UNIVERSITÀ DEGLI STUDI DI TERAMO

UNITE

FOODQA
TRAINING

DAY 1: 29 JANUARY 2018

FOOD SAFETY

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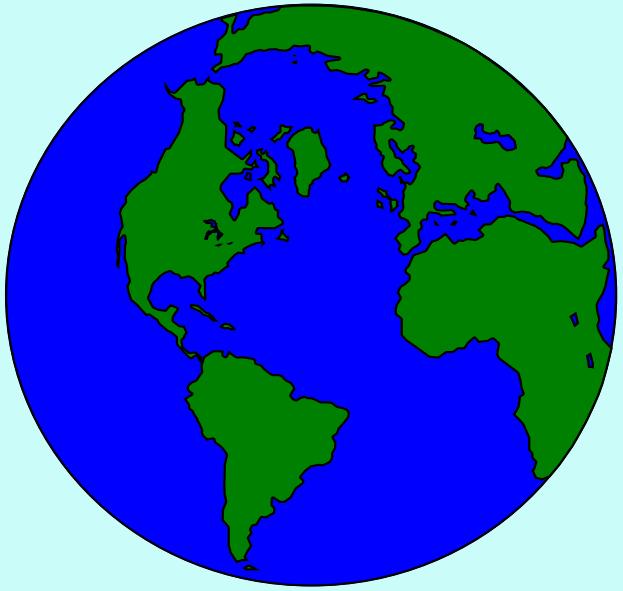
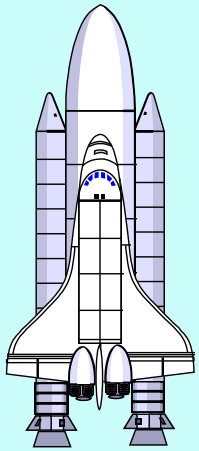
Hazard
Analysis
Critical
Control
Points





1959: NASA - Pillsbury Project

"Food safety for the first manned space missions"

HACCP DEFINITIONS

HAZARD:

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. (Recommended International Code of Practice, Codex rev 1997).

HACCP DEFINITIONS

MICROBIOLOGICAL HAZARD:

Unacceptable contamination, growth or survival of microorganims and their metabolites with the potential to cause an adverse health effect.

HACCP DEFINITIONS

CCP (CRITICAL CONTROL POINT):

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.

HACCP STRUCTURE:

PREREQUISITE PROGRAMS + 7 CODEX PRINCIPLES

PREREQUISITE PROGRAMS (PRPs)

1. Conduct a Hazard Analysis (HA)
2. Determine the Critical Control Points (CCP)
3. Establish Critical limits and tolerances
4. Establish a monitoring system
5. Establish the corrective actions
6. Establish procedures for verification
7. Establish documentation

WHICH RISK LEVEL CAN BE TOLERATED BY A SPECIFIC POPULATION?

ALOP

ALOP = appropriate level of sanitary or phytosanitary protection. Also known as ALR = acceptable level of risk

"the level of protection that is considered acceptable by each country in order to protect human, animal or plant health"

TLR

TLR = tolerable level of risk

“risk that can be tolerated by society, in comparison with the other significant risks of daily life”

TLR

TLR are estabilished following consideration of public health impact, technological feasability, economic implications, and that society regards as reasonable in comparison with other risks in everyday life.

It can be indicated as the number of cases/year caused by a specific food hazard on 100 000 people.

TLR is closely connected to social and local factors but shall be established on scientific basis

TLR EXAMPLES

0.5 cases /year of listeriosis on 100 000 people

0.02 cases /year of cholera on 100 000 people

0.01 cases/year of food botulism on 100 000 people

18 cases/year of non-typhoid salmonellosis on 100 000 people

10 cases /year of hepatitis A on 100 000 people

DIFFERENCE BETWEEN TLR AND FSO

FSO (Food Safety Objective) aims to establish practical control measures that should be applied to obtain TLR. An FSO converts the TLR into parameters that can be controlled by manufacturers

"the maximum frequency and/or concentration of a microbial hazard in a food at the moment of consumption that provides the appropriate level of health protection"

FSOs: WHO IS GOING TO ESTABLISH THEM?

In the EU

Strategic role of the European Food Safety Authority (EFSA)

Possible role of the National Food Safety Authorities

FSO EXAMPLES

- concentration of staphylococcal enterotoxins in cheeses shall not exceed 1 µg 100 g^{-1}
- aflatoxins concentration in peanuts shall not exceed 15 µg kg^{-1}
- *Listeria monocytogenes* in ready-to-eat foods shall not exceed 100 ufc g^{-1} at the moment of consumption
- Salmonellae shall not exceed 100 ufc kg^{-1} in infant milk formulations

FSOs EVALUATION

IF FSO CAN BE TECHNICALLY ACHIEVED

⬇

IT BECOMES COMPULSORY FOR ALL MANUFACTURERS

IF FSO CANNOT BE TECHNICALLY ACHIEVED

⬇

- ✓**IF POSSIBLE, THE PRODUCT OF PROCESS SHOULD BE MODIFIED**
- ✓**IF MODIFICATION IS NOT POSSIBLE, THE PRODUCT SHOULD BE BANNED**

PREREQUISITE PROGRAMS (PRPs)

PREREQUISITES PROGRAMS

Preliminary step:	GMP verification (structure, management, equipment)
Step 1:	HACCP Team
Step 2:	Food description and storage conditions
Step 3:	Conditions of use and type of consumer
Step 4:	Flow Chart
Step 5:	Flow Chart verification

PREREQUISITES
ACCORDING TO ISO 22002-1
EVALUATE THE FOLLOWING ASPECTS:

1. Construction and layout of building
2. Layout of premises and workspace
3. Utilities - air, water, energy
4. Waste disposal
5. Equipment suitability, cleaning and maintenance
6. Management of purchased material
7. Measures for prevention of cross contamination
8. Cleaning and sanitizing
9. Pest control
10. Personnel hygiene and employee facilities
11. Rework
12. Product recall procedures
13. Warehousing
14. Product information
15. Food defense, biovigilance and bioterrorism

OPERATIONAL AND NON OPERATIONAL PREREQUISITES IN THE SO-CALLED "3-WAY SYSTEM" IN ISO 22000 NORMS

According to hazards and hazard management conditions, Self-Check can follow 3 directions:

1. NON OPERATIONAL PREREQUISITES
2. OPERATIONAL PREREQUISITES
2. HACCP PLAN

HACCP AND PRPs: AIMS

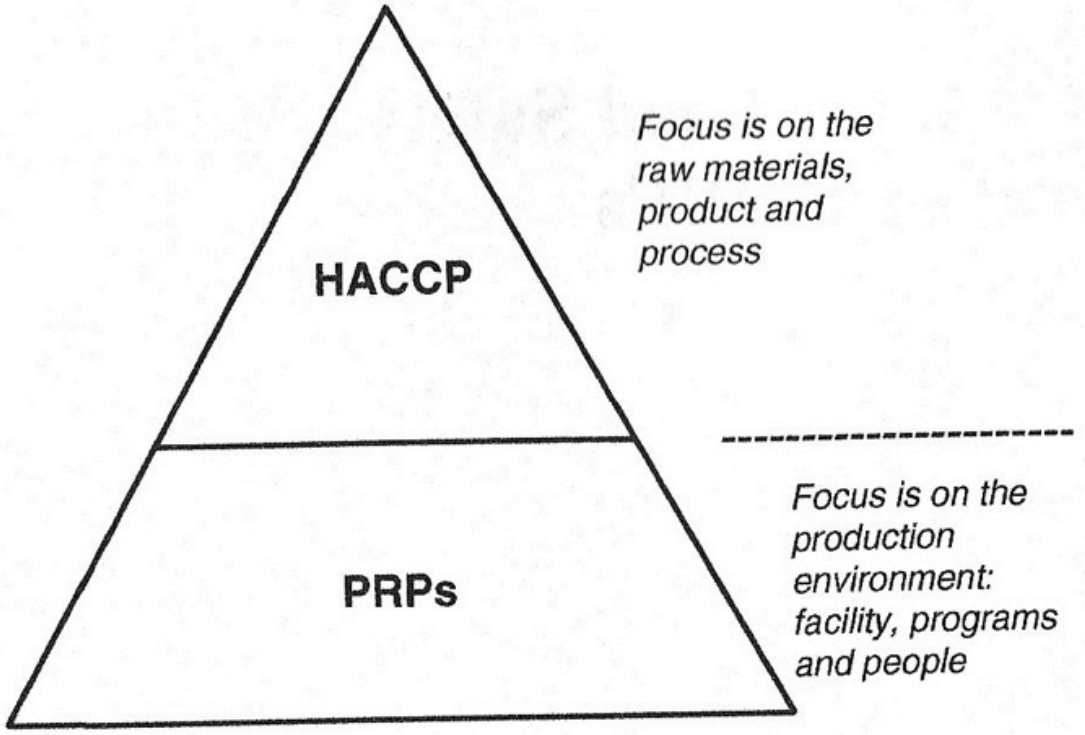


Fig. 4.1 The relationship between HACCP and PRPs (Warren 2012)

NON OPERATIONAL PREREQUISITE PROGRAM

It manages the basic activities in the self-check system

1. No specific hazard

2. It aims to keep good hygiene conditions

3. No continuous monitoring, Yes periodical verification

OPERATIONAL PREREQUISITES

They are targeted to specific hazards, where no corresponding CCP can be identified

(e.g. *L.monocytogenes* in smoked salmon

Salmonella enterica in raw meat and tiramisu)

Yes monitoring, Yes verification

HACCP PLAN

It aims to manage specific hazards by controlling the corresponding CCPs (or by SOPs)

Yes monitoring, Yes verification,
according to the 7 Codex Principles

HACCP AND PRPs: IMPACT ON FOOD SAFETY

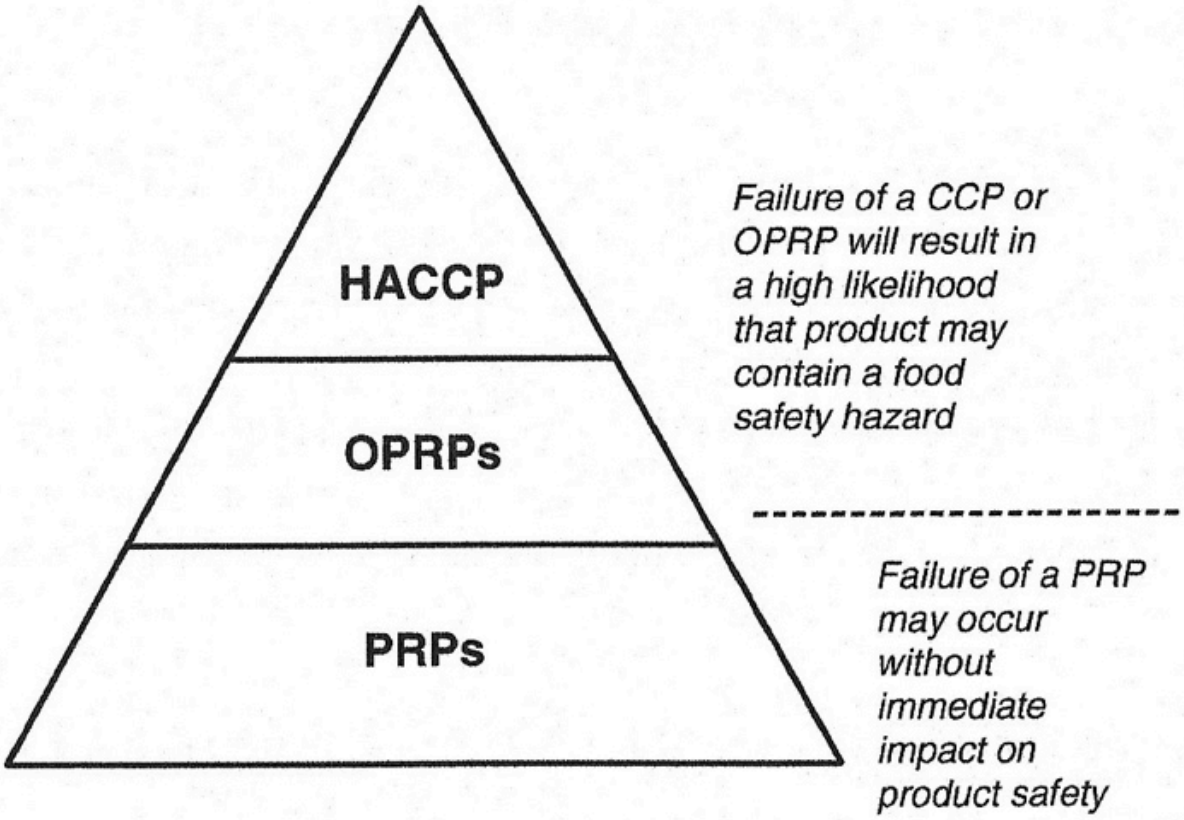
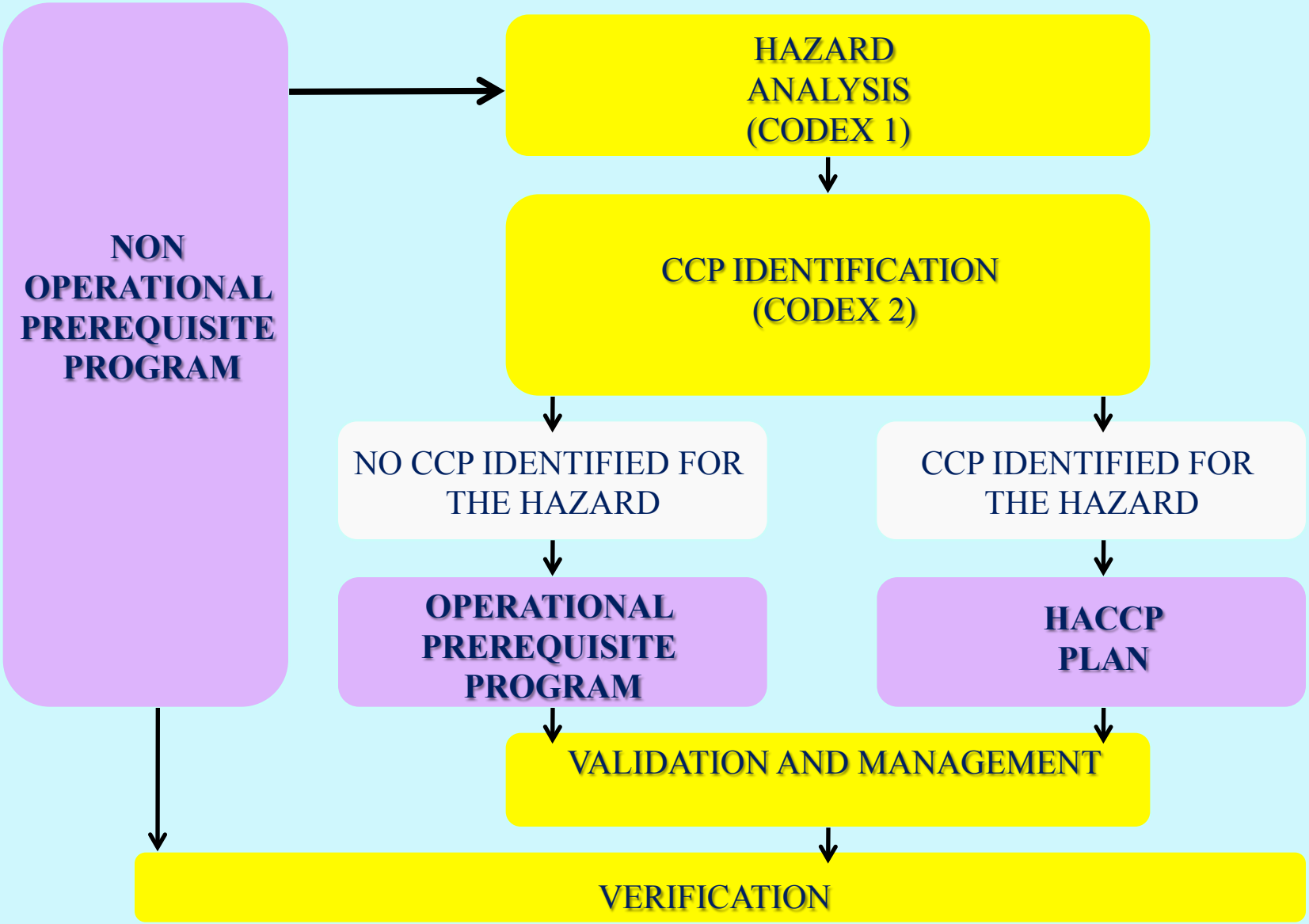


Fig. 4.3 The relationship between HACCP, OPRPs, and PRPs (Warren 2012)

"3-WAY SYSTEM"



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EXAMPLES OF PREREQUISITES DEVIATIONS

Workers wash their work clothes at home	MANAGEMENT
No hangers in the bathroom	EQUIPMENT
No separated cold store for food wastes	STRUCTURE
No automatic rewinding for flexible hoses	EQUIPMENT

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EXERCISE: DESCRIPTION OF INGREDIENTS

EXERCISE

Please describe the following food item: Mechanically Deboned Meat

NAME: MDM

USE: INGREDIENT FOR MEAT PRODUCTS

PACKAGING: WRAPPED IN AIR

SL AND TEMP: 12 MONTHS, -18°C

DISTRIBUTION: FOOD INDUSTRY (RAW MATERIAL)

CONSUMER: ALL

STORAGE: FROZEN, -18°C

EXERCISE

Please describe the following food item: YOGHURT

NAME:

USE:

PACKAGING:

SL AND TEMP:

DISTRIBUTION:

CONSUMER:

STORAGE:

HACCP

CODEX PRINCIPLE No. 1

Hazard Analysis

HAZARD HIERARCHY

UNITS OF MEASUREMENT FOR HAZARDS

1. SEVERITY: **importance**

2. RISK: **frequency**

HAZARD ANALYSIS:

THE METHODS

- Check epidemiological data
- Analyse scientific literature
- Gather quality control data
- Use specific software (e.g. Combase: www.combase.cc)
- If necessary, carry out experiments
- For zoonoses, evaluate animal epidemiological data

HAZARD ANALYSIS: WHAT WE NEED TO KNOW

Microbial ecology of foods

Technological data (process and product)

Health effects of possible pathogens

Risk Category Method

Aims:

1. Define monitoring priorities

2. Identify when a hazard occurs

3. Decompose the hazard according to ingredients

Risk Category Method

Risk Classes (for each hazard)	
RISK A	Non sterile product, intended for high-risk consumers
RISK B	Presence of ingredients that can contain the hazard
RISK C	No treatment eliminating the hazard
RISK D	Possible recontamination after processing
RISK E	Possible thermal abuse during distribution/consumption
RISK F	Eaten without heat treatment

Risk Category Method

RISK CATEGORIES (for each hazard)	
CATEGORY 6	Non sterile product, intended for high-risk consumers
CATEGORY 5	5 risk classes
CATEGORY 4	4 risk classes
CATEGORY 3	3 risk classes
CATEGORY 2	2 risk classes
CATEGORY 1	1 risk classes

Risk Category Method

Used to compare food hazards and classify food into RISK CATEGORIES

Risk Category:

Salmonella enterica in a traditional flan

Product/ingredient	Risk Class for the product/ingredient						Risk Category
	A	B	C	D	E	F	
Traditional flan	0	+	0	+	+	+	4
INGREDIENTS (as they are during preparation)							
UHT milk	0	+	0	+	0	+	3
Milk plus 50% UHT cream	0	+	0	+	0	+	3
Pasteurized egg	0	+	0	+	+	+	4
Sugar	0	0	0	0	0	0	0
Vanilla extract	0	0	0	0	0	0	0
Caramel	0	0	0	0	0	0	0

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EXERCISE: RISK CATEGORY IN TRADITIONAL BAKERY PRODUCTS

Risk Category: *Clostridium prefringens* in a Meat Pie

1. Evaluate formulation and processing method of a Meat Pie to establish risk classes and risk categories for the finished product and for each ingredient.
2. Please note that the ingredients should be considered as they are during preparation (e.g. minced or frozen or peeled).
3. For each risk class from A to F, mark + for presence and 0 for absence.

SA PANADA

Clostridium perfringens in a Meat Pie

Product/ingredient	Risk Class for the product/ ingredient						Risk Category
	A	B	C	D	E	F	
Meat Pie							
INGREDIENTS (as they are during preparation)							
Flour							
Durum wheat flour							
Sunflower Oil							
Water							
Beef cubes, chilled							
Potatoes							
Extra Virgin Olive Oil							
Fresh Parsley							
Spice Mix							
Salt							

HACCP

CODEX PRINCIPLE No. 2

CCPs IDENTIFICATION

CCPs IDENTIFICATION

A GENERAL RULE:

A STEP OR A PLACE CAN BE CONSIDERED A CCP ONLY IF WE CAN DISTINCTIVELY REDUCE OR ELIMINATE THE HAZARD, E.G . BY CONTROLLING MEASURABLE VARIABLES (temperature, pH, a_w, weight, % NaCl, % O_2, etc.)

CCPs IDENTIFICATION

MY HINT:

ANALYSE EACH STEP SEPARATELY ("Layer analysis") AND LOOK FOR THE HAZARDS THAT CAN OCCUR IN THAT STEP, INDEPENDENTLY FOR THE FOLLOWING STEPS.

CCPs IDENTIFICATION

MY RECOMMENDATION:

AVOID GENERALIZATION!

ONE STEP CAN BE A CCP IN ONE PLANT AND NOT IN ANOTHER: E.G. VEGETABLES WASHING WITH OR WITHOUT DISINFECTANTS (CCP IF WE CAN DOSE THE DISINFECTANT)

CCPs IDENTIFICATION

NEEDS TO BE TAILOR MADE

CCPs IDENTIFICATION

PLEASE DO NOT

CONFUSE CCPs WITH HAZARDS!

One step where a hazard occurs is NOT necessarily a CCP!

It can be considered a CCP only if we can apply specific measures to reduce or eliminate the hazard.

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EXERCISE: ANALYSIS OF A MICROBIOLOGICAL HAZARD

ANALYSIS OF *Salmonella* spp. HAZARD IN DEEP-FROZEN SPINACH

STEP	CONTAMINATION	GROWTH	SURVIVAL
Fresh spinach			
Blanching			
Deep freezing			
Cooking			

HACCP

CODEX PRINCIPLE No. 3

Critical limits and tolerances

PERFORMANCE CRITERIA

The effect of one or more control measure(s) needed to meet or contribute to meeting a performance objective, e.g. 6D reduction of *Salmonella* spp. in heat treatments.

ASSESSMENT OF PERFORMANCE CRITERIA

WE NEED TO TAKE INTO ACCOUNT THE INITIAL LEVEL OF THE HAZARD (H_0) AND THE CHANGES GENERATED BY THE PROCESS (REDUCTION ΣR OR INCREASE ΣI).

PERFORMANCE CRITERIA SHOULD BE BELOW OR EQUAL TO FSO.

$$H_0 - \Sigma R + \Sigma I \leq FSO$$

H_0 = Initial level of the hazard

ΣR = Summation of the effects of reducing hazards

ΣI = Summation of the effects of increasing hazards

FSO = Food Safety Objective

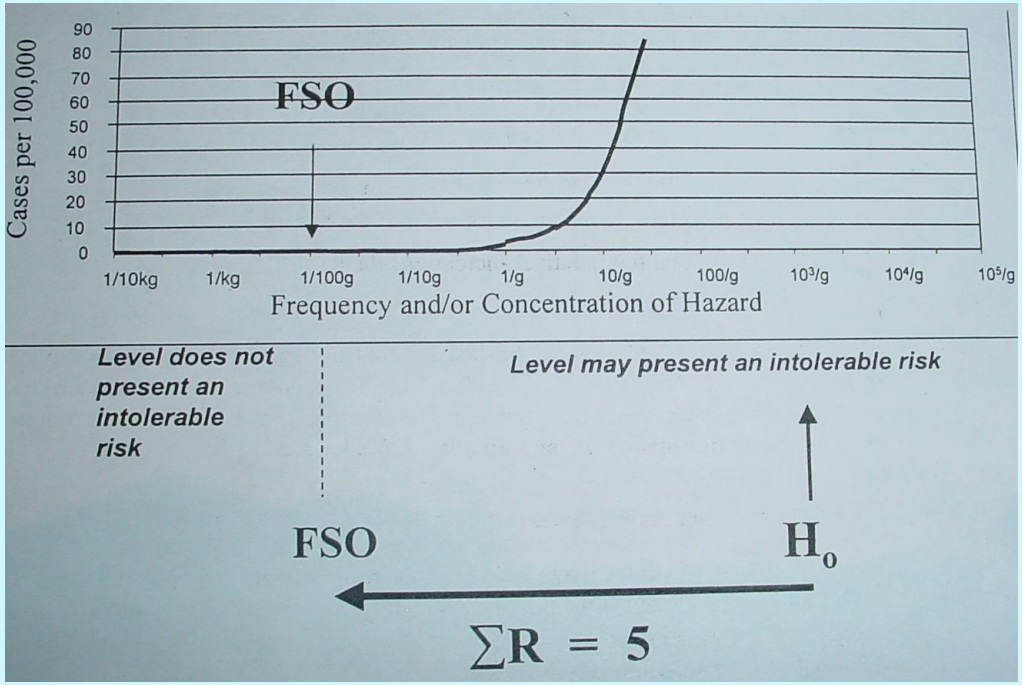
PERFORMANCE CRITERIA: EXAMPLE No. 1

(EHEC in frozen curd for cheese manufacturing)

Epidemiological data on a specific area show that the number of cases on 100 000 inhabitants increases when EHEC load exceeds 1 ufc g^{-1}.

Let's assume that FSO was fixed 100 times below:

1 ufc 100 g^{-1} (at the moment of consumption)



If the initial load of the curd is 10^3 ufc g^{-1} but the growth (ΣI) can be inhibited (frozen curd), the performance criterion of the whole manufacturing process of mozzarella can be calculated as:

$$H_0 - \Sigma R + \Sigma I \leq FSO; \qquad 3 - \Sigma R + 0 \leq -2$$

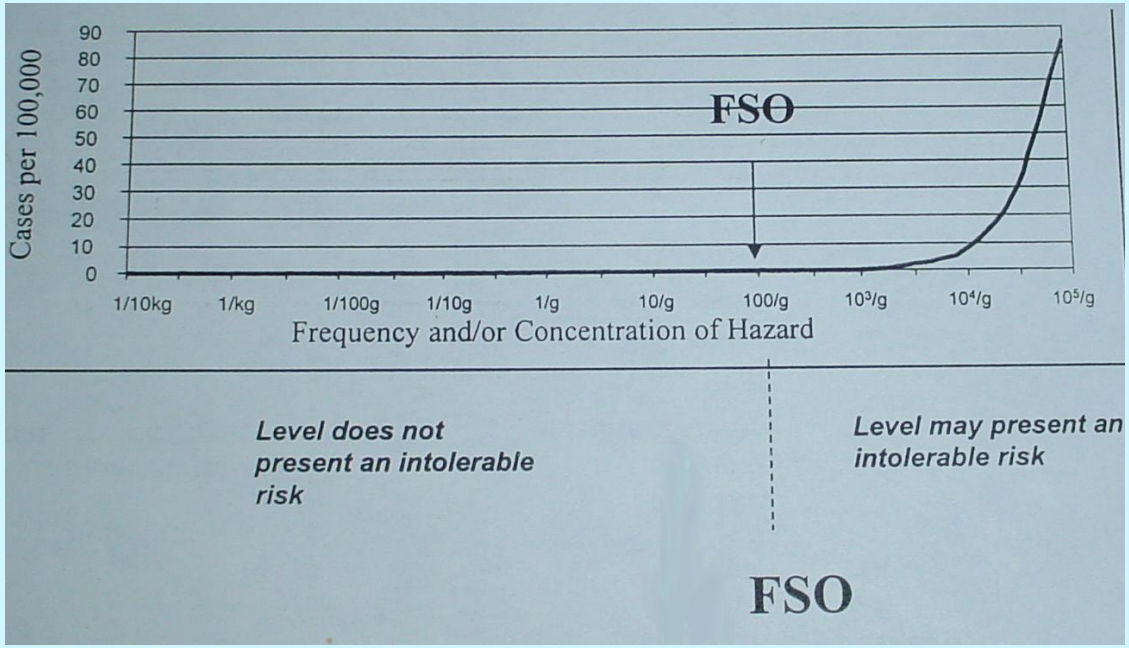
PERFORMANCE CRITERIA: $\Sigma R \geq 5$ (5D)

PERFORMANCE CRITERIA: EXAMPLE No. 2
(*Listeria monocytogenes* in gorgonzola)

Epidemiological data on a specific area show that the number of cases on 100 000 inhabitants increases when *L.m.* load exceeds 10^3 ufc g^{-1}.

Let's assume that FSO was fixed 10 times below:

100 ufc g^{-1} (at the moment of consumption)



If the product does not undergo any listericidal treatment ($\Sigma R=0$) and storage at temp. x for time y allows the increase of a single logarithmic cycle (1D), the initial count in gorgonzola (H_0) should correspond to the following performance criterion.

$$H_0 - \Sigma R + \Sigma I \leq FSO;\ H_0 - 0 + 1 \leq 2$$

PERFORMANCE CRITERION: $H_0 \leq 1$

HACCP

CODEX PRINCIPLE No. 4

Monitoring

DIFFERENCE BETWEEN MONITORING AND VERIFICATION

MONITORING: control measures for the real-time management of CCPs, mainly based on physical measurements

VERIFICATION: control measures for the periodical evaluation of the HACCP system, based on auditing, documentation, and experiments that do not necessarily generate real-time results (e.g. microbiological analyses)

METHODS FOR MONITORING

PROCEDURES: they are usually harmonized with quality management procedures. Key points: WHO WHAT HOW WHEN.

CONTROLS: whenever possible, rapid methods and official methods. The results should be obtained in time for corrective actions.

CODEX 4: PROCEDURES

They are the core of both HACCP and Quality Management System.

Fundamental procedures for HACCP: process control, cleaning and sanitizing, pest control, management of purchased materials, deviations management, labelling, traceability, allergens.

Each procedure should contain a responsibility assignment matrix, which describes who is accountable, responsible, consulted, or informed.

Example of Responsibility Assignment Matrix

RACI Matrix Template

Project Deliverable (or Activity) \ Role	Executive Sponsor	Project Sponsor	Steering Committee	Advisory Committee	Role #5	Project Manager	Tech Lead	Functional Lead	SME	Project Team Member	Developer	Administrative Support	Business Analyst	Role #4	Role #5	Consultant	PMO	Role #3	Role
	Project Leadership					Project Team Members					Project Sub-Teams					External Resources				
Initiate Phase Activities																				
- Submit Project Request	A/C	R/A				R/A	A/C	A/C	C											
- Request Review by PMO						R											A			
- Research Solution	I	C				R/A	A/C	A/C	C					C		C	A/C			
- Develop Business Case	I	A/C	I	I		R/A	C	C	C					C		C	C			
Plan Phase Activities																				
- Create Project Charter	C	C				R/A	C	C	C					C		C				
- Create Schedule	I	I	I	I		R/A	C	C	C	C	C	C	C			C	I			
- Create Additional Plans as required	I	I	I	I		R/A				I	I	I	I			C	I			
Execute Phase Activities																				
- Build Deliverables	C/I	C/I	C/I	C/I			R/A	R/A	R/A	R/A	R/A					A/C				
- Create Status Report	I	I	I	I		R/A	R/A	R/A	R/A							C	I			
Control Phase Activities																				
- Perform Change Management		C	C	C		R	A	A	A	A						C	I			
Close Phase Activities																				
- Create Lessons Learned	C	C	C	C		R/A	C	C	C	C	C	C	C			C	C			
- Create Project Closure Report	I	I	I	I		R/A	I	I	I	I	I	I	I				I			

A = Accountable; R = Responsible (works on); C = Consulted; I = Informed

From: http://todd.hello-ip.eu/rasci-matrix-template.html

Responsibility Assignment Matrix:

difference between Accountability and Responsibility

Dictionary.com defines each as:

Accountable: "subject to the obligation to report, explain, or justify something; responsible; answerable."

Responsible: "answerable or accountable, as for something within one's power, control, or management."

Responsibility can be shared while accountability cannot.

Accountability: being responsible for something but also being answerable for the actions.

A = Accountable; R = Responsible (works on); C = Consulted; I = Informed

TEMPLATES FOR HACCP PROCEDURES:

PREREQUISITES SOP AND PROCESS CONTROL PROCEDURE

(From: Snyder, 2005)

PREREQUISITE PROCESS

DOUBLE HAND WASHING WITH A FINGERNAIL BRUSH HACCP

Dept.: _____ Person responsible: _____ Effective date: _____
Process: To double wash fingertips and hands to reduce by 1,000,000 to 1 pathogens
The Hazard: Pathogens from feces

Standards and Operating Procedure

Get ready.

The double wash with the nail brush.
Apply detergent to the fingernail brush.

Brush and lather, particularly fingertips and fingernails.

Second wash for additional toilet / food pathogen reduction or first wash for reduction of food pathogens to a safe level.

Dry hands using paper towel(s).

FOOD (HACCP) PROCESS

QUALITY-ASSURED HACCP RECIPE PROCEDURES

Recipe Name:
Production style:
Written by: Date:
SA/QA by: Date:
Portion size (vol./wt.):
Number of portions:
Final yield (AS):
Preparation time:
Prepared by:
Supervisor:

Gp. #	Ingred. #	Ingredients and Specifications	Edible Portion (EP) (weight or volume)		EP Weight %	As served (weight)

Ingredients that could produce possible allergic reactions:

Prerequisite Procedures
SSOPs / GMPs. Control chemicals. Remove physical hazards from food. Double wash fingertips / personal hygiene (6-log reduction). Sanitize food contact surfaces (5-log reduction). Train. QC. Buy food and store.

Pre-preparation
1. Get food for recipe, <3-log increase *L. monocytogenes* (PHF <41°F).
2. Thaw <70°F.
3. Do pre-prep. No time-temperature hazard. No CCP.

Preparation
4. CCP. If making salad with uncooked ingredients, double wash all fruits and vegetables to reduce vegetative pathogens 2 log.
5. CCP. Cook for 5-log *Salmonella* reduction (155°F, 15 seconds).

Hold / Serve
6. Hot hold, transport, serve. No growth of *Clostridium perfringens* (>125°F).

Leftovers
7. CCP. Cool to prevent <1-log increase of *Clostridium perfringens* (135 to 41°F, 14 hours; <2 inches deep or 1-gallon pot).
8. Cold hold, <3-log increase *Bacillus cereus*. If making cold mixed salad, get all ingredients <50°F before mixing (PHF <41°F).
9. Throw leftovers away or hold <7 days and reheat to 165°F, 15 seconds (<3-log increase *Bacillus cereus*).
10. CCP. For allergen control, do not combine / mix leftovers.

Process step #	Start food ctr. temp. °F	Thickest food dimension (in.)	Container size HxWxL (in.)	Cover Yes/No	Temp. ctr/ around food	End food ctr. temp. °F	Process step time, hr:min.

TEMPLATES FOR HACCP PROCEDURES:

PRODUCT FORMULATION AND PROCESS CONTROL PROCEDURE

(From: Snyder, 2005)

Gp. #	Ingredients and Specifications	Edible Portion (EP) (weight or volume)		EP Wt. %
I	Onions, chopped	3.0 lb	1,360.00 g	13.26
	Mushrooms, cut	3.0 lb	1,360.00 g	13.26
	Peppers, green, cut	2.0 lb	907.2 g	8.84
	Garlic, chopped	6 Tbsp.	85.05 g	0.53
	Tomatoes, canned, crushed	13.25 lb	6,010.00 g	58.58
	Oil, vegetable	1/4 cup	54.00 g	0.53
	Wine, Marsala or Madeira	2 cups	472.00 g	4.60
	Oregano, crushed	2 tsp.	3.00 g	0.03
	Salt	1 tsp.	5.50 g	0.05
	Pepper	1 tsp.	2.10 g	0.02
	Total	22.6 lb	10,258.85 g	100.00
II	Chickens, whole	62 lb		

Preparation

1. Prepare sauce. Sauté onions, mushrooms, green peppers, minced garlic in oil. Add crushed tomatoes with juice, wine, and seasonings. Simmer (205°F, 10 min.).
   1a. Hold sauce (165°F, 20 min.) for use in Step 4.
2. Prepare chicken. Get chicken quarters (40°F). Remove rib bones.
3. CCP Place quarters, one layer deep in shallow roasting pans. Bake (brown) chicken in a convection oven at 350°F for 30 min. (>165°F) *(Temp & initials)*
4. Remove pans of chicken from oven (>165°F). Cover the chicken quarters with sauce (from Step 1a).
   4a. CCP Pour off liquid. Cool. (135 to 41°F). *(Temp & initials)*
5. Return pans of chicken and sauce to ovens at 300°F. Bake until all parts of the chicken reach 175°F (45 min.).
6. Check temperature of chicken. If temperature is not 175°F, continue to cook.
7. Cover and transfer to 150°F hot holding unit.

Hold / Serve

8. Hold, ≥150°F. Serve 1/4 chicken covered with 3 oz. sauce (>150°F, <2 hours).

Leftovers

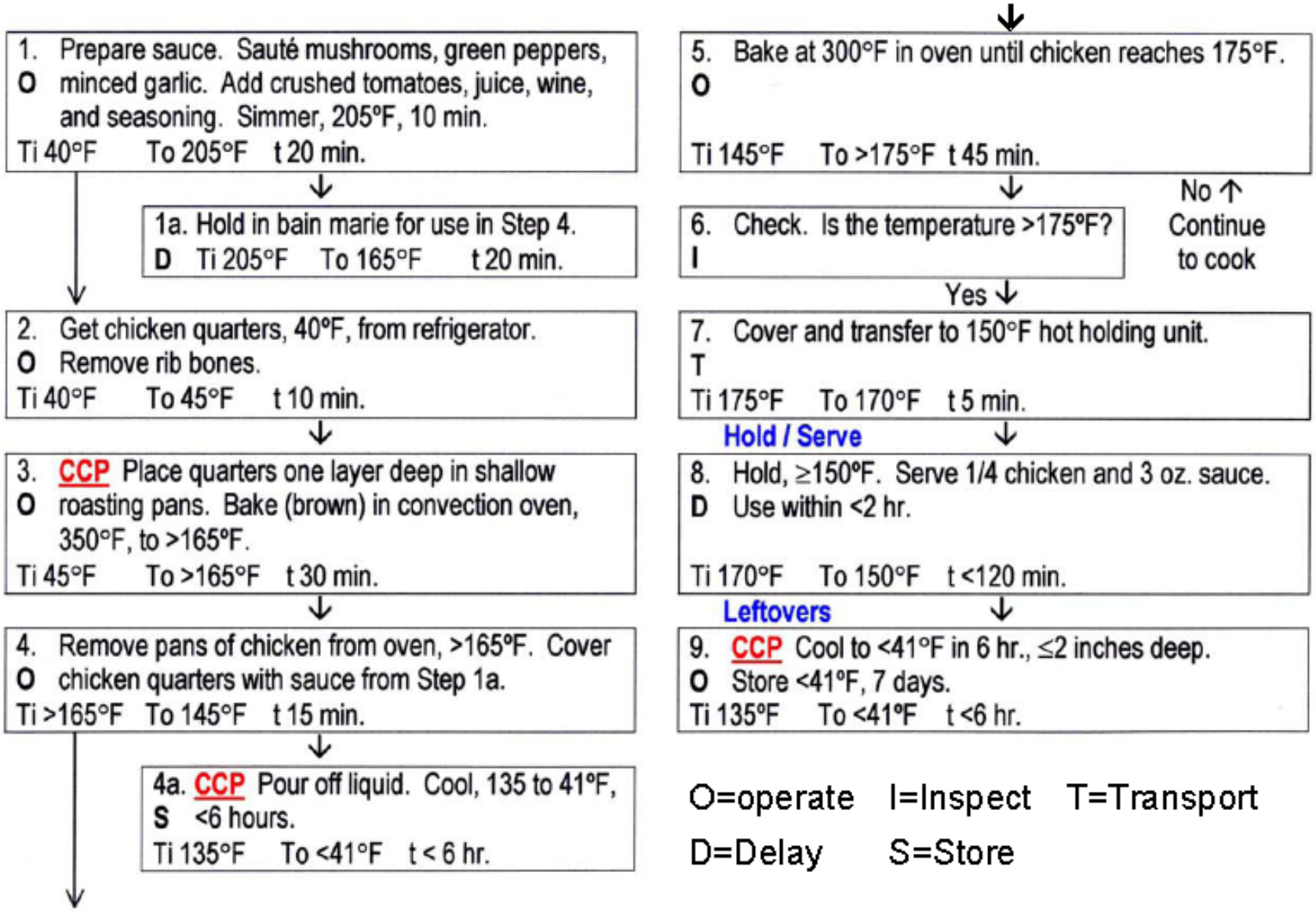
9. CCP Cool <41°F in <6 hours. ≤2 inches deep. *(Temp & initials)*

Ingredients that could produce allergic reactions:
Tomatoes, wine

TEMPLATES FOR PROCEDURES:

HACCP FLOW CHART FOR CASSEROLED CHICKEN

(From: Snyder, 2005)



CODEX 4: RECORDS AND DOCUMENTS

Document = "content file that has information in a structured or unstructured format". It is editable. It can be stored as paper or digitally. It can be changed and revised.

Record = "historical file that provides proof of existence of activities and results". It is not editable and cannot be recreated. It can be stored as paper or digitally.

In the current version of the quality norm ISO 9001:2015, documents and records are described together as "documented information".

CODEX 4: RECORDS AND DOCUMENTS

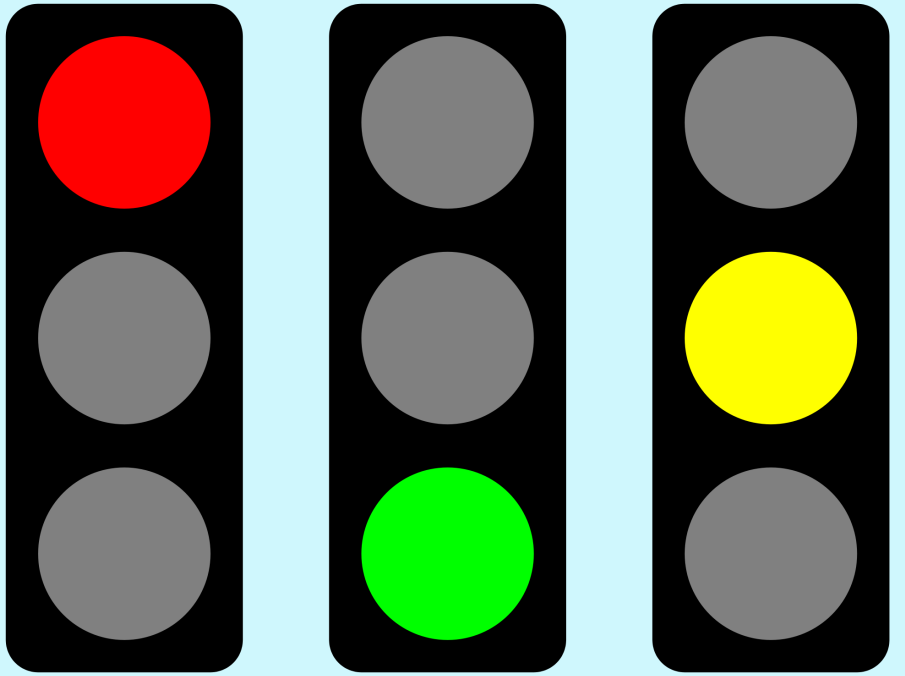
In HACCP, Records should provide proof of existence of both control measures and audits.

Aims: to give evidence of CCPs management and control, as well as to explain corrective actions and traceability.

In incoming materials control, traffic light labels are often used to provide proof of existence of inspections.

CODEX 4: TRAFFIC LIGHT LABELS

In both HACCP and Quality Systems, the traffic light method can be considered part of the suitable measurement traceability resources (ISO 9001:2015, par. 7.1.5.2.)



REJECTED OK WAIT

HACCP

CODEX PRINCIPLE No. 5

Corrective actions

CORRECTIVE ACTIONS

Corrective actions should be applied whenever a CCP is out of control (critical limit/tolerance) or when it tends to exceed the tolerance.

The choice of the corrective action depends on: hazard severity, regulatory constraints, processing step, available control systems, etc.

CORRECTIVE ACTIONS OR TREATMENT OF NON-CONFORMANCE?

CORRECTIVE ACTIONS can be considered as the TREATMENT OF CCP DEVIATIONS. For this reason, they are similar to the treatment of non-conformance in Quality Management Systems.

In HACCP, the term "deviation" is more appropriate than "non-conformance", because CCP management relies on tailor made control measures more than conformance to universal standards.

EXAMPLES OF CORRECTIVE ACTIONS

1. Stop production

2. Hold the product non in compliance

3. Isolate and hold product for safety evaluation

4. Correct the deviation on the line, and then continue with production

5. Reprocess

6. Destroy

7. Downgrade the product (e.g. decrease sell-by date, cook)

8. Analyse product, and then continue with production

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EXERCISE: CASE STUDIES FOR CORRECTIVE ACTIONS

HACCP

CODEX PRINCIPLE No. 6

Verification

VERIFICATION

VERIFICATION: control measures for the periodical evaluation of the HACCP system, based on auditing, documentation, and experiments that do not necessarily generate real-time results (e.g. microbiological analyses)

EXAMPLES OF VERIFICATION ACTIVITIES

1. Internal audits
2. Document review
3. External audits (suppliers, customers)
4. Analytical controls (also microbiological)
5. Statistical analysis
6. Feed-back on the results of corrective actions
7. Feed-back on complaints and recalls
8. Experimental trials (e.g. thermal evaluations on the equipment)
9. Mathematical modelling
10. Feed-back on the effects of staff changes

HACCP AUDITS

AUDIT (from the Latin *audire* = to listen)

"systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled"

THE EVIDENCE GATHERING METHOD

An audit is a systematic objective evidence gathering process.

Audits must be independent.

The auditor chooses the right questions and listen to the answers. By comparing the different versions, evidence must be evaluated objectively to determine how well audit criteria are being met.

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EXERCISE: CASE STUDIES FOR VERIFICATION

HACCP

CODEX PRINCIPLE No. 7

Documentation

REMEMBER THE DIFFERENCE!

Document = "content file that has information in a structured or unstructured format". It is editable. It can be stored as paper or digitally. It can be changed and revised.

Record = "historical file that provides proof of existence of activities and results". It is not editable and cannot be recreated. It can be stored as paper or digitally.

In the current version of the quality norm ISO 9001:2015, documents and records are described together as "documented information".

HACCP DOCUMENTATION

HACCP PROTOCOL

It includes the fundamental and regulatory data of the HACCP System:

GOOD HYGIENE PRACTICE PROCEDURES

HACCP PLAN FOR ALL CCPs

HACCP DOCUMENTATION

HACCP PLAN

It is a part of the HACCP protocol. It describes the activities carried out for all the Codex Principles at any CCP.

HACCP DOCUMENTATION

HACCP MANUAL

It is NOT compulsory. Its structure is similar to a Quality Manual and includes several documents on the HACCP System:

HACCP PROTOCOL

ADDITIONAL PROCEDURES

OTHER DOCUMENTS: e.g. ingredients charts, packaging, maps, information on equipment, etc.

TRACEABILITY

“ability to trace the history, application or location of an object” (ISO 9000:2015).

The traceability system can be developed on any information technology (paper, magnetic media, ecc.).

TRACEABILITY

When considering a product or a service, traceability can relate to:

- the origin of materials and parts;

- the processing history;

- the distribution and location of the product or service after delivery.

GHP
(Good Hygiene Practice)

- General rules, not intended for single processes
- They are not aimed to specific hazards
- They are not targeted at specific equipments
- They provide general information for prevention
- Records are not necessary

SOPs
(Standard Operating Procedures)

Procedures and activities that can be considered transversal in all manufacturing processes, as they create favourable conditions for food safety

In particular, they provide tools to manage specific hazards, when no CCP can be detected

SOPs
(Standard Operating Procedures)

Each manufacturer can develop and apply specific SOPs for its own company, e.g.:

- Cleaning
- Pest control
- Water supply
- Wastes
- Equipments
- Controls on workers
- Suppliers

SSOPs (Sanitation Standard Operating Procedures)

Procedures that should be applied daily to prevent contamination or spoilage or food products. Particular focus on food safety contact surfaces.

Compulsory in the companies with specific authorizations for export (e.g. USA and Japan).

SOPs EXAMPLES

Available in different websites, e.g.:

http://templatelab.com/sop-templates/

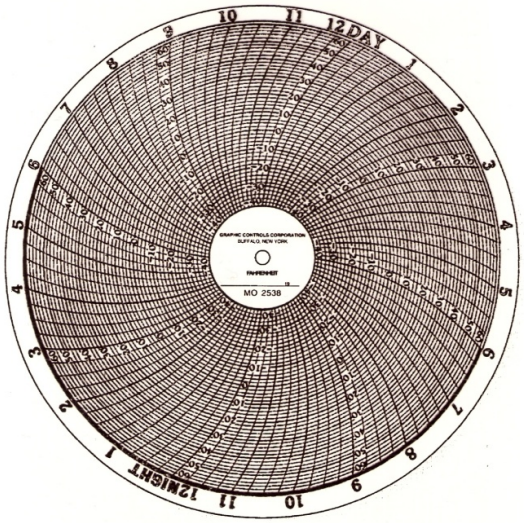
https://ncfreshproducesafety.ces.ncsu.edu/wp-content/uploads/2014/03/how-to-write-an-SOP.pdf?fwd=no

http://sop.nfsmi.org/HACCPBasedSOPs.php

EXAMPLES OF THERMOMETRIC RECORD

PAPER DISC

FIGURE 13 *EXAMPLE OF A DAILY RECORDER THERMOMETER CHART.*



Reviewed by: _____ Date: _____

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DATA LOGGER

TRACER DATA REPORT

RUN ID: LOMBPRO2 S/N: MTS18919
PROGRAMMED: 24 MAY 95 11:08:33
START TIME: 24 MAY 95 15:00:00
SAMPLE INT: 00:30:00
REPORT START POINT = 1
REPORT END POINT = 235
REPORT DATA INTERVAL = 1

26 MAY 95	06:00:00	10.7	DEG C
26 MAY 95	06:30:00	11.3	DEG C
26 MAY 95	07:00:00	11.5	DEG C
26 MAY 95	07:30:00	11.8	DEG C
26 MAY 95	08:00:00	12.2	DEG C
26 MAY 95	08:30:00	12.8	DEG C
26 MAY 95	09:00:00	11.3	DEG C
26 MAY 95	09:30:00	7.8	DEG C
26 MAY 95	10:00:00	5.0	DEG C
26 MAY 95	10:30:00	4.2	DEG C
26 MAY 95	11:00:00	3.7	DEG C
26 MAY 95	11:30:00	2.6	DEG C
26 MAY 95	12:00:00	1.7	DEG C
26 MAY 95	12:30:00	2.1	DEG C
26 MAY 95	13:00:00	2.6	DEG C
26 MAY 95	13:30:00	3.7	DEG C
26 MAY 95	14:00:00	3.7	DEG C
26 MAY 95	14:30:00	4.4	DEG C
26 MAY 95	15:00:00	4.8	DEG C
26 MAY 95	15:30:00	5.3	DEG C
26 MAY 95	16:00:00	5.9	DEG C
26 MAY 95	16:30:00	5.1	DEG C
26 MAY 95	17:00:00	3.9	DEG C
26 MAY 95	17:30:00	4.5	DEG C
26 MAY 95	18:00:00	5.0	DEG C
26 MAY 95	18:30:00	4.4	DEG C
26 MAY 95	19:00:00	3.7	DEG C
26 MAY 95	19:30:00	2.9	DEG C
26 MAY 95	20:00:00	1.9	DEG C
26 MAY 95	20:30:00	0.7	DEG C

—— END OF DATA ——

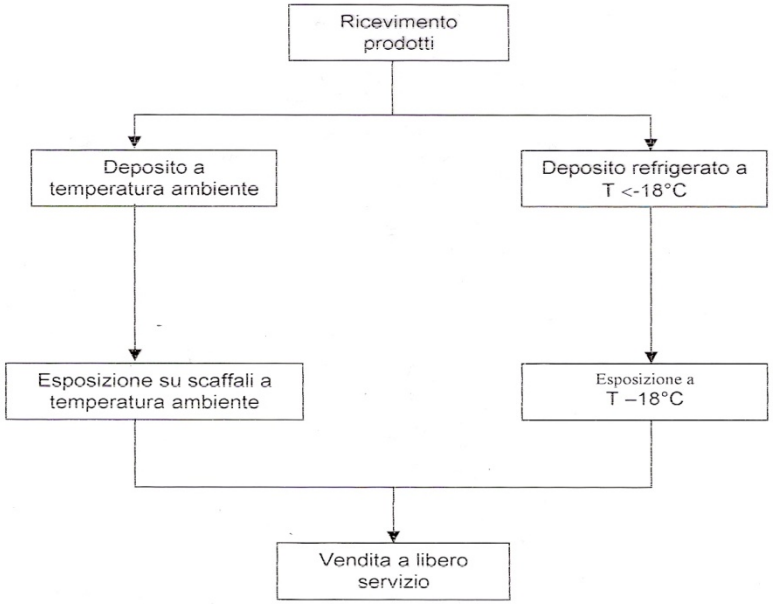
TELETHERMOMETER: any of various thermometers that indicate or record temperatures at a distance, as by means of an electric current

DATA LOGGER: individual records (old on paper disc/paper ribbon, now mainly on magnetic media)

EXAMPLE OF HACCP FLOW CHART: WRONG

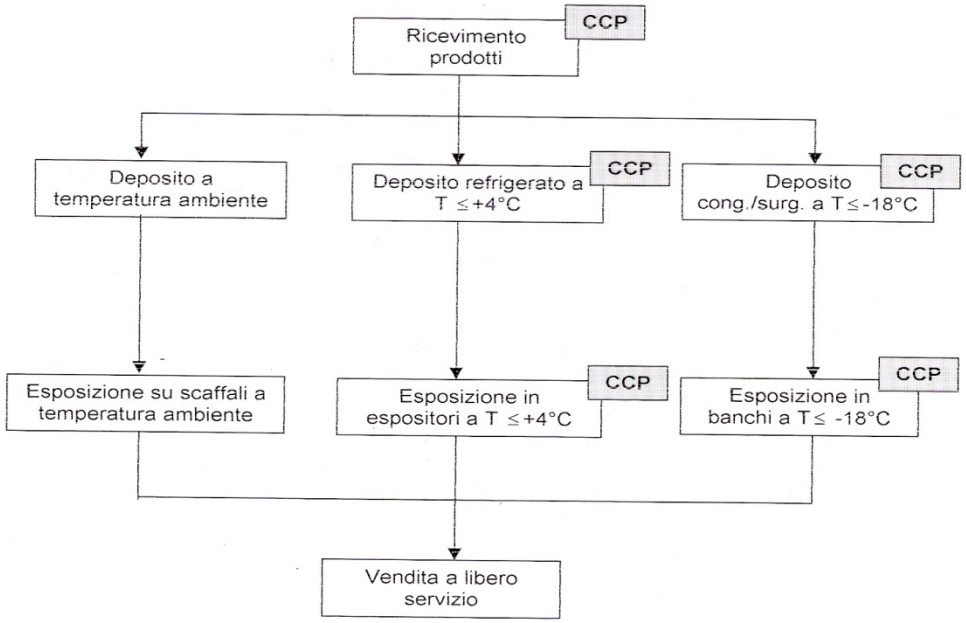
"La Banda Bassetti" Topolinia	REPARTO DI LIBERO SERVIZIO	Cap. 9.D Pag. 4 di 7

9.D.4 DIAGRAMMA DI FLUSSO



EXAMPLE OF HACCP FLOW CHART: RIGHT

8.1.3.4 DIAGRAMMA DI FLUSSO



HACCP plan form for pasteurized crabmeat

Glorious Crab, Inc.
123 Harvest Way, Seaside, MD 12345

Product Description: Pasteurized Crabmeat (ready-to-eat, cans and pouches)
Method of Storage and Distribution: Refrigerated storage and distribution
Intended Use and Consumer: Retail and foodservice, general public

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	Monitoring				(8) Corrective action	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Sealing / Seaming / Pouch handling	Recontamination of pathogens from loss of package integrity	Can seams: overlap, thickness and tightness = manufacturer's specifications: visually acceptable Pouches: no failures; visually acceptable	Can seams, Pouch seals and integrity	Cans: 1) seam teardown evaluation 2) visual inspection Pouches: 1) head seal destruction test 2) compression test 3) visual inspection	Cans: 1) one at start-up and when an adjustment is made to seaming machine, 2) one from every batch Pouches: 1 & 2) one each at start-up and when vacuum sealer is adjusted, 3) all pouches	Packing room Supervisor, Seamer Technician	Readjust sealing / seaming machine, repack product since previous seal / seam check or hold product and test seals / seams and repack lots containing affected pouches / cans. If already pasteurized, repack and re-pasteurize.	Weekly records review .	Blue Crab Can Seam Evaluation Record Pouch Integrity and Thickness Record
Pasteurization (heating step)	Survival of pathogens which could be favored by anaerobic conditions and extended storage	Cans*: Heat for a minimum of 121 minutes at 187°F or hotter. Pouches*: Heat for a minimum of 50 minutes at ≥187°F, thickness ≤1inch. (This shcedule achieves a minimum process lethality of F^{16}_{185} =31 minutes.) *Example only – use critical limits from process schedule established for your system.*	1) Hot waterbath temperature 2) Time at temperature specified in process schedule 3) Cans only -- Initial product temperature	Time/temperature chart recorder Indicating thermometer (glass or digital)	Continuously each batch Visual check once each batch	Pasteurizer operator	1) Fully reprocess or both of the following: 2) Extend process or elevate temperature to compensate for C.L. deviation; and 3) Segregate and hold product for evaluation by process authority	1) Process establishment documentation 2) Weekly records review 3) Check accuracy of chart recorder against reference thermometer for each batch 4) Calibrate reference thermometer twice yearly	Pasteurization Record Recorder Chart Pouch Integrity and Thickness Record
Pasteurization	Water containing	Measurable residual	presence of	Colorimetric test kit	Every 2 hours	Quality	Add chlorine to	Weekly records	Pasteurization

DA: S. Franke, 2016

HACCP AUDIT

The same procedures used in Quality Management Audits, focused on Prerequisites and Codex Principles

ISTISAN guidelines (Italian Istitute of Health)

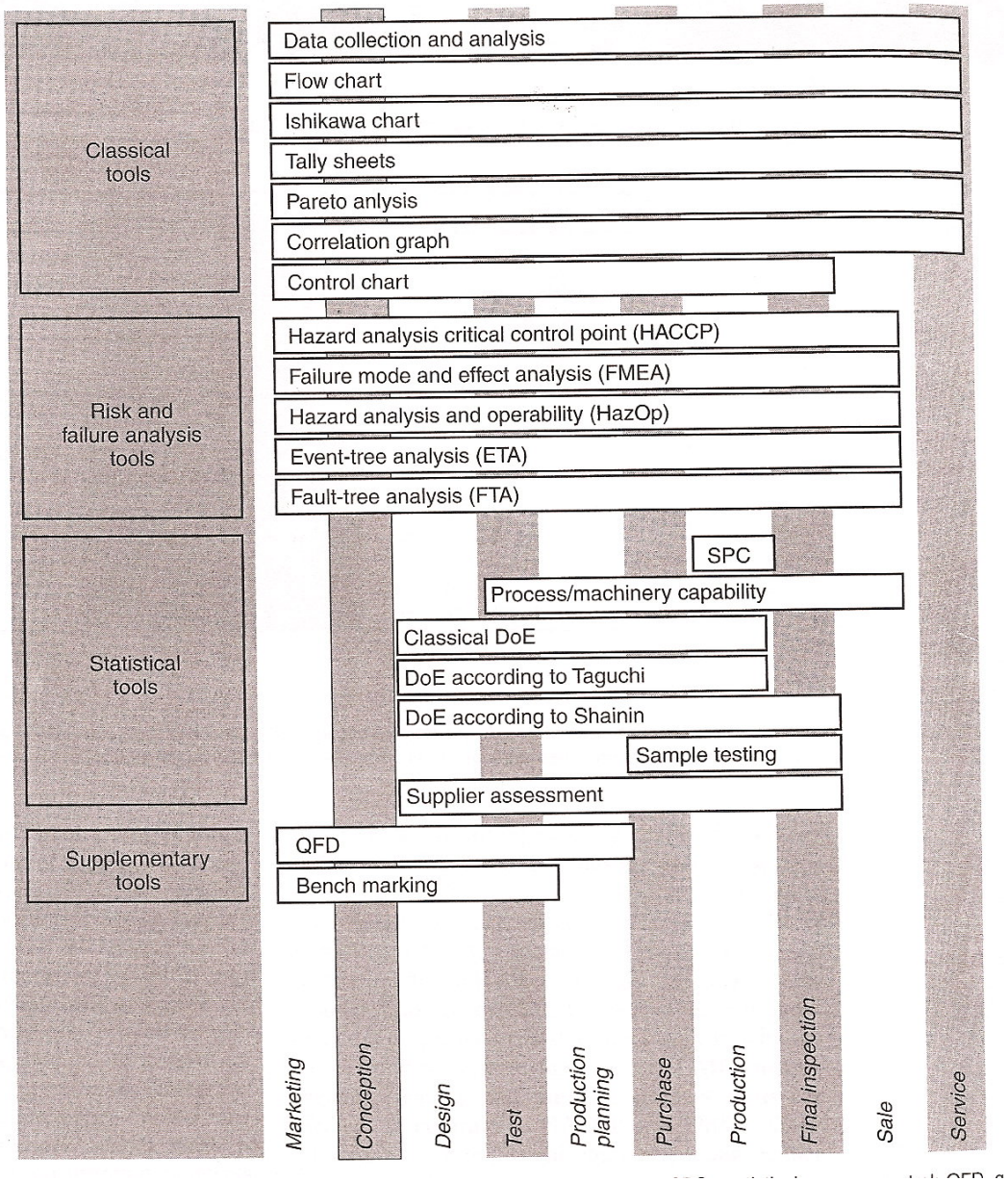
(Rapporto ISTISAN 99/10)

METHODS FOR THE HACCP AUDIT

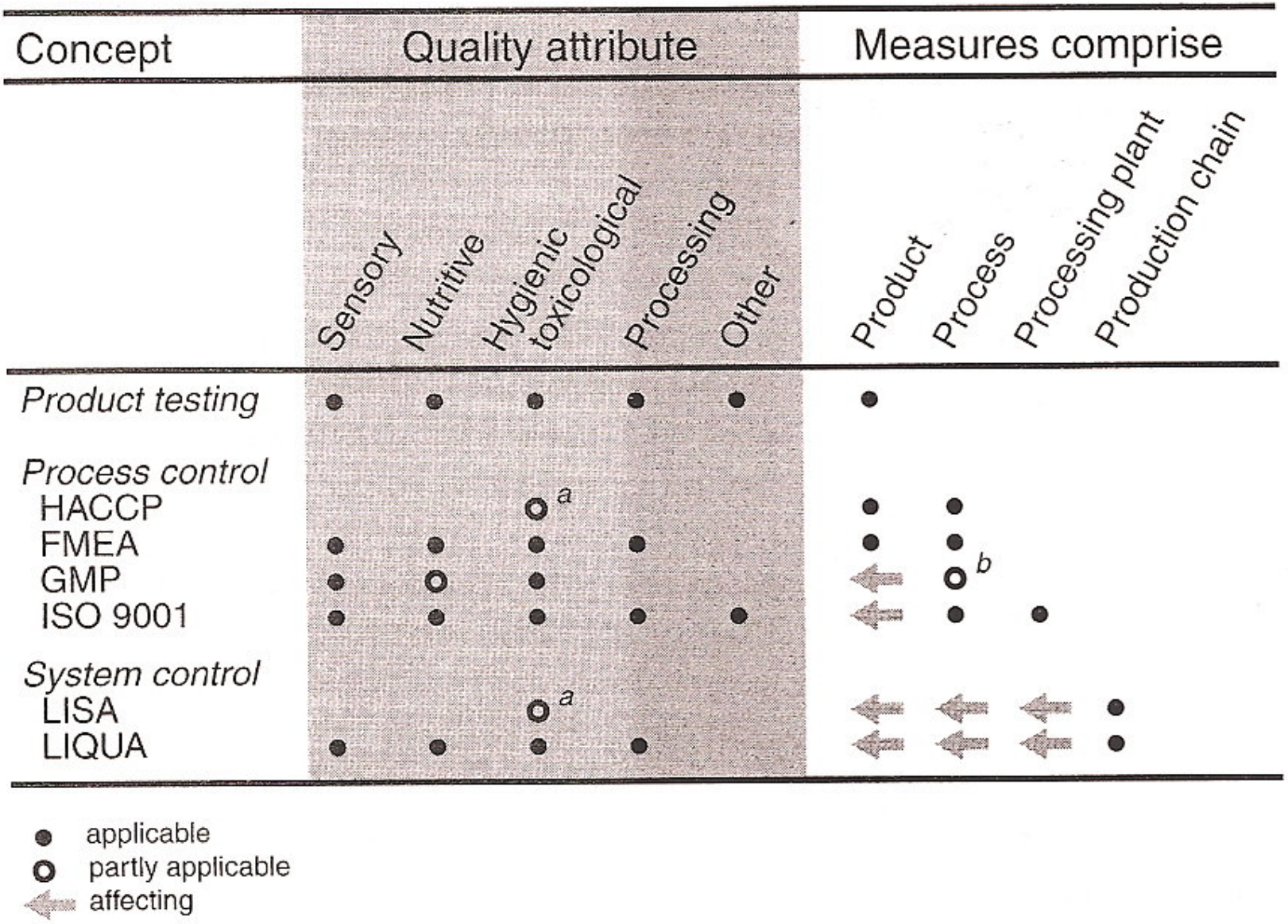
STEPS:

- Check-lists preparation
- HACCP audit: documents
- Data analysis according to PRPs and Codex Principles
- Deviations and observations according to PRPs and Codex Principles
- Reporting

COMPARISON BETWEEN HACCP AND OTHER QUALITY MANAGEMENT SYSTEMS



SPC: Statistical Process Control; QFD: Quality Function Deployment; DoE: Design of Experiments)



a: health aspects only; b: general rules, not specific for single processes

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EXERCISE: JUDGEMENT ON HACCP DEVIATIONS

Please identify which Codex Principle (or PRPs) is primarily involved in a HACCP deviation. Your goal is to identify the first deviated principle in the HACCP chain.

Example

In a cheese manufacturing line, the metal detector can detect metals in food samples but the diverter is not working correctly, thus nonconforming products are packaged.

ANSWER: PRPs or CODEX PRINCIPLE No.

5 (Corrective Actions)

The company is not carrying out fundamental checks (e.g. heat penetration curves, pH measurement, etc) that are necessary to apply corrective actions.

ANSWER: PRPs or CODEX PRINCIPLE No.

During the audit in the clean room, the guide illustrates the new procedure for air filtration test. However, this procedure is not mentioned in the HACCP Manual.

ANSWER: PRPs or CODEX PRINCIPLE No.

No alarm is available for the telethermometer.

ANSWER: PRPs or CODEX PRINCIPLE No.

The company is not able to provide any scientific justification for the different process setpoints used in the heat treatment of various formulations.

ANSWER: PRPs or CODEX PRINCIPLE No.

Verification only includes the same checks applied for Monitoring.

ANSWER: PRPs or CODEX PRINCIPLE No.

In a fish filleting line, there is no inspection table for parasites, and parasites are not mentioned in the HACCP Protocol.

ANSWER: PRPs or CODEX PRINCIPLE No.

In a company producing acidified vegetables in oil, no pHmeter is available in the production line. However, a pHmeter is present in the finished products storage area, where it is used for random controls.

ANSWER: PRPs or CODEX PRINCIPLE No.

No pest control activity is carried out in the raw ingredients area. The guide explained that they "never had that problem". However, the HACCP Manual does not explain why insects should be absent in that area and does not mention insects as a hazard.

ANSWER: PRPs or CODEX PRINCIPLE No.