

Guidelines on HACCP, GMP and GHP for ASEAN Food SMEs

A GUIDE OF GOOD PRACTICES FOR THE PRODUCTION OF FOOD THAT IS SAFE FOR HUMAN CONSUMPTION



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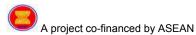
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European Committee for Standardisation Comité Européen de Normalisation

The information contained in this document reflects the views of the Implementing Agency and Experts, but does not necessarily reflect the position of the European Commission.



FOREWORD

These guidelines have been developed in the framework of the Food Sub-programme of the EC-ASEAN Economic Cooperation Programme on Standards, Quality and Conformity Assessment, 2003-2005. This programme funded by the European Commission was implemented by the European Committee for Standardisation (CEN).

The guidelines propose an innovative method towards food hygiene and HACCP for Small and Medium Enterprises of the food sector, entitled *Comprehensive Hygiene Management*. This method has been elaborated by Dr. Richard Bonne; a French veterinary inspector and teacher with more than 20 years of professional experience in inspection in the food industry in Europe, Asia and Mediterranean countries.

The methodology which is proposed in these guidelines is the result of a long observation of the problems which SMEs are facing when developing control systems to comply with European and international requirements for Food Hygiene and HACCP. It has been applied and taught in Europe for ten years, prior to being brought to this programme.

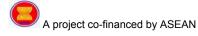
For the purpose of this programme, the method was tested through a pilot approach combining on-the-job training for young professionals and technical assistance to food SMEs in Indonesia, Philippines and Thailand in 2004-2005. Thirty food SMEs of different nature and more than 70 trainees have participated in this pilot experiment. Dr. Richard Bonne (in Thailand), Mr. Nigel Wright (in Indonesia) and Mr. Laurent Camberou (in the Philippines) have implemented the method with the assistance of 11 local experts and the trainees in the food SMEs. Each trainee was assigned a specific project to help one of the SMEs to apply the recommendations of the experts.

They have achieved remarkable progress in the participating SMEs in a period of only one year. Some companies have reduced their quality rejection rates (one of them by 9%) and increased their market opportunities (one of them by more than 50%). Others have significantly improved their audit scores with their international clients (world-wide pizza restaurants chain), or have been able to pass audits to become suppliers of international retail companies (French-owned hypermarket chain) operating locally.

These ASEAN food SMEs have demonstrated that with a strong commitment from their management, they could apply the Comprehensive Hygiene Management Method with success to gain competitiveness, through meeting the European and International requirements for food hygiene and HACCP.

These guidelines provide directions on how to apply the method, with examples taken from the pilot programme which took place in Indonesia, Philippines and Thailand. The guidelines also contain an Audit Guide to assess the situation in food SMEs and guide them towards GMP, GHP and HACCP through a practical and systematic approach. They can be used in combination with the EC-ASEAN HACCP training manual available at CEN-PCU.

To all users of these guidelines, we wish success in the application of the method and a most prosperous future for their enterprise.



ACKNOWLEDGMENTS

CEN-PCU would like to express its gratitude to Dr. Richard Bonne who has been providing the technical leadership in this activity and has allowed his method – *the Comprehensive Hygiene Management* - to be applied for the benefit of the participating food SMEs and ASEAN. We hereby express our thanks for his sustained efforts in the preparation of the teaching and application tools, as well as his technical guidance which has benefited to all the actors and beneficiaries of this programme.

Our deep appreciation also goes to Mr. Laurent Camberou and Mr. Nigel Wright who have been accompanying the participating food SMEs in Indonesia and the Philippines, throughout the process since 2004, and have directly contributed to the preparation of these guidelines, enriching them with their experience and knowledge.

Warm thanks are also extended to the group of Indonesian, Filipino and Thai experts who have been relaying the EU experts in the participating SMEs, and have made this project a success story, namely: Mr. Visith Chavasit, Mrs. Ratih Dewanti, Mrs. May Gatchalian, Mr. Tenku A.R. Hanafiah, Mr. Somchai Komolyingcharoen, Mrs. Lilis Nuraida, Mr. Pisit Rangsaritwukul, Mrs. Puangpetch Silkarn, Mrs. Katchaporn Temyord, Mrs. Lusiani Tjokronegoro, and Mr. Priyo Waspodo.

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Lastly, we would like to thank all the participating food SMEs which have voluntarily participated in the pilot programme and allowed the team to use examples taken from their operation to illustrate key aspects of these guidelines, namely:

- In Indonesia: PT. Macroprima Panganutma, Tangerang, PT. Ciptayasa Putra Mandiri, (Goldfrance Jakarta Timur), PT. Niramas Utama (Bekasi), PT. Nutrifood Indonesia (Bogor), PT. Bina Mentari Tunggal (Fiva Food Subang), PT. Madusari Nusa Perdana (Cikarang), PT. Morindo International (Cikarang), PT. Trias Sukses Dinamika (Bogor), PT. Japfa Santori Indonesia (Tangerang),
- In the Philippines: DGS (Metro Manila), Mura Sarap (Manila), Lety's Buko Pie Factory (Manila), TSB (Manila), Gracious Food Dried Mangoes (Manila), Anjo Farms (Pangasinan), Castillejos Farms (Manila), Cabalen (Manila), Le Chef International (Manila), Prime Fruit Company,
- In Thailand: PC. Farm Hydroponics (Bangkok), Rimping Foodland Products Ltd (Nonthaburi), P. Bangkok Meat Ball Ltd (Pathumthani), S. Khon kaen (Bangkok), Nongmon SMJ Products co Ltd (Chonburi), Nakornthai Edible Oils (Suratthani), Namprik Maesri Ltd (Nakorn Pathom), Chokpethsamut 1999 (Bangkok), Foodland Supermarket (Bangkok)

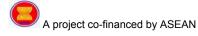


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PREAMBLE

This guide has been designed to take food producers through practices that may be adopted in order to assure the production of safe food. It has been devised by a team of European food specialists in a one year EC-ASEAN cooperation project.

It is designed to provide practical advice to food SMEs towards the application of the ASEAN Common Principles and requirements for Food Hygiene¹.

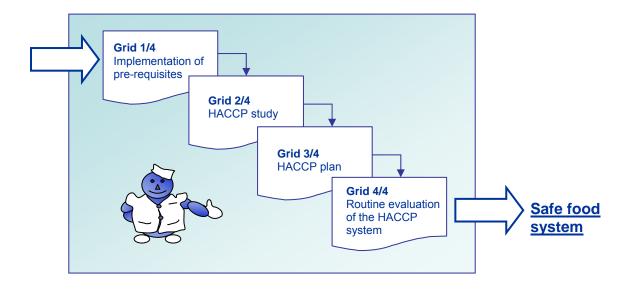
Control for safe food should not be viewed only as a tool for the preservation of health and life. It maintains financial economy by enforcing good visible practices, reducing waste, assuring customers and other parties (including insurance companies) of good management, and minimising the risk of food recalls (which can be almost impossible in an export context). Businesses using this approach will also find improvements in the competence of management and staff because this methodology involves such people in exercises that require discipline, self-critique, analysis and the implementation of resulting controls in a systematic way.

In essence, this guide covers the important stages of establishing:

- a. good practices throughout the food production process (nowadays, often described as 'Prerequisites')²; and
- b. a risk analysis process called HACCP (Hazard Analysis Critical Control Point) that has been adopted worldwide because of its success in controlling identified hazards.

The intent is a **practical** route for identifying gaps in safe-food control systems. It involves the use of four audit grids (matrices) (numbers 1/4, 2/4, 3/4 and 4/4) that direct the user along a path to a complete safe-food system.

Figure 1: Practical Route for identifying gaps in safe-food control systems



¹ Harmonised ASEAN requirements for food hygiene based on Codex standard, 2006.

² The term 'prerequisite' has been adopted since HACCP methodology came into use because implementers of safe-food programmes have found that basic good practices need to be in place *before* HACCP is introduced in order to keep the HACCP analysis and resulting control methods within a manageable scale – **in fact**, **HACCP is impossible without effective prerequisite establishment.**





Note

It is recognised that, in the supply chain (particularly when applied to sourcing ingredients from primary agricultural sources, such as small market gardeners or from local markets) that food manufacturers face difficulties in applying complete control on such supplies (e.g. for pesticide residue and other chemicals control etc.).

This must not be used as an excuse to not address these issues.

Co-operation between agencies (e.g. food producer associations, government health / agriculture ministries, test businesses), must be taken to promote hazard control by the adoption of agreed protocols or chemical application schemes. By taking a lead in this matter, food manufacturers will be well placed if there is ever any dispute following a safety incident.

Critical Note

All safe-food programmes lead to systems that need to be REVIEWED (as times, people, processes and regulations change). No system is perfect. There is a tendency for businesses to assume that, once a system is in place, all is O.K....

THIS SIMPLY IS NOT THE CASE.

A system is only as good as its worst failure. Use, re-use and re-use again the audit grids.



INTRODUCTION

This guide involves a practical four stage approach to the introduction of Prerequisite and HACCP programmes:

1. Good practices: Assessment and Implementation of Prerequisites

- Compare the situation of the company with a scheme of Comprehensive Hygiene Management for SMEs.
- Identify the items of the scheme which have not, or have only been partially satisfied amongst those which have been fully implemented, by answering the following questions:

item 1

- are the buildings and equipment in compliance with regulations and standards?
- o does a contractual relationship with raw material suppliers exist?
- o does an effective pest control plan exist?

item 2

o is a policy of staff health control defined and applied?

item 3

- are the rules of hands washing and personal hygiene defined and applied?
- does a cleaning plan of the buildings and equipment exist and is it effectively applied?

item 4

- do control procedures of the different "time/temperature" couples implemented in the company exist?
- is there a control of the products formulation constancy?

item 5

o does a sampling and analysis plan of the finish products exist?

training

- o is staff training ensured and regularly updated?
- The first part of this guide is devoted to good practices and to the search for provisions that need to be implemented in order to comply with any practices that have not, or have only partially been, implemented;
- Using audit grid 1/4 (developed for this guide), an initial assessment phase is completed by an evaluation of the prerequisites implementation stage
- With the help of the explanatory booklet, assurance is provided that criteria of the audit (grid 1/4) are entirely fulfilled before starting to carry out HACCP implementation (first phase) that is devoted to a preliminary study of the food manufacturing process.





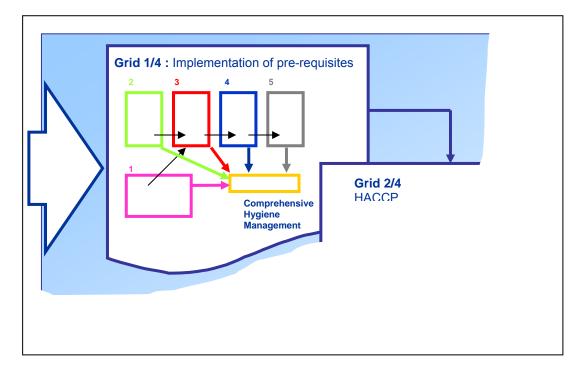


Figure 2: Detail of the first stage of the approach

2. First phase of the HACCP method (tasks 1 to 8)3: the HACCP Study

- HACCP method analysis, task-by-task, without being allowed to pass to the next task until
 the preceding one is entirely carried out;
- Audit by the use of grid 2 /4 (relating to the preliminary analysis phase of HACCP method) to check that each task carried out is completely and correctly fulfilled;
- With the help of the explanatory booklet, assurance that the criteria of audit grid 2/4 are entirely fulfilled, before being allowed to proceed to implementation of HACCP method second phase (devoted to HACCP plan design).

3. Second phase of the HACCP method (tasks 9 to 12): design of the HACCP plan

- HACCP method implementation, task-by-task, without being allowed to pass to the next task until the preceding one is entirely carried out;
- Audit by the use of grid 3/4 (relating to HACCP plan design) to check that each task has been carried out is completely and correctly fulfilled;
- With the help of the explanatory booklet, assurance that the criteria of audit grid 3/4 are entirely fulfilled, before being allowed to start operating the HACCP plan.

³ HACCP is based on seven principles, but these are utilised through a process involving a number of activities or Tasks. There is a variety of systems devised for HACCP implementation, each defining a different number of such Tasks. This guide uses the 12 tasks recommended in the joint FAO/WHO *Codex Alimentarius* General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4-2003).



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4. Third phase: Routine evaluation of the operating HACCP plan

- With the help of the explanatory booklet, make sure that the criteria of the audit grid 4/4 (relating to the real and effective operation of the HACCP plan) are entirely fulfilled;
- If all of the criteria of audit grid 4/4 are not fulfilled, return to stages 3, 2 or even 1 (above).

The methodology described in this guide has been designed to deliver an effective safe food system for all food producers.

There will be circumstances where producers use or develop, under their responsibility, other methods of management.

This is, of course, perfectly acceptable so long as the method delivers:

- EFFECTIVE CONTROL;
- ANY EVIDENCE OF EFFECTIVENESS REQUIRED.



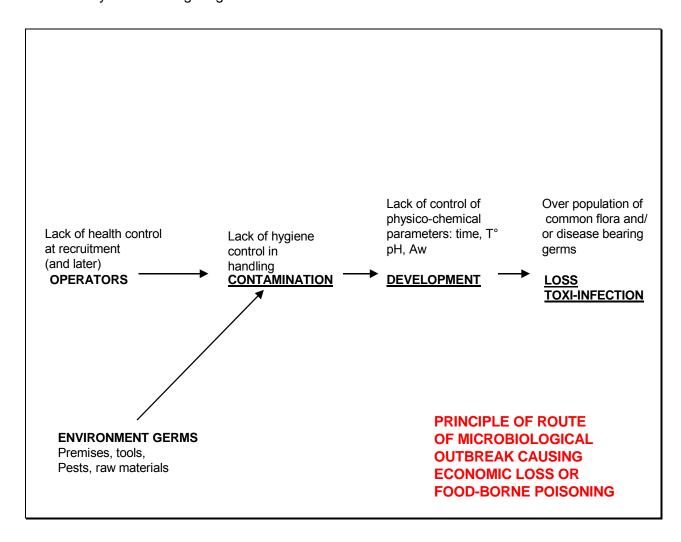
REMARK



CHAPTER 1: GUIDE TO GOOD PRACTICE

1.1. Construction of the Guide to Good Practice

This guide follows a logical route to defining the organisation of good practice, which can be illustrated by the following diagrams:







KEY DEDUCTIONS FROM THE DIAGRAM OF OUTBREAK OF ECONOMICAL LOSS OR FOOD- BORNE POISONING

- The concomitant intervention of the contamination and the multiplication is essential to the appearance of a food accident
- This diagram explains the mechanism of action of all the preservation methods, which reciprocally establishes its validity
 - total control of contamination <u>or</u> multiplication induces a long lasting preservation (canning, freezing)
 - partial control of only one factor or of the both , induces a short lasting preservation (refrigeration, pasteurization)

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Mode & duration (long lasting or limited)

ACTION MODE & DURATION OF PRESERVATION METHODS

Methods

pressure

| Cold | Refrigeration | Limitation of bacterial growth |
|---------------|----------------------------------------|------------------------------------------|
| | Freezing | Inhibition of growth |
| Heat | Canning | Total elimination of contamination |
| | Pasteurization | Reduction of contamination (followed by |
| | | refrigeration) |
| | Hot chain | Inhibition of growth |
| Modified | Vacuum package | Inhibition of adulteration aerobic flora |
| atmosphere | Gas (CO ² ,N ²) | Inhibition of adulteration aerobic flora |
| _ | | |
| Stabilization | By sugar | Growth inhibition through lowering of Aw |
| | By salt | Growth inhibition through lowering of Aw |
| | By vinegar | Growth inhibition through lowering of pH |
| Irradiation | Ionisation | Total elimination of contamination |
| | | |
| Dehydratation | Drying | Growth inhibition through lowering of Aw |
| | Freeze-drying | Growth inhibition through lowering of Aw |
| Pressure | Ultra high | Total elimination of contamination |

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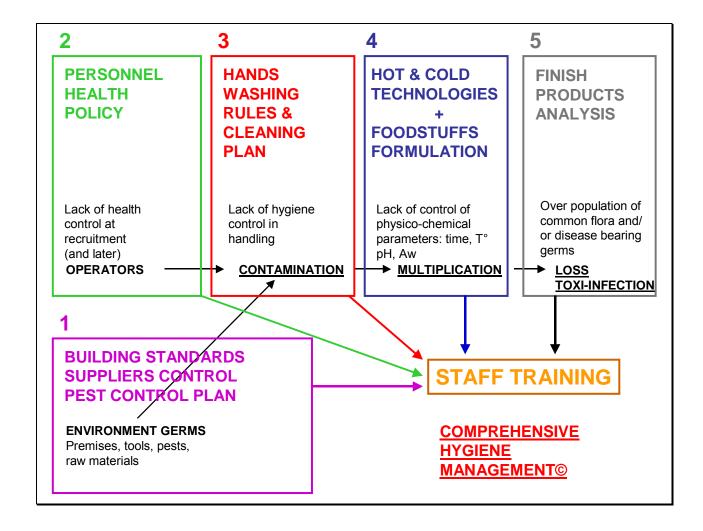
This flow can be used to define and organise the food safety policy of the company. All elements of the above schematic will be addressed by 5 sets of control provisions to organise the Comprehensive Hygiene Management© scheme.

Each set of control provisions is explained in chapter one of this guide.

Each set of control provisions is referred to by a specific colour code: Cian, Green, Red, Bleu or Grey.



Figure 3: Five sets of control provisions



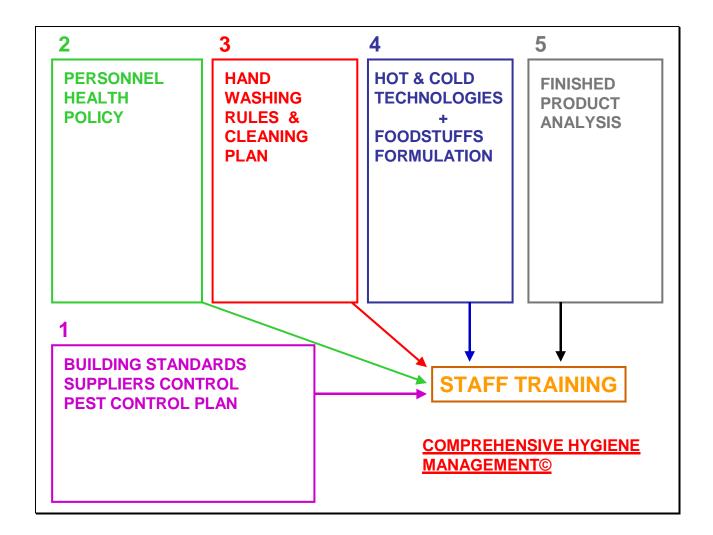




And hence:

The General Organization of the Guide of Good Practice or Comprehensive Hygiene Management© scheme:

- 1 Building Standards, Suppliers Control, Pest Control Plan
- 2 Personnel Health Policy
- 3 Hand Washing Rules & Cleaning Plan
- 4 Hot & Cold Technologies + Foodstuffs Formulation
- 5 Finish Products Analysis





1.2. Building Standards, Suppliers Control, Pest Control Plan

Buildings and Environment Conformity

The design of new buildings, or the improvement of the existing buildings and equipment, should respect the following principles:

> General principles

The plant should have at least four doors:

one door for the entry of raw materials one door for the entry of production staff one door for the shipment of finished products one door for waste disposal

• The onward flow principle.

Successive production operations should ensure a forward progression of products, without back return, from the lowest level of development towards the highest one, from the least healthy condition towards the healthiest one, from the least susceptible condition towards the most susceptible one.

In order not to flout this rule, operators should not move from place to place - they should maintain work at the station at which they are placed.

No production line criss-cross.

Two (or more) production lines should not crisscross. They can be connected (e.g. assembly of composed products put into a previously washed package) or split (e.g. manufacturing lines of by-products obtained during the preparation of the main product).

Separation of cool and warm zones.

Zones where hot foodstuffs are treated shall be clearly differentiated from those where cold ones are treated in order to avoid their thermal pollution.

Separation of clean and dirty areas.

Waste produced with each stage of manufacture should be removed in the most direct way possible towards its treatment location(s) (e.g. dishwashing) or storage (e.g. waste handling).

Construction Regulation and Standards

Floors shall be:

smooth and impermeable non-skid hard-wearing washable not subject to rot

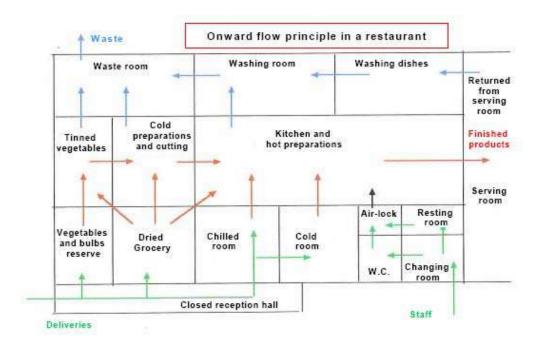




The onward flow principle (example: onward flow principle of a restaurant):

The following chart illustrates the onward flow principles in a restaurant, characterized by the following elements:

- there are <u>different doors for the different flows</u>, first for raw materials and staff, and secondly for finished product and waste;
- the layout respects the onward flow principle (no back return);
- -there are no criss-crossing issues between raw materials/finished product/waste/staff;
- Separation of dirty and clean areas is respected;
- Separation of cold and hot areas is respected.





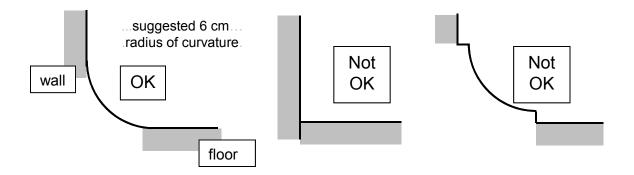
· Walls shall be:

smooth light coloured washable not subject to rot

'shock-resistant' (up to 2 metres high)

bonded to the floor by semicircular joints, with no nooks or crannies, to allow easy cleaning and drainage of wash and rinse water (see diagram below)

Figure 4: Semicircular joints between walls and floors



Ceilings shall be:

light coloured washable smooth

- Passive or mechanical ventilation devices must ensure the elimination of steam and smoke
- Lighting shall be:

bright

neutral in colour (so as not to modify the foodstuff colours)



Constructing a new plant (an example on how to apply HACCP from scratch):

Anjo's farm is a fish producing company, located in Pangasinan in north of the Philippines, specialized in deboned "bangus" fishes. In order to comply with the requirements of EU for fish products, the company launched an HACCP study before starting the construction of its new premisses.

The following benefits, in terms of food safety, were identified:

- the layout of the factory dimishes criss-crossing issues;
- the number and location of washing-stands has been revised;
- -the changing rooms and toilets have been located in an appropriate area;
- the monitoring of temperatures in the premises is now under control.



Equipment conformity

Equipment shall be:

smooth not subject to rot

stainless

washable (without nooks and crannies that are inaccessible for cleaning)

Compliance with these rules prohibits the use of undressed wood, cardboard or tape for the manufacture of furniture (or their use in temporary repairs)

Equipment should not be placed adjacent to walls so as to allow for proper cleaning and for proper pest and cleaning inspection.

Materials used to manufacture tables shall be:

smooth not subject to rot light coloured hard-wearing washable impermeable

The compliance with these rules prohibits the use of undressed wood or cardboard, and porous or rough materials like undressed concrete. The materials most often used are stainless steel, plastics and glazed earthenware tiles.

Tools shall be:

inalterable in all parts.

The compliance with this principle prohibits the use of wood even for the handles of tools. The materials most often used are stainless steel, aluminium (which may not be allowed by some food control authorities, in the US for example) and plastics.

Machines shall be:

not subject to deterioration, preferably stainless, definitely non-corrosive. easily dismantled.

washable (without nooks and crannies that are inaccessible for cleaning).



1

Building Standards, Suppliers Control, Pest Control Plan

"Breaking the glass" (an example of physical hazards):

Detecting shards of glass in the product is almost impossible.

Trying to avoid this hazard implies that the company is able to put the "sources" of glass under control.

A fish processing plant from the Philippines had been provided with lamps, but the light bulbs were not properly covered.

The management decided to adapt a plastic sheet or plexiglass on each lamp in order to avoid any possibility of glass debris in the fishes.





Pest Control Plan

Pests generally taken into account are rodents and insects (and, in S.E. Asia, some small amphibians). In certain sectors (e.g. hypermarkets or other large spaces) birds may settle in the superstructures of the buildings or cats (e.g. in slaughter-houses) can soil the environment whilst attacking stored foodstuffs.

Passive control, surroundings and outbuildings keeping

In order not to allow the settlement of pests on the plant surroundings, (i.e. not to provide them places of refuge and feed resources) it is necessary to maintain a non-attractive environment which includes:

- Isolated storage of unutilised materials, pallets and machines, without contact with the walls of the buildings.
- Design and maintenance of external spaces, including:
 - The elimination of holes and spaces in waste land with high vegetation.
 - The regular short shearing of grass lawns.
 - The absence of rags, papers, plastic films and other detritus abandoned on the ground (sources of materials for the construction of rodent nests).
- Keeping of interior surfaces (racks, tops of furniture pieces) clean so as not to leave feed sources for rodents and insects.
- Tidying and cleaning of technical buildings (machine shop, boiler room) so as not to support rodent settlement.
- Installation of mosquito nets at windows and suitable screens on access doors.
- Rigorous management of waste containers which shall include:
 - Frequent washing so as not to attract insects.
 - Storing on a clean and easily washable surface (water tap and floor drainage of waste water).
 - Kept closed (to prevent use as a feed source by all types of pests).
 - Filling without overflowing (not to drop food waste on the ground).

Active control

Pests detection

- Insects:
 - Search for dead insects.
 - Search for alive insects in places of refuge (drawers).
 - Search and careful removal of bodies in electric insects trap collectors.
- Rodents:
 - Search for rodents dropping or traces of urine.





- Search for attacks on foodstuffs (biting traces) or attractive conditions (torn open bags).
- Presence of traces of grease of rodents on the usual passing through points.
- Search for nests of rodents.

Rodents control plan

This plan is composed of a complete (set of) document(s), defining actions to be implemented, and including:

- Technical cards of rodent poisons utilised.
- Procedure and time tabling of rodent control operations, including the checking and renewal of distributed poison baits.
- Time tabling and procedure for identification, evaluation and elimination of possible rodent infestation.
- Implementation procedure of additional treatment in the event of a residual infestation.
- Factory plan on which the locations of poison baits are identified.
- Identification on walls of the premises in order to locate poison baits.

Insect control plan.

This plan is composed of a complete (set of) document(s), defining actions to be implemented, and including:

- Technical cards of insecticides utilised.
- Time tabling and procedure of insect control operations (walls insecticides, paint application and renewal, premise insecticide spraying).
- Factory plan on which are localized the poison baits devoted to crawling insects.
- Factory plan on which the locations of electric insect traps are identified.
- Timetabling and procedure for traps emptying and trapped insects monitoring in order to evaluate infestation levels.



Preventing chemical hazards on raw materials (an example):

Prime Fruits is a banana chips factory, located in the southern island of Mindanao, in the Philippines.

In order to prevent any chemical hazards on their raw material ("saba" or "cardaba" bananas), the company decided to implement a series of measures, comprising the following elements:

- precisely specifying their requirements in terms of quality and safety (in written form);
- regularly checking the level of those requirements in their raw materials;
- training the staff collecting and peeling the bananas;
- advising their suppliers about their safety/quality requirements;
- regularly auditing their main suppliers and applying a premium price policy when buying their raw materials.



Contractual Relationship with Suppliers and Deliveries Control

Raw materials specification.

In order to have a sound basis for deliveries' control, the characteristics of ordered raw materials need to be specified precisely with suppliers. The conditions of acceptance / rejection of batches also need to be clearly defined. Raw materials specifications should include:

- Cards of specification of raw materials.
- Formulation defining physico-chemical composition, presentation, particle or chunk size and variability, constants (e.g. pH, Aw, salt or sugar concentration, viscosity of the liquids).
- Condition defined by type, volume, shape.
- Labelling (in particular with food safety official marks and elements of traceability).
- Bacteriological standards (lawful or contractual) (possibly including contractual access to results of bacteriological control plans set up by suppliers).
- Purity criteria, including absence of, or allowed levels of, foreign bodies (plastic, glass, metals) or residues (heavy metals, pesticides,...).
- Condition for and responsibilities in case of inspection failure (removal, replacement etc).

Preferential choice of suppliers benefiting from:

- Certification (e.g. ISO 9001, ISO 22000),
- or of a national or international approval (e.g. EEC and USA approvals),
- or of other approvals (Halal, Kosher, vegetarian, GM free, retailer promoted assurance schemes, etc),
- or of an accreditation or a referencing by a recognized customer.



Hazard(s) control on raw materials ?:

Small food companies are sometimes faced with the following questions:

- how to control the quality/safety of their raw materials when buying from several small supliers?
- Is control at reception, or when buying the raw material on the market a Critical Control Point (CCP)?
- How to set up **effective control** of the raw materials in both cases?

Food SMEs should try to implement the following elements:

- clarify their quality and safety specifications with their suppliers (in written form);
- implement easy-to-check criteria (e.g. visual or simple measurements) at reception of the raw materials;
- consider reception of a raw material to be a CCP only if no subsequent operation reduces or eliminates the hazard(s) and when you have got a parameter (to, pH, aW,...) to control.



> Preferential choice of suppliers accepting customer visits of their production site.

Recording cards of deliveries check.

These cards shall allow for minimum control of the following criteria:

- Delivery temperature of the product (see Appendix Calibration).
- Use-by date or deadline of optimal use.
- Labelling conformity and, in particular, official food safety marks.
- Appending of batch identification marks necessary to operate any upstream and downstream traceability system.
- Free from packaging damage.
- Cleanliness of delivery vehicles.

Details of parameters checked / inspected on deliveries may be recorded in a variety of ways, perhaps either on check cards or by use of an inspection grid, printed from ink pad, on the reverse of delivery orders.

Receiving (into storage) procedures for raw materials following delivery checks, and any initial decontamination operations.

Some care must be taken during introduction of raw materials into storage:

- Maximum time duration following arrival of raw materials into temperature controlled storage (chill rooms and cold rooms) shall be defined and respected.
- Soiled packaging (outer cardboard boxes, wooden pallets or supports, etc) shall be eliminated before placing raw materials in clean stores.
- If fruits or vegetables undergo a decontamination treatment by steeping in disinfectant solution (chlorination, ozonisation, ...) the concentration of disinfectant and process time (max and / or min) shall be defined and controlled for each batch.

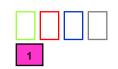
> Rejection. Procedures.

The application of a rejection procedure must correspond to the clauses drawn up by contract with the supplier. The following needs to be recorded on rejection cards:

- Reference(s) of the rejected batch (identification, constitution).
- The reason for rejection by reference to conditions defined in the supply contract.
- Signatures of the conveyer and the receiver.







Traceability (some definitions) :

How can you recognize the difference between:

- upstream traceability;
- downstream traceability.

Caption 1 : Upstream traceability

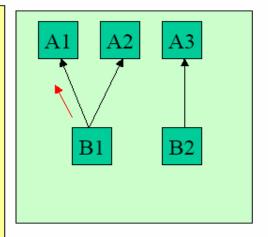
In this case, we are able to trace **up** the origins of batches B1 and B2 due to the identification of the lots and to records kept.

But for B1, there are several possible origins.

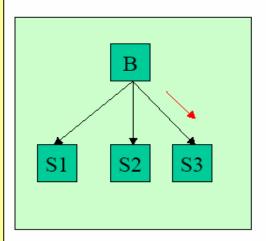
Caption 2 : Downstream traceability

Thanks to the identification of the fabrication batch (B) and to records kept, it is possible to trace **down** the destination of lot F.

But in this case the lot is split and follows different distribution routes.



A1: agricultural production lot A2: agricultural production lot A3: agricultural production lot



S1: distribution lotS2: distribution lotS3: distribution lot





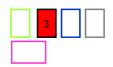
Personnel Health Policy

1.3. Personnel Health Policy

Enforcement of staff (and management) health policy depends theoretically on food factory occupational health care. It is nevertheless necessary to recommend the following provisions:

- An annual medical consultation of every operator concerned in handling or manufacturing of foodstuffs.
- The systematic monitoring of staff for lesions caused by staphylococcus through clinical examinations of arms, hands, face, throat and other exposed skin, to be carried out by a medical practitioner of appropriate food handling experience.
- The systematic monitoring of staff for potential Salmonella carriers (probably subject to frequent bouts of diarrhoea) by conversing with a medical practitioner from industrial medicine.
- Enforcement of detection procedures for operators likely to carry Staphylococcus or Salmonellas, by way of bacteriological analysis.
- Medical treatment for those diagnosed positive with one of these two micro-organisms (without penalty so as to ensure staff confidence in the scheme).





1.4. Hand Washing Rules and Cleaning Plan

Hand Hygiene

The hands, frequently in direct contact with foodstuffs, need to be considered as the first operational tool. For this reason, detailed attention must be given to their cleanliness (just as with any equipment placed at the operator's disposal) and to their washing regime. It should be noted that the hands, if not subjected to strict hygiene rules, constitute the first vector of contamination of food stuffs, by germs (pathogens) passed on from the operator.

The implementation of training to demonstrate the proper technique for hand washing and drying is recommended.

Hand wash sinks

Hand wash sinks shall conform to the following principles:

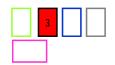
- Water flow shall not be operated by hand, but by foot or knee or by an automatic presence detector.
- Liquid (or foam) soap shall be bactericidal but not a skin irritant (thereby excluding toilet soaps without bactericidal effect).
- Soap dispensers shall be placed in a position adjacent to the wash sinks.
- A second dispenser reserved for a disinfecting solution (e.g. of alcohol solution) can be associated with the liquid soap dispenser.
- The device devoted to hand drying must be of single use (paper towels being practically the only possible solution).
- Nailbrushes complete the wash-stand equipment. They should be made entirely from synthetic matter (handle and bristles) and need to be kept in a dilute clean disinfectant solution, renewed for each work period.

Hand washing procedure

- Wetted, liquid soap-smeared hands must be rubbed for 20 seconds (the operator counting: 101 . . . 102 . . . 103 . . . up to 120).
- The rinsing of hands, which are rubbed under running water, must last a minimum of 10 seconds (counting...).
- Wiping of the hands is not systematic, not being necessary for certain types of activities.
- If a disinfectant solution is used, it shall be allowed to dry naturally on the hands.







Hand washing frequency

With effective hand washing taking a long time, strict definition of the frequency and circumstances of this procedure is needed. Hands must be effectively washed whenever and wherever their contamination is practically certain. This washing, carried out immediately after dirty operations, will restore hands to satisfactory cleanliness and will prevent any points in contact with hands from gross contamination. If these contact points are themselves grossly contaminated, hand hygiene is not possible because, as work continues, they are immediately recontaminated.

Complete hand washing after dirty operations (or dirty situations)

(practically the same in all branches of the food industry⁴:

- Arrival at the work station.
- Passing through and / or using toilets or changing rooms.
- After nose blowing.
- After dustbin handling.
- After handling cardboard boxes from delivery (cardboard box bases are often very dirty).
- After handling shell eggs (frequent contaminated by salmonellae).
- After handling non-cleaned vegetables direct from the soil.
- After handling game or poultry 'in fur or feather'.
- while passing from raw food production areas to cooked food product areas (i.e. from low risk to high risk areas).
- In this case materials used (cutting boards, knives, etc...) must similarly be changed or correctly cleaned.

Quick hand washing before conducting clean operations

There is a multiplicity of clean operations, each specific to a branch of the food industry (e.g. cooked meat cutting, assembly of pastry making...). Whilst remaining at work within the confines of an appointed process, only a quick hand wash procedure is necessary, so long as operators systematically care about washing their hands after previous dirty operations and if contact point hygiene control is maintained.

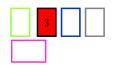
Hands contact points hygiene

- Hands contact points shall be listed (handles of refrigerators or doors, kitchen utensil handles, machines, electric switches, etc).
- These contact points must be the object of meticulous daily cleaning (or even at each restart at the work station or with a change of operator).

⁴ This list is not limitative and sometimes must be completed according to the specific situation of each food establishment.



3



Additional rules

- No smoking at the work station, in the work place or whenever wearing work clothes.
- No food tasting involving hand-to-mouth.
- No nail varnish (or perfume this is not a hygiene concern, but is one of potential food taint).
- Maintaining neat short finger nails.
- No rings, jewellery or watches to be worn (even if wearing work gloves).
- The washing of gloved hands must be carried out with the same régime as for bare hands.
- No reuse of disposable gloves after removal.

Work Clothing Hygiene

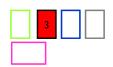
In agro-food industries, clothing can be a major vector involved in food contamination. Work clothing, when not clean, can be a source of contamination for hands, whenever it is used to wipe them. In certain sectors, such as butchery, clothing is in direct contact with handled carcasses, (e.g. in shouldering carcasses when loading delivery vehicles).

Work clothing management must respect some specific principles:

- It is of a standard type and is provided by the company.
- It is put in a locker (or a compartment of cupboard), physically separated from personal clothing (the locker shall be maintained in a clean manner).
- Its colour, or the colour of one of its elements (cap, overall), may be specific to a work station or a zone of assignment of operators.
- It includes a cap or net which covers all hair this includes snoods for moustaches and beards (head covering may also be devoted to other purposes, such as shock proof helmets).
- It includes shoes (crush proof and non-skid) which are only worn in the factory (foot wear shall not contaminate work wear in a locker).
- It is laundered by the company or under its responsibility (e.g. by contract with an industrial laundry in this case the wash method shall be defined to ensure that laundry is not cross contaminated from dirty clothing from other sources).
- It is :
- hard-wearing to mechanical actions (tear) and frequent washing,
- ignition proof.
- permanent devices (boots/shoes washstands) or movable ones (trays), containing a disinfecting solution, must allow cleaning/disinfection of shoes or boots before getting into the production zone







<u>Premise Hygiene – The Cleaning Plan</u>

Good hygiene of buildings and equipment involves the enforcement of a cleaning plan.

- > There are at least two copies of the cleaning plan in the factory:
 - A complete version of the document, held and updated by the department of quality management, and to which technical cards of cleaning and disinfection products used are attached, as well as directions for use of machines used in cleaning processes;
 - A divided version, allowing each cleaning operative of the cleaning plan to have the part(s) which relates to her/his duty.
- ➤ In the cleaning plan file, tasks checklists are included, as well as expected results of surface bacteriological tests.
- ➤ The execution of cleaning tasks must be followed up by recorded checks by the operative, immediately monitoring its effectiveness.
- Conducting microbiological analyses of surfaces makes it possible to check the effectiveness of the cleaning plan.



IMPORTANT

The method known as 'W.W.W.W.H.' (*mnemonic* - five **W**ives and one **H**usband) makes it possible to draft a suitable cleaning plan. These letters stand for six questions (when? who? what? where? why? and how?)⁵ that direct the development of the plan.

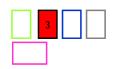
The choice of the first question (asked from $\underline{\text{When}}$? or $\underline{\text{Who}}$? or $\underline{\text{What}}$?) defines the process of organising tasks in the cleaning plan:

- 'When?' cleaning tasks will be organised by day, by week, by month (by schedule)
- 'Who?' cleaning tasks will be assigned by operator, by team...
- What? cleaning tasks will be organised according to building, department and equipment

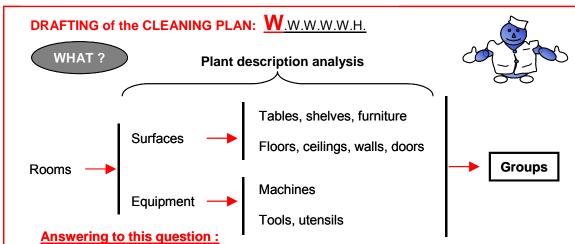
⁵ Frequently referred to as 'The Six Honest Serving Men' – for the poetic minded, refer to 'Just So Stories' by Rudyard Kipling.



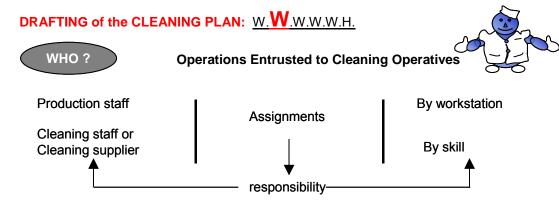
3



'W.W.W.W.W.H.' method application



- > ensures that all components of the establishment are included in cleaning operations.
- > eliminates useless equipment and objects which get in the way of cleaning.
- ➤ identifies each mobile component of a group (trolleys, container . . .) with a marked number to ensure its regular cleaning and maintenance.
- constitutes component groups, for which cleaning responsibility is entrusted to a defined operator.

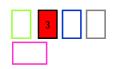


Answering this question must respect some principles:

- > even if employing an internal cleaning team or a cleaning contractor, production staff must never be completely detached from cleaning
- ➤ the cleaning plan must define the state in which production staff hands on materials to the cleaning team (switched off, dismantled, rinsed, excess dirt removed . . .)
- ➤ the cleaning plan must define the state in which the cleaning team hands back materials to the production staff (lubricated, reassembled, switched on . . .)
- ➤ if a contractor is responsible for cleaning, the cleaning plan provides the basis for the customer / supplier relationship by defining tasks set out in the contract







DRAFTING of the CLEANING PLAN: W.W.W.W.H.



At work place or at cleaning site



WHEN?

Cleaning Frequency

- > after each operational time (batch, shift . . .)
- > in catering, after each service
- ➤ daily

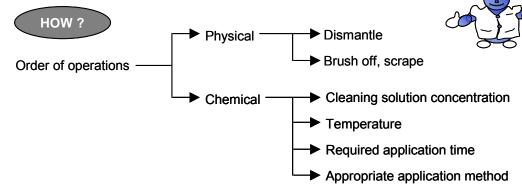
Defining cleaning days is required for any longer time intervals demanded:

- ☐ in order to check if the frequency is really applied
- ☐ to be able to control the continued application of identified cleaning tasks

For example Weekly every Monday

Monthly every first Tuesday of each month
Quarterly every first Saturday of each quarter
Annually during each annual shut down

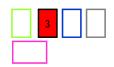
DRAFTING of the CLEANING PLAN: W.W.W.W.W.H.



- > the drafting of this procedure must ensure that it is legible and comprehensible for operators
- > cleaning procedures must take account of the nature of the dirt (mineral or organic)
- cleaning procedures must take account of the nature of surfaces to be cleaned







DRAFTING of the CLEANING PLAN: W.W.W.W.W.H.



Required Results



Visual Cleanliness

Required

Daily or Weekly defined check lists

Microbiological cleanliness (microbiological testing for surface contamination)

Standards: microbial population tolerated per unit of surface

• Methods: culture medium, Petri film, swabbing . . .

Providing information as a role in the implemented system of risk control

- Confirmation of the effectiveness of the cleaning plan (GHP).
- In the event of non-satisfactory results:
 - any action needed on the products manufactured during the control period – no action on products because such testing is only a 'snap shot' validation of effectiveness of cleaning operations and has no bearing on the potential hazardous state of a product.
 - > is cleaning plan discipline being maintained?
 - > is revision and modification of the cleaning plan required?

> Tool cleanliness during production time

During use, manual tools need to be subject to cleaning and frequent disinfection practices by rinsing and putting in a hot water sterilizer (82°C):

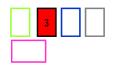
- the same tool is regularly cleaned and decontaminated by putting in the sterilizer,
- or several tools are used and placed in the sterilizer alternately,
- or all tools are changed periodically to be replaced by clean and disinfected material (every hour, every 30 minutes, etc...).

These operations of cleaning and disinfection of manual tools shall be carried out:

- After work on a soiled product (e.g. hide cutting in slaughter-house).
- Before passing from working on raw foodstuffs to cooked foodstuffs.
- In some operations, such as hide removal in an abattoir, operators are required to pass the tool from one hand to the other. In this case the secondary hand, already soiled, becomes the operating hand which holds the tool. Care needs to be taken to ensure effective cleaning of both tool and hand.





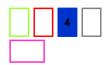


Checking hygiene/ cleanliness by yourself? (practical hints):

- Select 20 to 30 control criteria for hygiene/cleanliness that you will assess visually (or by simple measurements e.g. t°).
- Build-up a quarterly diagram with 13 colums (13 weeks/quarter) and as many lines as your control criteria (C).
- Select one person, responsible to perform the checks for the quarter (change this person every quarter, you could train a person from another department of the factory to perform the checks). Perform the assessment each week at the same hour.
- Each time a control criteria is checked, two possible answers:
 - the assessment is positive, that is an + (in blue)
 - the assessment is negative, that is an (in red)
- The total time for this assessment should be between 15 to 20 minutes.

| W | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
|----|---|---|---|---|---|---|---|---|---|----|----|----|----|
| | | | | | | | | | | | | | |
| C1 | + | + | + | + | + | - | _ | _ | _ | + | + | + | + |
| C2 | + | + | + | + | + | + | + | + | + | + | _ | - | + |
| С3 | + | _ | + | + | + | + | + | + | + | + | + | + | + |
| C4 | + | + | - | - | - | - | - | + | + | + | + | + | + |
| C5 | + | + | + | + | + | + | + | + | - | + | _ | _ | + |





1.5. Hot & Cold Technologies and Foodstuffs Formulation

Cold Chain Technology

The application of cold chain technology allows a routine control of physical parameters (time and temperatures), their monitoring and their recording. The monitoring of these parameters, for each batch stored or processed, allows the introduction of CCPs, if an HACCP risk analysis indicates that this is necessary.

In general, cold storage (frozen or chill) is reserved for high quality products. Cold application (freezing or chilling) needs to be conducted as quickly as possible and the appropriate low temperatures maintained continuously until further processing or consumption.

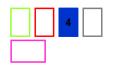
> Chilling

Chilling is the application of non-freezing cold temperature conditions to preserve foodstuffs. This technique only allows for the slowing down (not cessation) of deterioration. Consequently, it can be applied to foodstuffs only for relatively short periods according to food type, such as only 2 or 3 days for minced meat, to perhaps a few weeks for some pasteurized products.

- To avoid taint by other odours, or contamination from the cold storage ventilation, or dehydration, chill stored products must be protected:
 - by food wrapping film;
 - by an entire packing wrap.
- Any stacking of containers of unprotected foodstuffs must be avoided in order to prevent contamination of foodstuffs in lower containers from dirty bases of upper containers.
- Products of different food groups (meats, vegetables, fish...) need to be stored, if at all possible, in separate cold rooms.
- In the absence of separate chill storage rooms, it is necessary to store each type of
 product on a specific rack so as to avoid cross contamination (especially vertically) by any
 exuded liquids, with the most contaminated products on the lowest racks in order to
 minimise contamination by gravity.
- 'FIFO' (first in/ first out) must be followed for each type of product. (The use of products of the same type in order of expiry date is an alternative to FIFO).
- 'FIFO' is fulfilled by effective control of product turnover, made possible by enforcement of a traceability system.
- Expiry dates, on products' packaging, must be rigorously respected.







- Storage of unprotected foodstuffs directly on the floor (as well as packed products), must be rigorously prohibited, because it constitutes:
 - an obstacle to cleaning the floor;
 - subsequently, a source of contamination of work surfaces when products are used;
 - a potential source of hands contamination during the handling of heavy or bulky products.
- Ventilations ducts of chill rooms, and air dispersal socks in chilled work rooms, must be regularly cleared of dust and be washed, to avoid the spread of the spores of moulds accumulated on grids, ventilators and sock materials.
- The temperature of chill rooms must be regularly recorded for monitoring purposes, if at all possible by the use of automatic devices (automatic graph or computerised) for continuous recording.
- Alternatively, by direct temperature measurement and recording, checked in the stored product, at least once per day but preferably more frequently (based on the degree of confidence in the refrigeration equipment involved and use patterns of the store).

Quick chilling

This rapid cooling technique relates mainly to products cooked in advance, and to pasteurized products, after partial microbial decontamination by the heating process. Its use must respect particular principles:

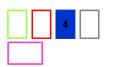
- The operation of a fast cooling chamber (or other suitable method) whereby the internal temperature of products must go down from 63°C (or more) to 10°C (or less) in under 2 hours.
- Dividing the mass of product into smaller quantities makes the achievement of good rapid chilling performance possible.
- To ensure the attainment of the required performances, for each batch of production identified, core product temperature shall be monitored, from chill start to finish.
- This monitoring, for each batch processed and then through storage, allows implementation of CCPs, if an HACCP risk analysis indicates that this is necessary.

Freezing

Freezing inhibits virtually all microbial activity (through low temperature and the effective withdrawal of available water). It also strongly retards deterioration of biochemical origin (such as rancidity). Consequently the frozen product can be successfully preserved for several months (generally for up to 12 months, although longer periods can provide acceptable product subject to strict control and possible testing).







However certain principles must be respected in using this technique:

- The core temperature must be reduced to below freezing point as quickly as possible.
- Dividing the mass of product into smaller quantities makes the achievement of good rapid freezing performance possible.
- Maintaining air circulation around each product piece when divided.
- Freezing in a frozen cold store does not produce foodstuffs of good organoleptic quality, due to cell breakdown caused by a slow freezing rate. It is also prejudicial to the quality of frozen products already within store.
- Foodstuffs intended to be frozen should be placed in its protective package before the freezing process, to avoid surface deterioration by cold burn.
- FIFO (see chilling above) principles should be maintained.
- The temperature of storage freezers must be regularly checked:
 - by using automatic devices (automatic graph or computerised) for continuous recording; or
 - by direct measurement and recording of temperatures, checked between two surfaces of the stored foodstuffs held tight together, at least once per day, by using thermometer probes.

Defrosting

Frozen foodstuffs, generally not usable in this state, are frequently subject to a defrosting phase prior to use. Defrosting is a slower process than freezing and therefore product undergoing treatment tends to be in a vulnerable state for longer than in freezing. This process can be a source of hazard and must follow specific control methods.

Defrosting can be carried out:

- By placing, well in advance, large frozen pieces in a chill room (without causing potential contamination risks to other stored products).
- By microwave technology.
- By direct cooking of frozen products.
- For small pieces, frozen in a protective package, a hot water bath actively kept to the boil can be used.

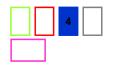
Some methods of defrosting should absolutely not be applied:

- at ambient temperature;
- in a tepid water bath.









Heat Processing Technology

There are three main techniques based on the use of heat:

- Cooking.
- Pasteurization.
- Sterilization in can, bottle or other pack.

They present similarities:

- They reduce the microbial flora of the food products.
- Their effect can be quantified by a reference rate:
 - cooking rate;
 - pasteurizing rate;
 - sterilizing rate.
- This quantified rate results from the combined effect of time and temperatures.
- The application of these technologies allows, for each manufactured or stored batch, a
 routine control of physical parameters (time and temperatures) and their recording. This
 monitoring, for each batch processed and then through storage, allows implementation of
 CCPs, if an HACCP risk analysis indicates that this is necessary.
- The application of these technologies is subject to common rules and some particular rules.

Rules suitable for cooking

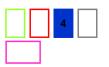
- The temperature and duration time of cooking must be the subject to measurement and recording for monitoring purpose.
- Constant unit volumes of food batches makes it possible to reproduce identical cooking conditions of for all manufactured batches.
- Cooking in advance shall never be followed by a slow cooling process.

Suitable rules common to pasteurization and canning

- Preliminary series of tests make it possible to establish a reference scale of sterilization parameters for each type of product.
- The evolution of the 'time / temperature' combination for effective processing must be checked and recorded:
 - by measurements carried out at regular intervals;
 - by the layout of a graph plotted by automated devices.
- The full complete sealing of the packages (cans, jars) in to which products for processing are placed must be ensured and controlled.







- Each manufactured batch shall be composed of identical products:
 - of the same chemical and physical composition (formula, viscosity...);
 - of the same size;
 - of the same shape;
 - enclosed in the same packaging.

Control by Foodstuff Formulation (composition)

Foodstuff formulation dictates physico-chemical characteristics of the product, used in food preservation, including:

- pH (acidity).
- Aw (water activity) corresponding to water availability for microbial activity.
- Viscosity.
- nutrient content:
 - proteins;
 - carbohydrates and other microbial growth factors.
- content of inhibiting elements:
 - nitrites;
 - fatty acids;
 - high salt levels;
 - high sugar levels.
- Some of these parameters, fluctuations of which have a direct effect on microbial activity, are easily and quickly quantifiable and can thus be exploited for the implementation of control at CCPs.
- To guarantee the precision of formulation, measurements of component ingredients are needed:
 - Weight;
 - Volume.
- For finished products, or for work-in-progress, some measurements are also taken, such as:
 - acidity (pH);
 - water availability (Aw);
 - viscosity;
 - liquid density (as a measure of dissolved solutes);
 - temperature (T°).





Finish Products Analysis

1.6. Finish Products Analysis – Bacteriological Tests

Products

Bacteriological testing carried out on finished products is generally characterised by a relatively long response time. As a result, it is not possible to await the receipt of tests results to affect production control, nor even to wait for them for product release.

Consequently, tests on finished products have an assessment function on GHP, as well as on the operating HACCP plan. Unfavourable results do not make it possible to employ corrective actions on finished product, but must lead to re-evaluation and improvement of GHP implementation, as well as of the HACCP plan.

Within the framework of risk analysis, carried out in an HACCP study, bacteriological tests on product at different production stages, makes it possible to evaluate the impact of each process activity/step, in terms of risk reduction or increase.

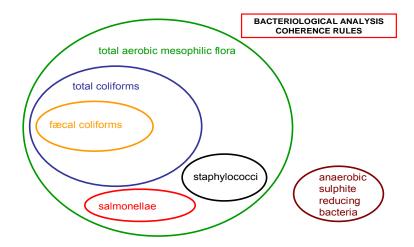
For analysis results to be interpretable, they must be compliant with specific rules of coherence based on the relative weighting of total bacterial populations and component populations.

Surfaces

Bacteriological tests carried out on tools or equipment surfaces are characterised by a relatively long response time. As a result, it is not possible to await the receipt of tests results to affect production control, nor even to wait for them for product release.

Consequently, tests on tool or equipment surfaces have an assessment function on GHP, as well as on operating HACCP plan. Unfavourable results do not make it possible to employ corrective actions on finished product, but must lead to re-evaluation and improvement of the factory cleaning plan.

Figure 5: Consistency criteria for bacteriological analysis of foodstuffs



for validity, bacterial counts, for any sample, must fit within the boundaries indicated



Finish Products Analysis

Interpretation of the Flora

- Total aerobic mesophilic flora:
 - is a reflection of total contamination;
 - reaches high values in any case of failure of the hot or cold thermal process chains (refrigeration, delayed hot distribution, cooling, ...);
 - the return to normal values will be obtained by reinforcement of thermal storage chain control.

Total coliforms:

- are witness to a possible fæcal contamination;
- to correct such a variance, it is necessary to seek out and control the sources of fæcal contamination (e.g. dirty operators' hands, animal gut contents, ground spread manure contaminating green vegetables, egg shells...).

Fæcal coliforms:

- are witness to definite fæcal contamination;
- to correct such a variance, it is necessary to seek out and control the sources of fæcal contamination (e.g. dirty operators' hands, animal gut contents, ground spread manure contaminating green vegetables, egg shells...).

Staphylococcus aureus:

- is responsible for food poisoning incidents;
- is particularly of human origin, often in partnership with fæcal coliforms:
- to correct such a variance, it is necessary to seek out and control the sources of human origin contamination (e.g. dirty operators' hands...).
- Clostridium perfringens (anaerobic sulphite reducing bacteria):
 - is responsible for food poisonings incidents;
 - is of fæcal or ground origin and is frequently in spore form;
 - to correct such a variance, it is necessary to seek out and control the sources of fæcal contamination (e.g. dirty operators' hands, animal gut contents, ground spread manure contaminating green vegetables, egg shells...).

Salmonellae:

- are responsible for serious food poisoning incidents;
- are of fæcal origin and most of the times associated to poultry/egg and related products;
- to correct this anomaly it is necessary to seek and control the sources of fæcal contamination (dirty operators' hands, animal gut contents, ground manure contaminating green vegetables, egg shells...).





1.7. Staff Training

The following simple principles can be followed to plan, design and implement staff training.

Sequence to be followed

- Analyse the training needs, taking into account the specific context of the enterprise and the different public to be addressed.
- Establish a training plan with clearly defined objectives and indicators.

For example: "Train all the seasonal personnel in hygiene before they are sent to production". The indicator in this case is the number of persons who have followed the session and the different skills to be acquired. Design and organise the session. This is where the training tools and materials are prepared and the logistical arrangements made.

- Carry-out the training.
- Assess the effects.

A few tips for trainers

- 2 weeks before the session: confirm the implementation conditions, i.e. : dates, list of
- participants, room...1 week before : is the equipment and material to be distributed available?
- 1 day before:
 - is the equipment in place?
 - is the room ready to receive the trainees ?
 - is the material to be distributed ready?
- 15 minutes before the training: verify that the equipment is working and the materials available for the trainees.
- In the beginning of the training:
 - welcome the trainees;
 - present the programme and schedule of the day.
- Every morning (if the session lasts several days): make a synthesis of the previous day, answer questions, present the programme of the day.
- During the session: alternate the functions (producer, regulator, facilitator), explain difficult
 points, have exercises done by the trainees, listen carefully to the trainees, answer all
 questions.

Assessment of the training

- Evaluate if the trainees have acquired the necessary skills and/or competences.
- Mesure deviations using the indicators defined in the beginning.







CHAPTER 2: HACCP Study

2.1 Transition to HACCP

The version of the HACCP method to which this guide refers is the official version published in the 'Codex Alimentarius'⁶. In the following lines of this guide, HACCP tasks are described in a summarised form, limited to some words or to short sentences. It is accepted that use of this guide cannot be considered without reference to the Codex version. Particular tasks will be studied from the practical point of view, in order to facilitate the implementation of the method under field conditions.

> Prerequisites

Enforcement of Good Hygiene Practice (GHP) and Good Manufacturing Practice (GMP) constitute essential prerequisites for the transition to the implementation of HACCP methodology.



In order to make sure of real and effective implementation of these good practices, it is necessary to refer to the audit grid 1/4 'Assessment of implementation of prerequisites' attached to this document. (To use all audit grids, it is necessary to refer to the explanatory booklet which is attached to them).

Success in implementing this HACCP process will depend on a thorough application of each task in sequence and of the real and effective application of its requirements. Jumping one or more task, or being satisfied with incomplete implementation, may well lead to a situation of failure, with potential dangerous conditions within an apparently safe system.

Procedures of implementation of HACCP – via each product or via manufacturing operations

A HACCP scheme can be easily approached product by product in companies which manufacture only one product or a restricted range of products. On the other hand, for companies which offer a larger range of products (often small firms in canning or in delicatessen product manufacture), specific application of HACCP to each product will constitute an insurmountable obstacle.

It should be noted, in this second case, that the large variety of products is obtained by the use of a limited number of basic technologies of manufacture (cooking, cooling, etc...), always the same ones, but combined in different ways. Under these conditions, all that is required is to choose a proper application of HACCP methodology to each one of these basic operations. For any complete product, association of each basic operation involved, properly managed by HACCP application, allows risk control to be established on the production line.

⁶ Codex Alimentarius Food Hygiene Basic Texts – Food and Agriculture Organization of the United Nations – General Principles of Food Hygiene (CAC/RCP, 1-1969, Rev.4 2003).



A project co-financed by

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How much is too much? (a case against bureaucracy in food factories):

What is the adequate level of records that a food company should maintain?

The following hints could lead you to the right decision(s):

- after an HACCP study, the food safety related reason(s) behind each record is better understood by operators;
- the HACCP team could propose to adapt/reduce the number of records maintained according to the requirements of the HACCP plan;
- usually the more complete the HACCP study, the more simpler is the corresponding monitoring system.





2.2 The HACCP Method

- The HACCP process sets out two missions (two main processes to be carried out, each with definable results).
- The HACCP method is the application of seven defined principles.
- The HACCP method defines twelve tasks for analysis, effective control implementation and system review.

> HACCP - The 2 missions

- 1. Hazard analysis (Objective determination of CCPs Critical Control Points).
- 2. Control of CCPs (Objective effective implementation of food safety control at CCPs).

> HACCP - The 7 principles

- Conduct a Hazard Analysis.
 - a Identify the hazards associated with food production at all the stages of this process
 - b Evaluate the probability of appearance of these hazards
 - c Identify the necessary preventive measures
- 2. Determine the Critical Control Points (CCPs) of these hazards.
- **3. Establish critical limit(s).** (which must be met to ensure that each CCP is under control) Establish operational criteria (limiting values, target levels, tolerances).
- **4.** Establish a system to monitor control of the CCPs. Establish a monitoring system to affirm real and effective control of the CCPs
- **5. Establish the corrective action** to be taken when monitoring indicates that a particular CCP is not under control.
- **6. Establish procedures for verification** to confirm that the HACCP system is working effectively.
- **7. Establish documentation** concerning all procedures and records appropriate to these principles and their application.







2.3 The HACCP 12 Tasks⁷

Task 1: Select the HACCP Team

- Constitution of the team: internal and external competences, flow chart;
- Training of the team in HACCP;
- Organisation of the team;
 - Functional mode
 - Organiser, secretary, team leader
- Definition of the necessary resources;
 - Office devices (computer, photocopier,...)
 - Budget
- Collection of information;
 - Data: historical, causes of food borne disease, epidemiologic, clinical
 - Normative and lawful data
 - Technological data
- Planning of activities;
 - Time table and duration of team work sessions
 - Programme of the implementation of successive HACCP stages
- Definition of the field of study (e.g. product, group of products, hazards under study, full product process or part(s) of process, etc.) Full food safety control for any product will only be complete when every process that goes towards its manufacture has been included, but practical and time restraints frequently lead to a division into realistic parts).

In order to prevent the HACCP programme taking too long:



- Draw up agreed, documented, unambiguous management commitment to effectively implement HACCP for the purpose of providing safe food for the consumer (and for the economic security of the business). See Notice regarding commitment in explanations about Task 10 of the HACCP method)
- Ensure that any delays are justified compared to the time table.
- Respect frequency and duration of planned HACCP team meetings (e.g.: once by fortnight, one hour duration) (management commitment will ensure that HACCP team members have time allocated, as well as adequate other resources).

PRACTICAL ADVICE

A detailed training manual for the application of the HACCP method has been prepared in the framework of the EC-ASEAN Economic Cooperation Programme on Standards, Quality and Conformity Assessment. Copies can be obtained from the Standards Unit in ASEAN Secretariat.









In order to prevent the HACCP programme taking too long (cont'd):

 Begin each meeting with a reiteration of the tasks which were to be completed, and finish by assignment of tasks to be achieved for the following meeting.

Task 2: Describe the Product

- Collect data on the finished product (and possibly in-process product)
 - General characteristics: denomination, composition, volume, structure...,
 - Physical-chemical characteristics: pH, Aw, redox potential (Eh), preservatives,
 - Modified atmosphere,
 - Packing,
 - Labelling,
 - Conditions of storage and lifespan.
 - Storage and distribution network conditions.
- Collect data on raw materials
 - Definitions,
 - Presentation: volume, type of packaging,
 - Formulation (% of each raw material used),
 - Physicochemical characteristics : pH, Aw, Eh, viscosity, ...,
 - Concentration rate of the solutions and additives rate,
 - Temperature of storage,
 - Lifespan.
 - Treatment, preparation, manufactured, use/purpose.



PRACTICAL ADVICE

For all raw materials, it is important that their condition at delivery is constant because control of their means of processing depends on it.

<u>For example</u>, for the same frozen raw material, defrosting time is tripled if the smallest package dimension is doubled. The defrosting step must therefore be adapted. If not, subsequent processing steps (cooking, etc.) must be adapted in order to avoid hazards and / or economic loss, because their efficacy will not be the same. If not taken into account, the tripled defrost time may lead to incompletely cooked meat in a subsequent stage.





Task 3: Identify Intended Use

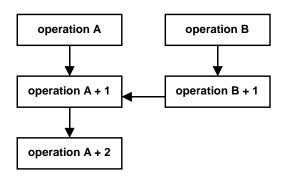
- Identification of the intended methods of use:
 - Lifespan,
 - Methods of preparation,
 - Instructions of use,
 - Foreseeable deviations,
 - Storage,
 - Intended target groups of consumers.
- Examination of the adequacy between product and its instructions of use.

PRACTICAL ADVICE

Foreseeable deviations from normal product use should be identified so that they can be avoided. This helps demonstrate company responsibility.

Task 4: Construct a Flow Diagram

• Identification of elementary operations/steps



- Collection of additional information on each elementary operation/step
 - Nature, function,
 - Process, method, parameters,
 - Inputs (raw materials and packaging),
 - Buildings, equipment, environment,
 - Flow,
 - Operators,
 - GHP (cleaning, disinfection, maintenance),
 - Instructions.









If a flow diagram is drafted by observing work on site, the best and most convenient method is by vocal recording, transcribed afterwards.

This allows a precise and continuous operations statement, produced without having to look away to write.

Task 5: On-Site Verification of the Flow Diagram

- On-site checking of flow diagram for different periods of production:
 - Regular.
 - High production rate.
 - Low production rate.
 - Different shifts.
- Modification of the flow diagram, or drafting of several versions of the diagram:
 - according to real conditions observed on production site;
 - or according to specific organisation during different production rates.

It is necessary to give a close attention to the low rate production periods as for those of high rate. The reduction of the number of operators like its increase, often makes important changes to the organisation of work: only one operator ensures the tasks of two work stations or two operators occupy only one work station. These significant changes are often generating hazards which do not exist under normal operation.



<u>Task 6: List all Potential Hazards Associated with Each Step, Conduct a Hazard Analysis,</u> and Consider any Measures to Control Identified Hazards

- Analyse causes of hazards to each operation/step.
- List causes of hazards (physical, chemical, microbiological) (see Text Box below).
- For microbiological hazards, causes are of three types:
 - **contamination** by germs of spoilage or pathogenic flora
 - multiplication of the germs/pathogens
 - **survival** of the germs/pathogens to a decontaminating treatment (heat, ionization, ...)
- Qualitative and quantitative hazard evaluation: Calculation of hazard criticality, subsequently used in risk evaluation, Hazard grading.
- Definition of the preventive measures.
- Formalise preventive measures (control means, procedures, instructions, records).









Physical and Chemical hazards are characterised by imparting danger only by contamination and not by multiplication / survival.

As such, most of these hazards are controlled by Good Practices or other prerequisites (see next page) and will generally found to be not subject to HACCP control, although there are exceptions.

PRACTICAL ADVICE

The HACCP analysis process is valid and should include physical and chemical hazards, in order to confirm where they fit into control mechanisms.

For the purpose of this guide, most attention is paid to microbiological hazards, but the process demonstrated is identical for these hazard types (see APPENDIX 2)

Figure 6: Hazard analysis process

hazard analysis Hazard - definition A biological chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect Note - there are families of hazards: microbiological, parasitic, physical, chemical Microbiological hazard analysis controlled by GHP and GMP Contamination not appropriate to CCP implementation 3 components depending on physical-chemical **Multiplication** parameters (time, temperature, acidity, water availability) suitable to CCP implementation Hazards analysis (transition from the concept of danger to that of hazard) application of the index of criticality to identified dangers: $Ic = S \times F \times P$ * S = seriousness notation scale from 0 to N * F = frequency * P = probability of no detection







Task 7: Determine Critical Control Points

DEFINITION Critical Control Point (CCPs):

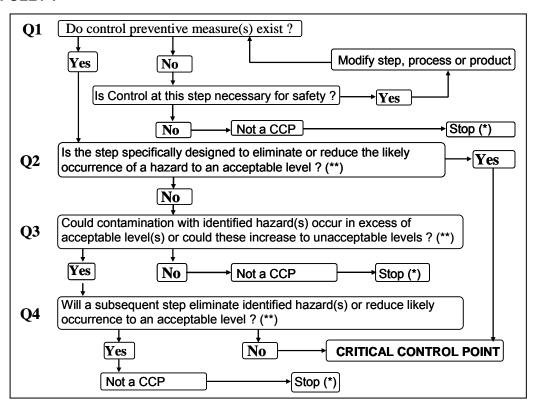
A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

For each elementary operation, determine if it constitutes a CCP.

You can use 3 different approaches to do so:

- 1. by use of a decision tree, or
- 2. by the application of INTUITIVE REASONING (using common sense), or
- 3. by carrying out Hazard Analysis on the Flow Diagram by an alternative method.

1 – by use of a DECISION TREE – each question MUST be considered and answered VERY CAREFULLY⁸.



⁸ For the interpretation of the questions please refer to the EC-ASEAN Training Manual pages 40-43.



3



2 - by the application of INTUITIVE REASONING (using common sense).

<u>IN PRACTICE</u> . . . for each ingredient or activity, answer two questions:

- If control is lost at this point, will the remaining hazard kill people or cause them harm?
 - If no, not a CCP. If yes, continue:
- Is there any subsequent manageable step before consumption that will remove the hazard or reduce its effect to an acceptable degree?
 If yes, not a CCP. If no, this is a CCP

3 - by carrying out Hazard Analysis on the Flow Diagram by an alternative method

Experience of regular use of the decision tree sometimes ends in a mind block – the tool seems inappropriate in some particular situations. At this point of failure, some HACCP specialists have recommended the use of intuition for CCP identification. In effect, this amounts to passing from one extreme (of complete logical thinking) to the other (of no logic) – from the mind-numbing objectivity of the decision tree to the utter subjectivity of intuition - may be a dangerous move.

As an alternative, it is suggested to apply the following method:

<u>Firstly</u>: identify in the process what are the sources of hazard: Contamination, Multiplication or Survival (failure of decontamination treatments like sterilisation or pasteurisation); and

Secondly: apply the following reasoning:

- A) As it is not possible to immediately quantify **C**ontamination levels at any one point of process, it may be concluded that control of Contamination depends on GHP and GMP implementation rather than on CCP establishment;
- B) Germ **M**ultiplication and **S**urvival of germs present in the product, depends on measurable parameters (time, temperature, acidity, water activity...). When these parameters can be monitored, compared to critical values in the course of the process and be exploited to eventually take action when there is a loss of control, then a CCP can be defined at this process step.

In short, the restraint of **contamination** depends on good practice, while that of the **multiplication** and **survival** is based on CCP establishment, made possible by the control of specific physical-chemical factors when effectively/practically possible.

This alternative method is illustrated in the next schematic.







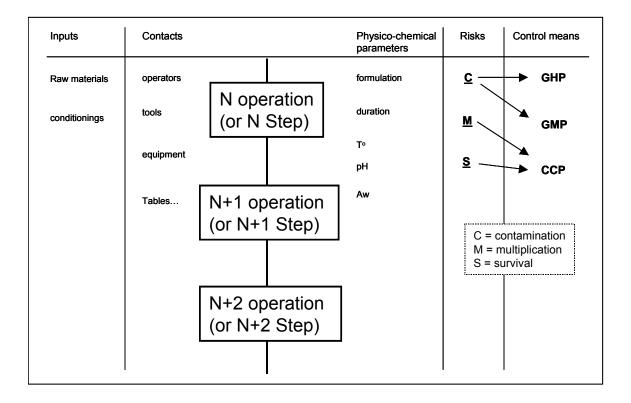
Finding the CCPs using an alternative method (practical hints):

After building-up your flow chart, you could:

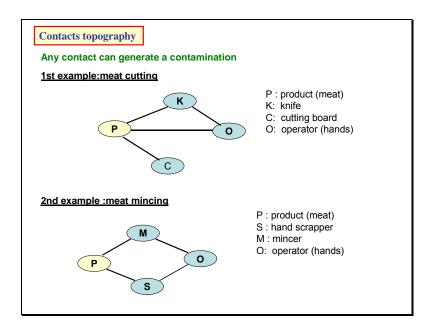
- add inputs and contacts on your diagram;
- add the specific physicochemical parameters (if any), operation by operation;
- analyse the **type of microbiological hazards**linked to each operation and add them on the diagram
 (there are 3 types:
 - Contamination (C)
 - Multiplication (M)
 - Survival (S)
- In short, the control of contamination depends on good practice (GMP) while the control of multiplication and survival hazards usually depends on Critical Control Points (CCPs); made possible by the control of some specific physico-chemical parameters, on which multiplication and survival depends.







Drafting contacts topography can help to index the sources of contamination.







Contacts topography diagram (because any contact can lead to a contamination):

Drawing a contacts diagram can help you identify possible sources of contamination during operations:

- firstly, identify the product(s) associated with a specific process operation (e.g. deboning fish);
- secondly, identify the differents elements (operator, equipment, tools,...) for the operation;
- thirdly, trace the links between the product(s) and the element(s) (materials, people) in contact with the product(s);
- finally trace the links between the element(s) that are in contact with one another (e.g. scissors and the operator's hand).

You will obtain a contacts diagram that will help you analyse any potential hazards of contamination within your process.





Task 8: Establish Critical Limits for each CCP

DEFINITION Critical Limit (CL):

A criterion (target value + tolerance) which separates acceptability from unacceptability.

- For any CCP, the critical limit represents the value beyond which the control of the identified hazard is no longer guaranteed. It makes sense to bring the process back to tight control <u>before</u> this value is reached or breached. Therefore, for safety (and economic) reasons, a target value more rigorous than the critical limit needs to be enforced.
- A target value needs a tolerance which ensures that, when intervention occurs, the critical limit is not exceeded.
- Identification for each CPP, based of the identified hazards, leads to characteristics to be controlled and appropriate preventive measures.
- For each characteristic, defined critical limits have to be respected in order to ensure CCP control.



IMPORTANT

When this task is completed, the first phase of implementation of the HACCP method has been completed. This phase constitutes the preliminary study: product defining, hazard analysis, good practice drafting, CCP determination. This phase also includes the determination of target values specific to each CCP.

The valid and effective carrying out of these first eight tasks of the HACCP method can be evaluated via the audit grid 2/4 'Assessment of the phase of preliminary HACCP study' (see annexe attached), also referring to its explanatory booklet. Attaining successful evaluation is essential to go through the final four tasks devoted to HACCP plan designing.

A meticulous and thorough application of the first eight tasks makes it possible to have a precise hazard analysis. Analysis precision, applied to each manufactured product, makes it possible to devise a HACCP plan, both simple and effective. Any uncertainties in an incomplete hazard analysis will lead to doubt and hence to an oversized HACCP plan, devised to ensure a satisfactory level of safety covering such doubt.



CHAPTER 3: HACCP Plan

The HACCP 12 Tasks⁹ (continued)

Task 9: Establish a Monitoring System for each CCP

DEFINITION Monitoring:

A planned sequence of observations or measurements of CCP control measures. The records of monitoring provide evidence for future use in verification that the CCP is under control.

- Monitoring provision: plan, method, device necessary to carry out the observations, tests
 or measurements employed to ensure that the critical limits of each CCP are respected.
- Define the monitoring provisions for each CCP.
- Formalise the monitoring provisions (responsibilities, procedures, instructions, records...).



Observations, tests or measurements taken within the monitoring scheme for CCPs, will have to produce results identifiable to a particular batch or product phase in the process.

This condition is essential for implementing predefined corrective actions, applied in manufacture to batches for which the observations, tests or measurements indicated a loss of hazard control. CCP monitoring results shall be such that they are delivered immediately, or with only a short delay, to ensure that any corrective action takes place fast enough to maintain process control.

Task 10: Establish Corrective Actions

DEFINITION Corrective Action:

Any action to be taken when the results of monitoring at the CCP indicates a loss of control or trend towards loss of control.

Corrective actions include:

- provisions to ensure the return to CCP control, and
- the management of any affected products.

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Define corrective actions to be implemented if the monitoring system shows unacceptable deviation.

Formalise clear corrective actions (responsibilities, procedures, instructions, recordings...).

Management of the deviation and the following up of actions on product batches, to be subject to corrective action, are made possible by the effective operation of a system of upstream and downstream traceability.



PRACTICAL ADVICE

Notice:

The commitment of Top Management to an effective HACCP system is most evident when monitoring indicates that control has been lost.

Decisions on actions to be employed in the event of control deviation have already been made and documented within the HACCP plan, so interference (crisis management?) from Top Management is **not needed**, (especially when economic losses are becoming evident due to corrective action).

This is principally important if monitoring indicates that a health issue has become evident due to loss of control. The business needs to swing into immediate emergency action without delay whilst Top Management looks at the situation to make decisions.

Task 11: Establish Verification Procedures

DEFINITION Verification:

The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.

Definition of all provisions for confirming an effective HACCP operating plan is needed. These provisions may include:

- Tests on products.
- Monitoring of target values.
- Implementation and concerned batches follow up.
- · Simulation of incidents.
- Auditing of the HACCP system.
- Review of records deviation review trend analysis.

All checking provisions shall be formalised into the HACCP system. It shall include verification of all parts of the HACCP system, including its records







Task 12: Establish Documentation and Record Keeping

Documentation:

Collection of documents which describes the provisions of the HACCP system, including records that prove its real and effective implementation.

- Report of HACCP study (stages 1 to 8)
- Design of HACCP plan (stags 9 to 12)
 - HACCP plan elements,
 - Specifications,
 - preventive measures,
 - critical limits and CCP monitoring system,
 - corrective actions,
 - document management,
 - verification methods,
 - checks.
 - reviews of the system,
 - records.

Task No12 completes the second of the two phases of the HACCP method implementation and accomplishes HACCP plan development. Before being able to evaluate the effectiveness of the plan it will be necessary to make it operate for a few weeks or months.



IMPORTANT

The valid, effective establishment of these last four tasks can be evaluated using the audit grid 3/4 'Evaluation off implemented HACCP plan' (see annexe attached), also referring to its explanatory booklet. It is essential to go through a phase of practical operation of the HACCP plan.

After a few weeks or months of operation, valid, effective implementation can be evaluated using the audit grid 4/4 'Routine evaluation of the valid and effective implementation of an HACCP plan, (see annexe attached), also referring to its explanatory booklet.





CHAPTER 4: GMP, GHP & HACCP AUDIT GUIDE

4.1 Presentation of the Audit Guide

The complete audit document consists of four evaluation grids.

The first one is devoted to pre-requisites and the following three to the HACCP method, (preliminary study, HACCP plan implementation, validity and effectiveness of the plan).

Two columns in each grid are reserved for noting observations taken at the time of audit:

- as appropriate, the observation will give a satisfactory (sa), acceptable (ac) or not satisfactory (ns) result;
- in other cases the observation makes it possible to note an absence (ab), good practice not implemented or documentation not appearing in the file;
- finally, an audit grid item available for observation may not be applicable in the context of the particular food process (na).

4.2 Grid 1/4 : Assessment of the Implementation of Pre-requisites

1.1 Conformity of the buildings: general organisation

Examination of the plans of premises makes it possible to examine matters of the fundamental principles of organization, often better than on the field, such as • observance of the 'onward flow' principle on production lines • separation of clean and unclean sectors • no criss-cross of production lines • separation of hot and cold zones.

Immediate surroundings must contain no source of contamination, such as a garbage dump or wet unhygienic zones. Passageways and parking areas must be paved or cemented. Lawns must be cut regularly to avoid high vegetation constituting a refuge for pests.

The plans provided in the file shall make it possible to identify each room and to locate each work station, each significant material, as well as water mains (or other supplies) and hand washing points.

Waste water and clean water circulations are also to take into account.

Finally, the plans make it possible to locate entrances and exits of various flows (production, waste, operators . . .) as well as their circulation within the physical plant.

The various points noted here must be acceptable so as to meet requirements regulation.







1.2 Conformity of the buildings: construction and materials

The descriptive booklet, either within the framework of a project, or associated with observations on the ground (at the time of the visit to the premises), makes it possible to control the conformity of materials and methods implemented in building the plant. The covering of the floor and the walls, the way in which they are joined, the devices used to collect water for floor washing, (the principles of which are stated in #1.2 of the guide), must conform to regulation. Passive or mechanical ventilation devices must ensure the elimination of steam and smoke. Lighting must be bright and neutral in colour (so as not to modify the foodstuff colours)

1.3 Conformity of the premises: equipment, materials and furniture

The technical documentation of these elements, associated to ground observations carried out at the time of the visit to the premises, make it possible to check their conformity with the regulation (point 1.3).

1.4 Lawful or normative conformity

The elements of conformity of the buildings presented under the former points (1.1, 1.2, and 1.3) can be controlled and confirmed within the framework of an official approval or a certification.

1.5 Upholding the condition of buildings, maintenance

Ageing and decay, by continued use of the establishments, can cause the loss of condition of the buildings. The implementation of regular maintenance, together with appropriate immediate remedial action for sudden breakage, confirmed by the keeping of a maintenance daybook (register of requests with records of repair), helps uphold the condition of buildings and equipment.

2. Supplies

2.1 Contractual relationship with suppliers

The criteria of acceptance for delivered consignments, with corrective actions required according to the significance of any noted variance, must be defined in advance and included in a contractual document drawn up between the producer and his suppliers.

2.2 Specification of raw materials

- of composition: this plays a significant role in the tendency of the product to deteriorate (water content) or in its stability (sugar or salt content). Also it guarantees the accuracy of the composition of the finished product as defined on final product labelling.
- of microbiological standards guarantees the safety of food by limiting the presence of pathogenic germs and of toxic metabolites (microbial toxins, histamine . . .).
- of the maximum allowed content of residues, covering such substances as heavy metals, antibiotics, pesticides.







- of packaging: ensuring by its characteristics protection of delivered raw material. By its
 volume it influences parameters such as duration of defrosting time or the utilisation period
 after opening.
- the condition of preservation is generally related to temperature and shelf life. These two
 measurable parameters can be the subject to monitoring for each consignment and are
 thus favourable to the introduction of CCPs.
- organization of stock turnover: it should comply with FIFO principles (First In / First Out).

2.3 Control of deliveries

Inspection of delivery check-lists makes it possible to control the conformity of certain major specifications of raw materials. Observation of variations in these specifications indicate a loss of hazards control and will result in the use of pre-established corrective actions.

Observations and measurements must be carried out at the time of delivery, and the check-lists must be checked at the same time. When a variance is noted, the 'customer/supplier' agreement must include the signature of a type-approval certificate or a card of anomaly specifically drafted for this purpose, by the supplier or his representative (delivery person).

If immediate inspection is not possible, (such as for large mixed palletised loads, or if a long term check is involved, such as for microbiological counts), then the customer / supplier agreement must be clear on the procedure adopted for inspection and on actions to be taken in the light of failure.

2.4 Potability of water

Water is a nutritious raw material and also a cleaning agent. Considering this double use, confidence in its microbiological quality, as well as its chemical quality, is of prime importance.

Analysis reports can be easily obtained from water suppliers. However, manufacturers using private water sources (well, borehole .) will have to employ their own water quality control plan.

3. Implementation of a system of traceability

A system of traceability makes it possible to manage any food safety crisis by going back to the origin of the products implicated. It also makes it possible to identify all the outlets where they have been sold.

A traceability system also allows, using the HACCP flow charts, to find those production batches that will be subject to corrective action, i.e. all batches that have been produced since CCP monitoring indicates the last time that the system was known to be still in control.

Frequently, (and particularly when computerized systems of traceability are implemented by specialist providers), those responsible for food product traceability do not know the configuration of the traceability system; they are simply trained how to use it. Under these conditions, it is good practice to submit this system to a simulation trial, rather than rely on a system audit. Simulation results allow the auditor to judge the efficacy of the traceability system and the capability of staff in its use.







3.1 System of upstream traceability

A simulation of upstream traceability needs to be able, for any real substance chosen randomly from within raw materials stocks, to divulge all information on its source, origin, batch, delivery date. The system of traceability must be able to provide an answer to these questions. Examination of delivery check-lists, supplier invoices and records of raw material stocks, can all help to understand the system of traceability.

3.2 System of downstream traceability

A simulation of downstream traceability needs to be able, for a product chosen randomly in finished products stocks, to divulge all information on recipients of any other parts of this batch, as well as batches of raw materials which were used for its manufacture. The system of traceability must be able to provide an answer to these questions. The examination of purchase orders, copies of clients' invoices and registers of finished product stocks, can also help understand the system of traceability.

4. Pest control

4.1 Implementation of a pest control plan

The presence of pests in a factory can be noted during a visit to the premises by the presence of dead insects or droppings / urine of rodents.

A plan of rodent extermination must be implemented. The file must include a plan of the factory where the poison baits are located, and the technical cards of rodent poisons being used.

Storage outside the buildings (equipments and materials) must not be placed next to the walls but kept as far from them as possible and must allow a minimum space of at least two meters. This arrangement makes it possible to avoid the settling of pests directly against the walls, their penetration and their establishment inside the plant.

Management of waste materials must prevent their overflow and the presence of any food waste on the ground which could attract pests.

A plan of insects control must also be implemented. The file must include the schedule of operations and technical information cards of insecticides.

The implementation of the programme of pests control operations must be recorded on appropriate checklists.

5. Control of human sources of contamination

5.1 Medical monitoring of the operators

Monitoring is proven by the delivery of an annual medical certificate of fitness for foodstuffs handling to each operator. In the event of a stoppage caused by a severe infectious condition, or presenting a significant risk of transmission via food, such a certificate may well be required for a return to work.





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5.2 Staff training to the principles of hygiene and good manufacturing practices

The company must implement a plan of staff training. As with medical monitoring, appropriate certificates of training shall be delivered for each successfully trained member of staff.

5.3 Professional clothing hygiene

• The documents relating to the internal system of management of professional clothing (clean or soiled) must makes it possible to check that it is provided and cleaned by the company (or under its responsibility). Moreover each member of the staff must use two cupboards in the cloakroom (or one single cupboard with two compartments), to ensure the separate storage of working garments and everyday wear. Permanent devices (boots/shoes washstands) or movable ones (trays), containing a disinfecting solution, must allow cleaning/disinfection of shoes or boots before getting into the production zone

5.4 Respect of the good hygiene practices and good manufacturing practice

Due to training and to the provision of guides of good hygiene practices and guides of good manufacturing practices, staff are able and are obliged to respect these good practices.

6. Hands cleaning and material cleaning

6.1 Hands

Visits to premises makes it possible to check that conforming washstands (non-manual taps, disinfectant liquid soap dispenser, disposable hands wiping system) are made available to operators in sufficient numbers. These washstands must be located near working stations, cloakrooms and toilets.

Contamination by hands, regarded as the 'first tool of the operators', is controlled by the training received and by the posting of hand-washing instructions near the washstands.

6.2 Material and buildings

The control of contamination of equipment and buildings requires the introduction of a cleaning plan, drafted by applying the problems resolution method known as 'the **W.W.W.H.W** method' (**W**ho? **W**hat? **W**here? **W**hen? **H**ow? **W**hy?)

Written procedures of cleaning, together with technical cards of cleaning products, are gathered in this cleaning plan. Each operator (production operator or member of the cleaning team) has a copy of the part which corresponds to his cleaning tasks. The good execution of this cleaning plan can be assured by checking with appropriate records.

- control of good execution of tasks using a check-grid completed as the work progresses
- control of visual cleanliness of surfaces using a weekly (or higher frequency) check-grid
- microbiological control plan of surfaces, valuable for validation of the cleaning plan, and resulting in analysis reports for appropriate action.







4.3 Grid 2/4: Assessment of preliminary HACCP study step

After evaluation of the implementation of pre-requisites in the former grid, this second grid approaches HACCP itself. This method is structured in twelve Tasks which are taken in order, one after the other. Grid 2/4 takes into account steps 1 to 8 inclusive.

Task n° 1

Management commitment

This commitment testifies to the sincere resolve of the management to apply HACCP methodology involves a letter addressed individually to each member of the staff of the company.

Set up of the HACCP team

The HACCP team organisation chart (organogram) should be the basis for specifying functions and responsibilities for each member. These functions and responsibilities need to be described on individual job specifications for the HACCP programme.

Resources

The resources available to the HACCP team (computer, photocopier, budget etc.) shall be clearly defined and recorded in the HACCP file.

HACCP team management

Organisation is planned around the scheduling of activities, setting out the frequency and duration of team working sessions. The plan defines time limits for the implementation of HACCP stages. With objectives being predicted for completion by specific dates, any delay needs to be justified.

Each working session starts with a statement of work completed since the former meeting and ends in the allocation of the tasks to be realised for the following meeting. Each working session must be recorded in a report.

Task n° 2

2.1 Description of the product

The product description file, completed by the execution of stage n° 2, collates all relevant information on the product including (but not restricted to):

- composition (ingredients, nutrition)
- volume, nature, storage, packaging, labelling,
- raw materials specifications (composition, proportion in the product, physicochemical characteristics, conservation, pre-processing, microbiological standards).







Task n° 3

3.1 Identification of expected use

This stage results in the drafting of documented instructions for use. The information provided by labelling of the product (storage temperature, shelf life . . .) also depends on the conclusions of this step.

This study on expected use needs to take into account the expected groups of consumers involved (e.g. children, older people). It also needs to include a study on potential foreseeable deviations of use and on any dangers which could result from these.

Task n° 4

4.1 Draft the flow diagram

Task n° 5

5.1 Verify the flow diagram

The flow diagram is the base for hazards analysis, so it must closely correspond to the real field conditions for all products or all families of products (as appropriate to the study), for all the production periods.

In certain sectors of production (catering, pastry baking), flow diagrams will relate to basic operations (oven cooking, fast cooling . . .). Combinations of these flow diagrams then make it possible to carry out study of all types of production schemes. When each one of these basic operations is controlled, the whole of the production can then be regarded as controlled.

It should be noted that the same product can present conditions for more than one flow diagram if the conditions of production change, for example between slack and busy periods. In this example, the number of operators, and hence also work organization, may change.

During inspection or audit, some sequences of production need to be compared with the flow diagram appearing in the file in order to assess its validity.

Task n° 6

6.1 Hazards analysis

Using the flow diagram and the list of potential hazards already in the file, the analyst now needs to evaluate the significance of hazards:

- by checking that no hazard has been overlooked;
- by checking that all hazards identified by using the flow diagram are collated in a summary (table, list . . .);
- by checking that the calculation of the criticality index (specified on a separate document) provides a valid evaluation and hence a correct rating of risks;







 by checking through the calculation of the criticality index, that identified risks are real (and thus excluding any risks with a zero index value)

A list of preventive measures, each specific to each identified hazard as applied in the particular establishment, with procedures for implementation, must appear in the file.

Task n° 7

7.1 Determine critical points

The use of the HACCP flow diagram, together with a CCP decision method (CODEX decision tree, or the intuitive method), allows for identification of CCPs, which are gathered into a summary (table, list, etc...)

The identification of a parameter, indicating maintained safety control or otherwise of each CCP, that can be monitored, allows differentiation from standard production operation control. This measurement needs to be timely so as to maintain production*, and at low cost.

Auditors need to verify that a measurable parameter is associated with each identified CCP.

Task n° 8

8.1 Establish critical limits for each CCP

By examination of the file documents, the limits of the criteria which separate acceptability from non acceptability need to be the assessed.

Each criterion, together with its possible justifications, are evaluated using:

- limits of performances of the available equipment . . .
- quantified data (from data sources) on the microbial flora (temperature, pH and Aw, growth limits . . .);
- results of ageing tests;
- lawful or normative obligations.

^{*} If results take too long to come back, production will be held up awaiting them, or expensive large stores of work-in-process or final product will be required







4.4 Grid 3/4: Assessment of the drafted HACCP plan

This third grid relates to the evaluation of the last four tasks of HACCP method. These are devoted to the drafting of the hazard control plan.

Task n° 9

9.1 Establish a monitoring system for each CCP

Initially, the significance and appropriateness of all monitoring procedures need to be evaluated. Then the framework of parameters for monitoring, (T°, Temps, Aw, pH, weight, volumes) and their recording, needs to be established and validated to ensure that any loss of control is immediately identified

9.2 Calibration plan of measuring instruments

Any instruments involved in monitoring of CCPs need to be included in calibration plans and the calibration plans need to be implemented.

(If an instrument is found to be out of calibration, an action plan needs to be in place, particularly indicating actions for all product that has been produced since the last time that the instrument can be confirmed as being correctly calibrated).

Task n° 10

10.1 Establishment of corrective actions

The HACCP plan needs to define the corrective actions implemented in the event of loss of control (i.e. observation of a deviation of values being monitored for control). To this aim the documentary system must fulfil certain constraints:

- to establish appropriate levels of corrective action to be implemented corresponding to the gravity of observed CCP deviation
- to define application of operational procedures of for the various corrective actions selected

10.2 Ensuring the follow-up of batches of products for corrective action(s)

The company must set up a system of monitoring sheets, based on traceability, to follow up the batches which need to be subject to corrective actions.







Task n° 11

11.1 Establish verification procedures

The inspector (or the auditor) controls the implementation of validation methods and documents for HACCP plan or for the implementation of GHP and GMP. The details of implementation means may include (but not be restricted to):

An analytical control plan (microbiological and chemical) of the finished product, (defining the finished product standards) including:

- sampling plan (number, size, frequency of samples)
- microbiological standards for different (types, groups of) products
- residue standards for such as: growth factors, pesticides, antibiotics, heavy metals
- standard analysis model report
- keys for interpretation of analyses

Analytical control plan of surface cleanliness:

- sampling plan (number and frequency of samples)
- microbiological standards for surfaces
- standard analysis model report
- keys for interpretation of analyses

11.2 Field verification

Confirmation of the verity rests on the execution of a documentary review or audits (by external or internal people) of the risks control system (GHP/GMP and / or HACCP).

If this step does not allow for satisfactory observation of results, it will lead to revising the set-up of the hazard control system.

Task n° 12

12.1 Establish documentation and record keeping

The inspector (or the auditor) needs to check that the HACCP system documentation effectively includes all documents (commitment, objectives and system establishment, procedures, analysis reports, outside technical data, checklists, etc...) as defined in the eleven steps of the HACCP outlined above or in the Pre-requisites section (- and for the control of this twelfth step)







4.5 Grid 4/4: Routine evaluation of the real and effective implementation of an HACCP plan in the company

This last grid is intended to be employed at the time of routine visits carried out in companies whose complete HACCP system has already been inspected (or audited), and has already received an official approval or a certification

13. Implementation of the GHP

13.1 Supplies control

The inspector (or the auditor) needs to confirm that raw material delivery check-lists are correctly kept. He needs to ensure, by examining preceding weeks' checklists, that corrective actions are actually implemented based on documented delivery controls, such as:

- documented warnings to the suppliers
- · rejection of raw materials batches

Available analysis reports also enable him to check that water used for production (as an ingredient or as a cleaning medium) is potable.

13.2 Validation of the cleaning plan

The inspector (or the auditor) needs to confirm that checklists of task implementation are correctly and immediately completed at the time of cleaning completion

He must also check the validity of results of microbiological cleanliness analyses for equipment and surfaces. In the event of nonconformity of the results, he must make sure that the company has taken appropriate action, such as bolstering its cleaning procedures or changing its cleaning / disinfection products (if contaminating microbiological flora have become resistant).

13.3 Validation of the pest control plan

The inspector (or the auditor) needs to confirm that any intervention forms of the pest control company, are correctly filled out for each visit.

During the visit of the premises, he must also seek out signs of pests:

- droppings and urine of rodents
- damage to foodstuffs bags (rice, pasta, beans...) caused by rodents
- insects bodies
- droppings of birds nesting / nests in the superstructures of buildings

13.4 Medical follow-up of the staff

This medical follow-up is validated by the presence of a medical certificate of aptitude to foodstuffs work, in the personal file of each operator employed by the company.







13.5 Staff training

The implementation of the continual training plan is confirmed by the presence of certificates delivered for each training course, in the personal file of each staff member.

The inspector (or the auditor) can also have informal conversations, (without breaking principles of hygiene), with operators posted on the lines of production, in order to evaluate their level of awareness and competence.

13.6 Maintenance of buildings and equipment

In addition to the visual observations that can be made during the visit to evaluate premises maintenance, the inspector (or the auditor) must check on the upkeep of the maintenance daybook

13.7 Upholding of the conformity and provisioning of the washstands

This part of the audit mainly depends on visual observations carried out during the visit to the production premises.

13.8 Upholding of the conformity and provisioning of the boots/shoes washstands

This part of the audit mainly depends on visual observations carried out during the visit to the production premises

14. HACCP plan, CCP monitoring

14.1 CCP monitoring

The implementation of this step (n° 9) of the method is validated by the records relating to the CCP monitoring. Assurance in the discipline in their keeping and their use is an essential point of the audit of any implemented HACCP plan. Without such rigour being applied to the keeping and use of these records, no real and effective HACCP plan can be implemented.

Any loss of control indicated by a deviation of the measured values, needs to be checked and coupled with necessary corrective action.

Recordings need to be dated and signed after reading and before archiving.

A (non exhaustive) list of records relating to the monitoring of CCPs

- records of cold store temperatures (chill and frozen) and of air-conditioned production areas
- records of inventory control (in respect of deadlines for use)
- records of the heat treatment pair of parameters 'duration / temperature'
- schedules of sterilisation, pasteurisation, cooking
- monitoring recordings of pH (dairy products, dry salted meats . . .)
- measurement recordings of water activity values (Aw)
- weighing, volume measurement of product ingredients, during recipe build







14.2 Follow-up of the corrective actions

The inspector (or the auditor) needs to confirm that monitoring sheets of corrective actions are correctly and progressively filled, until the effective reworking, removal or destruction of any affected batches

14.3 Conformity of the finished products

Conformity of finished products to microbiological and toxicological standards must be validated by analysis reports held by the company. Any observation of analysis reports not in accordance with standards, must lead to reconsideration, and subsequently to, improvement of the entire current system of hazard control. (GHP, GMP and HACCP plan)

14.4 Traceability

The inspector (or the auditor) needs to check simulations of upstream and downstream traceability at the time he is visiting the establishment – either on raw materials, or in production, or finished products randomly taken.

14.5 Simulations of incidents

The simulation of incidents is a method which can be used to check the validity and effectiveness of monitoring systems.

Losses of control are signalled by warning lights or hooters (cold stores, metal detectors . . .) Such simulations of incidents can be periodic recorded events which the auditor will be able t reports o trace from records.

They may also be carried out at the request of the inspector (or the auditor) at the time of visit.



Grid n° 1: Assessment of the implementation of pre-requisites

Grid n° 1/4 : Assessment of the implementation of pre-requisites

| Inspection (audit) n°: | |
|----------------------------------|--------------------------|
| HACCP Audit Grid (n° 1/4) | sa = satisfactory |
| | ac = acceptable |
| | $ns = non \ satisfactor$ |
| | ab = absence |
| Control of contamination sources | na = not applicable |

| Considered criteria | Documents associated to these criteria |
|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| | |
| 1 Buildings | |
| 1.1 Conformity of the premises: general organization: | Plan of the establishment (1/500 to 1/1000) showing: |
| - Conformity of the establishment immediate surroundings | - drinking water supply |
| - compliance with the onward flow principle | - waste water drain off |
| - separation of clean sector and unclean sector | Plan of the establishment (1/100 to 1/300)showing: |
| - no crisscross of the production lines | - identification of rooms |
| - separation of hot zone and cold zone | - position of workstations and the equipment |
| | - position of cloakroom and toilets |
| | - location of inputs/outputs of flows (staff, products,) |
| 1.2 Conformity of the manifest construction. | - flowchart of flows (staff, products, raw materials, waste,) |
| 1.2 Conformity of the premises: construction: - wall coverings: smooth, light coloured, washable, resistant | Explanatory leaflet of materials used and techniques of constructions employed |
| - floor covering: smooth, light coloured, washable, resistant | |
| floor and walls joined by round garge assembleges | |
| floor and walls joined by round gorge assemblages floor grids and U-bends to collect waste water | |
| - floor grids and U-bends to collect waste water | |
| - lighting bright and neutral in colour | |
| 1.3 Conformity of the premises : equipment and furniture | Evalenctory leaflet, of the agginment (machines.) |
| - materials: inalterable and easy to clean | Explanatory leaflet of the equipment (machines) |
| - furniture: smooth, washable, resistant | |
| - work surfaces: smooth, washable, resistant | |
| - work surfaces, smooth, washable, lesistant | |







Grid n° 1: Assessment of the implementation of pre-requisites

HACCP Grid 1 - Page1/4

| Considered criteria | Documents associated to these criteria |
|-------------------------------------------------|--------------------------------------------------------------------------------------|
| | |
| 1.4 Lawful or normative conformity | Documents attesting of: |
| · | national approval |
| | foreign country importation approval |
| | certification of voluntary setting in conformity with specific food safety standards |
| | |
| 1.5 Maintenance of buildings and equipment | Daybook of technical mending of buildings and equipment |
| | |
| 2 Supplies | |
| 2.1 Contractual relationship with the suppliers | Contracts past with suppliers |
| | criteria of acceptance of batches |
| | planed corrective actions for any case of loss of control |
| 2.2 Raw materials specifications | Cards of specifications of raw materials |
| • | Composition |
| | Microbiological standards |
| | Residues limit content |
| | conditioning (type, volume, weight) |
| | Preserving conditions |
| | lifespan |
| | Organization of stock turnover |
| 2.3 Checking of deliveries | Recording cards of control of deliveries |
| | temperature of delivered products |
| | intact conditionings |
| | compliance with consumption deadlines |
| | labelling compliance with official food safety marking rules |
| | cleanliness of the delivery vehicle |
| | |
| 2.4 Water portability | Analysis or certificate of water potability |

HACCP Grid 1 - Page2/4





Grid n° 1: Assessment of the implementation of pre-requisites

| Considered criteria | Documents associated to these criteria |
|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | |
| 3 Implementation of a system of traceability | |
| 3.1 System of upstream traceability | Specimen of simulation test of upstream traceability Recordings relating to upstream traceability: delivery control cards listing of raw materials stock Specimen of simulation test of downstream traceability Recordings relating to downstream traceability customers purchase orders listing of finished product stocks customers invoices |
| | COSTONICIO III (CICCO) |
| 4 Pest control | |
| 4.1 Implementation of a pest control plan | Pest control plan Insect control plan Intervention forms of the pest control company (department) |

HACCP Grid 1 - Page 3/4





Grid n° 1: Assessment of the implementation of pre-requisites

| Considered criteria | Documents associated to these criteria |
|----------------------------------------------------------------|-------------------------------------------------------------------------|
| | |
| | |
| 5 Control of staff originated contaminations | |
| 5.1 Medical follow-up of the staff members | Individual health certificates of food handling ability |
| 5.2 Plan of staff training | Time table and contents of training activities |
| | Staff members vocational training certificate |
| 5.3 Clothing hygiene : | In house management procedure of clothing, or washing supplier contract |
| standard work clothing supplied by the company | |
| washing of clothing by the company or under its responsibility | |
| management of clean and dirty clothing | |
| lockers with 2 compartments | |
| boots/shoes washstands in conformity with standards | |
| | Specific approved GHP and GMP guide of the production sector or |
| 5.4 Compliance with GHP and GMP | in house manual of the GHP and GMP of the company |
| 6 Hands and premises cleaning | |
| 6.1 Hands | Posting of washing hands instruction near the washstands |
| washstands in conformity with standards or regulations | |
| washing hands procedures | |
| | |
| 6.2 Premises | Sum of written cleaning procedures comprised in "cleaning plan" |
| enforcement of a cleaning plan | Check-grids of good execution of cleaning tasks |
| microbiological Control of effectiveness of cleaning | Weekly check-grid of visual cleanliness of equipment surfaces |
| interoriological control of effectiveness of cleaning | Reports of microbiological controls of surfaces |
| | Reports of interoofological controls of surfaces |

HACCP Grid 1 - Page 4/4





Grid n° 2: Assessment of the phase of preliminary HACCP study

Grid n° 2/4: Assessment of the phase of preliminary HACCP study

Assessment carried out following the chronological continuation of the method tasks

| Considered criteria | Documents associated to these criteria |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| | |
| Task n°1 | |
| 1.1 Management engagement | Management engagement declaration letter |
| 1.2 HACCP team founding members of the staff involved in the HACCP team assignment of technical tasks and responsibilities training of the team to HACCP method calling in external experts | Organisation chart of the HACCP team |
| 1.3 Means put at the disposal (computer, photocopy, budget) | Listing of the HACCP team functioning means |
| 1.4 Activities management organization, programming | Planning of activities |

HACCP Grid 2 - Page 1/3





Grid n° 2: Assessment of the phase of preliminary HACCP study

| Considered criteria | Documents associated to these criteria |
|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| | |
| The slave 0.2 | |
| Task n°2 | |
| 2.1 Description of the product | Descriptive file of the product |
| composition, volume, conditioning | |
| raw materials specifications: composition, proportion in the finished product, | |
| physicochemical parameters, lifespan, preservation, pre treatment | |
| Task n°3 | |
| 3.1 Identification of the expected use | User instructions manual |
| lifespan | Labelling |
| expected groups of consumers | Mandatory |
| conditions of use | Mandatory Informative |
| foreseeable deviations of use | |
| Task n°4 | |
| 4.1 Draft of the flow diagram | |
| | |
| | |
| Task n°5 | |
| 5.1 Verify the flow diagram | Flow diagram(s) |
| flow diagram in accordance with real field conditions | for each product or each family of products |
| taking into account of all the productions rates (high and low) | or by current elementary operations usually associated to carry out the products |
| contents of the diagram: nature of the stages, inputs, contacts, physicochemical | (cookery) |
| parameters (T°, time, Aw, pH) | or by work periods |
| | |

HACCP Grid 2 – Page 2/3





Grid n° 2: Assessment of the phase of preliminary HACCP study

| Considered criteria | Documents associated to these criteria |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| | |
| | |
| Task n°6 | |
| | |
| 6.1 Hazards analysis | List of identified hazards |
| analysis of the considered field hazards (biological, physical, chemical) based on the | |
| flow diagram | Transposition of the identified hazards on the flow diagram then on a table related |
| risk assessment by calculation of index of criticality | to the stages of production |
| | Identification and collection of the preventive measures relating to each risk |
| | |
| | |
| 6.2 Preventive measures drafting | Operational procedures of implementation of these measures |
| Task n°7 | Operational procedures of implementation of these measures |
| 7.1 Determination of CCPs | List of CCPs |
| | List of CC1's |
| by the use of the Codex decision tree | |
| plus identification of a related quantifiable and manageable parameter(s) | |
| Task n°8 | |
| 8.1 Determination of critical limits for each CCP | |
| selected criteria | List of the selected criteria and their required justifications |
| required justifications | J J |
| bibliographical data on the microbial flora | |
| results of ageing tests | |
| lawful obligations | |
| - | |
| | |

HACCP Grid 2 – Page 3/3





Grid n° 3/4 : Evaluation of implemented HACCP plan

Assessment carried out following the chronological continuation of the method steps

| Considered criteria | Documents associated to these criteria |
|-------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| Task n°9 | |
| 9.1Implementation of a monitoring system for each CCp | Manual of operational procedures |
| | Models of recording documents of the measured values, used within the framework of the monitoring procedures. Duration |
| Measuring instruments calibration | Plan of calibration of the measuring instruments |
| Task n°10 | |
| 10.1 Draft of corrective actions to implement in the event of loss of control (deviation of the monitored values) | Table of correspondence between the observed deviations and the corrective action type that must be implemented |
| 10.2 Ensure the follow-up of the batches subjected to corrective actions | Model of monitoring sheet of batches subjected to corrective action (traceability of these batches) |

HACCP Grid 3 – Page 1/2





Grid n° 3: Evaluation of implemented HACCP plan

| Considered criteria | Documents associated tothese criteria |
|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Task n°11 11.1 Establish verification procedures microbiological analysis of the finished products | Plan of analysis of products (raw materials, in production or finished products): sampling plan (number and frequency of samples) |
| 11 .2 Define practical methods of checking | Audit reports (in house or external) |
| Task n°12 | |
| 12.1 Establish documentation and records keeping | The whole of the documents taken into account at the preceding steps |

HACCP Grid 3 – Page 2/2





Grid n° 4: Routine evaluation of the real and effective implementation of an HACCP plan in the company

Grid n° 4/4: Routine evaluation of the real and effective implementation of an HACCP plan in the company

This fourth part is a documentary review. The documents relating to the good practices of hygiene are examined first. Then those relating to HACCP method are examined (in particular those which refer to the control of the CCP)

| Considered criteria | Documents associated to these criteria |
|----------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| · | _ |
| 13 Implementation of GHP and GMP: real and effective | |
| 13.1 Supplies monitoring | Raw material delivery checklists correctly and immediately kept |
| | Satisfactory water analyses reports |
| 13.2 Cleaning plan validation | Checklists of cleaning tasks execution correctly and immediately completed |
| | |
| 13.3 Pests control plan | Satisfactory results of microbiological analysis of surfaces |
| | |
| 12.4 Modical follow up of the stoff | Intervention forms of pest control service correctly filled |
| 13.4 Medical follow-up of the staff | Staff medical certificates correctly updated |
| | |
| 13.5 Staff training | Individual staff training certificates |
| 13.6 Maintenance of buildings and equipment | Maintenance daybook correctly kept |
| 13.7 Upholding of the conformity and provisioning of the washstands (observation | |
| in the course of visit) | |
| 13.8 Upholding of the conformity and provisioning of the boots/shoe washstands | |
| (observation in the course of visit) | |

HACCP Grid 4 - Page 1/2





Grid n° 4: Routine evaluation of the real and effective implementation of an HACCP plan in the company

| Considered criteria | Documents associated to these criteria |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | |
| 14 HACCP plan, CCPs control | |
| 14.1 CCP monitoring | Recording relating to CCPs monitoring: temperature recordings of the cold stores records of inventory control (respect of consumption deadlines) records of heat treatment couple "duration / temperature", schedules of sterilisation, pasteurisation, cooking |
| 14.2 Corrective action follow-up | Analysis reports of raw materials or in production or finished products |
| 14.3 Finished products conformity | Simulations of upstream and downstream traceability realized randomly at the time of the visit |
| 14.4 Traceability | Recordings of simulations of incidents / or simulation of incident during the audit session |
| 14.5 Simulations of incidents | |

HACCP Grid 4 – Page 2/2









Guidelines on HACCP, GMP and GHP for ASEAN Food SMEs

APPENDICES

- 1 Audit Report Template
- 2 Hazards
- 3 Calibration
- 4 HACCP Certification
- 5 Correlation with other Standards







Audit Report Template

APPENDIX 1 – AUDIT REPORT TEMPLATE

| Name of the establishment | | | | Branch of industry: Staff member met: |
|---------------------------|----------|----------|--------------|---------------------------------------|
| Adress | | | | Staff member met: |
| Phone n° | | | | Number of employees |
| Fax n° | | | | Number of employees |
| e-mail | | | | |
| | | | | |
| | | | | |
| Inspection (audit) n°: | | | | |
| <u>Page n°:</u> | | | | |
| Grid | Obs | Doc | Chautaomings | Possible solutions |
| ref | Obs | Doc | Shortcomings | Possible solutions |
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Conclusions:



A project co-financed by the European Union





A project co-financed by ASEAN





APPENDIX 2 - HAZARDS

(HAZARD EXAMPLES)

Chemical Hazards

Raw Materials

pesticides growth regulators antibiotics heavy metals natural toxins microbial toxins allergens

Packaging

plasticizers ink / adhesive metals

During process

cleaning agents incorrect ingredient concentrations hydrocarbon lubricants refrigerants pest control agents microbial toxins allergens fumes / dust

> Physical Hazards

The list is endless, including foreign objects of all kinds. The food industry tends to take special care over some types that easily cause damage if eaten by people, such as glass (prerequisite a glass management policy and management system) and metals (prerequisite - good maintenance management). However, in this latter case, metal detection also in use and is normally treated as a CCP. This, of course, means that the correct term is *metal rejection* – simply to detect metal is clearly not the object of the activity.

Microbiological Hazards

Pathogenic bacteria presence Parasites and protozoa contamination Viruses and algae Moulds

the organism or its toxic products





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APPENDIX 3 - CALIBRATION

Measuring equipment used to monitor Critical Control Points (CCPs) (and also product legality factors, such as fill volumes or average weights) shall be calibrated and, where possible, traceable to a recognised national standard. Where a national standard is not applicable, the nature of the basis of the calibration shall be described.

All too often, companies establish calibration methods involving routine use of subcontractors, or regular internal systems whereby instruments are calibrated very frequently with a very accurate method. This is not always necessary - calibration is required to keep systems in control, but this can be maintained with simpler methods that are referred back to a national standard on a less frequent basis. What matters is that the frequency and accuracy of calibration is appropriate to ensure that instrument variations are identified before they take the instrument out of allowed tolerance. Weight scales, for example, can be calibrated against a reference set of brass weights preserved by the company in good condition, (perhaps normally locked away in the Quality Manager's office). This reference set need calibration to national standards only, for example, every five years or so, unless damaged.

Thermocouple probe thermometers are notorious for going out of calibration. A frequent rapid method of checking is required to maintain good measurement systems, coupled with a less frequent reference back to a national standard.







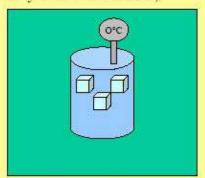




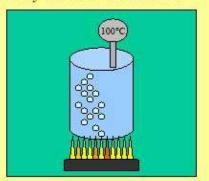
Self-calibration of thermometers (practical hints):

How to use a simple method for calibrating your thermometers in fields conditions:

- by putting your thermometer into iced water (o° Celsius) you can verify the zero measure;



- by putting your thermometer into (*) boiling water (100 °Celsius) you can verify the 100 °C measure.





(*) as a matter of facts the thermometer should be put just above the surface of boiling water.











APPENDIX 4 – HACCP CERTIFICATION

HACCP Certification - Warnings

A frequently defined objective for developing an HACCP system is to obtain recognition by an 'expert' body in the form of certification from a third party audit body (perhaps required due to customer pressure).

This practice has value in providing extra verification of validity and effectiveness of the system, but it does present a risk.

The award of a certificate does not mean that the system is faultless.

No auditor is perfect – the illusion of excellence provided by a certificate can lead to situations where a business may believe that it operates a flawless HACCP system. It may well then not maintain effectiveness of its own verification (auditing) processes.

actual observed example (from other sources)

product – smoked cooked chicken sausages, to be eaten either after home cooking OR DIRECTLY FROM THE PACKAGE (perhaps as a part of a salad, or other garnish)

process - filled sausages were smoked / cooked in a chamber and then cooled by water before packing in plastic pouches. Some of the cooling water was drawn from a well and was subject to a disinfection procedure.

There was a potential hazard of microbiological contamination from the water that would not have been removed by any subsequent process, so the disinfection point is ■ a CCP, and ■ should have been subject to a proper monitoring programme.

Neither of these points had been identified and yet the company had been awarded an HACCP certificate by a well known accredited certification body, which was even prepared to argue that this was not a CCP.

The award of the certificate had brought about a complacent attitude that meant that the company was satisfied with its HACCP system and had not subjected it to effective review.

THE OBJECTIVE OF DEVELOPING A HACCP SYSTEM IS SAFE FOOD -

- NOT CERTIFICATION

Companies should beware of HACCP certification that is offered as a route to enable a company to export into (for example) the European Union.

In all cases, the authorisation for exports to EU will be delivered only by the National Competent Authority (recognised by the EU) which approves the food establishments involved.

Demonstration of good practice with an HACCP certificate will only provide part of any evidence required and is a good route to demonstrating committed management, but other approvals are also needed at national level, such as:

Residues plan

Use of accredited laboratories











HACCP certificate a passport to the EU market? (a fictional story):

The company JollyGoodFood (*) wants to export to the EU market, it has been certified by a recognized private certification body, does the doors of the EU market will open for its products?

Some food for thought on this issue:

- the certificate from a private company is not a permission to deliver the product to the EU market:
- only the EU model certificate(s) accompanying the exported batche(s) together with the approval to export, delivered by an official authority recognized by the EU to the company, can help the product of the company enter the EU market.
- this official authority will check that the company follows the same requirements as EU ones.
- therefore setting-up a functional HACCP system based on a sound management of GMP is a fundamental requirement for all the companies that want to export to the EU.



(*) fictional company





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APPENDIX 5 – CORRELATION WITH OTHER STANDARDS

A concern expressed by participating companies has been a desire to understand the requirements of standards, or protocols, which may be needed for export to Europe and how far completion of an HACCP – GHP – GMP system will go to fulfil these requirements.

Of consideration here are two standards, one the result of worldwide co-operation in the field of formal international standards, ISO, the International Organization for Standardization, the other an approach adopted for harmonization of retailer requirements called the Global Food Safety Initiative. These provide different sets of requirements that reflect the objectives of the cooperating organisations. They are:

ISO 22000:2005 - Food safety management systems - requirements

As its title suggests, this standard sets out a systematic approach to food safety, combining two approaches into an effective tool for management. These approaches are:

- the management system approach, as normally understood in ISO 9001:2000, except that ISO 22000 looks at the customer requirement of food safety ONLY and not at all the other requirements that are expressed as 'customer requirements'. For companies that use management systems, this means that an ISO 22000 approach can fit food safety very easily into this pattern.
- HACCP, is broadly described in this EC-ASEAN guide. ISO 22000 is almost exclusively based on HACCP, with less attention to GHP, GMP, or other prerequisites (which it terms as 'supportive safety measures'). With this attention to HACCP, it provides a flow diagram demonstrating linkages between the twelve tasks of HACCP and its own sections.

Users of this guide will have attended to most, or all, of the HACCP requirements of ISO 22000 but may need manage their system in a more systematic fashion if they are looking for ISO 22000 certification.

The use of ISO 22000 is yet to be proved because its objective was never identified by a particular user group (such as retailers or importers / exporters). Its main use will probably come if an international trade organisation (such as the World Trade Organization), was to decide that a harmonised standard on food products was required for food trade.

For the moment the only standard recognised by WTO in the frame of the application of the SPS agreement are: i) Codex Alimentarius for Food Safety, ii) OIE for animal health and iii) IPPC for plant health (phytosanitary issues).

The Global Food Safety Initiative (GFSI)

This is a comprehensive private initiative for food safety resulting from co-operation between major European food retail super and hyper market chains. Because of their need to demonstrate 'due diligence', this protocole is comprehensive. Its specifications go beyond, but include, those of this GHP, GMP, HACCP guide. It is much more prescriptive in setting its requirements.









Those organisations who have established food safety management through this guide will find that they have addressed many GFSI needs. They will not have to alter their work, but will have to add in extra sections on:

- Quality Management System
- Particular requirements on
 - Factory Environment Standards
 - Product Control
 - Process Control and
 - Personnel

GFSI is not, in itself, a standard. Its objective is to set out common needs for other audit protocols, awarding such protocols GFSI status. Four such protocols have, so far, been approved, these being • The British Retail Consortium Technical Standard • The Dutch HACCP Code • EFSIS Standard • International Standard for Auditing Food Suppliers (International Food Standard).





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European Committee for Standardisation / Comité Européen de Normalisation This report reflects the view of the Implementing Agency and Experts and in any case can be considered as the view of the European Commission.