ASEAN AUSTRALIA DEVELOPMENT COOPERATION PROGRAM (AADCP)

Phase II

ASEAN GAP

Official Control Manual

Quality Assurance Systems for ASEAN Fruits and Vegetables
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1. Preambles

1.1 Introduction

The objective of the ASEAN GAP implementation is to enhance ASEAN agricultural products quality and competitiveness on the international market as well as on the ASEAN market by promoting ASEAN Good Agricultural Practices (GAP).

This “Preambles” document aims at giving the AMS wishing to implement the ASEAN GAP accreditation and certification systems an overview of the regulatory framework to study before the implementation. It also contains recommendations concerning national regulations contents and stakeholder’s organisation to insure equivalency between the AMS.

1.2 Abbreviations

For the purpose of the ASEAN GAP Manuals, the following abbreviations will be used:

**ABs:** Accreditation bodies  
**AMS:** ASEAN Member States  
**ASEAN:** Association of South East Asian Nations  
**CBs:** Control Bodies  
**CAs:** Control Authorities  
**GAP:** Good Agricultural Practices

Each abbreviation used at the national and regional level should be clearly explained in the national regulation. The list of useful abbreviations must be the subject of a specific paragraph in the national regulations.

**NAB:** National Accreditation Body

1.3 Definitions

Sharing the same vocabulary will facilitate exchanges at national, regional and international level. In order to insure implementation of equivalent production rules and control measures, use of a common glossary is recommended. It is recommendable that each country lists the technical wording used in the national regulation and give a clear definition for every item. Then each AMS should have a correspondence table between the national wording and the regional and international one.

This work has been done at the ASEAN level. For the purpose of the ASEAN GAP Manuals, the following definition will be used:

‘**Accreditation**’ means an attestation by a national accreditation body that a control body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.

‘**Applicant**’ means a legal entity applying for registration to achieve ASEAN GAP-standard certification. This applies to single farmers as well as to farmer groups only.
‘Audit’ means systematic, independent documented process for obtaining records, statements of facts or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. For group certification where Internal Control System-ICS is applied and established, ‘Audit’ means assessment of a farmer group’s compliance with the standard requirements regarding the quality management system.

‘Auditor’ means a person conducting audits and complying with the defined auditor’s qualification.

‘Certification scheme’ means certification system related to specified products, to which the same specified requirements, specific rules and procedures apply.

‘Competent authority’ means the central authorities of a Member State responsible for the organisation of official controls and of other official activities, in accordance with the national Regulation (Ministry of agriculture, specific department of the ministry of agriculture...).

‘Control authority’ means a public administrative organisation of a Member State to which the competent authorities have conferred, in whole or in part, their competences in relation to the application of the national regulation.

‘Control body’ means a separate private legal entity to which the competent authorities have delegated certain official control tasks.

‘Official control task’ means either an inspection or certification task.

‘Food law’ means the laws, regulations and administrative provisions governing food in general, and food safety in particular at national level.

‘Equivalent’ means different systems or measures that they are capable of meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity.

‘Handling unit’ means a production site, where product handling activities take place.

‘Inspection’ means verification of a product process, service, or installation or their design and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements.

‘Inspector’ means a person conducting inspections and complying with the defined inspector’s qualification

‘Official controls’ means activities performed by the competent authorities in order to verify compliance by the operators with the national regulation.

‘Operator’ means any registered natural or legal person subject to one or more of the obligations provided for in national GAP regulation;

‘National accreditation body’ means the sole body in a Member State that performs accreditation with authority derived from the State.

‘Non-compliance’ means the non-fulfillment of compliance criteria of control points.

‘Peer evaluation’ means an assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group

‘Private control body’ means an independent third party (private) to which the competent authority has delegated certain official control tasks.
‘Product handling’ means any handling of products done post-harvest, where the product may have physical contact with other materials or substances. It includes e.g. sorting, trimming, packing, storing, washing, treatments, but it excludes processing.

‘Production site’ means a production area (e.g. with separate on-site address, handling unit) that is owned or rented and ultimately managed by one legal entity, and where the same input factors (e.g. water supply, workers, equipment, stores, etc.) are used.

“Related bodies” means entities that may have access to data and/or may be perceived to influence decisions made during the certification process such as IT subcontractors, webmasters, committee members, training organisations, organisations promoting certification or administrative/governmental entities.

‘Scheme owner’ means person or organization responsible for developing and maintaining a specific certification scheme.

1.4 Regulatory framework

1.4.1 Mapping of the regulatory structure

A national GAP regulation shall contain both production rules and control measures. These two components of the regulation must be positioned in the existing regulatory structure.

Each country must realize a mapping of the existing texts related to food safety and concerning production rules, official controls rules, conferment rules, delegation rules... in order to:

- Know if it already exists other regulations covering these two components (production rules and control measures). It can be either generic regulation on food or specific ones on food safety, GAP, ... If the texts exist, they may be amended to be in compliance with the proposed certification/accreditation system. If they do not exist, the related rules shall be developed directly in the National GAP standard and be specific to GAP in order not to influence the legislation for other products or services.
- Be sure that there is no overlap between existing regulations and, most important, that there are not contradictory provisions.
- Determine the order of prevalence of texts between them.

The 1st step of the regulatory study consists in setting up a regulatory pyramid detailing the different types of documents and their hierarchy in the national regulatory structure.

Example of a regulatory pyramid:

In this example Laws prevail on all others types of documents, Decrees prevail on Circular and Guidelines and so on.

For a same type of document (same level in the pyramid), the most specific document prevails on the most generic one.

The 2nd step consists in listing all type of existing documents covering GAP production rules and control measures. A graphical representation (mapping) can be useful to well understand the current structure.
The 3rd step consists in determining and summarising the provisions which apply to GAP production rules and control measures. It is important to list the contradictory provisions and the missing ones.

1.4.2 Design of the best organisation

The first key element to design the best organisation is to validate the control model to implement. It exists two main control models depending on the GAP standard nature, namely private GAP standard and national GAP regulation.

Case 1: Private GAP standard

The following diagram details the current organisation encountered for the purpose of implementation of a private control system.

In this kind of organisation, the key elements to ensure a credible control system are:

- the existence of clear control rules,
- the accreditation of the CB (according to ISO norm)
- and the peer evaluation of the accreditation body, as explained below.

As in each AMS where GAP regulation is a national regulation, the proposed private GAP schemes is not selected to be part of the Manual.

Case 2: National GAP regulation

The following diagram details the possible organisations encountered for the purpose of implementation of an official control system as regard to GAP certification at a national level with the aim to reach regional and international markets.
As national GAP regulation exists in most of the AMSs, the targeted system is a mixed system involving CAs and CBs.

In cases where the CA has delegated official tasks to private sector, the CB shall be accredited according to ISO norms, for instance ISO 17065 for certification body and ISO 17020 for inspection body.

It should be also noted that to ensure the quality, effectiveness and consistency of the controls, sufficient number of suitably qualified and experienced staff, appropriate facilities and equipment must be provided. In case of CA, it is often difficult for AMSs to mobilize the necessary human and financial resources. This is why delegation to CBs is the solution adopted by most countries for the control of voluntary regulations such as GAP regulation. The question of financing is key: Before deciding which control system should be adopted, the means for financing have to be previously defined in each country.

Based on experience, financing control system by public founds do not permit to have access to sufficient public financial resources to dispose to a sufficient number of suitably qualified and experienced staff. One of the solution is to request control fees directly from the operators who can expect a better price for his certified products on the international market and also on the domestic one. A fair-trade supply chain organisation can guarantee this point. The exclusive use of CBs the guaranty to finance the system by the market.

1.4.3  Duties of the competent authority/ control authority

Most of the countries have a national GAP regulation. In this case, the AMS is the owner of the GAP standard and is responsible of the GAP scheme. Setting up the regulatory corpus is its sole responsibility. The AMS designates a competent authority and / or a CA. Through regulations, the AMS or its competent authority is in charge of laying down rules for the performance of official controls including the establishment of specific rules for the purpose of delegation of certain official control tasks to CBs.
However, the competent authority is recommended to involve stakeholders (such as organisations representing producers, processor, CBs, consumers, research sector if relevant) to ensure fairness, consistency, transparency and objectiveness of the system.

1.5 Mandatory elements for the national GAP standards

1.5.1 Definition of clear objectives

The Codex Alimentarius states that national regulation should integrate clear objectives. The first question an AMS has to answer is “why I need a GAP regulation in my country?”. Each AMS can have different reasons for setting up a GAP regulation.

Indeed, a GAP regulation can aim at:

- contributing to the healthy development of the agricultural and food industry in the country through the fair and transparent development and management of the regulation,
- enhancing the safety of imported produce by addressing common areas of concern in the growing, harvesting, sorting, packing, and distribution of fresh products,
- accessing main regional and international markets for fresh fruits and vegetables and fresh products,
- producing quality and safe agricultural crops for domestic consumers,
- keeping high regards for environment protection,
- improving workers’ health, safety and welfare,
- complete the existing provisions of the food safety law,
- …

The control measures scheme that will be developed depends on the objectives to be reached. An internationally recognised control measures scheme must be adopted to be able to access regional or international markets.

1.5.2 Basement of standards on appropriate risk analysis

Competent authorities must perform official controls regularly, on a risk basis and with appropriate frequency, on all the sectors and in relation to all operators, activities, animals and goods governed by AMS agri-food chain legislation.

The frequency of official controls shall be established by the competent authorities having regard to the need to adjust the control effort to the risk and to the level of compliance expected in the different situations, including the possible violations of the AMS agri-food chain legislation perpetrated through fraudulent or deceptive practices. Accordingly, the likelihood of non-compliance with all the areas of the AMS agri-food chain legislation which fall within the scope of the national GAP regulation must be taken into account where adjusting the control efforts. In some cases, however, and in view of the issuance of a certificate which is a pre-requisite for the placing on the market or for the movements of animals or goods, AMS agri-food chain legislation requires that official controls be performed irrespective of the level of risk or the likelihood of non-compliance. In such cases, the frequency of the official controls is dictated by the certification needs.
For GAP certification, the minimum number of controls required per operator is one per year. According to the above paragraph, the competent authority (CA or CB if relevant) shall carry out additional control visits, primarily unannounced, based on the general evaluation of the risk of non-compliance with the GAP production rules, taking into account at least the results of previous controls, the seriousness of the previous non-compliance and the quantity of products concerned.

1.5.3 Procedures for product recalls and to combat frauds

If an operator considers or has reason to believe that a food which it has produced, processed, manufactured or distributed is not in compliance with the food safety requirements including those of the national GAP standard, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial operator and inform the competent authority thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

An operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements including those of the national GAP regulation and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authority.

In case of export of products, the AMS shall immediately notify countries of destination of any measure it adopts which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action.

Concerning the protection of consumers’ interests, Food law in general and national GAP regulation in particular shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

(a) fraudulent or deceptive practices;
(b) the adulteration of food; and
(c) any other practices which may mislead the consumer.

As all AMSs are functioning with a national GAP regulation, all the following provisions shall be integrated in the existing regulatory structure through legal text (see regulatory pyramid).
2 Designation of competent authority / control authority

AMS designates the competent authority or authorities on which they confer the responsibility to organise and/or perform national AMS official controls. For competences reasons, regarding GAP standard, designation of existing services of Ministry of Agriculture or equivalent is recommended.

The competent authority may confer its control competences to one or more other CAs. For a question of consistence, AMS will designate only one competent authority for the purpose of the organisation of GAP official controls. When the competent authority has already conferred the responsibility to perform official controls on more than one CA, it ensures efficient and effective coordination between all authorities involved, and the consistency and effectiveness of official controls across its territory.

3 General obligations concerning the competent authority/ control authorities

The competent authority or the CA must:

- have procedures to ensure the effectiveness and appropriateness of official controls;
- have procedures to ensure the impartiality, quality and consistency of official controls and at all levels;
- have procedures to ensure that staff performing official controls are free from any conflict of interest. The staff contract can be used to inform employees of their obligations. A form can be signed each year by the staff to declare their potential conflict of interest in listing if the staff:
  o is the owner, director or employee of a certified company
  o has financial interest / a stake in a certified company
  o provides consultancy services to a certified company
  o has a non-financial conflict of interest with a certified company: family relative, personal or professional relationship
  o is running the risk of lacking of impartiality with regards to a certified company due to existing friendly relationships, pressure or intimidation
- have access to an adequate laboratory capacity for analysis, testing and diagnosis (see certification part);
- have a sufficient number of suitably qualified and experienced staff so that official controls can be performed efficiently and effectively. The number of staff mainly depends on:
  o the number of operators
  o the annual frequency of controls
  o the duration of controls.

The objective is to be able manage the entire certification process for each operator during a calendar year (including controls, control report review, certification decision...);

- have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively (see certification part). Competent authority can issue for each inspector a professional administrative card that can be presented before starting controls;
• have the legal powers to perform official controls and have legal procedures in order to ensure that staff have access to the premises of, and documents kept by, operators so as to be able to accomplish their tasks properly;
• have contingency plans and be prepared to operate such plans in the event of an emergency. An alert system for the notification of a direct or indirect risk to human health deriving from food or feed is established as a network (specific page on the Ministry of agriculture website). The competent authority shall be responsible for managing the network.

Staff performing official controls must:
• receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to perform official controls in a consistent manner;
• keep up-to-date in their area of competence and receive regular additional training as necessary; and
• receive training in the following subject matters and on the obligations of the competent authorities resulting from the national official controls regulation.
  o Different control methods and techniques, such as inspection, verification, screening, targeted screening, sampling,
  o Control procedures
  o The production rules referred to in the National GAP regulation
  o Assessment of non-compliance with the rules referred to in the National GAP regulation
  o The hazards in the production, processing and distribution of animals and goods
  o The different stages of production, processing and distribution, and the possible risks to human health, and where appropriate to the health of animals and plants, to the welfare of animals, to the environment
  o The evaluation of the application of HACCP procedures and of good agricultural practices
  o Management systems such as quality assurance programmes that the operators manage (including ISO norms such as 9001, 14000, 22000) and their assessment in so far as these are relevant for the requirements set out in the rules referred to in national GAP regulation
  o Official certification systems
  o Contingency arrangements for emergencies
  o Legal proceedings and implications of official controls
  o Examination of written, documentary material and other records, accreditation and risk assessment, which may be relevant to the assessment of compliance with the rules referred to in the National GAP regulation

4 Audits of the competent authority / control authorities

To ensure its compliance with this Manual and/or the National Official Controls Regulation and/or any relevant regulations, the competent authority shall carry out internal audits and must take appropriate measures in the light of the results of those audits.
These internal audits should be subject to independent scrutiny and carried out in a transparent manner. For example, a provision of the results could be done by publication on the Competent Authority website.

5 Right of appeal

The decisions taken by the competent authority concerning natural or legal persons, in case of non-compliance with the rules referred to in the national GAP regulation, shall be subject to such persons’ right of appeal in accordance with national law (if it exists).

30 days from the decision notification to the natural or legal persons for appealing this decision is a reasonable delay.

The appeal must be done in writing.

The right of appeal does not affect the obligation of competent authority to take prompt action to eliminate or contain the risks to human, animal or plant health, or any other risk. Moreover, the appeal is not suspensive, the initial decision / sanction applies until the appeal process is over and an eventual new decision/sanction was taken.

6 Complaint procedures

The competent authority (CA or CB if relevant) shall have a documented process to receive, evaluate and make decisions on complaints. It shall record and track complaints and appeals, as well as actions undertaken to resolve them.

Upon receipt of a complaint, the competent authority shall confirm whether the complaint relates to certification activities for which it is responsible and, if so, shall address it.

The competent authority shall acknowledge receipt of a formal complaint or appeal.

The competent authority shall give formal notice of the outcome and the end of the appeal process to the appellant.

7 Confidentiality obligations of the competent authority / control authority

Competent authority/ CA ensures that information acquired when performing its duties in the context of official controls is not disclosed to third parties unless where disclosure is required by national legislation and/or GAP regulation.

In case of required disclosure by national legislation, before publishing or making otherwise available to the public information about the outcome of official controls regarding individual operators, the following conditions must be met:

- the operator concerned is given the opportunity to comment on the information that the competent authority intends to publish or make otherwise available to the public, prior to its publication or release, taking into account the urgency of the situation; and
the information which is published or made otherwise available to the public takes into account the comments expressed by the operator concerned or is published or released together with such comments.

For that purpose, competent authority/CA should ensure that appropriate confidentiality obligations are established for staff and other individuals employed during official controls. The employment contract could be used as support.

8 Transparency of official controls

Competent authority shall perform official controls with a high level of transparency and shall, at least once a year, make available to the public, including through publication on the internet, relevant information concerning the organisation and the performance of official controls.

It must also ensure the regular and timely publication of information on the following (generic information and not nominative ones):

- the type, number and outcome of official controls;
- the type and number of cases of non-compliance detected;
- the type and number of cases where measures (including penalties) were taken following the detection of non-compliance.

The frequency referred to in point 9.2 must be adopted.

9 Delegation by the competent authorities of certain official control tasks

Competent authority shall be empowered to delegate certain official control tasks to one or more CBs.

The provisions laid down in 2. to 6. must apply mutatis mutandis to control body in addition to the following conditions (9.1) and obligations (9.2).

The competent authority shall ensure that the CB, to which such tasks have been delegated, have the powers needed to effectively perform these tasks.

A decree, ordinance (or any other legislative document) is an official tool for transmitting a legal power to carry out official controls. As for its administrative staff, the competent authority may issue for each control body inspector a professional administrative card that can be presented before starting controls.

9.1 Conditions for delegating certain official control tasks to control body

The delegation of certain official control tasks to a CB must be in writing and have to comply with the following conditions:

- the delegation contains a precise description of those official control tasks that the CB may perform, and the conditions under which it may perform those tasks;
- the CB:
  - has the expertise, equipment and infrastructure required to perform those official control tasks delegated to it (see certification part);
  - has a sufficient number of suitably qualified and experienced staff;
o is impartial and free from any conflict of interest and in particular is not in a situation which may, directly or indirectly, affect the impartiality of its professional conduct as regards the performance of those official control tasks delegated to it. In addition of the situations listed in point 2., the staff must declare if he is part of a related body that may be perceived to influence the certification decisions or to have access to certification data;

o is accredited in accordance with standards relevant to the delegated tasks in question, including to standard EN ISO/IEC 17020 ‘Requirements for the operation of various types of bodies performing inspection’ or to standard ISO 17065 ‘Conformity assessment – Requirements for bodies certifying products, processes and services’. A checklist related to ISO 17065, inspired by an existing Malaysian document, is annexed to the manual. This check list may also be used as a support to carry out audits referred to in point 3.;

o has sufficient powers to perform the official control tasks delegated to it; and

- there are arrangements in place ensuring efficient and effective coordination between the delegating competent authority and the control body (through directive or circular).

9.2 **Obligations of the CBs**

CBs to which certain official control tasks have been delegated shall:

- communicate the outcome of the official controls performed by them to the delegating competent authority on a regular basis and whenever competent authority request;

Type of information (as a minimum) and frequency (as a minimum) are as follow:

Once a year

- the name of operator,
- address,
- activity (producer, processor, distributor ...),
- list of products,
- quantities.

- immediately or within short delay inform the delegating competent authority whenever the outcome of the official controls indicates non-compliance;

Type of information (as a minimum) and frequency (as a minimum) are as follow:

Immediately in case of major non-compliance and every trimester in case of minor non-compliance:

- the name of operator,
- address,
- activity (producer, processor, distributor, ...),
- products concerned,
- lot number,
- quantities,
- type and wording of the non-compliance,
- certification decision / sanction taken.

- give competent authority access to their premises and facilities and cooperate and provide assistance.

All these obligations must be part of a written and signed commitment from the CB.

9.3 Obligations of the delegating competent authority

Competent authority that have delegated certain official control tasks to control body shall:

- organise audits or inspections of such body, as necessary and avoiding duplication, taking into account any accreditation audits;

A supervision audit is carried out once a year by the competent authority. All the provisions contained in this manual which apply to CB must be audited from the moment they are not covered by the accreditation audit. The certification system constitutive documents (procedures, guidelines, forms, technical sheets ...) shall be audited as well as their application (records) in checking operator’s files, carrying out witness audit (observer), and carrying out audits of already recently (no more than two months) audited operators to be able to compare its findings with those of the control body.

- fully or partly withdraw the delegation without delay where:
  - there is evidence that such a control body is failing to properly perform the tasks delegated to it;
  - the CB fails to take appropriate and timely action to remedy the shortcomings identified during the audits conducted by competent authority of accreditation body; or
  - the independence or impartiality of the CB has been shown to be compromised.

For transparency and fairness reasons, cases for which the delegation can be withdrawn should be listed by the competent authority.

10 Designation of the accreditation body

10.1 General principles

International standards developed by the International Organisation for Standardisation (ISO) must be used for the accreditation of the CBs as well as by the accreditation bodies for their operations. National standard with requirements recognised to be at least equivalent could be used.

Accreditation of CB must only be performed by:

- a national accreditation body; or
- an accreditation body that is a signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum (ISO 17011 accredited).

Concerning the national accreditation body, for simplification reasons, each AMS must appoint a single national accreditation body.
Where accreditation is not operated directly by the public authorities themselves, the AMS should entrust its national accreditation body with the operation of accreditation as a public authority activity and grant it formal recognition. As the formal recognitions see above, this one can also be done by decree.

The responsibilities and tasks of the national accreditation body must be clearly distinguished from those of other national authorities.

The national accreditation body shall not offer or provide any activities or services that conformity assessment bodies provide, nor shall it provide consultancy services, own shares in or otherwise have a financial or managerial interest in a conformity assessment body.

The national accreditation body shall operate on a not-for profit basis. It shall be subject to the economic and financial control of the AMS. Each AMS ensures that its national accreditation body has the appropriate financial and personnel resources for the proper performance of its tasks. For this purpose, the national accreditation body will invoice directly the CBs for the services it provides to them.

10.2 Requirements for national accreditation bodies

A national accreditation body shall fulfil the following requirements:

- It must be organised in such a manner as to make it independent of the conformity assessment bodies it assesses and of commercial pressures, and to ensure that no conflicts of interest with conformity assessment bodies occur. For this purpose, the list referred to in point 2. can be apply mutatis mutandis to accreditation bodies.
- It must be organised and operated so as to safeguard the objectivity and impartiality of its activities;
- It must ensure that each decision relating to the attestation of competence is taken by competent persons different from those who carried out the assessment;
- It must have adequate arrangements to safeguard the confidentiality of the information obtained;
- It must identify the conformity assessment activities for which it is competent to perform accreditation, referring, where appropriate, to relevant national legislation and standards;
- It must set up the procedures necessary to ensure efficient management and appropriate internal controls. The NAB must carry out at least one internal control per activity.
- It must have a number of competent personnel at its disposal sufficient for the proper performance of its tasks;
- It must document the duties, responsibilities and authorities of personnel who could affect the quality of the assessment and of the attestation of competence;
- It must establish, implement and maintain procedures for monitoring the performance and competence of the personnel involved;
- It must verify that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings and that due account is taken of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process;
AMS has the obligation to monitor its national accreditation body at regular intervals in order to ensure that they fulfil the requirements laid down above and at least once a year.

AMS must take the utmost account of the results of peer evaluation described below when carrying out the monitoring.

Where a national accreditation body does not meet the requirements of this manual or fails to fulfil its obligations hereunder, the AMS concerned takes appropriate corrective action including the suspension of the NAB.

### 10.3 Peer evaluation

National accreditation bodies must subject themselves to peer evaluation.

For this purpose, the NAB comply with and is accredited ISO 17011 and signatory of a multilateral recognition arrangement under the auspices of the International Accreditation Forum (IAF).

AMS ensures that its national accreditation body regularly undergo peer evaluation. Once every 4 years is a minimum.

Peer evaluation must be operated on the basis of sound and transparent evaluation criteria and procedures, in particular concerning structural, human resource and process requirements, confidentiality and complaints. Appropriate appeal procedures against decisions taken as a result of such evaluation should be provided for.

Peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in 10.2.

A checklist related to ISO 17011 is annexed to the manual.

### 11 Accreditation rules

#### 11.1 Objective of this part

The purpose of this part is to present the process and rules for the evaluation and accreditation of organizations listed in the scope of application, and to specify the rights and obligations of these organizations, accredited or candidates for accreditation.

Note: The obtaining of an accreditation by the National Accreditation Body (NAB) does not prejudge in any way the decision of approval or official recognition pronounced by the Public Authorities with regard to the statutory texts published in the Official Journal of the French Republic.

#### 11.2 Initial request for accreditation

11.2.1 Instruction and contracting of the accreditation application

The receipt by NAB of a request in writing (letter, fax or e-mail) by a duly authorized representative of the CB marks the beginning of the examination of the accreditation request by NAB.
This written request must specify the accreditation standard according to which the accreditation is requested as well as the scope of accreditation requested. It must be accompanied by all the administrative and technical information required by the application form which also contains the list of documents to be provided by the candidate.

Except in cases explicitly provided for by the regulations, before submitting an application for accreditation, the applicant must have started certification activities in one of the fields requested.

11.2.2 Examination of the completeness of the file

The processing of the application begins with an examination which aims to verify the completeness of the application file.

If the file is not considered complete, the applicant is informed of missing or incomplete documents. If the file is considered complete, the investigation continues with an examination called "administrative admissibility".

11.2.3 Examination of administrative admissibility

The purpose of the administrative admissibility examination is to verify:

- if the applicant's general organization is compatible with the accreditation application requested;
- if the NAB is able to respond to the request;
- to establish an estimate in case of request for a domain not yet opened. In this case, the objective of the evaluation will be to check whether the activity can be accredited.

Additional information may be requested before concluding of the administrative admissibility of the request.

It should be noted that an application can only be accepted if NAB can give a favorable response in its entirety.

The acceptance of the application following the examination of administrative admissibility is materialized by a proposal for an agreement between the NAB and the CB. At the agreement are attached annexes which define:

- the scope of accreditation requested,
- the list of contractual documents applicable in the context of the application for accreditation.

In case of refusal of the request, the decision notified to the applicant specifies the reasons for the refusal of the request.
11.2.4 Evaluation
The evaluation of the CB starts only after both parties have signed the accreditation agreement and its annexes.

If, within six months after the signing of the agreement, the CB did not respond to NAB’s requests regarding the progress of his file or did not honor the bill of costs of instruction, it would be closed and the relaunching of a procedure would be considered as a new application for initial accreditation.

The language of the evaluation is the national language. Any request for evaluation in another language is studied on a case by case basis and is subject to prior agreement between the parties.

11.2.5 Operational admissibility
A first review called "operational admissibility" is carried out by the NAB with the following objectives:

- identify whether the applicant’s quality system takes into account the requirements of the accreditation standard that accreditation is sought:
- to identify whether this system is sufficiently operational so that the application and effectiveness of the provisions and the technical competence of the applicant can be ascertained by an on-site evaluation;
- to identify the on-site evaluation procedures to be used to make a decision on the accreditation of the applicant.

This examination is carried out on the basis of:

- the identification questionnaire completed and returned by the applicant,
- documents requested in the questionnaire identification,
- the evaluation questionnaire, if any, provided by the CB when submitting the application,
- results of additional expertise as applicable.

The result of this admissibility examination is sent to the CB.

If the examination is satisfactory, the admissibility is pronounced, the initial on-site evaluation can then be scheduled within a period agreed between the applicant and the NAB, normally within three months after the end of the admissibility examination when the domain for which the CB applies for accreditation is open. If the evaluation at CB headquarters is not carried out within 9 months of the favorable opinion given by the NAB, the file is closed and the relaunching of a procedure is considered as a new application for initial accreditation.

Where the admissibility examination reveals significant deficiencies in the organization of the requesting CB, or if the CB activity does not provide sufficient evidentiary points of assessment, the initiation of the on-site evaluation may be put on hold for additional elements or for the correction of identified deficiencies, in agreement between the parties and within a period not exceeding one year from the beginning of the application review. If the elements provided are not satisfactory, the admissibility is not pronounced and the file is closed.

Once the admissibility is pronounced, the on-site evaluation can be carried out.
11.2.6 Evaluation on site

Accreditation cannot be based solely on the study of pre-established provisions of the CB. The application of these provisions should also be examined. Thus, during the initial assessment, the CB must have conducted an internal audit and a management review and, except in special cases provided for in a document of specific requirements, already made certification decisions for each of the domains, categories or families of products or services concerned by the application for accreditation.

The evaluation of the CB is carried out by the evaluation team proposed by NAB and accepted by the CB.

The evaluation team includes one or more technical evaluators in the field of GAP certifications, in particular the evaluators must:

- have minimum of 2 years of work experience in agriculture. The evaluators must be qualified for product categories (sub – scopes as fruits, vegetables, aquaculture, beverages, ...).
- and have at least participated in training provided by the AMS or have experience in the implementation of the requirements of the National GAP standard.

The evaluation team is composed of a quality assessor, in particular to review organizational arrangements, and as many evaluators and / or technical experts as necessary to review the set of technical competencies identified by the evaluation team for the accreditation scope.

The evaluation manager, appointed from among the members of the evaluation team, organizes the mission, prepares and sends to NAB and the CB a provisional evaluation plan.

The aim of the evaluation is to:

- review the relevance and compliance with accreditation requirements (organizational and technical);
- check the application of these requirements;
- evaluate the appropriateness of the means of the CB to carry out the services that are the subject of its application for certification;
- assess the proficiency of the CB staff in the services that are the subject of the accreditation application.

If the CB has several sites (except the main establishment) where essential activities are carried out, they are subject to on site evaluation during the accreditation cycle.

The evaluation is done by the following means:

- analysis of documented provisions and quality system records;
- examination of the communication made by the CB (website, for example);
- examination of the documentary traceability of the services performed;
- interviews with the staff, including with a member of the impartiality mechanism (ISO norm 17065) if it is not constituted in committee with formal meetings that could be subject to observation of the activity
- observation of the performance of all or part of the services within the scope of accreditation claimed.
The participation of the NAB evaluator on site as an observer is not always exhaustive in relation to the total duration of the observed activity. Nevertheless, it must allow an overview of all the data of its realization in order to verify that it is conducted in accordance with the requirements of the standards and in application of the procedures of the CB.

Observers must not in any way interfere in the activity observed during its progress. However, they may interview the observed CB persons or any other person representing the CB, outside the progression of the observed activity and in the absence of representatives of the audited organization.

During the assessment, deviations from the accreditation requirements may be identified by the evaluation team. Deviations and requests for clarification are formalized in writing and submitted to the CB for approval/confirmation.

At the end of its investigative work, and within a maximum of one month, the head of the evaluation team issues to NAB a report containing:

- a description of the evaluation scope and points examined
- a list of key documents reviewed and people evaluated
- a description of the situation observed,
- any non-compliance found, associated action plans and their progress,
- any request for clarification;
- the general and technical impressions, concluded by a judgment as to the quality of the services performed by the CB and the subject of the application for certification, and the CB's ability to solve the non-compliance.

At the closing meeting held on the last day of the evaluation at the headquarters of the CB, the evaluation report as well as any non-compliance and requests for clarification formalized in writing are submitted to the CB for approval/confirmation.

The headquarters evaluation and observation reports are sent by the evaluation team leader to the CB, which can react within eight calendar days to NAB on the content of the report.

11.2.7 Review for decision

Upon receipt at NAB, the headquarters and observation evaluation reports are pre-examined by the NAB, to ensure that each report is complete and comprehensible. If necessary, additional information or clarification is requested from the evaluation team or the CB. When the report is amended, a copy of the amended report is sent to the assessed CB.

Reports are reviewed by the NAB.

The NAB may requalify as non-compliance reported by the evaluator as requests for clarification. The justification for the requalification is notified to the CB and the evaluator.

When an unfavorable decision is considered, the CB is informed before the decision is made. CB can then have the possibility to make comments within 7 calendar days from the reception of the notification, if it considers that the envisaged decisions are erroneous.
11.2.8 Accreditation decision

The accreditation decision is taken by the Chief Executive Officer of NAB or his delegate.

In case of accreditation, the notification letter is accompanied by a certificate of accreditation and its technical appendix setting the limits of the accreditation granted.

When the scope of accreditation is fixed, the technical appendix mentions in particular standards or normative documents and regulatory requirements and certification reference standards subject to the certifications granted by the CB under accreditation. CBs are required to inform NAB of any changes to these documents.

In case of a favorable decision, the accreditation takes effect on the date of notification of the decision.

It is issued for a maximum duration of 4 years; it is renewable for periods of up to 5 years.

A surveillance plan, including periodic on-site assessments, is being implemented to maintain and renew the CB accreditation.

11.3 Accreditation surveillance

Accreditation monitoring is carried out by:

- periodic evaluations on site, as part of an individual monitoring plan;
- complementary and supplementary assessments, if necessary.

11.3.1 Rules for drawing up the surveillance plan

The surveillance accreditation plan is defined by NAB so that:

- the first on-site surveillance assessment is conducted after 10 months, and no later than 12 months after the initial accreditation takes effect;
- the CB is evaluated on site every 12 months during the first accreditation cycle (4 years);
- the CB is evaluated on site every 15 months during the following accreditation cycles (5 years).

Exceptionally, evaluation periods can be staggered but without the interval between 2 successive on-site evaluations exceeding 15 months for the first accreditation cycle (except for the first surveillance) and 18 months for the following cycles.

11.3.2 Surveillance evaluation

On-site surveillance covers the scope of accreditation specified.

The evaluation methods (establishments to be visited, observations to be made, team and evaluation period) are determined from:

- the surveillance plan initially established for the validity period of the current accreditation;
- information provided to NAB since the previous on site assessment (changes in the means, the staff, the organization, the business volume of the CB, complaints against the CB, ...);
- results of (the) assessment (s) to previous site (s) (weakness points raised, noncompliance solved, ...).
The evaluation team is composed of a quality assessor and as many evaluators and / or technical experts as necessary to review all of the technical competencies defined in the CB’s scope of accreditation. Whenever possible, the person in charge of the first cycle monitoring is the same as the person responsible for the initial evaluation.

The objective of on-site surveillance is to verify, by sampling, that:

- the provisions of the quality system continue to be applied and remain relevant to the activity of the CB and in accordance with accreditation requirements;
- the action plans decided as a result of any non-compliance identified in previous evaluations have actually been implemented, and to assess their effectiveness.;
- the arrangements made by the CB for its organization and resources since the last on-site evaluation have been satisfactorily managed;
- the skills / competences of the staff of the AB are maintained and demonstrated.

The evaluation is done in particular by the following means:

- analysis of new or revised documents and quality system records;
- review of the documentary traceability of the services provided, in particular from the reports on the results; review of records related to, among other things, the production and operation of internal audits and management reviews and the use of progress tools;
- interviews with staff, including new ones;
- observation of the performance of services within the scope of accreditation claimed.

Note: In the absence of services provided by the organization, the evaluation team will examine the specific provisions put in place by the organization as well as their application to ensure the maintenance of skills for the scope of accreditation granted.

The implementation of the surveillance assessment, the return of the findings and the processing of the assessment file until the notification of decision are identical to those of the initial assessment.

The headquarters evaluation and observation reports are sent by the evaluation team leader to the CB, which can react within eight calendar days to NAB on the content of the report.

11.3.3 Complementary and additional evaluations

Additional and additional assessments may be triggered by NAB at any time. The CB is advised of the scope and modalities of these evaluations by the NAB.

11.3.4 Review for decision

Upon receipt at NAB, the evaluation and observation reports of certification activities are subject to pre-examination by the NAB.

The pre-exam is intended to ensure that the report is comprehensive and understandable. If necessary, additional information or clarification is requested from the evaluation team or the CB. When the report needs to be amended, a copy of the amended report is sent to the CB evaluated.

Each evaluation report is then sent to a NAB committee for opinion on accreditation.
11.4 Renewal of accreditation

11.4.1 Revaluation

The renewal of the accreditation may be pronounced following an on-site re-evaluation including an evaluation at the headquarters of the CB and at least one observation per domain / certification reference, certification conducted by the CB as part of its accreditation application.

The reassessment is triggered so that NAB may, under normal conditions, issue a decision concerning the renewal of the accreditation before the end of its validity.

The purpose of the renewal evaluation is to be able to conclude on the compliance of the CB with all accreditation requirements.

Note that a quality assessor cannot be mandated:
- to conduct the first re-evaluation if it has completed the initial CB assessment;
- to carry out two consecutive reassessments of the same CB.

The assessment file review process for decision is the same as for a surveillance assessment.

11.4.2 Effective date and period of validity

In case of a favorable decision, a new certificate of accreditation is issued, specifying in particular the new accreditation period.

The accreditation renewal takes effect on 1st day of the month following the decision.

11.5 Suspension, termination and withdrawal of accreditation

11.5.1 Suspension and withdrawal of accreditation on the initiative of the NAB

In accordance with the procedures, NAB may decide at any time to suspend or withdraw all or part of the accreditation if any breaches or non-compliance with the accreditation requirements are noted.

Before suspension or withdrawal being effective, the CB is informed of this intention. It then has the possibility to make observations according to the modalities defined Review of decision on initial accreditation application.

- Cases of non-compliance recorded during on-site evaluations:

The suspension and withdrawal of accreditation decisions result from the examination of the evaluation report according to the principles set out by the NAB.

- Cases of non-compliance or non-compliance found by other means:

The suspension or withdrawal may follow an observation made by the staff of the NAB following the handling of complaints, or on the basis of information provided by the accredited body or any other source (competent authorities, ...) after verification of data.

Accreditation may be suspended if the CB no longer has the necessary resources to carry out the activities for which it is accredited (qualified personnel, material means, etc.).
Even if the CB could maintain the competence of its personnel to carry out the activities in question, the accreditation will not be renewed if the CB has not carried out these activities or activities requiring the same means and skills during the entire accreditation cycle elapsed.

- Inability to monitor the accredited body:

Situations beyond the control of NAB and the CB may preclude the conduct of an assessment, for example for health, climate or safety reasons. In such cases, the accreditation is suspended or not renewed if the organization has not been evaluated on site within 2 years of its last on-site evaluation.

### 11.5.2 Suspension and Termination of Accreditation Requested by CB

The CB has the option to voluntarily reduce the scope of its accreditation or terminate it in full.

In case of withdrawal, the CB is no longer allowed to issue certificates or maintain existing certificates. He shall inform the relevant customers so that they may apply to another accredited CB for this purpose.

In case of suspension, the CB is no longer allowed to issue certificates but the existing certificates remain valid.

In case of termination, the CB must inform the customers concerned as soon as possible so that they can apply to another accredited CB for this purpose. The existing certificates remain valid.

### 11.6 RIGHTS AND OBLIGATIONS OF CB

The rights and obligations of CB are specified in the accreditation agreement binding NAB to the CB.

The accreditation agreement is terminable with a notice of 3 months by either party by registered letter with acknowledgment of receipt.

#### 11.6.1 Rights of CB

**Confidentiality**

All information collected by NAB or by its evaluators and experts during the accreditation process and relating to the applicant CB are considered and processed by NAB as confidential.

When the accreditation is issued as part of a regulatory activity and the Competent Authority requests it, the latter is systematically informed in parallel with the CB of any decision taken by NAB regarding accreditation.

**Challenge of Experts and Evaluators**

The CB has the possibility to challenge all or part of the team proposed by NAB to proceed with the evaluation.
Appeal on decision

The CB has the possibility to appeal any decision of NAB affecting the status or scope of its accreditation. The appeals are handled under the conditions and following the provisions of NAB. Appeal examination does not suspend the contested decision.

Treatment of complaints

The CB has the opportunity to express dissatisfaction with the services provided by NAB. Complaints are handled under the terms and conditions of NAB.

Information

NAB keeps individually informed the signatory CB of an accreditation agreement of any evolution of the accreditation requirements and, in general, contractual reference documents concerning them.

NAB should make available on its website:
- the reference documents, information and guidelines
- the national and international news bulletins related to accreditation,
- the list of accredited CB with the scope of their accreditation,
- the list of accreditation bodies co-signatories with NAB of mutual recognition agreements.

11.6.2 Obligations of accredited CB

By signing an agreement with NAB, the CB is committed to:

- offer NAB or its representatives all the necessary reasonable cooperation, including:
  - access to all its premises, personal, documents and records concerned by the request and useful for conducting evaluations;
  - the opportunity to attend activities for which accreditation is requested;
  - the information of the evaluators on the security provisions to be respected in the context of their mission and the provision, when necessary, of personal protective equipment;
  - the communication prior to the evaluation of the documentation necessary for the preparation of the intervention of the evaluation team;

- make the necessary arrangements with regard to its customers, through a contract or by any other equivalent means, in order to be able to impose the presence accreditation body evaluators during an audit within the CB. Failure to comply with this requirement is considered as non-compliance with NAB's requirements and treated as such.
- consider as confidential the information relating to the evaluators transmitted via the declarations of interest and do not use this information for its benefit or to the detriment of the evaluators;
- pay all costs related to the assessments, regardless of the conclusions they reach, as well as annual fees;
• to declare that it is accredited only for the services for which the accreditation was delivered to it;
• not to use its accreditation in such a way as to damage the reputation of NAB and make no statement relating to accreditation that NAB could reasonably consider to be misleading;
• ensure compliance with the rules of use of the NAB brand and the reference to accreditation by its own customers;
• inform NAB of any significant change in the structure, organization and resources that have been accredited.

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