

7 PREREQUISITES TO HACCP (Hans Henrik Huss/John Ryder)

Hygiene standards and procedures usually described as Good Hygienic Practices (GHP) or Good Manufacturing Practices (GMP), have been in place for many years and constituted an essential tool in traditional food control. These concepts are still essential in a modern food control system by providing the basic environmental and operating conditions for production of safe food and thus being a requisite or foundation for HACCP in an overall food safety management programme (Figure 7.1). What is new is the concept of formalising the prerequisite programme alongside HACCP and the legal requirement in some countries (USA) of documented monitoring of certain sanitation areas.

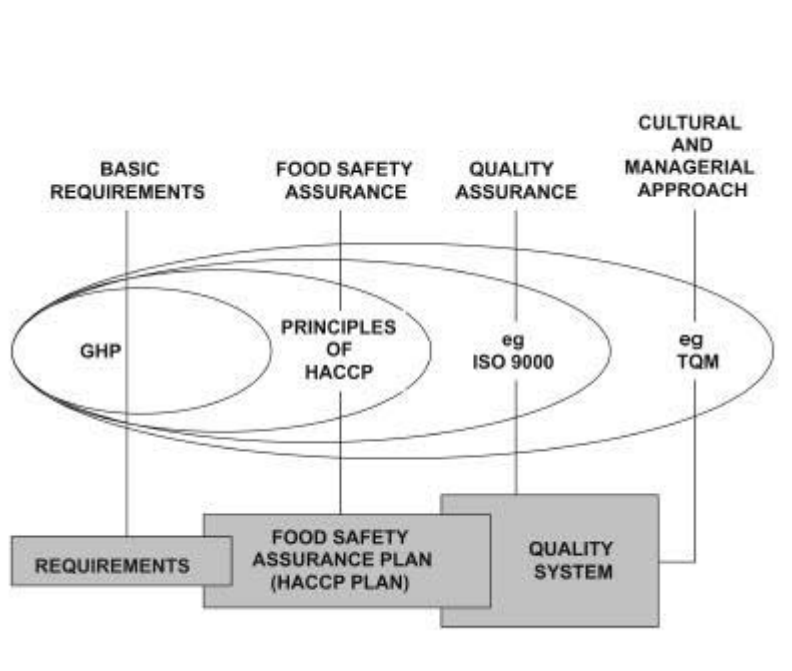


Figure 7.1 Food Safety and quality, an integrated approach (from Jouve, 1998).

In the Code of Federal Regulation (FDA, 2001) it is outlined what is covered by current GMP regulations. These include basically all procedures and practices necessary to produce safe foods.

Good Manufacturing Practices (GMP)

Those procedures for a particular manufacturing operation which practitioners of, and experts in, that operation consider to be the best available using current knowledge

There is no clear definition of the term Good Hygienic Practices (GHP). However, “food hygiene” has been defined by Codex (CAC, 2001) as “all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain” and GHP can therefore be regarded as:

Good Hygienic Practices (GHP)

all practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain

The terms GMP and GHP therefore basically cover the same ground and for the purpose of this book, the term GHP will mainly be used.

Various definitions of GHP or prerequisite programmes have been proposed by national and international organizations as shown:

Prerequisite programme = Good Hygienic Practices (GHP)

Prior to the application of HACCP to any sector of the food chain that sector should be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practices, and appropriate food safety legislation (CAC, 2001)	Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety (WHO, 1999)	Procedures, including GMP that address operational conditions providing the foundation for the HACCP system (NACMCF, 1998)
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According to the Draft Revision of the Recommended International Code of Practice for Fish and Fishery Products (CAC, 2000), the following aspects should be included in the prerequisite programme:

- requirements for fishing vessels – design and construction
- requirements for processing facility – design and construction
- design and construction of equipment and utensils
- hygiene control programme
- personal hygiene and health
- traceability and recall procedures
- training.

An example of the common prerequisite programme is given in an appendix to the publication by NACMCF (1998). Additional to the points listed by Codex it includes: Supplier control, specifications for all ingredients, chemical control and conditions for receiving, storage and shipping of raw materials and products. In the present publication some of these additional points, i.e. supplier control and specifications of ingredients, will be included in the HACCP plan and not in the prerequisite programme.

According to the US-FDA's seafood HACCP regulation (FDA, 1995), processors are required to have key sanitary conditions written into Sanitation Standard Operating Procedures (SSOPs). As outlined, SSOP are equivalent to GHP.

SSOP – Sanitation Standard Operating Procedures

the documented GMP for hygiene and sanitation required to meet the regulatory requirements for food control in the USA

They are also required to monitor these conditions and practices, correct unsanitary conditions and practices in a timely manner and maintain sanitation control records. Thus the sanitation control procedures are an integrated part of the seafood HACCP regulations, but not of the HACCP-programme. The SSOP should address at least the following conditions and practices:

- safety of water and ice
- condition and cleanliness of food contact surfaces
- prevention of cross contamination from unsanitary objects to food
- maintenance of facilities for personal hygiene
- protection of food and food contact surfaces from adulteration
- proper labelling, storage and use of toxic compounds
- control of employee health conditions
- exclusion of pests.

The written SSOP plan should explain the sanitation concerns, controls, in-plant procedures and monitoring requirements. This will demonstrate commitment to buyers and inspectors and also

ensure that everyone from management to production workers understands the basics of sanitation.

In the European Union (EU), the prerequisite requirements are included in both 'horizontal' legislation such as the Hygiene Directive (EC, 1993) and 'vertical' or commodity-specific legislation such as the Directive specifying the requirement for fish processing (EC, 1991).

Many activities can be considered part of a prerequisite programme depending on the product and the actual processing conditions. For this reason, it is unlikely that two processing facilities have identical prerequisite programmes.

Although definitions of prerequisites and/or SSOPs refer mostly to operational conditions, there are also basic requirements to the processing plant and the processing environment. Thus the SSOPs are specifying the quality of the water, maintenance of hygiene facilities etc., but it is equally important that the plant has access to enough water and hygiene facilities (quantitative aspects). Below is a list of key points and activities that need to be addressed in any prerequisite programme:

The Processing Plant:

- conditions of premises
- facilities: water, ice, steam (quantitative conditions)
water treatment system (chlorination plant, waste water treatment)
sanitary facilities and installations
- equipment: boxes, containers, and machinery.

Operational conditions and procedures (GHP):

- safety of water and ice (qualitative conditions)
- cleanliness of food contact surfaces
- prevention of cross contamination from insanitary objects to food
- maintenance of facilities for personal hygiene
- protection of food from adulterants
- safe storage and use of toxic compounds
- control of employee health conditions
- pest control
- waste management
- transportation
- traceability and recall procedure
- training.

A proper and well designed prerequisite programme allows the HACCP team to focus and concentrate on the hazards directly applicable to the product and the processing procedures without undue considerations and repetition of protection from hazards from the surrounding environment. It is important to point out that the prerequisite programme certainly relates to safety and therefore is an essential part of the total quality assurance programme. Thus part of the prerequisite programme (e.g. sanitation controls) must lend itself to all aspects of a Critical Control Point (CCP) such as establishing critical limits, monitoring, corrective actions, record keeping and verification procedures. However, occasional deviation from a prerequisite programme requirement would not by itself be expected to create a food safety hazard of concern. Therefore deviations from compliance in a prerequisite programme usually do not result in reaction against the product. This is in contrast to a CCP, where any deviation from the established critical limits always leads to reaction against the product.

The prerequisite programme is a good starting point for companies who have a long way to go to implement a HACCP system. Practical experience has shown that if the general issues related to

the prerequisite programme are dealt with first, the HACCP study will be much more straightforward and the resulting HACCP plan easier to manage. All issues related to GMP, hygiene and the environment will be dealt with in the prerequisite programme and only truly 'critical' control points, essential to safety of the product will be included in the HACCP plan.

7.1 The processing plant

7.1.1 Plant location, physical environment and infrastructure

Early considerations in building a new plant are the identification of a suitable location. A number of factors should be considered such as physical and geographical factors and infrastructure available.

Some of the physical needs for a plant location is a plot of adequate size (for present needs and future developments), with easy access by road, rail or water. An adequate supply of potable water and energy must be available throughout the year at a reasonable cost. Special considerations must be given to waste disposal. The plant should have proper sanitary sewers. Seafood processing plants usually contain significant amounts of organic matter which must be removed before waste water is discharged into rivers or the sea. Also solid waste handling needs careful planning, and suitable space – away from the plant – must be allocated or be available.

Assessment of pollution risk from adjacent areas must also be considered. Contaminants such as smoke, dust, ash, foul odours (e.g. neighbouring fish meal plant using poor raw material) are obvious, but even bacteria may have to be considered as airborne contaminants (e.g. proximity of a poultry rearing plant upwind may be a source of *Salmonella* spp).

The immediate physical surroundings of a seafood factory should be landscaped and present attractive appearance to the visitor (or potential buyer of products). However, this should be done in a way that rodents and birds are not attracted. Shrubbery should be at least 10 m away from buildings and a grass free strip covered with a layer of gravel or concrete should follow the outer wall of buildings. This allows for thorough inspection of walls and control of rodents. Ground immediately in front of doors and entrances should be paved to minimize dust. All areas around the plant and facilities should be well drained to prevent any standing water, where flies and microorganisms could breed and develop.

Figure 7.2

Surroundings of seafood processing plants should be clean and well kept (courtesy of Royal Greenland).



7.1.2 Buildings, construction and layout

A food processing plant shall provide (quoted from Troller, 1993):

- adequate space for equipment, installations and storage of materials
- separation of operations to avoid cross contamination
- adequate lightning and ventilation
- protection against pests.

External walls, roofs, doors and windows should be water-, insect- and rodent-proof. Internal walls, on the other hand, should be smooth, flat, resistant to wear and corrosion, impervious, easily cleanable and white or light coloured. Also the floors should ideally be impervious to spillage of product, water and disinfectants, durable to impact, resistant to disinfectants and chemicals used, slip resistant, non-toxic, non-tainting and of good appearance and easy repairable. Floors should be provided with a slope to drains to prevent formation of puddles. All openings (doors, windows, skylights, ventilators) must be adequately screened or otherwise constructed and fitted so as to prevent the entrance of any pests (flies or rodents).

Lighting should be adequate to carry out plant operations and protected so that broken glass will not be a potential hazard.

Proper ventilation is basic to good food plant sanitation. This will control condensation and help to eliminate any mould growth. Intake air should be filtered and positive air pressure maintained in the finished product area. The technical requirements, choice of materials, costs, etc. to obtain these goals may be found in a number of publications such as Shapton and Shapton (1991), Imholte (1984), Troller (1993).

The general layout and arrangement of rooms within a processing establishment is important in order to minimise the risk of contamination of the final product. A large number of bacteria (pathogens and spoilage bacteria) enter with the raw material. To avoid cross contamination it is therefore essential that raw material is received in a separate area and stored in a separate chill room. From here the sequence of processing operations should be as direct as possible – and a “straight line” process flow is regarded as most efficient (Hayes, 1992). This layout minimises the risk of recontamination of a semi-processed product.

Clear physical (e.g. a wall) segregation between “clean” and “unclean” areas is of prime importance. “Unclean” areas are those where raw material is handled and often a cleaning operation (wash) or for example a heat treatment (cooking of shrimp) is marking the point, where the process flow goes from “unclean” to “clean” areas. Thus a “clean” area is defined:

Clean area

An area where any contaminant added to the product will carry over to the final product (ICMSF, 1988)

i.e. there is no subsequent processing step that will reduce or destroy contaminating microbes.

Also cooled rooms must be separated from hot rooms where cooking, smoking, retorting etc. are taking place. Dry rooms must be separated from wet rooms and separate rooms must be provided for waste material, chemicals (cleaning and disinfection compounds, insecticides, all toxic materials), packaging materials and wood (for smoking).

The separation between the clean and unclean areas must be complete. There should be no human traffic between these areas, and equipment and utensils used in the unclean areas should never be used in the clean area. This means that there should also be separate wash and hygiene facilities for equipment and personnel in these areas. For easy identification the personnel should wear different coloured protective clothing for different operations (e.g. white in the clean and blue in the unclean).

Equally important in layout and design of food factories is to ensure that there are no interruptions and no “dead ends” in the product flow, where semiprocessed material can accumulate and remain for a long time at ambient temperature. Time/temperature conditions for products during processing are extremely important critical control points (CCPs) in order to prevent bacterial growth. This means that a steady and uninterrupted flow of **all** products is necessary in order to have full control of this critical factor. If any delays in product flow are necessary, the products should be kept chilled.

In addition, to facilitate product flow the factory layout and practices should ensure that:

- all functions should proceed with no criss-crossing and backtracking
- visitors should move from clean to unclean areas
- ingredients should move from “dirty” to “clean” areas as they become incorporated into food products
- conditioned (e.g. chilled) air and drainage should flow from “clean” to “dirty” areas
- the flow of discarded outer packing material should not cross the flow of products
- there is sufficient space for plant operations including processing, cleaning and maintenance. Space is also required for movement of materials and pedestrians
- operations are separated as necessary. There are clear advantages in minimizing the number of interior walls since this simplifies the movement of materials and employees, makes supervision easier, and reduces the area of wall that needs cleaning and maintenance (the list is partly after Shapton and Shapton, 1991).

Some of the principal requirements to an ideal establishment are outlined in Figure 7.3.

7.1.3 Facilities

Essential facilities in a seafood processing plant are:

- adequate supply of energy
- adequate supply of potable cold water. Hot water and steam must be available for cleaning and sanitation when necessary
- a suitable water treatment system where appropriate (chlorination plant, waste water treatment)
- adequate facilities for washing and disinfecting equipment
- adequate staff amenities (washing facilities, toilets, staff rooms).

Necessary hand-washing facilities must be located at the entrance to the processing areas and in all processing areas where GHP require employees to wash and disinfect their hands. They must be equipped with hand-cleaning and effective disinfection preparations and single use towels or other suitable hand-drying devices. Adequate and readily accessible toilet facilities must be available, properly located (no direct access to processing areas) and maintained in a hygienic condition and good repair.

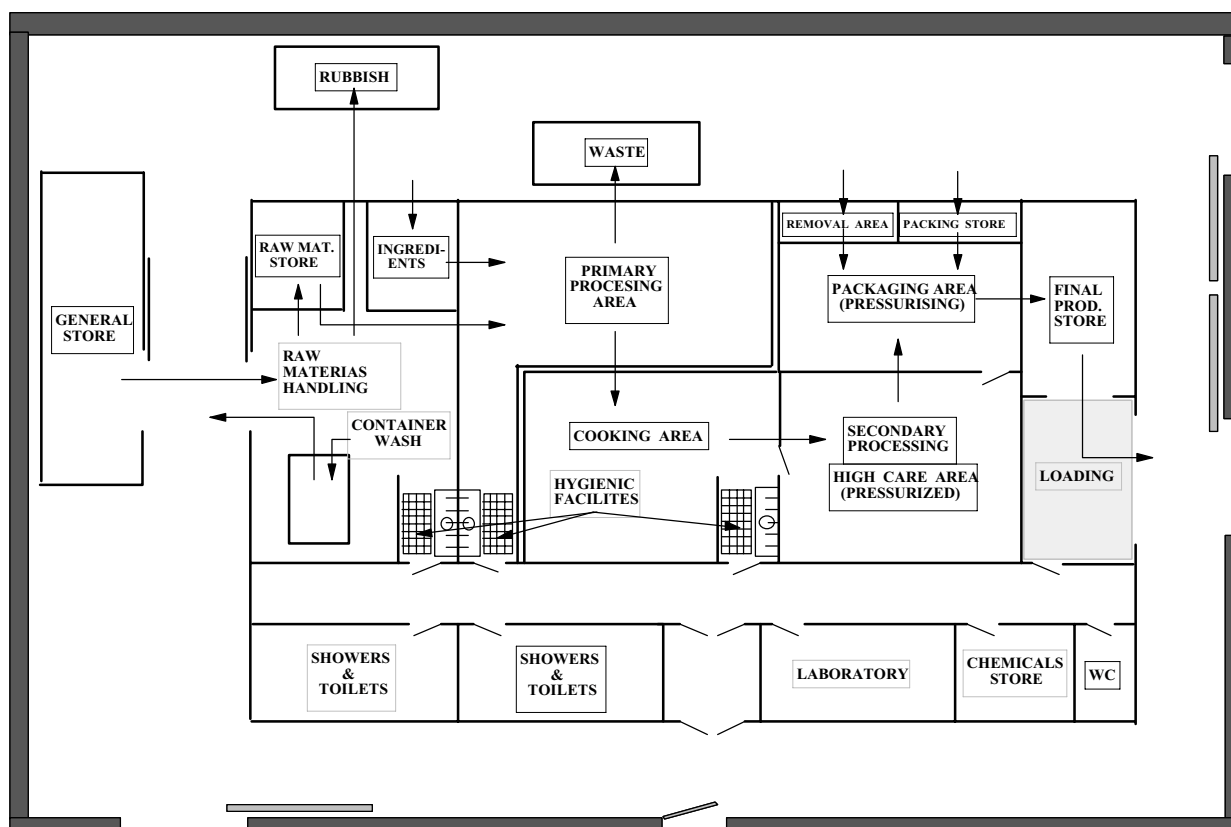


Figure 7.3. Example of a simplified factory layout (drawing by V. Popescu).

7.1.4 Utensils and equipment

A great variety of utensils and equipment is used in the fish industry. There is an abundance of advice and regulations available concerning the requirements for equipment. All of them agree that the food equipment should be non-contaminating and easy to clean. In particular, all food contact surfaces (utensils, knives, tables, cutting boards, boxes and containers, conveyer belts, gloves, aprons etc.) must be designed and of such material as to be easily cleanable. Such surfaces shall be constructed of non-toxic, non-absorbent material that is resistant to the environment, the food, cleaning and disinfecting agents. Food contact materials that should be avoided are: wood, ferrous metals, brass and galvanised metals. However, the degree of stringency in hygienic requirements must be related to the product being processed. Raw fish, for example, do not require the same standard of hygiene as cooked and peeled shrimp. Criteria for hygienic design are particularly important for equipment used in the later stages of processing and particularly after a bacteria-eliminating processing step. There are seven basic principles for hygienic design agreed upon by a working party appointed by the Food Manufacturers Federation (FMF) and Food Machinery Association FMA (FMF/FMA, 1967) as quoted by Hayes (1992):

- All surfaces in contact with food must be inert to the food under the conditions of use and must not migrate to or be absorbed by the food
- all surfaces in contact with food must be smooth and non-porous so that tiny particles of food, bacteria, or insect eggs are not caught in microscopic surface crevices and become difficult to dislodge thus becoming a potential source of contamination
- all surfaces in contact with the food must be visible for inspection or the equipment must be readily disassembled for inspection, or it must be demonstrated that routine cleaning procedures eliminate possibility of contamination from bacteria or insects
- all surfaces in contact with food must be readily accessible for manual cleaning, or if not readily accessible, then readily disassembled for manual cleaning, or if clean-in-place

techniques are used, it must be demonstrated that the results achieved without disassembly are the equivalent of those obtained with disassembly and manual cleaning

- all interior surfaces in contact with food must be so arranged that the equipment is self emptying or self draining
- equipment must be so designed as to protect the contents from external contamination
- the exterior or non-product contact surfaces should be arranged to prevent harbouring of soils, bacteria or pests in and on the equipment itself as well as in its contact with other equipment, floors, walls or hanging supports.

In the design and construction of equipment it is important to avoid dead areas where food can be trapped and bacterial growth takes place. Also dead ends (e.g. thermometer pockets, unused pipe work, T-pieces) must be avoided, and any piece of equipment must be designed so that the product flow is always following the “first in first out” principle

Cleanability of equipment involves a number of factors such as construction materials, accessibility and design. The most common design faults which cause poor cleanability are (Shapton and Shapton, 1991):

- poor accessibility - equipment should be sited at least 1 m from a wall, ceiling or the nearest equipment
- inadequately rounded corners - minimum radius should be 1 cm, but 2 cm is regarded as optimum by the American 3-A Sanitary Standards Committee (Hayes, 1992)
- sharp angles
- dead ends - including poorly designed seals.

One general problem of food processing involves the extremes of temperature, abundant use of water, development of condensations and contamination of food from overhead pipes and surfaces. Equipment design must consider this and include proper protection.

Equipment design is one of the major problems in modern food hygiene. A great number of new machines and equipment are designed and constructed without proper attention to the fact that these tools have to be cleaned and sanitised. The EC (1992) addresses machinery safety and hygiene regulations. Some of the highlights are:

- machinery containing materials intended to come in contact with food must be designed and constructed so that these materials can be cleaned before each use
- all surfaces and their joinings must be smooth, with no ridges or crevices that could harbour organic materials
- assemblies must be designed to minimise projections, edges and recesses. They should be constructed by welding or continuous bonding, with screws, screwheads and rivets used only where technically unavoidable
- contact surfaces must be readily cleaned and disinfected, and built with easily dismantled parts. Inside surfaces must be curved in a way to allow thorough cleaning
- liquid derived from foods, as well as cleaning, disinfecting and rinsing fluids should be readily discharged from machinery
- machinery must be designed and constructed to prevent liquids or living creatures – primarily insects – from entering and accumulating in areas that cannot be cleaned
- machinery must be designed and constructed so that ancillary substances, such as lubricants, do not come in contact with food.

The directive also sets out a certification system where machinery is checked for compliance and tagged with an EC mark if found to be satisfactory. Certification is not retrospective and manufacturers have two years to bring new machinery into compliance.

Apart from literature already cited, additional useful material and information on hygienic design are found in Milledge (1981) and Gould (1994).

A great variability exists in the size, of and extent of handling in, fish processing establishments. Accordingly, the hygienic requirements in, and the design of, fish handling areas may vary considerably. Quite obviously the requirements that a small establishment which is only repacking fish in ice and catering for a local market, must meet are different from the hygienic requirements of a large establishment that is processing a variety of sophisticated products including heat treated and composite products and exporting to countries all over the world. Also the requirements commonly listed in legislation and codes of practice are not equally important. The more important factors include: facilities for water supply, waste disposal and cooling and cold storage facilities and –capacity. Of less importance are buildings, ventilation, factory location, clothes changing facilities, lightning and roadways (ICMSF, 1988).

The forms shown in Appendix 1 have been utilized in assessing fish factories using the HACCP principles. Only the most important factors are evaluated and given a rating from A to C, where A and B are expressions of degrees of excellence and niceties, while a rating of C is given to a condition which is unacceptable and needs immediate correction before further operations can take place. Thus it is an attempt to “distinguish between the nice and the necessary” which is the same approach as applied in the HACCP principles.

7.2 Operational conditions including GHP

A range of operational conditions must be in place prior to the implementation of HACCP in order to control the risks or safety concerns related to the environment and the personnel. The existence and the performance of such a programme must be well documented with written procedures, assigned responsibilities, measurable acceptance criteria, defined record keeping activities and procedures to be followed when acceptance criteria are not met. A written standard format as shown below using 5 of the 7 HACCP principles is useful as a guideline or checklist and to ensure that all essential points have been considered.

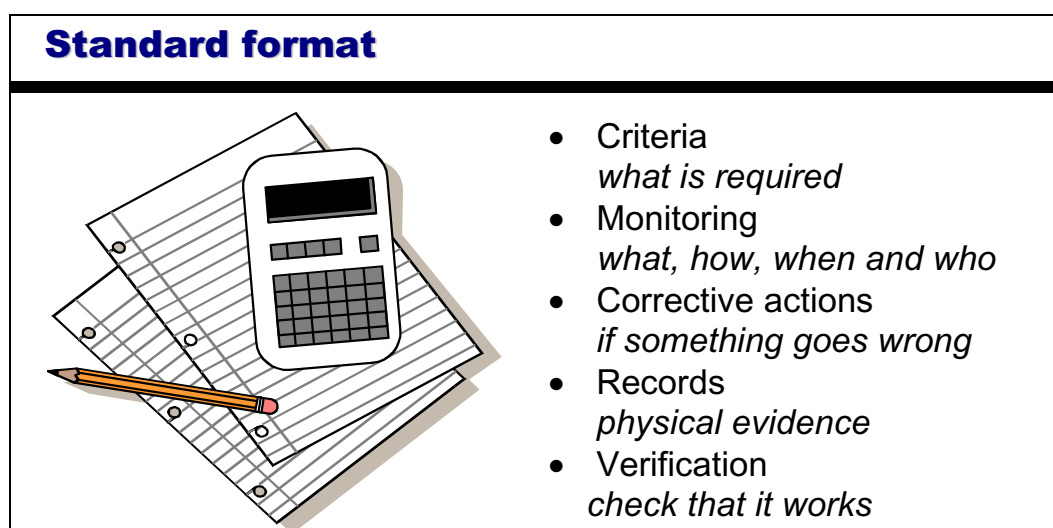


Figure 7.4 Standard format in assessing the prerequisite programme.

7.2.1 Safety of water and ice

Criteria for potable water

Water is used in food processing both as an ingredient and for cleaning and sanitation. Thus the quality of the water is of great importance. WHO (1993) and EC (1998) have published extensive guidelines on drinking water quality where standards for more than 60 parameters have been elaborated. The microbiological criteria suggested are shown in Tables 7.1 and 7.2.

Very often water needs to go through some form of treatment and disinfection before being suitable for use in food processing.

Water treatment

Water treatments vary from region to region depending on the water sources available. While groundwater from sedimentary aquifers has undergone extensive filtration the water from hard rock aquifers or surface water sources should be filtered as part of the water treatment in order to decrease the content of particulates, microorganisms, organic and inorganic matter.

Table 7.1 Bacteriological quality of drinking water (WHO, 1996)¹.

Organisms	Guideline value
<i>All water intended for drinking</i>	
<i>E. coli</i> or thermotolerant coliform bacteria ^{2,3}	Not detectable in any 100-ml sample
<i>Treated water entering the distribution system</i>	
<i>E. coli</i> or thermotolerant coliform bacteria ²	Not detectable in any 100-ml sample
Total coliform bacteria	Not detectable in any 100-ml sample
<i>Treated water in the distribution system</i>	
<i>E. coli</i> or thermotolerant coliform bacteria ²	Not detectable in any 100-ml sample
Total coliform bacteria	Not detectable in any 100-ml sample. In the case of large supplies, where sufficient samples are examined: Not detectable in 95% of samples taken during any 12-months period

1. Immediate investigative action must be taken if either *E. coli* or total coliform bacteria are detected. The minimum action in the case of total coliform bacteria is repeat sampling; if these bacteria are detected in the repeat sample, the cause must be determined by immediate further investigation.
2. Although *E. coli* is the more precise indicator of faecal pollution, the count of thermotolerant coliform bacteria is an acceptable alternative. If necessary, proper confirmatory tests must be carried out. Total coliform bacteria are not acceptable indicators of the sanitary quality of rural water supplies, particularly in tropical areas where many bacteria of no sanitary significance occur in almost all untreated supplies.
3. It is recognized that, in the great majority of rural water supplies in developing countries, faecal contamination is widespread. Under these conditions, the national surveillance agency should set medium-term targets for the progressive improvement of water supplies, as recommended in Volume 3 of Guidelines for drinking-water quality.

Table 7.2 Microbiological criteria for drinking water (EC, 1998).

Parameter	Parametric value	Method of examination
<i>E. coli</i>	0/100 ml	ISO, 9308-1
Enterococci	0/100 ml	ISO, 7899-2
Indicator		
Colony count, 22°C	[No abnormal change] ¹	Pr EN ISO 6222
Coliform bacteria	0/100 ml	ISO, 9308-1

1. Former directive 80/778/EC (EC 1980) used 100 cfu/ml as guidelines.

Parasites are removed to a large extent by filtration. The levels of bacteria and virus also decrease markedly and the removal mechanisms are both filtration and adsorption. The cation concentration influences adsorption, i.e. increasing concentrations give rise to increased adsorption. Ca²⁺ and Mg²⁺ seem to be especially efficient. These small cations will decrease the repulsive forces between the soil particles and the microorganisms. Iron oxides also have a high affinity for viruses as well as bacteria. Ferric hydroxide impregnated lignite has even been suggested as a local filtration/adsorption media (Prasad and Chaudhuri, 1989).

The disinfection efficiency is greatly affected by

- type of disinfectant,
- type and state of microorganism,
- water quality parameters such as turbidity (or suspended solids),
- organic matter,
- some inorganic compounds,
- pH
- temperature.

The “hardness” of the water may indirectly influence disinfection since deposits may harbour microorganisms and protect them from cleaning agents and disinfectants.

By far the most widespread disinfectant is chlorine but also chloramines, chlorine dioxide, ozone and UV are being used in some instances. **Chlorine** is cheap and available in most places and monitoring the free residual levels is simple. For disinfection WHO (1996) is recommending 5 mg chlorine/litre and for effective disinfection there should be a residual concentration of free chlorine of ≥ 0.5 mg/l after at least 30 minutes contact time at pH < 8.0 . For disinfection of clean equipment up to 200 mg/l is used. To avoid corrosion a lower concentration of 50-100 mg/l and longer contact times (10-20 minutes) are often used. Current guidelines are shown in Table 7.3.

Table 7.3 Concentrations of chlorine used in fish processing.

Type of water	Residual levels	Recommendation by
Drinking water	0.5 mg/l	WHO 1996
Water for clean-up	100 mg/l	Reilly 2000
Water in contact with fish	10 mg/l	Reilly 2000
Seawater for cooking of shrimp	20 mg/l	Watson and Prout 1996

Chloramines are more stable but less microbiocidal and much less efficient in killing parasites and virus than chlorine. **Chlorine dioxide** is, if anything, more microbiocidal than chlorine, especially at high pH, but there is concern with regards to the by-products. In the case of **ozone** and **UV** there is no residual matter to monitor. Ozone seems to be very efficient in killing protozoa. The efficiency of UV disinfection decreases markedly if there is any turbidity or dispersed organic matter and problems are often encountered due to a lack of lamp maintenance. The resistance of the various microbiological organisms varies a lot. In the case of most disinfectants the order of sensitivity in decreasing order is:

vegetative bacteria > viruses > bacterial spores, acid-fast bacteria and protozoan cysts.

The sensitivity varies within groups and even within species. Indicator bacteria are unfortunately among the more sensitive microorganisms and the presence of, for example, faecal coliforms in treated, disinfected water is therefore a very clear indication that the water contains potentially pathogenic microorganisms while the absence of such indicator bacteria does not guarantee pathogen-free water.

Bacteria from nutrient-poor media as well as otherwise stressed bacteria may also exhibit greatly increased resistance. Some of the effects mentioned on the efficiency of free chlorine are illustrated in Table 7.4.

Table 7.4 Inactivation of microorganisms by free chlorine.

Organism	Water	Cl ₂ residues mg/l	Temp. °C	pH	Time, min.	Reduction %	C•t ¹
<i>E. coli</i>	BDF ²	0.2	25	7.0	15	99.997	ND ³
<i>E. coli</i>	CDF ⁴	1.5	4	?	60	99.9	2.5
<i>E. coli</i> + GAC ⁵	CDF	1.5	4	?	60	<<10	>>60
<i>L. pneumophila</i> (water grown)	Tap	0.25	20	7.7	58	99	15
<i>L. pneumophila</i> (media grown)	Tap	0.25	20	7.7	4	99	1.1
<u>Acid-fast</u>							
<i>Mycobacterium chelonae</i>	BDF	0.3	25	7.0	60	40	>>60
<u>Virus</u>							
Hepatitis A	BDF	0.5	5	10.0	49.6	99.99	12.3
Hepatitis A	BDF	0.5	5	6.0	6.5	99.99	1.8
<u>Parasites</u>							
<i>G. lamblia</i>	BDF	0.2-0.3	5	6.0	-	99	54-87
<i>G. lamblia</i>	BDF	0.2-0.3	5	7.0	-	99	83-133
<i>G. lamblia</i>	BDF	0.2-0.3	5	8.0	-	99	119-192

1. C•t product of disinfectant concentration (C) in mg/l and contact time (t) in minutes for 99% inactivation (modified after Sobsey (1989))

2. BDF = buffered demand free

3. ND = no data

4. CDF = chlorine demand free

5. GAC = granular activated carbon

If microbes are associated with **granular material or other surfaces** the effect of a disinfectant such as chlorine decreases drastically. Attachment of *Klebsiella pneumonia* to glass surfaces may, for example, increase the resistance to free chlorine by 150-fold (Sobsey, 1989).

Organic matter may react and “consume” disinfectants such as chlorine and ozone and the presence will also interfere with UV light. The chloramines are less susceptible to organic matter.

pH is important in disinfection with chlorine and chlorine dioxide. There is greater inactivation of microorganisms at low pH in the case of chlorine and greater inactivation at high pH in the case of chlorine dioxide (Sobsey, 1989). In general, higher **temperatures** result in increased inactivation rates.

Use of non-potable water

The use of non-potable water may be necessary for water conservation purposes or desirable because of cost. Non-potable water may, for example, be surface water, sea water or chlorinated water from can cooling. Relatively clean water such as chlorinated water from can cooling operations may be used for washing cans after closing and before heat treatment, for transporting raw materials before processing (after the water has cooled off), for initial washing of boxes, for cooling of compressors, for use in fire protection lines in non-food areas and for fluming of waste material.

Separation of potable and non-potable water

It is absolutely necessary that potable and non-potable water should be in separate distribution systems which should be clearly identifiable

If potable water is used to supplement a non-potable supply the potable source must be protected against valve leakage, or back-pressure, for example, by adequate air-gaps. Back-flow, due to sudden pressure differentials or blockage of pipes, has unfortunately occurred in many systems.

Potentially contaminated water such as coastal water or surface water, should not be used at the production premises but may, if aesthetically acceptable, be used for removing waste material in places where no contact to food is possible.

Monitoring water quality

The responsible person should have continuously updated reference drawings of the pipe system and the authority to remove dead-ends. Especially in cases where a plant has undergone many changes, the piperuns, may become more and more complicated over the years. The person should also be in contact with the local waterworks and the authorities in order to be informed of special events (repairs, pollution accidents or other changes).

Water may be contaminated due to bad location of source (close to septic tanks, agriculture drainage systems), cracked or improperly sealed off piping systems or even floods and heavy rains. In the plant, contamination of the water may be due to cross-connections or backflow (back pressure or back siphonage). Where necessary, backflow should be controlled by air-gaps, vacuum breakers or check valves.

A quality monitoring scheme could consist of a plan of all the sampling points and a checklist describing what to examine and why, the frequency, who takes the sample, who does the analysis, what is the limit (value, tolerance) and what to do in case of deviation (Poretti 1990). If the water is obviously polluted there is of course no reason to wait for analytical results. The sampling frequency and the range of parameters will vary with the circumstances and a special monitoring program may be needed after repairs, or when using new water supplies, for example. A minimum monitoring program for water quality could be:

- measurement of free chlorine daily
- measurement of total viable count and coliforms on a weekly basis.

The technical procedures describing the analyses for the common indicator organisms are given in standard textbooks. The EC Directive (EC, 1998) specifies some methods and equipment to be used. The values used by the company should refer to the specific method employed and the recommendations should include how to sample (tap flow, volume, sampling vessel, labelling, etc.) and how to handle and examine the sample. Even though the commonly used methods for detecting, for example, faecal coliforms are standard analyses, faulty handling of the samples often occurs. Samples should be processed within 24 hours or less, be kept cool but not frozen (preferably below 5°C), and be kept in the dark. The impact of sunlight can be very dramatic, causing false negative results (Knøchel, 1990).

Model prerequisite programme: Safety of water and ice

Goal:	Water that comes into contact with food or food contact surfaces or is used in the manufacturing of ice is from a safe and sanitary source or is treated to make it safe
Criteria:	Water must pass potability standards (e.g. to <i>E. coli</i> , Enterococci, Coliform 0/100 mL Aerobic Plate Count (22°C) 10 ² cfu/ml (guide level) residual free chlorine 0.2-0.5 mg/l in water distribution system max 10 mg chlorine/l in water, that comes in contact with fish products
Monitoring:	When public water supply is used, the official records from the water works suffice. Water from own water supply: Check for residual chlorine: daily Check for microbiological contamination: A water sampling schedule must be worked out. Sampling must follow standard microbiological procedures. Responsible person is: chief, Q.A.
Corrective action:	Actions to be taken when criteria is exceeded must be outlined, e.g. adjusting water treatment, stop of production if water is contaminated, search for source of contamination
Records:	Records of all sampling, testing and actions must be kept for two years. Daily hygiene record form (chlorine)
Verification:	Once every year, water samples are tested by certified laboratory

If chlorination is used for disinfection monitoring of the free chlorine level is the simplest way of checking the water treatment and should be performed most often (e.g. on a daily basis). Simple laboratory methods and commercial dip-sticks are now available for on-the-spot measurements (e.g. Merchoquant Chlor 100 from Merck). The microbiological indicator parameters may be checked less frequently. If disinfection systems that leave no residuals are being used, then checking of equipment should be done regularly. The performance of the systems may be monitored at weekly intervals using indicator bacteria measurements. Above is a model of a control programme for this particular requirement.

7.2.2 Cleanliness of food contact surfaces

All food contact surfaces should be adequately and routinely cleaned and disinfected. Cleaning and disinfection belong to the most important operations in today's food industries. In the US, the term sanitation is sometimes used to describe the disinfection process. In some cases, sanitation may refer to the whole cleaning and disinfection process.

Food contact surfaces are

- Those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations
- Typical food contact surfaces include utensils, knives, tables, cutting boards, fish boxes, conveyor belts, ice makers, ice storage bins, gloves, aprons, etc.

The cleaning and disinfection process can be divided into clearly distinct operations. However, these are linked firmly together in that the final result will not be acceptable unless all processes are carried out correctly.

Sanitation

means adequately treating food contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer (FDA, 2001)

The various steps included in a complete cycle are outlined below.

- remove food products, clear the area of bins, containers, etc.
- dismantle equipment to expose surfaces to be cleaned
- remove small equipment, parts and fittings to be cleaned into a specified area. Cover sensitive installations to protect them against water etc.
- clear the area, machines and equipment of food residues by flushing with water (cold or hot) and by using brushes, brooms, etc.
- apply the cleaning agent and use mechanical energy (e.g. pressure or brushes) as required
- rinse thoroughly with water to completely remove the cleaning agent after the appropriate contact time (residues may completely inhibit the effect of disinfection)
- control of cleaning
- disinfect with chemical disinfectants or heat
- rinse the disinfection chemicals off with water after the appropriate contact time. This final rinse is not needed for some compounds e.g. H₂O₂ based formulations that decompose rapidly
- after the final rinse, reassemble equipment and allow to dry
- control of cleaning and disinfection
- in some cases it would be good practice to re-disinfect (e.g. with hot water or low levels of chlorine) just before production starts.

Cleaning

In the preparatory phase, the processing area is cleared of remaining products, spills, containers and other loose items. Machines, conveyors, etc. are dismantled so that all locations where microorganisms can accumulate become accessible for cleaning and disinfection. Electrical installations and other sensitive systems should be protected against water and the chemicals used.

AVOID starting the cleaning operation by splashing water (using the pressure hose) on floors and machinery before all food products are removed.

Before use of the cleaning agent, a gross food debris removal procedure should be carried out by brushing, scraping or similar action. All surfaces should be further prepared for the use of cleaning agents by a pre-rinse activity, preferably with cold water so as not to coagulate the proteins. Hot water may be used to remove fat or sugars in cases where protein is not present in significant amounts.

Completion of the preparatory work should be checked and recorded, as with any other process to ensure the quality of the complete cycle of cleaning and disinfection.

Cleaning is undertaken to remove all undesirable materials (food residues, microorganisms, scales, grease, etc.) from the surfaces of the plant and the process equipment, leaving surfaces clean, as determined by sight and touch and with no residues from cleaning agents.

Microorganisms present will either be incorporated in the various materials or attached to the surfaces as biofilms. The latter will not be removed completely by cleaning, but experience has shown that a majority of the microorganisms will be removed. However, there will still be some left to be inactivated during the disinfection. Bacteria in biofilm can be up to 1,000 times more resistant to common disinfectants compared to when in the free state.

The effectiveness of a cleaning procedure in general depends upon:

- the type and amounts of debris to be removed
- the chemical and physio-chemical properties of the cleaning agent (such as acid or alkali strength, surface activity, etc.) at the concentration, temperature and exposure time used
- the mechanical energy applied e.g. turbulence of cleaning solutions in pipes, stirring effect, impact of water jet “elbow-grease”, etc.
- the condition of the surface to be cleaned.

Some surfaces, e.g. corroded steel and aluminium galvanised metal can not be cleaned easily which means that disinfection also becomes very inefficient. The same applies to other surfaces, e.g. wood, rubber, etc. The preferred material is high quality stainless steel.

The types of residues to be removed in food plants, will mainly be the following:

- organic matter, such as protein, fat and carbohydrate. These are most effectively removed by strong alkaline detergents (especially caustic soda, NaOH)
- inorganic matter, such as salts of calcium and other metals. In beer stone, milk stone, etc. salts are encrusted with protein residues. These are most effectively removed by an acid cleaning agent
- biofilms, formed by bacteria, moulds, yeast and algae can be removed by cleaning agents that are effective against organic matter.

Most cleaning agents work faster and more effectively at higher temperatures, so it can be profitable to clean at a high temperature. Cleaning is often carried out at 60-80°C in areas where it pays, energy-wise, to use such high temperatures.

Water is used as a solvent for all cleaning and sterilising agents and also for intermediate rinses and the final rinse of equipment. The chemical and microbiological quality of the water is important for the efficiency of the cleaning procedures as already described in a previous section of this Chapter. In principle, water used for cleaning must be potable.

Hard water contains a large amount of calcium and magnesium ions. When the water is heated, any calcium and magnesium salts will precipitate as insoluble salts. Also, some cleaning agents, especially alkalis, can precipitate calcium and magnesium salts.

Apart from reducing the effectiveness of detergents hard water leads to the formation of deposits or scales. Scales are not only unsightly but objectionable for several reasons:

- they harbour and protect microorganisms
- they reduce the rate of heat exchange on heat exchange surfaces. This could lead to under-processing, under-pasteurisation or under-sterilisation
- presence of scales tends to increase corrosion.

The formation of scales can be reduced by addition of chelating and sequestering agents, which bind calcium and magnesium in insoluble complexes. However, it is advisable to prevent precipitations by softening the water before it is used for cleaning. Softening can be effectively achieved by ion exchange, in which the calcium and magnesium ions are replaced by sodium ions,

the salts of which are soluble. A modern, and more costly, method of softening water is by means of reverse osmosis.

To be effective, a suitable **detergent** or **cleaning agent** must be applied. The ideal detergent would be characterized by the following properties:

- it possesses sufficient chemical power to dissolve the material to be removed
- it has a surface tension low enough to penetrate into cracks and crevices; it should be able to disperse the loosened debris and hold it in suspension
- if used with hard water, it should possess water softening and calcium salt dissolving properties to prevent precipitation and build-up of scale on surfaces
- it rinses freely from the plant, leaving this clean and free from residues, which could harm the products and affect sterilisation negatively
- it does not cause corrosion or other deterioration of the plant. It is recommended always to check by consulting the supplier of machines, etc.
- it is not hazardous for the operator
- it is compatible with the cleaning procedure being used, whether manual or mechanical
- if solid, it should be easily soluble in water and its concentration easily checked
- it complies with legal requirements concerning safety and health as well as biodegradability
- it is reasonably economical to use.

A detergent with all these characteristics does not exist. So one must, for each individual cleaning operation, select a compromise by choosing a usable cleaning agent and water treatment additives so that the combined detergent has the properties that are most important for the procedure concerned.

All cleaning methods, including foams and soaks, require sufficient contact time to fully loosen and suspend soils. A moderately alkaline detergent, which is normally used in plants processing high protein foods such as fish, will typically require 10-15 minutes to fully loosen most processing soils.

Disinfection

Traditionally, the terms “disinfection” and “disinfectants” are used to describe procedures and agents used in food industries to ensure a microbiologically acceptable standard of hygiene. It is realised that the procedures and agents described will rarely introduce “sterility” i.e. total absence of viable microorganisms.

Disinfection can be effected by physical treatments such as heat, U.V. irradiation, or by means of chemical compounds.

Use of heat in the form of steam or hot water is a very safe method and a widely used method of disinfection. The most commonly used chemicals for disinfection are shown in Table 7.5.

With the use of chemical disinfectants, the death rate for microorganisms depends, among other things, upon the agent's microbiocidal properties, concentration, temperature and pH as well as the degree of contact between disinfectant and microorganisms. Good contact is obtained by stirring, turbulence, smooth surfaces and low surface tension. As with heat disinfection, different microorganisms show different resistance to chemical sterilants. Contamination by inorganic or organic matter can reduce the death rate considerably.

Cleaning precedes disinfection
An effective disinfection can only be
obtained after an effective cleaning

The desirable plant disinfectant would be characterized by the following properties:

- it has sufficient anti-microbial effect to kill the microorganisms present in the available time and should have a sufficiently low surface tension to ensure good penetration into pores and cracks
- it rinses freely from the plant, leaving this clean and free from residues which could harm the products
- it does not lead to development of resistant strains or any surviving microorganisms
- it does not cause corrosion or other deterioration of the plant. It is recommended that the suppliers of machines etc. be asked before chlorine or other aggressive disinfectant are used
- it is not hazardous to the operator
- it is compatible with the disinfection procedure being used, whether manual or mechanical
- if solid, it should be easily soluble in water
- its concentration is easily checked
- it is stable for extended storage periods
- it complies with legal requirements concerning safety and health as well as biodegradability
- it is reasonably economical in use.

It will often be necessary to combine disinfectants with additives in order to obtain the required properties. The following are among the most widely used disinfectants and shall be described briefly.

Chlorine is one of the most effective and widely used disinfectants. It is available in several forms, for instance sodium hypochlorite solutions, chloramines and other chlorine containing organic compounds. Gaseous chlorine and chlorine dioxide are also used. Chlorinated disinfectants at a concentration of 200 ppm free chlorine are very active and have a cleaning effect. The disinfectant effect is considerably decreased when organic residues are present. The compounds dissolved in water will produce hypochlorous acid, HOCl, which is the active disinfecting agent, acting by oxidation. In solution it is very unstable, particularly in acid solution where toxic chlorine gas will be liberated. Furthermore, solutions are more corrosive at low pH.

Unfortunately, the germicidal activity is considerably better in acid than in alkaline solution, thus the working pH should be chosen as a compromise between efficiency and stability. Organic chlorinated disinfectants are generally more stable but require longer contact times. When used in the proper range of values (200 ppm free chlorine), chlorinated disinfectants in solutions at ambient temperatures are non-corrosive to high quality stainless steel, but they are corrosive to other less resistant materials.

Table 7.5 Types of disinfectants (based on anon. 2000).

Disinfectant	Forms/ Description	Advantages	Disadvantages
Chlorine	Hypochlorites Chlorine gas Organic chlorine, e.g., chloramines	<ul style="list-style-type: none"> - Kills most types of microorganisms - Less affected by hard water than some - Does not form films - Effective at low temperatures - Relatively inexpensive - Concentration easily determined by test strips 	<ul style="list-style-type: none"> - May corrode metals and weaken rubber - Irritating to skin, eyes and throat - Unstable, dissipates quickly - Liquid chlorine loses strength in storage - pH sensitive
Iodophors	Iodine dissolved in surfactant and acid	<ul style="list-style-type: none"> - Kills most types of microorganisms - Less affected by organic matter than some - Less pH sensitive than chlorine - Concentration determined by test strips - Solution colour indicates active sanitiser 	<ul style="list-style-type: none"> - May stain plastics and porous materials - Inactivated above 50°C - Reduced effectiveness at alkaline pH - More expensive than hypochlorites - May be unsuitable for CIP¹ due to foaming
Quaternary Ammonium Compounds	Benzalkonium chloride and related compounds, sometimes called quats or QACs	<ul style="list-style-type: none"> - Non corrosive - Less affected by organic matter than some - Residual antimicrobial activity if not rinsed - Can be applied as foam for visual control - Effective against <i>Listeria monocytogenes</i> - Effective for odour control - Concentration determined by test strips 	<ul style="list-style-type: none"> - Inactivated by most detergents - May be ineffective against certain organisms - May be inactivated by hard water - Effectiveness varies with formulation - Not as effective at low temp. as some - May be unsuitable for CIP due to foaming
Acid-Anionic	Combination of certain surfactants and acids	<ul style="list-style-type: none"> - Sanitize and acid rinse in one step - Very stable - Less affected by organic matter than some - Can be applied at high temperature - Not affected by hard water 	<ul style="list-style-type: none"> - Effectiveness varies with microorganism - More expensive than some - pH sensitive (use below pH 3.0) - Corrode some metals - May be unsuitable for CIP due to foaming
Peroxy Compounds	Acetic acid and hydrogen peroxide combined to form peroxyacetic acid	<ul style="list-style-type: none"> - Best against bacteria in biofilms - Kills most types of microorganisms - Relatively stable in use - Effective at low temperatures - Meets most discharge requirements - Low foaming; suitable for CIP 	<ul style="list-style-type: none"> - More expensive than some - Inactivated by some metals/organics - May corrode some metals - Not as effective as some against yeasts and moulds

Disinfectant	Forms/ Description	Advantages	Disadvantages
Carboxylic Acid	Fatty acids combined with other acids; sometimes called fatty acid sanitizers	<ul style="list-style-type: none"> - Kills most types of bacteria - Sanitize and acid rinse in one step - Low foaming, suitable for CIP - Stable in presence of organic matter - Less affected by hard water than some 	<ul style="list-style-type: none"> - Inactivated by some detergents - pH sensitive (use below pH 3.5) - Less effective than chlorine at low temp. - May damage non-stainless steel materials - Less effective against yeasts and moulds than some
Chlorine Dioxide	A gas formed onsite and dissolved in solution or by acidification of chlorite and chlorate salts	<ul style="list-style-type: none"> - Kills most type of microorganisms - Stronger oxidiser (sanitizer) than chlorine - Less affected by organic matter than some - Less corrosive than chlorine - Less pH sensitive than some 	<ul style="list-style-type: none"> - Unstable and cannot be stored - Potentially explosive and toxic - Relatively high initial equipment cost
Ozone	A gas formed onsite and dissolved in solution	<ul style="list-style-type: none"> - Kills most type of microorganisms - Stronger oxidiser (sanitizer) than chlorine and chlorine dioxide 	<ul style="list-style-type: none"> - Unstable and cannot be stored - May corrode metals and weaken rubber - Potentially toxic - Inactivated by organic matter (similar to chlorine)
Hot Water / Heated Solutions	Water at 77-88°C	<ul style="list-style-type: none"> - Kills most types of microorganisms - Penetrates irregular surfaces - Suitable for CIP - Relatively inexpensive 	<ul style="list-style-type: none"> - May form films or scale on equipment - Burn hazard - Contact time sensitive

1. CIP = cleaning in place

Iodophors contain iodine, bound to a carrier, usually a non-ionic compound, from which the iodine is released for sterilisation. Normally the pH is brought down to 2-4 by means of phosphoric acid. Iodine has its maximum effect at this pH range.

Iodophors are active disinfectants with a broad antimicrobial spectrum like chlorine. They are inactivated by organic material. Concentrations corresponding to approximately 25 ppm free iodine will be effective.

Commercial formulations are often acidic making them able to dissolve scales. They can be corrosive depending on the formulation and they should not be used above 45°C as free iodine may be liberated. If residues of product and caustic cleaning agents are left in dead ends and similar places, this may, in combination with iodophores, cause very unpleasant "phenolic" off-flavours.

Hydrogen peroxide and **peracetic acid** are effective disinfectants acting by oxidation and with a broad antimicrobial spectrum. Diluted solutions may be used alone or in combination for disinfection of clean surfaces. They lose their activity more readily than other disinfectants in the presence of organic substances and they rapidly lose their activity with time. They should be used in concentration of 200-300 ppm.

Quaternary ammonium compounds are cationic surfactants. They are effective fungicides and bactericides but are often less effective against Gram negative bacteria. To avoid development of resistant strains of microorganisms, these compounds should only be used by alternating with the use of other types of disinfectants.

Due to their low surface tension, they have good penetrating properties and for the same reason, they can be difficult to rinse off. If quaternary ammonium compounds come into contact with anion-active detergents, they will precipitate and become inactivated. Mixing or successive use of these two types of chemicals must therefore be avoided. They can be used in concentrations of 200 ppm on food contact surfaces. Table 7.6 summarizes the concentrations of commonly used disinfectants.

Table 7.6 Disinfectant concentrations commonly used in food plants (anon., 2000).

Disinfectant	Concentrations of disinfectants commonly used in food plants		
	Food contact surface	Non-food contact surfaces	Plant water
Chlorine	100-200 ¹ ppm	400 ppm	3-10 ppm
Iodine	25 ¹ ppm	25 ppm	
Quats	200 ¹ ppm	400-800 ppm	
Chlorine dioxide	100-200 ^{1,2} ppm	100-200 ² ppm	1-3 ² ppm
Peroxyacetic acid	200-315 ¹ ppm	200-315 ppm	

1. The higher end of the listed range indicates the maximum concentration permitted without a required rinse (surfaces must drain)

2. Includes mix of oxychloro compounds

Monitoring of cleaning and disinfection

Effective cleaning is a prerequisite for an efficient disinfection. This indicates the importance of controlling cleaning. The most important control is sensory (visual, touch, smell) inspection to demonstrate:

- that all cleaned surfaces are visibly clean
- that all surfaces, by feeling, are free from food residues, scales and other materials and, by smelling, free from undesirable odours

Further, the concentrations and pH-values of cleaning agents, the temperatures, if hot cleaning is used, and the contact times should be monitored and registered. pH measurements, or similar testing, of rinse water may be used to ensure that the cleaning agent is removed so that it will not interfere with the disinfectant. These controls are all rapid and allow immediate decisions to be made as to whether cleaning should be repeated, partly or completely, or to proceed to the process of disinfection. All actions shall be registered as part of the Quality System. At this stage, microbiological control serves no real purpose. Firstly biofilms and surviving microorganisms are likely to be present and secondly, reliable rapid methods are not available.

Control of disinfection will be the final control of the complete cycle of cleaning and disinfection. Provided cleaning has been controlled effectively as described above, control of disinfection will be effective when the following conditions are met:

- control of time and temperature conditions for disinfection by heat
- control of active concentrations of chemical disinfectant
- control that all surfaces to be disinfected are covered by the disinfectant
- control of contact time.

The above controls should be documented and the observations reported and registered as required in standard Quality Systems.

Microbiological testing and control serve the purpose of verification. Various techniques are available, but none are ideal and they are not "real time" methods. "Real time" methods are highly desirable for control of cleaning and disinfection. Methods (bacterial counting) that require overnight incubation are too late to correct critical situations. However, if conducted at regular

intervals and planned to cover all critical points, useful information from microbiological control can be accumulated with time. Various methods are used and shall be mentioned briefly.

- swab testing. This is the most usual technique and one of the better ones. By use of a sterile swab of cotton-wool, part of the disinfected surface is swabbed, and the bacteria now on the swab are transferred to a diluent for determination of colony forming units in standard agar substrates. Swabs are especially useful in places where other control methods can only be used with difficulty i.e. pockets, valves, etc.
- final rinse water. Membrane filtration of rinse water and incubation on agar substrate is a very sensitive technique for control of CIP systems as well as other cleaning and disinfection systems, where a rinse can be applied
- direct surface plates. In these methods petri dishes or contact slides with selective or general purpose agar media are applied to the surface to be examined, followed by incubation and counting of colony forming units. These techniques can only be applied to flat surfaces, which is a limiting factor
- bioluminometric assay of ATP. This is almost a “real time” method giving the answer within minutes. It is very sensitive and can be combined with swabbing for collection of microorganisms from surfaces. The method is rather non-specific, and it may not be able to distinguish between microorganisms and food residues. However, if applied under defined conditions it may prove useful and superior to the conventional methods because it provides the answer in minutes.

Regardless of the technique used, it is valuable to know from the verification analyses that the system was working when it was established. There is also a value in knowing trends as expressed in the verification results recorded. The objective of studying trends and conducting the microbiological control of cleaning and disinfection will be to take corrective action before loss of control of products or processes occur.

Model prerequisite programme: Cleanliness of food contact surfaces

Criteria:	<p>A permanent cleaning and disinfection schedule must be drawn up specifying the frequency of cleaning and disinfection at each location. Food contact surfaces are most important, but non-food contact surface must also be kept clean. In addition, good housekeeping of all areas including employee restrooms and locker rooms is necessary. The following procedure should be followed in cleaning and disinfection procedures:</p> <ul style="list-style-type: none">- pre-cleaning, preparation of area for cleaning.- pre-rinse or soak in tanks.- cleaning – with appropriate detergent (type of detergent, concentration, contact time must be specified).- rinse- disinfection – application of approved chemical (name disinfectant, concentration, contact time).- post rinse. <p>A full cleaning schedule must be applied at the end of a working day on all locations, but part of the schedule can be omitted in a “clean as you go” policy.</p>
Monitoring:	<p>What: Cleanliness of food contact surfaces, concentrations of cleaning and disinfection agents, cleaning operation, contact time for sanitation chemicals.</p> <p>How: Visual inspection, smelling for offensive odours, feeling for greasy surfaces. Check labels.</p> <p>When: Daily.</p> <p>Who: Foreman.</p>
Corrective action:	Repeat operation
Records:	All observations and actions. Daily sanitation control records.
Verification:	Microbiological testing of food contact surfaces, review of records and procedures.

7.2.3 Prevention of cross-contamination

A key element in any hygiene programme is the prevention of cross-contamination, i.e. contamination of final product with any hazards originating in the raw material or the processing environment. This is of particular concern if the final product is a ready-to-eat product that is not usually cooked before being eaten. There are many possible routes of contamination of the final product as shown in Figure 7.5. It is not always possible to identify the most important routes and all of them must be included in a preventive programme.

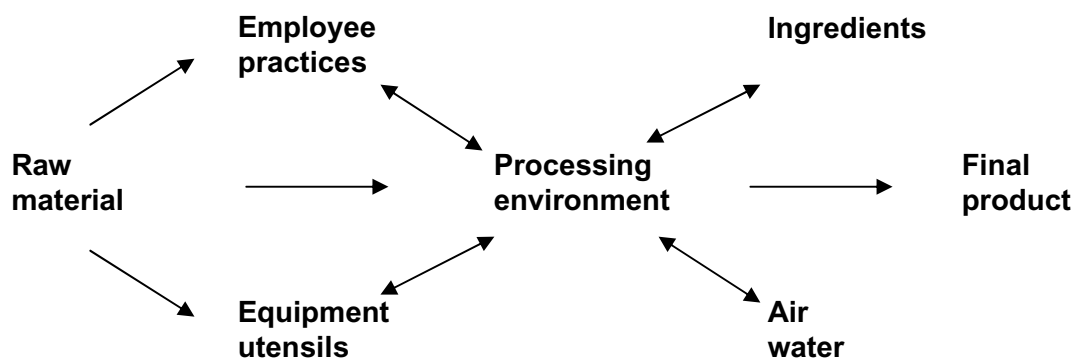


Figure 7.5 Routes of contamination in a seafood processing plant.

The main preventive measures to avoid cross-contamination are:

- a clear and effective separation of raw material and cooked or ready-to-eat products during processing, handling and storage (see section 7.1)
- proper employee hygiene, clothing and handling practices
- restricted and controlled traffic or movement about the plant (employees, product, equipment)
- food handling and processing areas and equipment adequately cleaned and disinfected (see section 7.2.2)
- use of potable water (see section 7.2.1).

Personnel can contaminate the final product directly with pathogens from their skin or hands, digestive system or respiratory tract. They can also function as an intermediary vector carrying bacteria, virus, etc. from raw material or the environment to the product. For this reason, employee hygiene and food handling practices are very important – particularly when ready-to-eat products are handled. Below some points on personal hygiene to consider in this part of the prerequisite programme:

- clean protective clothing, footwear, hair- and beardnets, caps or other effective hair restraints must be issued by the company and should be worn in the processing area only
- nail varnish, false nails and eyelashes, watches and jewellery should not be worn in processing area
- personal items (handbags, shopping bags, etc.) must not be taken into processing area
- eating food or sweets, chewing gum, drinking beverages or using tobacco should not occur in any processing area and spitting should be forbidden
- an effective hand washing program should be implemented, including:
 - how to wash hands:
 - wet hands with warm water
 - lather and rub using warm water
 - rinse
 - dry with disposable towels or
 - disinfect by dipping in sanitizing solution (iodine or 100 ppm chlorine).
 - when to wash hands:
 - before starting work – in the mornings and after breaks
 - after visiting the toilet
 - after coughing and sneezing
 - after handling soiled equipment

Model prerequisite programme: Prevention of cross-contamination

Criteria:	Cooked, ready-to-eat products must be physically separated from raw materials during processing and storage Waste must be removed by the most direct route or at least downstream out of the processing-area. Care must be taken to avoid any possible contact with food products No traffic of employees, products or utensils between clean and less clean areas is permitted Food handling and processing areas must be clean and orderly at start-up Description of dress-code Description of hand-washing requirements
Monitoring:	Adequate separation of raw and cooked or ready-to-eat products and processing activities Cleanliness of food handling areas Employee hygiene, handling practices and traffic in the plant The monitoring should be carried out continuously by all supervisors in their areas of responsibility
Corrective action:	Stop all activities until areas or utensils are cleaned and disinfected or faulty procedures are corrected Further training of personnel If contamination of cooked or ready-to-eat products is likely to have happened, these products must be identified and segregated until a decision is made on their safety
Records:	Daily sanitation records – including specified time for checks on cleaning and disinfection procedures All observations and actions

7.2.4 Maintenance of facilities for personal hygiene

According to the US Federal Seafood HACCP regulations (FDA, 1995) the condition of the personal hygiene facilities should be monitored separately.

The number and location of toilets and hand-washing facilities needs consideration. An adequate number of readily accessible toilet facilities must be available and maintained in a hygienic condition and good repair. Hand-washing facilities must be strategically and conveniently located near toilets and at entrances to the processing areas. Wash basin taps must not be hand-operated.

Hand-washing facilities should be dedicated to hand-washing only and never be used for washing dishes, utensils or equipment. Similarly, hand-washing should never take place in sinks or tanks used for food preparation. Hand-washing facilities should include:

- liquid soap in a dispenser
- hot water (~40-43°C)
- disposable paper towels or air blowers (- refuse receptacles if needed)
- hand disinfection facilities (bowls for hand dip).

Typically hand disinfectants are composed of chlorine compounds (100-200 ppm chlorine) or iodine compounds (20-25 ppm iodine).

Model prerequisite programme: Maintenance of facilities for personal hygiene

Criteria:	Toilets and hygiene areas kept cleaned and in good repair Hand-washing and disinfection facilities must be located at toilets and at the entrance to all processing areas and maintained in a good condition The facilities must be equipped with liquid soap, disposable towels and effective disinfectant dips
Monitoring:	Daily check of facilities for cleanliness and good repair. More than one daily check for concentration of disinfectant dip One person (e.g. the Q.A. supervisor) should be designated to carry out this monitoring
Corrective action:	Immediate repair if facilities are broken down or not functioning properly Replenishing of supplies if lacking or concentration is inadequate
Records:	The daily Hygiene Record form should include all observations made and actions carried out

7.2.5 Protection of food from adulterants

Food, food contact surfaces and food packaging material must be protected from adulteration with filth, lubricants, fuel, pesticides, cleaning compounds, disinfection agents, condensates, floor splash and other chemical, physical and biological agents. Thus it is clear, that this part of the programme goes beyond safety aspects addressing also contamination with filth.

Model prerequisite programme: Protection of foods from adulteration

Criteria:	Food, food contact surfaces and food packaging material must be protected from adulteration with lubricants fuel, pesticides, cleaning compounds, disinfection agents, condensate and other chemical, physical and biological contaminants. Specify chemicals to be used in the facility and the requirements to handling and storage (refer to section 7.2.6)
Monitoring:	Daily check at start-up and every four hours during work hours by supervisor to observe on conditions
Corrective action:	Any unsatisfactory activity must be corrected. Possible correction could be to erect a screen to protect a product, correct air flow and ventilation to prevent condensation on the food or to reinforce training of employee
Records:	Must be kept on all actions. A daily hygiene record is kept

Processors need to be aware of all avenues that could cause the food to be adulterated. The maintenance department needs to establish a regular maintenance programme for the facility's ventilation system to avoid formation of condensation. Also floors must be maintained in good order to avoid formation of pools of water and supervisors must ensure that no floor splash occurs during processing or when food is exposed.

Only food grade lubricants should be used on all moving machinery parts that come into direct contact with food. Only approved chemicals for cleaning, disinfection, pesticides and rodenticides should be used in the processing plant.

7.2.6 Proper labelling, safe storage and use of toxic compounds

All food processing plants use chemicals such as cleaning agents, disinfectants, rodenticides, insecticides, machine lubricants and various additives. These chemicals must always be used according to the manufacturer's instructions, have proper labelling and be stored in a safe manner

that protects against contamination of food or food contact surfaces. Original containers (stock solutions) must be kept in a separate room for this purpose only. Working solutions of cleaning and/or disinfection compounds should be in the processing area only when in use – and when no food products are handled.

Model prerequisite programme: Safe storage and use of toxic compounds

Criteria:	List all chemicals used in the plant, manufacturer's instruction must be followed when used. Specify storage conditions (separate room with limited access)
Monitoring:	Check labels Storage conditions and check if manufacturer's instructions are followed. Monitoring daily and visual by supervisor
Corrective action:	Toxic compounds without proper identification or documentation are discarded (or returned to supplier) Improperly placed or stored toxic compounds are removed to correct area Retraining of employee in case of misuse of toxic compounds
Records:	Daily hygiene control records

7.2.7 Control of employee health conditions

It is well known that poor personal hygiene has been implicated in a number of food-borne disease outbreaks. Even apparently healthy persons may carry pathogens, which can spread and contaminate food. However, persons showing symptoms such as: diarrhoea, vomiting, open skin sores, boils, fever, jaundice or discharge from ear, eye or nose, are likely to be infected with pathogens that can be transmitted to food. A food worker displaying any of these symptoms should therefore be excluded or restricted from food handling areas.

Model prerequisite programme: Control of employee health conditions

Criteria:	No person suffering from any communicable disease should be engaged in handling of fish or fish products Before starting to work at the factory, for the first time, the employee should produce a medical certificate The new employee should be trained on GHP
Monitoring:	Supervisors check daily for infected lesions or signs of any communicable disease
Corrective action:	Workers who represent a potential risk are re-assigned to non-food contact jobs
Records:	Daily hygiene control records

7.2.8 Pest control

This programme relates to pests such as rodents, birds and insects as well as dogs and cats. These pests can carry a variety of human disease agents, which can be introduced into the processing environment. For this reason, the presence of pests in a processing plant is unacceptable.

A pest control programme should be based on three principles:

- exclusion or preventing access
- restriction by avoiding to create an environment conducive to pests
- destruction and eradication. This part of the programme must be carried out by qualified personnel as strong poison may be handled. An outside, specialist company is often contracted to carry out this part of the programme.

Model prerequisite programme: Pest control

Criteria:	<p>Presence of rodents, insects and other animals on the premises <u>is not</u> allowed in any area of the processing plant</p> <p>An effective plan for pest control will be in place and includes:</p> <ul style="list-style-type: none"> - elimination of harbourage and attractant areas (Rapid removal of waste see section 7.2.9) - exclusion. All openings (doors, windows, ventilators) must be filled with fly protection - extermination. Company XX is hired for extermination of rodents
Monitoring:	<p>What: Inspection of plant for presence or trace of pests (droppings), attractant areas, exclusion arrangements (screening of openings, windows etc.) and of rodent traps</p> <p>How: Visual</p> <p>When: Daily</p> <p>Who: Q.A. manager</p>
Corrective action:	Immediate repair of defect screenings, removal of attractant areas
Records:	All actions and observations

7.2.9 Waste management

All offals and other waste materials must be removed from the processing area and premises on a regular basis. Separate facilities for containment of offal and waste material must be provided for this purpose only and those facilities should be properly maintained. A hygienic waste water disposal system must be in operation. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

Model prerequisite programme: Waste management

Criteria:	<p>Offal, waste and sewerage will be contained in closed containers, separate rooms or connected directly to a public septic system and be removed from the premises on a regular basis</p> <p>Any container, room etc. used for waste will be marked accordingly</p>
Monitoring:	<p>What: Inspection of waste management utensils and procedures</p> <p>How: Visual</p> <p>When: Daily</p> <p>Who: Processing manager</p>
Corrective action:	Repair of system
Records:	Daily hygiene report

7.2.10 Storage and transportation

The conditions for storage and transportation must be as such to minimise contamination and damage of the fish. Storage areas and vehicles used for the transportation of fish and fish products must be clean. They must provide the fish with protection against contamination from dust and exposure to higher temperatures. Where appropriate, vehicles must be fitted with refrigeration and equipment to maintain fish at 0°C (chilling) or ≤-18°C (freezing). Below is an example of this part in a prerequisite programme.

Model prerequisite programme: Storage and transportation

Criteria:	Storage rooms must be kept clean and orderly and equipped to maintain products at chilled (<+5°C) or frozen temperature (<-18°C) Vehicles for transportation of fish and fish products should be designed and constructed so the fish is protected against contamination and exposure to higher temperatures. Where appropriate vehicles must be equipped to maintain chilled (≤5°C) or freezer temperature (≤-18°C)
Monitoring:	What: Inspection of rooms and vehicles, recording of temperature How: Visual When: Daily (store-rooms) and all shipments Who: Loading foreman
Corrective action:	Correct room temperatures or remove products Replacement of vehicle
Records:	All actions and observations Documented cleaning and disinfection procedures

7.2.11 Traceability and recall procedures

A system for tracing all raw materials and finished products is a necessary component in a prerequisite programme. No process is fail-safe and traceability that includes lot identification is essential to an effective recall procedure. A crisis response plan should be in place to handle any incidents.

Appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf life of the product. Where there is a health hazard, products produced under similar conditions may be withdrawn. The need for public warning should be considered. Once retrieved, products must be held under supervision until the manner of product disposition e.g. rework or destruction has been determined.

Model prerequisite programme: Traceability and recall procedures

Criteria:	Each container of fish and fish product will be clearly marked to identify producer/processor and lot. Written procedures for recall of products and possible information to the public are laid down
Monitoring:	What: Inspection of packaging material and identification labels How: Visual When: Daily Who: Processing supervisor
Corrective action:	When there is a health hazard, products produced under similar conditions may be withdrawn. The need for public warnings should be considered. Recalled products to be held under supervision until decision on further action (destroyed, processed, used for other purposes)
Records:	Records of processing and production must be kept and retained for a period that exceeds the shelf life of the products All other actions and observations must be recorded
Verification:	Checks of final products in storage for proper labelling

7.2.12 Training

All employees should receive documented training on personal hygiene, GHP, cleaning and disinfection procedures, product handling and protection, the HACCP-system and process control. Periodic refresher training should be part of the overall training programme. Training in basic food hygiene is fundamentally important. All personnel should be aware of their roles and responsibilities in protecting fish and the fish products from contamination and deterioration.

An example of a checklist to be used in assessing the prerequisite programme is shown in Appendix 1.

Model prerequisite programme: Training

Criteria:	All fish handlers must have participated in a training course in personal hygiene, GHP, cleaning and disinfection procedures before starting to work in the plant Those who handle strong chemicals must be instructed in safe handling techniques Appropriate training in application of HACCP-system and process control to key personnel Periodic training of all employees so they understand the principles in the HACCP-system
Monitoring:	What: Skill, knowledge and code of conduct of employees How: Visual observation, occasional interviews When: Continuously Who: Supervisors
Corrective action:	Re-training
Records:	Number and type of training sessions/courses for personnel Interviews with personnel

References

- Anonymous 2000. *Sanitation control procedures for processing fish and fishery products*. Manual available from Florida Sea Grant College Program. PO Box 110409 Gainesville, FL
- CAC (Codex Alimentarius Commission) 2000. *Proposed Draft. Code of Practice for Fish and Fishery Products*. Alinorm 01/18. Food and Agriculture Organization / World Health Organization, Rome, Italy.
- CAC (Codex Alimentarius Commission) 2001. *Food Hygiene Basic texts*. 2nd ed. Food and Agriculture Organization / World Health Organization, Rome, Italy.
- EC (European Commission) 1980. Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption. *Official Journal of the European Communities* L 229, 30/08/1980 pp. 11-26.
- EC (European Commission) 1991. Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products. *Official Journal of the European Communities* L 268 , 24/09/1991 pp. 0015 – 0034.
- EC (European Commission) 1992. Proposal for a council directive on the hygiene of foodstuffs. *Official Journal of the European Communities* C 24/11, 31/01/1992 pp. 11-16.
- EC (European Commission) 1993. Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs. *Official Journal of the European Communities* L 175 , 19/07/1993 pp. 0001 – 0011.
- EC (European Commission) 1998. Council directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. *Official Journal of the European Communities* L330, 05/12/1998. pp 0032-0054.
- FDA (US Food and Drug Administration) 1995. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule. Code of Federal Regulations, Parts 123 and 1240. Volume 60, No 242, 65095-65202.
- FDA (US Food and Drug Administration) 2001. Current Good Manufacturing Practices. 21 CFR Part 110. <http://seafood.ucdavis.edu/GUIDELINES/gmps.htm>
- FMF/FMA (Food Manufacturers Federation/Food Machinery Association) 1967. Joint Technical Committee. *Hygienic Design of Food Plant*. London, UK
- Gould, W.A. 1994. *Current Good Manufacturing Practices. Food Plant Sanitation* 2nd ed. CTI Publications Inc., Baltimore, MD, USA.
- Hayes, P.R. 1992. *Food Microbiology and Hygiene*. 2nd ed. Elsevier Applied Science. London and New York.
- ICMSF (International Commission on Microbiological Specifications for Foods) 1988. *Microorganisms in Foods 4. Application of the Hazard Analysis Critical Control Point (HACCP) system to ensure microbiological safety and quality*. Blackwell Scientific Publications.
- Imholte, T.J. 1984. *Engeneering for Food Safety and Sanitation*. Crystal, MINN: The Technical Institute for Food Safety, Medfield, MA, USA.
- Jouve, J.L. 1998. Principles of food safety legislation. *Food Control* 9, 75-81.
- Knøchel, S. 1990. *Microbiology and Groundwater: Aesthetic and Hygienic Problems*. Water Quality Institute, Hørsholm, Denmark.
- Milledge, J.J. 1981. The hygienic design of food plant. Institute of Food Science and Technology (UK). *Proceedings* 14, 74-86.
- NACMCF (National Advisory Committee on Microbiological Criteria for Foods) 1998. Hazard analysis and critical control point principles and application guidelines. *Journal of Food Protection* 61, 762-775.
- Poretti, M. 1990. Quality control of water as raw material in the food industry. *Food Control* 1, 79-83.
- Prasad, V.S. and M. Chaudhuri 1989. Development of filtration/adsorption media for removal of bacteria and turbidity from water. *Water Science Technology* 21, 67-71.

- Reilly, A. 2000. *Discussion paper on the use of chlorinated water*. Prepared for Proposed Draft. Code of Practice for Fish and Fishery Products. CX/FFP/00/13. Food and Agriculture Organization / World Health Organization, Rome, Italy.
- Shapton, D.A. and N.F. Shapton 1991. *Principles and Practices for the Safe Processing of Food*. Butterwood & Heinemann.
- Sobsey, M.D. 1989. Inactivation of health-related microorganisms in water by disinfection processes. *Water Science Technology* 21, 179-195.
- Troller, J.A. 1993. *Sanitation in Food Processing*. Academic Press.
- Watson, P. and P. Prout 1996. *Technical development to improve hygiene in the inshore shrimp industry*. Seafish report No. SR 466. The Seafish Industry Authority, UK.
- WHO (World Health Organization) 1993. *Guidelines for drinking water quality*. 2nd ed. Vol 1. World Health Organization, Geneva, Switzerland.
- WHO (World Health Organization) 1996. *Guidelines for drinking water quality*. 2nd ed. Vol 2. Health criteria and other supporting information. World Health Organization, Geneva, Switzerland.
- WHO (World Health Organization) 1999. *Strategies for implementing HACCP in small and/or less developed businesses*. Report on at WHO Consultation. WHO/SDE/PHE/FOS/99.7. World Health Organization, Geneva, Switzerland.

8 THE HACCP SYSTEM

8.1 Development and adoption of the HACCP principles (Hans Henrik Huss)

The traditional approach to food safety assurance was based on applying codes of Good Hygiene Practices (GHP) and Good Manufacturing Practices (GMP) in food processing. Confirmation of safety and identification of potential problems were obtained by end-product testing. Inspectors checked for compliance with the codes and sampled the foods for laboratory analysis. Although these actions are still essential parts of any foods control programme, they have certain limitations and shortcomings as pointed out in section 3.1.

In contrast, the HACCP system clearly identifies food safety problems and also where and how they can be controlled or prevented. To assure that these actions are executed regularly and consistently, they have to be described and people who are responsible for their execution have to be trained. A record-keeping system has to be developed to provide documentation for all actions and measurements.

HACCP
is a system which identifies, evaluates and controls hazards
which are significant for food safety (CAC, 2001)

Originally, HACCP was developed and used by the private food industry. The concept was used by the Pillsbury Company in the late 60ies for the safety of food intended for the US Space Program. However, it took many years and endless discussions between regulatory agencies and the food industry on the value of end-product testing and microbiological standards for the food before the HACCP concept was generally accepted as the primary means to assure food safety. A few milestones in this development are shown below:

- 1971: The HACCP concept presented at the US National Conference on Food Protection
- 1973: Comprehensive treatise on HACCP published by the Pillsbury Co. HACCP – with only three principles
- 1980: WHO/ICMSF report on HACCP
- 1983: WHO EUROPE recommends HACCP
- 1985: National Academy of Sciences (NAS) (USA) recommends HACCP (Anon., 1985)
- 1988: Book on HACCP by International Commission on Microbiological Specifications for Foods (ICMSF, 1988)
- 1989: The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), USA, approved the first major document on HACCP
- 1992: NACMCF issues a revised document on HACCP (NACMCF, 1992). HACCP now has seven principles
- 1993: Codex issues the first HACCP Guidelines which were adopted by the FAO/WHO Codex Alimentarius Commission
- 1997: Based on a number of FAO/WHO Consultations, Codex issues a revised document (CAC, 2001). NACMCF issues the third revised document (NACMCF, 1997). The two revised documents from Codex and NACMCF are very similar.

Integration of HACCP into the official regulations in the European Union (EU) and the United States (US) took place as follows:

- 1991: Council Directive no. 91/493/EEC (EC, 1991) which places the responsibility of product safety on the industry and introduces the concept of 'own checks' and Critical Control Points during processing
- 1993: Council Directive no. 93/43/EEC (EC, 1993) on the hygiene of foodstuffs
- 1994: Commission Decision 94/356/EEC (EC, 1994) detailing the rules for the application of the HACCP system
- 1995: US-Food and Drug Administration (FDA, 1995) issues the Code of Federal Regulations on safe and sanitary processing and importing of fish and fishery products
- 1996: US Department of Agriculture, Food Safety and Inspection Service adopts the final rule on the HACCP system (USDA, 1996).

Although the HACCP system both in EU and US is based on the same seven principles, there are some differences between the two systems. These differences are mainly related to the prerequisite programmes, the way they are documented and verified, and the scope and content of the identification of hazards.

Until April 1995, acceptance of the work of Codex by the member governments was voluntary. However, with the establishment of the World Trade Organization (WTO) in April 1995 the situation has changed. According to two of the Agreements of the WTO (the Agreement on Sanitary and Phytosanitary measures (SPS) and the Agreement on Technical Barrier to Trade (TBT)), the work of Codex is recognised as the reference for international food safety requirement. This implies that in the future member states of WTO cannot reject food, which meets Codex recommendations and standards without providing justification based on risk assessment. Since the application of HACCP is recommended by Codex, this means that HACCP has become the international reference system for food safety assurance.

Many excellent books and articles on the principles and the application of HACCP have been published in recent years. Examples are: ILSI (1997), Mortimore and Wallace (1998), Corlett (1998), Dillon and Griffith (2001), Motarjemi and van Schothorst (1999), and National Seafood HACCP Alliance (1997).

These publications should be consulted for detailed information. The present Chapter is intended as a general introduction to HACCP giving sufficient information to the reader to understand the system and to enable him/her to apply or assess the system in practical food safety assurance programmes.

8.2 The basic seven principles of HACCP (Hans Henrik Huss)

The HACCP system is science-based and uses a systematic approach to the identification of specific hazards and measures for their control or prevention to ensure the safety of food. The preventive measures must be described in detail and people who have to execute them must be trained. HACCP involves careful recording of all details and actions in order to provide documentation that the system is in operation and in full control of all hazards in food processing. The HACCP system consists of seven basic principles as outlined by CAC (1997) and NACMCF (1997):

- Principle 1: Conduct a hazard analysis
- Principle 2: Determine the critical control points (CCPs)
- Principle 3: Establish critical limits
- Principle 4: Establish monitoring procedures
- Principle 5: Establish corrective actions
- Principle 6: Establish verification procedures
- Principle 7: Establish record-keeping and documentation procedures.

8.3 Application of the HACCP principles (Hans Henrik Huss)

Guidelines for the application of the HACCP system have been presented by CAC (1997). In these guidelines it is pointed out that, prior to application of HACCP to any food operation, this sector should be operating on the basis of a prerequisite programme as outlined in Chapter 7. Furthermore, it is essential that top-management is firmly committed to introduce the system. Many departments and different personnel from chiefs to line operators will be involved and responsible for part of the system, and their full support and cooperation will be needed.

The Codex guidelines suggest that the introduction and application of the HACCP principles should follow a series of 12 steps in a logic sequence as described below:

Step 1: Assemble the HACCP team

Introduction of a HACCP system in large food factories is a complex process and requires a multidisciplinary approach by a team of specialists. The microbiologist is of paramount importance, and must advise the team on all matters related to microbiology, safety and risks. He must have an updated knowledge on these matters and also access to technical literature on the most recent developments in his field. In many cases, he will also need access to the use of a well-equipped laboratory if specific questions and problems cannot be solved by studying the technical literature. Examples are investigations of the microbial ecology of specific products, challenge tests and inoculation studies for evaluation of safety aspects.

Another important member of the HACCP team is the processing specialist. He must advise on production procedures and constraints, prepare the initial process-flow diagram, advise on technological objectives at various points in the process and on technical limitations of equipment.

Other technical specialists such as a food chemist, a food engineer as well as packaging technologists, sales staff, training and personnel managers can provide valuable information to the HACCP team and they should attend some of the meetings.

Key-members of the HACCP team (including the leader) must have an intimate knowledge of the HACCP system. Small and medium size industries are not likely to have qualified personnel on the payroll and must therefore buy assistance from outside consultants in order to implement the system. One person should be appointed as leader of the team.

When the HACCP team is assembled, the scope of the HACCP plan should be identified, describing which segment of the food chain is involved and addressed in the work.

Step 2: Describe product

A full and detailed description of the final production must be drawn up. The raw materials and ingredients used must be specified including the market name or Latin name of the fishery component. Details regarding hazards in the raw material will be included in the HACCP plan. All factors which influence safety such as composition, physical/chemical structure including water activity (a_w) and pH must be described, and any microbiocidal/-static treatment such as heating, freezing, brining and smoking must be specified as well as packaging type, storage conditions and methods of distribution. The normal shelf life under specified condition should also be recorded as shown below.

Elements of the product description

- 1 Product name
- 2 Raw material and ingredients used
- 3 Parameters influencing safety (a_w , pH, salt%, etc.)
- 4 Processing
- 5 Packaging and packaging material
- 6 Storage conditions and shelf life
- 7 Conditions during distribution
- 8 Intended use and consumer
- 9 Labelling instructions

Step 3: Identify intended use and consumer

The HACCP team will need to identify the intended use and consumer of the product. The intended use should be based on expected use by the consumer. The use and preparation before use greatly influence the safety of the product. Certain products may be contaminated or carry pathogenic organisms as a part of the natural flora. If the processing does not include a killing step, the only critical control point (CCP) which can render the product safe is adequate heat treatment during preparation.

The intended consumer may be the general public or a particular segment of the population such as infants or elderly. If the product is to be sold to hospitals or groups of the population with high susceptibility, more safety is required and critical limits need to be more strict.

Step 4: Construct flow diagram

The purpose of the flow diagram is to provide a clear simple description of all steps involved in the processing. Receiving and storage steps for raw materials and ingredients should be included. Time and temperature conditions during processing should be mentioned whenever there is a holding step e.g. in holding vats, buffer tanks or other areas, where this could be a potential delay in processing.

Step 5: On-site confirmation of flow diagram

The constructed flow diagram should be verified on-site for accuracy. The site should be inspected during all hours (night shifts, weekends) of operation to check for correctness and ensure that nothing crucial was overlooked.

Step 6: List all potential hazards associated with each step in the operation, conduct a hazard analysis and consider any measure to control identified hazards (Principle 1)

The words “hazard” and “hazard analysis” have been defined by Codex (CAC, 2001):

Hazard

A biological, chemical or physical agent in, or a condition of, food with the potential to cause an adverse health effect (CAC, 2001)

Hazard Analysis

The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan (CAC, 2001)

Thus, the word hazard has a particular meaning. It refers to both a specific agent and/or a condition (e.g. elevated temperature) with the potential to cause harm. After having identified all potential hazards all the information available must be evaluated in order to decide, which ones of the hazards are significant and reasonably likely to cause illness if not effectively controlled.

The hazard analysis is the key to preparing an effective HACCP plan and serves three purposes (NACMCF 1997):

- The hazards and associated control measures are identified,
- Needed modifications to a process or product is identified,
- Providing a basis for determining CCPs (principle 2).

Examples of questions to be considered, when conducting a hazard analysis has been listed by NACMCF (1997) and includes¹:

- Raw materials and ingredients – do they contain any hazardous agents?
- Intrinsic factors – will the food permit survival, multiplication of pathogens or toxin formation?
- Processing conditions – are any pathogens destroyed, are there any possibilities for recontamination?
- Packaging – does the packaging affect the microbial population?
- Preparation and intended use – will the food be heated by the consumer?
- Intended consumer – is the product for the general public or for consumption by a population with high susceptibility to illness?

A decision tree with a number of questions can be used to determine if potential hazards are “real” as demonstrated in Figure 8.1.

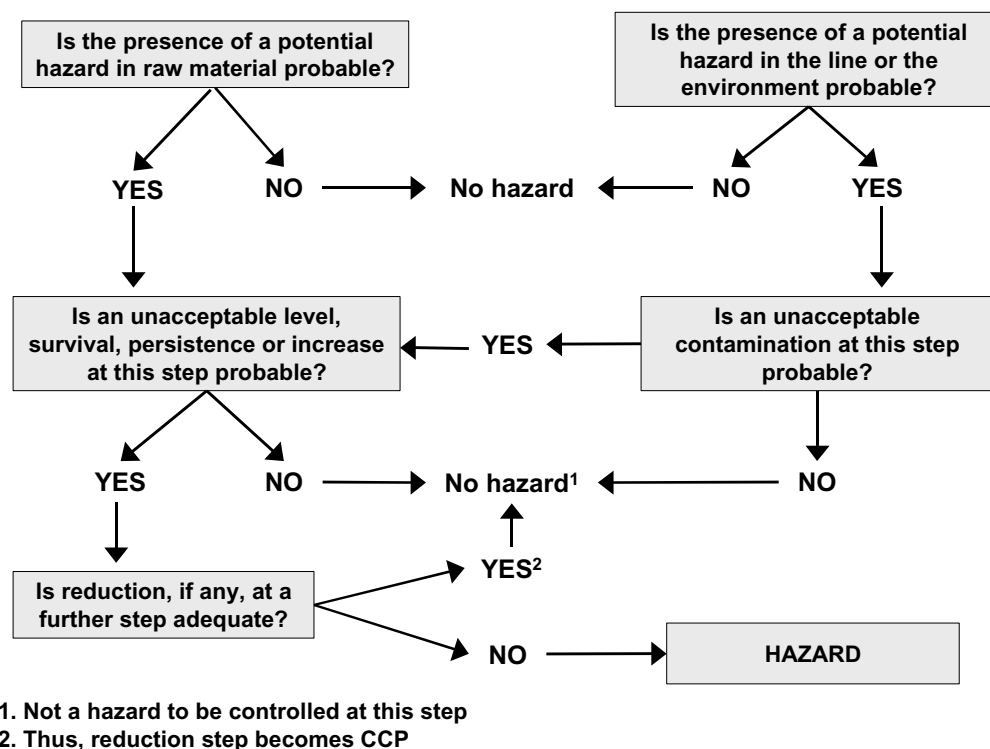


Figure 8.1 Hazard determination - Questions to be answered for each potential hazard at each step (based on ILSI, 1997).

¹ Conditions covered by the prerequisite programme have been excluded from the list

The questions in Figure 8.1 have to be asked at each step of the processing chain and all hazards must be considered.

An element of risk assessment is involved in the evaluation of potential hazards. Only these hazards which are likely to occur and which will cause a reasonably serious adverse health affect are regarded as significant as shown in Figure 8.2.

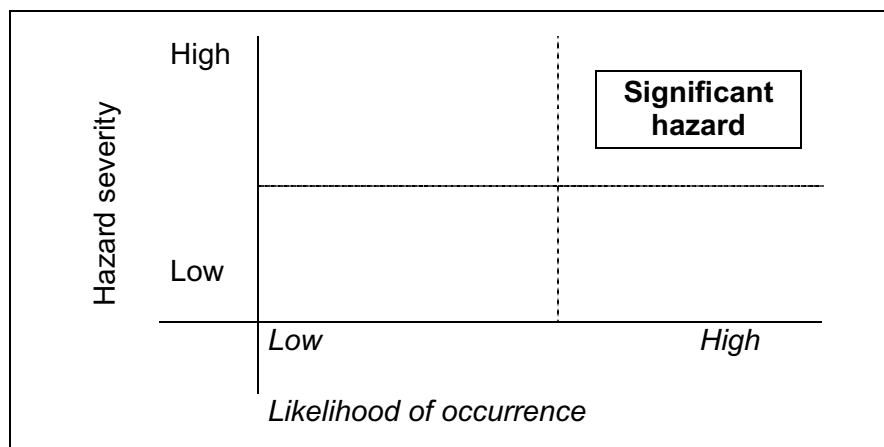


Figure 8.2 Determination of hazard significance (after Mortimore and Wallace, 1998).

Thus, the basic procedures to use in conducting the hazard analysis are as follows:

- based on the product description and the flow diagram, all the potential hazards associated with the product and at each processing step is determined and listed
- Make a hazard evaluation:
 - assess severity of health consequences if potential hazards are not controlled
 - determine likelihood of occurrence of potential hazards if not properly controlled
 - using information above, determine if this potential hazard is to be addressed in the HACCP plan
 - describe control measures.

Control measure(s) is (are) any factor or activity, which can be used to prevent, eliminate or reduce a food safety hazard to an acceptable level. More than one control measure may be required to control a hazard.

Upon completion of the hazard analysis, the hazards associated with each step in the production should be listed along with any measure(s) that is (are) used to control the hazards. A “hazard analysis worksheet” can be used to organize and document the considerations in identifying food safety hazard. An example of a hazard analysis worksheet is shown in Appendix 2.

Step 7: Determine the critical control points (CCPs) (Principle 2)

Complete and accurate identification of all the CCPs is fundamental to controlling food safety hazards. To facilitate this identification, the use of a CCP decision tree can be of great help. Example of decision trees are found in NACMCF (1997), CAC (1997) and in the ILSI (1997) document. The latter is shown in Figure 8.3.

Critical Control Point (CCP)

Is 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 (CAC, 2001)

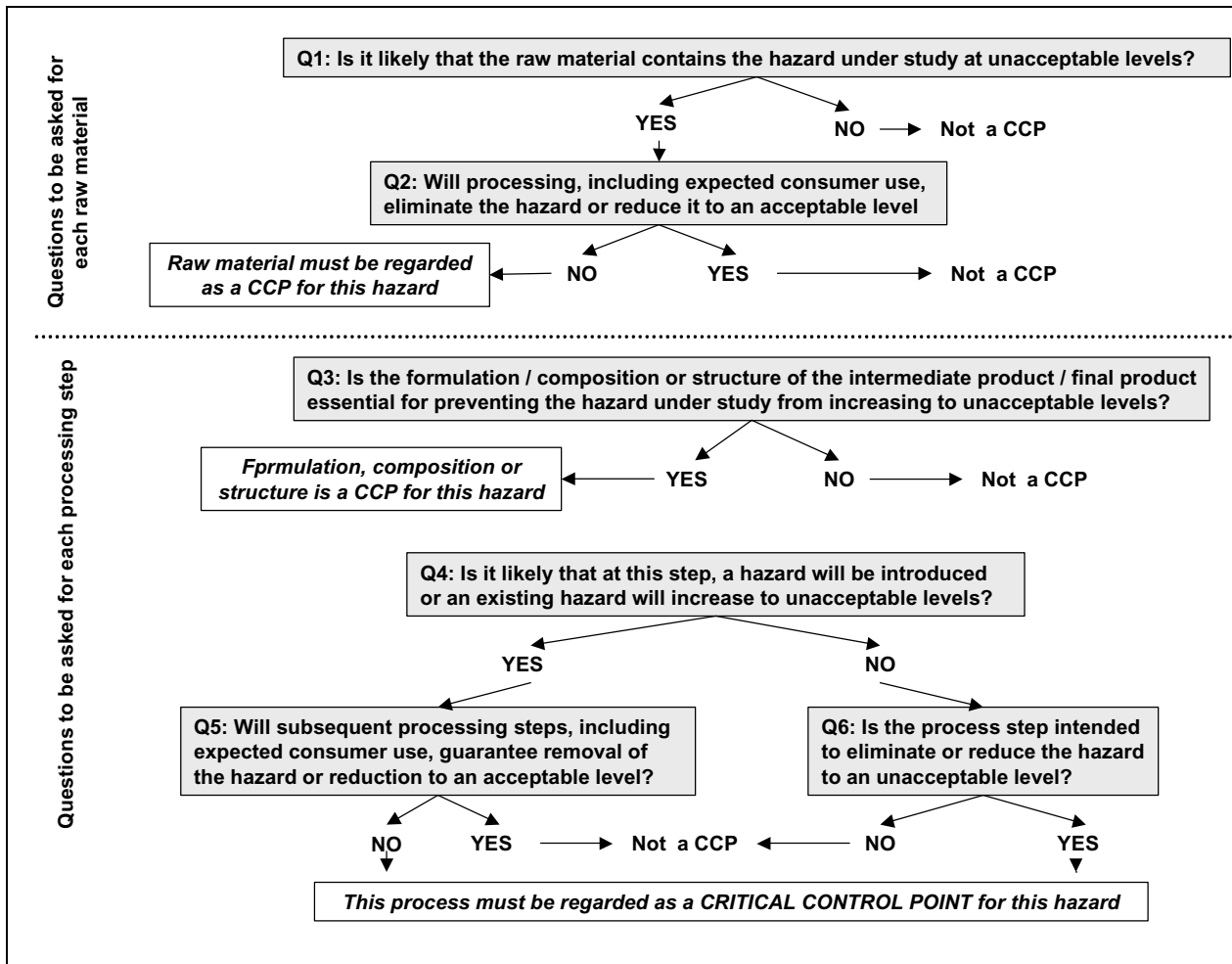


Figure 8.3 Critical control point decision tree (ILSI, 1997).

The first two questions in Figure 8.3 deal with the raw material. It is important to note, that if an identified hazard is eliminated or reduced at a later process step or by normal consumer use, the raw material is not a CCP. Question 3 deals with formulation or composition of the product. In Chapter 5 of this publication it has been pointed out, that in preventing multiplication of pathogens the pH or a_w or presence of specific antibacterial compounds may be extremely important. Question 4 asks, if contamination, recontamination or even multiplication of pathogens can take place at this step. If the answer is 'No', question 6 thus has to be answered, but if the answer is 'Yes', the answer to question 5 will decide whether this step is a CCP or not.

Only points where truly significant hazards can be controlled should be designated CCPs. A tendency exists to control too much and to designate too many CCPs. This should be avoided as it will create confusion and divert attention from the true CCP.

Step 8 Establish critical limits (Principle 3)

The third HACCP principle deals with establishing one or more maximum or minimum critical limits that must be controlled at each CCP.

Critical limit
is a criterion which separates acceptability from unacceptability (CAC, 2001)

All critical limits should be scientifically based and refer to factors such as: time/temperature conditions, moisture level, water activity (a_w), pH, titratable acidity, salt concentration, available chlorine, preservatives, organoleptic or sensory quality.

Microbiological limits should normally be avoided. This is because microbiological data can usually only be produced by a process, which may take several days. The monitoring of microbiological limits would therefore not allow you to take instant action when the process deviates.

Authoritative critical limit information is available from sources such as the “Fish and Fisheries Products Hazards and Control Guide” (FDA, 1998) or may be found in scientific publications or obtained from regulatory agencies, universities or export groups or institutions.

When critical limits have been established, they should be entered on the “HACCP PLAN FORM”. An example of a HACCP plan form is shown in Appendix 3.

Step 9: Establish monitoring procedures (Principle 4)

Monitoring of CCPs serves three purposes (NACMCF, 1997):

- to determine if there is a loss of control and a deviation occurs at a CCP. Appropriate action must then be taken
- monitoring keeps check on the operation and provides information whether there is a trend towards loss of control and action can be taken to bring the process back into control before a deviation occur
- provides written documentation for use in verification and audit. All records must be signed.

Monitoring
is the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control (CAC, 2001)

To be effective, all monitoring must be done rapidly and results must be evaluated by a designated person with knowledge and authority to carry out corrective actions. Typically, monitoring methods are:

- time/temperature recording
- pH and a_w measurements
- sensory quality.

Thus, in planning the monitoring procedures there are typically four questions to be answered (CAC, 2001):

- Planning monitoring procedures**
- What – usually a measurement or observation
 - How – by observation and/or use of instruments
 - When (frequency) – continuous or intermittent – but in real time
 - Who – someone who is qualified and with authority

As already stated, the main purpose of monitoring is to determine if there is loss of control or deviation.

Deviation
is failure to meet a critical limit (CAC, 2001)

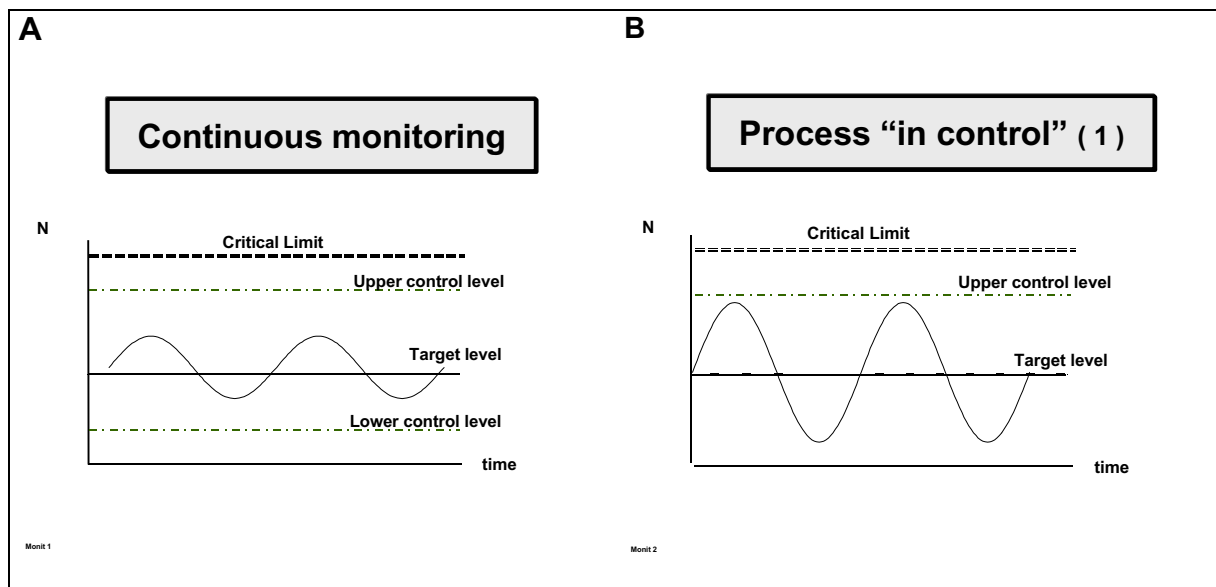
An example of a process being in control and out of control (deviation) has been illustrated by Motarjemi and van Schothorst (1999) as shown in Figure 8.4.

Step 10: Establish corrective actions (Principle 5)

Corrective Action
is any action to be taken when the results of monitoring at the CCP indicate a loss of control (CAC, 2001)

Whenever there is a deviation from established critical limits a corrective action must be instituted to ensure that defective products do not reach the consumer. These actions should include the following (NACMCF, 1997):

- determine and correct the cause of deviation
- determine the disposition of products that were produced during the process deviation
- record the corrective action taken.



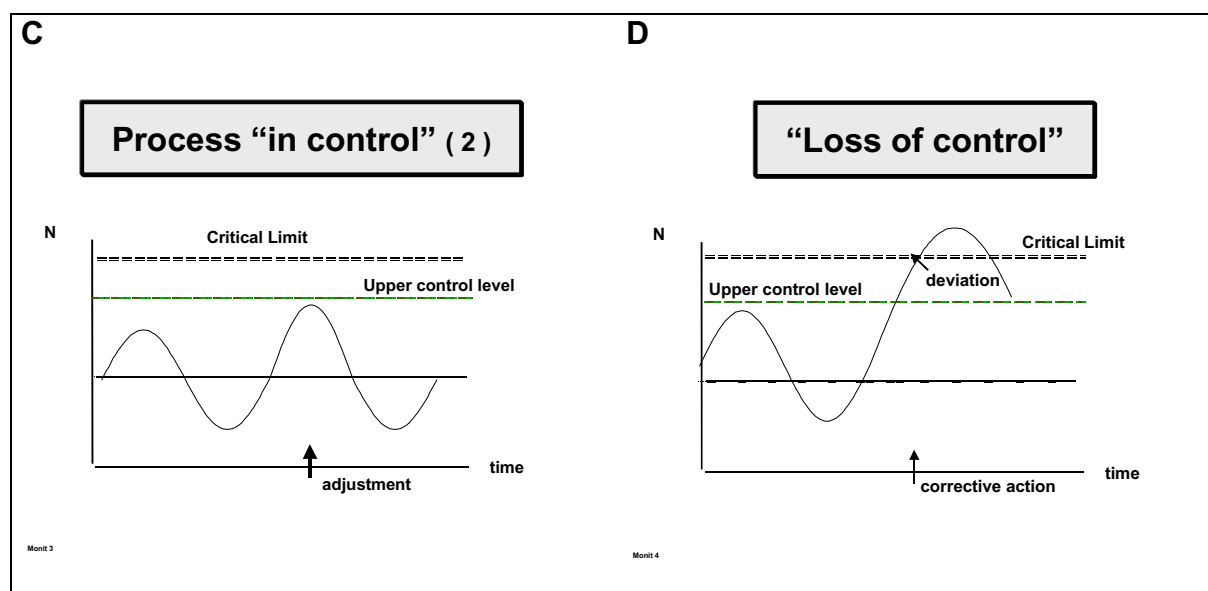


Figure 8.4 Monitoring: A: small fluctuations always occur around a target level, B and C: the process is under control but adjustment is needed in situation C as abnormal fluctuations are noted, D: a deviation occurs and corrective action is needed (from Motarjemi and van Schothorst ,1999).

Options for disposition of products placed on hold include:

- isolating and holding products for safety evaluation
- reprocessing
- rejecting and/or destroying of product
- use as by-product (animal feed).

Corrective action procedures should be developed by the HACCP team in advance and specified in the HACCP plan. Any action should be recorded on the HACCP Plan Form (Appendix 3). If necessary, a more detailed corrective action report should be elaborated including the following information (National Seafood HACCP Alliance, 1997):

- product identification
- description of the deviation
- results of the product evaluation
- corrective action taken including the final disposition of the affected product
- actions to prevent the deviation from recurring
- name of the individual responsible for taking action.

Step 11: Establish verification procedures (Principle 6)

Verification

is the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (CAC, 2001)

The purpose of the HACCP plan is to prevent food safety hazards from occurring. Verification activities must provide a level of confidence that the HACCP plan is working properly and is adequate to control hazards. The NACMCF (1997) document is providing guidance on what elements should be included in the verification activities:

- Validation – initial and subsequent validation of the HACCP plan
- Verification of the CCP-monitoring
 - CCP-record review
 - calibration of instruments
 - targeted sampling and testing
 - microbiological testing
- Review of monitoring, corrective action records
- Comprehensive HACCP system verification.

Thus, the verification procedures include verification of both the individual CCP and the overall HACCP plan. An essential component of verification is validation.

Validation
is obtaining evidence that the elements of the HACCP plan are effective (CAC, 2001)

In validation of the HACCP plan it needs to be established that the plan is scientifically and technically sound. This means that scientific validation includes review of each part of the HACCP plan from the hazard analysis through to each CCP. The needed information can be obtained from expert advice, scientific studies and literature, in-plant observations and measurements.

Validation	<ul style="list-style-type: none"> • are the right things done? • will the system work when put into practice?
Verification	<ul style="list-style-type: none"> • are the things done right? • are they done as they were planned to be done?

Apart from the initial validation, subsequent validation as well as verification must take place whenever there is a change in raw materials, product formulation, processing procedures, consumer and handling practices, new information on hazards and their control, consumer complaints, recurring deviations or any other indication, that the system is not working. Figure 8.5 shows where validation fits into the process of HACCP implementation.

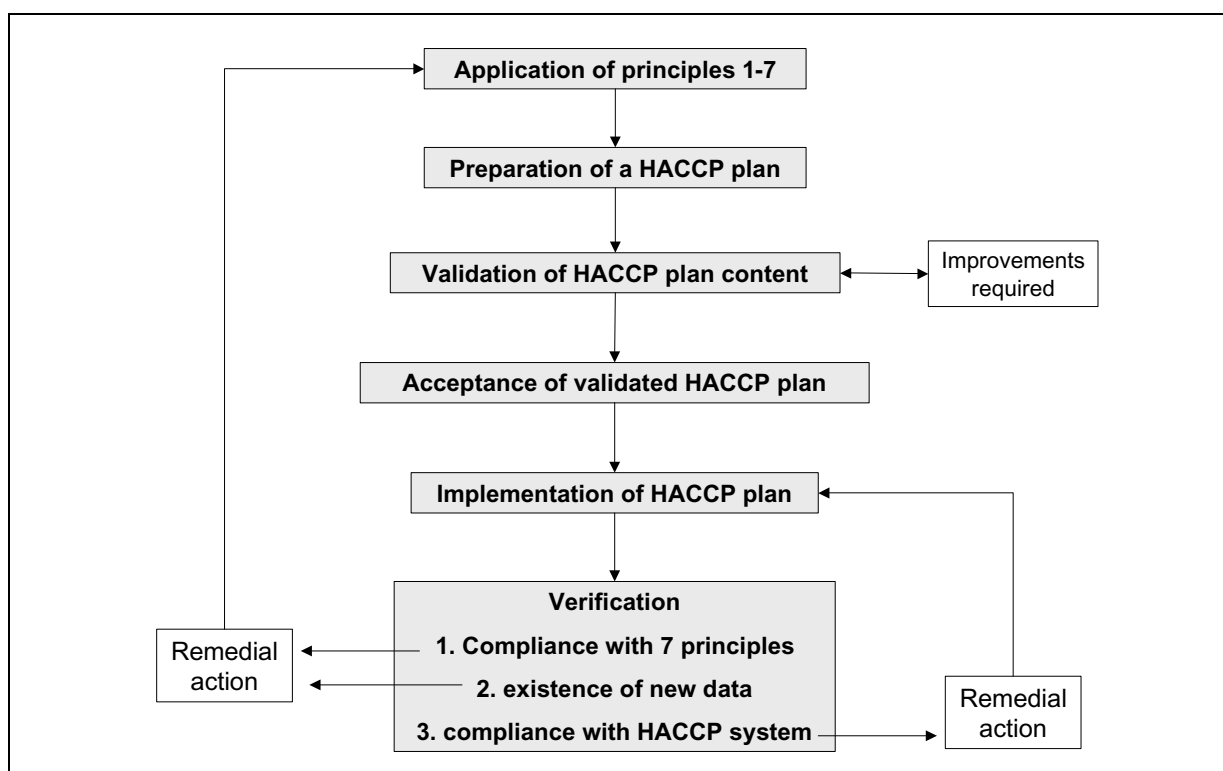


Figure 8.5 HACCP validation and verification (based on ILSI, 1999).

A periodic comprehensive verification of the HACCP system should be conducted yearly by an unbiased, independent authority. This should include a review of the HACCP plan for completeness, confirmation of the flow diagram, review of all records and validations, sampling and testing to verify CCPs (NACMCF, 1997).

Verification is the responsibility of the producer or food handler. However, where regulatory agencies are conducting audits or sampling end-products the results can be used by industry as part of the verification programme.

Verification procedures should be entered on the HACCP Plan Form (Appendix 3) and results into special verification records.

Step 12: Establish record-keeping and documentation procedures (Principle 7)

Record keeping

ensures that the information resulting from the HACCP study and implementation of the resulting HACCP plan is available for validation, verification, review, auditing and other purposes (ILSI, 1997)

Records and documentation are vital for the verification and auditing to determine, if the HACCP system in operation is in compliance with the HACCP plan and operating correctly. Also records of support documents must be kept such as data used to establish critical limits, reports from consultants or experts, a list of the HACCP team and their responsibilities and the preliminary steps taken before development and implementation of the HACCP plan. Examples of HACCP records are shown in NACMSF (1997). The CAC (1997) publication mentions the following examples of documentation:

- hazard analysis worksheet
- CCP determination
- critical limit determination

and as examples of records:

- CCP monitoring activities
- deviations and associated corrective actions
- modifications of the HACCP system.

8.4 HACCP implementation in the fish industry (Hans Henrik Huss)

It is generally accepted that responsibility for producing safe food is in the hands of the producer. It is therefore the responsibility of the producer to ensure the development and application of a proper HACCP plan.

It is of paramount importance, that senior management of a company needs to understand and support the implementation of HACCP in the processing facilities. They need to understand the benefits as well as the cost and the resources needed.

While the HACCP team is conducting the HACCP study, it is advisable to initiate training of key-personnel. No plan will work if the people who have to implement it are not trained. People who have to develop the plan as well as people responsible for implementation and maintenance may all need training.

When the HACCP plan has been developed, it needs to be approved by senior management. During the development of the HACCP plan including the prerequisite programme, it often becomes clear that improvements may be needed in construction or layout of facilities, or utensils need to be replaced. This could involve considerable costs and run into budgetary constraints. However, modifications, which are essential to food safety, should always be executed immediately, while a timetable for less necessary modifications should be made.

Although implementation of HACCP is the responsibility of the industry, government (that is regulatory fish safety and quality control authorities) also have a role to play. Government authorities can play three roles: they can act as facilitators, enforcers or trainers (Motarjemi and van Schothorst, 1999):

- as facilitators they can help industries understand the goals and scope of HACCP and provide expertise during the establishment of a HACCP plan or its verification
- as enforcers their task is to assess the correct application and implementation of the seven HACCP principles
- they can provide training courses and also participate in training courses organized by or for the industry.

Thus, it is a key role of government agencies to show leadership by promoting and facilitating the implementation of HACCP. However, the government has also a strategic role (i.e. a plan how to achieve a pre-set goal) as well as an ongoing role in assessing the HACCP systems applied in the industry.

With regard to the actual assessment of HACCP, government agencies also play an important role in providing guidance on the assessment process needed to be developed and provided to officials for its uniform and acceptable application. This guidance should be developed by government agencies in collaboration with, when possible, food control officials and industry (see also section 8.5).

Proper implementation of HACCP may also need the support of other institutions such as academia and research, trade associations, private sector etc. A consequence of the WTO/SPS agreement is that food safety criteria such as FSOs, performance criteria and microbiological end product criteria have to be based on scientific evidence, and where appropriate on a risk assessment. Scientific results produced *lege artis* and published in international literature is

therefore the background for the HACCP plan and provides the transparency required by WTO/SPS.

Finally, consumers and consumer advocate groups have a counter-balancing role to ensure that safety and quality are not undermined by political and socio-economical considerations when drafting legislation or implementing safety and quality policies.

8.5 HACCP audit (Lahsen Ababouch)

Many fish producing, exporting and/or importing countries have undertaken a thorough evaluation and reorganization of fish inspection and control systems with the aim to improve efficiency, rationalize human resources and introduce risk analysis-based approaches. The HACCP principles play a pivotal role in these preventive approaches. Their application is the responsibility of the fish industry, whereas government control agencies are responsible for monitoring and assessing their proper implementation.

Many inspection agencies have developed approaches and procedures for carrying out HACCP compliance auditing. These approaches and modalities have used the terminology and basic requirements of the ISO 10011 standards (ISO, 1993a,b) that were adapted to the specificities of HACCP and to the countries regulations. Information regarding these procedures will not be reviewed here in details as it is widely accessible, especially via internet. This Chapter will rather attempt to demystify the issues and advise on how to achieve practical HACCP auditing.

8.5.1 Planning and conducting an HACCP audit

Audit is a systematic and independent examination to determine whether activities and results comply with the documented procedures; also whether these procedures are implemented effectively and are suitable to achieve the objectives (ISO, 1993a,b). In HACCP terms, achieving the objectives means managing the production and distribution of safe fish products through the use of an HACCP based approach.

The outcome of the audit is to have established whether the manufacturer has

- implemented a sound HACCP system
- the knowledge and experience needed to maintain it
- the necessary support (or prerequisite) programmes in place to assess adherence to Good Hygienic and Good Manufacturing Practices (GHP/GMP).

The audit will encompass assessment of the management commitment to support the system and assessment of the knowledge, competency and decision-making capabilities of the HACCP team members to apply the system and maintain it. Four types of HACCP audits can be envisaged:

- An internal HACCP audit to establish the effectiveness of the HACCP system using the company's own human resources or by bringing in an external HACCP assessor.
- An external HACCP audit of suppliers of critical raw materials or of packed finished products to establish whether they have robust HACCP systems in place. This includes regulatory HACCP auditing
- Audit of the customers HACCP system. This may be important where the customer is responsible for the distribution and sale of a high risk (e.g. a chilled ready meal) product which bears the brand of the manufacturing company
- An investigative audit can also be conducted to analyse a specific problem area. This may be used for example when a CCP regularly goes out of control and more studies are needed to investigate the real cause in order to take corrective action, or where a previously unknown problem has arisen.

An HACCP audit needs to be properly prepared. Figure 8.6 describes the steps generally required in a HACCP audit. This guidance is useful for independent (third-party) audits as well as for internal or compliance audits. It should be adapted to the particular circumstances of the firm being audited.

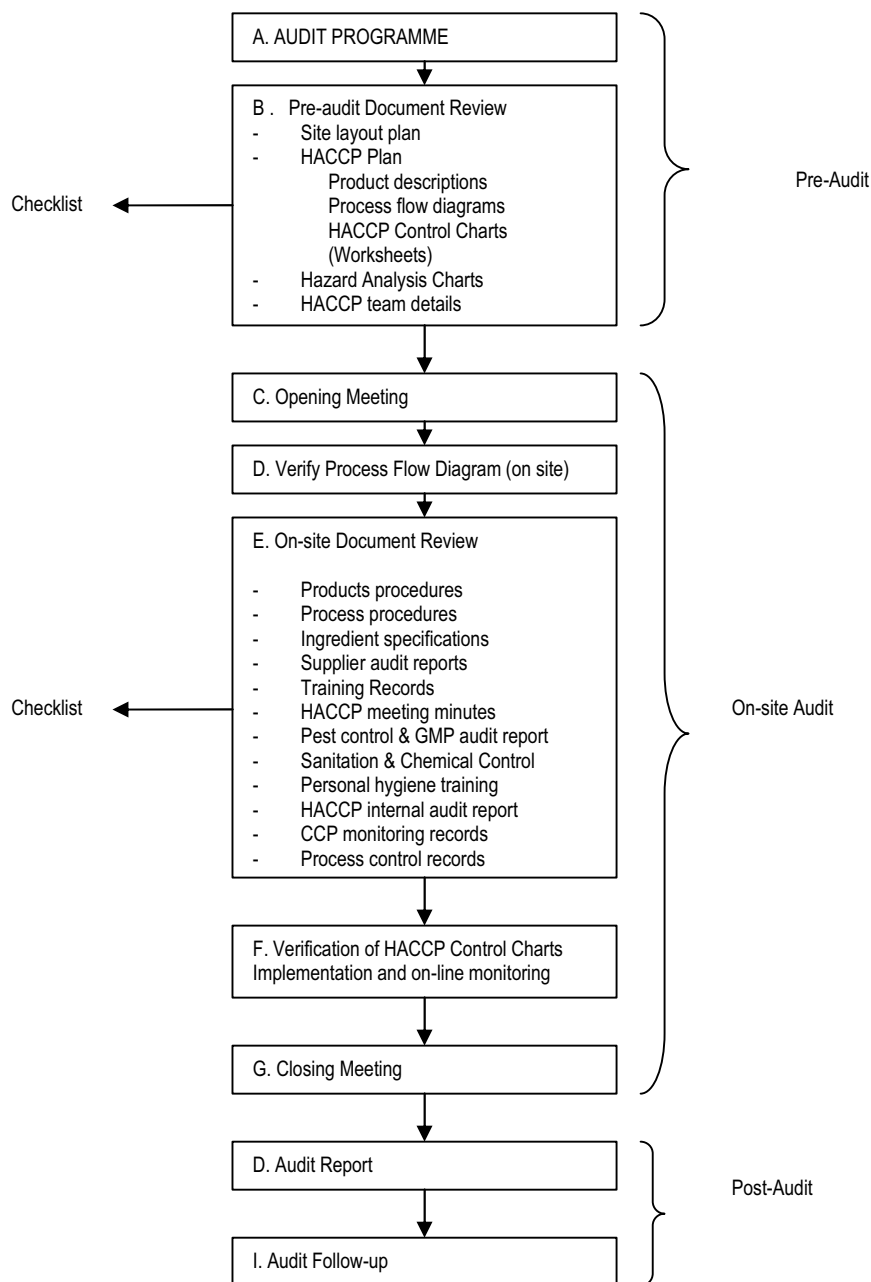


Figure 8.6 Steps in HACCP auditing (Mortimore and Wallace, 1998).

Pre-audit

A preparatory phase is necessary to elaborate the schedule and the definition of the scope of the audit. All the personnel required during the audit should be notified to ensure that they are available. Also the necessary documentation should be made available for the audit.

This starts with a "desktop assessment" of the HACCP system, to review all of the documentation relating to the scope of the audit such as the flow diagram layout, the time/temperature and other technological information, the hazard analysis, etc.

The pre-audit document review can be done as an initial scan to get a feel for who carried out the HACCP study, its style, its completeness, and also familiarisation with the site being audited and the products and process itself. It will give an opportunity for the auditor to carry out some research before the assessment. At this stage, it is important to build up knowledge of the product/process technology concerned. Literature searches of the technology, fish contamination outbreaks and legislative controls should be included. Guides and other support documents can be useful.

It is also important to gauge the level of commitment of the management and the competency of the HACCP team members by asking for their training and experience.

If the pre-audit indicates obvious inadequacies, it may be advisable to stop the assessment at this point prior to the on-site audit. The deficiencies should be discussed with the HACCP team, who can then review their HACCP system and implement any required corrective measures.

On-site audit

An opening meeting is useful to present the team of auditors, the scope and the tentative timetable and to identify the personnel and documentation required.

At this stage, the accuracy of the process flow diagram will be carefully checked, followed by a full review of operational procedures for CCP monitoring, CCP monitoring records, training records, etc. The prerequisite GMP and hygiene maintenance records, pest control and also the HACCP team meeting minutes can be reviewed. In the latter case, it may be helpful to use this to get an idea of the decision making process, who attended the meetings on each occasion and whether difficulties were encountered. The review will also include previous audit records where non-compliances may have been found. The assurance of the effectiveness of any corrective actions taken must be sought. Other quality and safety related data for review will include customer complaints and customer audit reports.

It is often useful to use checklists during the audit. An example of a checklist is presented in Table 8.1. The “considerations” column can be completed during the document review step of the process, and the “auditors’ findings” column during the audit itself.

During a closing meeting, the overall assessment findings are presented and an overall view of the proceedings is given. Non-compliances should be discussed together with supporting evidence and a schedule for the corrective actions agreed. The auditor must ensure that identified deficiencies are clearly understood and that the recommended corrective actions are feasible and agreed by a senior manager.

Table 8.1 Example of a checklist for assessing HACCP implementation (Ababouch, 2000).

Component to assess	Compliance, con- siderations, points to raise on site	Findings of the auditor
(1) <i>Commitment of the management</i> Financial commitment Awareness/support		
(2) <i>HACCP team</i> The HACCP team leader has effective power of decision The HACCP team members are qualified		
(3) <i>Composition of products</i> Fish composition is properly described Any modification is recorded and taken into account for HACCP revision		
(4) <i>Intended use</i> Valid description of the intended use Any modification is recorded and taken into account for HACCP revision		
(5) <i>Process flow diagram(s)</i> The flow diagram is correct Any modification is recorded and taken into account for HACCP revision		
(6) <i>Hazard analysis</i> All control measures are correctly implemented, eventually validated Personnel in charge of control measures are identified and qualified New hazards, introduced because of changes in product, process,... were taken into consideration Control measures have been identified for these new hazards		
(7) <i>Critical control points (CCPs)</i> CCPs are properly identified (e.g. using the decision tree) Introduction of new hazards has resulted in CCP analysis to implement proper control measures		
(8) <i>Critical limits</i> Critical limits are properly identified and eventually validated Introduction of new hazard has resulted in the revision of the critical limits		
(9) <i>Monitoring procedures</i> Monitoring procedures are properly identified The reliability of the monitoring procedures has been validated Personnel in charge of monitoring is well identified and trained All necessary modifications have been made to take into account the introduction of new control measures		
(10) <i>Corrective actions</i> Corrective actions are properly identified and eventually validated Personnel in charge of corrective actions has been identified and trained All necessary modifications have been made to take into account the introduction of new control measures		
(11) <i>Verification of the HACCP system</i> The method and frequency of verification are appropriate The validity of the verification method has been confirmed Personnel in charge of verification is identified Changes of products, processes, standards, regulations, were taken into consideration		
(12) <i>Record-Keeping System</i> Forms are appropriate and complete Forms are up to date for recording the following: <ul style="list-style-type: none"> • Monitoring results, • Corrective actions, • Modifications of the HACCP system • HACCP Verification/revision results Some records have been tampered with		

Post- audit

Audit reports should provide evidence of the findings of the assessment - primarily what deficiencies have been found in the HACCP system, the non-compliance notes, the recommended corrective measures and the timetable to implement them.

During the audit follow-up, the auditor should ensure that the non-compliances are closed off. The effectiveness of corrected non-compliances should be verified as soon as the corrective action has been taken and reviewed during subsequent audit to ensure that the corrective actions taken have been effective on an ongoing basis

8.5.2 Frequency of audit

The frequency of HACCP audit should be based on:

- the risk category of the fish product being processed
- the level of commitment of management and the decision-making leverage of the HACCP team
- the reputation of the fish company: previous safety and quality records, HACCP manual and implementation classification, training and qualification.

8.5.3 Qualifications of HACCP auditors

An HACCP audit exercise should lead to an audit report which should state whether the system provides enough assurance to control fish safety and quality. However, fish processors look for a formal recognition (validation, certification). It should be stressed that although this is legitimate, an HACCP audit is a snapshot punctual evaluation and any recognition should not lead to false assurance. It is a temporary recognition and audit should be as frequent as seen fit.

In international fish trade, there is a danger of duplication of HACCP audit efforts. This can be alleviated by the development of an internationally recognized equivalency system, for example through the Codex Committee on import/export inspection and certification systems.

Furthermore, third party certification can complement the work of government inspectors in assessing HACCP. However, certifying bodies should demonstrate proper qualifications and integrity in HACCP development and verification. This may require the establishment of a certification system for third party HACCP assessors.

8.5.4 Qualifications of HACCP auditors

Proper assessment of HACCP requires demonstrated knowledge and qualifications in different areas of science and technology pertinent to the products and processes of interest, in addition to confidentiality, objectivity and experience and skills in auditing and communication (ISO, 1993b). These qualifications are acquired through training and experience. It should be stressed that any training activity should provide evidence of satisfactory completion through examination. Also, the training programs and examinations should be harmonized to allow for easy recognition and equivalency between countries.

References

- Ababouch., L. 2000. The role of government agencies in assessing HACCP. *Food Control* 11, 137-142.
- Anonymous 1985. An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients. National Research Council, National Academy Press. Washington, DC, USA.
- CAC (Codex Alimentarius Commission) 2001. *Food Hygiene Basic Texts*. 2nd ed. Food and Agriculture Organization / World Health Organization, Rome, Italy.
- Corlett, D.A. 1998. HACCP Users Manual. A Chapman and Hall Food Science Title. Aspen Publishers Inc., Gaithersburg, Maryland, USA.
- Dillon, M. and C. Griffith 2001. How to HACCP. 3rd ed. M.D. Associates, 32a Hainton Avenue, Grimsby, North East Lincolnshire DN 329 BB, UK.

- EC (European Commission) 1991. Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products. *Official Journal of the European Community* L268, pp.15-34.
- EC (European Commission) 1993. Council Directive 94/43/EEC of 14 June 1993 on the hygiene of foodstuffs. *Official Journal of the European Communities* L175, pp. 1-112.
- EC (European Commission) 1994. Commission Decision 94/356/EC of 20 May 1994 laying down detailed rules for the application of Council Directive 91/493/EEC, as regards own health checks on fishery products. *Official Journal of the European Communities* L156, pp. 50-57.
- FDA (US Food and Drug Administration) 1995. *Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products*; Final Rule. Code of Federal Regulations, Parts 123 and 1240. Volume 60, No 242, 65095-65202.
- FDA (US Food and Drug Administration) 1998. *Fish and Fisheries Products Hazards and Controls Guide*. 2nd ed. Washington, USA.
- ICMSF (International Commission on Microbiological Safety of Foods) 1988. *Microorganisms in Foods 4: Application of the Hazard Analysis Critical Control Point (HACCP) to ensure microbiological safety and quality*. Blackwell Scientific Publications, London, UK.
- ILSI (International Life Sciences Institute) 1997. A simple Guide to understanding and applying the Hazard Analysis Critical Control Point Concept ILSI Europe, Brussels, Belgium.
- ILSI (International Life Sciences) 1999. Validation and verification of HACCP. ILSI Europe, Brussels, Belgium.
- ISO (International Standards Organization) 1993a. ISO 10011-1. Guidelines for auditing quality systems. Part 1: auditing. 8 pages. Geneva. Switzerland.
- ISO (International Standards Organization) 1993b. ISO 10011-1. Guidelines for auditing quality systems. Part 2: Qualification criteria for quality systems auditors. 6 pages. Geneva. Switzerland.
- Mortimore, S. and C. Wallace 1998. *HACCP, A practical approach*. A Chapman and Hall Food Science Book. Aspen Publishers Inc., Gaithersburg, Maryland, USA.
- Motarjemi, Y. and M. van Schothorst 1999. HACCP, Principles and Practice. In Jongeneerl, S. (ed) *Teacher's Handbook*. A WHO/ICD Training Manual in Collaboration with FAO. World Health Organization, Geneva, Switzerland.
- NACMCF (National Advisory Committee on Microbiological Criteria for Foods) 1992. HAZARD Analysis and Critical Control Point System. *International Journal of Food Microbiology* 16, 1-23.
- NACMCF (National Advisory Committee on Microbiological Criteria for Foods) 1997. HAZARD Analysis and Critical Control Point Principles and Application Guidelines. *Journal of Food Protection* 61, 762-775.
- National Seafood HACCP Alliance 1997. HACCP: Hazard Analysis and Critical Control Point Training Curriculum. 2nd ed. (Chairman editorial committee: Donn Ward). Publication UNC-SG-96-02, North Carolina State University, Raleigh, North Carolina.
- USDA (US Department of Agriculture, Food Safety and Inspection Service) 1996. 9 CFR Pathogen reduction; hazard analysis and critical control point (HACCP) systems: final rule. *US Federal Register*, 61, 38806-38989, 25 July.

Web Sites relevant to seafood HACCP

FDA-Center for Food Safety & Applied Nutrition-Seafood

<http://vm.cfsan.fda.gov/seafoo1.html>

HACCP Manual – Food Safety Canada

<http://www.haccp-seafood.com/>

NOAA Fisheries-National Marine Fisheries Service

<http://www.nmfs.gov/>

SeafoodNIC Home Page

<http://www-seafood.ucdavis.edu/>

Seafood NIC Home Page – Compendium of Fish and Fishery Products Processing Methods, Hazards and Controls

<http://seafood.ucdavis.edu/haccp/compendium/compend.htm>

Seafood NIC Home Page – HACCP Plans

<http://www-seafood.ucdavis.edu/hacp/Plans.htm>

9 CONSIDERATIONS IN THE APPLICATION OF THE HACCP PRINCIPLES TO SEAFOOD PRODUCTION (Hans Henrik Huss)

The safety of seafood products varies considerably and is influenced by a number of factors such as origin of the fish, microbiological ecology of the product, handling and processing practices and preparations before consumption. Taking most of these aspects into consideration, seafood can conveniently be grouped as shown below (modified from Huss (1994))

- Molluscan shellfish
- Raw fish to be eaten without any cooking
- Fresh or frozen fish and crustaceans – to be fully cooked before consumption.
- Lightly preserved fish products i.e. NaCl <6% in water phase, pH >5.0. The prescribed storage temperature is <5°C. This group includes salted, marinated, cold smoked and gravad fish
- Fermented fish, i.e. NaCl <8% NaCl, pH changing from neutral to acid. Typically, the products are stored at ambient temperature
- Semi-preserved fish i.e. NaCl >6% in water phase, or pH < 5, preservatives (sorbate, benzoate, nitrite) may be added. The prescribed storage temperature is <10°C. This group includes salted and/or marinated fish or caviar, fermented fish (after completion of fermentation)
- Mildly heat-processed (pasteurised, cooked, hot smoked) fish products and crustaceans (including pre-cooked, breaded fillets). The prescribed storage temperature is <5°C
- Heat-processed (sterilised, packed in sealed containers)
- Dried, smoke-dried fish, heavily salted fish. Can be stored at ambient temperatures.

However, the safety of seafood products and –processing cannot be studied in isolation. A large number of hazards are related to the pre-harvest situation or the raw material handling and must be under control, when the raw material is received at the processing factory.

9.1 Hazard analysis of raw material

Most fish and shellfish are still extracted from a wild population, but aquaculture is a very fast growing food production system as outlined in Chapter 2. While there are specific safety aspects associated with wild fish caught in the high sea, the intensive husbandry in aquaculture pose new and increased risks. It is imperative that the HACCP principles are extended beyond the factory-gate and applied throughout the total food production chain from harvest to the consumers' plate.

In a general hazard analysis of the pre-harvest conditions for fish and shellfish and the procedures for handling the raw material before being received at the processing plant a number of significant hazards can be identified:

Pathogenic bacteria

Pathogenic bacteria from the aquatic or general environment may be present in low numbers in all fish and shellfish at the time of harvest (see section 5.1.1.1). This is not a significant hazard as it is unlikely that these pathogens will be there in sufficient numbers to cause disease – even if the fish are eaten raw. However, if growth and toxin production of these organisms is taking place as a result of time/temperature abuse, it is reasonably likely that these pathogens and their toxins could reach unsafe levels. For fish to be eaten raw or used as raw material in products that are not heat-treated, this situation is a significant hazard that must be controlled. High numbers of e.g. pathogenic *Vibrio* spp. may accumulate in bivalves, but it is unlikely that pathogenic levels will be reached (see section 5.1.1.1.).

Pathogenic bacteria from animal/human reservoir may be present in fish and shellfish harvested in contaminated waters. This is a significant hazard for fish and shellfish to be eaten raw due to the low MID (Minimum Infective Dose) for some of these organisms.

The preventive measures for these hazards are control and monitoring of harvest areas for faecal pollution (see section 11.2) and placing a limit on the time between harvest and refrigeration to prevent growth and toxin production.

Viruses

The presence of viruses in the harvest area is of particular concern in molluscan shellfish because:

- environments where molluscan shellfish grow are often subject to contamination from sewage which may contain pathogens (bacteria, viruses)
- molluscan shellfish filter and concentrate pathogens that may be present in the water
- molluscan shellfish are often consumed raw or only partially cooked.

Thus, the presence of virus is a significant hazard in molluscan shellfish and fish to be eaten raw. The preventive measure is control and monitoring of harvesting areas for faecal pollution (section 11.2).

Biotoxins

Contamination of fish and shellfish with natural toxins from the harvest area can cause serious consumer illness. The toxins accumulate in fish when they feed on marine algae, where the toxins are produced. They occur in fish from the tropical and subtropical area (ciguatera) and in shellfish worldwide (see section 5.1.5). In order to determine if ciguatera fish poisoning (CFP) is a significant hazard, some guidance can be provided by the historical occurrence of the toxin and knowledge about the safety of the reefs from which the fish has been obtained.

The preventive measures for the presence of toxins in shellfish are control and classification of shellfish harvesting areas (section 11.1). As a result, shellfish harvesting is only allowed from “safe” waters. Significant elements in this system is the requirement, that all shellfish containers bear a tag that identifies the type and quantity of shellfish, the harvester, harvest location and date of harvest.

The preventive measure for CFP is to ensure that incoming fish have not been caught in an area for which there is a CFP advisory or for which there is knowledge that CFP is a problem.

Biogenic amines

These amines are produced as a result of time/temperature abuse of certain fish species and they can cause illness in consumers. It is therefore a post-harvest hazard, but very often a pre-receiving hazard introduced during handling on board the fishing vessel or during transportation to the plant after landing.

The preventive measure is rapid chilling of fish immediately after capture. Generally, fish should be packed in ice or chilled sea water in less than 12 h after catch or – in case of large fish such as tuna – chilled to an internal temperature of 10°C or less within 6 h after capture.

Parasites

It is reasonably likely that parasites will be present in significant numbers of wild caught fish species – and certain aquaculture fish if they are fed on an unheated processing waste or by-catch fish. Thus, parasites should be considered a significant hazard and a preventive measure to eliminate parasites must be identified during processing of any particular fish products.

Chemicals

Concern for this hazard primarily focus on fish harvested from fresh water, estuaries and near shore coastal waters and on fish from aquaculture. Without proper control it would be reasonably likely to expect that unsafe levels of chemicals could be present in the fish, thus representing a significant hazard. Apart from a few acutely toxic chemicals such as mercury, most chemicals are of medium severity from a health perspective.

The preventive measure is the presence of government controlled monitoring programme (see section 11.3) and ensuring that fish have not been harvested from waters that are closed to commercial fishing. For aquaculture fish the preventive measures are full controls of chemical contamination of the environment (soil/water) surrounding the aquaculture site, control of water quality and of the feed supply. Only approved agrochemicals and veterinary drugs should be used and only according to manufacturers' instructions. Correct withdrawal times must be observed.

Table 9.1 summarizes the hazard analysis of the pre-harvest/pre-receiving situation.

One of the great problems in ensuring the safety of seafood products is that processors often have no control and no information about the history of the raw material. This is a serious weakness and every effort to overcome this problem must be carried out. The significant hazards associated with the raw material must be identified and controlled before the raw material is received at the factory. The receiving step is the first CCP in any seafood processing, and the monitoring procedures will mainly be to check documents (certificates of origin, harvester, date and location of harvesting, copies and results of government monitoring programs, etc.).

Table 9.1 Hazard analysis of pre-harvest conditions and raw material handling.

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria							
indigenous	-	+	high	high	+	-	+
non-indigenous	+	+	high	high	+	+	+
Viruses	+	-	high	high/low ²	+/-	+	+
Biotoxins	+	-	high	high/low ²	+/-	+	+
Biogenic amines	-	+	low	high/low ²	+/-	-	+
Parasites	+	-	low	high	+	-	+
Chemicals	+	-	medium	high/low ²	+/-	+	+

1. PP = Prerequisite Programme

2. depending on fish/bivalve shellfish species, geographical position and season, the likely occurrence may be high or low

Table 9.2 Hazard analysis of processing of bivalve shellfish.

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria							
indigenous	+	+	high	high	+	-	+
non-indigenous	+	+	high	high	+	+	+
Viruses	+	-	high	high	+	+	+
Biotoxins	+	-	high	high	+	+	+
Biogenic amines	-	-					
Parasites	-	-					
Chemicals	+	-	medium	high	+	+	+

1. PP = Prerequisite Programme

9.2 Molluscan shellfish

The molluscan shellfish are harvested by being raked or trawled from the bottom (oysters, mussels) or dug from the sand at low tide (clams and cockles). After harvesting, the shellfish are sorted (size), washed and packed in bags or crates or just left in a pile on deck. The shellfish may be transported and sold live to the consumer or they may be processed (shucked) raw or by use of heat. The heat applied in processing is only enough to facilitate shucking by causing the animal to relax the adductor muscle, and has no effect on the microbial contamination of the animals. The shucked meat is washed, packed and sold fresh, frozen or further processed and canned.

Most molluscs (oysters, mussels, clams, cockles) grow and are harvested in shallow, near-shore estuarine waters. Thus there is a strong possibility that the live animals may be contaminated with sewage-derived pathogens (pathogenic bacteria, viruses) as well as those from the general environment. Also biotoxins and chemicals can be present. Due to the filter feeding of molluscs, a high concentration of disease agents may be present in the animals and therefore constitutes a serious hazard. During processing further contamination with pathogens (bacteria, virus) may take place including growth of bacteria if time and temperature conditions are favourable. As most molluscs are traditionally eaten raw or very lightly cooked, this will further increase the risk. This is confirmed by the epidemiological evidence presented by Garret and Hudak-Roos (1991), who reported that 7% of all outbreaks of seafood-borne diseases (20% of all cases) in the USA in the period 1982-87 were caused by molluscan shellfish.

Although molluscan shellfish constitutes less than 0.1% of the seafood consumed in the USA, they are responsible for a great number of disease outbreaks caused by pathogenic bacteria, toxic marine algae or viruses. Available surveillance data suggests that seafood-borne diseases due to unknown aetiologies, such as unspecified hepatitis and certain *Vibrio* species (*V. parahaemolyticus*, *V. vulnificus*, non O1 *V. cholera*) represent the greatest risk for persons consuming raw molluscan shellfish (Ahmed, 1992). In England and Wales, 17 general outbreaks of gastroenteritis in 1996 and 1997 were associated with consumption of shellfish (Anon., 1998) where a total of 232 people became ill. Five outbreaks were associated with small round structured viruses (SRSV). Astrovirus, diarrhetic shellfish poisoning (DSP) and salmonellae were each associated with one outbreak. In another five outbreaks, a viral aetiology was suspected and in four outbreaks no pathogen was identified.

Viruses were also the most significant cause of shellfish-associated diseases in New York State (Lipp and Rose 1997). A total of 339 seafood-associated outbreaks were reported in the period 1980-94 and shellfish accounted for 216 (64%) outbreaks. Norwalk virus and gastrointestinal virus (small round structured virus) were the most common cause of disease. Thus a number of significant hazards can be identified as shown in Table 9.2 above:

It follows that the significant hazards to be controlled in molluscs processing are:

- a. Contamination with pathogens (bacteria, viruses, biotoxins, chemicals) from the harvesting area
- b. Further contamination with pathogens (bacteria, virus) during processing
- c. Growth of pathogens during processing and storage

The following *preventive measures* can be applied to minimise the risk outlined above:

- re a:
- Control and monitoring of harvesting areas (see Chapter 11). Check for tags and ensure that incoming raw material is from licensed harvesters or certified dealers
 - Depuration (see section 5.1.3)

It is well known that none of these measures are 100% effective, but unfortunately no other CCP can be identified for this hazard (contamination). For this reason, molluscs to be eaten raw should be provided with a warning label to inform consumers of the risk.

re b: • Further contamination during processing is a hazard, which will be controlled by the pre-requisite programme

re c: • limit the time from harvest to refrigeration
• proper chilling (<5°C) at all times during storage (raw material and final product). This aspect is included in the prerequisite programme.

Therefore, the only two critical control points to be identified and included in the HACCP plan are 1) the receiving step where it is possible to exercise control of the source of the molluscs, and 2) the labelling step, where it can be checked that the raw consumption warning is on the label. The following details could be entered in the HACCP plan for the receiving step:

<i>Critical limits</i>	<ul style="list-style-type: none"> • All shell stock containers must bear a tag that discloses the date and place where harvested, the quantity and name and license number of harvester. No molluscs from closed areas must enter the plant
<i>Monitoring program</i>	<ul style="list-style-type: none"> • What: tags, labels, licence of fisherman • How: visual check • When: all containers • Who: receiving employee, supervisor or QC-staff
<i>Corrective actions</i>	<ul style="list-style-type: none"> • reject if untagged or from closed areas
<i>Record keeping</i>	<ul style="list-style-type: none"> • Receiving records on all shellfish (quantity, harvesting details)
<i>Verification</i>	<ul style="list-style-type: none"> • Daily review of records

A generic HACCP plan for production and processing of oysters to be consumed raw is shown in Appendix 4.

9.3 Raw fish – to be consumed raw

The hazards related to these products are primarily associated with the pre-harvest / pre-receiving situation (section 9.1). However, in the hazard analysis some of these hazards can be excluded. As already stated, contamination of raw fish with indigenous pathogenic bacteria is unlikely to be high enough to provoke disease and therefore not a significant hazard. Growth of these bacteria and of histamine producing bacteria is a potential hazard, but it is very unlikely in a product to be eaten raw. For this to happen the fish must be kept for some time at elevated temperatures and in this case also spoilage organism will grow. Since the latter will grow much faster than the pathogens the fish is likely to spoil or be unfit for raw consumption before sufficient growth of pathogens and histamine producing bacteria has taken place. The results of a general hazard analysis are shown in Table 9.3.

The significant hazards are:

- a. Contamination of fish with non-indigenous bacteria, viruses, biotoxins or environmental chemical contaminants (heavy metals, pesticides, drugs in aquaculture)
- b. Presence of parasites.

The following preventive measures can be applied:

- re a: • Control and monitoring of harvesting areas (see Chapter 11) including control of the use of drugs in aquaculture
• Contamination (bacteria, viruses) during processing is controlled by the pre-

- requisite programme
- Prohibition of the use of puffer fish for human consumption
- Avoidance (sorting) of fish with a record of causing ciguatera

re b: • Introduction of a freezing step to eliminate the risk from parasites.

While the preventive measure for control of parasites is 100% effective, this is not the case for control of the pre-harvest contamination of fish with pathogenic organisms or compounds. There are serious weaknesses in a monitoring program as outlined in Chapter 11, and no effective CCP can be identified for the control of ciguatera.

Only two CCPs are identified in the processing of raw fish to be eaten raw:

- the receiving step
- the freezing step

<i>Critical limits</i>	<ul style="list-style-type: none"> • in situations where contamination with non-indigenous pathogens from the harvest area as well as contamination with any chemical is a possibility, a source control or certificate must accompany all lots of fish. This certificate must ensure that the fish were not harvested in waters that are closed to fishing or in any way contaminated with unwanted compounds (i.e. drugs in aquaculture fish) • A list of tolerances for environmental chemical contaminants is show in section 5.2 • Critical limits for the freezing step are show in section 5.1.4
<i>Monitoring program</i>	<ul style="list-style-type: none"> • What: time and temperature at freezing step. Tags, labels, licence of fisherman • How: visual check • When: all containers. Continuous recording of freezing temperature • Who: receiving employee, supervisor or QC-staff
<i>Corrective actions</i>	<ul style="list-style-type: none"> • reject if untagged or from closed areas • adjust freezer. Refreeze material not properly frozen
<i>Record keeping</i>	<ul style="list-style-type: none"> • Receiving records on all fish raw material (quantity, harvesting details) • Temperature records
<i>Verification</i>	<ul style="list-style-type: none"> • Daily review of records

9.4 Fresh/frozen fish and crustaceans – to be fully cooked before consumption

The hazard analysis of these products is fairly straightforward and uncomplicated. The animals are in most cases caught in the sea or freshwater, handled and processed without any use of additives or chemical preservatives and finally distributed with chilling or freezing as the only means of preservation.

The epidemiological evidence has shown that the presence of histamine or biotoxins accounts for nearly 80% of all disease outbreaks caused by “fish”. Low levels of pathogenic bacteria and viruses may be present on raw fish as part of the natural flora and/or as a result of contamination during handling and processing. As the product will be cooked before consumption, it is very unlikely that this low level of pathogens will cause any disease. Even if any growth has taken place in the raw fish to be cooked, it is unlikely to produce any disease. Pathogenic bacteria and viruses are therefore not significant hazards, which need to be controlled.

In contrast the biotoxin (ciguatoxin and tetrodotoxin) are heat stable and cooking the fish before consumption is not likely to eliminate this hazard. In areas where this hazard is likely to occur (see section 5.1.5) it must be noted as a significant hazard.

Similarly the biogenic amines (histamine) are resistant to heat, and if present in the raw fish it is likely to cause disease. Production of histamine in raw fish is therefore a significant hazard that must be controlled (see also section 5.1.2).

Parasites are common in fish, but normal household cooking will kill the parasites, and their possible presence is therefore not a significant hazard.

Chemical contamination of fish is unlikely and not a significant hazard except for aquaculture fish and fish from coastal areas subject to industrial pollution (see section 5.2).

Table 9.3 Hazard analysis of raw fish to be consumed raw.

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria indigenous	-	+	high	low	-		
non-indigenous	+	-	high	high	+	+	+
Viruses	+	-	high	high	+	+	+
Biotoxins	+	-	high	high/low ²	+/-	(+)	+
Biogenic amines	-	+	low	low	-		
Parasites	+	-	low	high	+	-	+
Chemicals	+	-	medium	high/low ²	+/-	+	+

1. PP = Pre-requisite Programme

2. depending on fish/bivalve shellfish species, geographical position and season, the likely occurrence may be high or low

Table 9.4 Hazard analysis of fresh/frozen fish and crustaceans to be cooked before consumption.

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria indigenous	-	+	high	low	-		
non-indigenous	+	+	high	low	-		
Viruses	+	-	high	low	-		
Biotoxins	+	-	high	high/low ²	+/-	+	+
Biogenic amines	-	+	low	high/low ²	+/-	-	+
Parasites	+	-	low	low	-		
Chemicals	+	-	medium	high/low ²	+/-	+	+

1. PP = Pre-requisite Programme

2. depending on fish/bivalve shellfish species, geographical position and season, the likely occurrence may be high or low

Table 9.4 summarize the hazard analysis for this product. Thus, the significant safety hazards are:

- Presence of biotoxins. This hazard only applies to fish from warm waters with a history of causing ciguatera (Ciguatera fish poisoning, CFP) and to puffer fish
- Formation of histamine. This hazard only applies to scombroid fishes (see section 5.1.2)
- Presence of chemicals. This hazard only applies to fish from aquaculture or coastal areas.

For all other fish (~ the large majority of marine fish) there are no safety hazards and no HACCP plan is required, only a Hazard Analysis Worksheet needs to be elaborated.

The preventive measures that can be applied to the significant hazards are:

- Sorting of the catch to exclude puffer fish. Making sure that the fish have not been caught in an area for which there is a CFP advisory or for which there is knowledge of a CFP-problem. It is clear that the latter preventive measure is not 100% effective, but no other means are available
- Rapid chilling of fish immediately after catch to temperatures $<10^{\circ}\text{C}$ is the most important element in any strategy for preventing the formation of histamine. Further chilling towards the freezing point is desirable to prevent long-term low-temperature development of histamine. Control of temperature is part of the prerequisite programme
- The preventive measure for chemical contamination of fish is to compare information on capture area with government ban on fishing.

Based on the above, the only CCP for raw fish to be cooked before consumption is the receiving step [possible histamine formation during processing and storage of scombroid fish is taken care of by the pre-requisite programme]. The following details can be entered in the HACCP plan:

<i>Critical limits</i>	<ul style="list-style-type: none"> • No puffer fish allowed in processing. No fish from an area where there is an CFP advisory is allowed in processing • No fish harvested in an area closed for fishing is allowed in processing • For histamine the critical limit is <50 ppm
<i>Monitoring program</i>	<ul style="list-style-type: none"> • What: sorting procedures, tags, labels, harvesting vessels record decomposition of lot. Temperature records • How: Visual check • When: All lots • Who: Receiving employee
<i>Corrective action</i>	<ul style="list-style-type: none"> • Reject lots with no information on catching area, or if from closed area • Reject the lot or perform histamine analysis on lots of poor sensory quality • Inform harvester, adjust cooling procedures
<i>Record keeping</i>	<ul style="list-style-type: none"> • Receiving records, all lots, temperature records
<i>Verification</i>	<ul style="list-style-type: none"> • Records review, calibration of thermo-recorders, histamine analysis of selected samples

9.5 Lightly-preserved fish products

This group includes fish products with low salt content (Water Phase Salt (WPS) $<6\%$) and low acid content ($\text{pH} > 5.0$). Preservatives (sorbate, benzoate, NO_2 , smoke) may or may not be added. The products may be prepared from raw or cooked raw material, but are normally consumed without any prior heating. Product examples are salted, marinated, cold smoked or gravad fish. These products have a limited shelf life and are typically stored at temperature $\leq 5^{\circ}\text{C}$. The presence in these products of low numbers of pathogenic bacteria normally found in the aquatic and the general environment (*Clostridium botulinum*, pathogenic *Vibrio* sp., *Listeria monocytogenes*) is a potential hazard. Due to their low numbers, the mere presence is not a

significant hazard. However, if these organisms are allowed to grow to high numbers, they are very likely to cause a serious disease, and are therefore representing a significant hazard. It should be remembered, that growth and toxin production can take place in the raw material as well as in the final product.

Contaminations of products during processing with viruses and non-indigenous pathogenic bacteria as well as possible growth of the latter are also potential hazards. However, these hazards are prevented by the prerequisite programme and therefore not likely to occur.

The presence of biotoxins (Ciguatera Fish Poison, CFP) is a potential hazard if the raw material is a fish specie with a history of causing CFP and originating in an area where CFP is known to occur.

Production of biogenic amines is a significant hazard in all products based on scombroid fish or all fish containing large amounts of free histidine in the flesh. The production requires growth of histamine-decarboxylating bacteria. A number of different bacteria are able to produce histamine at various conditions (as discussed in section 5.1.2). It should be remembered that biogenic amines may be produced in the raw material as well as in final products.

Parasites are common in many fish species in all parts of the world, and the processing conditions and preservative parameters for lightly preserved fish products are not sufficient to kill the parasites. Thus, a "processing for safety" step must be included in the process of this type of products to control this significant hazard.

Chemical contamination of raw material is a potential hazard if it originates in aquaculture or certain coastal fisheries. Only if this is the case, should chemical contamination be regarded as a significant hazard.

The hazard analysis is summarized in Table 9.5. The significant hazards are the result of:

- a. Growth of pathogenic bacteria from the aquatic or the general environment
- b. Production of biogenic amines (scombroid fish)
- c. Presence of parasites
- d. Chemical contamination (depending on geographical area).

The following preventive measures can be applied:

- re a:
- Growth of *C. botulinum* can be prevented by WPS $\geq 3.5\%$ and a storage temperature $\leq 5^{\circ}\text{C}$ (see also section 5.1.1.1.)
 - Growth of *L. monocytogenes* cannot with certainty be prevented by the parameters used in the preservation of this category of products
 - An alternative solution is to reduce shelf life of the products to a period of no growth of *L. monocytogenes*. The length of this period needs to be established by experimentation
- re b:
- Storage at low temperature ($< 5^{\circ}\text{C}$) will prevent the growth of a number but not all of histamine producing bacteria. There are no experimental data to demonstrate complete control of this hazard
- re c:
- Introduction of a freezing step (-20°C for at least 24 h, see also section 5.1.4)
- re d:
- Securing raw material from areas with no chemical contamination.

Based on the considerations above, the following CCPs can be identified: Receiving step, salting step and freezing step. The following details can be entered in the HACCP plan:

<i>Critical limits</i>	<ul style="list-style-type: none"> • Receiving step: only raw material of good sensory quality will be used. No fish from an area where there is a CFP advisory must be used. No fish harvested in area closed for fishing is allowed • Salting: $\text{WPS} \geq 3.5\% \text{ NaCl}$ • Freezing step: -20°C for at least 24 hours • Storage temperature $\leq 5^{\circ}\text{C}$
<i>Monitoring program</i>	<ul style="list-style-type: none"> • What: sensory quality of raw material. Certificate of origin of fish. Salting procedures. Temperatures and times of freezing • How: visual • When: all lots. Continuous recording of temperature • Who: receiving employee. QC staff
<i>Corrective action</i>	<ul style="list-style-type: none"> • Reject lots of poor quality or with no certificate of origin • Adjust salting process • Check WPS in lots produced when process is out of control • Adjust freezing procedures.

9.6 Fermented fish

Traditionally the term “fermented fish” covers both enzyme hydrolysed and microbial fermented fish products. However, a clear distinction should be made between these products. Thus, Paludan-Müller (2002) suggests to define fermented fish as “products which contain a carbohydrate source and in which the level of salt is less than 8% water phase salt (WPS)”. This level of salt ($\leq 8\%$) allows the fermentative growth of lactic acid bacteria and a concomitant decrease in pH to <4.5 . In contrast enzyme hydrolysed fish has a $\text{WPS} > 8\%$ and a final pH between 5-7. A large number of different fermented fish products are found in South-East Asia. The products are traditionally stored at ambient temperatures and consumed without any cooking. Fermented fish products have been associated with a number of outbreaks of food-borne diseases such as botulism, trematodiosis, salmonellosis and vibriosis.

The natural presence of pathogenic bacteria from the aquatic and general environment is not considered a significant hazard in this product due to the low numbers. However, conditions for growth of some of these organisms (*C. botulinum* type A and B, *Listeria monocytogenes*, *Vibrio* sp.) are good until the pH decreases to near 4.5. This takes about 1-2 days at 30°C in a natural fermentation. Rapid and adequate acidification is therefore the preventive measure for this significant hazard. For complete safety, temperatures during fermentation should be kept at $<10^{\circ}\text{C}$ until final pH has been reached.

Contamination of fermented fish products with pathogenic bacteria from the animal/human reservoir and with pathogenic virus are potential hazards, which will be controlled by the prerequisite programme.

Most fermented fish products are based on freshwater fish as raw material. However, if marine fish are used, the presence of biotoxin (CFP) should be considered a potential hazard as discussed in section 9.1.

Formation of biogenic amines (histamine) is a health hazard primarily related to marine, scombroid fish species and is not a potential hazard when freshwater fish are used as raw material.

Parasites, particularly trematodes are very common in fish used as raw material for fermented fish. As there is no killing step for these parasites in the normal processing they are very likely to cause disease and must be regarded as a significant hazard. The preventive measures are food safety education and to bring about changes in the traditional consumption practices of eating non-cooked fermented fish. Until then fermented fish to be eaten without any cooking must have a freezing step included (see section 5.1.4). The concern for chemical hazards are related to the raw material and described in section 9.1.

Table 9.5 Hazard analysis of lightly preserved fish products.

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria							
indigenous	-	+	high	high	+	-	+
non-indigenous	+	+	high	high	+	-	+
Viruses	+	-	high	high	+	-	-
Biotoxins	+	-	high	high/low ²	+/-	+	+
Biogenic amines	-	+	low	high/low ²	+/-	-	+
Parasites	+	-	low	high	+	-	+
Chemicals	+	-	medium	high/low ²	+/-	+	+

1. PP = Prerequisite Programme

2. depending on fish/bivalve shellfish species, geographical position and season, the likely occurrence may be high or low

Table 9.6 Hazard analysis of fermented fish.

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria							
indigenous	-	+	high	high	+	-	+
non-indigenous	+	+	high	high	+	-	-
Viruses	+	-	high	high	+	-	-
Biotoxins	+	-	high	high/low ²	+/-	(+)	+
Biogenic amines	-	+	low	high/low ²	+/-	-	+
Parasites	+	-	low	high	+	-	+
Chemicals	+	-	medium	high/low ²	+/-	+	+

1. PP = Prerequisite Programme

2. depending on fish/bivalve shellfish species, geographical position and season, the likely occurrence may be high or low

The hazard analysis for fermented fish products is summarized in Table 9.6. The CCPs in production of fermented fish are:

Receiving step: Check on raw materials as described in section 9.1

Time/temperature conditions during fermentation: Inhibition of growth of indigenous pathogens

Freezing step: Control of parasites.

9.7 Semi-preserved fish

These are fish products with >6% water phase salt (WPS) or a pH <5.0. Preservatives (sorbate, benzoate, nitrate) may or may not be added. These products require chill storage (< 10°C) and may have a shelf life of 6 months or more. Normally, there is no heat-treatment applied neither during processing nor in the preparation before consumption. Traditional production often includes a long ripening period (several months) of the raw material before final processing. Product examples are salted and marinated fish, fermented fish and caviar products.

There is epidemiological evidence that this type of products has been the cause of illness related to the presence of bacterial toxins (botulism), parasites, biotoxins and histamine.

The presence of low numbers of pathogenic bacteria normally found in the environment is not a significant hazard in these products (not likely to cause disease). Contamination with non-indigenous pathogens (bacteria and viruses) is a potential hazard to be prevented by the prerequisite programme.

Growth and possible toxin production of pathogenic bacteria is not possible in these products if correctly processed and storage temperature is kept at $\leq 10^{\circ}\text{C}$. As for lightly preserved fish products it must be pointed out that growth and toxin production may take place in the raw material. Bacterial toxins, incl. botulinum toxins are very stable at high salt and low pH (Huss and Rye Petersen, 1980). Any toxin present or preformed in the raw material will be carried over to the final product, and this hazard can only be controlled by having full control over the complete handling and processing steps from harvesting to consumption.

Biotoxins (ciguatera) is a potential hazard only if the raw material used is a fish specie with a history of causing CFP and originating in an area where CFP is known to occur. This is not very likely to happen, and therefore biotoxins are not a significant hazard for this product.

Production of biogenic amines may take place both in the raw material and in the final product. It is a significant hazard as it is very likely to occur in scombroid fish if there is a loss of control.

Parasites are very common in fish species used as raw material for semi-preserved products. This hazard is therefore significant (likely to occur) and must be prevented.

Chemical contamination of raw material is a potential hazard if it originates from aquaculture or certain coastal fisheries. Table 9.7 summarizes the hazard analysis of these products. The CCPs in production of semi-preserved fish products are:

Receiving step: Check on raw material as described in section 9.1

Time-temperature conditions: Chilled storage for prevention of growth of pathogens.
Critical limits are:
< 5°C for raw materials
< 10°C for final products

Salting step: Critical limit is WPS $\geq 6\%$

Critical limits for killing parasites: see section 5.1.4

Addition of acids and/or
preservatives:

Critical pH limit ≤ 5

Freezing step:

Killing of parasites. Critical limits, see section 5.1.4.

Monitoring procedures, corrective action programme and verification procedures must be set up and records kept of all actions

9.8 Mildly heat-processed fish products

A number of fish products receive a heat treatment during processing. Examples are: pasteurised or cooked and breaded fish fillets, cooked shrimp and crabmeat, cook-chill products and hot smoked fish. After the heat-treatment the various products may pass through further processing steps before being packed and stored/distributed as chilled or frozen products. Some of these products may receive additional heat treatment before consumption (cooked and breaded fillets, cook-chill products) or they may be eaten without further treatment (hot smoked fish, cooked shrimp). Thus, some of these products are ready-to-eat and extremely sensitive to contamination after the heat treatment.

To further illustrate the safety aspects, there is ample epidemiological evidence that this type of product has been the cause of food poisoning due to growth of coagulase-positive *Staphylococcus aureus* and enteropathogenic organisms among the Enterobacteriaceae and Vibrionaceae. Marine crustaceans, usually shrimp, crab or dishes made from them, accounted for 25 outbreaks of food-borne diseases reported in the USA during the period 1977-84 (Bryan, 1988).

In the application of the HACCP system to these types of products, the heat-treatment is a very critical processing step. Hazards identified before this step may or may not be eliminated depending on the degree of heat being applied. Most criteria for heat-treatments have been laid down as a consequence of economical and technological considerations and not for hygienic or public health reasons. Increased safety will be obtained if the cooking/heating procedures could be designed to eliminate vegetative cells of pathogens and spores of the most sensitive species. Generally, a reduction of six orders of magnitude (six logarithms) in the level of contamination is recommended. This performance criterion is the so-called 6D process ("D" stands for "decimal reduction") as described in section 13.2.

Listeria monocytogenes is normally used as a target organism for measuring the heat treatment and is regarded as the most heat-resistant food-borne pathogen that does not form spores.

Most products in this group are depending entirely on the heating process and chilled storage for safety and shelf life as they do not contain any bacteria controlling ingredients. It is very likely that pathogens will cause disease if these factors are out of control. Pathogen survival during the cooking/heating procedure and pathogen growth during storage are significant hazards that must be included in the HACCP plan. In contrast, it is very unlikely that viruses, parasites and histamine producing bacteria will survive the heat treatment.

Recontamination of products after the heat-treatment and before packaging can also cause consumer illness. In many productions this hazard will be controlled by the prerequisite programme. In others, where e.g. the recontamination is caused by faulty container sealing or incorrect hot-filling procedures, recontamination is a significant hazard that needs to be included in the HACCP plan.

Considerations to the possible presence of biotoxin and chemical contamination should be as outlined in section 9.1. Table 9.8 summarizes the hazard analysis of these products.

In a simple production (e.g. cooked shrimp vacuum-packed in plastic bags) the significant hazards are:

- a. Survival of pathogens
- b. Recontamination after cooking
- c. Growth of pathogens
- d. Raw material quality (chemical hazards).

The CCPs during production will be:

Receiving step: Control of raw materials

Cooking step: Control of survival of pathogens

Recontamination and growth of pathogens will be taken care of by the prerequisite programme. The critical limits for the cooking step (time/temperature conditions) should be set at a point that if not met the safety of the product may be questionable. If a more restrictive limit is set, the result will be a loss of product.

Table 9.7 Hazard analysis of semi-preserved fish.

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria							
indigenous	-	+	high	high	+	-	+
non-indigenous	+	+	high	high	+	-	-
Viruses	+	-	high	high	+	-	-
Biotoxins	-	-					
Biogenic amines	-	+	low	high/low ²	+/-	-	+
Parasites	+	-	low	high	+	-	+
Chemicals	+	-	medium	high/low ²	+/-	+	+

1. PP = Prerequisite Programme

2. depending on fish/bivalve shellfish species, geographical position and season, the likely occurrence may be high or low

Table 9.8 Hazard analysis of mildly heat-processed fish.

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Survival or re- contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria							
indigenous	+	+	high	high	+	-	+
non-indigenous	+	+	high	high	+	-	+
Viruses	+	-	high	high	+	-	+
Biotoxins	+	-	high	high/low ²	+/-	+	+
Biogenic amines	-	+	low	high/low ²	+/-	-	+
Parasites	+	-	low	low	-	-	+
Chemicals	+	-	medium	high/low ²	+/-	+	+

1. PP = Pre-requisite Programme

2. depending on fish/bivalve shellfish species, geographical position and season, the likely occurrence may be high or low

9.9 Heat-sterilized fish products packed in sealed containers (canned fish)

The basis for canning is the use of thermal processing to achieve sterility of the final product. The containers are distributed at ambient temperatures and often stored for months even years under these conditions. The contents of the cans are normally eaten without any heating immediately before consumption.

Canned fish has been the cause of outbreaks of botulism and cases of histamine and staphylococcal enterotoxin poisoning (Ababouch, 2002). The general hazard analysis is shown in Table 9.9.

The significant hazards related to this type of products are:

- Quality of raw material (biotoxins, chemicals)
- Survival of pathogens (*C. botulinum*) during heat processing
- Presence of heat-stable toxins (biotoxins, histamine, *S. aureus* ET)
- Recontamination of product after heat processing (faulty containers, poor sealing, contaminated cooling water, faulty container handling).

The CCPs for these hazards are:

Receiving step:	Hazards are raw material quality as described in section 9.1 Quality of cans Critical limit: Cans must meet container specifications for safety. Monitoring: Letter of guarantee from supplier. Visual examination of all lots of empty cans Corrective action: Reject defect cans. Contact supplier
Filling:	Corrective filling is important for proper heat-penetration Visual check regularly (every half hour) by floor supervisor
Sealing:	Faulty sealing may result in recontamination Can closures must be checked at regular intervals (every half hour) visually and always when setting up a new machine or adjusting an old one. Tear down measurements must be done at the beginning of the shift and every 2 hours thereafter by Q.C. Corrective actions: Shut down of processing line and inform plant manager. All products produced since last good check is put on hold. The cause of the problem must be identified before start up again Any actions and measurements are recorded
Retorting:	The hazard is survival of pathogens Critical limit is the botulinum cook or 12-D process (see section 5.1.1.1.) If time/temperature requirements are violated, products must be put on hold for reprocessing and the cause must be identified. Records on all actions and measurements must be kept The verification programme should include a review of all operations and monitoring procedures and calibration of thermometers and automatic recorders
Cooling:	Recontamination is possible if minute quantities of water enter the can. Use of chlorinated cooling water is a safe precaution. There must be measurable residual chlorine in the water (critical limit) and samples should be tested at least two times per day by a designated person (monitoring).

Post-process handling: Contamination of hot and wet cans with *S. aureus* is prevented by isolation of the storage area of hot and wet cans and application of GHP by personnel.

Additional verification procedures are common practice and in some cases a legal requirement (EC 1991). This includes checks carried out at random to ensure that products have undergone appropriate heat treatment. This requirement involves taking samples of the final product for:

- incubation tests. Incubation of samples must be carried out at 37°C for seven days or at 35°C for ten days or any other equivalent combination
- microbiological examination of contents of containers in the establishments laboratory or in any other approved laboratory.

9.10 Dried, smoke-dried, heavily-salted fish

These are products with a very high salt content (>10% WPS) and/or a very low water activity ($a_w \leq 0.85$). Dried or salted fish are usually considered stable at high temperatures and therefore stored and distributed at ambient temperatures.

No growth of pathogens is possible in these products if correctly processed, not even at ambient temperatures. The most salt-tolerant pathogenic organism is *Staphylococcus aureus* (which can grow at $a_w \geq 0.83$ and produce toxin at $A_w \geq 0.85$, see also section 5.1.1.2), and this organism should therefore be considered as target pathogen for drying.

A critical phase in processing is the time until salt has penetrated and the WPS reaches 10% or the a_w is below 0.85 in the thickest part of the fish. For this reason larger fish (>15 cm in length) should be eviscerated prior to processing.

Contamination of dried or salted fish with enteropathogenic bacteria and viruses is a potential hazard, which will be prevented by the prerequisite programme.

The presence of toxic fish and chemical contamination of raw material are potential hazards as discussed in section 9.1.

The possible presence of parasites is not a significant hazard in these products. It is very unlikely they will cause a disease due to the rapid killing of the parasites in an environment with very high salt content (see section 5.1.4).

Table 9.9 Hazard analysis of heat sterilised products packed in sealed containers (canned fish).

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Survival and/or re- contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria							
indigenous	+	+	high	high	+	-	+
non-indigenous	+	+	high	high	+	-	+
Viruses	+	-	high	low	-		
Biotoxins	+	-	high	high/low ²	+/-	+	+
Biogenic amines	+	+	low	high/low ²	+/-	-	+
Parasites	+	-	low	low	-	-	
Chemicals	+	-	medium	high/low ²	+/-	+	+

1. PP = Prerequisite Programme

2. depending on fish/bivalve shellfish species, geographical position and season, the likely occurrence may be high or low

Table 9.10 Hazard analysis of dried, smoke-dried or heavily salted fish.

Organism/ component of concern	Potential hazard		Analysis of hazard			Control	
	Re- Contamination	Growth	Severity	Likely occurrence	Significant	Govt. monitoring programme	PP ¹ Incl. in HACCP plan
Pathogenic bacteria							
indigenous	-	-					
non-indigenous	+	-	high	high	+	-	+
Viruses	+	-	high	high	+	-	+
Biotoxins	+	-	high	high/low ²	+/-	+	+
Biogenic amines	-	+	low	high/low ²	+/-	-	+
Parasites	+	-	low	low	-	-	
Chemicals	+	-	medium	high/low ²	+/-	+	+

1. PP = Pre-requisite Programme

2. depending on fish/bivalve shellfish species, geographical position and season, the likely occurrence may be high or low

When scombroid fish are used as raw material, formation of histamine is a significant hazard. Histamine may be formed in the raw material before processing (see section 9.1.) but also in the final product as some halophilic bacteria are able to produce this compound (Kimmerling *et al.*, 2001). However, there is some uncertainty if this is a theoretical risk only. There are no reported cases of histamine poisoning from these products and there are no experimental data to demonstrate the possible risk.

The CCPs in the production of dried or salted fish are:

- Receiving step: Hazard to be controlled is the raw material quality (presence of biotoxin, chemical contamination and histamine)
- Salting/drying step: The hazard is growth of pathogens
Critical limit is time to reach 10% WPS or a_w 0.85 in fish flesh.

9.11 Seafood risk categories

In ranking seafood into risk categories, the method of NACMCF (1992) with some modifications has been applied. The following six hazard characteristics and risk factors have been considered:

1. No terminal heat treatment. Apart from raw fish to be eaten cooked or fried, all other fish products are ready-to-eat
2. The safety record. Is there any evidence, that this particular product has been associated with food borne disease many times – or with very serious diseases? With reference to tables in section 4.1 it can be stated, that the safety record is poor for:
 - molluscan shellfish and fish to be eaten raw due to the presence of (accumulated) biological hazards (viruses, pathogenic bacteria, parasites, biotoxins)
 - molluscan shellfish, tropical reef fish and scombroid fish to be cooked before consumption due to the presence of heat stable aquatic toxins or scombrototoxin
 - presence of heat stable biogenic amines in canned sterilised products and few outbreaks of botulism caused by the same type of product
 - some fermented fish; e.g. salted fish from the Middle East or products from Alaska
3. The production/processing does not include a Critical Control Point for at least one identified hazard. This situation applies to the:
 - accumulation of biological hazards in shellfish (see section 5.13)
 - presence of biotoxins (ciguatera) in fish from tropical reefs (see section 5.13).
4. The product is subject to potentially harmful contamination or recontamination after processing and before packaging. All raw fish and fish product, which has not been subject to any bactericidal treatment, are likely to harbour pathogenic organisms as part of their natural flora (see section 5.1.1.). Potentially harmful recontamination is possible and reasonably likely to occur for products being mildly heat-treated before being placed in the final container (cooked shrimp, hot smoked fish). However, also the risk associated with lightly preserved fish and fish and shellfish to be eaten raw may increase due to this factor (e.g. contamination of cold smoked fish with *L. monocytogenes*).
5. Products with a potential for abusive handling. This hazard refers mainly to handling and storing the fish product at abuse (elevated) temperatures. With the exception of sterilised, canned or fully preserved products, there is a potential for this hazard for all other types of fish products. However, this is not likely to occur for fish to be consumed raw, as spoilage will be very fast at elevated temperatures
6. Growth of pathogens. The growth of pathogens, particularly in ready-to-eat products is a serious hazard. Two potential hazards of this nature are known and likely to occur: the possible growth of *L. monocytogenes* in lightly preserved fish products and the growth of *C. botulinum* in some types of fermented seafoods. Growth of other pathogens in preserved

or heat-processed products is possible only if the preserving parameters are not applied as specified (see text) and other potential hazards are in fact occurring (temperature abuse, recontamination of heat processed fish). Spoilage bacteria will grow in all types of fish products (except sterilised products) and in most cases they will grow faster than any pathogen. This is particularly the case in raw, unprocessed or unpreserved fish, and for this reason growth of pathogens it is not considered an additional hazard likely to occur and influence the safety of this product.

The above considerations above are summarized in Tables 9.11 and 9.12. The various seafoods are assigned to a risk category in terms of health hazards by using a “+” (plus) to indicate a potential risk related to the hazard characteristics. The number of plusses will then determinate the risk category of the seafood concerned.

Table 9.11 Risk categories for fresh seafood products (modified after Huss *et al.*, 2000).

Seafood product	Characteristic that increases risk			Events that are reasonably likely to occur and which will increase risk			Risk Category
	No terminal heat application	Bad safety record	No CCP for identified Hazard	Harmful recontamination	Abusive handling	Growth or accumulation of hazard	
Molluscan shellfish							
Live, raw	+	+	+	+	+	+	High ¹
Cooked	-	+	+	-	-	+	Medium
Raw Fresh / frozen fish and crustacean							
Tropical reef	+	+	+	+	-	+	High
Scombroid	+	+	-	+	-	-	Medium
Other	+	-	-	+	-	-	Low
Fresh / frozen fish and crustacean to be cooked							
Tropical reef	-	+	+	-	-	+	Medium
Scombroid	-	+	-	-	+	+	Medium
Other	-	-	-	-	-	-	Low

1. High risk products have 4 or more plusses. Medium risk products have 3 plusses. Low risk products have 2 plusses or less.

Table 9.12 Risk categories for processed seafood products (modified after Huss *et al.*, 2000).

Seafood product	Characteristic that increases risk			Events that are reasonably likely to occur and which will increase risk			Risk Category
	No terminal heat application	Bad safety record	No CCP for identified Hazard	Harmful recontamination	Abusive handling	Growth or accumulation of hazard	
Lightly preserved NaCl < 6%, pH > 5.0; e.g. cold-smoked	+	-	(-)	+	+	+	High ¹
Fermented NaCl < 8%, pH changing	+	+	(+)	+	-	+	High
Semipreserved NaCl > 6%, pH < 5.0; e.g. marinated	+	-	-	-	+	+	Medium
Heat processed Hot smoked, pasteurised	+	-	-	+	+	+	High
Heat processed Canned, sterilised	+	+	-	-	-	-	Low
Dried, smoke dried, heavily salted	+/-	-	-	-	-	-	Low

1. High risk products have 4 or more plusses. Medium risk products have 3 plusses. Low risk products have 2 plusses or less

References

- Ababouch, L. 2002. HACCP in the fish canning industry. In: Bremner, H.A. (ed) *Safety and quality issues in fish processing*. Woodhead Publishing Limited, Cambridge, UK. pp. 31-53.
- Ahmed, F.E. 1992. Review: Assessing and managing risk due to consumption of seafood contaminated with microorganisms, parasites and natural toxins in the U.S. *International Journal of Food Science and Technology* 27, 243-260.
- Anonymous 1998. Communicable Disease Report, vol 8, No 3, PHLS Public Health Laboratory Service, UK.
- Bryan, F.L. 1988. Risks associated with vehicles of foodborne pathogens and toxins. *Journal of Food Protection* 51, 498-508.
- EC (European Commission) 1991. Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products *Official Journal of the European Communities* L 268 , 24/09/1991 p. 0015 – 0034.
- Huss, H.H. 1994. *Assurance of Seafood Quality*. FAO Fisheries Technical Paper No. 334., FAO, Rome, Italy.
- Huss, H.H. and E. Rye Petersen 1980. The stability of *Clostridium botulinum* Type E toxin in a salty and/or acid environment. *Journal of Food Technology* 15, 619-627.
- Huss, H.H., P.K. Ben Embarek and A. Reilly 2000. Prevention and control of hazards in seafood. *Food Control* 11, 149-156
- Garrett, E.S. and M. Hudak-Ross 1991. Development of an HACCP based inspection system for the seafood industry. *Food Technology* 45, 53-57.
- Kimma, B., Y. Konagaya and T. Fujii 2001. Histamine formation by *Tetragenococcus muriaticus* a halophilic lactic acid bacterium isolated from fish sauce. *International Journal of Food Microbiology* 70, 71-77.
- Lipp, E.K. and J.B. Rose 1997. The role of seafood in foodborne diseases in the United States of America. *Revue Scientifique et Technique Office International des Epizooties* 16, 620-640.
- NACMCF (National Advisory Committee on Microbiological Criteria for Foods) 1992. *Hazard Analysis Critical Control Point System*. FSIS Information Office, Washington DC, USA.
- Paludan-Müller, C. 2002. Microbiology of fermented fish products. Ph.D. thesis. Danish Institute for Fisheries Research, Department of Seafood Research, Lyngby, and The Royal Veterinary and Agricultural University, Copenhagen.

10 APPLICATION OF HACCP PRINCIPLES IN THE MANAGEMENT OF OTHER QUALITY ASPECTS (Lone Gram)

Whilst the HACCP principles and concepts of farm-to-fork in risk assessments are clearly developed to ensure food safety, the approach and thinking can easily be applied to cover other quality aspects, such as sensory quality, composition or labeling, as well. Instead of identifying the hazards of the process / product, potential defects are considered. The steps or points at which control of the defects are to be controlled are called defect action points (DAPs) (CAC, 2002) as a parallel to the critical control points (CCPs) where hazards can be controlled. Similar to the procedures for CCPs, limits, monitoring procedures, corrective actions and verification procedures must be established at the DAPs.

Defect

A condition found in a product which fails to meet essential quality, composition and/or labelling provisions of the appropriate standards or specifications (NOAA, 2000)

Defect Action Point (DAP)

A point, step or procedure at which control can be applied and a defect can be prevented, eliminated or reduced to acceptable level, or a fraud risk eliminated (NOAA, 2000)

The analysis of potential defects and identification of DAPs follows the same procedures as when conducting a hazard analysis. For instance, the decision tree used to determine if a point is really a critical control point, can be used equally well to decide if a given point is a DAP.

Defects may, as hazards, be of (micro) biological, chemical or physical nature. The substitution of one (lower value) fish species for another (high value) is an example of a biological defect, fraud. Similarly, raw materials for production of semi-preserved herring must have specific lipid content for the right ripening and texture to develop. Therefore lower or higher lipid content is a biological defect. This should be monitored on the incoming raw material and batches with wrong lipid content should be used for other products.

Other kinds of defects include incorrect weight or incorrect labelling.

10.1 Microbiological aspects

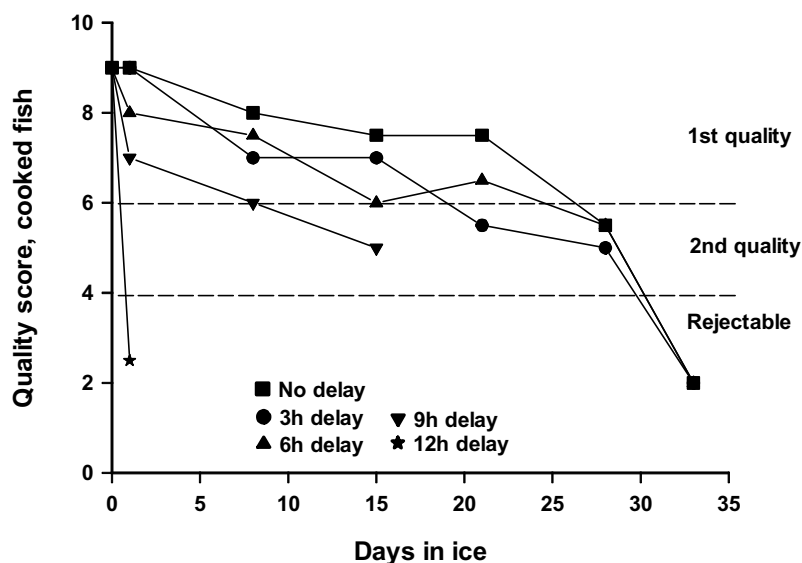
This book has so far focused on the risk to consumer health arising from the presence and growth of microorganisms. However, microorganisms may have other adverse effects on the quality of fish and fish products. Thus growth and activity of microorganisms is the major cause of decomposition (spoilage) of all types of products where microorganisms have not been completely eliminated (such as in canned foods) or where growth of microorganisms has not been completely arrested (such as in frozen foods). A description of the spoilage patterns of different fish products and the microorganisms involved can be found in Huss (1995), Gram and Huss (2000) and Gram *et al.* (2002).

It has been estimated that between 10 and 50% of all foods produced are lost *post harvest* or *post slaughter* due to microbial activity (Kaferstein and Moy, 1993; cf Baird-Parker, 2000; WHO, 1995). Decomposition or presence of filth is the most common cause of detention of fish products imported into the US (FDA, 2002). Thus, out of 4,527 detentions in April, May and June 2002, 443 of the detained products were fish or seafood products. Of the 443 detentions, half (213) were detained because of filth and/or spoilage (FDA, 2002).

In principle control of decomposition of fish and fish products is simple since low temperature will retard all spoilage processes. In contrast, just a few hours exposure to high temperatures may accelerate spoilage. In some tropical countries, icing is not done on board the fishing boats and this leads to rapid reduction in eating quality (Figure 10.1). It also follows indirectly from the figure that temperature during storage is critical. Loss of quality occurs rapidly.

Figure 10.1

Quality changes in iced Nile perch, iced immediately after trawl-catch (v) or with 3, 6, 9 or 12 hours delay in icing (Gram, 1989).



Therefore control of the time x temperature chain is critical. This DAP applies to all steps from catch, through processing and distribution to the consumer. Several initiatives are on the way, where different tags will allow monitoring of the accumulated time x temperature, however, none are used commercially in the fish industry. To date, the most efficient and reliable way of determining whether or not this DAP is under control is sensory evaluation.

Monitoring of time x temperature during handling and processing can be done by date marking of boxes and containers and by visual inspection of icing and chilling conditions. Time and temperature recording at specific points and during processing should preferably be controlled automatically. Process flow must be designed to avoid stops and interruptions, and chill rooms must be supplied with thermometers. Visual inspection (e.g. quantity of ice) and control checks of temperature must be done in a daily routine. A log of temperature recordings (manually or automatically read) must be kept and be available at all times.

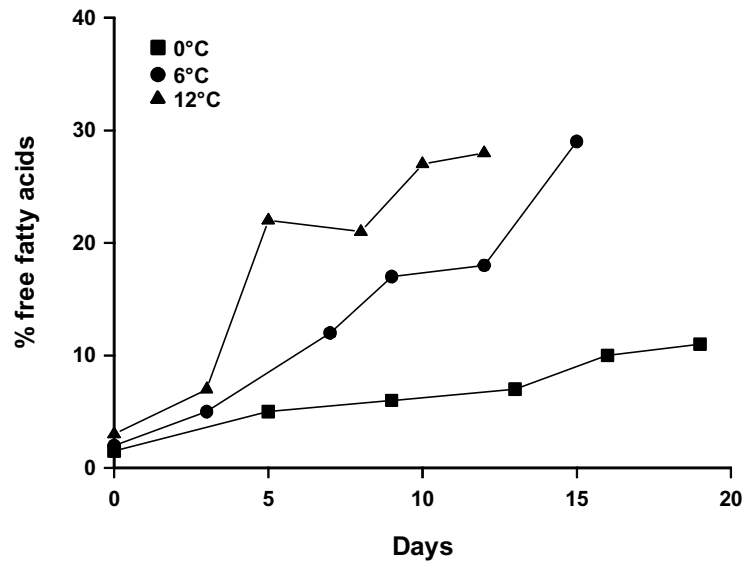
Off-flavour may also arise in fish due to microbial growth that is not related to spoilage aspects. The muddy flavour often detected in fresh water fish such as trout is caused by the compound geosmin. Blue-green-algae, actinomycetes and cyanobacteria are capable of producing geosmin. The compound accumulates in the fish flesh and is not toxic to fish nor humans. Again, sensory evaluation is the most reliable detection technique. Allowing the fish to swim in clean water for 4-7 days can reduce (purge) the off-flavour.

10.2 Chemical aspects

Chemical defects refer to quality deterioration due to chemical reactions. Very common are the changes which may occur in the fish lipid fraction. This may be either oxidation or hydrolysis. Both reactions result in the production of substances with unpleasant – rancid – off-flavours. Other changes such as dehydration and autolysis may lead to poor texture and freeze burns. During frozen storage, especially of gadoid fish species, trimethylamine oxide (TMAO) is reduced to dimethylamine (DMA) and formaldehyde (FA). This adds to the changes in texture and flavour occurring during frozen storage.

Availability of oxygen (or other oxidizing compounds) is required for oxidative rancidity to develop and non-oxygen containing packaging of fatty fish species will control this defect. As with microbial reactions, temperature is important. Thus, the development of free fatty acids in herring is greatly accelerated at 12°C as compared to 0°C (Figure 10.2)

Figure 10.2
Development of free fatty acids in herring stored at different temperatures (redrawn from Huss 1995).



Any contamination occurring during processing – which is not included as a hazard in the HACCP plan – will also constitute a defect. This could be (re)contamination by cleaning agents, by mechanical grease or by using wrong ingredients. During canning of foods, metals may leak from the cans and contaminate the product.

10.3 Physical aspects

Defects of physical nature cover a range of aspects such as the presence of small bones, foreign matter (e.g. hairs, straw) or material which should not be there (scales, pieces of skin etc.). Other physical defects can damage the packaging causing bruising or change of carton shape.

10.4 Example

CAC (2002) provides a good example of the use of defect analysis and identification of DAPs (Tables 10.1, 10.2 and 10.3). As with the hazard-analysis, the production flow must first be outlined (Figure 10.3).

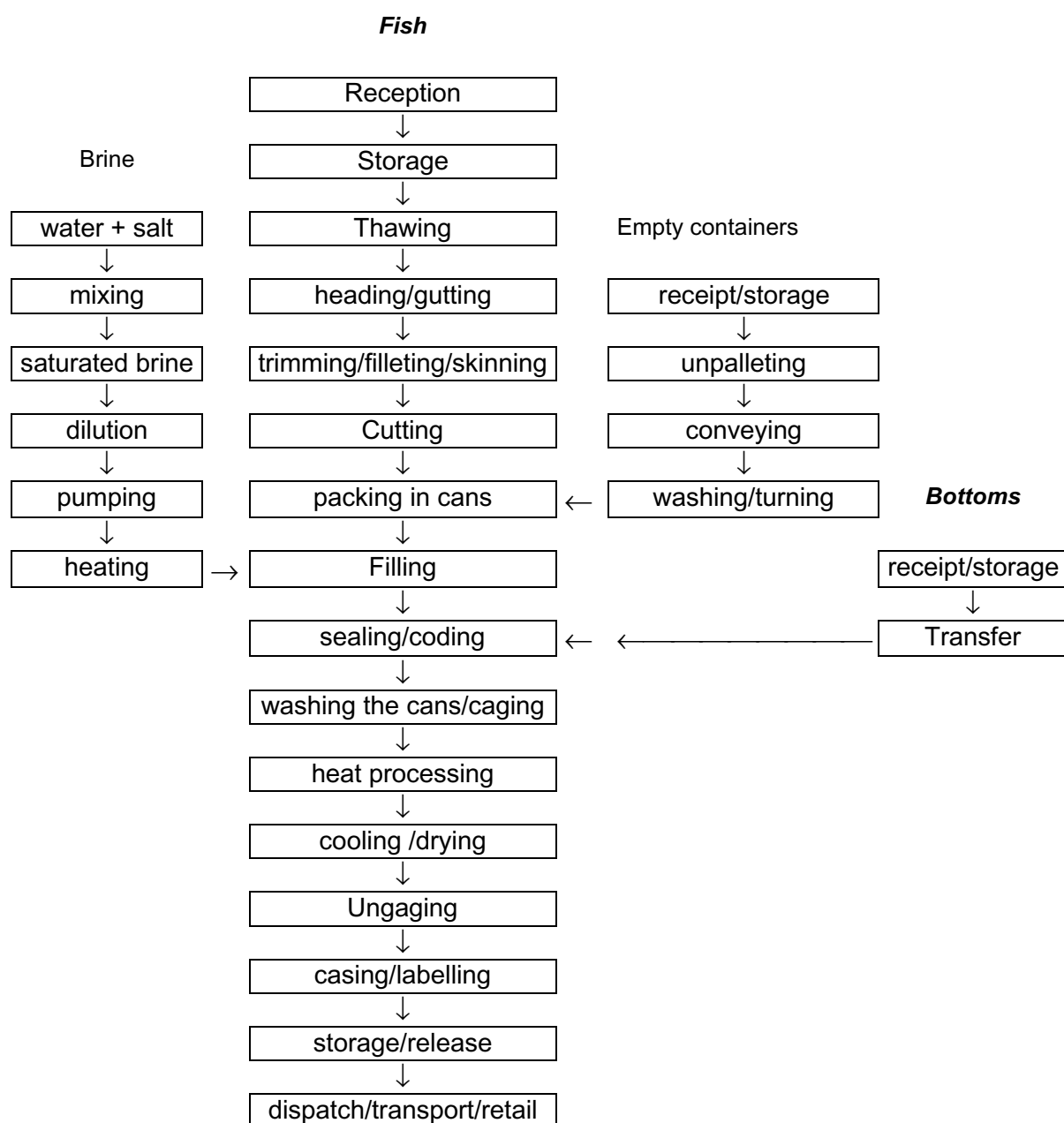


Figure 10.3 Example of a flow diagram for a processing line of canned tuna fish in brine (CAC, 2002).

The defect analysis identifies several possible defects (Table 10.1).

Table 10.1 An example of potential defects of canned tuna (modified from CAC, 2002).

Defect type	In raw tuna	During processing, storage or transportation
Biological	spoilage	spoilage, survival and growth of spoilage microorganisms
Chemical	oxidation	Oxidation
Physical		objectional matter (viscera, scales, skin...), formation of struvite crystals, container defects
Other	species substitution	abnormal flavours, incorrect weight, incorrect coding, incorrect labelling

Spoilage is as outlined mainly a problem of time x temperature control of the non-frozen or non-canned fish. Further analysis points to the development of rancid off-odours as a potential defect. Each processing step should then be considered to determine if it is a possible action point for the defect. Table 10.2 illustrates the preliminary analysis of step two in the fish flow, i.e. the frozen storage step. Since the frozen tuna are often stored in bulk, the frozen storage period could be a potential DAP.

Table 10.2 An example of the significant defect rancidity during the storage of frozen tuna for canning tuna (modified from CAC, 2002).

Processing step	Potential defect	Is the potential defect significant	Justification	Control measures
Storage of frozen tuna	persistent and distinct rancid odours and flavours	Yes	product does not meet quality or customer requirements	<ul style="list-style-type: none"> • glazing • controlled temperature in the storage premises • packaging • stock management procedure • maintenance of procedure of the refrigeration system • personnel training and qualifications

The analysis indicates that the frozen storage could be a DAP for development of rancid off-odours. A more detailed analysis – similar to the decision tree for critical control points – is presented in Table 10.3.

Table 10.3 A schematic example of a defect analysis with corresponding control measures and the application of the Codex decision tree for the determination of a defect action point during storage of frozen tuna (CAC, 2002). Q = question; A = answer.

Q1: Do control measures exist? If yes – go to Q2 If no – consider whether control measures are available or necessary within the process proceed to next identified defect	Q2: Is the step specifically designed to eliminate or reduce the likely occurrence of rancidity to an acceptable level? If yes – this step is a DAP If no – go to Q3	Q3: Could rancidity occur in excess of acceptable levels or could it increase to unacceptable levels If yes – go to Q4 If no – not a DAP	Q4: Will a subsequent step eliminate rancidity or reduce its likely occurrence to an acceptable level? If yes – not a DAP If no – DAP
A: Yes, the storage temperature is controlled, procedures exist	A: No	A: Yes, if the storage time is too long and/or the storage temperature is too high or if packaging is broken or unsuitable, or if glazing is inadequate	A: No
Decision: storage of frozen tuna is a defect action point			

References

- Baird-Parker, T.C. 2000. The production of microbiologically safe and stable foods. In: Lund, B.M., T.C. Baird-Parker and G.W. Gould (eds.) *The Microbiological Safety and Quality of Foods*. Aspen Publishers Inc., Gaithersburg, Maryland, USA. pp.3-18.
- CAC (Codex Alimentarius Commission) 2002. *Draft Code of Practice for Fish and Fishery Products*. Alinorm 03/18. Food and Agriculture Organization / World Health Organization, Rome, Italy.
- FDA (Food and Drug Administration) 2002. Import refusal reports for OASIS http://www.fda.gov/ora/oasis/ora_oasis_ref.html
- Gram, L. 1989. Isolation, identification and characterization of bacteria isolated from tropical fish. Ph.D. thesis. The Technological Laboratory of the Danish Ministry for Fisheries and The Royal Veterinary and Agricultural University, Denmark.
- Gram, L. and H.H. Huss 2000. Fresh and processed fish and shellfish. In: Lund, B.M., T.C. Baird-Parker and G.W. Gould (eds.) *The Microbiological Safety and Quality of Foods*. Aspen Publishers Inc., Gaithersburg, Maryland, USA. pp. 472-506.
- Gram, L., L. Ravn, M. Rasch, J. B. Bruhn, A.B. Christensen and M. Givskov 2002. Food spoilage – interactions between food spoilage bacteria. *International Journal of Food Microbiology* 78, 79-97.
- Huss, H.H. (eds) 1995. *Quality and Quality Changes in Fresh Fish*. FAO Fisheries technical paper No. 348., FAO, Rome, Italy.
- Kaferstein, F.K. and G. Moy 1993. Public health aspects of food irradiation. *Journal of Public Health Policy* 3, 502-510.
- NOAA (National Oceanic and Atmospheric Administration) 2000. *NOAA HACCP Quality Management Program. Program Requirements*. National Marine Fisheries Service, Seafood Inspection Program, Maryland, USA.
- WHO (World Health Organization) 1995. *Food Safety Issues: Food Technologies and Public Health*. WHO/FNA/FOS 95.13. WHO, Geneva.

11 MONITORING PROGRAMMES (Hans Henrik Huss)

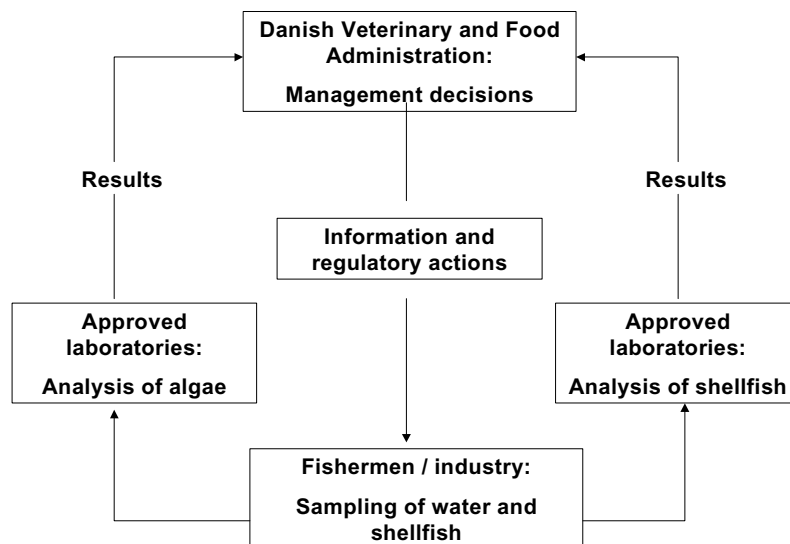
11.1 Toxic algae

The goal of a monitoring programme is to protect public health by providing information on toxic algae sufficiently early to take management action. The basic elements of monitoring and management programmes are the following (Anderson *et al.*, 2001):

- environmental observations including plankton observations, fish kills and anomalous animal behaviour
- sampling of plankton, shellfish or fish
- analysis of samples (identification of harmful algae, quantification of harmful algae and measurement of toxicity in shellfish)
- evaluation of results
- dissemination of information and implementation of regulatory action
- action plans/mitigation measures

The complete monitoring and management programme can be the responsibility of one agency, or it can be split between a government agency, industry/fishermen and private consultancy as shown in Figure 11.1.

Figure 11.1
Monitoring and management of toxic algae in Denmark.



The structure of a monitoring programme can be complex and vary according to the local situation, but it should preferably be kept as simple as possible to facilitate fast and uncomplicated flow of information. The operational structure should be well documented and it should be clear to everyone involved who is responsible for different parts of the programme.

Environmental observations, including plankton observations, fish kills and anomalous animal behaviour are most often done by local residents or field officers on patrol. Aircraft Visual Operation, underway ferry monitoring and moored sensors can be applied in remote sensing for bloom detection and tracking.

Sampling of water, plankton and shellfish are most easily done by fishermen and industry or by inspection officers. The frequency of sampling and the number of sampling stations depends on the local situation and historical data. Routine sampling every week may be increased to daily sampling when low levels of toxic phytoplankton are observed.

Analysis of samples must be done at a certified laboratory and only approved and official methods of analysis should be applied. In the EU, a national reference laboratory must be designated to

coordinate the analysis of biotoxins (EC, 1993). The national reference laboratories shall collaborate with the Community reference laboratory in Vigo, Spain (Laboratorio de biotoxinas marinos del Area de Sanidad).

Results of analysis should immediately be forwarded to the competent authority for evaluation and possible action. An effective communication system is important for rapid action and possible closure of fisheries. Results can be distributed instantly to the users of the monitoring system by telephone, automatic telephone answering machine, fax, e-mail and Internet. The use of Internet is quite common in many countries, although in some cases restricted access websites or list servers available only to governmental officials are used to control sensitive information.

Information and education of the public should be an integral part of the communication programme. It is recommended that booklets and pamphlets about health problems associated with algal blooms and toxic algae, the diagnosis and treatment of poisonings be prepared and published. Using the Internet is also an obvious way of distributing general information. Local web-pages can be linked to other general web-pages such as <http://www.redtide.whoi.edu/hab/>.

The action or regulatory limits for toxins are shown in section 5.1.5. For cell concentration in the water the action level varies from presence (some *Alexandrium* spp. and *Prorocentrum* spp.) to several thousands cells/L of other algae (see Anderson *et al.*, 2001). In the USA a closed status shall be established when the cell count of *Gymnodium breve* exceeds 5 000/L (NSSP, 1999).

When toxin levels in bivalve or cell numbers of toxic algae exceeds the accepted limit, harvesting areas are closed or some sort of restriction of harvesting is imposed. A toxic bloom may vary, being extensive or sporadic only, thus affecting large areas or only spotty locations. The intensity of a bloom may also vary resulting in significant differences in toxicity levels among bivalves of the same species. The decision to close an area should therefore be affected by the dynamics of the bloom, but it is always advisable to include a safety zone in the closure of an affected area.

Procedures to re-open closed areas include increased sampling from the area and adjacent open areas. Samples should be free of toxin for at least two weeks before re-opening is considered. Species with long retention time should, however, remain on the closure list. An example of an action plan for a shellfish-monitoring program is shown in Figure 11.2.

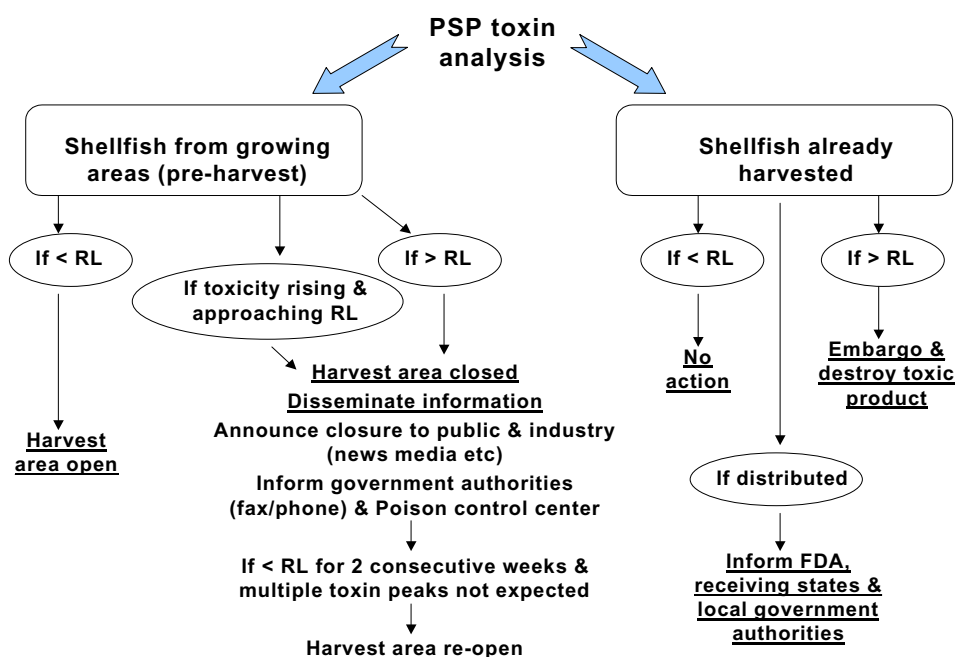


Figure 11.2 Action plan for shellfish monitoring program in the State of Maine, Atlantic, USA. RL = regulatory level (modified from Anderson *et al.*, 2001).

In the USA as well as in the EU, all containers and all consignments of shellfish must be accompanied by a tag and a health certificate that identifies the production area of origin, the harvester and the date of harvesting. This information must follow the shellfish during transport, processing, distribution until retail sales allowing tracing of the product should a health problem arise.

11.2 Pathogenic bacteria and viruses

Pathogenic bacteria and virus may be present in water from which shellfish are harvested. Of particular concern is the situation, when the environment where shellfish grow is contaminated from sewage. Molluscan shellfish filter and concentrate these pathogens from the surrounding water, and high numbers sufficient to cause disease may be reached. As shellfish are often consumed raw or only partially cooked, these pathogens (bacteria or viruses) will not be eliminated, and the risk of causing disease will be high.

To minimize this risk, Government authorities must have a monitoring programme for classifying the waters where shellfish are harvested. This monitoring programme can be based on examination of samples of shellfish or in part on an assessment of water quality. The programme must then be managed so that harvesting only takes place when the area is free of contamination. This programme also requires that all consignments and containers of shellfish are tagged as described above and that shell-fish harvesters and processes are licensed.

The EU requirements and conditions for productions areas are shown in Table 11.1.

Table 11.1 Classification of harvesting areas for shellfish in the EU. Microbiological examination of shellfish samples (EC, 1991).

Classification		Microbiological criteria (cfu /100 g shellfish)	Method
A	No restriction. Shellfish acceptable for immediate consumption	<230 <i>E. coli</i> or <300 faecal coliforms no <i>Salmonella</i> in 25g	5 tubes 3 dilutions MPN-test
B	Shellfish must be depurated or relayed until they meet category A standard	<4,600 <i>E. coli</i> or <6,000 faecal coliforms in 90% of samples	5 tubes 3 dilutions MPN-test
C	Shellfish must be relayed over a long period (>2 months) until they meet category A standard	<60 000 faecal coliforms	5 tubes 3 dilutions MPN-test

Sampling plans for the purpose of monitoring harvesting and production areas must be established by the competent authorities. Sampling must be done at regular intervals or on a case-by-case basis in the event of irregular periods of harvesting. The sampling plan must take account of likely variation in faecal contamination at each production and relaying area.

In the USA either a total coliform or a faecal coliform standard is applied in classification of a growing area as shown in Table 11.2.

Table 11.2 Classification of shellfish growing areas. Microbiological examination of water samples (NSSP, 1999).

Classification	Faecal coliform		Method
	Geometric mean	<10% of samples	
Approved	MPN <14/100 ml	MPN <43/100 ml	5 tube dec. dilution
		MPN <49/100 ml	3 tube dec. dilution
Restricted	MPN <88/100 ml	MPN <260/100 ml	5 tube
		MPN <300/100 ml	3 tube

It will be noted that both the EU and the USA classification programmes are relying heavily on conventional bacterial pollution indicators for measuring water quality. Although it has been generally accepted that it is better to monitor for the indicators of faecal pollution than for specific bacterial pathogens this is not the case for pathogenic viruses. There is ample evidence that viral pathogens are more resistant to environmental conditions, sewage and water treatment processes compared to coliform organisms (review by Leclerc *et al.*, 2000). Enteric viruses can survive for months in the marine environment, which is far longer than any bacterial indicator (Lees, 2000). New viral test methods are needed and under development as reliable faecal pollution indicators, but a number of critical issues must be addressed before their use.

11.3 Chemical contaminants

Chemical contaminants (heavy metals, persistent organic pollutants) may pose a potential human health hazard (section 5.2). Concern for these contaminants are mainly related to fish harvested in fresh water, estuaries and coastal waters where shore-side industries are located or intensive agriculture are using large amounts of pesticides or other agro-chemicals. In such areas, a government programme for monitoring all possible chemical contaminants in the harvesting area for fish and shellfish should be implemented and in place. The council directive (EC, 1991) makes reference to the compounds listed in the annex of directive 79/923/EEC (EC, 1979) and specify that these substances must not occur on shellfish in quantities that the calculated dietary intake exceeds the permissible daily intake (PDI). The directive (EC, 1979) states sampling frequency of several chemical contaminants, such as organohalogenated substances and metals which must be measured half-yearly. Tolerances, action levels and guidance levels for the more toxic chemical contaminants are discussed in section 5.2.

References

- Anderson, D.M., P. Andersen, V.M. Bricelig, J.C. Cullen and J.E.J. Rensel 2001. *Monitoring and Management Strategies for Harmful Algal Blooms in Coastal Waters*, APEC # 201-MR-01.1. Asia Pacific Economic Program, Singapore and Intergovernmental Oceanographic Commission, Technical Series No. 59, Paris.
- EC (European Commission) 1979. Council Directive 79/923/EEC of 30 October 1979 on the quality required of shellfish waters. *Official Journal of the European Communities* No.L 281, 10/11/1979. pp. 0047-0055.
- EC (European Commission) 1991. Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and placing on the market of live bivalve molluscs. *Official Journal of the European Communities* No.L 268, 24/09/1991. pp. 001-0014.
- EC (European Commission) 1993. Council Decision 93/383/EEC of 14 June 1993 on reference laboratories for the monitoring of marine biotoxins. *Official Journal of the European Communities* L116, 08/07/1993. pp. 0031-0033.
- Leclerc, H., S. Edberg, V. Pierzo and J.M. Del  the 2000. A review. Bacteriophages as indicators of enteric viruses and public health risk in groundwaters *Journal of Applied Microbiology* 88, 5-21.

- Lees, D. 2000. Viruses and bivalve shellfish. *International Journal of Food Microbiology* 59, 81-116.
- NSSP (National Shellfish Sanitation Program) 1999. *Guide for the Control of Molluscan Shellfish, Model Ordinance*, Chapter IV. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Washington, DC, USA.

12 EXAMPLES OF FSOs FOR BACTERIA OR TOXINS IN SEAFOOD PRODUCTS (Lone Gram)

12.1 *Listeria monocytogenes* in RTE seafoods¹

Both FAO/WHO (2001) and FDA/FSIS (2001) are currently in the process of carrying out quantitative risk assessments on *Listeria monocytogenes* in ready-to-eat foods. This section relies heavily on these documents. *L. monocytogenes* is a ubiquitous bacterium typical of decaying plant material and it is also associated with several animals. *L. monocytogenes* can cause listeriosis in humans. The main form of listeriosis is a food-borne infection which affects particular risk groups such as immuno-compromised, elderly and neonates. Recently, a milder form of gastro-enteritis affecting otherwise healthy people was reported. Many ready-to-eat (RTE) food products have been linked to listeriosis which typically occurs in sporadic, small outbreaks. *L. monocytogenes* is halo- and psychrotolerant and capable of multiplying in RTE foods, especially with extended shelf lives. Whilst dairy and meat products seem to be the most common causes of listeriosis, the disease has also been traced to lightly preserved fish products such as smoked mussels or cold-smoked fish (trout).

L. monocytogenes can easily be isolated from RTE food products in low concentrations. Thus between 0 and 80% of samples of cold-smoked fish are positive for the organism. It typically occurs in levels of < 10 /gram but is sporadically isolated at higher levels. Inoculated trials have shown that rapid growth may occur in the vacuum-packed chill-stored product. Based on German data on prevalence and levels of *L. monocytogenes*, Buchanan *et al.* (1997) developed a dose-response curve for the organism. The study used cold-smoked salmon as the food case. This study, as well as the very thorough studies by FAO/WHO and US FDA conclude that although one cannot define a threshold concentration, i.e. a minimal infectious dose, low levels of the organism (< 100 cfu/g) are very unlikely to cause the disease. The WHO/FAO team concluded as part of an expert consultation in May 2001 that if levels of *L. monocytogenes* were kept below 1000 cfu/g at point of consumption, then 99% of all listeriosis cases would be eliminated.

Due to the widespread occurrence of *L. monocytogenes* it will be extremely difficult (and expensive) to produce all RTE foods without sporadic occurrence of the organism in low levels. The dose-response relationships (and resulting Risk Estimate) indicates that such low levels constitute a very low risk. In the terminology introduced above, an "appropriate level of protection" / "tolerable level of risk" (ALOP/TLR) could be 100 cfu/g (assuming serving sizes of ≤ 100 gram). Following this line of thought, a Food Safety Objective is derived directly from the ALOP and could be 100 *L. monocytogenes* per gram at point of consumption.

Risk management options

In principle, two interlinked options exist for the management of microbial risks: the implementation of GHP and of HACCP. A HACCP analysis of *L. monocytogenes* in cold-smoked salmon reveals that with current processing and storage practices, no critical control point exists for the hazard which is growth of *L. monocytogenes*. The organism survives the processing steps (no listericidal step) and the typical product and storage conditions (vacuum-packed, chill-stored (5°C), NaCl at 3-6% (water phase salt) and pH of approximately 6.2) does not guarantee against growth to hazardous levels. It must be emphasised that CCPs that guarantee that counts do not increase to hazardous levels can be introduced, e.g. by frozen storage or by limiting shelf life. *L. monocytogenes* is capable of colonizing food processing environments and product contamination typically is caused by contamination during processing rather than by survivors from the raw material. *L. monocytogenes* may hide in brines, colonise slicers and have its harbouring niches in drains and on floors. Therefore the GHP programme of a food processing plant with *L. monocytogenes* as an identified hazard, must focus specific actions on eliminating and surveying this bacterium.

¹ The text in this *Listeria* section has been prepared and modified from text prepared for an FAO/WHO Expert Consultation in Kiel, March 2002. The concepts of this Chapter are based on ICMSF 2002.

Performance standards

The performance standard (PS) is the level of the hazard (here *L. monocytogenes*) that the processor must meet. In several RTE products, *L. monocytogenes* will not grow during storage and the PS for instance at the end of processing can then equal the FSO. However, if growth of the organism is possible/likely during storage and distribution, the FSO must be translated to PS depending on the amount of growth expected between sampling and consumption. It has been demonstrated that in naturally contaminated cold-smoked salmon stored at 5°C, approximately 1 log increase occurs during a 3 week storage period (Jørgensen and Huss, 1998). Thus, using a shelf life limit of 3 weeks or shorter at chill temperatures, a PS of 10 *Listeria* per gram off processing line will allow the FSO to be met. Most processors will set a PS of <10 *Listeria* per gram to built in safety margins.

Process and Product Criteria

Process or product criteria are levels of e.g. a heat treatment or a salting concentration that ensures that the hazard is under control. The preservation and safety of cold-smoked salmon depends on use of appropriate raw materials and combinations of salt and low temperature after processing. Since no listericidal step is included in the processing and neither of the food preservation parameters will control growth of *L. monocytogenes*, process or product criteria cannot be identified.

Microbiological criteria

It is possible, when appropriate, to develop microbiological criteria using an FSO of 100/g or PS of lower values. Such criteria may be used as acceptance criteria in situations where the pre-history of the product is not known, such as at port-of-entry or at certain retail outlets. Clearly, such criteria should only be used where other acceptance criteria, such as product criteria, cannot be developed. Also, the product should be epidemiologically linked to the hazard – or a hazard analysis should indicate reason for concern (van Schothorst, 1996). This is the case with cold-smoked salmon since listeriosis has been linked to cold-smoked trout (Swedish outbreak with 9 infected people and 2 fatalities), and several inoculated food trials have demonstrated growth in the product (Table 12.1).

Table 12.1 Questions evaluating the use of MC for *Listeria monocytogenes* in cold-smoked salmon (based on CAC, 2001)

Questions	Answers	Action
1) Has the food received a listericidal treatment	No, the cold-smoking process although sometimes reducing numbers of <i>L. monocytogenes</i> cannot guarantee that the organism is removed	
2) Is (re)-contamination likely	Yes. Several studies have documented that the main source of <i>Listeria</i> contamination is the process environment (slicers, brine) itself	
3) Is the presence of <i>Listeria monocytogenes</i> likely?	Yes. Although plant contamination can be minimized, its presence in the product is not un-expected.	If no: Do not test
4) Will the food receive a listericidal treatment prior to consumption?	No, Cold-smoked salmon is typically eaten without heat processing	If yes, Do not test
5) Is it likely that multiplication to levels of > 100/g or ml at the moment of consumption will take place during the intended conditions of storage, distribution and use?	Yes No	Examine 20 samples c=0 and m=100 c=0 and m= N – where N is a product specific level that is set (a PS) so that the level does not increase above the FSO of 100/g at point of consumption absence in 25 g samples if no data on the product are available. Examine 10 samples Reject if any sample contains > 100 <i>L.m.</i> per gram

As with other microbiological criteria, careful consideration must be given to the choice of sampling plans and the degree of assurance it provides. Currently spreadsheet systems are available that allows one to determine the performance of a particular sampling plan (<http://www.foodscience.afisc.csiro.au/icmsf/samplingplans.htm>). For instance, if a sampling plan with 20 samples are used and c= 0 and m=100, then there is a 95% (or higher) probability of rejecting lots if the mean concentration of *Listeria* in the lot is ≥ 15 cfu/g. It therefore follows that even with 20 samples, the probability of accepting a lot which actually contains *L. monocytogenes* increases rapidly if the mean concentrations drops below 15 cfu/g.

Similarly, a sampling plan with 10 samples and c=0 and m=100 has a 95% (or higher) probability of rejecting the lot if the mean concentration is ≥ 30 cfu/g. If a sampling plan uses only 5 samples and c=0 and m=100, then there is a 95% probability of rejecting the lot if the mean concentration is ≥ 80 cfu/g. These figures emphasise the well-known fact, that low levels of pathogens are difficult to control using product sampling and testing.

If products are inspected just before consumption or the products do not support growth, the MC can equal the FSO. Depending on the assurance required from the sampling, i.e. the probability of only accepting acceptable lots, the number of samples is decided upon. If growth is supported, a PS and a MC of "not detectable" in 25 g may be opted for.

12.2 Staphylococcal enterotoxin in cooked crustaceans

Staphylococcus aureus is, as described in Chapter 5, a mesophilic, Gram-positive bacterium associated with warm-blooded animals. It is a common member of the skin and nasal microflora of humans. Many strains of *S. aureus* may produce enterotoxins which upon ingestion causes a sudden reaction in terms of cramps, abdominal pain and vomiting. Several different enterotoxins may be produced and they have, based on antigenic properties been divided into sero-types A to J. Enterotoxin A is assumed to be the most commonly involved in food-poisoning outbreaks, however, recently type C has become prevalent (Jablonski and Bohack, 1997).

S. aureus is commonly detected from foods, either raw foods from warm-blooded animals or foods that have been manually handled. *S. aureus* can be detected sporadically on raw fish but is clearly more typical of seafood products that have been heat treated and manually handled, such as crustacean products (Table 12.2).

Table 12.2 Prevalence of *S. aureus* in seafood commodities (modified from Jablonsky and Bohach, 1997).

Product	No of samples tested	% positive for <i>S. aureus</i>	No. <i>S. aureus</i> per gram
Salmon steaks	86	2	>3.6
Oysters	59	10	>3.6
Blue crabmeat	896	52	> 3
Peeled shrimp	1,468	27	> 3
Lobster tail	1,315	24	> 3

The enterotoxins are part of a larger family of toxins produced by *S. aureus* (and *Streptococcus pyogenes*), the pyrogenic toxin family that can act as so-called super-antigens. These toxins can provoke a very strong response from the host immune defence system.

Disease symptoms may occur with ng levels of enterotoxin per gram, however, in most disease outbreaks, an estimated 1 to 5 µg has been ingested. The dose depends on the food matrix and the consumer – thus several children became ill after eating chocolate containing 100-200 ng enterotoxin. The enterotoxins are small molecules that are not degraded by gut proteases and that are relatively heat-stable and require prolonged boiling to inactivate.

Enterotoxins are produced in extremely low amounts during exponential growth but production increases markedly in the late exponential phase and stationary phase. It therefore follows that marked growth of *S. aureus* has to take place before toxic levels of enterotoxin are formed. Thus, it is the growth and toxin-production of the organism that is the hazard – not its mere presence. Stewart *et al.* (2002) when assaying 94 samples detected toxin in all samples with a positive OD-reading (i.e. cfu $\geq 10^7$ /ml) and not in any samples with a negative OD-reading. In a range in inoculated foods, Notermans and Otterdijk (1985) found that enterotoxin was not detected in any sample with less than 10^7 cfu/g. Many samples with higher *S. aureus* counts were positive (>0.1 µg enterotoxin/100g) but also several samples with counts of 10^9 - 10^{10} were negative. Hence, it can be concluded that $\geq 10^6$ cfu/g food are required to produce toxin at hazardous levels (Adams and Moss, 2000).

S. aureus is a poor competitor with respect to other microorganisms and outbreaks have mostly been associated with cooked foods, that have been manually handled and temperature abused. Thus cooked, hand-peeled crustaceans which may be temperature abused are high-risk products.

Quantitative risk assessments using mathematical representations of all steps from farm-to-fork have not been conducted on staphylococcal enterotoxins. However, based on evaluations of dose-response, an FSO of 1 µg per gram (of cheese) has been suggested as an example of an FSO (van Schothorst, 1998). However, as indicated above lower levels have been causing disease when ingested in a protective (fatty) food matrix and when consumed by children. Therefore an FSO of 50 ng may be a safer option.

Risk management options

The presence of *S. aureus* in cooked seafoods is clearly a result of cross-contamination from people handling the product. Therefore the GHP procedures must specify the hygienic level during handling of cooked foods. Obviously people with sores or infected scratches must not handle such foods. Also, sneezing and coughing which will spread *S. aureus* from the nasal reservoir must be avoided. Gloves and mouth protection wear may, if used appropriately, minimise the spread. However, control of the hazard (growth and toxin production) is, in principle straight forward. Clearly, all storage/processing conditions that prevent growth (see tables in Chapter 5) will control the hazard. Proper cooling is essential to prevent growth. Also, staphylococcal enterotoxins are formed under a more limited range of conditions compared with growth (ICMSF, 1996). Whilst *S. aureus* may grow down to 7°C, toxin is not formed below 10°C and only very limited amounts are produced between 10 and 20°C. Growth occurs down to a_w values of 0.83 but toxin production stops at 0.87 (Table 12.3).

Performance Standards

Although the FSO is based on the agent, the toxin, it is not likely that producers of foods in which *S. aureus* growth is a risk will measure toxin on a regular basis. Therefore most criteria and standards “translate” the toxin levels to levels of *S. aureus*. As mentioned, significant growth is required for toxin to be produced.

Table 12.3 Limits for growth and enterotoxin production (from ICMSF, 1996)

Parameter	Temperature, °C	pH	Water activity	NaCl ¹
Growth, optimum	37	6-7	0.98	3.5
Growth, range	7-48	4-10	0.83 – >0.99	25 – >1.7
Toxin production, optimum	40-45	7-8	0.98	3.5
Toxin production, range	10-48	4.5-9.6	0.87->0.99	17 – >1.7

1. NaCl % (water phase salt) calculated based on water activity values. Note that some studies report 20% as maximum for growth and 10-15% as maximum for toxin production.

Therefore the FSO of 50 ng toxin/gram could theoretically be translated to 10⁵-10⁶ cfu/g. This requires that the number is reached by growing, toxin producing bacteria and not a result of massive recontamination. However, the producer is unlikely to set e.g. 10⁵ *S. aureus* per gram but will target a much lower level to incorporate extra safety. In most foods, a PS of 100 *S. aureus* per gram will ensure that the FSO is met – assuming that the appropriate controls are in place.

Process and Product Criteria

In cooked crustaceans, the most important criteria ensuring control of the hazard is keeping the temperature low (< 10°C). The products do not *per se* include other preservation parameters that can be relied upon for growth control. However, if the cooked crustaceans are used for brined foods, the combination of low pH, salt and preservation compounds such as sorbate or benzoate can guarantee that growth does not occur.

The EU (EC, 1991) has set a microbiological standard for *S. aureus* in cooked crustaceans with a 5 sample sampling plan and $c = 2$, $m = 100$ cfu/g and $M = 1000$ cfu/g. Such standards are widely used at port-of-entry where there is no knowledge of the GHP or HACCP programmes of the producer.

References

- Adams, M.R. and M.O. Moss 2000. *Food Microbiology*. 2nd ed. Royal Society of Chemistry, Cambridge, UK.
- Buchanan R.L., W.G. Damert, R.C. Whiting & M. van Schothorst 1997. Use of epidemiologic and food survey data to estimate a purposefully conservative dose-response relationship for *Listeria monocytogenes* levels and incidence of listeriosis. *Journal of Food Protection* 60, 918-922.
- CAC (Codex Alimentarius Commission) 2001. Report on the thirty-fourth session of the Codex Committee on food hygiene. Alinorm 03/13. Food and Agriculture Organization / World Health Organization, Rome, Italy.
- EC (European Commission) 1991. Council Directive 91/493/EEC of 22 July laying down the health conditions for the production and placing on the market of fishery products. *Official Journal of the European Communities*. No. L268. pp.15-34.
- FAO/WHO (Food and Agriculture Organization/World Health Organization) 2001. *Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. Risk characterization of Salmonella spp. in eggs and broilers and Listeria monocytogenes in ready-to-eat foods*. FAO Food and Nutrition Paper No. 72.
- FDA/FSIS (US Food and Drug Administration/Food Safety Inspection Service) 2001. *Draft Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes among Selected Categories of Ready-to-Eat Foods*. FDA Center for Food Safety and Applied Nutrition.
- ICMSF (International Commission on Microbiological Specifications for Foods) 1996. *Microorganisms in Foods 5. Characteristics of Microbial Pathogens*. Blackie Academic & Professionals.
- ICMSF (International Commission on Microbiological Specifications for Foods) 2002. *Microorganisms in Foods 7. Microbiological Testing in Food Safety Management*. Aspen Publishers Inc.
- Jablonsky, L.M. and G.A. Bohach 1997. *Staphylococcus aureus*. In Doyle, M.P., L.R. Beauchat and T.J. Montville (eds.) *Food Microbiology. Fundamentals and Frontiers*. ASM Press, Washington, USA. pp.353-375.
- Jørgensen, L.V. and H.H. Huss 1998 Prevalence and growth of *Listeria monocytogenes* in Danish Seafood. *International Journal of Food Microbiology* 42, 127-131.
- Notermans, S. and R.L.M. van Otterdijk 1985. Production of enterotoxin A by *Staphylococcus aureus* in food. *International Journal of Food Microbiology* 2, 145-149.
- Stewart, C.M., M.B. Cole, J.D. Legan, L. Slade, M.H. Vandeven and D.W. Schaffner 2002. *Staphylococcus aureus* growth boundaries: Moving towards mechanistic predictive models based on solute-specific effects. *Applied and Environmental Microbiology* 68, 1864-1871.
- van Schothorst, M. 1996. Sampling plans for *Listeria monocytogenes*. *Food Control* 7, 203-208.
- van Schothorst, M. (International Commission on Microbiological Specifications for Foods) 1998. Principles for the establishment of microbiological food safety objectives and related control measures. *Food Control* 9, 379-384.

13 USE OF CRITERIA (Hans Henrik Huss)

Control measures to ensure safety and hygienic processing of food have traditionally included the use of criteria. Two types of criteria will be discussed in this Chapter:

- Microbiological criteria
- Performance- and process criteria

13.1 Microbiological criteria (MC) and testing

Traditionally, control of microorganisms in food was demonstrated by microbiological testing of samples at various stages of production and the final product. Results were compared with criteria developed to give some degree of assurance that the food was safe and of good quality. It is now fully recognized that this type of activity can never give an absolute assurance of product quality and safety. A much higher degree of assurance can be provided by a preventative approach based on the application of the Hazard Analysis Critical Control Point (HACCP) principles at all steps in the food supply and processing system.

Nevertheless it is recognised that MC are widely used in the food industry and by government authorities. For this reason, the basic requirements of MC will be discussed below. As outlined by the Codex Alimentarius Commission (CAC, 2001) and in published opinion papers and recommendations by scientific bodies such as EU Scientific Committee for Food (EU, 1997) and the Institute of Food Science and Technology (Stannard, 1997). A part of this section (13.1) has already been published in Huss, 2001.

13.1.1 Definitions and components of MC

Three types of MC are generally recognized according to their use:

- standards
- guidelines
- specifications

These terms have been defined and redefined a number of times, but it is generally recognised that the term "standard" is a MC contained in a law or regulation with mandatory compliance. In case of non-compliance some (specified) action is required by the regulatory agency. A microbiological "guideline" is a MC applied at any stage in food processing and aids in identifying situations requiring actions for food safety or quality reasons. Results obtained from testing assist in trend analysis and situations (products, processes) not complying with guidelines should result in investigative action to identify and rectify the cause. A "specification" is a MC used for contractual purposes by food business as part of their own safety management system and should not be confused with legal requirements. Codex Alimentarius and EU now operate with only one definition:

Microbiological Criteria

Microbiological criteria for food defines the acceptability of a product or a food lot based on the absence or presence or number of microorganisms, including parasites and/or quantity of their toxins / metabolites per unit of mass, volume, area or lot (CAC, 1997; EC, 1997)

It is recommended in the documents (CAC, 2001; EC, 1997) that the components of MC for foods should consist of:

- a statement of the microorganisms of concern and/or their toxins/metabolites and the reason for that concern
- the analytical method for their detection

- a sampling plan and the size of the analytical units
- the microbiological limits (ML) considered appropriate for the food at the specified points(s) of the food chain
- the number and size of analytical units that should be tested and conform to these limits
- the food to which and where in the food chain MC applies
- actions to be taken when the criterion is not met, (non-compliance).

The analysis of foods for compliance with mandatory microbiological criteria must be undertaken in an official laboratory in compliance with the Official Control of Foodstuffs Directive (EC, 1989).

Both the Codex- and the EU document specify that in situations of non-compliance with a mandatory MC some regulatory control actions are required such as sorting, reprocessing, rejection or destruction of product or further investigations into the situation. The decision on control action depends on an assessment of the possible risk to the consumer, the point in the food chain and the type of product. This means that non-compliance is not automatically followed by destruction of products. The decision on possible action depends on a carefully scientific evaluation of the whole situation and the stated microbiological limits in the MC are in reality guidelines to assist the authorities in choosing the correct control action.

In the EU directives applicable to fish (see Table 13.2) it is specified that if the products do not comply with the mandatory criteria set out in the Directives, the products cannot be placed on the market. This applies both to the criteria for pathogens and for organisms that are "indicators of poor hygiene" (*Staphylococcus aureus*, thermotolerant coli (44°C) and *E. coli*).

In contrast, it is stated that the "guidelines" used for indicator organisms (Standard Plate counts) are meant to help manufacturers decide whether their plants are operating satisfactorily and to assist them in implementing the production monitoring procedures.

Thus the EU Directives for fish have:

- mandatory criteria for specified pathogens (*Salmonella*) and for "unspecified pathogens"
- criteria for specific organisms as indication of poor hygiene and for the checking of GMP and HACCP (also mandatory criteria)
- and use of other parameters ("coliforms" and "plate count") in guidelines to be used solely by the manufacturers.

13.1.2 Purpose and application of MC

MC should only be applied to products or processes when no other means of securing safety and shelf life are available and when the use of a MC enhances food safety. Thus, there must be scientific evidence that a MC is effective, practical and meaningful in terms of consumer protection.

MC may be useful in the following situations:

- to indicate the microbiological status of raw materials, ingredients and final products of unknown origin (e.g. at port-of-entry)
- as validation and verification of HACCP-based control systems, Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP)
- to assess whether the prevalence of a pathogen in specific foods is increasing/decreasing relative to a target level (e.g. a FSO)
- for contractual purposes by food business.

MC cannot stand in isolation, but should only be established and used within the framework of a general risk management programme. They should be based on scientific analysis and advice

together with an assessment of the risk appropriate to the foodstuff and its use. Furthermore they should be developed in a transparent fashion and meet the requirements of fair trade.

13.1.3 Principles for establishing MC

When establishing MC, consideration must be given to the following (CAC, 2001):

- evidence of actual or potential hazards to health
- possibility of controlling the hazard by other means (e.g. at a CCP in a HACCP-programme or by use of process criteria)
- likelihood of improved safety to consumers by applying a MC
- microbiological status of the raw material. A number of potential pathogenic organisms are present as part of the normal microflora on the raw material and are therefore likely to be present on raw, non-heat treated final products. This is a potential hazard which need to be controlled by controlling the growth conditions for the pathogen (e.g. by salt, temperature control etc.)
- effect of processing on the microbiological status of the food
- likelihood and consequences of microbial contamination and/or growth during subsequent handling, storage and use
- category of consumers concerned
- intended use of the food. It must be included into the evaluation of a possible need for a MC if the risk will be eliminated by normal preparation before consumption
- cost/benefit ratio associated with application of a criterion. It must be taken into consideration, if the microbiological examination can be carried out for a reasonable price
- when establishing MC they must be based on a thoroughly well-documented examination of the particular product produced when GMP and GHP have been applied. The MC should be technically attainable and realistic in terms of achievability.

Based on these principles a number of situations can immediately be excluded as suitable for application of mandatory MC for pathogens:

- raw products (intended to be cooked before consumption)
- ready-to-eat products where a Critical Control Point or a process criteria can be identified for growth/elimination of relevant pathogens.

13.1.4 Sampling and microbiological testing

According to the principal documents on MC (CAC, 2001; EC, 1997) the choice of a sampling plan should take into account:

- consideration of severity of the hazard and assessment of the risk to public health
- susceptibility of the target group of consumers
- heterogeneity of distribution of microorganisms
- statistical probability of detecting unacceptable food lots.

A sampling plan should include the sampling procedure and the decision criteria to be applied to a food lot based on the examination of a prescribed number of sample units by defined methods. A sampling plan should further be administratively and economically feasible. Statistically based, 2- or 3 class sampling plans are defined by ICMSF (1986).

A 2-class plan is used essentially for pathogens and/or where a presence/absence test is to be performed, while a 3-class plan is mainly used for hygiene indicators.

Microorganisms are not distributed homogeneously in fish and fish products and pathogens, if present, are usually at low levels. For these reasons, no practical sampling plan can ensure complete absence of a target microorganism, nor can it ensure that the concentration of a microorganism measured may be exceeded in a part of the fish product that was not sampled.

A 2-class sampling plan will mainly detect gross defects. Table 13.1 shows the calculated acceptance probabilities for 2-class sampling plans with different numbers of samples and percentages of defective lots. Application of a sampling plan with five samples of which none should contain pathogens ($n = 5$, $c = 0$) would lead to acceptance of a lot that contains 10% defective samples with a probability of 59.1%. When it comes to food safety, food processors would aim at much lower rate of defective samples in a lot.

Table 13.1 Effect of lot quality (% defective in a lot) on the probability of acceptance (%) for different 2-class sampling plans (EC, 1998).

% defective samples in lot	probability of acceptance (%) given sampling plans with a total of n samples and allowance of " c " defect samples			
	$n = 1$; $c = 0$	$n = 5$; $c = 0$	$n = 10$; $c = 0$	$n = 60$; $c = 0$
1	99.0	95.1	90.4	54.7
2	98.0	90.4	81.7	30
5	95.0	77.4	59.9	4.6
10	90.0	59.1	34.9	0.18
20	80.0	32.8	10.7	0.00015

The most stringent sampling plan proposed by ICMSF (1986) is the sampling plan for *Salmonella* in baby food. In this plan 60 samples are analysed ($n = 60$) and none are allowed to contain *Salmonella* ($c = 0$). Even in this case there is a 30% chance of accepting products with 2% of sample units contaminated with *Salmonella*.

If the level of contamination in a lot is 0.5% it can be estimated that examination of 600 samples would be necessary for a 95% probability of detecting the contaminated lot. This probability would decrease to 45%, if the level of contamination is 0.1%. It can be concluded that if the level of contamination is not at least in the order of 5% or more, there is very little chance of detecting contaminated lots, and sampling and testing would therefore not improve the safety or decrease the risk. Sampling and microbiological testing is in this situation not suitable means for defining the acceptability of food lots and a MC is meaningless.

When evaluating the need for MC, the principle discussed above can be applied in a decision tree as shown in Figure 13.1.

13.1.5 MC applied by the EU and others

Food safety and hygienic practices throughout the EU is controlled by a multitude of "Vertical Directives" dealing with specific products of animal origin (meat, milk, eggs, fish) or the so-called "Horizontal Directives" covering all foodstuffs entering the market. Directives that include MC for fish are:

- Live Bivalve Molluscs Directive (91/492/EEC) (EC, 1991a)
- Fishery Products Directive (91/493/EEC) (EC, 1991b)
- Commission Decision on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish (93/51/EEC) (EC, 1993)

In addition a number of Directives have provision for MC to be added in the future (e.g. Council Directive 93/43/EEC on the hygiene of foodstuff).

The ML listed in the Directives above are shown in Table 13.2.

Table 13.2 Microbiological limits for fish and fish products laid down in EU Directives (EC, 1991a,b, 1993).

Products	Microorganisms	Microbiological standard	Status/action
Live bivalve molluscs	<i>Salmonella</i> spp.	absent in 25 g	w
"	<i>Escherichia coli</i>	< 230/100g	w
"	Faecal coliforms	< 300/100g	w
"	Paralytic shellfish poison (PSP)	≤ 80µg/100g	w
"	Diarrhetic shellfish poison (DSP)	Negative in bioassay	a
Cooked crustaceans and molluscan shellfish	<i>Salmonella</i> spp.	Absent in 25g, n=5, c=0	w, n, r
"	Other pathogens and toxins thereof	Not present in quantities such as to affect health	w, n, r
Whole products	Mesophilic aerobic bacteria (30°C)	m=10 000, M=100 000, n=5, c=2	r
Shelled or shucked products	<i>Staphylococcus aureus</i>	m=100, M=1000, n=5, c=2	w, n, r
"	<i>Escherichia coli</i> (on solid medium)	m=10, M=100, n=5, c=1	n, r
"	Thermotolerant coliforms (44°C on solid medium)	m=10, M=100, n=5, c=2	n, r
Shelled or shucked products except crabmeat	Mesophilic aerobic bacteria (30°C)	m=50 000, M=500 000, n=5, c=2	r
Crabmeat	Mesophilic aerobic bacteria (30°C)	m=100 000, M=1 000 000, n=5, c=2	r

w = withhold from market

n = notify the competent authorities of findings and action taken

r = review the methods and checking at CCPs.

The criteria listed in the EU Directives were developed 5-10 years ago, and there is a wide diversity and complexity in some of the MC selected. None of the MC is based on current Codex Alimentarius principles as outlined in this paper and many of the MC applied does not appear to be meaningful in terms of consumer health protection (e.g. aerobic plate counts, coliform counts in certain foods). The terminology used is not harmonised as MC is named as: MC, obligatory criteria, analytical criteria, guidelines, or standard without any clear definition of the meaning of these designations. Thus in the MC for cooked shellfish and molluscs the microbiological limit for aerobic mesophilic bacteria is called a "standard", while it is specified in the heading of the table to be a "guideline". None of the current MC is based on a formal risk assessment and sampling plans and detection methods to be used are not prescribed either.

The number of non-harmonised microbiological criteria in EU member states varies considerably. Thus France have more that 80 MC for foods while in Germany no microbiological criteria exist in the German Federal Legislation except those laid down by EC Directives. Countries which have non-harmonised, national microbiological criteria for fish and fish products are France, Norway, Spain, Denmark and Belgium (EC, 1998).

Some of the microbiological limits specified in the national non-harmonised MC mentioned above are given in Table 13.3. Other figures are from industry specification. However, it is claimed by Stannard (1997) that figures in Table 13.3 are considered to be practical, realistic and relevant.

Table 13.3 Microbiological limits for fish and fish products considered to be practical and relevant (extracted from Stannard, 1997).

Product	Organism/Toxin	GMP ¹	Maximum
Raw fish/shellfish to be cooked	Bacterial pathogens	Criteria for absence not applicable	
	Histamine	< 50 ppm	50 ppm
	PSP (bivalves)	ND/100 g	80 µg/100g
	DSP (bivalves)	ND in bioassay	ND in bioassay
	ASP (edible parts of molluscs)	< 20 mg domoic acid/g by HPLC	< 20 mg domoic acid/g by HPLC
Non-heated, ready-to-eat products (e.g. cold smoked, salted, marinated or fermented fish)	<i>Salmonella</i> spp.	ND in 25 g	ND in 25 g
	<i>V. parahaemolyticus</i>	ND in 25 g	10 ² /g
	<i>L. monocytogenes</i>	ND in 25 g	10 ³ /g
	<i>S. aureus</i>	< 10 ² /g	10 ³ /g
	Histamine	< 50 ppm	50 ppm
	PSP (bivalves)	as above	
	DSP (bivalves)		
	ASP (edible parts of molluscs)		
Cooked, ready-to-eat products (e.g. cooked shrimp)	<i>Salmonella</i> spp.	ND in 25 g	ND in 25 g
	<i>L. monocytogenes</i>	ND in 25 g	10 ³ /g
	<i>V. parahaemolyticus</i>	ND in 25 g	10 ² /g
	<i>S. aureus</i>	< 20 /g	10 ³ /g
	Histamine	< 50 ppm	50 ppm
	PSP (bivalves)	as above	
	DSP (bivalves)		
	ASP (edible parts of molluscs)		

1. see text

It must be emphasised that the figures in Table 13.3 are microbiological limits which may be included in MC. GMP-values are those expected immediately following production of food under good manufacturing conditions. Maximum values are those regarded as the maximum acceptable at any point in the shelf life of a product.

In the table it is pointed out that criteria requiring the absence of pathogens in raw foods are generally not practical. Absence of pathogens in raw food which are eaten raw is desirable but can never be guaranteed. In contrast, it is stated that pathogens (*Salmonella*, *V. parahaemolyticus*, *L. monocytogenes*) should be non-detectable in 25 g immediately following production of ready-to-eat products. This is clearly unrealistic for *V. parahaemolyticus* and *L. monocytogenes* in non-heated ready-to-eat products. The figures quoted under maximum values are more realistic and could be used as guidelines for microbiological testing also during and immediately after processing.

However, in many countries 10²/g of *Listeria monocytogenes* is regarded as maximum.

S. aureus is a toxin-producing organism and growth in the fish product is required before there is any risk to the consumer. Since *S. aureus* competes very poorly with a large associate microflora, it is unlikely to grow in non-heated ready-to-eat products like cold smoked salmon. Thus the authors cannot agree that a MC for this organism in this type of products is relevant. In contrast, cooked peeled shrimp, which may have been recontaminated with *S. aureus* after cooking can be of risk and a MC for *S. aureus* may be very useful in this situation.

13.1.6 Concluding remarks

Many of the microbiological examinations of foods both by industry and regulatory agencies are meaningless and a waste of time and resources. Indiscriminate application of microbiological testing and criteria should be avoided. As the existence of a MC always requires some degree of microbiological testing, it needs very careful consideration, before any MC is established.

Testing foods for pathogens is not very effective as a tool to protect health of the consumer. Safety is obtained by the application of GMP, GHP and HACCP as safety management tools throughout the food chain. Microbiological analysis and MC can be used to support and to verify the effective application of these management tools. Any MC introduced for this purpose should not be used as rejection criteria but as guidelines taking into consideration all other factors of importance. In most cases the corrective action will be a re-evaluation of the processing- and HACCP procedures.

The real problem is how to control the food in international trade. At the port-of-entry the regulatory agency may not always know whether the incoming food was produced under hygienic conditions and application of the HACCP-principles. In this situation some MC will be needed, but then they should be established according to the principles described in the Codex documents. However, a much better and more modern approach would be to let control of foodstuffs in international trade be based on signed agreements between internationally recognised and competent authorities or business partners approved by such authorities (e.g. Memoranda of understanding, purchasing agreements). Alternatively, food may be passed without testing, but with some restrictions on storage condition (e.g. keep frozen until use), limitation on shelf life after thawing or some degree of warning to the consumer (see Figure 13.1).

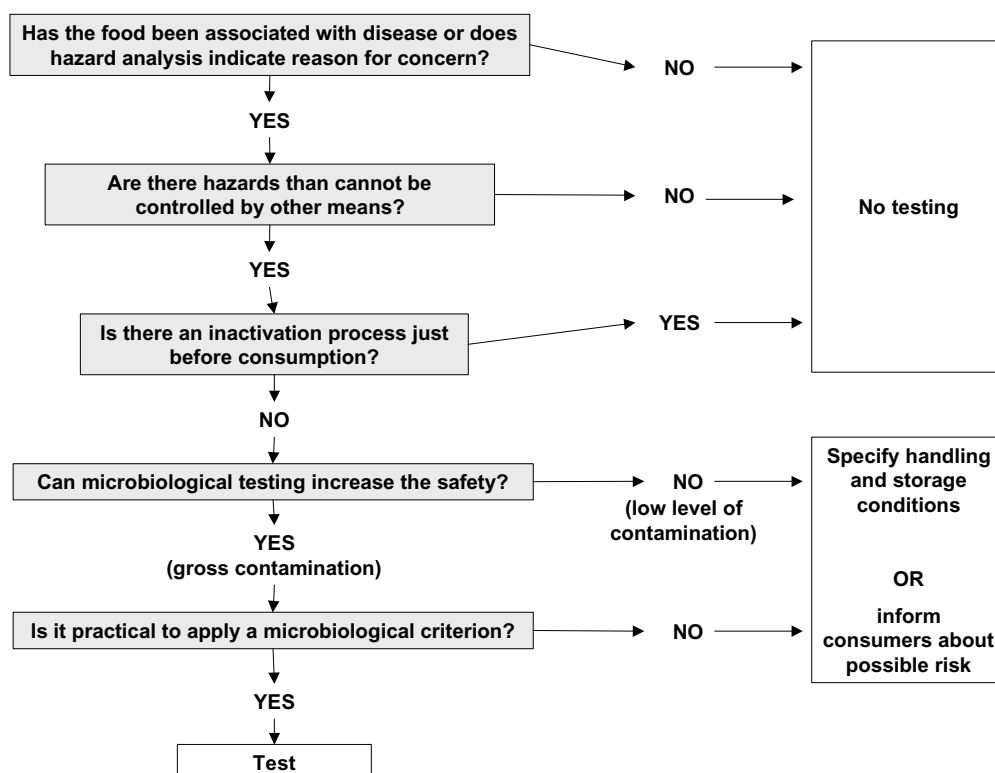


Figure 13.1 Establishment of MC for pathogens (Modified after ICMSF, 2002).

13.2 Performance and process criteria

Performance Criterion

A performance criterion is the required outcome of one or more control measures at a step or combinations of steps which will assure the safety of a food (van Schothorst, 1998)

Examples of performance criteria are:

- the requirement of a 12 D-reduction in the number of *Clostridium botulinum* spores in sterilized canned food
- the prevention of any growth of a given pathogen
- a 6 D-reduction in number of *Listeria monocytogenes*
- destruction of non spore forming pathogens that are known to occur in raw milk.

Process criteria are applied during the production of food, with the aim of building into the manufacturing process effective measures to control the risk of identified microbiological hazards.

Process Criteria

Process criteria are the control parameters (e.g. time, temperature, pH, a_w) at a step or combinations of steps, that can be applied to achieve a performance criterion (van Schothorst, 1998)

Process criteria will commonly appear as critical limits for CCPs in HACCP plans. Some examples are shown in Table 13.4.

Table 13.4 Performance and process criteria in food processing.

Performance criteria	Process criteria
12 D Kill of <i>C. botulinum</i>	2.4 - 3 min. At 121°C
6 D Kill of non proteolytic <i>C. botulinum</i>	90°C for 10 min
6 D Kill of <i>Listeria monocytogenes</i>	70°C for 2 min
Kill of non spore formers in raw milk	71,7°C for 15 sec. (pasteurisation)
Destruction of pathogenic virus in shellfish	90°C for 90 sec. (Lees 1995)
No growth of <i>C. botulinum</i>	pH < 4.6 or Water Phase Salt (WPS) > 10%
No growth of <i>C. botulinum</i>	WPS > 3.5%, Storage temperature <10°C

In an early and extremely important report (NRC, 1985) it was pointed out very clearly, that microbiological testing has severe limitations as a control option. The report also came out with a strong recommendation of applying the HACCP system in all segments of the food industry.

With the increased use of the Hazard Analysis Critical Control Point (HACCP) system in the management of food quality and safety one may ask, if microbiological testing and –criteria are still necessary as the HACCP system aims at controlling hazards during processing. A number of microbiological criteria (MC) are still required by both national and international legislation, but there is a considerable debate whether MC are needed or necessary in all instance to increase food safety.

Already in 1970, Sir Grahame Wilson when summarizing a meeting on the use of microbiological, criteria, stated: "Bacteriologists are better employed in devising means to prevent or overcome contamination than in examining more and more samples". Processing concerns the whole volume

of food; samples' only a minute fraction of it. Thirty years later two other distinguished and eminent microbiologists further pointed out that "It is an historical fact that the major advances in public health have been made by applying interventions, such as the use of milk pasteurisation or water chlorination to control specific microbiological hazards, i.e., application of performance and process criterion. We are not aware where significant food borne hazards to health have been reduced through the application of a microbiological criterion of a foodstuff as the primary means of control" (Baird Parker and Tompkin, 2000).

Thus it can be concluded, that while process criteria can be extremely effective in control of microbiological hazards and should be build into the HACCP system, microbiological testing and the use of microbiological criteria should never be carried out at the expense of a HACCP based system of control.

References

- Baird -Parker, T.C. and R. Bruce Tompkin 2000. Risk and Microbiological criteria. In Lund, B., T.C. Baird-Parker and G.W. Gould (eds) *The Microbiological Safety and Quality of Foods* Vol II Aspen Publishers, Inc. Gaithersbury, Maryland, USA. pp.1852-1885.
- CAC (Codex Alimentarius Commission) 1997. *Principles for the Establishment and Application of Microbiological Criteria for Foods*. Alinorm 97/13A, Supplement to Volume 1B, Appendix III CAC/GL, 21. Food and Agriculture Organization / World Health Organization, Rome, Italy.
- EC (European Commission)1989. Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs. *Official Journal of the European Communities* L 186, 30/06/1989
- EC (European Commission) 1991a. Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs *Official Journal of the European Communitites* L 268, 24/09/1991 pp. 0001 - 0014
- EC (European Commission) 1991b. Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products *Official Journal of the European Communities* L 268, 24/09/1991 pp. 0015 - 0034
- EC (European Commission) 1993. Commission Decision 93/51/EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish. *Official Journal of the European Communities* L 013, 21/01/1993 p. 0011 - 0013
- EC (European Commission) 1997. *Report of the Scientific Committee for Food (39th series)*. Luxembourg: Office for Official Publications of the European Communities.
- EC (European Commission) 1998. *Report on tasks for scientific cooperation. Report of experts participating in Task 2.1*. Luxembourg: Office for Official Publications of the European Communities.
- ICMSF (International Commission on Microbiological Specifications for Food) 1986. *Microorganisms in Food 2. Sampling for microbiological analysis: Principles and specific applications*. 2nd ed. Blackwell Scientific Publications, UK.
- ICMSF (International Commission on Microbiological Specifications for Food) 2002. *Microorganisms in Foods 7. Microbiological testing in food safety management*. Aspen Publishers.
- Huss, H.H. 2001. Use and misuse of microbiological criteria for seafood. In Gudjonsson and O. Niclasen (eds) *Proceedings of the 30th WEFTA Plenary Meeting*. June 2000. Thorshavn, the Faroe Islands. *Annales Societatis Scientiarum Færoensis Supplementum XXV* pp.63-73.
- Lees, D. 1995. Control measures in seafood. In *Workshop on Foodborne Vital Infections* Advisory Committee on the Microbiological Safety of Food, pp. HMSO, London, UK.
- NRC (US – National Research Council) 1985. *An evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*. National Academy Press. Washington DC, USA.
- Stannard, C. 1997. Development and use of microbiological criteria for foods. *Food Science and Technology Today* 11, 137-177.
- van Schothorst, M. 1998. Principles for the establishment of microbiological food safety objectives and related control measures. *Food Control* 9, 379-384.

14 PREDICTIVE MICROBIOLOGY (Paw Dalgaard)

Growth and/or inactivation of pathogenic and spoilage microorganisms are very important factors determining safety and shelf-life of seafood. Clearly, assessment and management of safety and quality is facilitated when microbial growth and inactivation can be quantitatively related to characteristics of products and processes like temperature, atmosphere, pH and NaCl %. Predictive microbiology is the area of food microbiology where such relations between controlling factors in foods and responses of pathogenic and spoilage microorganisms are quantified and modelled by mathematical equations. Predictive microbiology has numerous practical applications and is an active area of research.

14.1 Development and validation of predictive models

Large amounts of experimental data are required to predict the effect of controlling factors on growth, probability of growth, survival or inactivation of microorganisms (Table 14.1). Such data have often been generated using liquid laboratory media as levels of controlling factors (pH, NaCl %, etc.) are easy to adjust. In addition, automated methods for measuring microbial growth such as absorbance or conductance measurements can be used to facilitate the generation of data in liquid media. However, to accurately predict microbial growth in seafoods, liquid media cannot be used uncritically. With apparently similar levels of controlling factors, growth rates in seafood and standard liquid media like Brain Heart Infusion or Tryptone Soya Broth may differ by a factor of two. Therefore generation of data in product storage trials can be required for development of accurate predictive models (Dalgaard *et al.*, 2002). Knowledge about controlling factors is a prerequisite for development of accurate predictive models. In fact, major controlling factors and even the microorganisms responsible for seafood spoilage have in some cases remained unknown until mathematical modelling studies was initiated.

Table 14.1 Summary of general methodology for development of predictive growth models.

Data generation	Primary modelling	Secondary modelling	Product validation
Generate growth curves for combinations of controlling factors (temp., atmosphere, pH, etc.). Often liquid laboratory media are used.	Estimate kinetic parameters, primarily lag time and maximum specific growth rate, by fitting of growth curves with appropriate model	Model the effect of controlling factors on lag phase and growth rates	Evaluate the performance of a model by comparison of predictions and kinetic parameter values determined in product studies

To estimate lag times, maximum specific rates of growth (μ_{max}) or rates of inactivation, simple primary models are available and include:

- (i) the exponential model, with or without a lag phase (Lodge and Hinshelwood 1943)
- (ii) the three parameter Logistic model (Eqn. 14.1; solid line in Figure 14.1) or
- (iii) four parameter versions of the Logistic model (Eqn. 14.2).

Numerous more flexible and complex primary models have been suggested but in most cases they have no advantage over the simpler primary growth models (Dalgaard, 2002). Nevertheless, the practical usefulness of at least one of the more complicated primary growth models has been increased by including it in the *MicroFit* software which is available free of charge (www.ifr.bbsrc.ac.uk/MicroFit/).

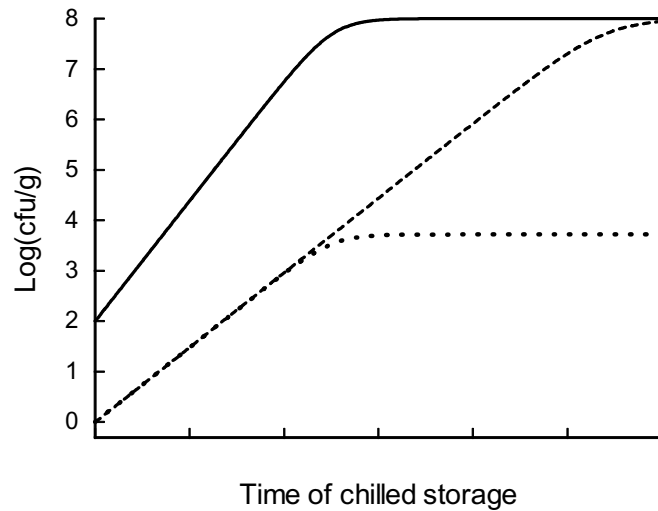
$$\text{Log}(N_t) = \text{Log} \left[\frac{N_{\max}}{1 + \exp[-\mu_{\max}(t - t_i)]} \right] = \text{Log} \left[N_{\max} / \left(1 + \left[\frac{N_{\max}}{N_0} - 1 \right] \times \exp(-\mu_{\max} \times t) \right) \right] \quad 14.1$$

$$\text{Log}(N_t) = \text{Log} \left[N_{\min} + \frac{N_{\max} - N_{\min}}{1 + \exp[-\mu_{\max}(t - t_i)]} \right] \quad 14.2$$

In eqn. 14.1 and 14.2 N_t is the cell concentrations (cfu g⁻¹) at the time t , N_{\max} and N_{\min} , respectively, are the maximum and minimum cell concentrations (cfu g⁻¹), μ_{\max} the maximum specific growth rate (h⁻¹) and t_i the time when $N_t = N_{\max}/2$ i.e. the inflection point.

Microbial interactions can be an important factor controlling growth of pathogenic microorganisms in seafood. E.g. for sliced and vacuum packed cold-smoked salmon, growth of *Listeria monocytogenes* has been found to cease when lactic acid bacteria reach their maximum cell concentration (Figure 14.1). This so-called Jameson effect can be modelled by a simple expansion of the differential form of the Logistic model (Eqn. 14.3, Jørgensen, 2000; Ross *et al.*, 2000a; Dalgaard, 2002).

Figure 14.1
Predicted growth of *Listeria monocytogenes* (Lm) and lactic acid bacteria (LAB) during chilled storage of cold-smoked salmon. LAB (solid lines), Lm growing alone (dashed lines) and Lm growing together with LAB (dotted line).



$$\frac{dLm}{dt} = Lm_t \times \mu_{\max}^{Lm} \times \left(1 - \frac{Lm_t}{Lm_{\max}} \right) \times \left(1 - \frac{LAB_t}{LAB_{\max}} \right) \quad 14.3$$

In eqn. 14.3 Lm and LAB signifies lactic acid bacteria and *L. monocytogenes*, respectively. dLm/dt is the absolute growth rates, Lm_t and LAB_t cell concentrations (cfu g⁻¹) at the time t , Lm_{\max} and LAB_{\max} the maximum cell contractions (cfu g⁻¹) and μ_{\max}^{Lm} the maximum specific growth rate (h⁻¹).

Polynomial equations have been used extensively as secondary models for estimating the combined effect of several controlling factors on values of lag time and maximum specific growth rates (McClure *et al.* 1994). The polynomial models include a relatively large number of parameters and this makes it difficult to compare values from different studies particularly as the parameters have no biological interpretation. In contrast, square root type models like eqn. 14.4 include parameters with some biological meaning. The parameters T_{\min} , $a_{w \min}$, pH_{\min} and $\%CO_2 \max$ correspond to theoretical growth limits for temperature, water activity, pH and CO₂. Rather than

corresponding to the lowest temperature, water activity, pH or the highest CO₂ level where growth is actually observed T_{min} , $a_{w\ min}$, pH_{min} or %CO₂ max are determined mathematically as the extrapolated values where the growth rate as a function of these controlling factors theoretically becomes zero. Thus, T_{min} –values of –5°C to –10°C are common for psychrotolerant Gram-negative bacteria although these microorganisms are typically inactivated at –5°C to –10°C. Nevertheless, T_{min} , $a_{w\ min}$, pH_{min} or %CO₂ max each seems little influenced by other controlling factors. Therefore, when reliable estimates of these parameters are available, only few data are required to develop new models for specific pathogen/product combinations. As an example a model for growth of *L. monocytogenes* in a specific seafood may be developed from values of existing parameters and storage trials required to estimate the value of ‘b’ in eqn. 13.4 (Ross *et al.*, 2000a). This approach has not yet been extensively used and deserves further study. Table 14.2 shows values of T_{min} , $a_{w\ min}$, pH_{min} or %CO₂ max for selected pathogenic and spoilage bacteria of importance in seafood.

$$\begin{aligned} \sqrt{\mu_{\max}} &= b \\ &\times (T - T_{\min}) \\ &\times \sqrt{(a_w - a_{w\ \min})} \\ &\times \sqrt{(pH - pH_{\min})} \\ &\times (\%CO_{2\ \max} - \%CO_2) / \%CO_{2\ \max} \end{aligned} \quad 14.4$$

Irrespective of the approach and the type of equations applied, development of a predictive model must always include product validation studies to evaluate the performance of the model. Graphs showing observed and predicted values of lag times, maximum specific growth rates or times for e.g. a 1000-fold increase in cell concentrations are useful to evaluate the performance of predictive growth models. In addition, the bias factor (Eqn. 14.5) and accuracy factor (Eqn. 14.6) are most important indices of performance for predictive models (Ross, 1996).

Table 14.2 Values of T_{min} , $a_{w\ min}$, pH_{min} and %CO₂ max for selected pathogenic and spoilage bacteria of importance in seafood. Data from Ross and McMeekin 1991, Miles *et al.* 1997, Presser *et al.* 1997, Ross *et al.* 2000a, Dalgaard 2002.

	T_{min}	$a_{w\ min}$	pH_{min}	% CO ₂ max
<i>Escherichia coli</i>	+4.0	0.93	3.9	-
<i>Listeria monocytogenes</i>	0	0.92	4.2	-
<i>Staphylococcus aureus</i>	+7.4	0.87	-	-
<i>Vibrio parahaemolyticus</i>	+5.4	0.92	-	-
<i>Brochothrix thermosphacta</i>	-10.9	-	-	187*
<i>Lactobacillus curvatus</i>	-3.3	0.93	4.2	-
<i>Photobacterium phosphoreum</i>	-9.0	0.95	4.3	376
<i>Shewanella putrefaciens</i>	-8.0 to -9.9	0.95	-	150-156

* Values of CO₂ above 100% correspond to partial pressures above atmospheric pressure.

$$\text{Bias factor } (\mu_{\max}) = 10^{(\sum \log(\mu_{\max\ \text{predicted}} / \mu_{\max\ \text{observed}}) / n)} \quad 14.5$$

$$\text{Accuracy factor } (\mu_{\max}) = 10^{(\sum |\log(\mu_{\max\ \text{predicted}} / \mu_{\max\ \text{observed}})| / n)} \quad 14.6$$

The bias factor indicates systematic over- or under prediction and a value of 1.0 shows predicted and observed values to be equal on average. A bias factor value between 0.75 and 1.25 has been suggested as a criterion for successful validation of microbial models to predict shelf-life of seafood. For pathogenic microorganisms limits for bias factors has been suggested to be slightly closer to 1.0 (Dalgaard, 2000; Ross *et al.*, 2000a).

Bias factor

Index of performance to compare predicted growth and values observed in product studies. Successful validation of a predictive model requires a bias factor value between 0.75 and 1.25 for a specific seafood

Predictive models developed in liquid laboratory media may not include all major factors actually limiting microbial growth in seafood. Predictions from such incomplete models can be strongly biased and if used uncritically predictions can be misleading. As an example, models including the effect of temperature, NaCl/ a_w , pH and lactate were unable to accurately predict growth of *L. monocytogenes* in naturally contaminated cold-smoked salmon. In fact, the bias factor was above 5 and it was pointed out that the effect of microbial interactions and smoke components was missing in the existing models (Dalgaard and Jørgensen, 1998; Ross *et al.*, 2000a). Recent studies confirmed that predictions could be substantially improved when the effect of interaction between *L. monocytogenes* and lactic acid bacteria (Eqn. 14.3) was added to a model already including the effect of temperature, NaCl/ a_w , pH and lactate (Ross *et al.*, 2000b; Dalgaard, 2002).

Experimental data continuously indicate that the major factors controlling microbial growth in seafood are not all identified. Clearly, predictive models may be incomplete and should never be used uncritically. Users of a model must verify that a bias factor between 0.75 and 1.25 has been obtained in product validation studies before predictions are applied for assessment or management of seafood safety. Most important, the validation studies need to be carried out with seafood having microbial ecology similar to the product of interest. Furthermore, if a bias factor is e.g. 1.4 and a single controlling factor like smoke components in cold-smoked salmon is lacking in the model, then predictions can be corrected by the value of bias factor. In this way, a corrected model can be used (with caution) to predict the effect of the factors actually included in the model.

14.2 Practical use of models and application software

Successfully validated predictive models have numerous applications in assessment and management of seafood safety and quality, particularly when models are included in application softwares. Application software does not improve the models but they allow users, including people without interest in the mathematics of microbial kinetics, to obtain prediction rapidly and conveniently.

Seafood is never distributed at a constant temperature and in practice fresh and lightly preserved products that are supposed to be chilled can be exposed to between ~ 0°C and ~ 15°C. In tropical regions the temperature of fish raw material may be in the range of 25-30°C. Thus, the rate of chilling is a very critical parameter for both shelf-life and safety of products. The Seafood Spoilage Predictor (SSP) software has been developed specifically to predict the effect of constant and fluctuating temperature conditions on shelf-life of products from temperate and tropical waters as well as on growth of the spoilage bacteria *Photobacterium phosphoreum* and *Shewanella putrefaciens*. SSP is available free of charge at www.dfu.min.dk/micro/ssp/ (Dalgaard *et al.*, 2002). The Food Spoilage Predictor (FSP) software (www.geminidataloggers.com) and several predictive models are available (Koutsoumanis 2001, Rasmussen *et al.* 2002) for prediction of growth of psychrotolerant pseudomonads in fresh aerobically stored fish.

Pathogen Modeling Programme (PMP, www.arserrc.gov/mfs/PATHOGEN.HTM) includes 13 models for growth and survival and 9 models for inactivation of pathogenic bacteria. Food MicroModel (Anon., 1997) includes 23 growth and survival models and 7 models for heat inactivation of primarily pathogenic microorganisms. These software packages do not yet allow models to be used for time-temperature integration as described above. Models in PMP and Food MicroModel include the effect of wide ranges of several controlling factors. Thus, the models may be used to determine how one controlling factors e.g. NaCl % can be substituted by other factors such as a reduction of temperature or a change in packaging from aerobic to vacuum or modified atmosphere. Models in PMP and Food MicroModel may also be used to establish limits for critical control point as part of HACCP plans. Unfortunately, successful validation of the growth, survival

and inactivation models in PMP and Food MicroModel remain to be documented for most types of seafood.

For *L. monocytogenes* in cold-smoked salmon and *Vibrio parahaemolyticus* and *V. vulnificus* in raw oysters predictive models have recently been included in exposure assessment models. By using the predictive models together with Monte Carlo simulation software the effect of initial product contamination, product temperature and product characteristics on levels of the pathogens can be predicted at the time product are consumed. Used in this way predictive models become a key component in quantitative risk assessments (Ross *et al.*, 2000b; FAO/WHO, 2002).

In the future, the use of predictive models in the assessment and management of seafood safety and quality will most likely increase substantially. New software to predict safety and shelf-life is likely to appear and predictive models may be combined with seafood traceability systems.

References

- Anonymous 1997. *Food MicroModel - User Manual v. 2.5*. Food Micromodel Ltd., Surrey, UK.
- Dalgaard, P. 2000. Fresh and lightly preserved seafood. In: Man, C.M.D. and A.A. Jones (eds) *Shelf-Life Evaluation of Foods*. Aspen Publishers Inc., London, UK. pp. 110-139.
- Dalgaard, P. 2002. Modelling and prediction the shelf-life of seafood. In: Bremner, H.A. (ed.) *Safety and quality issues in fish processing*. Woodhead Publishing Ltd. pp. 191-219.
- Dalgaard, P. and L.V. Jørgensen 1998. Predicted and observed growth of *Listeria monocytogenes* in seafood challenge tests and in naturally contaminated cold smoked salmon. *International Journal of Food Microbiology* 40, 105-115.
- Dalgaard, P., P. Buch and S. Silberberg 2002. Seafood Spoilage Predictor - development and distribution of a product specific application software. *International Journal of Food Microbiology* 73, 227-233.
- FAO/WHO (Food and Agriculture Organization/World Health Organization) 2002. Joint FAO/WHO Activity on Risk Assessment of Microbiological Hazards in Foods. Hazard identification, exposure assessment and hazard characterization of *Vibrio* spp. in seafood. Preliminary document.
- Jørgensen, L. V. 2000. *Spoilage and safety of cold-smoked salmon*. Ph.D. thesis. Danish Institute for Fisheries Research, Lyngby, and the Royal Veterinary and Agricultural University, Frederiksberg, Denmark.
- Koutsoumanis, K. 2001. Predictive modeling of the shelf life of fish under nonisothermal conditions. *Applied and Environmental Microbiology* 67, 1821-1829.
- Lodge, R.M. and C.N. Hinshelwood 1943. Physiological aspects of bacterial growth. Part IX. The lag phase of *Bact. Lactis Aerogenes*. *Journal of the Chemical Society* 288, 213-219.
- McClure, P.J., C.D. Blackburn, M.B. Cole, P.S. Curtis, J.E. Jones, J.D. Legan, I.D. Ogden and M.W. Peck 1994. Modelling the growth, survival and death of microorganisms in foods: the UK Food Micromodel approach. *International Journal of Food Microbiology* 23, 265-275.
- Miles, D.W., T. Ross, J. Olley and T.A. McMeekin 1997. Development and evaluation of a predictive model for the effect of temperature and water activity on the growth rate of *Vibrio parahaemolyticus*. *International Journal of Food Microbiology* 38, 133-142.
- Presser, K.A., D.A. Ratkowsky and T. Ross 1997. Modelling the growth rate of *Escherichia coli* as a function of pH and lactic acid concentration. *Applied and Environmental Microbiology* 63, 2355-2360.
- Rasmussen, S.K.J., T. Ross, J. Olley and T.A. McMeekin 2002. A process risk model for the shelf-life of Atlantic salmon fillets. *International Journal of Food Microbiology* 73, 47-60.
- Ross, T. 1996. Indices for performance evaluation of predictive models in food microbiology. *Journal of Applied Bacteriology* 81, 501-508.
- Ross, T.A. and T.A. McMeekin 1991. Predictive microbiology: Application of a square root model. *Food Australia* 43, 202-207.

- Ross, T., P. Dalgaard and S. Tienungoon 2000a. Predictive modelling of the growth and survival of *Listeria* in fishery products. *International Journal of Food Microbiology* 62, 231-245.
- Ross, T., E. Todd and M. Smith 2000b. Exposure assessment of *L. monocytogenes* in ready-to-eat foods. World Health Organization, Geneva, and Food and Agriculture Organization of the United Nations, Rome, Italy.

15 TRACEABILITY (Marco Frederiksen/Lone Gram)

An important aspect of quality and safety assurance is to be able to trace products, ingredients, suppliers, retailer, processing operations or storage procedures through the food production chain. This is especially relevant when failures occur. The term “traceability” has been introduced to describe systems in which information about a particular attribute of a food product is systematically recorded from creation through marketing (Golan *et al.*, 2002). For instance if a particular batch of cold-smoked fish has caused an outbreak of listeriosis, authorities will want to trace the product in question to the producer to establish re-call procedures. Similarly, the producer will want to determine if contamination with *L. monocytogenes* occurred in the plant and/or if temperature abuse occurred during distribution or during storage at the retailer or at the consumer. One may regard an epidemiological investigation as part of a traceability study, e.g. determining the sources of an agent involved in an outbreak of food-borne disease.

Traceability systems have been used for many years in several other sectors such as the aviation, automobile and pharmaceutical industry. As the food chain has lengthened from local production, processing and consumption to more global commercial opportunities, the need to transfer information related to production and public health and the complexity of these transfer vehicles have expanded (McKean, 2001). With the increase in complexity, the consumer wishes to know the origin (species, place, condition of rearing or catch.....), the transformations and the distribution of their food products (Pascal and Mahé, 2001).

Quantitative risk assessments typically aim at covering the whole “farm-to-fork” chain and at any point in time, one must therefore be able to trace an event or a product. ISO 9000 (ISO, 2000) defines traceability as the ability to trace the history, application or location of that which is under consideration. When considering a product, traceability can relate to

- the origin of materials and parts
- the processing history
- the distribution and location of the product after delivery.

In general the term “trace” is used when the history of product origin is searched and the term “track” is used for searching its history after delivery. Moe (1998) described the terms used in traceability studies as

- a step is referring to a discrete operation or location at which some task or process is performed on the product
- a chain is composed of the sequence of these steps, and
- a product can be any material at any stage of processing, e.g. a live fish, a whole fish, or a processed fish product.

Interest in traceability in food processing has been increasing in recent years, primarily because of the different crisis in the food sector such as the mad cow disease (BSE) in 1996 in the UK and the dioxin contamination in Belgium in 1999. Authorities have focused on traceability to assure consumer safety to be able to re-call defective/hazardous products and to identify the source of the problem.

Also, traceability may be advantageous within a company allowing different raw materials to be directed to production of different categories of product – and subsequently allowing the company to determine if yield, quality, or safety of a particular category was related to a particular raw material – or a particular ingredient. Since traceability systems basically are record-keeping systems, these are in some form required for a HACCP system to be implemented. However, the record keeping step of the HACCP system aims at documenting that the system is under control, that corrective actions are taken when pre-defined critical limits are exceeded, and that re-call of unsafe products is undertaken when required (Caporale *et al.*, 2001). A fully implemented traceability system is broader and covers also a range of aspects not related to safety.

Finally, implementation of traceability systems, although costly to implement, can also be an economic benefit to the producer. The whole chain from vessel to retailer can be managed in a more effective way, when the traceable information is used actively to enhance mutual trust and cooperation between steps in the chain. Significantly less time (and money) can be spent on quality checks and storage, and when recalls are to be carried out traceability is an insurance that the company limits the loss, and protect its brand on the market (Frederiksen, 2002).

15.1 Internal versus external (chain) traceability

The widespread acceptance of hazard analysis and critical control point (HACCP) systems for safety management has increased the need for product chain information throughout the chain (McKean, 2001). Many food (fish) processing companies already have effective internal traceability systems as part of their HACCP based quality assurance systems. In many cases, however, traceability is lost before and after the company deals with the raw materials and the final products. Much effort is spent on quality and safety grading of in-coming raw material. This effort can be minimised if the external traceability, the so-called chain traceability, and the attached information on quality is established. The traceable information must be reliable and this is substantiated by open access from other chain members to audit the quality assurance systems in the chain. Chain traceability is the key to cooperation and mutual trust between independent companies in a chain. More developed industries as for instance the automotive industry focus on auditing their sub-suppliers quality assurance systems today and makes less inspection of incoming products and the same already happens in some food industries.

15.2 Traceability systems

Traceability in its simplest form is in the form of a paper trail. This implies that every relevant piece of information is written on paper that follows the raw material through the processing line to retail. This method can be used for products of high value that are only produced in small quantities, but for basic commodity fish products the costs are too high for manual tracking (Frederiksen and Bremner, 2001). Despite the costs, analysis of three different fish chains in Denmark, Iceland and Norway (fresh whole fish, frozen fish and fresh farmed salmon) have shown that the paper-based systems (faxes, notes, postal letters) are widely used (Pálsson *et al.*, 2000).

With the explosive development in electronic data analysis, traceability systems based on information technology must be developed (Frederiksen *et al.*, 2002). Several e-business companies produce software allowing integration of financial and production data in one program package, and most of these have traceability capabilities components implemented (e.g. i2 technologies Inc., Dallas, USA; SAP AG, Walldorf, Germany). However, such systems are typically too costly for the small business units in the fish industry. In an EU concerted action project (Tracefish) - an open and voluntary industry standard for how traceability may be implemented electronically is now being developed (Tracefish, 2002). The work will be transferred to a CEN (Comité Européen Normalisation) standard in early 2003.

The EDIFACT (electronic data interchange for administration, commerce and transport) standard is currently the standard most used for transferring data between steps in the chain. Transfer costs are high and the standard is mostly used by supermarkets at the retail end of the chain. Clearly the Internet is the future as transfer medium and XML (extensible mark-up language) is the new Internet standard allowing transfer of information in a readable, easy, and cheap way (W3C, 2002).

15.3 Labelling products

The minimum requirement for traceability is that each traceable unit has been uniquely labelled to allow identification. The most common labelling method is to label products with barcodes of which the EAN-13 and UCC-12 codes (European Article Number and Uniform Code Council) are the most used. However, these codes, which can be read by retail units, do not allow inclusion of a unique identifier, which is crucial for traceability. Other bar codes (EAN/UCC-128) include the identifier but cannot be read by the retail bar code scanner.

The newest development is the use of RFID (radio frequency identification) tags, but the price is too high to justify their use in the consumer end of the chain. However it is today used for some reusable fish tubs and as internal traceability keeper in the meat industry (Rowan, 2002). The advantage of these tags is that they are fast and easy to read. It must be anticipated that the price of the RFID tags will decrease to a level allowing them to be introduced more widely in the food chain.

15.4 Fresh fish quality traceability

Traceability is important in the fresh fish chain where it may allow tracing of fish from tropical reef waters (potentially containing marine toxins) or tracing of fish from waters polluted with e.g. heavy metals. However, the most important issue in fresh fish trading is the assurance of freshness. Freshness is – for all species – almost exclusively a function of time and temperature. In principle, each fish should be continuously monitored with a time-temperature recording device; however, this is not technically or economically feasible. Therefore these two aspects are dealt with separately. In a well-functioning distribution chain where each step can be relied upon in terms of temperature control, the quality traceability can be implemented by a time recording. Clearly, spot checks of quality must be carried out using standardised fresh fish quality inspection methods such as the Quality Index Method (QIM) (Bremner, 1985; Jónsdóttir *et al.*, 1991).

A traceability system has been developed for fresh fish supply chains in the Danish domestic market and initial studies determined that temperature could be appropriately controlled in this particular chain (Figure 15.1, Frederiksen *et al.*, 2002).

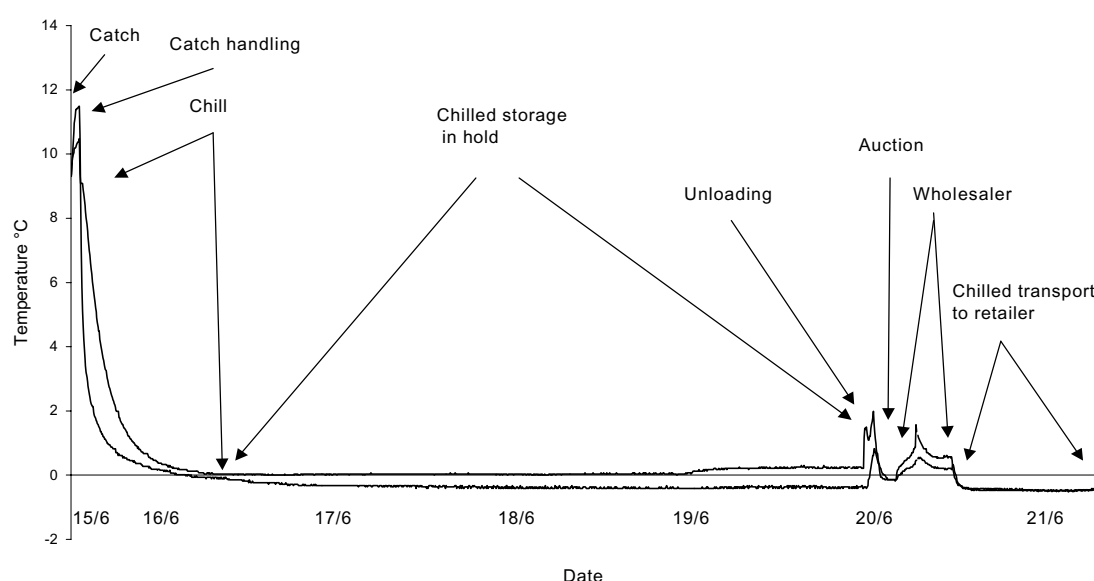


Figure 15.1 Time-temperature measurements of two fish in two different boxes (positions) through the whole chain from vessel to retailer (modified from Frederiksen *et al.*, 2002).

Internet technology (XML) has been used to transfer data from five steps in the chain from fisherman to retailer (Figure 15.2).

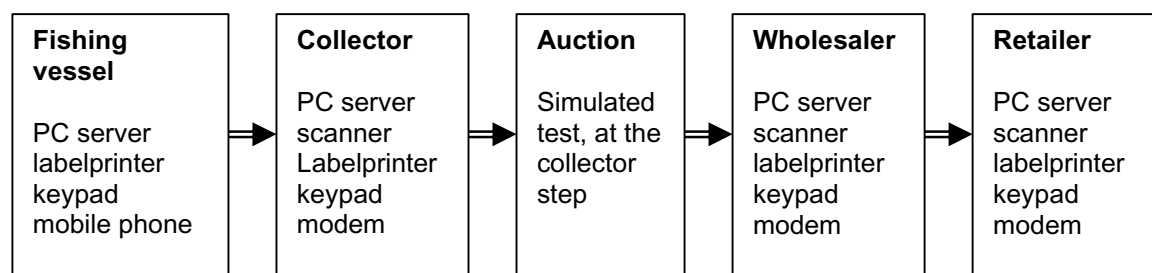


Figure 15.2 The complete test chain and the equipment installed in each step of the chain. Modified from Frederiksen *et al.* (2002).

Fish are sorted on-board according to species and iced in boxes. Each box is labelled with information on fish species, catch date, vessel name/number, and a unique box number, readable as ordinary numbers and in the form of a barcode. The information is registered in a computer onboard the vessel, and the data are transmitted via a mobile phone to a computer at the next step in the chain, the collector. The collector receives all information from the vessel before it enters the harbour. At the collector, each species is sorted according to size, keeping fish from each catch date separate (the traceable unit is fish from the same vessel with the same catch date). The fish is ice-packed in boxes, with new labels attached, and information about collector name, fish size/weight and a new box number registered at the computer adding this new information to the database.

The boxes were distributed through a wholesaler and further on to a retailer and same procedures were used in all steps to retrieve and add new information to existing product data. At the wholesaler information on wholesaler name, new fish weight and new box number was added. At the retailer information on retailer name, new fish weight, process type and customer number was added.

All information was available at the retailer step. An example on a possible customer label is shown in Figure 15.3.

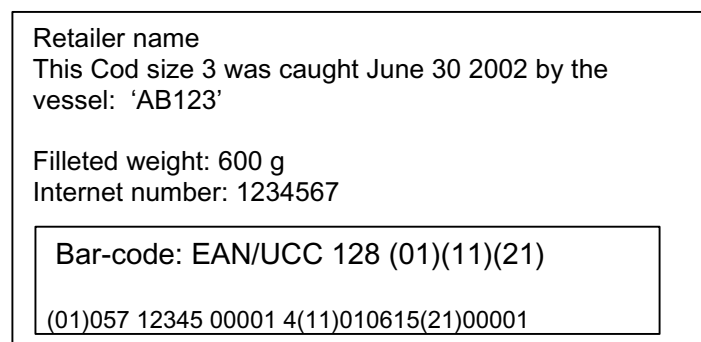


Figure 15.3 An example of a possible customer label. Modified from Frederiksen *et al.* (2002).

15.5 EU legislation on traceability of fish and fish products

There is a great international awareness with respect to the need for traceability. Recent international working documents, e.g., The European White Paper on Food Safety (EC, 2000) and the Bangkok Declaration and Strategy on Aquaculture Development (NACA/FAO, 2000), both include statements encouraging the development of traceability to be applied throughout the supply chain.

The general EU principles and requirements of food law including traceability definition and requirements are contained in EU commission regulations 178/2002 (EC, 2002). The present legislation for traceability of fish and fish products is described in EU council regulation 104/2000 (EC, 2000a) and commission regulation 2065/2001 (EC, 2001) that has been in action since

January 2002. This regulation states that at the point of consumer purchase, the following aspects should be documented

- Species (Trade name and/or Latin name)
- Production method ('Caught at sea' or 'in inland waters' or 'Farmed')
- Catch area. For fish caught at sea the FAO area from (FAO, 2002) must be stated. For fish from inland waters the country of origin must be given and for farmed fish the country of the final development of the product must be given.

These are the first implemented demands for traceability for fish products in the EU system and more demands will follow in the years to come. For instance, the catch area demand is very broad and currently only requires a distinction between fish from the whole North Sea and the Baltic Sea for catches from the North of Europe. This has far reaching consequences if, for example, pollution is detected in a small sea area in the North Sea, then all fish caught from the North Sea must be recalled.

Recently, the European Union proposed government-mandated traceability for genetically engineered crops and foods to help distinguish them from their conventional counterparts (Golan *et al.*, 2002).

References

- Bremner, H.A. 1985. Estimating time-temperature effects by a rapid systematic sensory method. In: Kramer, D.E. and J. Liston (eds) *Seafood quality determination*. Elsevier, Amsterdam, The Netherlands. pp. 59-70.
- Caporale, V., A. Giovannini, C. Di Francesco and P. Calistri 2001. Importance of the traceability of animals and animal products in epidemiology. *Revue Scientifique et technique de l'Office International des Epizooties* 20, 372-378.
- EC (European Commission) 2000. *White Paper on Food Safety*. Office for Official Publications of the European Communities, Brussels, Belgium (www.cordis.org 05/06/2002).
- EC (European Commission) 2000a. Commission Regulation (EC) No 104/2000 of 17 December 1999 on the common organization of the markets in fishery and aquaculture products. *Official Journal of the European Communities* No. L 17, 21.01.2000, 22-52.
- EC (European Commission) 2001. Commission Regulation 2065/2001 22 October 2001 laying down detailed rules for the application of Council Regulation (EC) no 104/2000 as regards informing consumers about fishery and aquaculture products. *Official Journal of the European Communities* No. L 278, 23.10.2001, 6-8.
- EC (European Commission) 2002. Regulation No 178/2002 of the European parliament and of the council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European food safety and laying down procedures in matter of food safety. *Official Journal of the European Communities* No. L 31, 01.02.2002, 1-24.
- FAO (Food and Agriculture Organization) 2002. Public server of FAO (ftp://ftp.fao.org/fi/maps/world_2001.gif 05/06/2002).
- Frederiksen, M. (2002). Quality chain management in fish processing. In: Bremner, H.A. (ed) *Safety and Quality in Fish processing*. Cambridge: Woodhead Publishing Ltd, pp. 289-307.
- Frederiksen, M. and H.A. Bremner 2001. Fresh fish distribution chains. An analysis of three Danish and three Australian chains. *Food Australia* 54, 117-123.
- Frederiksen, M., C. Østerberg, S. Silberg, E. Larsen, and H.A. Bremner 2002. Info-fisk. Development and validation of an Internet based traceability system in a Danish domestic fresh fish chain. *Journal of Aquatic Food Product Technology* 11, 13-34.
- Golan, E., B. Krissoff and F. Kuchler 2002. Traceability for food marketing & food safety: what's the next step?. *Agricultural Outlook*, January-February, 21-25.
- ISO (International Organization for Standardization) 2000. *Quality management systems – Fundamentals and vocabulary*. European Standard (EN ISO 9000:2000, Point 3.5.4). Committee for Standardisation, Brussels, Belgium.

- Jónsdóttir, S., Larsen, E., Martinsdóttir, E., Brattár, R. and Gudjónsson, A. (1991). *'Kvalitetsnormer på fisk'*, A report and manual (sensory evaluation of fish) to the Nordic Industry Foundation.
- McKean, J.D. 2001. The importance of traceability for public health and consumer protection. *Revue Scientifique et technique de l'Office International des Epizooties* 20, 363-371.
- Moe, T. 1998. Perspectives on traceability in food manufacture. *Trends in Food Science and Technology* 9, 211-214.
- NACA/FAO (Network of Aquaculture Centres in Asia-Pacific /Food and Agriculture Organization) 2000. *Aquaculture development Beyond 2000*. The Bangkok Declaration and Strategy. Conference on Aquaculture development in the Third Millennium, Bangkok, Thailand. (www.fao.org 05/06/2002).
- Palsson, P.G., Storøy, J., Frederiksen, M. and Olsen, P. (2000). Nordic Ministry Council. Project 66031400: *Traceability and electronic transmission of qualitative data for fish products*, status report no. 3 June 2000, Lyngby, Denmark: Danish Institute for Fisheries Research, Department of Seafood Research.
- Pascal, G. and S. Mahé 2001. Identity, traceability, acceptability and substantial equivalence of food. *Cellular and Molecular Biology* 47, 1329-1342.
- Rowan, C. 2002. Traceability: Integration is key. *Food Engineering and Ingredients* February, 14-19.
- Tracefish (2002). Homepage of Tracefish (www.tracefish.org 05.06.2002).
- W3C 2001. The World Wide Web Consortium consists of more than 500 organizations. The current work and the latest version of XML and SOAP are available from: www.w3.org.

APPENDIX 1 ASSESSMENT OF FOOD SAFETY PROGRAMMES (Hans Henrik Huss)

The assessment process covers the following 7 steps:

1. Pre-assessment document review
 - process flow diagram with location of CCPs
 - product specifications
 - HACCP plan including worksheets and records
 - Prerequisite plans including worksheet and records
2. Opening meeting
 - scope
 - process
 - schedule
 - amenities needed
3. On-site verification of process flow diagram
4. On-site document review and observations
 - product and ingredients specifications
 - previous audit reports and minutes of HACCP meetings
 - assessment of prerequisite programmes and functions (form attached)
 - assessment of HACCP programmes and functions (form attached)
5. Closing meeting
6. Assessment report
7. Assessment follow-up

The following five pages give examples of forms that can be used for on-site evaluation of the HACCP and prerequisite programmes.

ON-SITE DOCUMENT REVIEW AND OBSERVATIONS

Assessment of HACCP Programme

<i>Name and address of establishment audited</i>	<i>Phone/fax/email</i>
<i>Facility Owner (company or person)</i>	<i>Date of audit</i>
<i>Products Concerned</i>	<i>Products - High or low risk</i>
<i>Name and Number of Inspector</i>	
<i>Name and Title of Accompanying Individual</i>	

HACCP				
	A	B	C	Note
HACCP team used was appropriate				
Raw materials specifications defined and written down				
Product and ingredient specifications are defined and written down				
Product end use is defined and recorded (high or low risk product)				
Flow diagram is written down and is accurate and complete				
Hazard analysis is written down and is accurate and complete (evidence of Hazard Worksheets)				
Identification of CCPs is documented and CCPs are appropriate for product and end use of product				
Critical limits have been established, documented and are appropriate for the CCP				
Monitoring procedures for each CCP are documented, are followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist				
Verification procedures are documented and are followed. Records exist				
All necessary documentation exists and are available for inspection				

A = excellent, good or only minor deficiencies (no safety risk)

B = major or serious deficiencies, which could lead to a safety risk if not controlled. Any condition or situation rated as a B requires a plan or programme for rapid improvement. Repetitive or cumulative B-ratings can lead to a critical situation.

C = an unacceptable or critical situation representing a safety risk. Any C-rating requires immediate response and corrective action.

Assessment of Pre Requisite Programmes

FACTORY CHECK					
Processing Plant		A	B	C	Note
<i>Outside</i>					
Condition of grounds outside the factory					
Condition of the factory outside wall - especially holes through to inside					
<i>Inside</i>					
Rooms	- layout and flow of goods and people allows easy cleaning and prevents cross contamination				
Rooms	- for clean and unclean areas are separated (including waste areas)				
Rooms	- for non food items are separated e.g. packaging, chemicals, etc.				
Ceilings, walls, floors, doors and windows are well designed and maintained in good repair -					
	- for areas directly affecting food product or primary packaging material				
	- for other areas				
Drains	- are well designed, sufficient and maintained in good repair				
Drains	- there is protection against back-flow, back-siphoning, or other sources of contamination				
Lighting	- is sufficient and lights are covered				
Pest control	- exclusion devices (screens, mesh, etc.) are present at all openings to outside and maintained in good repair				
Pest control	- No areas present to harbour or attract pests				
Ventilation	- is sufficient, well designed and there is no condensation evident				
Facilities in Processing Plant		A	B	C	Note
Water	- sufficient quantity of cold water available, clear marking and separation of potable and non-potable water				
Water	- sufficient quantity of hot water/steam available				
Ice	- sufficient quantity available and storage facility well designed and kept in good order and repair				
Chilling and freezing facilities – sufficient capacity					
Waste-water - leaves the property in a condition that meets environmental laws					
Hygiene	- changing rooms are sensibly located, are well designed and are kept in good repair				
Hygiene	- toilets are sensibly located and in sufficient numbers and kept in good repair				
Hygiene	- Hand-washing and sanitizing stations are in sufficient numbers, well designed, well located and kept in good repair				
Equipment	- containers made of appropriate materials, in proper repair and removed when necessary				
Equipment	- machinery designed well, easy to clean and kept in good repair - Food contact surfaces				
Equipment	- machinery designed well, easy to clean and kept in good repair - Non-food contact surfaces				

PROCEDURES				
Safety of water and ice	A	B	C	Note
Criteria are written down and are appropriate				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Cleaning and disinfection	A	B	C	Note
Cleaning and disinfection methods (food contact and non-contact surfaces) are written down and are appropriate				
Monitoring procedure for cleanliness is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations in factory by auditor				
Personnel hygiene and health	A	B	C	Note
Personnel hygiene criteria (cleanliness, dress code) are written down and are appropriate				
Procedures to handle illness are written down and are appropriate				
Monitoring procedure for personnel hygiene and health is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations of personnel by auditor				
Prevention of cross contamination	A	B	C	Note
Criteria to prevent cross contamination are written down and are appropriate				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations in factory by auditor				
Maintenance of facilities for personal hygiene				
Methods to maintain personal hygiene facilities are written down and are appropriate				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations in factory by auditor				
Protection of food from adulterants	A	B	C	Note
Criteria to protect food from adulteration are written down and are appropriate				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations in factory by auditor				

Waste management	A	B	C	Note
Methods to handle sewage and processing waste are written down and are appropriate				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations in factory by auditor				
Recalls and traceability	A	B	C	Note
Methods to allow full traceability and recall of product are written down and are appropriate				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations in factory by auditor				
Training	A	B	C	Note
Training policy and programme are written down, are appropriate and followed				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations of training in factory by auditor, if possible				
Pest Control	A	B	C	Note
Pest control procedures are written down and are appropriate				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations in factory by auditor				
Labeling and safe storage and use of toxic chemicals	A	B	C	Note
Toxic chemical handling, use and storage procedures are written down and are appropriate				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations in factory by auditor				
Transport and storage	A	B	C	Note
Temperature and cleanliness criteria for transport and storage are written down and are appropriate				
Monitoring procedure is written down, is followed and records are kept				
Corrective actions identified, written down and are followed when critical limits exceeded. Records exist.				
Personal observations in factory by auditor				

NOTES

[illegible]

SUMMARY

SUMMARY					
Totals numbers of each category					
General comments from auditor					
General comments from establishment representative					

SIGNATURES

<i>Signature of auditor</i>	<i>Date</i>
<i>Signature of establishment representative</i>	<i>Date</i>

APPENDIX 2 HAZARD ANALYSIS WORKSHEET (based on National Seafood HACCP Alliance, 1997)

(1) Ingredient/ processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(3) Is this step a critical control point? (Yes/No)
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				
	BIOLOGICAL CHEMICAL PHYSICAL				

APPENDIX 3 HACCP PLAN FORM (based on National Seafood HACCP Alliance, 1997)

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) (5) (6) (7) Monitoring				(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who			

APPENDIX 4 GENERIC HACCP PLAN FOR THE PRODUCTION AND PROCESSING OF OYSTERS

Product description:

Name:	Shucked raw oysters
Raw material:	Live oysters from: (specification of harvesting area) No ingredients used
Parameters influencing safety:	None
Processing:	Manually shucked, washed and packed
Packaging:	In buckets
Storage conditions and shelf life	5 days at temperatures < 2°C
Intended use and consumer:	To be eaten raw by the general public
Labelling instructions:	Storage and distribution at temperatures < 2°C

The process flow chart and hazard analysis is shown in the following table:

Hazard analysis – Raw, shucked oysters

(1) Ingredient/ processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any potential food-safety hazards significant? (Yes/No)	(4) Justify your decision for column 3	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(3) Is this step a critical control point? (Yes/No)
Harvesting	Contamination with pathogenic bacteria, virus Biotoxins Chemical	Yes Yes Yes	Water filtration and accumulation of pathogenic compounds from harvesting area	Monitoring of harvesting area. Licensing of harvester. Tagging of all lots	Yes
Cooling / transport	Growth of pathogenic bacteria	Yes	Pathogenic bacteria will increase in numbers at high temperatures	Limit the time from harvesting to refrigeration	Yes
Receiving	As above	Yes	As above	Check labels, certificates, tags	Yes
Storage	Growth of pathogens	Yes	Prevented by PP ¹		No
Shucking	Contamination	No	Prevented by PP ¹		No
Washing / draining	Contamination	No	Prevented by PP ¹		No
Packing	None				
Labelling	<i>Failure in applying warning label</i>	Yes	All hazards are not fully controlled	Check labelling procedure	Yes
Storage / distribution	<i>Growth of pathogens</i>	No		Prevented by PP ¹	No

1. PP = prerequisite programme

HACCP Plan Form – Raw, shucked oysters

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) Monitoring				(7)	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who				
Harvesting	Contamination with pathogenic bacteria, virus, biotoxins, chemicals	Harvesting area must be monitored and open for fishing	Check with monitoring programme	Phone Fax Internet	Before harvesting	Fishermen		Do not harvest Reject harvest if area is closed	Copies of permits	Record review
Cooling / transport	Growth of pathogens	Oysters should be cooled to 10°C in less than 24 h	Time / temperature conditions	Visual check Thermometer	After 24 h and every 2 h	Fishermen, transporter		Adjust cooling system, Evaluate based on exposure	Temperature records Capture time	Record review
Receiving	Unsafe products As above	Must bear a tag from a certified harvester	Identification tag and harvester licence	Visual	Every container	QC person		Reject untagged containers or from unlicensed harvester	Receiving records	Record review
Labelling	Failure in applying warning label	All final product containers must carry label	The presence of label	Visual	Every container	QC person		Apply label	Statement of actions and observations	Record review