GLOBALG.A.P. GENERAL REGULATIONS

PART II | RULES FOR OPTION 2 AND OPTION 1 MULTISITES WITH QMS

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This part establishes the requirements producer groups and multisites (where a QMS has been implemented) must comply with to achieve certification. These requirements need to be internally and externally assessed via the GLOBALG.A.P QMS Checklist to ensure completeness and effectiveness.

1 REQUIREMENTS FOR MULTISITES WITH QMS AND PRODUCER GROUPS

1.1 LEGALITY, ADMINISTRATION AND STRUCTURE

1.1.1 Legality

- a) There shall be documentation, which clearly demonstrates that the applicant is or belongs to a legal entity.
- b) The legal entity must have been granted the legal right to carry out agricultural production and/or trading, and be able to legally contract with and represent the group members and production sites.
- c) The legal entity shall enter into a contractual relationship with GLOBALG.A.P. through the signature of the GLOBALG.A.P. Sublicense and Certification Agreement with a GLOBALG.A.P. approved CB, and becomes the sole holder of the GLOBALG.A.P. Certificate.
- d) A single legal entity can only operate one QMS per crop per country. Only a legal entity that can be certified under Option 1 can join a group for Option 2 certification. If a group or multisite joins another group or multisite, the 2 quality management systems shall merge into one to be managed by one single legal entity that will be the certificate holder.

1.1.2 Producers and Production Sites

1.1.2.1 Requirements for Producer Groups

- (i) There shall be written contracts in force between each producer member and the legal entity. The contracts shall include the following elements:
 - a) Producer group name and legal identification
 - b) Name and/or legal identification of the producer
 - c) Producer contact address
 - d) Details of the individual production locations and any production management units (PMU), including certified and non-certified products
 - e) Details of area (crops) or quantity (tonnage)
 - f) Producer commitment to comply with the requirements of the GLOBALG.A.P. Standard, demonstrated by the product acceptance status in the GLOBALG.A.P. Database
 - g) Producer agreement to comply with the group's documented procedures, policies and where provided, technical advice
 - h) Sanctions that may be applied in case of GLOBALG.A.P. and any other internal requirements not being met
 - i) Signature of producer and group representatives
- (ii) The producer group registered members must be legally responsible for their respective production locations (and any declared PMUs), although this takes place under the common QMS of the group.
- (iii) The producer cannot sell own products that are certified under the group option except through the group.

1.1.2.2 Requirements for Multisites

- (i) All PMUs shall be owned or rented and under the direct control of the legal entity.
- (ii) For PMUs that are not owned by the legal entity, there shall be written contracts in force between each PMU owner and the legal entity. The contracts shall include the following elements:
 - a) Certificate holder name and legal identification
 - b) Name and/or legal identification of the site owner
 - c) Site owner contact address
 - d) Details of the individual PMUs
 - e) A clear indication that the site owner does not have any responsibility or input or decision capacity regarding the production operations over the rented-out site

- f) Signature of both parties' representatives
- (iii) The certificate holder is legally responsible for all the registered production, including placing the product on the market.

1.1.3 Producer and Site Internal Register

(i) A register shall be maintained of all contracted group member producers and of all the applicable sites used for production in accordance with the GLOBALG.A.P. Standard.

1.1.3.1 Requirements for Producer Groups

- (i) All producers in the producer group internal register must be registered individually on the GLOBALG.A.P. Database according to the requirements of the General Regulations PART I: Annex I.2.
- (ii) The register shall at least contain the following information for each producer:
 - a) Name of producer
 - b) Name of contact person
 - c) Full address (physical and postal)
 - d) Contact data (telephone number and e-mail and/or fax number)
 - e) Other legal identity ID (VAT Number, ILN, UAID, etc.) where required for the country of production as published in Annex I.1
 - f) Product registered
 - g) Growing/Production area and/or quantity for each registered product
 - h) Certification body(ies) if a producer makes use of more than 1 CB
 - i) GLOBALG.A.P. Status
- (iii) Those producers of the legal entity who do not apply to be included in the GLOBALG.A.P. Group Certification must be listed separately and are not required to be registered in the GLOBALG.A.P. Database (unless they have applied for a benchmarked option or any other GLOBALG.A.P. Standard). This list is for management purposes within the producer group, and the disclosure of its contents externally is not required, unless it is needed for clarification of any issues raised for example on the effectiveness of the producer group's quality management system. The additional rules for Parallel Production and Ownership are not applicable for these cases. All data protection rules shall be published and observed.

1.1.3.2 Requirements for Multisites

- (i) Additionally, the register shall at least contain the following information for each site:
 - a) Relation of legal entity with the production management unit (ownership, rented, etc.)
 - b) PMU location
 - c) Product registered
 - d) Growing/Production area and/or quantity for each registered product

1.2 MANAGEMENT AND ORGANIZATION

a) The QMS must be robust and show that the group's registered members or PMUs comply in a uniform manner with the GLOBALG.A.P. standard requirements.

1.2.1 Structure

- a) The structure must enable the appropriate implementation of a quality management system (QMS) across all registered producer members or PMUs.
- b) The applicant shall have a management structure and sufficient suitably trained resources to effectively ensure that the requirements of GLOBALG.A.P. are met by all producers and at all PMUs.
- c) The organizational structure shall be documented and shall include individuals responsible for:
 - (i) Managing the implementation of GLOBALG.A.P.
 - (ii) Managing the QMS
 - (iii) The internal inspections of each producer member and/or PMU annually (i.e. internal inspector(s))

- (iv) The internal audit of the quality management system and verifying the internal inspections (i.e. internal auditor)
- (v) Technical advice to the group (depending on the scope of the group). *This could be the same person as in (i) above*

1.2.2 Competency and Training of Staff

- a) The competency requirements, training and qualifications for key personnel (those mentioned in 1.2.1 but also any other identified personnel) shall be documented and shall meet any defined competency requirements laid out in the GLOBALG.A.P. Standard.
- b) The management shall ensure that all personnel with responsibility for compliance with the GLOBALG.A.P. Standard are adequately trained and meet the defined competency requirements.
 - (i) Internal auditor competence (as set out in Annex II.1) shall be checked by management.
 - (ii) Internal inspector competence (as set out by Annex II.1) shall be checked by the internal auditor.
 - (iii) Where the internal auditor does not have the necessary Food Safety and G.A.P. training, but only QMS training/experience, another person with these qualifications (and identified in the QMS) must form part of the "audit team" to perform the approval of the farm inspections
- c) Records of qualifications and training shall be maintained for all key personnel (managers, auditors, inspectors, etc.) involved in compliance with GLOBALG.A.P. requirements to demonstrate competence.
- d) Records of completed online training and passed exams as offered by GLOBALG.A.P. for every internal inspector/auditor shall be maintained.
- e) If there are more than one internal auditor or inspector, they shall undergo training and evaluation to ensure consistency in their approach and interpretation of the standard (e.g. by documented shadow audits/inspections).
- f) Systems shall be in place to demonstrate that key staff is informed and aware of development, issues and legislative changes relevant to the compliance to the GLOBALG.A.P. Standard.

1.3 DOCUMENT CONTROL

- a) All documentation relevant to the operation of the QMS for GLOBALG.A.P. Compliance shall be adequately controlled. This documentation shall include, but is not limited to:
 - (i) The Quality Manual
 - (ii) GLOBALG.A.P. operating procedures
 - (iii) Work Instructions
 - (iv) Recording Forms
 - (v) Relevant external standards, e.g. the current GLOBALG.A.P. normative documents
- b) Policies and procedures shall be sufficiently detailed to demonstrate compliance checks of the requirements of the GLOBALG.A.P. Standard.
- c) Procedures and policies shall be available to relevant staff and producer group registered members.
- d) The contents of the Quality Manual shall be reviewed periodically to ensure that it continues to meet the requirements of the GLOBALG.A.P. Standard and those of the applicant. Any relevant modifications of the GLOBALG.A.P. Standard or published guidelines that come into force must be incorporated into the Quality Manual within the period given by GLOBALG.A.P.

1.3.1 Document Control Requirements

- a) There shall be a written procedure defining the control of documents.
- b) All documentation shall be reviewed and approved by authorized personnel before issue and distribution.
- c) All controlled documents shall be identified with an issue number, issue date/review date and be appropriately paged.
- d) Any change in these documents shall be reviewed and approved by authorized personnel prior to their distribution. Wherever possible an explanation of the reason and nature of the changes shall be identified.

- e) A copy of all relevant documentation shall be available at any location where the QMS is being controlled.
- f) There shall be a system in place to ensure that documentation is reviewed and that following the issue of new documents, obsolete documents are effectively rescinded.

1.3.2 Records

- a) There shall be records to demonstrate effective control and implementation of the QMS and compliance with the requirements of the GLOBALG.A.P. Standard.
- b) Records shall be kept for a minimum of 2 years.
- c) Records shall be genuine, legible, stored and maintained in suitable conditions and shall be accessible for inspection as required.
- d) Records that are kept online or electronically are valid. If a signature is required, this can be a password or electronic signature that ensures the unique reference and authorization of the person signing. If a written signature of the responsible person is needed then this must be present. The electronic records must be available during the CB inspections. Back-ups must be available at all times.

1.4 COMPLAINT HANDLING

- a) The applicant shall have a system for effectively managing customer complaints and the relevant part of the complaint system shall be available to the producer members.
- b) There shall be a documented procedure that describes how complaints are received, registered, identified, investigated, followed up and reviewed.
- c) The procedure shall be available to customers as required.
- d) The procedure shall cover both complaints to the applicant and against individual producers or sites.

1.5 INTERNAL QUALITY MANAGEMENT SYSTEM AUDIT

- a) The QMS for the GLOBALG.A.P. Scheme shall be audited at least annually.
- b) Internal auditors shall comply with the requirements set in Annex II.1
- c) Internal auditors shall be independent of the area being audited.
 - (i) It is permitted for the same person to initially develop the QMS and then undertake the required internal annual QMS audit, however the person responsible for the day-to-day ongoing management of the QMS is not allowed to undertake the internal QMS audits.
- d) Records of the internal audit, audit findings and follow up of corrective actions resulting from an audit shall be maintained and available.
- e) The completed QMS checklist with comments for every QMS control point must be available on site for review by the auditor during the external audit.
- f) Where the internal audit is not performed in one day but continuously over a 12-month period, a pre-defined schedule shall be in place.

1.6 INTERNAL PRODUCER AND PRODUCTION MANAGEMENT UNIT (PMU) INSPECTIONS

- a) Inspections shall be carried out at each registered producer (and corresponding production locations) or PMU at least once per year against all the relevant GLOBALG.A.P. Control Points and Compliance Criteria.
- b) Internal inspectors shall comply with the requirements set in Annex II.1
- c) Internal inspectors shall be independent of the area being audited. Internal inspectors cannot inspect their own daily work.
- d) New members of the group and new PMUs shall always be internally inspected and approved prior to entering into the internal GLOBALG.A.P. register.
- e) The original inspection reports and notes shall be maintained and available for the CB inspection.
- f) The inspection report shall contain the following information:
 - (i) Identification of registered producer and/or production location(s)
 - (ii) Signature of the registered producer or PMU responsible
 - (iii) Date
 - (iv) Inspector name
 - (v) Registered products
 - (vi) Evaluation result against each GLOBALG.A.P. control point
 - (vii) The checklist shall include details in the comments section for the

- 1. Major Musts control points that are found to be compliant,
- 2. Major and Minor Musts control points that are found to be non-compliant, and
- 3. Major and Minor Musts control points that are found to be non-applicable; unless a checklist is issued by GLOBALG.A.P. that pre-determines which CPCCs must be commented on. This is needed to enable the audit trail to be reviewed after the event.
- (viii) Details of any non-compliances identified and period for corrective action
- (ix) Inspection result with calculation of compliance
- (x) Duration of the inspection
- (xi) Name of Internal auditor that approved the checklist
- g) The internal auditor (or audit team; see Annex III.2) shall review and make the decision on whether the producer or site is compliant with the GLOBALG.A.P. requirements, based on the inspection reports presented by the internal inspector.
- h) In case there is only one internal auditor who also performs the internal inspections, another person, e.g. management representative identified in the QMS, must approve the internal inspections.
- i) Where the internal inspections take place continuously over a 12-month period, a pre-defined schedule shall be in place.

1.7 NON-COMPLIANCES, CORRECTIVE ACTION AND SANCTIONS

- a) There shall be a procedure to handle non-compliances and corrective actions, which may result from internal or external audits and/or inspections, customer complaints or failures of the QMS.
- b) There shall be documented procedures for the identification and evaluation of non-conformances and non-compliances to the QMS by the group or by its members, respectively.
- c) Corrective actions following non-compliances shall be evaluated and a timescale defined for action.
- d) Responsibility for implementing and resolving corrective actions shall be defined.
- e) A system of sanctions and non-conformances shall be operated with producers or PMUs that meet the requirements defined in the GLOBALG.A.P. General Regulations Part I.
- f) Mechanisms shall be in place to notify the GLOBALG.A.P. approved certification body immediately of suspensions or cancellations of registered producers or PMUs.
- g) Records shall be maintained of all sanctions including evidence of subsequent corrective actions and decision-making processes.

1.8 PRODUCT TRACEABILITY AND SEGREGATION

- a) Product meeting the requirements of the GLOBALG.A.P. Standard and marketed as such shall be traceable and handled in a manner that prevents mixing with non-GLOBALG.A.P. approved products.
- b) There shall be a documented procedure for the identification of registered products and to enable traceability of all products both conforming and non-conforming to the applicable production sites. A mass balance exercise must be carried out to demonstrate compliance within the legal entity.
- c) Effective systems and procedures shall be in place to negate any risk of mislabeling or mixing of GLOBALG.A.P. certified and non-GLOBALG.A.P. certified products.
- d) If a member of the group registers for Parallel Production, the Traceability and Segregation control points (AF 12) shall be applicable for that member.
- e) For Fruit and Vegetables Certification: The produce handling site shall operate procedures which enable registered product to be identifiable and traceable from receipt, through handling, storage and dispatch.

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1.9 WITHDRAWAL OF PRODUCT

- a) Documented procedures shall be in place to effectively manage the withdrawal of registered products.
- b) Procedures shall identify the types of event that may result in a withdrawal, persons responsible for taking decisions on the possible withdrawal of product, the mechanism for notifying customers and the GLOBALG.A.P. approved certification body, and methods of reconciling stock.
- c) The procedure shall be capable of being operated at any time.
- d) The procedure shall be tested in an appropriate manner at least annually to ensure that it is effective and records of the test retained.

1.10 SUBCONTRACTORS

- a) Where any services are subcontracted to third parties, procedures shall exist to ensure that these activities are carried out in accordance with the requirements of the GLOBALG.A.P. Standard (see Control Point All Farm AF 4.1).
- b) Records shall be maintained to demonstrate that the competency of any subcontractor is assessed and meets the requirements of the standard.
- c) Subcontractors shall work in accordance with the group's QMS and relevant procedures and this shall be specified in service level agreements or contracts.

1.11 REGISTRATION OF ADDITIONAL PRODUCERS OR PMUS TO THE CERTIFICATE

New producers and sites may be added (subject to internal approval procedures being met) to a certificate in effect. It is the responsibility of the certificate holder (group or multisite) to immediately update the certification body on any addition or withdrawal of sites to/from the list of registered producers.

- a) Up to 10% of new producers sites in one year can be added to the approved list by registering the producers sites with the GLOBALG.A.P. approved certification body without necessarily resorting to further verification by the certification body.
- b) When the number of approved registered producers sites increases by more than 10% in one year, further external sample inspections (minimum is the square root of new producers/sites) of the newly added producers-sites and optionally an audit of the QMS will be required during that year **before** additional producers can be added to the approved list.
- c) Regardless of the percentage by which the number of approved registered producers sites increases in one year, should the newly registered farms increase the area or number of livestock of previously approved registered products by more than 10% in one year, or there is a 10% change of producers, further external sample inspections (minimum is the square root of new producers/farms) of the newly added farms or producers and optionally an audit of the quality management systems will be required during that year **before** additional farms or producers can be added to the approved list.

ANNEX II.1 INTERNAL AUDITOR AND INSPECTOR QUALIFICATIONS AND RESPONSIBILITIES

1 KEY TASKS

1.1 Inspectors:

- a) May undertake inspections of farms (PMUs within a multisite or those of members of a producer group) to assess compliance with the certification requirements
- b) May not perform auditors' tasks
- c) Must produce timely and accurate reports on such inspections

1.2 Auditors:

- a) Auditing the QMS of the producer group or multisite to assess compliance with the certification requirements
- b) The approval of the members of the group or approval of the PMUs of a multisite, based on inspection reports of the internal inspector. *If an internal auditor conducts the inspection, he/she cannot approve that inspection report*
- c) To produce timely and accurate reports on such audits

2 QUALIFICATION REQUIREMENTS

2.1 Formal Qualifications

2.1.1 Inspector:

(i) A post high school diploma in a discipline related to the scope of certification (Crops and/or Livestock and/or Aquaculture) or an agricultural high school qualification with 2 years experience in the relevant sub-scope after qualification.

2.1.2 Auditor:

(i) A post high school diploma in a discipline related to the scope of certification (Crops and/or Livestock and/or Aquaculture) <u>or</u> an agricultural high school qualification with 2 years experience in the relevant sub-scope after qualification <u>or</u> 2 years experience in quality management systems with 2 years experience in the relevant sub-scope after qualification.

2.2 Technical Skills and Qualifications

2.2.1 Inspector Training

- (i) One-day practical inspection course setting out basic principles of inspection.
- Two witness inspections (accompanying an audit, could be GLOBALG.A.P. or other) OR 2 shadow audits by the CB.

2.2.2 Auditor Training

- (i) Practical knowledge of quality management systems.
- (ii) Completion of an internal auditor-training course related to QMS (min. 16 hours).

2.2.3 Food Safety and G.A.P. Training

- (i) Training in HACCP principles either as part of formal qualifications or by the successful completion of a formal course based on the principles of Codex Alimentarius or training in ISO 22000.
- (ii) Food hygiene training either as part of formal qualifications or by the successful completion of a formal course.
- (iii) **For Crop Scope:** Plant protection, fertilizer and IPM training either as part of formal qualifications, or by the successful completion of a formal course.
- (iv) For Livestock and Aquaculture Scopes: Basic veterinary medicine and stockmanship training including animal health and welfare issues.

2.3 Communication Skills

- a) "Working language" skills in the corresponding native/working language. This must include the locally used specialist terminology in this working language.
- b) Exceptions to this rule must be consulted beforehand with the GLOBALG.A.P. Secretariat.

NOTE: The relevant CB shall have a complete and current list of all the producer group internal inspectors and auditors. These internal inspectors shall be approved by the CBs during the external inspections.

ANNEX II.2 GLOBALG.A.P. STATUS DEFINITIONS FOR PRODUCER GROUP MEMBERS

GLOBALG.A.P. defines 2 types of statuses:

- 1. Producer Statuses (linked to the legal entity of a producer group member)
- 2. Product Statuses (linked to the products of a producer group member)

1. PRODUCER STATUS

The following status refers to the producer members of a producer group. The status definitions for producers certified individually and producer groups are explained in Annex III.3.

1.1 Producer Status: "Not confirmed"

Producers group members in the status "Not Confirmed" are those whose registration data are recorded in the database and associated with a Farm Assurer (CB/3rd party). The registration information has not yet been confirmed or reconfirmed by the Farm Assurer. Registration fee is not yet payable by the producer group member in this status.

1.2 Producer Status: "Registered"

Producers or producer groups in the status "Registered" are linked to a farm assurer. The producer status "Registered" is a pre-condition for product acceptance and certification. The status "Registered" can only be set by a farm assurer.

1.3 Producer Status: "CB/PG Accepted"

Producer group members will be automatically set from the producer status "Registered" to the producer status "CB/PG Accepted", as soon as one or more products have been set to the product status "Accepted". "CB/PG Accepted" producer group members must pay the registration fee to the farm assurer, according to the current fee table published on www.globalgap.org.

1.4 Producer Status: "Annulled"

Producer group members in the status "Annulled" are still recorded in the database (they still have a valid GGN), but not linked to a certification body or a producer group anymore. All registration information will be stored in the database for at least 5 years and can be re-activated at anytime. Producer group members in this status do not pay the registration fee.

2. PRODUCT STATUSES

Product statuses within GLOBALG.A.P. Certification refer to the status of the production process of the product under consideration. The producer can only be certified with reference to one or more production processes of the product(s). Although the term "product status" is used, it only refers to the status of the production process of the product out of which the product is delivered and not to that of the product itself.

2.1 Product Status: "Not confirmed"

As soon as a producer group member or producer group registers products in the database, these products are set to the status "Not confirmed". Additional products can be entered at any time when the producer group member is in the status "Not Confirmed", "Registered" or "CB/PG Accepted". If a product certificate is not renewed, the product status is automatically set to "Not confirmed". New products cannot be registered when the producer is in the status "Annulled".

2.2 Product Status: "Accepted"

The producer group itself sets the product status "Accepted" for the producer members of the group. All products of producer group members shall be set to the product status "Accepted" before they can be set to the status "Internally Approved" and be affiliated to the producer group certificate. This status is the trigger for the registration fee. Products with status "Self-declared suspension" or "Suspension" cannot be re-accepted. Product quantities/growing areas need to be entered for producer members of the producer group. The product quantities of the group will be aggregated based on the information of the group members.

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2.3 Product Status "Internally Approved"

As soon as the producer group sets the product status to "Internally Approved" for one or more product(s) of the producer group member, the producer will form part of the group certificate and take on the overall product status within the group certificate and will appear on the Annex. The producer group shall, at this time, pay the certificate license fee to the CB according to the GLOBALG.A.P. fee table available on www.globalgap.org. Additional products that have already been accepted by the CB on group level may be added later, i.e. by changing the product status of these products to "Internally Approved" and by the CB issuing an updated certificate, without changing the certificate validity.

2.4 Product Status "Self-declared suspension"

A producer group member can ask the producer group for a voluntary suspension of a product.

2.5 Product Status: "Product Suspended"

A suspension of the product of producer group member from the certificate of the group is issued when a producer group member does not present evidence of corrective actions that close out a nonconformity after a warning has been issued. The respective producer group must set the respective products to the status "Product Suspended". The respective producer group must lift the suspension.

EDITION UPDATE REGISTER

New document	Replaced document	Date of publication	Description of Modifications
120206_gg_gr_part_II_eng_v4_0-1	110301_GG_GR_PART_II_IF A_ENG_Final_V4	6 February 2012	Modification GLOBALG.A.P to GLOBALG.A.P.; 1.10 – corrected reference; Annex II.1 – Key tasks c) took reference off
120306_gg_gr_part_II_v4_0-1_en	120206_gg_gr_part_II_eng_v 4_0-1	6 March 2012	1.1.3.1 (i) – corrected reference
130315_gg_gr_part_II_v4_0-2_en	120306_gg_gr_part_II_v4_0- 1_en	15 March 2013	Annex II.1 – 2.2.4 deleted

If you want to receive more information on the modifications in this document, please contact the GLOBALG.A.P. Secretariat mailto:translation_support@globalgap.org.

When the changes do not affect the accreditation of the standard, the version will remain "4.0" and edition update shall be indicated with "4.0-x". When the changes do affect the accreditation of the standard, the version name will change to "4.x".