RULES FOR THE CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEMS

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This rule is divided into 5 sections depending on the requested certification service:

Section 1:

Certification of Food Safety Management Systems according to ISO22000: 2018

Section 2:

Certification of Food Safety Management Systems according to ISO22000: 2005

Section 3:

Transition of certification from ISO22000: 2005 to ISO22000: 2018

Section 4:

Certification of Food Safety Management Systems according to the FSSC22000 v.4.1 scheme

Section 5:

Certification of Food Safety Management Systems according to the FSSC22000 v.5 scheme

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SECTION 1: CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEM IN CONFORMITY WITH ISO22000:2018

CHAPTER 1 - GENERAL

1.1

These Rules define the additional and/or substitutive procedures applied by RINA for the certification of Food Safety Management Systems in relation to what is already defined in the

General Rules for the Certification of Management Systems

The paragraphs of these Rules refer to (and maintain the same numbering of) the corresponding paragraphs of the General Rules for the Certification of Management Systems for which changes and/or additions have been made.

1.2

RINA issues certification in accordance with the requirements of the ISO/IEC 17021:2015 Standard to organizations whose Management System has been recognized as fully conforming to all the requirements of the

ISO 22000:2018 standard.

CHAPTER 2 - REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

2.1

In addition to what is stated in the General Rules for the Certification of Management Systems, to obtain RINA certification a Food Safety Management System must first and henceforth satisfy the requirements of ISO 22000 and the additional requirements, if any, of the accreditation bodies.

2.2

In substitution to what established in the paragraph 2.2.2 of the general rules, in particular, to obtain the certification of the management system, the Company shall have prepared the Documentation which is:

- defining the goal/scope/field of application of the Food Safety Management System, describing the main processes among which the communication protocols, the conduction and application of the hazard analysis, the traceability system.

  The description of the processes and their applications is to be extended to all those developed by the organisation (also to outsourced processes required to manufacture/provide a particular product/service which is decisive as regards the capacity of the product/service to satisfy the applicable requirements).

  This can be done in different ways:

  - descriptions
  - flow charts or logograms
  - tables or matrices
  - other

- taking into consideration the requirements of the standard and giving a description, not necessarily detailed, of the resources and procedures used to ensure compliance with these requirements;
- containing a suitable description of the company organisation.

Every information received from the client is reserved.

CHAPTER 3 - INITIAL CERTIFICATION

3.1

The Organisations wishing to obtain RINA certification for their Food Safety Management System must provide RINA with their main Organisation/production data and site location by filling in all parts of the "Informative questionnaire" form available on the website www.rina.org, and sending it to RINA, which will use it to prepare a quotation.

In particular, the organisation must inform RINA of:

- the scope requested for the certification;
- general information of the organization
- the number sites involved in certification, together with the name, the addresses and the relative activities carried out there;
- The number of HACCP plan related to the scope;
- The Involvement with bigger companies, if is the case;
- Other certification obtained, if is the case;
- The involvement of consultants for the management system, if is the case.

3.4

In addition to what is stated in the General Rules for the Certification of Management Systems, together with or following the certification request, the Organization is to make the following documents available to RINA:

- the document SELF ASSESSMENT QUESTIONNAIRE FOR FIRST CERTIFICATION filled in all its parts, enclosing any necessary documents ;
- list of the sanitary authorizations/EU registrations held by the organization.

RINA examines the above documents for conformity with the reference standard and with the requirements of these Rules.

3.5

As well as what is stated in point 3.5 of the General Rules for the Certification of Management Systems, during the stage 1 audit, it will be checked the correctness of the information provided by the Organization through an information questionnaire.

In case of differences between the data initially provided by the organization in the informative questionnaire and the homologous data verified during the stage 1 audit by the audit team, the total audit duration will be reviewed and eventually modified.

In case the audit duration, resulting from the new revision, is greater than the duration previously defined, specific communication to the customer will be given by e-mail to the client providing the correct and new audit duration.

If the organization does not want to accept the new duration, the organization has to pay RINA for the Stage 1 audit as previously agreed, to provide adequate justification

within 10 working days from the receiving communication and to accept the interruption of the certification process.

In absence of response from the Organization to the specific communication, it is tacitly accepted the new term, because based on data verified by the audit team and transparently presented and discussed during the final stage 1 audit meeting.

CHAPTER 4 - MAINTENANCE OF CERTIFICATION

4.2

In addition to what is stated in the General Rules for the Certification of Management Systems, the organization must keep records of:

- food safety aspects/impacts;
- any withdrawals or recalls of products;
- accidents/emergencies on the site/s and other events that could have had negative effects on the product safety;
- any complaints received concerning food safety impacts;
- any observations or reports from national or local authorities responsible for food safety Control and must make them available to RINA together with the relative corrective action implemented during the periodic audits.

The organisation must keep RINA informed of any observations/remarks from national or local authorities responsible for food safety control and of any situations of legislative non-compliance related to all the organisation's activities, regardless of the field of application of the Management System.

CHAPTER 6 – PERFORMANCE OF AUDITS

6.1 GENERAL

6.1.3

In addition to what established at point 6.1.3 of the General Rules for the Certification of Management Systems is considered as major NC as well a situation which can compromise the security if the food products, the failure of the legal requirement[1] of the production and destination country and every situation that can be a serious danger or the consumers.

Moreover , if there aren't authorization or registration of the site, as requested by the current legislation, the certification process is suspended.

6.2. The initial certification audit consists of two stages (Stage 1 and Stage 2)

6.2.1. Stage 1

In substitution of what is mentioned at paragraph 6.2.1. of the General Rules, Audit Stage 1 carried out at the organization, aims to:

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1 Si intendono per requisiti legislativi cogenti:
- Limiti e/o disposizioni di legge;
- Limiti e/o prescrizioni riportate su autorizzazioni o su altri documenti prescrittivi etc.

- Verify that the documentation of the Food Safety Management System, including procedures, meet all the requirements of the standard;
- Assess whether the internal audit and the review by senior management have been planned and executed at all the sites of the organization covered by the certification.
- Review the status and understanding of the client regarding the requirements of the standard, with particular reference to the identification of key performance or significant aspects, processes, objectives and operation significant for the Food Safety Management System
- Gather the necessary information concerning the scope of the management system, processes and / and localization / the customer, including related legal and regulated, and compliance with them;
- That the organization has all necessary authorizations / licenses on Food Safety and its activities and that they are valid and consistent with applicable law;
- Investigate the site / s Production / Organization to assess the possible problems not considered by Food Safety Management System of the Organisation;
- Review the allocation of resources for stage 2 audit and agree with the customer details of the audit stage 2;
- Focus on the audit planning stage 2, gaining a sufficient understanding of the management system and activities and the customer site, with the possible significant aspects;
- That the FSMS is operational for at least three months and that procedures are efficaciously implemented.

The outcome of the audit stage1 is leaving the organization released a copy of the audit report of stage 1 on which are among other reported any findings that may be encountered including those classified as non-conformities (major or minor) during the 'audit stage 2.

The actions taken by the Organisation for the resolution of these findings are verified during the audit stage 2 in paragraph 6.2.2.

In the presence of NC that are very critical, the technicians who performed the audit stage 1 decide if they must be resolved before proceeding with the Stage 2 audit at the organization. In case of audit stage 1 and stage 2 consecutive audit Stage 2 will be rescheduled and postponed to a date (not exceeding 6 months from the date of the audit stage 1).

6.2.2. Stage 2

As substitution of what determined by the corresponding point 6.2.2 of the general rules, the audit stage 2 at the organization must be made within a maximum period of 6 months following completion of Phase 1 of the audit.

The stage 2 audit at the organization is carried out to verify the correct and effective implementation of the Management System.

RINA sends the organization, before the audit stage 2 at the site / s, an audit plan in which is given in detail, the description of assets and provisions for the conduct of the audit.

If the activities are carried out to check on multiple operating sites, the audit is conducted according to criteria previously established and communicated by the Organization RINA.

The stage 2 audit is performed by qualified RINA technicians based on the audit report stage 1 and on the documents of the Food Safety Management System prepared by the Organization in the updated review.

Essentially the audit stage 2 consists of:

- an initial meeting with the Technician of the Organization to agree on the scope and methods of the audit and to confirm the audit plan;
- a review of the implementation of effective adaptation measures with regard to remarks made during the audit phase 1;
- an inspection of the site / s Production / Organization to verify the compliance of the for Food Safety Management System reference documents and its full implementation;
- A final meeting to explain the outcome of the investigation.

In the presence of non-compliance (of type A) the certification process is suspended. In case of observations whose numerous, in the opinion of the audit team, would undermine the proper functioning of the management system, the certification process is also suspended.

In such cases, within three months, RINA must perform a supplementary audit aimed at verifying the effectiveness of treatments and proposed corrective actions; if there is a successful outcome of this audit, the certification process is resumed.

The additional audit may be conducted on site or on the basis of documents according to the type of corrective actions to be verified in the opinion of the audit team.

All expenses relating to any additional audits resulting from deficiencies of the Management System shall be payable by the Organization.

If this deadline is exceeded, the Management System of the Organization must be submitted to complete review within a period of six months from the end of stage 2 audit.

At the expiration period of six months without a successful conclusion of the assessment, RINA can considered closed the certification, charging time and expenses incurred up to that point. In such cases, the organization that wishes to continue with the RINA certification must submit a new request and repeat the certification process.

These time limits may be varied in special cases on a reasoned request of the Organization, in the opinion of RINA.

CHAPTER 9 – MULTISITE ORGANIZATIONS

9.1

In replacing paragraph 9.1 of the General Rules for the Certification of Management Systems, where an organization operates across multiple sites and all functions relating to the Food Safety Management System are managed by a central head office and a single certification is required, the audit may be performed by sampling the sites audited only for the categories allowed by ISO / TS 22003:2013 and if the number site exceeds 20 units, provided that:

- The Activity to be certified is the same for all sites and the organization applies the same Food Safety Management System (managed from a central location) for all sites;

- At all sites of the Organization products / services provided are essentially the same kind and are made basically with the same methods and the same procedures;
- At least the following activities are managed from the headquarters of the Organization:
    - Communication procedures;
    - Management and emergency response;
    - Analysis of the hazards and individuation of associated risks
    - The traceability system;
    - The assessment of training needs;
    - The control of document and its amendments;
    - The review of the management system by senior management;
    - Evaluation of the effectiveness of corrective and preventive actions;
    - Planning / execution of internal audit and evaluation of their results;
    - Before the audit of RINA the organization must have performed internal audits of each site.

9.2

As substitution of the point 9.2 of the General Rules for the Certification of Management Systems, during the initial certification audit, surveillance and recertification will be carried out sampling in accordance with the ISO/TS 22003:2013.

SECTION 2: CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEM IN CONFORMITY WITH ISO22000:2005

CHAPTER 1 - GENERAL

1.1

These Rules define the additional and/or substitutive procedures applied by RINA for the certification of Food Safety Management Systems in relation to what is already defined in the

General Rules for the Certification of Management Systems

The paragraphs of these Rules refer to (and maintain the same numbering of) the corresponding paragraphs of the General Rules for the Certification of Management Systems for which changes and/or additions have been made.

1.2

RINA issues certification in accordance with the requirements of the ISO/IEC 17021:2015 Standard to organizations whose Management System has been recognized as fully conforming to all the requirements of the

ISO 22000:2005 standard.

ISO22000:2005 certifications can be issued within the end of the transition period.

Certificates issued and issued again in conformity with ISO22000:2005 will expire on 18th June 2021, date of the end of transition period.

To maintain its food safety management system, an Organisation that is certified in accordance with ISO22000:2005 must perform transition to new edition of ISO22000:2018 according to the section 3 of this RINA rule, within 18th June 2021.

CHAPTER 2 - REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

2.1

In addition to what is stated in the General Rules for the Certification of Management Systems, to obtain RINA certification a Food Safety Management System must first and henceforth satisfy the requirements of ISO 22000 and the additional requirements, if any, of the accreditation bodies.

2.2

In substitution to what established in the paragraph 2.2.2 of the general rules, in particular, to obtain the certification of the management system, the Company shall have prepared the Documentation which is:

- defining the goal/scope/field of application of the Food Safety Management System, describing the main processes among which the communication protocols, the conduction and application of the hazard analysis, the traceability system.

  The description of the processes and their applications is to be extended to all those developed by the organisation (also to outsourced processes required to manufacture/provide a particular product/service which is decisive as

regards the capacity of the product/service to satisfy the applicable requirements).

This can be done in different ways:

- descriptions
- flow charts or logograms
- tables or matrices
- other

- taking into consideration the requirements of the standard and giving a description, not necessarily detailed, of the resources and procedures used to ensure compliance with these requirements;
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CHAPTER 3 - INITIAL CERTIFICATION

3.1

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In particular, the organisation must inform RINA of:

- the scope requested for the certification;
- general information of the organization
- the number sites involved in certification, together with the name, the addresses and the relative activities carried out there;
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As well as what is stated in point 3.5 of the General Rules for the Certification of Management Systems, during the stage 1 audit, the following will be checked the correctness of the information provided by the Organization through an information questionnaire.

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In case the audit duration, resulting from the new revision, is greater than the duration previously defined, specific communication to the customer will be given by e-mail to the client providing the correct and new audit duration.

If the organization does not want to accept the new duration, the organization has to pay RINA for the Stage 1 audit as previously agreed, to provide adequate justification within 10 working days from the receiving communication and to accept the interruption of the certification process.

In absence of response from the Organization to the specific communication, it is tacitly accepted the new term, because based on data verified by the audit team and transparently presented and discussed during the final stage 1 audit meeting.

CHAPTER 4 - MAINTENANCE OF CERTIFICATION

4.2

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The organisation must keep RINA informed of any observations/remarks from national or local authorities responsible for food safety control and of any situations of legislative non-compliance related to all the organisation's activities, regardless of the field of application of the Management System.

CHAPTER 6 – PERFORMANCE OF AUDITS

6.1 GENERAL

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In addition to what established at point 6.1.3 of the General Rules for the Certification of Management Systems is considered as major NC as well a situation which can compromise the security if the food products, the failure of the legal requirement[2] of the production and destination country and every situation that can be a serious danger or the consumers.

Moreover , if there aren't authorization or registration of the site, as requested by the current legislation, the certification process is suspended.

6.2. The initial certification audit consists of two stages (Stage 1 and Stage 2)

6.2.1. Stage 1

In substitution of what is mentioned at paragraph 6.2.1. of the General Rules, Audit Stage 1 carried out at the organization, aims to:

- Verify that the documentation of the Food Safety Management System, including procedures, meet all the requirements of the standard;

2 Si intendono per requisiti legislativi cogenti:
- Limiti e/o disposizioni di legge;
- Limiti e/o prescrizioni riportate su autorizzazioni o su altri documenti prescrittivi etc.

- Assess whether the internal audit and the review by senior management have been planned and executed at all the sites of the organization covered by the certification.
- Review the status and understanding of the client regarding the requirements of the standard, with particular reference to the identification of key performance or significant aspects, processes, objectives and operation significant for the Food Safety Management System
- Gather the necessary information concerning the scope of the management system, processes and / and localization / the customer, including related legal and regulated, and compliance with them;
- That the organization has all necessary authorizations / licenses on Food Safety and its activities and that they are valid and consistent with applicable law;
- Investigate the site / s Production / Organization to assess the possible problems not considered by Food Safety Management System of the Organisation;
- Review the allocation of resources for stage 2 audit and agree with the customer details of the audit stage 2;
- Focus on the audit planning stage 2, gaining a sufficient understanding of the management system and activities and the customer site, with the possible significant aspects;
- That the FSMS is operational for at least three months and that procedures are efficaciously implemented.

The outcome of the audit stage1 is leaving the organization released a copy of the audit report of stage 1 on which are among other reported any findings that may be encountered including those classified as non-conformities (major or minor) during the 'audit stage 2.

The actions taken by the Organisation for the resolution of these findings are verified during the audit stage 2 in paragraph 6.2.2.

In the presence of NC that are very critical, the technicians who performed the audit stage 1 decide if they must be resolved before proceeding with the Stage 2 audit at the organization. In case of audit stage 1 and stage 2 consecutive audit Stage 2 will be rescheduled and postponed to a date (not exceeding 6 months from the date of the audit stage 1).

6.2.2. Stage 2

As substitution of what determined by the corresponding point 6.2.2 of the general rules, the audit stage 2 at the organization must be made within a maximum period of 6 months following completion of Phase 1 of the audit.

The stage 2 audit at the organization is carried out to verify the correct and effective implementation of the Management System.

RINA sends the organization, before the audit stage 2 at the site / s, an audit plan in which is given in detail, the description of assets and provisions for the conduct of the audit.

If the activities are carried out to check on multiple operating sites, the audit is conducted according to criteria previously established and communicated by the Organization RINA.

The stage 2 audit is performed by qualified RINA technicians based on the audit report stage 1 and on the documents of the Food Safety Management System prepared by the Organization in the updated review.

Essentially the audit stage 2 consists of:

- an initial meeting with the Technician of the Organization to agree on the scope and methods of the audit and to confirm the audit plan;
- a review of the implementation of effective adaptation measures with regard to remarks made during the audit phase 1;
- an inspection of the site / s Production / Organization to verify the compliance of the for Food Safety Management System reference documents and its full implementation;
- A final meeting to explain the outcome of the investigation.

In the presence of non-compliance (of type A) the certification process is suspended. In case of observations whose numerous, in the opinion of the audit team, would undermine the proper functioning of the management system, the certification process is also suspended.

In such cases, within three months, RINA must perform a supplementary audit aimed at verifying the effectiveness of treatments and proposed corrective actions; if there is a successful outcome of this audit, the certification process is resumed.

The additional audit may be conducted on site or on the basis of documents according to the type of corrective actions to be verified in the opinion of the audit team.

All expenses relating to any additional audits resulting from deficiencies of the Management System shall be payable by the Organization.

If this deadline is exceeded, the Management System of the Organization must be submitted to complete review within a period of six months from the end of stage 2 audit.

At the expiration period of six months without a successful conclusion of the assessment, RINA can considered closed the certification, charging time and expenses incurred up to that point. In such cases, the organization that wishes to continue with the RINA certification must submit a new request and repeat the certification process.

These time limits may be varied in special cases on a reasoned request of the Organization, in the opinion of RINA.

CHAPTER 7 - MANAGEMENT OF CERTIFICATES OF CONFORMITY

7.1

ISO22000:2005 Certificates will expire on 18th June 2021.

CHAPTER 9 – MULTISITE ORGANIZATIONS

9.1

In replacing paragraph 9.1 of the General Rules for the Certification of Management Systems, where an organization operates across multiple sites and all functions relating to the Food Safety Management System are managed by a central head office and a single certification is required, the audit may be performed by sampling the sites

audited only for the categories allowed by ISO / TS 22003:2013 and if the number site exceeds 20 units, provided that:

- The Activity to be certified is the same for all sites and the organization applies the same Food Safety Management System (managed from a central location) for all sites;
- At all sites of the Organization products / services provided are essentially the same kind and are made basically with the same methods and the same procedures;
- At least the following activities are managed from the headquarters of the Organization:
    - Communication procedures;
    - Management and emergency response;
    - Analysis of the hazards and individuation of associated risks
    - The traceability system;
    - The assessment of training needs;
    - The control of document and its amendments;
    - The review of the management system by senior management;
    - Evaluation of the effectiveness of corrective and preventive actions;
    - Planning / execution of internal audit and evaluation of their results;
    - Before the audit of RINA the organization must have performed internal audits of each site.

9.2

As substitution of the point 9.2 of the General Rules for the Certification of Management Systems, during the initial certification audit, surveillance and recertification will be carried out sampling in accordance with the ISO/TS 22003:2013.

SECTION 3: TRANSITION OF CERTIFICATION FROM ISO22000:2005 TO ISO22000:2018

A.0 GENERAL

This section applies when an Organization certified in compliance with ISO22000:2005 asks for transition to the new edition of the standard ISO22000:2018.

To obtain RINA ISO22000:2018 certification a Food Safety Management System must first and henceforth satisfy the requirements of ISO22000:2018 and the additional requirements of the accreditation bodies.

The Organization must demonstrate to have correctly implemented and acted the elements of change, for example it must demonstrate:

- to have considered its context defining the scope of food safety management system and planning the management system based on its risks and opportunities;
- that the planning and operational control of food safety management system is consistent with life cycle perspective.

A.1 TRANSITION APPLICATION

During the transition period, the certified Organisation can decide to perform transition to the new standard:

1. during a surveillance audit (with possible audit time increase);
2. during a recertification audit;
3. between two scheduled audits.

An authorised representative of the applicant organisation has to submit a transition request to RINA.

Upon receiving an application for transition, RINA sends to the Organisation document FSMS SELF ASSESSMENT QUESTIONNAIRE FOR TRANSITION that must be filled in all its parts, enclosing any necessary documents.

According to the information written in document FSMS SELF ASSESSMENT QUESTIONNAIRE FOR TRANSITION, RINA decides whether it is possible to proceed with transition and, in the presence of an audit time increase, prepares a specific economic offer for the transition audit.

A.2 PERFORMANCE OF AUDITS

Transition audit is divided into two steps:

- documental review of the elements of change, based on the "SELF ASSESSMENT QUESTIONNAIRE FOR TRANSITION" and on documented information required by ISO22000:2018;
- on-site audit to assess the fulfilment of the new requirements of ISO22000:2018.

With regard to the execution of the audits, what is stated in the General Rules for the Certification of Management Systems applies.

During the transition period, if any major non conformities are raised as per ISO22000:2018 and not closed within the terms foreseen by the General Rules for the certification of Management Systems, these non-conformities will not negatively affect

maintenance of current certification provided that it is obviously verified that the food safety management system is always compliant with ISO 22000:2005.

The dates and the extension of the following audits for maintenance of the certification remain the same as per three-year surveillance programme.

A.3 ISSUE OF THE CERTIFICATE IN CONFORMITY WITH ISO22000:2018

Following the successful outcome of the transition audit and the approval by RINA, a certificate of conformity with new edition of the standard is issued; the validity will be calculated based on previous certification/recertification decision date.

A.4 VALIDITY OF THE CERTIFICATES IN CONFORMITY WITH ISO22000:2018

ISO22000:2005 Certificates will expire on 18th June 2021.

After the expiry date of its ISO22000:2005 certificate, an Organization that needs to obtain an ISO22000:2018 certification, must submit a new application for certification following the requirements of the initial certification.

SECTION 4 - CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEMS ACCORDING TO THE FSSC22000 v.4.1 SCHEME

CHAPTER 1 – GENERAL

1.1

These Rules define the additional and/or substitutive procedures applied by RINA for the certification of Food Safety Management Systems and technical sector specification (PRPs) in relation to what is already defined in the

General Rules for the Certification of Management Systems

The paragraphs of these Rules refer to (and maintain the same numbering of) the corresponding paragraphs of the General Rules for the Certification of Management Systems for which changes and/or additions have been made.

1.2

RINA issues certification in accordance with the requirements of the ISO/IEC 17021:2015 Standard to organisations whose Management System has been recognized as fully conforming to all the requirements of the scheme

FSSC 22000 v.4.1.

The certifications in compliance with the FSSC22000 v.4.1 scheme may be issued no later than December 31, 2019.

The certificates issued and reissued in accordance with the FSSC22000 v.4.1 standard will expire on June 29, 2021.

To maintain the certification, the organization that obtains a certification in accordance with the FSSC22000 v.4.1 scheme will have to make a transition to the new edition of the FSSC22000 v.5 scheme according to the procedures defined in section 5 of this Regulation starting from 01 January 2020.

CHAPTER 2 – REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

2.1

In addition to what established at point 2.1 of the General Rules for the Certification of Management Systems organisations wishing to obtain RINA certification for their Food Safety Management Systems[3] must first and henceforth satisfy the requirements of ISO 22000 and the additional ones (e.g. technical sector specification-PRPs like the ISO/TS 22002-1). If expected by the accreditation bodies and/or by the private organisation which manage the standard (FSSC22000, for detail www.FSSC22000.com).

2.2

In substitution to what established in the paragraph 2.2.2 of the General Rules for the Certification of Management Systems, in particular, to obtain the certification of the management system, the Company shall have prepared the Documentation which is:

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3 FSMS (Food Safety Management System): the ISO22000 reference standard is to be understood always applicable for organizations applying for certification in accordance with the private scheme FSSC22000 (FSMS and technical specifications for sector PRPs).

- defining the goal/scope/field of application of the Food Safety Management System, describing the main processes among which the communication protocols, the conduction and application of the hazard analysis, the traceability system.

  The description of the processes and their applications is to be extended to all those developed by the organisation (also to outsourced processes required to manufacture/provide a particular product/service which is decisive as regards the capacity of the product/service to satisfy the applicable requirements).

  This can be done in different ways:

  - descriptions
  - flow charts or logograms
  - tables or matrices
  - other
- taking into consideration the requirements of the standard and giving a description, not necessarily detailed, of the resources and procedures used to ensure compliance with these requirements;
- containing a suitable description of the company organisation.

Every information received from the client is reserved.

2.3

For FSSC22000 specific certification, in addition to what established above, the following rules apply:

- The contract stipulated between RINA and the organization about FSSC22000, always include the fees for certification to be paid annually to the FSSC Foundation;
- RINA will submit to the FSSC Foundation the following information (within 4 weeks after the delivery of the certificate):
  - name and location of the certified organization,
  - scope of the certification,
  - date of the initial certification,
  - expiry date of the certificate,
  - in case of suspension or withdrawal; the date of suspension or withdrawal

  These information about the certified organizations will be made publicly available on the website of the FSSC Foundation.
- The certified organization must notify RINA of any food safety prosecution, significant regulatory food safety nonconformity, or any product recall relating to food safety. This notification must be made immediately to RINA.
- The certified organization shall inform RINA that will have the right to investigate[4] the case to ensure integrity of certification after such notification:
  - immediately of any food safety prosecution, significant regulatory food safety nonconformity, or any product recall relating to food safety;
  - immediately of serious events that impact food safety and / or the integrity of the certification and the organization's entry in the FSSC 22000 Register of Certified organizations;

4 According to the point nr.4.4 of the General Rules for the certification of Management Systems

- within three (3) working days, of significant changes that affect the capability of the management system to continue to fulfil the Scheme requirements including other causes of interruption of business continuity (e.g. earthquakes, fires, floods, tsunamis, force majeure, etc.).

- The certification activities relevant to scope categories for which RINA is accredited are performed in compliance with the applicable accreditation rules and the certificates issued are provided with the logo of the relevant Accreditation Body.
- In case of any change and/or information by FSSC Foundation in regards to the FSSC22000 scheme requirements, the certified organization will be informed within a two month period. The related rules will apply accordingly.

CHAPTER 3 – INITIAL CERTIFICATION

3.1

The Organisations wishing to obtain RINA certification for their Food Safety Management System must provide RINA with their main Organisation/production data and site location by filling in all parts of the "Informative questionnaire" form available on the website www.rina.org, and sending it to RINA which will use it to prepare a quotation.

In particular, the organisation must inform RINA of:

- the scope requested for the certification;
- general information of the organization
- the number sites involved in certification, together with the name, the addresses and the relative activities carried out there;
- The number of HACCP plan related to the scope;
- The Involvement with bigger companies, if is the case;
- Other certification obtained, if is the case;
- The involvement of consultants for the management system, if is the case.

3.5

As well as what is stated in point 3.5 of the General Rules for the Certification of Management Systems, during the stage 1 audit, it will be checked the correctness of the information provided by the Organization through an information questionnaire.

In case of differences between the data initially provided by the organization in the informative questionnaire and the homologous data verified during the stage 1 audit by the audit team, the total audit duration will be reviewed and eventually modified.

In case the audit duration, resulting from the new revision, is greater than the duration previously defined, specific communication to the customer will be given by e-mail to the client providing the correct and new audit duration.

If the organization does not want to accept the new duration, the organization has to pay RINA for the Stage 1 audit as previously agreed, to provide adequate justification within 10 working days from the receiving communication and to accept the interruption of the certification process.

In absence of response from the Organization to the specific communication, it is tacitly accepted the new term, because based on data verified by the audit team and transparently presented and discussed during the final stage 1 audit meeting.

3.7

The version FSSC22000 4.1, mandatory since 1st January 2018 for all the first certification, surveillance and recertification audit, has introduced the unannounced surveillance.

At least one of the two surveillance have to be planned as unannounced. RINA decides which of the scheduled surveillance audits shall be chosen for the unannounced audit. The certified organization can voluntary choose to replace all surveillance audits by unannounced annual surveillance audits.

If the certified organization refuses to participate in the unannounced audit, the certificate shall be suspended immediately, and RINA shall withdraw the certificate, if the unannounced audit is not conducted within a six-month timeframe.

If access is denied to the auditor the certified organization will be liable for all costs.

CHAPTER 4 - MAINTENANCE OF CERTIFICATION

4.2

In addition to what is stated in the General Rules for the Certification of Management Systems, the organization must keep records of:

- food safety aspects/impacts;
- any withdrawals or recalls of products;
- accidents/emergencies on the site/s and other events that could have had negative effects on the product safety;
- any complaints received concerning food safety impacts;
- any observations or reports from national or local authorities responsible for food safety Control

and must make them available to RINA together with the relative corrective action implemented during the periodic audits.

The organisation must keep RINA informed of any observations/remarks from national or local authorities responsible for food safety control and of any situations of legislative non-compliance related to all the organisation's activities, regardless of the field of application of the Management System.

CHAPTER 6 – PERFORMANCE OF AUDITS

6.1 GENERAL

6.1.3.

In replacing paragraph 6.1.3 of the General Rules for the Certification of Management Systems, a written report is prepared for each audit, in which are indicated any Critical nonconformity, Major nonconformity and any Minors nonconformity.

A minor nonconformity is issued when the finding does not affect the capability of the management system to achieve the intended results:

1) When a minor nonconformity is issued during an audit, the organization must provide the RINA with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP). This must be provided within three (3) months after the audit.

2) Corrective action (CA) must be implemented by the organization within 12 months after the audit.
3) Implementation of the corrective action plan and determination of its effectiveness must be reviewed, at the latest, at the next scheduled on-site audit.
4) A major nonconformity is raised in the event of non-completion of the approved action plan at the next scheduled on-site audit.

A major nonconformity is issued when the finding affects the capability of the management system to achieve the intended results:

1) When a major nonconformity is issued during an audit, the organization must provide RINA with objective evidence of an investigation into causative factors, exposed risks and the proposed CAP. This must be provided within 14 days after the audit.
2) Corrective action must be implemented by the organization within 14 days after the audit.
3) RINA shall close the major nonconformity within a further 14 days after implementation of the corrective action by the organization. The organization must submit objective evidence of implementation to RINA.
4) RINA shall conduct a follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, RINA may decide to perform a desk review.
5) The completion of corrective actions might take more time depending on the potential severity of the major nonconformity and the amount of work necessary to eliminate the causative factors. In such cases, the CAP must include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented. A follow-up audit shall be conducted to verify the permanent corrective action and to close the major nonconformity.
6) A critical nonconformity is raised in the event of non-completion of the approved corrective action.

A critical nonconformity is issued when a direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/or certification integrity are at stake:

1) When a critical nonconformity is issued at a certified site, the certificate must be immediately suspended for a maximum period of six (6) months.
2) When a critical nonconformity is issued during an audit, the organization must provide RINA with objective evidence of an investigation into causative factors, exposed risks and the proposed CAP. This must be provided within 14 days after the audit.
3) A follow-up audit shall be conducted by RINA within the six (6) month timeframe to verify the closure of the critical nonconformity.
4) The full certification audit shall be repeated.

Moreover, if there are not authorization or registration of the site, as requested by the current legislation, the certification process is suspended.

6.2. INITIAL CERTIFICATION AUDIT

The initial certification audit consists of two stages (Stage 1 and Stage 2)

6.2.1. Stage 1

In substitution of what is mentioned at paragraph 6.2.1 of the General Rules for the Certification of Management Systems, Audit Stage 1 carried out at the organization, aims to:

- Verify that the documentation of the Food Safety Management System, including procedures, meet all the requirements of the standard;
- Assess whether the internal audit and the review by senior management have been planned and executed at all the sites of the organization covered by the certification.
- Review the status and understanding of the client regarding the requirements of the standard, with particular reference to the identification of key performance or significant aspects, processes, objectives and operation significant for the Food Safety Management System
- Gather the necessary information concerning the scope of the management system, processes and / and localization / the customer, including related legal and regulated, and compliance with them;
- That the organization has all necessary authorizations / licenses on Food Safety and its activities and that they are valid and consistent with applicable law;
- Investigate the site / s Production / Organization to assess the possible problems not considered by Food Safety Management System of the Organisation;
- Review the allocation of resources for stage 2 audit and agree with the customer details of the audit stage 2;
- Focus on the audit planning stage 2, gaining a sufficient understanding of the management system and activities and the customer site, with the possible significant aspects;
- That the FSMS is operational for at least three months and that procedures are efficaciously implemented.

The outcome of the audit stage1 is leaving the organization released a copy of the audit report of stage 1 on which are among other reported any findings that may be encountered including those classified as non-conformities (major or minor) during the 'audit stage 2.

The actions taken by the Organisation for the resolution of these findings are verified during the audit stage 2 in paragraph 6.2.2.

In the presence of NC that are very critical, the technicians who performed the audit stage 1 decide if they must be resolved before proceeding with the Stage 2 audit at the organization. In case of audit stage 1 and stage 2 consecutive audit Stage 2 will be rescheduled and postponed to a date (not exceeding 6 months from the date of the audit stage 1).

6.2.2. Stage 2

As substitution of what determined by the corresponding point 6.2.2 of the General Rules for the Certification of Management Systems, the audit stage 2 at the organization must be made within a maximum period of 6 months following completion of Phase 1 of the audit.

The stage 2 audit at the organization is carried out to verify the correct and effective implementation of the Management System.

RINA sends the organization, before the audit stage 2 at the site / s, an audit plan in which is given in detail, the description of assets and provisions for the conduct of the audit.

If the activities are carried out to check on multiple operating sites, the audit is conducted according to criteria previously established and communicated by the Organization RINA.

The stage 2 audit is performed by qualified RINA technicians based on the audit report stage 1 and on the documents of the Food Safety Management System prepared by the Organization in the updated review.

Essentially the audit stage 2 consists of:

- an initial meeting with the Technician of the Organization to agree on the scope and methods of the audit and to confirm the audit plan;
- a review of the implementation of effective adaptation measures with regard to remarks made during the audit phase 1;
- an inspection of the site / s Production / Organization to verify the compliance of the for Food Safety Management System reference documents and its full implementation;
- A final meeting to explain the outcome of the investigation.

In the presence of non-compliance (of type A) the certification process is suspended. In case of observations whose numerous, in the opinion of the audit team, would undermine the proper functioning of the management system, the certification process is also suspended.

In such cases, within three months, RINA must perform a supplementary audit aimed at verifying the effectiveness of treatments and proposed corrective actions; if there is a successful outcome of this audit, the certification process is resumed.

The additional audit may be conducted on site or on the basis of documents according to the type of corrective actions to be verified in the opinion of the audit team.

All expenses relating to any additional audits resulting from deficiencies of the Management System shall be payable by the Organization.

If this deadline is exceeded, the Management System of the Organization must be submitted to complete review within a period of six months from the end of stage 2 audit.

At the expiration period of six months without a successful conclusion of the assessment, RINA can considered closed the certification, charging time and expenses incurred up to that point. In such cases, the organization that wishes to continue with the RINA certification must submit a new request and repeat the certification process.

These time limits may be varied in special cases on a reasoned request of the Organization, in the opinion of RINA.

6.2. SURVEILLANCE AUDIT

6.3.3 Unannounced audit

RINA sets the date of the unannounced audit. The site will not be notified in advance, by RINA, of the date of the unannounced audit. When there are legitimate business reasons, blackout days may be agreed in advance between RINA and the certified

organization to avoid periods of extreme inconvenience during which the client would find it difficult to participate fully and/or there is no production.

The unannounced audit takes place during operational working hours including night shifts.

The unannounced audit is a full surveillance audit during which the auditor shall spend at least 50% of the time in production area (shop floor) assessing the implementation of the applicable CCPs, PRPs and OPRPs.

The audit will start 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 site the auditor shall, based on the risks, decide which buildings/facilities shall be inspected in which order.

The auditor shall audit the organization operating on a representative number of product lines covered by the scope of certification.

Head offices controlling certain functions pertinent to certification separate to the site(s) are not audited during the unannounced audit but are audited in an announced manner.

Secondary sites (off-site activities) and off-site storage, warehouses and distribution facilities are also audited during the unannounced audit.

6.5 TRANSFERRING (UPGRADING) FROM ISO 22000 TO FSSC22000 CERTIFICATION

In addition of what is mentioned at chapter 6 of the General Rules for the Certification of Management Systems and in the above paragraphs, the followings establish the rules to be applied when a company ask for transferring (upgrading) an existing ISO 22000 certification to FSSC22000.

6.5.1. Upgrade from ISO 22000 to FSSC22000

When transferring (upgrading) an ISO 22000 certification to FSSC22000 certification, a full stage 1 and 2 audit will not be required to upgrade the ISO 22000 part of the FSMS to FSSC22000.

The certification audit is a single Stage (Stage 1 and 2) audit usually combined with a scheduled ISO 22000-surveillance audit or re-certification audit, but it should be done as a specific audit in a subsequent different time.

In case the FSSC22000 certification audit is combined with a ISO 22000 scheduled surveillance audit, with a scheduled re-certification audit or it is done as a specific audit in a subsequent different time, the audit must include ISO 22000, the applicable technical specification for sector PRP's and the additional FSSC22000 requirements.

CHAPTER 7 – MANAGEMENT OF CERTIFICATES OF CONFORMITY

In addition of what is mentioned at chapter 7 of the General Rules for the Certification of Management Systems, the followings establish the rules to be applied when a company ask for transferring (upgrading) an existing ISO 22000 certification to FSSC22000.

7.4 - ISSUING AND VALIDITY OF THE CERTIFICATE

In the case of transferring (upgrading) from ISO22000 to FSSC22000 certification, the certified organisation will usually move away from the ISO 22000 certificate. In this case the newly issued certificate will be a FSSC22000 certificate only. Therefore the ISO 22000 certificate will be withdrawn.

The scope shown on the certificate must cover the full-certified process.

It is not allowed to exclude part of the process in the scope.

The date of issuing on the certificate is the date of issuing the FSSC22000 certificate. The original date of issuing the ISO 22000 certificate is not shown on the FSSC22000 certificate.

The upgrade audit will result in a FSSC22000 certificate with a validity of three years.

7.5 - CONSEQUENCE FOR THE EXISTING ISO 22000 CERTIFICATE

It is not usual to issue an ISO 22000 certificate for the same scope as the FSSC22000 certificate. Therefore the ISO 22000 certificate will usually be withdrawn.

In case the certified organization wants to maintain the ISO 22000 certificate for the same scope as the FSSC22000, then the related processes will remain valid and managed accordingly. The ISO 22000 certificate will remain valid with the original dates of issuing and expiry unchanged.

A separate ISO 22000 certificate for processes that are not covered by the FSSC22000 scope can be allowed under condition that the activities, processes, products or services covered by the scope of the ISO 22000 certificate do not have an influence on the food safety of the end products covered by the scope of FSSC22000 certificate.

CHAPTER 9 – MULTISITE ORGANIZATIONS

9.1

In replacing paragraph 9.1 of the General Rules for the Certification of Management Systems, where an organization operates across multiple sites and all functions relating to the Food Safety for Management System are managed by a central head office and a single certification is required, the audit may be performed by sampling the sites audited only for the categories allowed by ISO / TS 22003:2013 and if the number site exceeds 20 units, provided that:

- The Activity to be certified is the same for all sites and the organization applies the same Food Safety Management System (managed from a central location) for all sites;
- At all sites of the Organization products / services provided are essentially the same kind and are made basically with the same methods and the same procedures;
- At least the following activities are managed from the headquarters of the Organization:
    - Communication procedures;
    - Management and emergency response;
    - Aanalysis of the hazards and individuation of associated risks
    - The traceability system;
    - The assessment of training needs;
    - The control of document and its amendments;

- The review of the management system by senior management;
- Evaluation of the effectiveness of corrective and preventive actions;
- Planning / execution of internal audit and evaluation of their results;
- Before the audit of RINA the organization must have performed internal audits of each site.

9.2

As substitution of the point 9.2 of the General Rules for the Certification of Management Systems, during the initial certification audit, surveillance and recertification will be carried out sampling in accordance with the ISO / TS 22003:2013.

SECTION 5 - CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEMS ACCORDING TO THE FSSC22000 v.5 SCHEME

CHAPTER 1 – GENERAL

1.1

These Rules define the additional and/or substitutive procedures applied by RINA for the certification of Food Safety Management Systems and technical sector specification (PRPs) in relation to what is already defined in the

General Rules for the Certification of Management Systems

The paragraphs of these Rules refer to (and maintain the same numbering of) the corresponding paragraphs of the General Rules for the Certification of Management Systems for which changes and/or additions have been made.

1.2

RINA issues certification in accordance with the requirements of the ISO/IEC 17021:2015 Standard to organisations whose Management System has been recognized as fully conforming to all the requirements of the scheme

FSSC 22000 v.5.

CHAPTER 2 – REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

2.1

In addition to what established at point 2.1 of the General Rules for the Certification of Management Systems organisations wishing to obtain RINA certification for their Food Safety Management Systems[5] must first and henceforth satisfy the requirements of ISO 22000 and the additional ones (e.g. technical sector specification-PRPs like the ISO/TS 22002-1). If expected by the accreditation bodies and/or by the private organisation which manage the standard (FSSC22000, for detail www.FSSC22000.com).

2.2

In substitution to what established in the paragraph 2.2.2 of the General Rules for the Certification of Management Systems, in particular, to obtain the certification of the management system, the Company shall have prepared the Documentation which is:

- defining the goal/scope/field of application of the Food Safety Management System, describing the main processes among which the communication protocols, the conduction and application of the hazard analysis, the traceability system.

  The description of the processes and their applications is to be extended to all those developed by the organisation (also to outsourced processes required to manufacture/provide a particular product/service which is decisive as regards the capacity of the product/service to satisfy the applicable requirements).

5 FSMS (Food Safety Management System): the ISO22000 reference standard is to be understood always applicable for organizations applying for certification in accordance with the private scheme FSSC22000 (FSMS and technical specifications for sector PRPs).

This can be done in different ways:

- descriptions
- flow charts or logograms
- tables or matrices
- other

- taking into consideration the requirements of the standard and giving a description, not necessarily detailed, of the resources and procedures used to ensure compliance with these requirements;
- containing a suitable description of the company organisation.

Every information received from the client is reserved.

2.3

For FSSC22000 specific certification, in addition to what established above, the following rules apply:

- The contract stipulated between RINA and the organization about FSSC22000, always include the fees for certification to be paid annually to the FSSC Foundation;
- RINA will submit to the FSSC Foundation the following information (within 4 weeks after the delivery of the certificate):
  - name and location of the certified organization,
  - scope of the certification,
  - date of the initial certification,
  - expiry date of the certificate,
  - in case of suspension or withdrawal; the date of suspension or withdrawal

  These information about the certified organizations will be made publicly available on the website of the FSSC Foundation.

- The certified organization must notify RINA of any food safety prosecution, significant regulatory food safety nonconformity, or any product recall relating to food safety. This notification must be made immediately to RINA.
- The certified organization shall inform RINA that will have the right to investigate[6] the case to ensure integrity of certification after such notification:
  - within three (3) working days:
    - about significant changes that affect the capability of the management system to continue to fulfil the Scheme requirements;
    - any significant changes that affect the compliance with the Scheme requirements and obtain advice of the CB in cases where there is doubt over the significance of a change;
    - serious events that impact the FSMS, legality and/or the integrity of the certification which include legal proceedings, prosecutions, situations which pose major threats to food safety, quality or certification integrity as a result of natural or man-made disasters (e.g. war, strike, terrorism, crime, flood, earthquake, malicious computer hacking, etc.);
    - public food safety events (such as e.g. public recalls, calamities, food safety outbreaks, etc.);
    - changes to organization name, contact address and site details;

6 According to the point nr.4.4 of the General Rules for the certification of Management Systems

- changes to organization (e.g. legal, commercial, organizational status or ownership) and management (e.g. key managerial, decision-making or technical staff);
- changes to the management system, scope of operations and product categories covered by the certified management system;
- any other change that renders the information on the certificate inaccurate.
-

- The certification activities relevant to scope categories for which RINA is accredited are performed in compliance with the applicable accreditation rules and the certificates issued are provided with the logo of the relevant Accreditation Body.
- In case of any change and/or information by FSSC Foundation in regards to the FSSC22000 scheme requirements, the certified organization will be informed within a two month period. The related rules will apply accordingly.

CHAPTER 3 – INITIAL CERTIFICATION

3.1

The Organisations wishing to obtain RINA certification for their Food Safety Management System must provide RINA with their main Organisation/production data and site location by filling in all parts of the "Informative questionnaire" form available on the website www.rina.org, and sending it to RINA which will use it to prepare a quotation.

In particular, the organisation must inform RINA of:

- the scope requested for the certification;
- general information of the organization
- the number sites involved in certification, together with the name, the addresses and the relative activities carried out there;
- The number of HACCP plan related to the scope;
- The Involvement with bigger companies, if is the case;
- Other certification obtained, if is the case;
- The involvement of consultants for the management system, if is the case.

3.5

As well as what is stated in point 3.5 of the General Rules for the Certification of Management Systems, during the stage 1 audit, it will be checked the correctness of the information provided by the Organization through an information questionnaire.

In case of differences between the data initially provided by the organization in the informative questionnaire and the homologous data verified during the stage 1 audit by the audit team, the total audit duration will be reviewed and eventually modified.

In case the audit duration, resulting from the new revision, is greater than the duration previously defined, specific communication to the customer will be given by e-mail to the client providing the correct and new audit duration.

If the organization does not want to accept the new duration, the organization has to pay RINA for the Stage 1 audit as previously agreed, to provide adequate justification within 10 working days from the receiving communication and to accept the interruption of the certification process.

In absence of response from the Organization to the specific communication, it is tacitly accepted the new term, because based on data verified by the audit team and transparently presented and discussed during the final stage 1 audit meeting.

3.7

The version FSSC22000 5, mandatory since 1st January 2020 for all the first certification, surveillance and recertification audit, involves the performance of unannounced surveillance.

At least one of the two surveillance have to be planned as unannounced. RINA decides which of the scheduled surveillance audits shall be chosen for the unannounced audit. The certified organization can voluntary choose to replace all surveillance audits by unannounced annual surveillance audits.

If the certified organization refuses to participate in the unannounced audit, the certificate shall be suspended immediately, and RINA shall withdraw the certificate, if the unannounced audit is not conducted within a six-month timeframe.

If access is denied to the auditor the certified organization will be liable for all costs.

CHAPTER 4 - MAINTENANCE OF CERTIFICATION

4.2

In addition to what is stated in the General Rules for the Certification of Management Systems, the organization must keep records of:

- food safety aspects/impacts;
- any withdrawals or recalls of products;
- accidents/emergencies on the site/s and other events that could have had negative effects on the product safety;
- any complaints received concerning food safety impacts;
- any observations or reports from national or local authorities responsible for food safety Control

and must make them available to RINA together with the relative corrective action implemented during the periodic audits.

The organisation must keep RINA informed of any observations/remarks from national or local authorities responsible for food safety control and of any situations of legislative non-compliance related to all the organisation's activities, regardless of the field of application of the Management System.

CHAPTER 6 – PERFORMANCE OF AUDITS

6.1 GENERAL

6.1.3.

In replacing paragraph 6.1.3 of the General Rules for the Certification of Management Systems, a written report is prepared for each audit, in which are indicated any Critical nonconformity, Major nonconformity and any Minors nonconformity.

A minor nonconformity is issued when the finding does not affect the capability of the management system to achieve the intended results:

1) When a minor nonconformity is issued during an audit, the organization must provide the RINA with objective evidence of an investigation into causative factors, exposed risks and the proposed corrective action plan (CAP).
2) RINA review the corrective action plan and the evidence of correction and approve it when acceptable. The CB approval shall be completed within three (3) months after the last day of the audit. Exceeding this timeframe shall result in a suspension of the certificate.
3) Implementation of the corrective action plan and determination of its effectiveness must be reviewed, at the latest, at the next scheduled on-site audit.
4) A major nonconformity is raised in the event of non-completion of the approved action plan at the next scheduled on-site audit.

A major nonconformity is issued when the finding affects the capability of the management system to achieve the intended results:

1) When a major nonconformity is issued during an audit, the organization shall provide RINA with objective evidence of an investigation into causative factors, exposed risks and evidence of effective implementation;
2) RINA review the corrective action plan and conduct an on-site follow-up audit to verify the implementation of the CA to close the major nonconformity. In cases where documentary evidence is sufficient to close out the major nonconformity, RINA may decide to perform a desk review. This follow-up shall be done within 28 days from the last day of the audit;
3) the major nonconformity shall be closed by RINA within 28 calendar days from the last day of the audit. When the major cannot be closed in this timeframe, the certificate shall be suspended;
4) where completion of corrective actions might take more time, the CAP shall include any temporary measures or controls necessary to mitigate the risk until the permanent corrective action is implemented

A critical nonconformity is issued when a direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/or certification integrity are at stake:

1) When a critical nonconformity is issued at a certified site, the certificate must be immediately suspended for a maximum period of six (6) months.
2) When a critical nonconformity is issued during an audit, the organization must provide RINA with objective evidence of an investigation into causative factors, exposed risks and the proposed CAP. This must be provided within 14 days after the audit.
3) a separate audit shall be conducted by RINA between six (6) weeks to six (6) month after the regular audit to verify the effective implementation of the corrective actions. This audit shall be a full on-site audit (with a minimum on-site duration of one (1) day). After a successful follow-up audit, the certificate and the current audit cycle will be restored and the next audit shall take place as originally planned (the follow-up audit is additional and does not replace an annual audit). This audit shall be documented and the report uploaded;
4) the certificate shall be withdrawn when the critical nonconformity is not effectively resolved within the six (6) month timeframe.
5) in case of a certification audit (initial), the full certification audit shall be repeated.

Moreover, if there are not authorization or registration of the site, as requested by the current legislation, the certification process is suspended.

6.2. INITIAL CERTIFICATION AUDIT

The initial certification audit consists of two stages (Stage 1 and Stage 2)

6.2.1. Stage 1

In substitution of what is mentioned at paragraph 6.2.1 of the General Rules for the Certification of Management Systems, Audit Stage 1 carried out at the organization, aims to:

- Verify that the documentation of the Food Safety Management System, including procedures, meet all the requirements of the standard;
- Assess whether the internal audit and the review by senior management have been planned and executed at all the sites of the organization covered by the certification.
- Review the status and understanding of the client regarding the requirements of the standard, with particular reference to the identification of key performance or significant aspects, processes, objectives and operation significant for the Food Safety Management System
- Gather the necessary information concerning the scope of the management system, processes and / and localization / the customer, including related legal and regulated, and compliance with them;
- That the organization has all necessary authorizations / licenses on Food Safety and its activities and that they are valid and consistent with applicable law;
- Review the allocation of resources for stage 2 audit and agree with the customer details of the audit stage 2;
- Focus on the audit planning stage 2, gaining a sufficient understanding of the management system and activities and the customer site, with the possible significant aspects;
- That the FSMS is operational for at least three months and that procedures are efficaciously implemented.

The outcome of the audit stage1 is leaving the organization released a copy of the audit report of stage 1 on which are among other reported any findings that may be encountered including those classified as non-conformities (major or minor) during the 'audit stage 2.

The actions taken by the Organisation for the resolution of these findings are verified during the audit stage 2 in paragraph 6.2.2.

In the presence of NC that are very critical, the technicians who performed the audit stage 1 decide if they must be resolved before proceeding with the Stage 2 audit at the organization. In case of audit stage 1 and stage 2 consecutive audit Stage 2 will be rescheduled and postponed to a date (not exceeding 6 months from the date of the audit stage 1).

6.2.2. Stage 2

As substitution of what determined by the corresponding point 6.2.2 of the General Rules for the Certification of Management Systems, the audit stage 2 at the organization must be made within a maximum period of 6 months following completion of Phase 1 of the audit.

The stage 2 audit at the organization is carried out to verify the correct and effective implementation of the Management System.

RINA sends the organization, before the audit stage 2 at the site / s, an audit plan in which is given in detail, the description of assets and provisions for the conduct of the audit.

If the activities are carried out to check on multiple operating sites, the audit is conducted according to criteria previously established and communicated by the Organization RINA.

The stage 2 audit is performed by qualified RINA technicians based on the audit report stage 1 and on the documents of the Food Safety Management System prepared by the Organization in the updated review.

Essentially the audit stage 2 consists of:

- an initial meeting with the Technician of the Organization to agree on the scope and methods of the audit and to confirm the audit plan;
- a review of the implementation of effective adaptation measures with regard to remarks made during the audit phase 1;
- an inspection of the site / s Production / Organization to verify the compliance of the for Food Safety Management System reference documents and its full implementation;
- A final meeting to explain the outcome of the investigation.

In the presence of non-compliance (of type A) the certification process is suspended. In case of observations whose numerous, in the opinion of the audit team, would undermine the proper functioning of the management system, the certification process is also suspended.

In such cases, within three months, RINA must perform a supplementary audit aimed at verifying the effectiveness of treatments and proposed corrective actions; if there is a successful outcome of this audit, the certification process is resumed.

The additional audit may be conducted on site or on the basis of documents according to the type of corrective actions to be verified in the opinion of the audit team.

All expenses relating to any additional audits resulting from deficiencies of the Management System shall be payable by the Organization.

If this deadline is exceeded, the Management System of the Organization must be submitted to complete review within a period of six months from the end of stage 2 audit.

At the expiration period of six months without a successful conclusion of the assessment, RINA can considered closed the certification, charging time and expenses incurred up to that point. In such cases, the organization that wishes to continue with the RINA certification must submit a new request and repeat the certification process.

These time limits may be varied in special cases on a reasoned request of the Organization, in the opinion of RINA.

6.2. SURVEILLANCE AUDIT

6.3.3 Unannounced audit

RINA sets the date of the unannounced audit. The site will not be notified in advance, by RINA, of the date of the unannounced audit. When there are legitimate business reasons, blackout days may be agreed in advance between RINA and the certified organization to avoid periods of extreme inconvenience during which the client would find it difficult to participate fully and/or there is no production.

The unannounced audit takes place during operational working hours including night shifts.

The unannounced audit is a full surveillance audit during which the auditor shall spend at least 50% of the time in production area (shop floor) assessing the implementation of the applicable CCPs, PRPs and OPRPs.

The audit will start 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 site the auditor shall, based on the risks, decide which buildings/facilities shall be inspected in which order.

The auditor shall audit the organization operating on a representative number of product lines covered by the scope of certification.

Head offices controlling certain functions pertinent to certification separate to the site(s) are not audited during the unannounced audit but are audited in an announced manner.

Secondary sites (off-site activities) and off-site storage, warehouses and distribution facilities are also audited during the unannounced audit.

6.5 TRANSFERRING (UPGRADING) FROM ISO 22000 TO FSSC22000 CERTIFICATION

In addition of what is mentioned at chapter 6 of the General Rules for the Certification of Management Systems and in the above paragraphs, the followings establish the rules to be applied when a company ask for transferring (upgrading) an existing ISO 22000 certification to FSSC22000.

6.5.1. Upgrade from ISO 22000 to FSSC22000

When transferring (upgrading) an ISO 22000 certification to FSSC22000 certification, a full stage 1 and 2 audit will not be required to upgrade the ISO 22000 part of the FSMS to FSSC22000.

The certification audit is a single Stage (Stage 1 and 2) audit usually combined with a scheduled ISO 22000-surveillance audit or re-certification audit, but it should be done as a specific audit in a subsequent different time.

In case the FSSC22000 certification audit is combined with a ISO 22000 scheduled surveillance audit, with a scheduled re-certification audit or it is done as a specific audit in a subsequent different time, the audit must include ISO 22000, the applicable technical specification for sector PRP's and the additional FSSC22000 requirements.

CHAPTER 7 – MANAGEMENT OF CERTIFICATES OF CONFORMITY

In addition of what is mentioned at chapter 7 of the General Rules for the Certification of Management Systems, the followings establish the rules to be applied when a company ask for transferring (upgrading) an existing ISO 22000 certification to FSSC22000.

7.4 - ISSUING AND VALIDITY OF THE CERTIFICATE

In the case of transferring (upgrading) from ISO22000 to FSSC22000 certification, the certified organisation will usually move away from the ISO 22000 certificate. In this case the newly issued certificate will be a FSSC22000 certificate only. Therefore the ISO 22000 certificate will be withdrawn.

The scope shown on the certificate must cover the full-certified process.

It is not allowed to exclude part of the process in the scope.

The date of issuing on the certificate is the date of issuing the FSSC22000 certificate. The original date of issuing the ISO 22000 certificate is not shown on the FSSC22000 certificate.

The upgrade audit will result in a FSSC22000 certificate with a validity of three years.

7.5 - CONSEQUENCE FOR THE EXISTING ISO 22000 CERTIFICATE

It is not usual to issue an ISO 22000 certificate for the same scope as the FSSC22000 certificate. Therefore the ISO 22000 certificate will usually be withdrawn.

In case the certified organization wants to maintain the ISO 22000 certificate for the same scope as the FSSC22000, then the related processes will remain valid and managed accordingly. The ISO 22000 certificate will remain valid with the original dates of issuing and expiry unchanged.

A separate ISO 22000 certificate for processes that are not covered by the FSSC22000 scope can be allowed under condition that the activities, processes, products or services covered by the scope of the ISO 22000 certificate do not have an influence on the food safety of the end products covered by the scope of FSSC22000 certificate.

CHAPTER 9 – MULTISITE ORGANIZATIONS

9.1

In replacing paragraph 9.1 of the General Rules for the Certification of Management Systems, where an organization operates across multiple sites and all functions relating to the Food Safety for Management System are managed by a central head office and a single certification is required, the audit may be performed by sampling the sites audited only for the categories allowed by ISO / TS 22003:2013 and if the number site exceeds 20 units, provided that:

- The Activity to be certified is the same for all sites and the organization applies the same Food Safety Management System (managed from a central location) for all sites;
- At all sites of the Organization products / services provided are essentially the same kind and are made basically with the same methods and the same procedures and all sites are located in the same country;
- At least the following activities are managed from the headquarters of the Organization:
    - Communication procedures;
    - Management and emergency response;
    - Analysis of the hazards and individuation of associated risks
    - The traceability system;
    - The assessment of training needs;

- The control of document and its amendments;
- The review of the management system by senior management;
- Evaluation of the effectiveness of corrective and preventive actions;
- Planning / execution of internal audit and evaluation of their results;
- Before the audit of RINA the organization must have performed internal audits of each site.

9.2

As substitution of the point 9.2 of the General Rules for the Certification of Management Systems, during the initial certification audit, surveillance and recertification will be carried out sampling in accordance with the ISO / TS 22003:2013.

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Technical rules