applicability of the scope of certification.

The recertification audit considers the performance of the management system during the certification period and includes the review of reports of previous surveillance audits.

The activities of recertification audit shall include a 1st stage of audit, when there have been significant changes in the system, the client or the operational framework of the management system (e.g. changes in legislation).

In the case of multiple facilities, the audit design shall ensure adequate onsite audits, in order to strengthen the confidence in the certification.

Part of the recertification audit may also be carried out using the remote audit method* using ICT means. This percentage will be determined on a case-by-case basis and may be increased if conditions and the subject (scope of certification) allow it. In any case, there will be a justification for this increase. The above will be allowed after sufficient justification and in accordance with the regulatory framework.

**Remote audit also means the audit of remote facilities of the organization using ICT means, even if*

the audit is carried out onsite at a facility of the organization.

3.7.3 Recertification Audit

The recertification audit includes an onsite audit, which covers the following issues:

a) the effectiveness of the entire management system regarding the internal and external changes, and the continuous relevance and applicability of the scope of certification;

b) the demonstrated commitment to maintaining and improving the effectiveness of the management system, in order to improve the overall performance;

c) whether the operation of the certified management system contributes to the achievement of quality and objective targets of the organization;

d) the findings and the effectiveness of the corrective actions recorded throughout the last certification cycle.

If recertification activities are successfully completed prior to the expiration date of the existing certificate, the issue date of the new certificate can be based on the expiry date of the existing certificate. The issue date on the new certificate may be the same as the recertification decision or later.

If the recertification audit has not been completed or any non-conformities are not resolved before the expiry of the existing Certificate, then there can be no recommendation for recertification and the validity of the certification shall not be extended. To avoid this, BQC shall notify the organization at least five (5) months prior to the expiration of the certificate, so that the recertification audit can be scheduled at least three (3) months prior to the expiration of the certificate. For each such case, the organization shall be informed of the consequences.

If an organization's existing certificate has expired, BQC may restore the certification, provided that the pending items of the audit have been resolved within six (6) months. Otherwise, a second-stage audit shall be at least conducted. The date of the recertification certificate shall be the same as the recertification decision or later and the expiration date will be based on the expiration date of the previous certification cycle.

3.7.4 Information for Granting Recertification

BQC takes decisions on the renewal of certification based on the results of the recertification audit, as well as on the results of the system review during the period of certification validity and any complaints received from users of the certification.

3.8 Main Processes for the Conduct of Audit

3.8.1 Opening Meeting

The opening meeting is convened by the Lead Auditor immediately after the arrival of the Audit Team at the audit site.

Participants:

- From BQC, all members of the audit team
- On the part of the organization, at least the Management Representative and the Food Safety Management System Coordinator of the organization.

Purpose:

- Confirmation of the audit plan
- Introduce the audit team and their roles
- Ensure that all planned audit activities can be performed
- A reference to the method the audit will be conducted
- Confirmation of the communication channels
- Questions of the auditee

The following items are taken into account:

a) introductions among the attendees and description of their roles;

b) confirmation of certification scope;

c) confirmation of the audit plan (including the type, purpose and criteria of the audit), any changes and other relevant arrangements with the client, such as the date and the time of the closing meeting and interim meetings between the audit team and the client's representative,

d) confirmation of formal communication channels,

e) confirmation that the resources and facilities needed by the audit team are available,
f) confirmation of matters relating to confidentiality and information security,
g) confirmation of work safety, emergency and security procedures for the audit team
h) confirmation of the availability, roles and identity of observers and guides,
i) the method of reporting, including the classification of audit findings,
j) conditions under which the audit may be prematurely terminated,
k) confirmation that the lead auditor and the audit team, representing BQC, are responsible for conducting the audit and following the audit plan,
l) confirmation of the status of findings of previous audits,
m) methods and procedures to be during the audit,
n) confirmation of the language to be used during the audit,
o) confirmation that, during the audit, the client will be kept informed of the audit progress,
p) the client can ask questions.

3.8.2 Role and Responsibility of Guides and Observers

Guides and observers may accompany the audit team with approval of the lead auditor, and/or the auditee, if required. They should not influence or interfere with the conduct of the audit. For the observers, any details concerning access, health and safety, environment, security and confidentiality should be arranged with the audited organization. The guides, appointed by the audited organization, should assist the audit team and act on the request of the lead auditor or the auditor to which they have been assigned. Their responsibilities include the following:

- assisting the auditors to identify individuals to participate in interviews and confirm the time and location of the interview,
- arranging access to specific locations of the audited organization
- ensuring that rules concerning location-specific arrangements for access, health and safety, environment, security, confidentiality and other issues are known and respected by the audit team members and observers and any risks are addressed
- witnessing the audit on behalf of the audited organization
- providing clarifications or assisting in collecting information, when required.

Note: The Lead Auditor has the right to ask the organization to change the guide or the observer when proven and repeatedly they deviate from their role and obstruct the work of the audit team.

3.8.3 Audit Conclusions – Completion of Audit Documents

3.8.3.1 Audit Conclusions

During the audit, under the responsibility of the Lead Auditor, the audit team shall evaluate the audit progress and exchange information. The Lead Auditor is responsible, if necessary, to amend the initial audit plan and reassign work between the audit team members. During the audit, the Lead Auditor shall inform the representative of the audited organization for the progress and any points of concern.

The audit team, under the responsibility of the Lead Auditor, shall convene before the closing meeting in order to:

- submit to review the audit findings and other relevant information collected during the audit according to the objectives of the audit
- agree on the conclusions of the audit, considering the inherent uncertainty of the audit process,
- agree on the follow-up actions,
- categorize any identified non-conformities,
- confirm the appropriateness of the audit program or identify any modification needed for future audits.

3.8.3.2 Completion of Audit Documents

The Lead Auditor completes the **F050-2** Audit Report, the **F050-8B** Audit Questionnaire or the

F050-7 Auditor's Note form and the **F050-26b** Three Year Audit Program.

3.8.4 Closing Meeting

Participants:

- From BQC, all members of the audit team
- On the part of the organization, at least the Management Representative and the Food Safety Coordinator of the organization.

Purpose:

- Formalities.
- Declaration of confidentiality and information security.
- Inform the audited organization that the compliance audit, is based on sampling and therefore contains an element of uncertainty.
- Presentation of audit findings.
- Discussion on the audit findings.
- Method and schedule of reporting, including grading of any audit findings.
- Briefing by the Lead Auditor about the procedure for handling non-conformities and the consequence on the client's certification status.
- Schedule for the client to send a plan of corrections and corrective actions for any non-conformities identified during the audit.
- BQC post certification activities.
- Information about the complaint and objection handling process.
- Recommendation on certification.

At the end of the closing meeting, the Management Representative shall sign the audit report **F050-2** and receive a copy of it. In case that he/she refuses to accept the audit findings and therefore to sign the audit report, the Lead Auditor records the disagreement or reservation, and gives a copy of the audit report to the audited organization.

3.9 Granting of Certificate

The positive or negative decision on the issuance of the certificate of conformity is decided by the defined person in the BQC Decision Making Matrix following a recommendation of the Lead Auditor. The decision evaluates, among other things, the audit report and the documentation of the corrective actions taken to resolve non-conformities recorded during the audit. The certification decision shall be communicated to the organization in writing.

The positive or negative decision on certification of the audited organization shall be taken by the person who has not been involved in the certification process.