"Setting up a network of Technology Dissemination Centres to optimise SMEs in the olive and olive oil sector".

OLIVE SECTOR RELATED EUROPEAN LEGISLATION AND HACCP

Index

This booklet has been written to help producers/ consumers of olives and olive oil across Europe.

"The olive encyclopaedia is a collection of 12 publications part of the project **TDC-OLIVE** which aim is to collect the information related to the olive sector and make it accessible to the interested public".

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TDC OLIVE

Introduction

TDC-OLIVE project is an initiative included in the Sixth Framework Programme of the European Union, aimed to table olive and olive oil SMEs. Its main target is the creation of a physical and virtual network of Technology Dissemination Centres (TDC) as means of support to enterprises of this sector, as well as a bridge between them and Research and Development institutions. TDC Olive pretends to:

✓ Achieve a modern SME, with qualified staff, that employs new technologies in order to access information and, in general, to implement technological innovation systems.

✓ Achieve an SME committed to the optimisation of the product quality and to the treatment, recycling and reuse of all the wastes generated in its activity.

Since Mediterranean olive oil and table olive producers (particularly SMEs ones) need to modernize and to increase their competitiveness, TDCs aim to accelerate the necessary technology innovation process of SMEs by establishing a training program and by providing updated information in those topics of interest for SMEs. Simultaneously, TDCs will carry out a series of actions and promotion activities in order to achieve a certain change of mentality in central and northern European consumers, thus an increase in the consumption of olive oil and table olives.

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European legislation affecting olive industry

In order to understand the sources of European legislation it is important to know that it can be classified as primary legislation- **Treaties** - and secondary legislation- **Laws**. Treaties establish the objectives and lay down the powers of the EU institutions. The two main sources of secondary legislation are **Directives** and **Regulations**. Most legislation is in the form of Directives, which set common objectives and deadlines for Member States to implement through the enforcement of appropriate national legislation. Conversely, Regulations have direct applicability, which means they do not have to be transformed into domestic law. They confer rights and impose duties directly on all citizens of the Union.

The olive oil and table olives industries have to comply with all European legislation in force for food industries and with the specific one for the sector. A general review of most important legislations affecting food industries and the specific ones affecting the olive industry, including environmental legislation, is presented below.

General European legislation affecting food industry

- *Council Directive 93/43 EEC on the Hygiene of Foodstuffs* that lays down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules. It states that the preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs shall be carried out in a hygienic way. Systems of HACCP (hazard analysis and critical points control) should be developed.
- *Council Directive 95/2/EC on Food Additives Other Than Colours and Sweetener*. It applies to additives other than colours, sweeteners and flour treatment agents, such as preservatives, antioxidants, carriers, acids, acidity regulators, anti-caking agents, anti-foaming agents, bulking agents, emulsifiers, emulsifying salts, firming agents, flavour enhancers, foaming agents, gelling agents *hu*mectants, modified starches, packaging gases, propellants, raising agents, sequestrants, stabilizers and thickeners.
- *Council Directive 89/391 on the introduction of measures to encourage improvements in the safety and health of workers at work* to ensure a higher degree of protection of workers at work through the implementation of preventive measures to guard against accidents at work and occupational diseases, and through the information, consultation, balanced participation and training of workers and their representatives.
- *Council Directive 2000/13/EC on the Approximations of the Laws in Member States on labelling, presentation and advertising of foodstuffs.* The Directive applies to foodstuffs for consumer delivery as well as for mass caterers and states general terms to be used in the different Member States labelling procedures. Its Annex I listing categories of ingredients has been amended by Directive 2001/101.
- *Council Regulation 178/2002 laying down General Principles and Requirements of Food Law.* This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures for decision-making in food. It also establishes the European Food Safety Authority.
- *Council Regulation 2200/96 on the Common Organisation of the Market in Fruit and Vegetables.* It sets up a common organisation of the market in fruit and vegetables.

European environmental legislation

- *Council Directive 96/61/EC concerning integrated pollution prevention and control,* better known as the IPPC-Directive, sets out measures to prevent, reduce and eliminate pollution at the source of the pollutant and to ensure sensible management of natural resources. These provisions should enable a move towards a sustainable balance between human activity and the environment's resources and regenerative capacity. The overall aim of this directive is to bring about accountability through the "polluter pays principle".
- *Council Directive 75/439/EEC on the disposal of waste oils*, former Directive 75/439/EEC as amended by Directive 87/101/EEC and Directive 91/692/EEC provides measures to ensure that waste oils are collected and disposed of without causing any avoidable damage to man and to the environment.

- *Council Directive 75/442/EEC on waste* constitutes the legal framework for Community policy on waste management to limit its production. After entering into force in 1977 it was amended by the Waste Framework Directive 91/156/EEC in order to incorporate the guidelines set out in the Community Strategy for Waste Management in 1989.
- *Council Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community,* amended by Council Directive 90/656/EEC and Council Directive 91/692/EEC, applies to inland surface water, territorial waters, internal coastal waters and groundwater.
- *Council Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances.* Further amended by Council Directive 90/565/EEC and Council Directive 91/692/EEC. Their purpose of these Directives is to prevent the discharge of certain toxic, persistent and bio-accumulable substances into groundwater.
- *Waste Framework Directive 91/156/EEC.* This Council Directive is an amendment of the Directive 75/442/EEC on Waste and sets out the legislative framework for waste at the Community level.
- *Council Directive 1999/31/EC on the landfill of waste.* The Council Resolution on waste policy (7 May 1990) welcomes and supports the Community strategy document and invites the Commission to propose criteria and standards for the disposal of waste by landfill. In preference to landfill use, the prevention, recycling and recovery of waste should be encouraged as should the use of recovered materials and energy so as to safeguard natural resources and obviate wasteful use of land. Further consideration should be given to the issues of incineration of municipal and non-hazardous waste, composting, bio-methanisation and the process of dredging sludge.
- *Water Framework Directive 2000/60/EC.* Amended by Decision No 2455/2001/EC of the European Parliament and the Council, of 20 November 2001 [Official Journal L 331, 15.12.2001]. Under this Directive, Member States have to identify all the river basins lying within their national territory and assign them to individual river basin districts. River basins covering the territory of more than one Member State will be assigned to an international river basin district. By 22 December 2003 at the latest, a competent authority will be designated for each of the river basin districts.
- *Council Directive 2000/76/EC on the incineration of waste.* The fifth Environment Action Programme: Towards Sustainability, sets as an objective that critical loads and levels of certain pollutants such as nitrogen oxides (NOx), sulphur dioxide (SO2), heavy metals and dioxins should not be exceeded. In terms of air quality the objective is that all people should be effectively protected against recognised health risks from air pollution. The Programme further sets as an objective a 90% reduction of dioxin emissions by 2005 (1985 level) and at least a 70% reduction from all pathways of cadmium, mercury and lead emissions from 1995.

Specific European legislation affecting olive industry

- *Council regulation 136/66/EEC on the establishment of a common organisation of the market in oils and fats*
- *Commission regulation 616/72/EEC on detailed rules for the application of export refund and levies on olive oil* (UPDATED)
- *Council Regulation 154/75/EEC on the establishment of a register of olive cultivation in the Member States producing olive oil*
- *Commission Regulation 2960/77/EEC on detailed rules for the sale of olive oil held by intervention agencies*
- *Council Regulation 1562/78/EEC amending Regulation No 136/66/EEC on the establishment of a common organization of the market in oils and fats*
- *Commission Regulation 3130/78/EEC determining intervention centres for olive oil*
- *Commission Regulation 3136/78/EEC laying down detailed rules for fixing the import levy on olive oil by tender*
- *Commission Regulation 1963/79/EEC laying down detailed rules for the application of the production refund on olive oil used in the manufacture of certain preserved foods*
- *Council Regulation 1413/82/EEC amending Regulation No 136/66/EEC on the establishment of a common organization of the market in oils and fats*

- *Council Regulation 2261/84/EEC laying down general rules on the granting of aid for the production of olive oil and of aid to olive oil producer organizations*
- *Council Regulation 2262/84/EEC laying down special measures in respect of olive oil*
- *Commission Regulation 27/85/EEC laying down detailed rules for the application of Regulation 2262/84/EEC laying down special measures in respect of olive oil*
- *Commission Regulation 3472/85/EEC on the buying-in and storage of olive oil by intervention agencies*
- *Council Regulation 1915/87/EEC amending Regulation 136/66/EEC on the establishment of a common organization of the market in oils and fats.*
- *Council Regulation 2658/87/EEC on the tariff and statistical nomenclature and on the Common Customs Tariff*
- *Commission Regulation 2568/91/EEC on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis*
- *Commission Regulation 183/93/EEC amending Regulation 2568/91/EEC on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis*
- *Commission Regulation 1476/95/EC laying down special detailed rules for the application of the system of import licences for olive oil*
- *Commission Regulation 2543/95/EC of laying down special detailed rules for the application of the system of export licences for olive oil*
- *Commission Regulation 2138/97/EC delimiting the homogenous olive oil production zones*
- *Council Regulation 2008/97/EC laying down certain rules for the application of the special arrangements for imports of olive oil and certain other agricultural products originating in Turkey*
- *Council Regulation 1638/98/EC amending Regulation 136/66/EEC on the establishment of a common organisation of the market in oils and fats*
- *Commission Regulation 2366/98/EC laying down detailed rules for the application of the system of production aid for olive oil for the 1998/1999, 1999/2000, 2000/01, 2001/02, 2002/03 and 2003/04 marketing years*
- *Commission Regulation 2768/98/EC on the aid scheme for the private storage of olive oil*
- *Commission Regulation 528/1999/EC laying down measures to improve the quality of olive oil and table olive production*
- *Council Regulation 1513/2001/EC of amending Regulations 136/66/EEC and 1638/98/EC as regards the extension of the period of validity of the aid scheme and the quality strategy for olive oil.* The Annex includes the descriptions and definitions of olive oils and olive-pomace oils.
- *Commission Decision of 9 August 2001 on the granting of aid for the production of table olives in France (*notified under document number C(2001) 2486) (Only the French text is authentic) (2001/648/EC)
- *Commission Decision of 9 August 2001 on the granting of aid for the production of table olives in Greece* (notified under document number C(2001) 2487) (Only the Greek text is authentic) (2001/649/EC)
- *Commission Decision of 9 August 2001 on the granting of aid for the production of table olives in Spain* (notified under document number C(2001) 2488) (Only the Spanish text is authentic) (2001/650/EC)
- *Commission Decision of 10 August 2001 on the granting of aid for the production of table olives in Italy* (notified under document number C(2001) 2492) (Only the Italian version is authentic) (2001/658/EC)
- *Commission Decision of 10 August 2001 on the granting of aid for the production of table olives in Portugal* (notified under document number C(2001) 2491) (Only the Portuguese text is authentic) (2001/670/EC)
- *Commission Regulation 312/2001/EC laying down detailed rules of application for the importation of olive oil originating in Tunisia and derogating from certain provisions of Regulations 1476/95/EC and 1291/2000/EC*
- *Commission Regulation 327/2001/EC authorising the conclusion of private storage contracts for olive oil and opening an invitation to tender for a limited period for aid relating thereto*
- *Commission Regulation 796/20027EC amending Regulation 2568/91/EEC on the characteristics of olive oil and olive-pomace oil and on the relevant*

methods of analysis and the additional notes in the Annex to Council Regulation 2658/87/EEC on the tariff and statistical nomenclature and on the Common Customs Tariff.

- *Commission Regulation 1019/2002/EC on marketing standards for olive oil*
- *Commission Regulation 1334/2002/EC laying down detailed rules for the application of Council Regulation 1638/98/EC as regards the work programmes of operators organisations in the olive sector for the marketing years 2002/03 and 2003/04*
- *Commission Regulation 1964/2002/EC amending Regulation 1019/2002/EC on marketing standards for olive oil*
- *Commission Regulation 1176/2003/EC amending Regulation 1019/2002/EC on marketing standards for olive oil*
- *Commission Regulation 1432/2004/EC of amending Regulations 2366/98/EC laying down detailed rules for the application of the system of production aid for olive oil for the 1998/99 to 2003/04 marketing years and 2768/98/EC on the aid scheme for the private storage of olive oil*
- *Council Regulation 864/2004/EC amending Regulation 1782/2003/EC establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers, and adapting it by reason of the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia to the European Union*
- *Council Regulation 865/2004/EC on the common organisation of the market in olive oil and table olives and amending Regulation 827/68/EEC*

Quality

Introduction

What is quality? This is a multifaceted question, difficult to address in the abstract. A very good sentence, which synthesises the evolution of the concept of quality in the last years, could be: “from the obsession for selling to the passion for the customer”.

An official definition of quality, commonly accepted is:

Quality: *is the totality of features and characteristics of a product or service that bear upon its ability to satisfy stated or implied needs.*

This highlights that the service must satisfy a given need, and that is the need of the customer. Quality is providing a product or service that is "Fit for the Purpose". In many areas the popular choice of purchase is not the cheapest but it is chosen because its quality and reliability are perceived by the customer as being the best value for money.

Quality could therefore include:

- Knowing the customer's needs
- Designing to meet them
- Reliable bought-in equipment and materials
- Clear and precise instructions
- Punctual delivery
- Faultless production
- Effective support services
- Feedback of field experience

It is very important to distinguish the concept of quality from the quality assurance, which can be defined as follows:

Quality assurance: *are all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.*

The mentioned requirements are those specified by the customer, or for the purposes of external recognition, those specified by the Standard for Quality Systems, e.g. ISO9000.

ISO9000 specifies the minimum requirements for a Quality Assurance system; this can be extended to achieve greater improvements in efficiency and profitability by "Cost Effective Quality Management".

Quality assurance is therefore designed to aid reduction of avoidable costs and satisfy given needs, however this must be achieved in such a way as to maximise profits.

Some olive oil and table olive producers have already established integral quality systems in their companies. In these systems is included the hygienic quality represented by the self-control systems based on the HACCP imposed by the administrations (more information is given in chapter 3). But also they are certified in quality systems based in international - ISO- European –EN- or national level -e.g. UNE (Spain)-, and accredited through well known accrediting bodies.

The most exigent producers protect their brands and ways of elaborating through other guarantees of quality: DOP (Denomination of Protected Origin), IGP (Protected Geographic Indication), ETG (Environmental Technology Group), Ecological Agriculture, etc. The consumer wants to know all these quality measures and also which are the brands that offer them and those which do not. And which price is to be paid for that.

Quality assurance

Quality Assurance is repeating good performance on every contract by the use of a system of documented procedures, which are known, understood and operated by all personnel. These procedures are used when no other criteria are specified by the customer. Obviously, customer specified criteria must take precedence if satisfaction is to be achieved and, in these circumstances, a degree of liability is assumed by the customer.

Quality Assurance has developed over a long period from more traditional Quality Control activities like final inspection and test. If an item is rejected at the final stage of a process it represents a large investment, which cannot be sold to the customer, and rectification at this stage is expensive, difficult, and fully visible to the customer.

Quality Assurance (QA) offers control at each stage of the process such that it becomes very difficult to create a reject. If faults exist, they are identified and corrected prior to any further value being added.

✓ **Why is quality assurance necessary?**

Because an increasing number of customers require assurance that products, systems and services are provided to a suitable definitive standard by modern quality means, even if the customer has good previous experience with the company.

The list of customers who require QA Registration is growing rapidly, and in the near future it is probable that only those companies with certification or registration e.g. to ISO9000 will be eligible to tender in certain business sectors.

Certification means that companies have been examined, and found to have an effective management system, which is capable of consistent performance. This examination is conducted against a published standard known throughout the world as ISO (International Standard) 9000 series.

Therefore, the benefits of having a QA fall into two distinct categories. Firstly the marketing benefits of becoming a Registered or Certified company, as a demonstration to all customers (and potential customers) that the company has a consistent quality management system, and on the other hand, the internal benefits in increased efficiency and productivity.

✓ **How does a company achieve Registration?**

The primary requirement is that the company has a consistent management system, including a degree of consistent performance resulting from its employees, and the training they receive. QA requires the use of a set of documented procedures containing the "best practice" of the company, and available to all personnel as a single source of reference.

If an individual is to be encouraged to use a procedure for reference, the procedure needs to be understandable, simple and available. A good example is a recipe. This normally contains simple instructions, and is more usable if it contains a photograph of the finished article, enabling to perform a complex process, producing consistently good product, time and time again.

✓ **What are the requirements of ISO9000?**

The requirements are sound common sense. Systems would be required for customer related activities, e.g.:

- *Contract Review* -ensuring that the customer's needs are correctly identified
- *Document Control* -ensuring that staff are issued with the correct versions of documentation (including software) needed to perform the task; and removing obsolete documents
- *Purchasing* -ensuring identity of preferred suppliers; and a system for advising them of what is expected to be supplied
- *Training* -ensuring that training needs are identified; and records of who has been trained, in which topics
- *Non-conformance* -documenting errors and ensuring that they are corrected
- *Corrective Action* -preventing errors from recurring

The standard does not specify what the systems should be it only clarifies that certain systems should exist. The nature of the system is developed by the company to suit its own needs, as simply and effectively as possible.

✓ **Who performs the examination?**

This is undertaken by one of many Registration Bodies. These are independent bodies established to assess company management systems to ISO9000. They employ *assessors* or *auditors*, who are registered under a national recognition scheme.

✓ **What is the process of Registration?**

Once a Registration Body has been chosen, the company's procedures are reviewed (by an auditor) for compliance to ISO9000. This results in a report confirming compliance, or highlighting areas where further clarification is required.

The final stage is for auditors to visit the company in order to check that its operations are in accordance with its procedures. If some items are not working correctly, these will be documented as *discrepancies* or *non-compliances*, for correction by the company. Whether a company succeeds at the first attempt will depend upon the nature of the discrepancies raised (not necessarily on the quantity).

Once Registration is achieved, the auditors will return, normally twice per year, for routine surveillance visits. These brief examinations ensure that the management system continues to operate effectively.

✓ **What are the costs and timescales involved?**

The timescale is decided by the company; it may be as short as 3 months, or as long as many years. Speed is a positive benefit as it can develop a momentum of its own, making any change easier to achieve.

Costs split into 3 main categories:

- *Company:* this is the cost of time spent by company personnel
- *Consultant:* it is common to use a consultant to help with development and implementation of a quality management system, as this may achieve the objectives more cheaply, effectively or rapidly.
- *Registration:* this cost is variable depending upon the choice of Registration Body. There are now approximately 120 Registration Bodies throughout the world. All of them operate in similar fashion, however their prices and operating timescales differ widely.

Documented Quality system

ISO9000 requires the development of a documented quality system describing the policies and operations of a company. This provides an accurate description of the organization and advice on the "best practice" adopted in order to consistently satisfy customer expectations. A documented quality system would commonly consist of a number of levels (or tiers) of documentation as represented in figure 1.

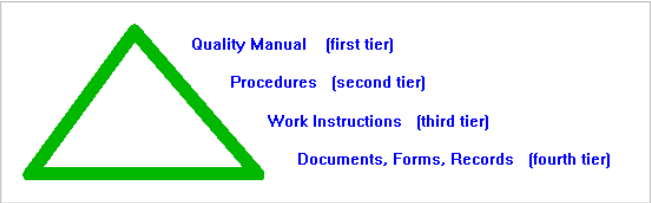


Figure 1: levels of documented quality system

Independent Registration to ISO 9000 is achieved when the Company has a documented quality system, which addresses each clause of ISO 9000, and the procedures can be demonstrated to work in practice. The registration process is summarised in figure 2:

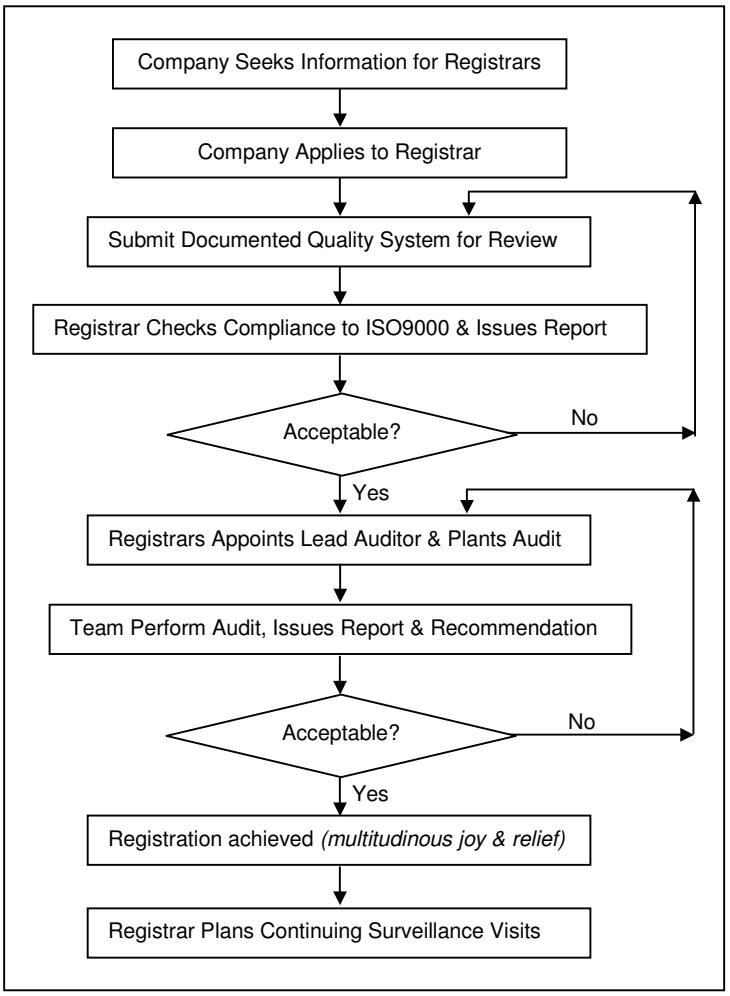


Figure 2: Registration process

- **Quality Manual**

This document normally describes the policy, organisation and responsibilities of the organisation. It would also commonly contain a brief policy statement on each of the individual clause requirements of ISO 9000

- **Procedures**

These documents describe the processes of the organization, and the best practice to achieve success in those processes. It is a good idea to ensure that the procedures answer the following questions about each process:

Why?	*Who?*	*When?*	*Where?*	*What?*	*How?*

- **Work Instructions**

These documents normally describe a sub-process in some detail, answering one of the above questions (e.g. what or how).

- **Documents**

These are the items completed while undertaking the process, forming a means of communication and a record of events. There are no "hard and fast" rules for the production of quality system documents. Compliance to ISO 9000 should be found in the documented quality system; not solely in the quality manual.

Design of the system can be difficult as, above all else, it must also be useable. It is possible to document every facet of a process in great detail. The resulting document will be so large that staff do not want to use it because it appears difficult to find the precise information required, and it is so full of details that are already known to the *expert* doing the job.

The art is to reduce the content to that which is really useful to the staff, and to omit that which is already known to all.

***Example**: the vast majority of adults know how to drive a car, they have been taught in the past and transfer the skills from one vehicle to another without ever looking at a procedure! This is fine until something unexpected happens, when a drivers' manual is consulted for advice.*

HACCP

Introduction

HACCP (Hazard Analysis and Critical Control Point), is a prevention-based food safety system, designed to prevent the occurrence of potential food safety problems in all of the steps of the food chain, from the raw material to the distribution and final consumption by the consumers. Through this system specific food borne hazards -biological, chemical and physical- that can negatively affect the safety of the food products, are identified and monitored.

The identification of the hazards is the basis for establishing the critical control points (CCPs) in the process. CCPs are those points in the process that must be controlled to ensure the safety of the food. Next, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to ensure that potential risks are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan. Seven are the principles developed by the National Advisory Committee on Microbiological Criteria for Food (NACMCF) for the HACCP system to guide in the development of an effective HACCP plan. These principles are:

1. *Analyze hazards*
2. *Identify critical control points (CCPs)*
3. *Establish preventive measures with critical limits for each control point*
4. *Establish procedures to monitor the critical control points*
5. *Establish corrective actions to be taken when monitoring shows that the critical limit has not been met*
6. *Establish procedures to verify that the system is working properly*
7. *Establish effective record keeping to document the HACCP system*

The **Council Directive 93/43/ECC** sets out the hygiene standards to ensure food safety throughout Europe and establishes HACCP as a legal requirement for all food companies. The importance of the use of hazard analysis, risk assessment and other management techniques to identify, control and monitor critical points is recognised in this Directive and it establishes that *"food business operators shall*

identify any step in their activities which is critical to ensure food safety and that adequate safe procedures are identified, implemented, maintained and reviewed on the basis of the HACCP principles". In the same way, the Council Directive 93/43/EEC establishes that *food business operators are responsible for the hygienic conditions in their food business*. In addition, **the Codex Alimentarious Commission adopted HACCP in 1997 as the international standard of food** safety. Therefore, HACCP has becoming the most important system used to ensure food safety worldwide.

Why HACCP?

Several factors influence in the necessity of a system to ensure food safety. One of the most relevant ones is the high increased in the number of food industries in the last years and the development a wide range of new products. This has lead in an increasing of exports of these products together with the risk of contamination of the food due to the lack of controls and/or the lack of homogeneity in the food safe systems used worldwide. In addition, there have appeared recently new food pathogens that can cause serious damages to the health of the consumers, which were unknown and not controlled by the methods normally used.

The traditional methods to ensure food safety have depended on spot-checks of manufacturing conditions and random sampling for microbiological analysis of final products. This approach is more reactive than preventive and seems to be less efficient, only when something happened this could be detected. These traditional methods imply several disadvantages such as:

- *Need of taking a huge number of samples what involves economical and time investment.*
- *In case of a problem, the whole batch has to be discharged*
- *Responsibility always falls on the boss even is the problem comes from the use of unsafe raw materials.*
- *Subjective evaluation without record keeping.*
- *There is no systematic record keeping of process parameters that can be presented in case of inspection.*
- *If a problem occurs once the product is commercialised, the company with loose the confidence of the consumers in addition to the health damages that it problem could produce.*

Apart from the factors already mentioned, recent food scandals at worldwide level have contribute to a greater awareness of the consumers on the importance of a system that assures the safety of foods.

HACCP brings to the control of food safety several advantages that solve almost completely the problems listed above. HACCP most importantly:

- *focuses on identifying and preventing hazards from contaminated food,*
- *is based on sound science,*
- *makes possible a more efficient and effective government oversight,*
- *places responsibility for ensuring for ensuring food safety appropriately on the food manufacturer or distributor,*
- *helps food companies to be more competitive,*
- *reduces barriers for international trade.*

In addition to the advantages, it is important to remind that HACCP is a legal requirement in Europe since the Directive 93/43/EEC is in force. And, if a company wants to implement a quality system following the UNE-EN-ISO 9001:2000 norms, it obliges to include HACCP in the quality management system of the company.

Definitions

To understand clearly about the development and implementation of a HACCP system, it is important to clarify from the very beginning some terms that are very often used. These terms are:

- ***Acceptable level****:* the presence of a hazard, which does not pose the likelihood of causing an unacceptable health risk.
- ***Control****:* to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan
- ***Control point****:* any point in a specific food system at which loss of control does not lead to an unacceptable health risk.
- ***Critical control point (CCP):*** a step at which control can be applied and is essential to prevent or eliminate an unacceptable health risk derived of a hazard, or reduce it to acceptable level.

- ***Critical limit:*** a criterion (maximum or minimum value), which separates acceptability from unacceptability.
- ***Deviation:*** failure to meet a required critical limit for a critical control point.
- ***HACCP:*** a system which identifies, evaluates and controls hazards which are significant for food safety
- ***HACCP plan:*** a document that delineates the formal procedures for following the HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods. (NACMCF developed the seven principles of the HACCP)
- ***Hazard:*** a biological, chemical, or physical property that may cause an unacceptable consumer health risk.
- ***Monitoring:*** a planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety.
- ***Preventive measure:*** an action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.
- ***Risk:*** an estimate of the likely occurrence of a hazard.
- ***Verification:*** the application of methods, procedures, and tests to determine if the HACCP system in use is in compliance with the HACCP plan.
- ***Validation*****:** obtaining evidence that the elements of the HACCP plan are effective.
- ***Step:*** a point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.
- ***Flow diagram:*** systematic representation of the steps for the production of the food product under study.

HACCP implementation

Pre-requisite programs

The implementation of the HACCP system should be preceded by compliance of a number of requisites included in the "Recommended International Code of Practise, General Principles of Food Hygiene of the Codex Alimentarius", as also established in the Council Directive 93/43/EEC.

These pre-requisites programs were proposed by the NACMCF and are not included in the HACCP plan but should be implemented in all food industries to ensure the safety of their food products. They represent all the programs, procedures and practices that must be applied to produce safe products in a clean and sanitary environment. The compliance of these pre-requisites programs has been traditionally carried out by applying the Good Manufacturing Practices (GMP) and Food Hygiene Practices, being essential for the implementation of a successful HACCP.

Therefore, HACCP system is only a part of a large control system and pre-requisite programs are the universal procedures to control the conditions in the industry that contribute to the overall safety of the food product. During the design and the implementation of the HACCP plan, the existence and effectiveness of the pre-requisites programs should be revised.
These pre-requisites programs refer, mainly but not exclusively, to the following aspects:

- Building and equipment design according to sanitary principles.
- Maintenance plan for monitoring the appropriateness of the installations and production equipment according to sanitary design principles.
- Prevention of cross-contamination from unsanitary objects and/or practices to food products, packaging materials and other food contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product. Also to prevent cross-contamination with residues and wastes and to ensure compliance with the legislation.
- Control of potable water to ensure the safety of the water that comes into contact with food or food contact surface.
- Personal hygiene, maintenance of hand washing, hand sanitising and toilet facilities. It should be included into the Food Hygiene Practice plan.
- Control of all suppliers to work always with certified ones that provide specifications of every product and certificate of analysis for each delivery. It should exist an annual suppliers audit.
- Quality control of the product: from the raw materials to the final product. It must include chemical, biological and physical analyses.
- Process control, including all parameters related to each specific step must be established and controlled (T°, time, …).

- Control of packaging process and packaging materials to ensure that the manipulation of the packaged product and packaging material prevents damage from occurring. Packaging material for food purposes must be used.
- Proper labelling of any product stored and mainly of the chemical products used for cleaning in order to avoid cross-contamination.
- Cleaning, sanitising and pest control plan of all establishment and procedures. It should include conditions and cleanliness of food contact surfaces.
- Control of the reception, storage and transport conditions: time, temperature and any parameter, which might be dangerous for the safety of product, raw material and ingredients.
- Personnel training including PPs, cleaning and sanitation procedures, personal hygiene and safety (Food Hygiene Practice) and principles of the HACCP system.
- Maintenance of traceability in the whole chain. It is necessary for a quick response if any sanitary problem occurs and the product must be brought out from the market; and also to find out the source of the problem. In order to ensure the traceability, all products should be lot-coded and a recall system should be taken in place.
- Maintenance of records for all these procedures. It must be appropriate recorded and written; monitored and corrective actions must be established. There should also be specifications for all ingredients, products and packaging materials.

The application of these PPs is very important in order to prevent the most common hazards. Then, the HACCP can be implemented and it is used to prevent hazards which cannot be e*ffectively* avoided only with the implementation of PPs and which are closely related to the production process.

Preliminary tasks and HACCP principles

In addition to the pre-requisites mentioned above, five preliminary tasks should take place before the application of the HACCP principles to make easier and clearer the implementation of the HACCP system. In the following figure (figure 3) the 12 steps for the implementation of the HACCP system, the five preliminary tasks and the seven HACCP principles, are represented in a logic sequence.

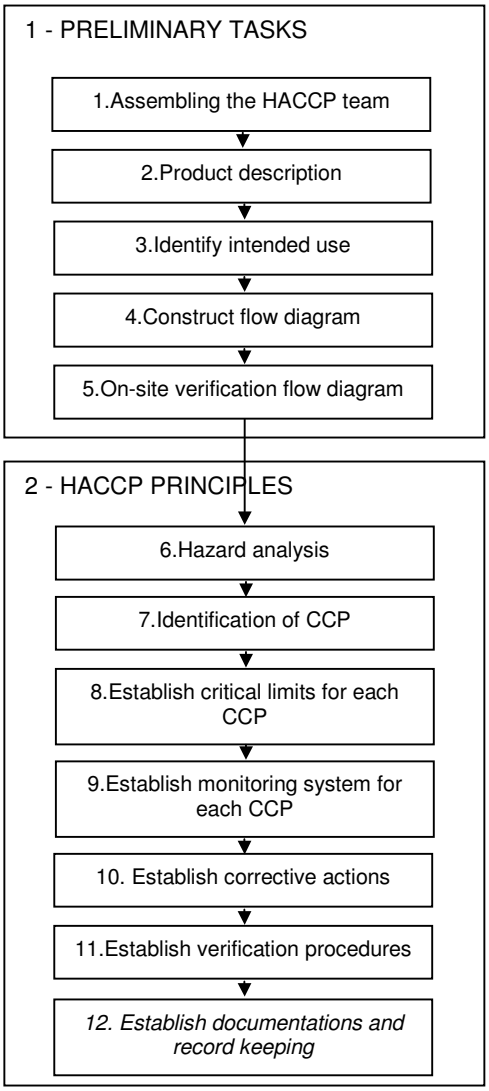


Figure 3: Logic sequence of preliminary tasks and HACCP principles

All tasks and principles to implement the HACCP system successfully are explained in detail below:

Task 1: Assembling of the HACCP team

The company should ensure that the HACCP team is formed by workers that have specific knowledge and appropriate expertise about the product and the process, in order to develop an effective HACCP plan. It means a multidisciplinary team is needed including plant operators, maintenance, logistic, marketing and quality and HACCP experts. If such as staff is not available in the company, experts should be contracted from outside. Moreover, a team leader should be nominated in order to ensure the coordination of the

work for the successful development in the implementation of the HACCP system. The scope of the HACCP plan to be develop should be defined, the steps of the production involved and the types of hazards to be addressed.

It is very important that all personnel involved, direct or indirectly, in the product chain should be also informed and even trained in the HACCP system. It has no sense to implement an HACCP plan if the operators have no knowledge of it and are not aware of the importance of the food safety and hygiene. The personnel training is essential.

Task 2: Product description

The HACCP team have to make an exhaustive product description including all ingredients, the processing steps, packaging material used, etc. The detailed information about the product formulation is necessary to identify all potential hazards affecting the selected product.

The product description must ensure a good understanding of the product to be studied by the HACCP team and should be as short as possible but containing the most important information about of the production chain and the raw materials used.

The templates given (table 1 and table 2) by FAO for the product description are the following:

Table 1: Product description form

1. Product name(s)	Bottled Extra Virgin Olive Oil
2. Important product characteristics of end product (e.g. A_w, pH, etc)	pH
	Aw
	acidity
3. How the product is to be used	Normally raw as dressing for salads and to eat with bread. It can be also consumed heated, use for frying.
4. Packaging	plastic bottles (PET)
5. Shelf-life	1 year
6. Where the product will be sold	In any type of supermarkets for all type of consumers
7. Labelling instructions	Not required to ensure product safety
8. Special distribution control	Preserve in a cold and dry place. Avoid direct light.
DATE: _____APPROVED BY: _____	

Table 2: product ingredients and incoming materials

Product name(s)	Bottled Extra virgin Olive oil
Raw materials	Olives
Packaging materials	Plastic bottles (PET)
Additives	-
Others	-
DATE: _____APPROVED BY: _____	

Another way of describing the product is given as follows for Pasteurised olive filled with anchovies

Pasteurised olive filled with anchovies: *these type of preserves are produced from fermented olives, sevillian style, whose pit is remove and the anchovies paste together with thickeners to avoid disintegration, is injected in the remaining hole. Acidulated water is added and are packed in hermetic cans and treated terminally (pasteurisation) to ensure the preservation of the product.*

The product is produced for consumption of consumers in general.

The raw materials, ingredients and packaging materials used for the production are:

- *Olives*
- *Water*
- *Salt*
- *Anchovies paste*
- *Lactic, citric and ascorbic acid*
- *Tin cans*

The HACCP team could add any parameters to the description, which are considered important. The fact is that all the characteristics of the product must be taken in account to ensure that it is completely safe.

Task 3: Identify intended use

The intended use refers to the normal use of the product by the consumers, but also has to be defined where it is going to be sold and the target groups to whom it is destined.

It is important to define the target consumers very well since it will influence the HACCP implementation through the selection of the Critical Control Points (CCPs). This selection depends, among other aspects, on the target consumers of the product selected since there are some products, which are destined to sensitive groups of consumers and special parameters

should be considered and an accurate analysis must be done.

In addition, it has to be recorded as well the instructions for using the product properly and it must appear in the label. Take into account that it also has an influence on the hazard analysis. For instance, products, which will be heated by the users, could be in lower risk class. This step is especially important for functional products, such as dietary products or babies feedings, which must be designed in accordance to the vulnerability of the consumers. This kind of products should be grouped in the highest risk class. Consumers of the food and intended use are both usually included in the Product Description (task 2)

Task 4: Construct the flow diagram

The construction of the flow diagram, that should represents all the steps of the process, is important to identify easily all potential hazards that could affect the product chain by the HACCP team. It is an effective way to follow the flow of the raw materials from the point they enter the premises until the consumer gets the final product. If HACCP is going to be implemented ONLY in a specific step of the process, the steps, which are before or after the processing should be considered as well.

The following figure (figure 4) shows an example of the flow diagram for the production of pasteurized olive filled with anchovies

The flow diagram shows the flow of the olives from the receiving to the distribution. The information about the inputs and outputs of the other ingredients and water should accomplish the flow diagram as well as the different steps through which the packaging material goes.

This information can be presented in a table (see table 3 next page). Using such a table, it is possible to follow up all the steps through which the different raw materials, ingredients and miscellanies material go

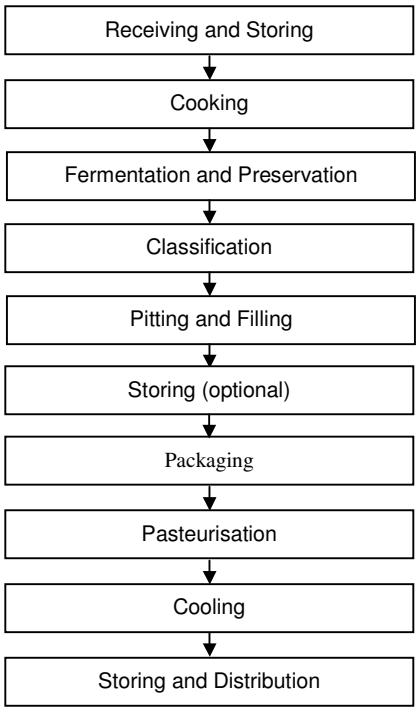


Figure 4: pasteurized olive filled with anchovies production flow diagram

Task 5: On-site verification of the flow diagram

The flow diagram must be revised on the production site in order to verify and completed if necessary. The verification is necessary to check if the flows of the raw materials and ingredients, as well as the tasks performed by the workers, are correct. All the members of the HACCP team should be present for this verification

The verification of the flow diagram should take place in different times throughout the working day to be sure that the process steps are the same and therefore, to verify the validity of the flow diagram constructed.

Task 6: Hazard analysis (Principle 1)

The Hazard analysis is one of the most important tasks for the successfully implementation of the HACCP system. It is based on the development of a list in which all potential hazards which may occur during the whole food chain -from raw materials to consumption. A hazard is defined *as a biological, chemical, or physical property that may cause an unacceptable consumer health risk if not effectively controlled*. Thus, all hazards must be analysed by the HACCP team whose main task is to decide which ones have a likely

occurrence and severity and their elimination or control is essential to produce a safe product.

Those will need a preventive measure must be included in the HACCP plan. The others *should be* controlled by the Pre-requisite program.

For the hazard identification it has to be decided if a Hazard requires consideration or not in the HACCP, it must be analysed carefully, using as much information as possible and taken into account that the PPs control the environment hazards and the HACCP control the process hazards. So, a good way to do the analysis could be to ask oneself the following question: *Is there any Preliminary Program, which reduces the likelihood of the hazard? (figure 5)*

Pre-requisite programs exit to reduce the likelihood of a hazard to acceptable and safe levels, it does not have to be included in the HACCP plan. Then, it is just necessary to check that the PPs are appropriately written, monitored and all records involved are established. On the other hand, if none of the PPs reduces the hazard to safe levels, it is therefore a significant hazard and it must be considered in the HACCP plan and preventive measures must also be set up. Then the HACCP team has to analyse it carefully and decide if the hazard is a Critical Control Point or just a Control Point, as it will be shown in the next principle.

It is important to point out that if after identifying a hazard, it is not possible to establish a preventive measure, the production process must be changed to eliminate it or al least to allow its control.

Task 7: Identification of Critical Control Points (CCPs) (Principle 2)

A Critical Control Point is any step, which must be controlled to prevent or eliminate a hazard, or at least to reduce it to acceptable levels. If not, the product could become a health hazard for the consumers. Thus, all significant hazards found throughout the process must be carefully analysed to decide if they are or not Critical Control Points. It is recommended to study the whole process step by step.

Hazard evaluation: a decision tree may be used to verify of the food preparation steps should be defined as a CCP. Figure 6 shows the decision tree adapted from NACMCF

Table 3: flow of all incoming materials

Olives	Salt	Filling	Ascorbic, lactic and citric acids	Bleach	Packaging	Water
receiving	receiving	receiving	receiving	receiving	receiving	
cooking	storing	storing cool	storing	storing	storing	intake
washing						intake
fermentation preservation	adding					intake
classification						
pitting						
filling		adding				
packaging			adding		filling with the products	intake
pasteurisation					Pasteurisation	
cooling					cooling	intake
storing					storing	
distribution					distribution	

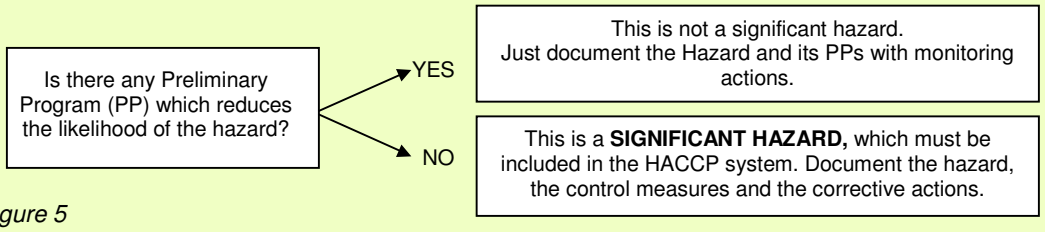


Figure 5

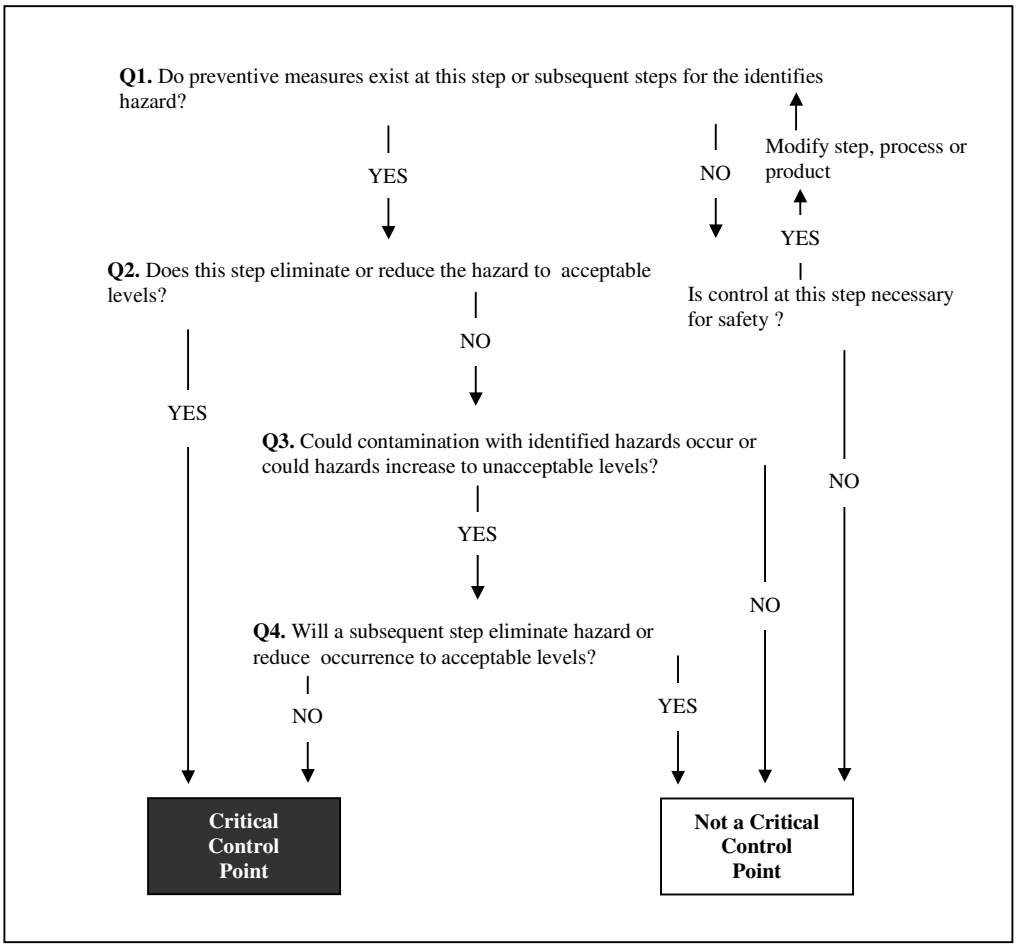


Figure 6: decision tree adapted from NACMCF

The following example shows how to decide if a hazard in a certain step of the process is a CCP or not.

The selected step for the example is: **fermentation and preservation** in the production of **pasteurised olive filled with anchovies.**

Hazards identification:

- *During fermentation no hazards have been considered since the pH decrease enough to avoid microbial growth.*
- *During preservation, the following hazards have been considered:*
- *Microbial growth due to insufficient cleaning of the fermentation tanks, and/or to the breaking down of the tanks.*
- *Physical-chemical contamination due to a bad cleaning or defects on the recipients use.*

The results from the application of the decision tree can be presented and recorded in a table as table 4.

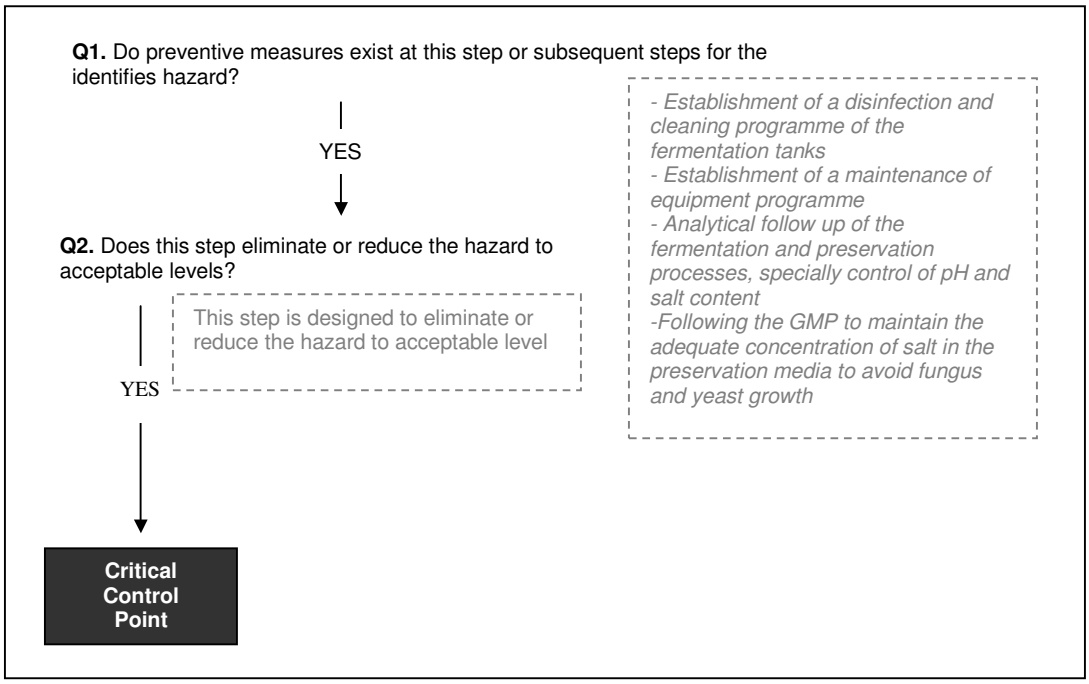
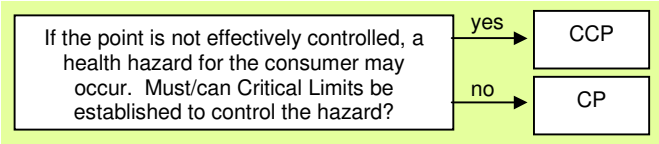


Figure 7: example of application the decision tree for one step of the process

Table 4: Part of the hazard analysis of the production of ***pasteurised olive filled with anchovies***

Step	Potential Hazard	Significant hazard?	Control measures	Q1	Q2	Q3	Q4	CCP?	Justification
Step2- cooking	Physical-chemical contamination	no	PPs: - *adequate design of the equipnent* *-disinfection and cleaning programme* -maintenance of equipment programme	--	--	--	--	--	It is not considered a significant hazard due to the cooking characteristics
Step3- fermentation and preservation	Physical-chemical and biological contamination	yes	PPs: *-disinfection and cleaning programme* -maintenance of equipment programme -GMP -Process control	Yes	Yes	---	---	Yes	This step is designed to eliminate or reduce the hazard to acceptable level
Step 6 Storing	Biological contamination	yes	-pH control -temperature of refrigeration	Yes	No	Yes	No	Yes	This step is not designed to eliminate or reduce the hazard to acceptable level and the growth of microrganisms can perish the anchovies filling. It could happen if the storage period is too long.

This decision tree is an effective tool to decide which hazards are really CCP. However, sometimes it becomes difficult because it is not easy to understand the main difference between a CP and a CCP. There are a lot of significant hazards which need special control measures, but not all of them will be CCPs; most of them will be just stages which are important to be controlled to ensure quality, safety and legal attributes of the product. They have to be controlled by thoroughly checking of the control measures or by an extra control, but the process history shows that these measures are enough to ensure food safety. So, another simple question could be used in order to make the decision:



Therefore, while CP are managed by PPs and by specific control measures, the CCP are strictly controlled by the HACCP plan , and they require special attention and Critical Limits have to be set up as it will be explained in the next task.

Task 8: Establishment of critical limits for each CCP (Principle 3)

For each CCP the maximum or minimum value for **all** biological, chemical and physical measurable **parameters** involved in the step has to be established. Thus, the Critical Limits are used to distinguish between safe or unsafe operating conditions at a CCP. However, if a CCP is identified but no Critical Limits can be established this point can only be considered as a CP and it has to be thoroughly controlled.

For the establishment of the critical limits a revision of the legislation, internal norms of the company, literature and experimental validation must be performed.

The critical limit should be an exact value but a range of tolerance can also be established to allow for instrumental and operator actuation.

It is also necessary to set up monitoring requirements, corrective actions, responsibilities, records and verifications in each CCP as explained in the next tasks.

Table 5: Example of a design of a CCP form

Process step	**Fermentation and preservation**
Hazard	Microbial growth due to bad preservation Microbial and physical-chemical contamination in the equipment
Critical limits	pH< 4,5
	Salt concentration >6%
Monitoring Activity and Frequency	Periodical checking of the pH and the salt concentration in the preservation media. Checking to maintain the adequate level of the preservation media
Corrective Action Activity	Reestablishment of: - hygiene equipment general conditions - functionality of equipment Acidification and addition of salt Reestablishment of the levels in the fermentation tank Reestablishment of the GMP
Responsibility for Monitoring and Corrective Actions	Operator/ Supervisor
Documentation and record	Results of the inspections Analytical results Corrective actions

Task 9: Establishment of a monitoring system for each CCP (Principle 4)

The standardization of the monitoring methods includes the planning of the type, frequency and the overseeing methods (including the responsible) for the processes and products to that all CCPs are under control.

The type and the frequency of measurements has to be established depending on each CCP. However, the main parameters used to monitoring procedures are those ones, which require less measurement time. Thus, biological parameters are seldom used for this control system because they need too much time to be determined. Biological measurements are normally used to control the final product.

If the monitoring system shows that any parameter is going to be out of control, actions have to be taken in order to prevent that the deviation goes over or below the critical Limits. If any deviation during the production chain is not controlled, an unsafe product may result that could lead to health problems of the consumers.

Task 10: Establishment of corrective actions (Principle 5)

Corrective actions must be established for each CCP in order to ensure that if a deviation occurs, the process will be under control by applying these actions as quickly as possible, reducing the risk of producing unsafe products.

This corrective measures may include equipment repairs, changes to storage or working conditions. At the same time, the cause of the non-performance should be determined and all the facts involved in this step must be recorded.

Corrective actions are important also to prevent foods, which may be hazardous from reaching consumers. Whatever is necessary to do with these foods must be written down and it should even exist an action plan for those products, which are dangerous and require a special treatment to prevent cross-contamination. This constitutes the Control of Non Conforming Products.

Task 11: Establishment of verification procedures (Principle 6)

Verification Procedures are used to ensure that the HACCP plan is working correctly. It should be done regularly and also under special conditions such as: the food product have been involved in food poisoning, if thee is a new safety information regarding the product or the process that was not taken into account for the elaboration of the plan, if there are changes in the process that could invalidate the plan, and after making modifications in the HACCP plan.

Depending on the nature of the verification, the verification procedures are:

- Internal verifications: by the HACCP team (it is necessary to appoint a verification responsible and a Reviewer) or by co-workers outside the HACCP-team
- Verifications by the competent authority,

Internal verifications are to determine if the system is working as established in the HACCP plan. In addition, it will show if the HACCP plan is effective and suitable for the products and processes selected.

Once the HACCP plan is implemented a initial verification is carried out. If through it, problems are detected, the plan has to be corrected or even modified. If the results are is positive, the plan is validated and it can be maintained.

The verifications procedures can include:

- Audit of the plan
- Audit of the documentation and record system
- Revision of the deviations occurred and the corrective actions adopted
- Analysis of intermediated and final products
- Surveys on the marketable products

Once the plan is validated, it has to be notified to the competent authority. From this moment, the HACCP plan has to be reviewed and verified periodically to ensure that is working correctly.

You could write down a verification plan including all the steps, which must be checked to carry out a verification in any case. In this way you will be sure that all the facts involved in the HACCP plan are always revised.

All the results from the verifications should be included in a verification report.

Task 12: Establishment of a documentation system and record keeping (Principle 7)

All facts and actions involved in the HACCP system should be recorded in appropriate forms. It is very important to assemble all this documentation in a manual. The manual should include:

- The Pre-requisite programs. Although they are not included in the HACCP plan they are essential for its effective implementation. Therefore, all of them should be documented.
- The HACCP plan, which is the main document and contains all the information related to the principles of the HACCP system and the specific process (product description, flow diagram,...). All the documents resulting from the implementation of this system must be addressed and detailed in the HACCP plan. At the same time all this documents must refer to the HACCP plan.
- The documents and records resulting from the HACCP plan implementation, such as:
  - All the monitoring forms to be filled periodically or whenever is required.
  - All records generated in process.
  - Corrective measures in case of Non - Performance.
  - Verification procedures and results.
  - Modifications of the HACCP System or any document related.

Although this is not a legal requirement in all the European countries, it is important to demonstrate that the HACCP System is properly established and is also working correctly. The European legislation obliges to have a quality control system, being the HACCP the most often recommended. Moreover all these records will be used whenever the HACCP Plan is reviewed and improved.

The documents must be designed according to the necessities and the interests of each company. In the same way, the codification of the forms will depend on how the company organise its infrastructure. It must be taken in account that if the enterprise is implementing also the UNE-EN ISO 9001-2000, the documentation will be closely related with this normative.

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