



SAFE FOOD IN ACP  
A PROGRAMME FUNDED BY THE EU

HANDBOOK

6.6

TOPIC 6

6

# Self-Assessment Systems

SECTORIAL SELF-ASSESSMENT GUIDELINES



The handbooks are tools designed for civil servants in charge of restructuring the food safety system, and for all operators involved in drawing up the food safety policy and organising official controls (qualified civil servants, heads of laboratories, heads of departments in official organisations, those in charge of official controls, trainers, technicians, researchers, experts or company executives). They aim to provide an overview of the main points of a specific subject. All of the topics addressed by EDES during the training sessions are covered in separate handbooks.

The handbooks have been designed and drawn up by the EDES Training Unit in cooperation with the Consortium members.



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**EDES c/o COLEACP**

130, rue du Trône • B-1050 Brussels • Belgium  
 Tel : +32 (0)2 627 52 90 • Fax : +32 (0)2 627 52 99  
 Email : edes@coleacp.org  
[www.coleacp.org/edes](http://www.coleacp.org/edes)



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# 1. Good practices guides and the self-assessment guide

To guide producers, manufacturers and distributors, and to enable them to meet their hygiene obligations, the professionals of a sector (e.g., fruits and vegetables, meat, milk, chocolate, etc.) can work together to create a “Good Hygiene Practices Guide” specific to their activities and the risks of their sector.

Initially, this type of guide primarily brings together all of the hygiene rules applicable to the various steps of the food chain. Within the framework of European regulations on food security and food product hygiene (Regulations (EC) 178/2002 and 852/2004) and also including elements related to the systematic control of practices throughout the entire process, the concept of «Good Practices» has been extended to «self-assessment» in production.

The self-assessment guide is built on a “**sector risk analysis**”,<sup>1</sup> based on the identification of hazards relevant **for a given type of product** (e.g., meat production, milk production, flour manufacturing, plant production, etc.). In addition, it also includes: the bases of a production risk management system, the application of HAC-CP principles (recording of critical control points and their management), a proposal for a sampling plan made by the sector (type and number of samples to be taken each year and the analysis parameters deemed to be relevant: residues, heavy metals, micro-organisms, etc.), compulsory records and the notification procedure for the authorities in the event of non-compliance with standards.

## There should be a guide for each production “sector” because:

- There are different hazards tied to activities, processes, equipment, employees, the environment and the products.
- “Sensitivity” to contamination will depend to a large extent on the product but also on the local production and packing conditions.
- Operators active in the sector have **the best understanding** of the problems usually encountered.
- These operators are the best judges of which control measures will be **financially feasible for them**.

On one hand, the «sector self-assessment guides» are developed by professionals and evaluated by a committee of experts appointed by the authorities to ensure that the sector hazard analysis on which the guide is based is complete and that the measures are appropriate. On the other, once a guide has been validated, the authorities will verify its correct application at the sector level.

There are national guides available in Europe which can be found on the websites of national agencies (ANSES, AFSCA, etc.). There are also community guides developed at the European food sector level and published in the Official Journal of the European Union (C series).

<sup>1</sup> Defining a “sector” is not always as self-evident as it might seem. Work can involve one supply chain (e.g., coffee) or several at a time (e.g., “fruit and vegetables” or even “Fisheries products”). The important thing is to always maintain consistency of requirements throughout the various sector guides. The authorities must remain attentive to this point. There can be “overlapping” between the application fields of self-assessment guides: thus, there can be a “cocoa production guide” and also a “processing cocoa guide”.

**A self-assessment guide must:**

- Be valid for all companies in a channel (or «sector»)
- ...and be transferable to each company
- Provide **a sampling plan** based on a sector risk analysis
- Be **easy to use** by the companies concerned: understandable (illustrations, diagrams, etc.), easily applicable (detailed HACCP examples), accessible (distributed or sold by the sector)
- Be written and distributed by the different sectors or sub-sectors in **consultation with the representatives of the parties concerned...** whose interests can **really be affected**
- Be validated. The **reliability** of the guide comes from the **authorities**.

*The **general recommendations** for guide development are found in part B of Appendix 1 of **Regulation (EC) 852/2004**.*

## 2. Contents of the self-assessment guides

A sector guide is developed to assist small and large companies in the sector to comply with hygiene rules and to apply HACCP rules. This type of guide **must be practical, understandable**, even for poorly qualified operators and **illustrated with examples and real cases** to facilitate understanding and use. It must be a **reference document based on a solid scientific foundation**.

Concrete examples, including a hazard analysis, presented based on the HACCP approach can facilitate comprehension and application of the guide. However, it is often preferable to **prepare** a number of **training leaflets along with** the guide. These should be illustrated and simplified and targeted at each category of operator working on the production chain. For example, a first leaflet for small farmers, another one for collectors and a third for exporters.

An example of a **typical summary** of a self-assessment guide for the plant sector is presented below (e.g., self-assessment guide for mangoes prepared for Mali and Burkina Faso in 2009 by PCDA and PAFASP in collaboration with COLEACP) :

### Part one: General provisions of the guide

- Object and scope
  - Activities covered by the guide
  - Production and commercialisation procedures
  - Mango growing
  - Quality criteria
- Use of the guide
  - Guide users
  - Guide user instructions
  - Goal and relationship to legislation
  - Producer user instructions
  - Company control instructions
- Work groups and guide writing
  - Expertise
  - Work group make-up
  - Sector representativity
  - Concept of sector self-assessment guide
- Standards reference
  - National and European legislation
  - Other standards
- Terms, definitions and abbreviations
- Distribution, guide updating and access to the guide

### Part two: Risk analysis and general requirements for the sector

- General requirements for sanitary and phytosanitary quality
- Production process risk analysis
  - Production scheme
  - Hazard identification
  - Risk characterisation (scores)

- General hygiene requirements (self-assessment, GHP, HACCP)
  - Employees and third parties
  - Production site
  - Company and buildings
  - Machines, equipment and tools in contact with the product during pre- and post-harvest treatment
  - Boxes, containers, packing materials and box pallets
- Description of the growing techniques:
  - Crop management and GAP
  - Identification of harmful organisms
  - Pesticide treatments
  - Post-harvest treatments
  - Waste management
  - Operations control: *Checklist* of general guide requirements (major and minor requirements and recommendations)
- Traceability:
  - Identifications required
  - Records
  - Documentation

### **Part three: Non-conformity control and follow-up plan**

- Sampling plan
- General conditions:
  - Basis for a statistical approach for sampling
  - Sampling and analysis done by an independent third party
  - Creation of the sector sampling and analysis plan
  - Collection and use of results
- Controls to be carried out pre-harvest
- Sampling and controls to be carried post-harvest
- Notification procedure for the authorities:
  - Generalities
  - Overview of action limits (notification)
  - Blocking and recall procedures

### **Part four: Certification of the company self-assessment system**

- Framework and objectives of the certification
- Object and scope of application
- Inspection and audit procedures
- Conditions for independent certification organisations (ICO)
- Certification procedures
- Auditor/controller and producer obligations
- Sanctions



# 3. Recommendations for writing self-assessment guides

## 3.1. Generalities

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The guide presented must have a clearly indicated **version number** because only the version presented will be validated later.

Likewise, communication about the guide will refer to this number.

## 3.2. Defining the field of application

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Definitions:

- Activities covered by the guide (based on the complete process)
- Production, transport, commercialisation and other procedures
- Finished products (fresh fruit, dried fruit, vegetables, juices, preserves, etc.)

A single guide per field of application. A guide must clearly specify the activities, manufacturing and commercialisation processes and products it covers. This must be relevant to self-assessment.

A given field of application (same activities and/or same type of products) cannot be covered in separate guides.

However, based on social, economic or traditional factors, some cases can be considered as separate sub-sectors and separate guides will be authorised if the need can be justified.

## 3.3. Defining the expected use

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Specification of all potential users.

Directions for use, instructions, etc.:

- Goal
- Data included in the guide
- How the specifications pertain to legal requirements
- How to make practical use of the data

All **potential users** must be identified and defined.

It must be clearly stated for which (what type) of users the guide is intended. Only the specified users will use the guide. Potential users must understand the relevance to food and crop safety.

**The use of this guide** must be explained. **Directions for use** must motivate potential users to use the guide for their operations (for example, by attracting attention to certain aspects that encourage ease of use/application of the guide). They must indicate **the goal of the guide** within the context of legally required self-assessment.

Users must be made aware of the reasons for using the guide. The importance of self-assessment and of the **assumption of responsibility** tied to it must be clearly explained. Users who have been made aware of the objectives will put more goodwill into implementing, applying and maintaining their self-assessment system.



In addition to the goal, the recommendations/data contained in the guide must also be pointed out (a clear table of contents with a brief commentary describing the data contained in the guide). Users must be able to find their way around the guide easily.

Given that the guide will be used to meet legal requirements, it will be necessary to clearly state how the guide's provisions **relate to regulatory requirements**.

It is very important to explain how the recommendations can be put to practice. Therefore, a **step-by-step explanation of how users can use the guide to build their own self-assessment system** adapted to their company should be provided.

### 3.4. Appointment of the work group and consultation

The sector:

- Sector data
- Indicate representativity

The work group (composition):

- Names of the work group members
- Their position (chairman, observer, etc.)
- Their origin (home organisation)
- Their expertise (local and external experts)

The parties involved:

- List of all the parties affected by the writing/application of the guide
- The way in which all of the parties have been consulted

Guides must clearly mention **all professional associations** (with their names and contact information).

If the validation request is presented by a **coordinating organisation**, their name and contact information must be provided. In addition to the data for the coordinating organisation, data must also be provided for associated professional organisations (name, contact information and the field they represent).

The **level of representation** of the association(s) in the sector(s) in question must also be provided. Various parameters are used to demonstrate their representation. These include the number of companies (e.g. % of sector companies who are members of the professional association), the number of people employed, tonnage, revenues, etc. or a combination of this information. A reason must be provided as to why a given parameter was used to demonstrate representativity in the sector.

The **work group** tasked with developing and writing the guide must be **clearly identified**. The names of all of the members of the work group must be listed for this purpose. In addition to the name, the position (chairman, observer, etc.), origin (from which organisation) and expertise of each member must be provided.

**All parties taking part** in writing a guide must be listed in the guide along with the way in which they were consulted for its development (via the work group or some other way, in writing or via meetings, etc.). Therefore, parties not included in the work group but involved must be listed, and the way and extent to which they were involved must be described. Parties involved include producers, "facilitators", collectors, suppliers (seed, seedlings, inputs, etc.) and customers (including importers).

### 3.5. List the means used

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Description of the means and **expertise used**. The means (e.g., consultation in production areas) and expertise (local and external) called on to write the guide must be mentioned in the guide. For example: consultation with research and project centres and consulting companies, university studies, laboratory analyses (soil, water, residues, etc.), bibliographical references and other. Relevant URL's (internet site addresses) can also be an added plus for users.

### 3.6. Content recommendations

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Starting points and inclusion of expected users:

- The guide should be **adapted** to the expected users
- Notices about potential examples
- The starting point for writing must be, and take into account, the following:
  - A hazard analysis (based on HACCP)
  - Use codes recommended at the international level
  - Relevant legislation
  - All other relevant sources

The provisions of a guide **must be suited** to the expected users. The latter must be able to read, understand and **easily put the guide into practice**.

The guide should be written taking as its starting point and taking into account:

- A hazard analysis of activities, processes, equipment, employees, the environment and the products in question
- International codes recommended in the field of the products in question (e.g., those of the *Codex Alimentarius*)
- The various legislative and regulatory requirements (based on each market)
- All other relevant sources (e.g., scientific articles, the results of analyses to build a sampling plan).

**Hazard analysis and local, regional and European legislation are key compulsory elements.**

**Concrete examples** of the self-assessment system should be described in the guide. It must be clearly indicated that these are only examples and that a self-assessment system **must be created specifically for the company in question**.

For this purpose, the example should at least be preceded by the following warning - or a similar one: *"This example is provided for illustration purposes only. It can under no circumstances be used as is for a self-assessment system application in any given company."*

This point is quite critical because taking the examples without modification can, in fact, be assumed to mean that there is no effective self-assessment system.

All essential requirements for the following must be included:

- GAP (Good Agricultural Practices)
- GHP (Good Hygiene Practices)
- HACCP (Hazard Analysis and Critical Control Points): take into account **all** types of contamination hazards: biological, chemical and physical.

The provisions of the guide cannot simply paraphrase basic regulatory requirements. All key GAP (and therefore GPP<sup>2</sup>) requirements must be described and detailed in the guide. All key hygiene requirements must be **developed in detail in the guide's provisions**. The provisions and their application method must be suited to the various companies of the sector.

The guide must draw the attention of companies to a series of significant hazards, all the more so because the guide must be based on a hazard analysis and contain clear directives explaining to companies how to carry out an effective analysis based on the seven HACCP principles<sup>3</sup>. An HACCP example can be provided in the appendix.

The guide must take into account all types of product contamination hazards with respect to food safety (biological, chemical and physical hazards) even if they are theoretical only. Criticality (probability x severity) should be established on this basis.

Never simply paraphrase basic legal requirements).

#### Two particularly important points:

The following are found nowhere in local and international regulations:

- Interpretations
- Derogations
- Contradictions

The guidebook must contain all relevant information about:

- Food safety and product quality
- Traceability

Notification of the authorities and the management of non-conformities.

A guide is expected to explain to users how they can comply with legislation in matters of food safety. **The guide must contain a reference to relevant legislation for** each area of food safety covered. The way in which the company can meet the legal requirements must also be indicated.

In addition, a specific chapter containing an **inventory of relevant legislation** should be included. It must also be clear for the control body that all legal aspects (related to food safety) must be controlled (e.g., **provide a legislation checklist**). Insofar as aspects related to quality are covered in the guide, it is recommended (but not compulsory) that the legal reference be provided in this context (e.g., Codex standards).

Items related to food safety and traceability are compulsory. The guide must indicate how the link between incoming and outgoing products is made and at what minimum level the link must be set. In addition to this internal traceability, it is also important to provide techniques that must/can be used to prevent recording errors in the logs. Likewise, **notification** is compulsory item.

Quality-related items do not necessarily have to be covered in the guide, but it is **recommended**. Private international **standards** (for example, GLOBALG.A.P, BRC, IFS, etc.) are not “self-assessment guides” and can, therefore, not be validated as such by a national “food agency”. They are missing elements or contain elements that cannot be validated by this type of agency.

<sup>2</sup> GAP: Good Agricultural Practices, BPP: Good Phytosanitary Practices

<sup>3</sup> See handbook No. 6.2 – HACCP Method: principles and implementation.

### 3.7. Requirements for external control bodies

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Description of the rules for certified control bodies:

- Reference standards for accreditation;
- A certification system with certification rules (including the frequency and extent of audits);
- An inspection system with the frequency of inspections;
- Documentation on quality, records, and technical aspects which must, at a minimum, be checked by the auditors/inspectors;
- The rules for product sampling and analysis;
- The minimum number of hours/workdays to be applied;
- The minimum contents of reports;
- Qualifications required for inspectors and auditors.

Given that application of the guide and compliance with its requirements may be carried out by external bodies, the guide must also **mention the accreditation standard** the inspection or certification body potentially involved is associated with (reference standard EN 45004, EN 45011 or EN 45012 or the ISO 17000 series). The final decision must be documented.

The certification rules to be applied in a certification system must be defined (they will, notably, include the delivery of certificates, including monitoring of the certificates delivered, user obligations, etc.) and include the frequency and extent of audits.

The **frequency of inspections** must be defined in an inspection system. Documentation on quality, records and technical aspects which must, at a minimum, be controlled by auditors/inspectors must also be specified. The minimum content of inspection reports must be defined, taking its recipients into account.

Rules for **sampling and product analysis** must be covered. This will range from methods and frequencies to the way in which operations are organised.

In order to be able to properly carry out the audit/inspection, directives on the minimum time auditors/inspectors (number of hours or days of work, depending on volume and activity) must spend in the company to review application of the guide must be written. These data must be written in a way that removes any possibility for interpretation.

The setting of requirements for **inspector/auditor** qualifications will be of particular importance!

**Along with the content of the guide, the competence of the auditors will determine the value of the self-assessment system implemented.**

Among the skills that can be required are basic qualifications, training (for example in HACCP), experience in the sector, number of years of work experience and in auditing (in this type of production sector).

### 3.8. Directives for layout

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The contents of the guide must be:

- Accessible to producers
- Clear
- Coherent
- Logical

All aspects of the guide must be presented in a clear, coherent and logical way. This will all impact the ease of use of the guide. A great deal of thought must therefore be given to the **layout of the guide** (illustrations, photos, etc.) and to the language used.

### 3.9. Distribution

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The conditions under which the guide will be available. The guide must also list the conditions under which it is available. It must be available to any person whose interest in the guide is reasonable. Following validation, the guide should be made available on the Internet.









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## Handbook Topics

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- 2 Regulations and Standards
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