PROCEDURE: Certification Protocol & Regulations

These Regulations are part of the certification system of the limited company ISACert B.V., established at Ede, the Netherlands, as accredited certification body, hereafter called ISACert.

General

1. These Regulations describe the working methods used by ISACert, with respect to the audit/inspection, qualification & certification, surveillance and complaint handling. These regulations are published on the website (www.isacert.com) under publications.
2. This certification scheme fits in the structure of audit/inspection and certification and has an accredited status (by Dutch Council for Accreditation– RvA or by United Kingdom Accreditation Service-UKAS). The accredited ISACert scope of certification activities is mentioned in ISACert Scope of certification activities and on the ISACert website under publications.
3. These Regulations regulate the application, planning and execution of the audit/inspection, the qualification and the certification. In addition, they describe the working methods and principles for surveillance, consultation with parties concerned and the interrelationships.
4. If ISACert judges that the company meets the requirements for certification of its activities, ISACert is willing to make a positive certification decision for this company. The company thus certified is authorised to use the certificate and the certification mark of ISACert. The certification decision is based on the results of an audit or inspection carried out on behalf of ISACert.
5. If ISACert has subcontracted the execution of the audit/ inspection in the framework of this certification, ISACert has made a mutual agreement in this respect with that Audit/ Inspection Company. The Audit/ Inspection Company is hereafter referred to as Partner.
6. ISACert and the persons who carry out work in this framework on behalf of ISACert are not permitted to make announcements to third parties regarding the application and the handling thereof.

Article 1 Application and determination of rates and costs

1. A company applies for certification (by phone or website).
   a. In the situation of an audit for certification: ISACert or the Partner will send a Company Information Sheet to the applicant with the request to return the filled and signed Company Information Sheet in order to make up a quotation for the applicant. If applicable, quotations shall be made according minimal audit days requirements as mentioned in the certification scheme concerned. If multi-site applications are received, the general or specific multi-site requirements for certification are used for quotation and planning. The quotation together with the order confirmation form/application and attached general certification conditions shall be send to the applicant company for confirmation (quotation and general certification conditions) and with the request to return the order confirmation form directly to ISACert or to the Partner.
   With the quotation a specified costs overview and a short introductory information regarding the application handling procedure are enclosed.
   b. In the situation of an inspection for certification (e.g. GLOBALGAP option 1, Branch Hygienic Codes, IKB and KAT certification) ISACert or the Partner will send a dedicated application form including a specified standard fee table together with the general certification conditions and a short introductory information regarding the application handling procedure to the applicant with the request to return the filled and signed application form directly to ISACert or to the Partner.
2. In the event that a company applies directly to the Partner, the latter shall send the quotation and application directly to the company with approval of ISACert.
3. Signing of the order confirmation form/ application shall be considered as that the applicant company enters into a certification agreement with ISACert.
4. In case an application is received for certification outside the accredited scope of ISACert, the certification manager (CM) of ISACert HO shall consult the managing director (MD), the QA manager and the Partner concerned to decide if extension of the accredited scope is desired. The applicant shall be informed about the decision.

Article 2 Planning of initial audit/inspection, reassessment and subsequent surveillances

1. After receipt of the application/order confirmation, ISACert or the Partner concerned shall review the application (also for scope amendment) on any misunderstanding and arrange a date for the initial audit/ inspection or subsequent surveillance audit/inspection in consultation with the applicant.
2. Surveillances are planned by ISACert or the Partner according the frequency as mentioned in the standard protocol concerned.
3. A confirmation of the agreed date shall be sent to the applicant together with a program proposal and appointed auditor/audit team or appointed inspector. The company can challenge ISACert in a motivated writing for the appointed auditor(s)/inspector on impartiality.
4. When a GMP+ audit is planned the applicant will also be informed about the product sampling & testing procedure and when relevant which organisation will carry this out. The company can challenge ISACert in a motivated writing for the appointed organisation on impartiality.

Article 3 Execution and registration of the audit and surveillance

1. The execution shall take place according an established working method as accounted for in the report and the proposed program (audit/inspection plan) according prescribed protocol and the standard requirements (e.g. 2-stage initial audit). It consists of documentation, records and prerequisite requirements review, interviews of and demonstration by management and operating personnel at their working area and observations on these and on inspections from premises, production, processing and utilities. Besides the certification requirements the surveillance can also be focussed on the use of the certificate and of the ISACert certification hall mark by the company.
2. Visible irregularities in the premises, in processing or in the documented system concerned or if there is any doubt about the capability concerned, or if for reasons the planning of the audit/inspection is exceeding or the audit/inspection proceeding is obstructed, the auditor/ team leader or inspector shall report this directly to the Scheme manager of ISACert or to the operational manager of the Partner and afterwards to the responsible company management and shall report this in the audit/ inspection report. In consultation with the end responsible management of the company the auditor/ team leader or inspector can decide to terminate the audit/ inspection. At the other hand the applicant company can always prematurely terminate his application. Termination in both situations shall not affect the company's payment obligations.
3. The results of the audit/ inspection are directly reported in Non Conformities (NC's) and confirmed with the company representative guide. All reported NC's shall be discussed and agreed upon with the end responsible management during the final meeting at the end of the audit/inspection. The agreed results are reported in an 'end of audit/inspection' letter which shall be signed for acceptance by auditor/inspector and the company representative.
4. If an audited/inspected company does not meet the requirements which have been set, the company will be given the opportunity to formulate and execute Corrective Actions (CA) related to the impact of the Non Conformity (NC's: critical, major or minor) according a prescribed CA-plan and inform ISACert or the Partner by electronic input data for verification purpose within the prescribed number of days after the audit/inspection. NC's shall be rectified before qualification or the number and type of NC's shall be limited according the certification scheme requirement concerned.
5. Supplementary audits/re-inspections may be necessary to verify whether an audited/inspected company has taken sufficient corrective actions to rectify the reported NC's. The need for the supplementary audit shall be determined by the auditor with the approval of ISACert or the Partner, in accordance with the impact of the reported NC's and the Standard requirements concerned as set out in the report. The costs to be made in this respect are at the expense of the company concerned and are not included in the quotation. The need for re-inspections shall be decided by the Scheme manager, if applicable in consultation with the operational manager of the partner. The fee for re-inspection is mentioned in the standard fee table concerned. The audited organisation shall be informed accordingly.
6. A standard report of audits/ inspections and surveillances which have been carried out, as well as supplementary audits or re-inspections, shall be made per certified company by ISACert to such extent that demonstrable traceability is possible. The storage term of this record is in any event 2 full certification cycles with a minimum of 5 years. These records will not be supplied to third parties (other than scheme owners) without written consent of the applicant company. Only in case of a legal

mandatory request the applicant will be informed about the supply of a requested complete record.

Article 4 Qualification

1. After the audit/inspection has taken place, the auditor/inspector shall make an impartial recommendation to ISACert. This recommendation shall be reported in the provisional report after the verification of the implementation of corrective actions of noted NC's is completed.
2. If applicable the operational/technical manager of the Partner shall review the audit/ inspection and audit/ inspection results including the underlying evidence of the auditor/ inspector and will make up an advice for certification.
3. The certification manager of ISACert shall review the audit/inspection, the underlying evidence, the audit/inspection results and consider the recommendation and advice and in case of GMP+ the test result and recommendation of the testing laboratory and shall qualify for certification or in case of surveillance review for continuation of the existing certificate by the certification decision maker. In the situation that the certification manager authorises a change in the report, the supplier will be informed by the certification manager or his representative about the reason.

Article 5 Certification

1. As certification principal Non Conformities should be closed before certification is possible. Or the number and type of NC's shall be limited according the certification scheme requirement concerned.
2. In the event of agreement of the recommendation and advices, the contact person of the audited company shall be informed of the result in writing or by mail within a prescribed number of days after the audit. If no agreement is reached, the auditor/inspector in question shall be consulted by the ISACert certification manager in order to reach a uniform opinion. If no uniform opinion is achieved in the second instance, the managing director of ISACert shall decide the matter. The contact person of the company shall be informed of this decision in writing within 14 working days.
3. A positive recommendation shall be confirmed to the contact person of the company by sending a registered certificate in the name of the certified company together with the final report concerned. The company has always the possibility to react on this report to ISACert.
4. The company concerned shall be notified by (registered/ electronic) letter of a negative qualification which shall either result in a denial of the certification application or in a suspension or withdrawal of the certificate. In the latter situations the company shall be reminded by ISACert to notify his customers of the change in status if required by the certification scheme concerned. The suspension status can be rectified by a positive qualification of a follow up audit as mentioned in article 11. Withdrawal of the certificate results in the termination of the certification agreement as mentioned in article 12. Only after receipt of sufficient evidence that the reasons for the negative qualification or for the prematurely termination of the audit/inspection have been eliminated ISACert can decide to restart the application handling.

Article 6 Audit/Inspection & Surveillance frequency

1. A certified company must continually comply with the applicable certification criteria. This principle is set out in the general certification conditions belonging to this certification scheme.
2. After the date the certificate is granted, audits/inspections shall be carried out in accordance with an established audit/inspection frequency which is laid down in the relevant Standard and according the before mentioned articles 2 till 5. Reassessment will be actual after the regular termination of the certification period as indicated on the certificate.
3. ISACert's certification manager can adjust the surveillance frequency, for certain certification schemes as prescribed, per customer in consultation with auditor/inspector and operational manager of the Partner if relevant, also when NC's repeatedly have been observed and for verifications after taking corrective actions. The customer will be informed about this and about the financial consequences.

Article 7 Fees

1. When an application has been completed or the handling has been terminated in the interim in mutual consultation, the applicant company shall be bound to pay the costs after receipt of the invoice within the set term.

2. If the applicant defaults on paying the costs of the audit/inspection in due time, ISACert can suspend further handling of the application and/or the making of the certification agreement.
3. All costs and fees shall be charged in accordance with the applicable quotation or fee table concerned. Underlying rates list shall be evaluated by ISACert annually to the national inflation correction index and adjusted, if applicable after consultation and in agreement with the relevant partner.

Article 8 Publicity

1. The certified activities of the company, as mentioned on the certificate, shall be registered in the ISACert register for certificate holders and, when applicable, in the database of the scheme owner. This register can be requested from ISACert. ISACert has the right to publish the withdrawal of a certificate or termination of a certification agreement.
2. The certified company may use the certificate, the complete final report and the ISACert hallmark for publicity purposes according the Regulation for the use of ISACert's hallmark as published on the ISACert website (www.isacert.com) under publications.

Article 9 Consultation with parties concerned with regard to changes and preparation

1. The consultation with parties concerned regarding changes is the responsibility of the Standard or Scheme owner. If so desired, ISACert shall participate in harmonisation.
   In the situation that the audit protocol is developed by ISACert and is therefore part of this certification scheme, a significant change in this protocol does not have to be presented for agreement to any external board Such changes however should be published by ISACert, e.g. on its website.

Article 10 Change in circumstances (including recalls and withdrawals)

1. If the certification criteria or the protocol are altered by the standard owner, a general announcement shall be made to this effect. The transition term shall be at least six months after the general announcement or as long as the standard owner specifies. ISACert will inform his certificate holders by referring to the website of the standard owner about these alterations and adjustments as result of these alterations as well as about the transition period if this is not specified.
2. The certified company must give ISACert or it's representative written notice if there has been or will be a relevant change in circumstances on the basis of which a certificate has been granted (e.g. legal, commercial, organizational status or ownership, key management, contact address & sites, changed or reduced certification scope, major changes in the management system and processes concerned). For a merger, this is the date of publication.
3. Recalls and withdrawals shall be reported to ISACert within 3 working days.
4. With regard to such alterations ISACert can decide to carry out a supplementary audit (e.g. a 2-stage audit with recertification) or to take corrective measures in accordance with the following article. The costs to be made in this respect are at the expense of the certified company.

Article 11 Corrective measures and sanctions (e.g. suspension of certification)

1. If the standard owner or the scheme owner or ISACert has specified (types of) non conformities, procedures for handling corrective actions, sanctions and obligations for the certified company, ISACert is authorised to verify whether these corrective measures have been taken and are effective. The costs to be made in this respect are at the expense of the certified company.
2. In this respect ISACert can decide to prohibit the certified company from making use of the certificate, as proof of certification, and of the certification mark for a maximum term of six months (e.g. in advertising), or can decide to reduce the certification scope of the company involved to exclude the parts not meeting the requirements only if this is in line with the scheme requirements, without prejudice to the provisions of the certification agreement regarding the right of ISACert to withdraw a certificate.
3. In respect to a reduced certification scope the invalid certificate shall be withdrawn and the articles 12.2 and 12.3 are applicable.

Article 12 Withdrawal of the certificate

1. ISACert can withdraw the certificate if:
   a. a surveillance or an supplementary surveillance shows that the criteria for certification are no longer met, if applicable according the requirements of the certification scheme concerned;
   b. the certified company abuses the certificate granted in such sense that due to its action or omission an incorrect impression could be created among third parties with regard to the nature and the scope of the certificate;
   c. the certified company, despite repeated reminders, does not perform its obligations to ISACert;
   d. it cannot reasonably be demanded of ISACert to continue with the certification agreement, such as in the event of the certified company's bankruptcy, in the event it petitions for a moratorium on payment, in the event the certified company has attempted to influence the ISACert auditor/inspector in an inappropriate manner or if the certified company in any way harms the good name of ISACert.
2. If ISACert decides to withdraw the certificate, it shall give the certified company a written notice of withdrawal stating the reasons. The certified company must immediately stop using all advertising matter that contains a reference to certification and return the relevant certificate and if relevant the sticker to ISACert.
3. ISACert can publish the withdrawal of a certificate, as well as the termination of the certification agreement as a result of the validity term, in accordance with the term that applies for the certified company to file an appeal.

Article 13 Liability

1. ISACert, the Partner and the person who by order of ISACert is executing audits, except in the event of intent or gross negligence, are not liable for damage which the applicant company suffers pursuant to the non-granting or not continuing of the certificate.
2. ISACert and the Partner are, except in the event of intent or gross negligence on their part, not liable for damage arising due to actions or omissions of those persons whom it instructs to carry out the work as described in this regulation.

Article 14 Confidentiality

1. The managing director and all persons in the employ of ISACert or of the Partner, who carry out work on behalf of ISACert are bound by a duty of the strictest confidentiality with regard to all information which comes to their attention in the framework of this regulation, including all business information, insofar as the applicant company can reasonably claim confidentiality, in accordance with what is set out in the Articles of Association in this respect. ISACert shall impose this duty of confidentiality by means of a signed statement of confidentiality. The signed confidentiality statements are available, upon request by the applicant or certified company.
2. The applicant nor the certified company is permitted, under any name or title whatsoever, to persuade or attempt to persuade the auditors/inspectors or other employees of the Partner or of ISACert, who due to their position could have knowledge of information as a result of the execution of handling certification applications, to act or try to act as its advisor in the relevant field.

Article 15 Possibility of Appeal

According to the certification system of ISACert, all parties concerned have the option of appealing against a decision of ISACert regarding decisions and/or measures, insofar as such ensues from any agreement to which ISACert is a party. This option of appeal is regulated in the Rules of Appeal, which are part of the Certification Regulations. These Rules are published on the website of ISACert under publications.

Article 16 Complaints

According to the certification system of ISACert, all parties concerned have the option to filing a complaint regarding the certification activities of ISACert or its Partners. The complaint handling procedure is detailed in the General Certification Conditions published on the website of ISACert under publications.

Article 17 Disputes

1. In case a dispute in the certification procedure arises, all parties concerned can ask the Managing Director of ISACert to settle the problem.
2. The concerning party will send a description of the dispute in writing to the Managing Director.
3. The Managing Director will review the file and will interview all parties concerned.
4. The Managing Director will take a binding decision and send this in writing to all parties concerned.
5. If necessary the Managing Director can consult an external expert.

Article 18 Final provisions

1. The managing director of ISACert can alter these Regulations in accordance with the provisions of the Articles of Association
2. ISACert shall immediately inform the certified company of any relevant alteration of these Regulations, specifying the transition period.
3. These Regulations can be cited under the name ISACert Certification Regulations.

Prerequisite documents, being part of the audit system of ISACert or of the audit body

1. **Company Information Sheet**
   To be filled and signed for by the applicant company.
2. **ISACert Quotation letter and Order confirmation/Application form**
   Standard quotation letter with costs overview, a short introduction on the application handling procedure and an order confirmation form as certification application. This filled and signed form is considered to be the certification agreement between applicant and ISACert. This form refers to the ISACert General certification conditions
3. **ISACert General certification conditions**
4. **Standard assignment confirmation**
   in which audit date and appointed inspector/ auditor(s) and inspection/ audit program are proposed with sufficient notice to challenge the appointment which should be motivated and delivered in writing by the auditee. No reaction of the applicant is considered as agreement with the proposal.
5. **Inspection application form**
   To be filled and signed for by the applicant company to be sent together with the general certification conditions and short introductory information regarding the application handling procedure.
6. **Instructions & Forms (electronic) for the audit records**
   - standard report for registration of observations
   - standard Non Conformity (NC) form
7. **Working method description for non conformities**
   verification of non conformities (NC's): NC's on documents can be delivered in writing for assessment, while operational NC's have to be verified on site.
8. **Description of traceability of executed audits/inspections**
   Data specifications (reports) of audited/ inspected company, dates/ reports of audit/ inspection, follow up audits/ inspections or verifications, name auditor(s)/ inspector, audit/inspection results, copy certificate and possible written evidence.