

# QUALI-JUICE

Quality assurance and development of an early warning system for  
microbial spoilage for the European fruit juice industry



**QUALI-JUICE**

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## **Recommendation Guide for the SME Juice Producer**

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## INTRODUCTION

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### Scope

This guide applies to the whole sector of fruit and vegetable juices and nectars from the fruit processor to the manufacturers of the consumer product. This guide applies to the products defined in the Council Directive 2001/112/EC relating to fruit juices and certain similar products with the exception of dehydrated products. It therefore applies to:

- Fruit and vegetable juices and purees
- Concentrated fruit and vegetable juices and purees
- Fruit nectars

They will be referred to as « product » in this guide.

### Use

Each section in this document states both the objectives to be achieved and the rationale behind those objectives in terms of safety and suitability of food.

Section 3 covers primary production and associated procedures. Although hygienic practices may differ considerably for the various fruit derived products and specific codes should be applied where appropriate, some general guidance is given in this section. Sections 4 to 10 set down the general hygienic principles which apply throughout the fruit juice chain to the point of sales.

There will be inevitable situations where some specific requirements contained in this document are not applicable. The fundamental question in every case is « what is necessary and appropriate on the grounds of the safety and suitability of the product for consumption ».

The text indicates where such questions are likely to arise by using the phrases « where necessary » and « where appropriate ». In practice, this means that, although the requirement is generally appropriate and reasonable, there will nevertheless be some situations where it is neither necessary nor appropriate on the grounds of food safety and suitability. In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach. This approach allows the requirements in this document to be flexible and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In doing so it takes into account the wide diversity of activities and varying degrees of risk involved in producing the products.

## Definitions

### Critical Control Point (CCP):

a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level.

### Cleaning:

the removal of food residues and foreign matters including soils, dirt, grease or other potentially contaminating materials.

### Contamination:

occurrence in the beverages of micro-organisms, or chemicals, or foreign bodies.

### Corrective action:

the actions to be taken when the results of the monitoring of the CCP indicate a loss of control.

### Critical limit:

a value which separates acceptability from unacceptability applied to CCP's.

### Disinfection:

the reduction by means of appropriate chemical agents and/or physical methods, of the number of micro-organisms to an acceptable level.

### Fail-safe construction:

a construction that prevents contamination hazards following failure of auxiliary supplies.

### Fruit juices:

Fruit juices and related products as defined in Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and some similar products

### Good manufacturing practices (GMP):

A set of rules put in practice by the industry to ensure that manufactured foodstuffs are sound and safe for the consumer and of good quality

### Hazard Analysis and Critical Control Point (HACCP):

a system which identifies specific hazard(s) and preventive measures for their control.

### Hazard:

the potential to cause harm. Hazards can be biological, chemical or physical.

### Limit:

A limit applied to CP

### Lot:

a batch of sales unit of a product produced, manufactured or packaged under practically the same condition (Council Directive 89/396/EEC of 14 June 1989).

**Monitor:**

to conduct a planned sequence of observations or measurements to assess whether or not a CCP is under control.

**Must:**

compulsory, mandatory; to be implemented immediately

**Non potable water:**

Water (for instance well water which does not qualify as potable water) which can be used on the premises provided that it can be guaranteed that direct or indirect contact with the product is avoided.

**Pests:**

any animal capable of directly or indirectly contaminating fruit juices, such as: insects, rodents, mites, spiders and birds.

**Potable water:**

water that meets the requirements of Council Directive 98/33 of 20 December and that meets the requirement of Council Directive 2001/112/EC of 20 December 2001

**Preventive actions**

actions to avoid undesirable occurrences

**Process water:**

water used in direct contact with the product during processing (including reconstitution) of the product. The water can be derived from potable water by further treatment (e.g. demineralisation) or from evaporation. It should have the appropriate characteristics, particular from a chemical, microbiological and sensory point of view to maintain the requirements of the original product.

**Production facilities:**

any building or area in which fruit juices are manufactured

**Primary packaging:**

any material (glass, plastic, metal or carton, one-way or returnable container and its closure system) in direct contact with the product to be filled with a fruit juice, properly labelled and intended for distribution.

**Recommend:**

Desirable, optimal, preferred practice not necessary to be implemented

**Risk**

The statistical chance of a hazard occurring

Safe:

The status of a fruit juice which is not harmful to consumers.

Sanitary construction:

A construction designed and built to be easily cleanable.

Sanitation:

Combined action of cleaning and disinfection.

Secondary packaging:

any materials such as labels, cartons, boxes, cases, drums, crates or wrapping and covering material such as foil, film and cardboard not in direct contact with the product.

Should:

Recommend for current operations and not necessarily implemented immediately. However it will be compulsory in the future, i.e. implemented in all new investments.

Vegetable juices:

juices made from tomato and/or other vegetables

Wholesome:

fit for human consumption

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## 1. PRIMARY PRODUCTION

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This section describes the requirements and considerations for safe and hygienic production, handling and processing of fruit and vegetables into semi-industrial products destined for further processing and packaging.

Food sources should be managed in a way that ensures contaminants are not present in food and/or food ingredients to levels which would render end products potentially harmful to human health or unsuitable for human consumption. Where necessary, this will include:

- avoiding the use of areas where the environment poses a threat to food;
- controlling contaminants, pests and diseases in such a way as not to pose a threat to food;
- adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

### ■ 1.1 ENVIRONMENTAL HYGIENE

Potential sources of contamination from the environment should be considered. In particular, primary food production should not be carried out in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food or measures should be taken to reduce this risk to an acceptable level.

### ■ 1.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Application of crop protection products (pesticides) must be done with the minimal quantity of these products necessary to obtain the intended effect, and must comply with European legislation. Application of crop protection products must be done with the necessary care for the safety of the operator and of people in the neighbourhood, and for the environment in general. Crop protection materials must be stored safely and securely away from food products. Adequate self-protection equipment must be available for the operators who handle, prepare and apply crop protection products.

Good Agricultural practices (GAP) must be followed to minimize contamination of fruit with soil.

The water used for irrigation and/or spraying of plants with crop-protection products must not be contaminated with sewage water or water which is contaminated with human or animal faeces, with pathogenic micro-organisms, nor contain hazardous chemicals.

### **1.3 PROCESSING, HANDLING, STORAGE AND TRANSPORT**

The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular this includes identifying any specific points in such activities where a high risk of contamination may exist and taking specific measures to reduce that risk.

#### Fruits

Fruit is the Raw Material of this segment of the industry. Farmers and Processors must take care that sound fruit is delivered at the processing facility or at the intermediate storage with adequate transport vehicles that are clean and fit for use.

#### Storage

Fruit can be temporarily stored under conditions to keep damage of the fruit to a minimum, so that spoilage of a part of the fruit cannot create risks for the final product quality.

Overhead cover for fruit should be considered to avoid direct sun, rain and extremes of temperature. Adequate ventilation, cleanliness of the storage area and storage container(s) and also the length of time of fruit storage before processing should be considered.

#### Selection

Fruit must be sorted (whereby unsound fruit is eliminated).

#### Washing

Fruit washing with process water or potable water must remove dirt, soil and other contaminants from the surface of the fruit.

The water which serves for fruit-washing, as cleaning water or processing water to the fruit processing industry must be analysed for its potential risk of contamination. Such risk comes from sewage water or water which is contaminated with human or animal faeces, with pathogenic micro-organisms, or with pesticide residues or other hazardous chemicals.

Adequate quantity of water and depending on the type of fruit, simultaneous cleaning with rotating brushes must be applied. The pressure of the water should be optimized for each type of fruit. Water can be re-circulated but the frequency of replacement of the water must be related to the load of contamination.



If a detergent and /or disinfectant are used in the washing water, it must be ascertained that the residues are removed by the final washing. The final washing of fruit must be performed with fresh potable water or process water.

#### Extraction

Extraction equipment should be hygienically designed to minimize the contact of the extracted fruit/vegetables with those parts of the fruit/vegetable which are not suitable for the product.

#### Juice processing

All equipment should be closed as far as possible to avoid contamination with foreign material and/or lubricants. All contact surfaces of the equipment with the product must be suitable for the contact with food. All equipment must be easy cleanable.

#### Pasteurisation

The pasteurisation process must be designed to ensure appropriate reduction of the microbiological flora of the product, without overheating the product.

#### Concentration

The concentration process must be designed to avoid recontamination of the product.

#### Packing

The packing of the juice, puree or concentrate must take place under Good Manufacturing Practice (GMP), in order to avoid re-contamination of the product. The containers must be properly labelled and must be closed and should be sealed with tamper evident seals immediately after the filling process. The packaging material must meet the requirements of European legislation.

#### Storage

After packing, the product must be kept at the recommended storage conditions to prevent deterioration and spoilage. Appropriate storage conditions may include controlled temperature, humidity and/or inert gas-blanketing.

Furthermore, products unfit for human consumption must be stored separately.

### **1.4 CLEANING, MAINTENANCE AND PERSONAL HYGIENE**

Appropriate facilities and procedures should be in place to ensure that:

Any necessary cleaning and maintenance is carried out effectively:

- effective cleaning requires that residues of product and residues of cleaning chemicals and/or of disinfectants are removed.
- cleaning schedules and cleaning procedures must be defined and must be followed by the operators,
- records of cleaning operations and control of effectiveness must be maintained,
- effective maintenance is scheduled to guarantee production as per intended schedule, and must be directed to prevent contamination of the product caused by breakdown of the equipment.

An appropriate degree of personal hygiene is maintained.

Special attention is required to establish rules and instructions for cleaning of hands before working, after toilet usage and before and after eating.

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## 2. DESIGN OF ESTABLISHMENT

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The nature of the operations in fruit juice plants requires that:

- design and layout permit adequate maintenance, cleaning and/or disinfection;
- equipment materials in contact with beverage and ingredients are of good quality and easy to sanitise;
- temperature, humidity and environment can be controlled in beverage processing areas where necessary; and
- protection against pest access is effective.

### 2.1. ESTABLISHMENT

#### 2.1.1. General requirements

- Buildings and facilities should:
  - permit easy and adequate cleaning and facilitate proper supervision of hygiene;
  - ensure a rational production flow in order to avoid cross contamination;
  - provide appropriate temperature conditions for the raw materials, the process and the products.

#### 2.1.2. Perimeter

It is recommended to have good housekeeping practices for the grounds. It is also advisable to have paved road systems and parking areas which are properly drained.

#### 2.1.3. Maintenance

- Any external opening such as doors, windows, ventilation systems and drain outlets should be maintained to prevent pest access.
- The inside of the buildings should be maintained in high standard of repair and decoration.

## ■ 2.2. *PRODUCTION AREAS*

### 2.2.1. General requirements

- Design and layout of raw materials, semi-finished products and finished products rooms and filling halls should:
  - permit efficient cleaning and/or disinfection;
  - protect the product against the ingress of any foreign material;
  - minimize condensation and mould growth on surfaces;
  - avoid cross contamination between and during operations;
  - have suitable environmental conditions for the hygienic processing;
  - where product is exposed to the environment, processing needs to be in a closed building.
  - provide washbasins;
  - have effective ventilation systems;
  - have adequate lighting; and,
  - have adequate drainage systems.
  - have cleaning schedules for facilities
  - have record keeping on cleaning measures for floors, walls, ceilings, facilities
- Fruit processing, blending, preparation, filling, packaging and water treatment should be performed in separate systems such that these systems prevent cross contamination.

### 2.2.2. Specific requirements

#### 2.2.2.1. Wall and floor surfaces in blending, preparation and filling areas

- The surfaces of walls, partitions and floors should be made of impervious, non-absorbent and easily washable materials. The materials should be chemical resistant and should comply with food regulations.
- Floors should have a non-slip finish and be sloped to drain effectively. Drains should have an adequate capacity and be provided with covers, sediment traps and water locks. Floors should be constructed to must be applied withstand heavy loads, where necessary.

#### 2.2.2.2. Ceilings and lighting

- Adequate lighting should be provided to monitor plant cleanliness.
- Ceilings and overhead fixtures should be of impervious nature and designed in order to prevent the accumulation of dirt.
- Light fixtures must be covered.
- Shatter proof material

### 2.2.2.3. Windows and skylights

Windows and sills should protect against external contamination and should be impervious and easily cleanable.

Fly screens should be put in place when windows are opened.

### 2.2.2.4. Doors

Doors should be impervious and easily cleanable and should protect from external contamination. Door curtains covering the whole door opening should be put in place when doors are permanently opened.

### 2.2.2.5. Auxiliary structures

Other constructions such as stairs, steps, platforms, etc. should be of sanitary construction.

There should be no openings in the wall through which animals could migrate into the production area.

## **2.3 EQUIPMENT**

### **2.3.1 General Requirements**

- Equipment and containers coming into contact with the product should be designed and constructed to ensure that they can be adequately cleaned, disinfected and maintained to avoid contamination.
- Equipment should be installed to allow adequate cleaning of the surrounding area.
- It is recommended that all product contact equipment is made of high-grade stainless steel. Non stainless steel equipment must be constructed from food grade material, suitable for the product, cleaning materials and operating temperatures.
- Tanks and containers must be suitably covered.
- The use of wood should be discouraged where possible.
- Flexible hoses and pipes should be properly cleaned, drained and capped.

### **2.3.2 Temperature Control Systems and Monitoring Equipment**

- Product pasteurisation temperatures and holding times must be controlled and monitored

### **2.3.3 Containers for waste and hazardous substances.**

- Containers for waste should be clearly identified, suitably constructed and, where appropriate, made of impervious material.  
Containers used for waste must not be used for product storage.
- There must be dedicated containers to collect waste in production areas. These bins should be emptied and cleaned regularly.
- Containers used to hold hazardous substances must be clearly identified and, where appropriate be lockable to prevent malicious or accidental contamination of the product.

## **2.4 FACILITIES**

### **2.4.1 Water Supply**

#### 2.4.1.1 Potable and process water

There must be an adequate supply of potable and process water.

#### 2.4.1.2 Non-potable water

The risk of potable water and final product contamination with non-potable water must be avoided. Non-potable water must have a separate system and water lines should be clearly identified. There should be no possibility of non-potable water entering the potable water network.

#### 2.4.1.3 Steam

Steam, which comes into contact with the product or product contact surfaces, must be food grade and generated from potable water or process water.

For this purpose boiler feed water additives must be checked for suitability s must be food grade standard and their concentrations must be controlled.

### **2.4.2 Gases**

Gases used as processing aids, which could come into contact with the product or product contact surfaces must be free from oil, water and dust. It should have a suitable microbiological standard.

### **2.4.3 Drainage**

- Product plants should have an effective drainage system.

- All effluent pipes, including sewer systems, should be of an appropriate capacity. They must be designed and constructed so that there is no risk of product contamination.

#### **2.4.4 Cleaning and disinfection**

- Facilities for cleaning and disinfection of equipment, utensils and work tools must be provided.
- Such facilities must be of sanitary construction and be fitted with an adequate supply of hot and/or cold potable water.

#### **2.4.5 Personnel hygiene facilities and toilets**

Hand washing facilities, toilets and changing facilities must be well lit, ventilated and available for all employees

##### 2.4.5.1. Hand Washing

Facilities for hand washing and hygienic drying must be available wherever the process demands. They should be provided with cold and / or hot water. Soap must be available. Hand disinfection is recommended.

Signs must be displayed requiring employees to wash their hands before commencing work.

##### 2.4.5.2. Toilets

- Toilets must be provided in production plants. Toilets must not open directly into production areas. They must be well lighted and ventilated.
- Hand washing, soap and hygienic drying facilities must be adjacent to toilets and hand disinfection is recommended.
- Signs must be posted directing personnel to wash their hands after using the toilet.

##### 2.4.5.3. Canteen

A separate room should be provided for breaks, to have meals, snacks and other refreshments.

#### 2.4.6. Ventilation

- Adequate means of natural or mechanical ventilation should be provided in all production areas in order to:
  - Prevent excessive build-up of heat, relative humidity, odours and dust.
  - Minimise the risk of contamination of products and ingredients.

- Mechanical ventilation systems including filters should be designed and constructed so that they can be easily maintained and cleaned.

#### 2.4.7. Storage Areas

- Production sites should have appropriate storage areas for products, ingredients, packaging materials, cleaning materials, waste and other materials/equipment necessary for the operation.
- They must be designed to:
  - Meet the requirements for the stored products, e.g. temperature, relative humidity and light.
  - Permit adequate cleaning.
  - Prevent access to pest
  - Ensure that no areas can harbour pests.
  - Protect the products from environmental influences.

#### 2.4.8 Thermic Engines

Thermic engines, such as fork lift trucks, should be discouraged from closed processing areas and replaced by electric engines.



## 3. CONTROL OF OPERATION

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To manufacture products for human consumption with a high standard of safety by applying an effective control program including a HACCP concept.

### ■ 3.1. CONTROL OF POTENTIAL PRODUCT CONTAMINATION

#### 3.1.1. General methodology

- Fruit juice processors and manufacturers shall :
  - define essential product characteristics such as target customers, formulation, process conditions, packaging, shelf-life storage conditions and traceability measures;
  - identify any step in their operations, which is critical to the safety of the product ;
  - implement effective control procedures including limits at those steps;
  - define corrective actions in case of deviations to the limits
  - monitor control procedures to ensure their continuing effectiveness;
  - review control procedures periodically, and whenever the operation changes;
  - keep process records at any step, which is critical to the safety of the product.
- A model of such a system is described in Codex document WHO/FNU/FOS93.3 entitled "Codex guidelines for the application of the hazard analysis critical control point (HACCP) system".

#### 3.1.2. Application to fruit juice manufacturing

Using the logic sequence of diagram 1 of the Codex document, a typical layout is presented in annex I. It is essential to realise that the principles of the HACCP system have to be applied to each factory for its particular products.

Critical limits and monitoring will be specific to each factory / product. Therefore annex 1 is only to be used as an example.

### ■ 3.2. MAIN CATEGORIES OF CONTAMINATION

#### 3.2.1. Microbiological contamination

Microbiological hazards include the following:

- micro-organisms in vegetative form,
- resistant forms e.g. spores,

- microbial toxins.

Proper pasteurisation or other appropriate microbiological inactivation of products with a pH of less than 4.5 prohibits the growth of pathogenic micro-organisms. Nevertheless the short-term survival of certain pathogens is possible after post process contamination

Fresh juices without microbiological inactivation carry a risk (see annex I)

Risk assessment for processing vegetables is different to that applied to fruit-based products. The higher pH-Value of the raw material and the risk of contamination with pathogenic micro-organisms makes it necessary to apply special washing-, peeling- and heating processes.

Mycotoxins can contaminate products. The most relevant contaminants are patulin and ochratoxin A .

#### 3.2.1.1. Sources

- Raw materials, ingredients and primary packaging;
- Inadequate processing
- Inadequate sanitation

#### 3.2.1.2. Preventive actions

- Assurance of raw materials, ingredients and primary packaging
  - Only raw materials, including both ingredients and primary packaging, complying with legal requirements and producer specifications should be accepted.
  - All raw materials should be clearly identified and inspected at receipt. Laboratory tests should be made where necessary and certificates of analysis / conformity should be supplied, when possible, by the manufacturer at each delivery.
  - Raw materials stored on the premises of the production plant are maintained under conditions that will protect their integrity. Storage premises shall be separated into allocated areas for each category of packaging materials e.g. labels, closures, bottles, cans. As packaging material can accumulate dust, care must be taken to avoid the contamination of containers.
  - Sensitive ingredients such as sugars, flavourings and juices require controlled storage conditions.
  - In the case of fresh un-pasteurised juices, particular attention should be paid for example to upstream selection of fruit and harvesting methods: in particular, all

- contact with the ground and animal faeces should be avoided as these are the main sources of contaminants.
- Stocks of raw materials and ingredients should be subject to effective stock rotation.
  - Inadequate processing conditions
    - Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety of the product.
    - Inadequate control is one of the most common causes of product spoilage.
    - Adequate controls include:
      - time and temperature for pasteurising operations
      - washing containers and cleaning-in-place operations
      - For high pressure processing, pressure applied, residence time and temperature
      - Time and temperature for chilling and freezing operations
    - Such systems should also specify limits for time and temperature.
    - Temperature recording devices should be checked at regular interval and tested for accuracy by internal or external audits.
  - Inadequate sanitation
    - Cross contamination can occur by direct or indirect contacts with raw materials, ingredients, primary packaging, equipment, environment and personnel.
    - Surfaces, utensils and equipments should be thoroughly cleaned and if necessary disinfected prior to, and after being used for production.
    - Separate filling areas and preparation rooms for processing activities should be available.
    - Access to preparation and filling areas needs to be restricted or controlled. Personnel must wear appropriate protective clothing.

### **3.2.2. Chemical contamination**

#### 3.2.2.1. Sources

- Cleaning and disinfection agents;
- Raw materials;

- Ingredients/Additives/Processing Aids.
- Lubricants
- Primary packaging material
- Processing and storage equipment

#### 3.2.2.2. Preventive actions

- Adequate control procedures
- The container washing and rinsing processes should be designed and constructed to ensure the complete draining and rinsing of containers. Re-usable packaging must be checked for residual liquid after washing by a visual or an electronic inspection. Re-usable bottles should be inspected with an appropriate detection system. These systems must be checked regularly.
- Sanitation processes must guarantee the complete draining and rinsing of the equipment. Checks must be performed after each sanitising operation.
- Only raw materials, including both ingredients and primary packaging, complying with legal requirements and in case further specifications and regulations.
- Processing equipment lubricants must be of food grade quality.

### **3.2.3. Physical contamination (foreign bodies)**

#### 3.2.3.1. Sources

- Raw materials;
- Parts of equipment and installation;
- Personnel;
- Pests;
- Ingredients/Additives/Processing Aids.

#### 3.2.3.2. Preventive actions

- Only raw materials, including both ingredients and primary packaging, complying with legal requirements and producer specifications should be accepted.
- Systems shall be in place to reduce the risk of product contamination by glass, metal shards paint flakes and dust.
- In preparation and filling areas, suitable detection systems or filters must be used. The efficiency of these devices shall be regularly verified.

- Re-usable packaging must be checked for foreign bodies after washing by a visual or an electronic inspection. The efficiency of these devices shall be regularly verified.

These concepts shall be applied through the whole manufacturing process.

### **■ 3.3 RAW MATERIAL REQUIREMENTS**

#### **3.3.1 Fruits/vegetables and related products**

The specifications must refer to relevant EU legislation and the AIJN Code of Practice for evaluation.

#### **3.3.2 Processing aids, additives and ingredients**

Manufacturers must ensure that processing aids, additives and ingredients comply with EU legal requirements and are not likely to contaminate the product. They should be stored in separated storage places in adequate packaging to avoid any risk of confusion.

#### **3.3.3 Packaging**

Packaging material for raw material and final product must comply with the EU legislation on materials in contact with foodstuff.

### **■ 3.4. MANAGEMENT AND SUPERVISION**

Management should be well informed about food hygiene principles and practices in order to evaluate potential risks, to take appropriate preventive and corrective action and to ensure effective monitoring and supervision.

### **■ 3.5. DOCUMENTATION AND RECORDS**

For each lot, production and quality records for processing, blending, preparation, filling, packaging and distribution must be kept at least for the duration of the product's shelf life. Materials can be traced if a problem is experienced.

### **■ 3.6. COMPLAINT AND RECALL PROCEDURES**

- An effective procedure should be in place to handle complaints by consumers and authorities.
- An effective recall procedure should be in place.

- Non-conforming products (raw material, packaging, finished products) must be identified, clearly labelled and put on hold in a specific area. They must be treated according to a non-conforming products procedure and if necessary be destroyed.

### **3.7 SAFEGUARDING PRODUCT AGAINST TERRORIST ACTS OR OTHER MALICIOUS CONTAMINATION**

The risks of contamination of food products by individuals with malicious intent have long been recognised, along with appropriate preventive measures. Action against terrorism on a world-scale has lent a further dimension to ensuring the safety and security of product.

The following are considered to be the key information and action points.

- Responsibility for process and product security needs to be assigned to a specific qualified individual or individuals.
- Staff should be encouraged to be alert for signs of tampering with product or equipment, or other possible breaches of security e.g.
  - unusual behaviour on the part of other workers
  - presence of people without security tags
- Consideration needs to be given to checking and screening employees references,
- An operation should have a clear identification system for employees and visitors. Restrictions may be required for access to particularly high-risk areas.
- Procedures need to be implemented to ensure the security of incoming mail and packages,
- Access to computing systems should be restricted to those with appropriate clearance.
- There should be an evaluation of lessons to be learned from previous incidents.
- Systems should be reviewed and tested at least annually (use mock incidents to test the systems).
- Ensure appropriate training is provided for a) staff awareness, b) staff responsible for implementing and monitoring the procedures

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## 4. HOUSEKEEPING

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To establish effective systems to ensure:

- tidiness of production and storage areas;
- adequate maintenance and sanitation of production equipment
- effective pest control and
- monitor effectiveness of maintenance and sanitation procedures

### ■ 4.1. *GENERAL HOUSEKEEPING*

- Buildings and processing equipment should be appropriately maintained.
- Cleaning should remove food residues and dirt, which may be a source of contamination. Disinfection may be necessary after cleaning.
- All utensils such as tools, change parts, packaging materials, auxiliary products, which are not needed for production, should be properly stored.
- Water hoses should be kept on reels when not in use.
- Sufficient waste bins should be located near the sources of waste and removed at adequate intervals
- Industrial sanitation chemicals should be handled and used carefully in accordance with the manufacturer's instructions to avoid the risk of contaminating fruit juices and ingredients.

### ■ 4.2. *SANITATION PROGRAMS AND METHODS*

Sanitation and /or cleaning can be done by separate or combined use of physical and chemical methods. For each part of the production area and processing equipment, written effective sanitation programs shall be in place and known by the operators. They should specify:

- The area in which the program is to be applied;
- The equipment and/or utensil;
- The method/and frequency of cleaning
- Monitoring arrangements
- The person responsible.

The method shall specify:

- The agents to be used;
- The contact time and concentrations;
- The documentation and
- The monitoring arrangements and verification.

### **4.3. RECORDING OF SANITATION**

Sanitation records shall include:

- When, where and what has been sanitised,
- Who was responsible for each task and,
- Conditions and results.

### **4.4. PEST CONTROL**

#### **4.4.1. General**

Pests pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Good Hygiene Practice should be employed to avoid creating an environment conducive to pests. Good sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

#### **4.4.2. Preventing access**

Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

#### **4.4.3. Harborage and infestation**

The availability of food and water encourages pest harborage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean. Where appropriate, refuse should be stored in covered, pest-proof containers.



#### **4.4.4. Monitoring and detection**

Production facilities and surrounding areas should be regularly examined for evidence of infestation according to a fixed schedule

#### **4.4.5. Eradication**

Should pest infestations occur, they must be dealt with immediately. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the quality and safety of the product.

### **4.5. WASTE MANAGEMENT**

For disposal of waste, suitable and clearly labelled containers have to be made available. Depending on their use, containers should be closable, non-leaking and where necessary lockable. Waste materials should only be stored in designated containers, ideally at designated positions. Waste containers in the production area should be removed or emptied at least daily, where necessary also cleaned on a daily basis.

Waste materials of any kind originating from the different production areas have to be stored in a way that they cannot affect the hygienic properties of finished products.

Storage areas have to be maintained properly in order to avoid infestation.

For fruit processing facilities conditions have to be defined which do not allow fermentation, rotting and/or deterioration of solid residues, which are designated for subsequent use.

### **4.6. MONITORING AND RECORDING EFFECTIVENESS OF HOUSEKEEPING**

Maintenance, cleaning and sanitation systems should be monitored for effectiveness and regularly reviewed and adapted to reflect changed circumstances. Records should be kept of inspection and corrective actions.

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## 5. PERSONAL HYGIENE

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To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by:

- maintaining an appropriate degree of personal cleanliness behaving and operating in an appropriate manner.

### ■ 5.1. *HEALTH*

Personnel, who have an infectious or contagious disease, or any illness or injury liable to contaminate the product, must not be assigned to the preparation or processing of the product.

Any person must immediately report illness or symptoms of illness to the management.

It must be ensured that any person outside a food-handling area cannot cross contaminate a person working within a food handling area

### ■ 5.2. *PERSONAL CLEANLINESS*

- All operators should maintain a high degree of personal cleanliness. Where appropriate, they must wear suitable protective clothing, head and beard covering, and footwear, provided by the company. Cuts and wounds, where personnel are permitted to continue working, should be covered by a detectable blue metal strip plaster issued by the company.
- Personnel must always wash their hands when personal cleanliness may affect food safety, for example:
  - at the start of food handling activities;
  - immediately after using the toilet; and
  - after handling raw food or any contaminated material, where this could result in contamination of other food items;

An appropriate notice will be provided, where hand washing is carried out, detailing the correct technique for effective hand washing to prevent food contamination.

The company will provide an appropriate hand-washing agent.

### ■ 5.3. *PERSONAL BEHAVIOUR*

- Smoking, eating and drinking in the production areas is prohibited.
- Jewellery and other personal possessions should not be worn or brought into processing areas, with the exception of plain band rings (e.g. wedding rings) and single piece earring sleepers.
- Nail varnish must not be worn, and nails must be kept short.
- False nails are not permitted.
- Product and ingredients containers must not be used for any other purpose than their intended use.

### ■ 5.4. *VISITORS*

Any visitor or contractor to the plant should be advised of hygiene requirements and their need to comply with them.

### ■ 5.5. *SUPERVISION*

Plant management shall be responsible for ensuring that all aspects of hygiene relating to personnel are applied.

## 6. TRANSPORT

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Measures should be taken to protect products during transport from damage or contamination in order to ensure that a sound product is offered to the user.

Vehicles and/or containers used for transporting foodstuffs must be kept clean and maintained in good repair. To protect foodstuffs from contamination, vehicles and/or containers must be designed and constructed to permit adequate cleaning and/or disinfection. Maintenance and hygiene procedures should be documented for all vehicles and/or containers.

Procedures should be in place to ensure that the integrity of the foodstuff is protected if there is a vehicle breakdown. Procedures should be in place to ensure that the product is maintained at the correct temperature during transportation. Maintenance and hygiene records should be kept for all vehicles and/or containers.

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## 7. TRACEABILITY

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Measures should be taken to identify all raw materials and to be able to trace work in progress and finished product at all stages during manufacture, storage, despatch, and where appropriate distribution to the customer.

Each organisation shall be able to trace each product backward to the processing plant and raw material suppliers, and forward to the delivery point. During the relevant stages of production (including rework) the traceability shall be maintained and records shall be kept. Traceability records shall be readily available.

From all raw materials and final products counter samples shall be stored appropriately and kept until the expiry date of the end product.

### **Remark to lot or batch identification**

A universal lot or batch identification system is necessary to provide information if foodstuffs are disputed, or if it is suspected that there may be a food safety issue.

- Within relevant EU legislation a 'lot' is a batch of sales units of a foodstuff produced, manufactured or packaged under practically the same conditions
- A foodstuff may not be marketed unless it is accompanied by an indication or mark.
- It is the responsibility of the producer, manufacturer or packager of the foodstuff, or the first seller in the community to determine and affix the lot identification. It must be preceded by the letter 'L' except where it can be clearly distinguished from other indicators on the label.
- Marks must be easily visible, clearly legible and indelible. An indication or mark need not be stated where the date of minimum durability or 'use by' date is stated on the label. This only applies where the date states at least the day and month in that order in uncoded form.

### **EU legislation relevant to lot marking**

The area falls under Council directive No. 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs (Off. J. European communities 1989, 32 (L186), 21-22); amended by Directive Nos 91 (238/ of 22 April 1991, (1991, 34 (L107), 50; 92/11/EEC of 3 March 1992 (1992, 35 (L65),32).

## 8. TRAINING

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### Objectives:

Factory personnel must be appropriately trained and supervised.

### ■ 8.1. *AWARENESS AND RESPONSIBILITIES*

Food hygiene training is fundamentally important.

- Managers and supervisors should have sufficient knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary actions to reduce the risks to an acceptable level.
- All personnel, including temporary workers and visitors must be aware of their role in protecting products from contamination or deterioration. Personnel must have the necessary knowledge for handling products hygienically. Those who handle chemicals must be instructed in safe handling techniques.

### ■ 8.2. *TRAINING AND QUALIFICATION PROGRAMS*

For certain hygienically critical operations, appropriate qualifications for personnel should be defined. Training programs should be developed, regularly applied and updated.

Factors to take into account in assessing the level of training required include:

- the nature of the product, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms,
- the manner in which the product is handled and packed, including the probability of contamination,
- the extent and nature of processing or further preparation before final consumption,
- the storage conditions of the products,
- the expected time before the product is consumed.

### ■ 8.3. *INSTRUCTION AND SUPERVISION*

Periodic assessments of training should be made, as well as routine supervision to check and ensure that procedures are being carried out effectively.

## **ANNEX I : Guideline for the application of a HACCP system**

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## Guideline for the application of a HACCP system

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## 1. Introduction

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This Annex describes a practical example of applying the principles of HACCP analysis to develop a HACCP system based on the CODEX Guideline for the application of the HACCP system as approved by the 20th Session of the Joint FAO/WHO Codex Alimentarius Commission, 1993.

The Hazard Analysis and Critical Control Point (HACCP) system identifies specific hazards and preventive measures for their control to ensure the safety of food.

HACCP is a tool to assess hazards and establish control system that focus on preventive measures rather than relying mainly on end product testing. The HACCP system is capable of accommodating change, such as advances in equipment, design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from the primary producer to the final consumer. As well as enhanced food safety, benefits include better use of resources and more timely response to problems. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a team approach; the team should include appropriate experts.

## 2. Definitions

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### HACCP.:

A system which identifies specific hazard(s) and preventive measures for their control.

### HAZARD:

The potential to cause harm. Hazards can be biological, chemical or physical.

### Critical limit:

A value which separates acceptability from unacceptability

### CCP.: (Critical Control Point)

A point, step or procedure at which controls can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level.

### Corrective action:

the actions to be taken when the results of monitoring the CCP indicate a loss of control.

### Monitor:

To conduct a planned sequence of observations or measurements to assess whether a CCP is under control.

### 3. Principles

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- Principle 1:

Identify the potential hazard(s) associated with food production at all stages, from growth, processing, manufacture and distribution, until the point of consumption. Assess the likelihood of occurrence of the hazard(s) and identify the preventive measures for their control.

- Principle 2:

Determine the points/procedures/operational steps that can be controlled to eliminate the hazard(s) or minimise its likelihood of occurrence (Critical Control Point). A “step“ means any stage in food production, harvesting, transport, formulation, processing, storage, etc.

- Principle 3:

Establish critical limit(s) that must be met to ensure the CCP is under control.

- Principle 4:

Establish a system to monitor control of the CCP by scheduled testing or observations.

- Principle 5:

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

- Principle 6:

Establish procedures for verification, which include supplementary tests and procedures to confirm that the HACCP system is working effectively.

- Principle 7:

Establish documentation concerning all procedures and records appropriate to these principles and their application.

## 4. Application of principles in the fruit juice industry

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General remarks:

This HACCP application considers the manufacturing of products as well as their raw materials, ingredients and additives and is specifically designed for use in the manufacture of a product, which does not constitute a risk to the health of the consumer.

Stage 1 to 5 are preparatory stages for the real HACCP analysis.

- **STAGE 1 : Assemble HACCP team**

The success of the HACCP study depends on the involvement both of management and of all staff of the company.

The HACCP team is composed of persons who have specific knowledge and skills of a product and/or production process and who are working in various disciplines within the company.

Generally speaking the team in the fruit juice industry consists of experts in the field of legislation, product development, production, quality assurance, technical engineering. Each member of the team can represent one or more fields of knowledge. In case sufficient in-house knowledge is not available the advice of external experts is required. It is recommended to appoint a co-ordinator (team-leader) with sufficient knowledge of the whole process.

Training: all members of the group are trained in the HACCP principles, its methods and the application thereof. In order to carry out its task, the HACCP team must have the necessary resources, such as:

- Time for team meetings
- Administrative support
- Training
- Analytical capability
- Relevant sources of information

- **STAGE 2 : Describe Product**

The HACCP study starts with the description of the end product of the operation. This product description will contain information on the raw materials, ingredients, manufacturing process and packaging, as well as the way in which the product reaches the

customer/consumer and the way in which the consumer will then store, (prepare) and consume the product.

**END PRODUCT (GROUP) DESCRIPTION:**

The following elements must be included in the product description form:

- Product (group) name
- Product (group) characteristics
- Relevant legislation
- Instructions for use or description of general use
- Packaging
- Shelf-life
- General sales areas / outlets
- Distribution conditions
- Labelling information

**Remark:** where appropriate, product groups can be defined, that follow the same process steps.

**RAW MATERIAL / INGREDIENTS / ADDITIVES product description**

- Fruits
- Fruit derived raw materials
- Ingredients
- Additives
- Aromas
- Primary + secondary packaging description

**Remark:** Groups of these materials can be defined such that they can be handled in a similar manner.

Generally speaking, for all these materials or material groups the following information is required:

- Relevant legislation
- General, physical and chemical characteristics
- Packing
- Storage conditions
- Shelf-life
- Distribution conditions

- **STAGE 3 : Identify Intended Use**

Description of the instructions for use, shelf life and storage conditions

Description of the user group (babies, the elderly, the sick, etc.)

Description of any known product-sensitivity or special labelling requirements.

Description of any known misuse and consequence

- **STAGE 4 : Construct Flow Chart**

This project stage includes the description of the whole manufacturing process from receipt of raw materials to the dispatch of end products (depending on the scope of operation). Based on the current knowledge the production must be displayed using flow charts.

These flow charts should provide a schematic representation of successive basic operations and can be more or less detailed depending on the scope of operation.

- **STAGE 5 : On-Site Verification of Flow Chart**

This stage involves an objective and critical assessment of the different flow charts.

All members of the HACCP team should be involved in this stage and a recommended methodology is:

- Carry out an on-site process review during the various periods of production in order to ensure that the flow chart and complementary information are complete and valid;
- If not, modify or complete the information

- **STAGE 6 : Hazard Analysis and the Identification of Preventive Measures**

**(Principle 1)**

Using the defined flow charts, this stage involves examining each process step to determine which hazards may occur during that step and what preventive measures can be taken to control such hazards.

Within the framework of this analysis, microbial, chemical and physical hazards must be carefully scrutinised during each process step (from arrival of raw materials up-to and including the distribution to the customer / consumer) within the well-defined area of responsibility.

As regards biological hazards, the analysis will consider the following:

1. Microbiological hazards:

- Raw materials and end products: osmophilic yeast, lactobacilli, fungi and pathogenic micro-organisms in products at pH >4.5
- Process water: Faecal streptococci, coliforms, total viable count

2. Other biological hazards:

- Pests, e.g. insects, seeds, rodents.

As regards chemical hazards, the analysis considers for example:

- the quantity of nitrate/nitrite in the process water
- contamination risks with cleaning products and disinfectants
- the presence of mycotoxins
- pesticide residues.

As regards physical hazards, the analysis considers for example:

- metals
- wood
- glass
- string and pieces of packaging material (paper, plastic,...).

The hazards and their causes are discussed within the HACCP team. For each hazard, the team determines what risks are present and what measures are or have to be implemented.

In this regard, the principal of "due diligence" applies: everything which can be done must be done, to the best of our ability and honourably and in good conscience, to protect the consumer from hazards.

It is recommended to carry out a risk assessment (consequence / seriousness and probability of occurrence /frequency of each hazard). This assessment establishes priorities and focuses corporate resources during the definition of preventive measures to address the most serious risks. This assessment should be documented.

Preventive measures are activities, techniques, resources, equipment or factors required to control hazards identified by the HACCP team. These measures eliminate hazards or limit their occurrence to an acceptable level.

It should be remembered that:

- more than one preventive measure may be necessary to control a given hazard and several hazards can be controlled by a single preventive measure.
- There may be a choice between several preventive measures and, in this case, it is appropriate to determine the relevance of the identified measures in order to select the most suitable for each situation. Where appropriate, it may be useful to determine the cost/efficiency ratio of the intended measures.
- The approach should be creative and not limited to what exists or is usual: in addition to the measures subject to immediate application, this approach may give rise to a timetable of modifications or investments in buildings, machinery or equipment.

N.B.: If a formal, objective risk analysis is carried out, one should be able to determine when "damage" will occur and how great the "damage" will be for a consumer of a non-conforming end-product.

- **STAGE 7: Apply HACCP Decision Tree to Each Process Step**

**(Principle 2)**

For each process step, the CCP decision tree is followed for each identified hazard and the accompanying preventive measures.

By answering the successive questions, the process steps where control is necessary can be identified so that possible food safety hazards can be prevented, eliminated or reduced to an acceptable level.

The decision tree should be used with common sense taking into consideration the hazard assessment in stage 6.

### **7.1 CCP-Decision Tree**

**Question 1: Do preventive measures exist for the identified hazard?**

If the preventive measures exist and are carried out, go to question 2.

If not the HACCP team must determine whether any control of the hazard is required for safety at this stage in the product flow chart.

Questions (3) and (4) can be useful when answering this question. If control is required, the process stage or product itself has to be adapted so that control is made possible and so that the analysis can be continued.



**Yes: go to question 2**

No: Is control necessary at this step in the process for the safety of the product?

>>>>>No: Not a CCP for this hazard at this step

>>>>>Yes: Modify step, process or product and go back to question 1

**Question 2: Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level?**

When answering this question, you must have a clear idea of the relevant technical details of the product (acidity/pH, Brix, etc.) and the purpose of the process step.

If the team answers YES to this question, this step in the production process is a CCP for the identified hazard. The team must then determine which parameter in the CCP is critical (ingredients, process criteria or handling operations).

If the team answers NO, go to question 3.

**Yes: CCP for this hazard at this step****No: go to question 3****Question 3: Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable level(s)**

Are the ingredients, raw materials, the immediate (production) environment (e.g. personnel, materials, discharge pipes a source of the identified hazard such that the end product may be contaminated?

The answer is YES if the team has any doubts regarding this question.

It must also be borne in mind that one single step in the entire production flow chart will not increase the hazard to an unacceptable level, but that the total accumulated hazard will reach the threshold level through a combination of different steps. Account must therefore be taken of the additional hazard of the subsequent steps in the flow chart.

If the answer is NO, this step is not a CCP; if the answer is yes, go to question 4.

**Yes: go to question 4****No: Not a CCP****Question 4: Will a subsequent step eliminate identified hazard(s) or reduce likely occurrence to an acceptable level?**

If the answer to question 3 is YES, examine the following steps in the production process and determine whether the hazard will be eliminated or reduced to an acceptable level.

If the team decides that the answer is NO, this step is a CCP

The team determines in each case which parameter in the CCP is critical (e.g. raw material, process step). By contrast, if the team decides that the answer to this question is YES, this step is not a CCP.

**Yes: Not a CCP**

**No: CCP for this hazard at this step**

For each process step and hazard in the flow chart, the decision tree is once again followed

- ***STAGE 8 : Establish critical limits for each CCP***

**(Principle 3)**

The HACCP team establishes the control parameters and their critical limits for each CCP.

These parameters must be measurable and/or observable and controllable e.g.:

Physical parameters: e.g. temperature, time, brix value (water activity)

Chemical parameters: e.g. acidity (pH), mycotoxins

Biological parameters: e.g. total plate count, yeasts, coliforms, insects

Critical limits must be drawn up based on own experience, external expertise or on precise experiments and which must be met in order to ensure that a CCP is under control.

Target values and tolerances may relate to one or more characteristics i.e. physical, chemical, microbiological characteristics of the process and/or product.

- ***STAGE 9 : Establish a monitoring system for each CCP***

**(Principle 4)**

In this step, we must determine how the monitoring of the identified CCP's will be carried out. Monitoring is the process of measuring and observing specific parameters according to a predefined plan. The inspection methods implemented are visual observations, physical measurements and chemical and microbial analyses.

Methods that can supply a rapid response are preferable. These methods, quite often take the form of visual observation and physical or chemical measurements. Microbial methods are

often difficult to use in this context (lack of rapidity, too large sampling to be statistically significant). However, they are essential to establish requirements (risk analysis) and to check that the system functions effectively and properly.

For these measurements, attention must be paid to the location, the frequency with which they are taken and the calibration of the measuring instruments.

- **STAGE 10 : *Establish corrective actions***

**(Principle 5)**

It is important that adjustments can be carried out in case of any deviations from the defined critical limit. For this reason, for each CCP, corrective actions must be defined which allow the CCP to be brought back under control.

Corrective actions must be covered by specific operational procedures. Their implementation must be recorded in an appropriate manner.

Recorded information includes the following:

- product identification
- type of deviation
- cause of deviation
- corrective action taken
- person responsible for corrective action
- quantity of product affected
- other actions implemented

- **STAGE 11 : *Establish verification procedures***

**(Principle 6)**

Verification entails that checks are carried out at regular intervals to determine to what extent the HACCP plan is being implemented and to ensure that it is functioning effectively. Verification of the system can range from a daily inspection of the registration forms to the execution of more extensive controls such as internal audits.

A review of the HACCP plan is necessary in case of reconstruction, new investments and when the verification suggests that the current system no longer comes up to standard.

- ***STAGE 12: Establish record keeping and documentation***

**(Principle 7)**

The filing of the HACCP data at all steps is important for traceability, for verification, for official organisations (food inspection) and as a proof of product safety.

Examples are records associated with:

- raw materials
- ingredients
- product safety
- processing
- packaging
- storage and distribution
- deviation files
- modifications to the HACCP system

The records can be in the form of registration forms, checklists, audit reports, analysis reports, control reports, complaint records, etc.