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Hazard Analysis and identification of Critical Control Points of collagen extraction from cod by-products

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1. Introduction

The aim of the European research project “UTILISATION AND STABILISATION OF BY-PRODUCTS FROM COD SPECIES” (QLK1-CT-2000-01017 QLRT-2001-02829) is to investigate whether collagen from fish by-products could serve as an important raw material in high quality food. Since Atlantic cod is a major commodity in western European countries, better use of by-products from filleting could result in reducing waste and producing a valuable ingredient for the food industry.

In the application of collagen as a food ingredient, it has to be ensured that there are no human health risks implicated. EU legislation requires an analysis of hazards associated with the manufacturing of the ingredient, and that no toxic residues are present in the end product.

In order to establish the feasibility of this application, a hazard analysis of the production of collagen from cod skins and bones is carried out.

This paper presents the results of this analysis following the principles of Hazard Analysis and Critical Control Point (1), as explained in more detail in Annex 2. Based on experimental research and literature research on similar extraction processes, hazards are evaluated and critical steps in the experimental process are identified.

The process under study is still at an experimental level. Therefore it is important to note that when the process is expanded to a plant-scale level of operation, critical steps and operational procedures have to be reviewed to effectuate measures of control and verification.

2. Hazard Analysis

2.1 Introduction

To identify hazards that will occur in the extraction of collagen from cod skins and bones, the end product will be formulated in terms of application, product characteristics, safety aspects, and shelf life. Subsequently raw material and processing steps are defined to meet these specifications. A process description and a flow chart will be used as an aid in the hazard analysis. Potential hazards will be ranked based on risk and severity of occurrence and preventative measures will be suggested to control the risks.

2.2 End product specification

The end product is aimed to be suitable as a processing aid for food manufacturing for the improvement of texture and structure of fishery products.

Table 1. End product specifications

Application	Food constituent (food grade): for the improvement of texture and structure of fishery products
Consistence	freeze-dried or spray-dried powder
Appearance	white/opaqe colour
Odour	free of odour or as much as possible
Shelf life	6 months at 20°C
Application concentration	maximum: 1-3% g/100g
Water content	maximum water content in end product: <1%

2.3 Raw material

Collagen will be extracted from raw, frozen or defrosted skins and bones, hygienically collected as by-product from filleting fresh cod. The raw material should be hygienically stored at a temperature between min. –30°C and max. 1°C.

2.4 Initial process description

At this stage, the extraction process is still on laboratory scale (3). In scaling-up, process conditions may change the occurrence or severity of a hazard. Therefore, a redesigned process should be reviewed according to the analysis described in this article.

The process can be divided in three different stages resp. Preparation, Extraction and Preservation (see Annex 1). Activities are presumed to be carried out in three different separated production rooms to ensure control of temperature and prevention of recontaminating the product.

The process is designed to treat both cod skins and bones. Whenever the treatment for bones is different to that of skins, specific treatment for bones is described separately. See also Annex 1: Process description.

The process description starts from point of reception of the raw material entering the site for extraction. The site is considered to be a land-based factory, since application of the process on a boat is highly inappropriate, due to safety and practical limitations.

PREPARATION

Reception of raw material

At time of reception a batch of raw material will be determined for origin of capture, sensory and microbiological quality.

Thawing (if frozen) and washing

If the raw material is frozen, it will be thawed in air overnight, at 10°C, fresh material will be stored at 4°C. Defrosted and fresh material will be washed with water at 4°C.

Mincing

The fish skins will be minced with a Finis Meat Mincer at ≤4°C. Temperature will be controlled by addition of flake ice.

Temporary storage

Temporary storage before further processing may take place at 0°C for a maximum of three days.

EXTRACTION

All extractions are carried out with a 2-liter Erlenmeyer.

Extraction with NaOH

Minced skins (or bones) will be extracted by a NaOH solution in a fermentor order to remove non-collageneous protein. The mince will be continuously mixed with 0.1 N NaOH for 1 hour at 4°C; at a weight/volume ratio of 1:7.

The solution will be centrifuged with a Sorvall Superspeed RC2-B at 10.000 rpm in 10 minutes to separate the treated skins or bones from the dissolved non-collageneous material.

Washing

Stirring for 1 hour at 4°C with 2l Erlenmeyer and 1l distilled water.

Extraction with EDTA (only for bones)

In order to remove calcium the solution will undergo an extraction with 0.5M EDTA for at 1 hour at 4°C; at a weight/solute ratio: 1:7 followed by a centrifugation with Sorvall Superspeed RC2-B at 10.000 rpm in 10 minutes (100g isolate).

Washing (only for bones)

Stirring for 1 hour at 4°C with distilled water.

Extraction with butyl alcohol

In order to remove fat and aroma components the solution will be mixed with 10% butyl alcohol for 10 minutes at 4°C. Centrifugation of about 100g of isolate with Sorvall Superspeed RC2-B at 10.000 rpm in 10 minutes.

Important: this extraction can only be used when its absence in the final product can be guaranteed.

Washing

Stirring for 1hour at 4°C with 2l Erlenmeyer and 1l distilled water.

Extraction with HCl

In order to remove the insoluble fraction:

Prior to extraction: 125g isolate + 875ml distilled water adjustment with 0.4M HCl to pH4

Max 500ml 0.4M HCl to maintain pH 4, 24h at 6-9°C in 2L fermenter, continuous chilled, with stirrer at 200 rpm. Centrifugation of about 100g of isolate with Sorvall Superspeed RC2-B at 10.000 rpm in 10 minutes.

PRESERVATION

Freeze drying

Purpose: Drying of soluble fraction.
In a Virtis Freeze mobile 25SL 100g of collagen extract is frozen to by chilled air to a temperature of -40°C. Then the temperature is gradually increased to 0°C after 5 days and a water content of <1% is achieved. The dried product is packed in air-tight plastic bags.

2.5 Flow diagram

The flow diagram (see Annex 1) shows all processing steps as described in 2.4. It shows the flow of raw materials, ingredients, and equipment as input into the process as well as the separate rooms where processes take place.

2.6 Identification of potential hazards

There are several hazards that may threat the safety of a product of marine origin. These can be categorized by chemical, physical, and biological origin. Hazards may be present due to the presence of agents naturally present in the environment where the fish has been caught, due to increase in concentration or formation of hazardous components during processing, handling, transport and storage.

Chemical residues are pesticides, toxic heavy metals, and PCB's, antibiotics and growth hormones, either from the natural environment or ingested by feed, as well as processing chemicals like hydrogen chloride or sodium hydroxide. Butyl alcohol may remain present due to improper processing. A side effect of hydrogen chloride is the oxidation of stainless steel production equipment. This can be overcome by application of coated stainless steel (i.e. 'inox').

Physical hazards are hazards occurring due to bad separation or insufficient mincing of the raw material (bones) or elements introducing the process like glass, wood, metal, insects, plastics, jewellery, paper/cardboard, cigarette ends, flaked paint, string, and hair.

Biological hazards are the presence or activities of pathogenic micro-organisms (indigenous as well as non-indigenous), biotoxins, pathogenic viruses, parasites, and formation of biogenic amines like histamine.

Biological Hazards

The raw material before processing is highly perishable, causing decomposition of proteins, formation of biogenic amines, production of off-odours. The extraction with NaOH will provide an accurate reduction of viable micro-organisms (see Table 1). However, toxins produced before this treatment may not be inactivated by this treatment. Therefore strict hygiene and time-temperature control should be applied to keep the concentration of micro-organisms within limits.

Table 1: Microbiological analysis of the experimental process

Processing step	Analysis	
	Total Count (cfu/g)[1)]	**Spore forming bacteria (cfu/g)[2)]**
Raw material	1.2*10e5	<10
After NaOH extraction	<10	<10
After Butanol extraction	<10	<10
After HCl extraction	<10	<10

1) Total mesophilic aerobic count (30°C)
2) Sulphite reducing Clostridia

Enzymatic hydrolysis

Hydrolysis of collagen by constitutional enzymes or produced by micro-organisms can reduce the yield of collagen. This is considered to be only a quality aspect and therefore will not be discussed in this hazard analysis.

Environmental contaminants ingested by feed

Dioxins, 'old' style pesticides, and PCB's are fat-soluble. They persist in tissues, which are rich in fat. Fish skin may contain fat tissue. Cod contains low levels of fat, and apart from specific organs as the liver, low levels of these compounds (5). The process is targeted to concentrate the protein fraction and not the fat fraction. The proposed butylalcohol will lead to a reduction in levels, because of the release of fatty substances. Therefore, risk of concentration of these contaminants is not expected.

Antibiotics and growth hormones will not reside in the fat but in the other matrix, causing a potential problem, because the level of acid and alkali treatment is too mild to inactivate these substances. Wild catch appears to have neglectable levels of these contaminants, so the hazard is limited to farmed fish, which is excluded from this study.

Heavy metals will be mainly present in bones. In the decalcification step they will be attached to EDTA en therefore sufficiently removed from the isolate.

Note: If it is decided to include cod liver as raw material, there will be a serious problem, because of high concentrations of dioxins and PCB's.

Residues of processing chemicals

In the process of collagen extraction, low concentrations of NaOH and HCl are applied to the extraction steps. They will be washed away in the washing steps following the extraction. However, butyl alcohol may not be eliminated completely, while traces are not allowed to be present in the final product. It is suggested that the extraction step with butyl alcohol should be removed from the process.

Formation of immuno-active products during modification of the collagen

Modification of the isolated collagen is not within the scope of this process.

BSE pathogens/Transmissable spongiform encephalopathies (TSE's)

There is no evidence available that the occurrence of BSE is associated with the consumption of fish. EU funded research has recently started to evaluate the possible transmission of prions (scrapie and BSE) to different fish species (4). New insights from these studies may result in a reassessment of this hazard.

3. Identification of Critical Control Points

From the hazard analysis and the description of the process the following Critical Control Points can be identified:

- Microbiological evaluation of raw material
- Sanitary monitoring programme
- Hygiene control
- Time-temperature control
- Process control: strict control of process parameters to prevent residues of extraction aids.

Table 2: Hazard analysis worksheet for the extraction of collagen from cod skins and bones

Process step	**Potential Hazard**	**Risk / severity**				**Preventative measures**	**CCP**
		contamination					
			growth				
				severity			
					risk		
PREPARATION							
1. Reception of raw material	microbiological contamination - spoilage bacteria - pathogenic bacteria Environmental contaminants	 +++ +++ +++	 low low low	 low high high	 high high high	 Sensory evaluation and Microbiological evaluation Sanitary monitoring programme	 x
2. Thawing and washing	microbiological contamination - spoilage bacteria - pathogenic bacteria	 +++ +++	 high high	 low high	 high high	Hygiene control Water quality Time-temperature control	X X
3. Temporary storage	Microbial growth	++	low	low	high	Hygiene control Time-temperature control	x x
4. Mincing	Microbiological contamination	++	low	high	high	Hygiene control Time-temperature control	x x
EXTRACTION							
5. NaOH extraction	Residues of NaOH	+++	low	low	high	Process control	x
6. Butyl alcohol extraction	Residues of Butyl Alcohol	+++	low	low	high	Process control	x
7. HCl Extraction	Residues of HCl	+++	low	low	high	Process control	x
PRESERVATION							
8. Freeze drying	Microbial contamination and growth	++	low	low	low	Hygiene control	
9. Storage	Microbial growth	+	low	low	low		

The extraction step with butyl alcohol cannot be controlled: The component is not safe to apply in the production of foodstuffs, since the washing step cannot guarantee complete elimination of the toxic solvent. Therefore the butyl alcohol should be excluded from the process.

With the application of appropriate control instructions that can be developed based on Annex 2 this experimental process of extraction of collagen can be regarded as a basis for safe production of collagen from cod skins and bones.

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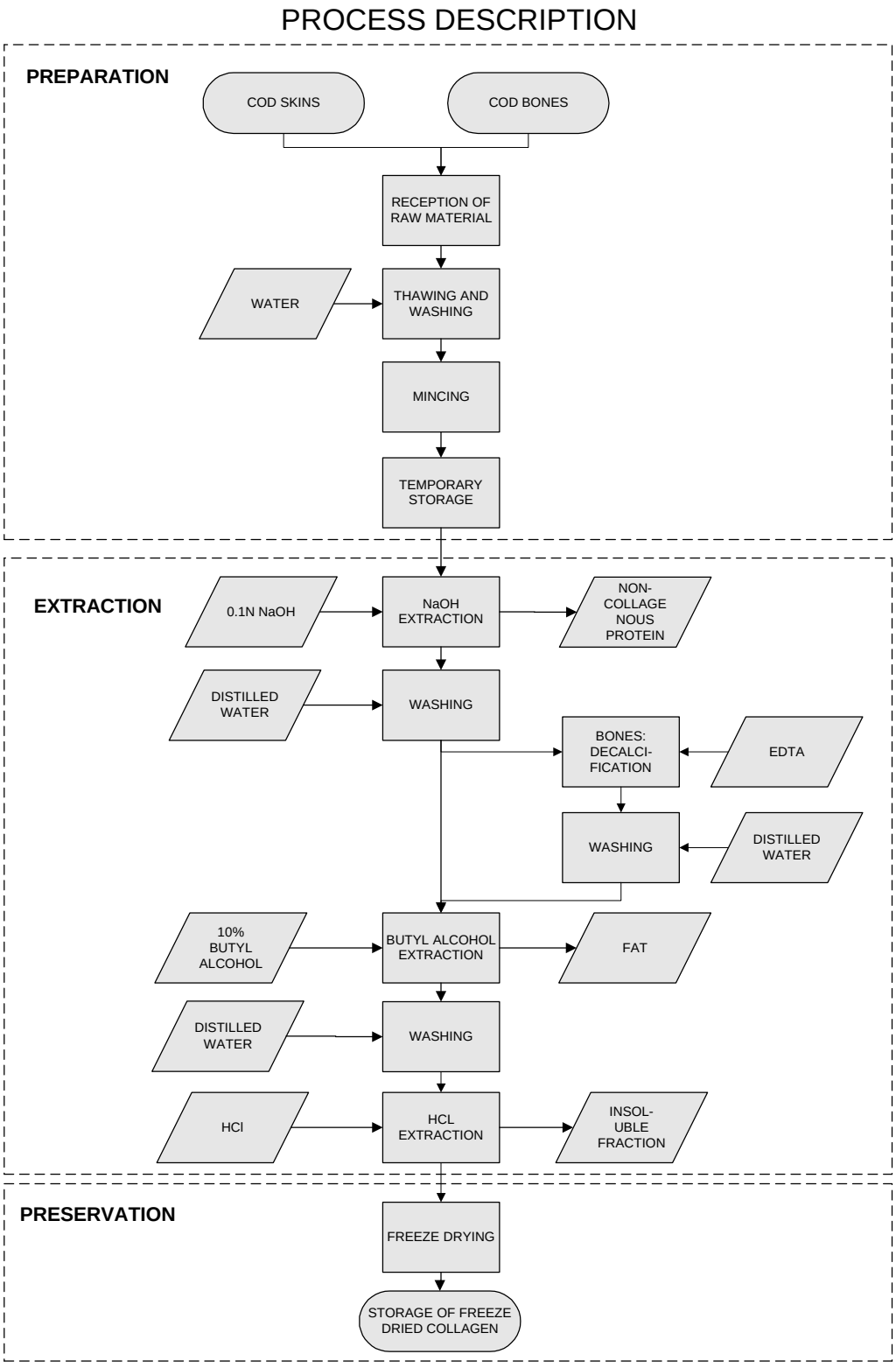
Annex 1: Process flow chart



Annex 2: Introduction to Hazard Analysis and Critical Control Points

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1 Introduction and regulatory needs/laws for Hazard Analysis of Critical Control Points

In the past regulatory authorities for food products had a duty to ensure that foods offered to the consumer are at least safe to eat. The authorities required a positive approach of using Good Manufacturing Practices (GMP), producing food in a hygienic manner, and by inspection of finished product. It is now realized that inspection of finished product gives a poor control over the safety of foods. Therefore, since 1 January 1993, regulatory authorities in Europe required that companies take a preventative approach to safety based on the principles of Hazard Analysis and Critical Control Points (HACCP). European Countries have food legislations, which are placing full responsibility for food quality on the producer (EEC Council Directive 91/493/EEC (EEC 1991b)). These requirements might be incorporated in primary legislation on food control, or be applied by executive action of the regulatory authority. The management of the company must then be able to produce for the regulatory authority a documented HACCP plan, and be able to demonstrate that the plan is being effectively implemented.

HACCP is therefore a major change for companies as it is a food safety management system, which concentrates prevention strategies on known hazards, occurring at specific points in the food chain, rather than end product testing with the chance of rejecting complete production lots. The major difference of this quality system, compared with final product check systems, is that by using HACCP a company is able to prevent problems before they occur. It controls all production steps and prevents food safety problems, which can occur. There will, however, always be a need for some end product testing, particularly for verification purposes.

Anyone exporting fish products to Europe or North America will have to implement a programme based on HACCP. If a company cannot demonstrate to the satisfaction of regulating agencies in importing countries that it has an effective programme operating in their processing plant, importers will not be permitted to accept the products.

The United Nations food standard group Codex Alimentarius Commission has recommended HACCP's adoption as a system for ensuring the safety of foods (including finfish and shellfish) and the prevention of foodborne diseases (ref: http://www.fao.org/DOCREP/005/Y1579E/y1579e00.htm#Contents)

2 Scope

HACCP is a powerful system, which can be applied to a wide range of simple and complex operations. For manufacturers to implement HACCP they must investigate not only their own production methods, but must also apply HACCP to their raw material supplies and to final product storage, and must consider distribution and retail operations up to and including the point of consumption.
It can be concluded that HACCP is not a 'stand alone' process control system but may be a part of a larger system, of viz. integral quality assurance.

3 HACCP step by step

3.1 Commitment

First of all the management of the companies must be committed to provide all the necessary resources for the study for implementation of HACCP. This includes appointing team members, provide time for HACCP analysis, writing the HACCP plan, implementation of the system, training and instruction of personnel, reviews and updates. Without such commitment there is no point in beginning the study. Everybody in the organisation must be aware of the needs of the company to comply with HACCP regulation.

3.2 HACCP team

It is important that a multi-disciplinary team, with knowledge and expertise required for the specific product line being considered carries out the study. The use of such team is known to improve greatly the quality of data considered and, therefore, the quality of decisions reached.
The team can for example consist of:

- A chairman who has knowledge of HACCP and should be responsible for managing the study.
- A quality assurance/quality control specialist: an individual who understands the microbiological and/or chemical hazards and associated with a particular product group (fish).
- A production specialist: an individual who has responsibility for, or is closely involved with the process under study. It is essential that this individual is able to contribute details of what actually happens on the production line throughout all shift patterns.

- An engineer: an individual who has a working knowledge of the hygienic design and engineering operation/performance of the process equipment under study.
- Others with special knowledge e.g. microbiology, hygiene, food technology, plant construction/maintenance, operations, market requirements etc.
- Sales representative: to consider quality expectations of the end product

3.3 Terms of reference

The HACCP study should be carried out on a specific product- or process-line, in this case the production of collagen from by-products of fresh filleting of cod. In order for the study to proceed quickly it is essential that the terms of reference be outlined clearly at the start. It is necessary to decide upon the process line, product and whether physical, chemical and microbiological hazards (or any combination of these) and whether product safety and/or microbiological quality aspects (i.e. spoilage) are to be considered with respect to food legislation. It may also be necessary to take into account demands of buyers of manufactured products. It is also to be considered when the product is judged as safe: the point of consumption or the point of manufacture with clear storage and use instructions.

It is to advise to keep it simple when you start to make it a successful operation; when a system is working, it can be further developed. At this stage the terms of reference is based upon the experimental production of collagen from skins and bones. As experience increases, and upscaling will take place, the terms of reference will be more applicable to an industrial process.

3.4 Product information

A full description of the product under study, or intermediate product if only part of the process is to be looked at, should be prepared.

Product information should contain:

- Composition
- Structure and physical characteristics
- Description of the processing (whether the product has been heated and to what extent)
- Packaging
- Storage and distribution conditions
- Required shelf-life
- Instructions for use

3.5 Identify the intended use

The intended use of the product by the consumer and the consumer target groups should be defined. This can be done in combination with the other product information you just made. Some groups of the population, elderly, very young, sick or immune compromised are much more susceptible to some hazards. For instance, it might be necessary to label the products with the text: 'not recommended to be eaten during pregnancy' when there is a risk of *Listeria monocytogenes* being present. The intended consumer group may affect your 'level of concern'. Are there specific requirements imposed by the importer or the importing country?

3.6 Process overview

Show all specific steps in the manufacturing process, from the time raw materials are received until the end product is on the market; receiving, preparation, processing, packaging, storage, distribution.

The more specific the flow-chart, the easier to understand the possible source of hazards. Take into account the delays that may occur during the process. Include sufficient technical data for the study to proceed.

Examples of information that might include:

- All raw materials and ingredients and packaging used (microbiological, chemical, physical data)
- Floor plans and equipment layout
- Sequence of all process steps (including raw material addition)
- Time/temperature history of all raw materials, intermediate and final products. Including potential for delay
- Product recycle/rework loops
- Equipment design features (including presence of void spaces)
- Efficiency of cleaning and disinfecting procedures
- Environmental hygiene
- Personnel routes
- Routes of potential cross-contamination
- High (dirty)/low (clean) risk area segregation
- Personal hygiene practices
- Storage and distribution conditions
- Consumer use instructions.

Confirm the flow chart and all recorded details during operating hours to verify that it is accurate and that all recorded details show what actually happens rather than what is wished to happen by the HACCP-team.

3.7 Hazards-analysis of each processing step

The flow chart, which was prepared, can now be used for assessment of hazard at each processing step.

Hazards have been defined as the unacceptable contamination, growth or survival of bacteria in food that may affect food safety or quality (spoilage) or the unacceptable production or persistence in foods of substances such as toxins, enzymes or products of microbial metabolism.

The team may decide in its terms of reference to include only particular groups of hazards, e.g. infectious pathogens or toxin forming pathogens. Equally the team may decide to study all potential microbiological, chemical, physical and economical hazards.

Hazard analysis requires two essential ingredients. The first is an appreciation of the pathogenic organisms or any disease agent that could harm the consumer or cause spoilage of the product, and the second is a detailed understanding of how these hazards could arise. Thus the hazard analysis requires thorough microbiological knowledge in combination with epidemiological and technological information.

In order to be meaningful, hazard analysis must be quantitative to assess both severity and risk. Severity means the seriousness of the consequences when a hazard occurs, while risk is an estimate of the probability or likelihood of a hazard occurring. It is only the risk, which can be controlled. It is however difficult to estimate risk, as it cannot be predicted what the chances are when an employer makes a mistake during processing. Therefore, we will not estimate chances for a hazard to occur.

Hazard Analyses:

a) Identify hazards

b) Identify contamination point

c) Determine the probability

d) Asses severity

e) Determine preventative measures.

A Identify hazards:

Identification and classification of hazards should be carried out. Different classifications (e.g. Food Safety, Other legislation, Other Quality aspects, Commercial aspects) are set, and in the terms of reference decide whether these hazards are considered in this study or not.

B Identify contamination points:

Identify contamination points by a so-called 'cause -> effect' analysis.

The principal causes are:

Manpower (skills, training, attitudes, and knowledge)

Method (procedures, inspections),

Machines (processing, engineering)

Materials (attributes of the product and its components).

C Determine probability:

It is advised to determine the probability by using historical data from quality controls or failures occurred in the past.

The potential for cross-contamination in food preparation is built by: food raw materials, cleaning methods, raw material preparation, equipment, environment, post cooking handling, people and personal hygiene.

D Asses severity:

Within the context of HACCP, risk can be defined as the likelihood that a hazard will occur. Within food safety it is helpful to consider food-risk-categories being high, medium or low.

Products of high risk: product not heated prior to consumption, containing fish, egg, vegetable, cereal and/or dairy ingredients which need to be refrigerated. Raw meat, fish and dairy products. Infant feed.

Products of medium risk: dried or frozen products containing fish, meat, egg, vegetable or cereal and/or dairy ingredients or any substitutes for these and other products excluded in the food hygiene regulations and heated prior to consumption.

Products of low risk: not relevant for fish products.

The rationale behind the allocation of foods to these groups is a consideration of: Is the fish likely to contain and/or support the growth of potential pathogens? Will the product undergo any additional heat processing? Will future storage conditions provide opportunities for the growth of pathogens or further contamination? Is the population consuming the fish especially susceptible?

E Preventative measures:

Control measures are actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specific control measure.

3.8 Identify critical control points

A CCP is identified as a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level. Thus for every step, location or procedure identified as a CCP, a detailed description of the preventative measures to be taken at that point must be provided. For the manufacturer those CCP's highlight where particular care has to be concentrated in the implementation of preventative measures. There are two levels of control, and therefore two kinds of CCP's: CCP1 is a Critical Control point where a food safety hazard is eliminated (for example sterilization), where as CCP2 is a Critical Control Point where a food safety hazard is reduced to an acceptable level (for example pasteurization).

In any operation many control points (CP) could be necessary but not critical due to low risk or low severity of the hazard involved. Some of these control points are a result of company rules for good manufacturing practice, product reputation, company policy or aesthetics. Such distinction between CP's and CCP's is one of the unique aspects of the HACCP-concept, which set priorities on risks and emphasizes operations that offer the greatest potential for control. Thus the HACCP points out what is necessary while further control may be nice.

It is not always easy to determine if a certain processing step is a CCP.
Examples of CCP's are: a specified heat process, chilling, specific sanitation procedures, prevention of cross contamination, adjustment to food to a given pH or NaCl content. When considering a possible increase in levels of the hazard the team should be aware that it is possible that a single process step will not allow development of the hazard to unacceptable levels. Over a number of process steps however, the amount of increase may reach unacceptable levels due to the cumulative time and temperature of holding the product during processing. The team must therefore take account of not only the specific process step under discussion, but also the accumulated effect of subsequent process steps when answering the question.

3.9 ` Target levels and tolerance

Proceed the HACCP system by identifying target levels (and specified tolerance) for the control measures at each CCP. The specific target levels and tolerance set for each CCP/control measure must represent some measurable parameter related to the CCP.

3.10 Monitoring procedures

Monitoring is the series of observations or measurements to ensure that the preventative measures being implemented correctly. The CCP's are 'in control'. Monitoring should provide this information in time for corrective action to be taken to regain control of the process before there is a need to segregate or reject the product. Therefore those that can be measured relatively easy and quickly are preferred. Examples of these measurements suitable for monitoring are: temperature, time, moisture level, metal detection, pH, aw, in some cases chemical analysis, visual assessments of product and management/operational practices. Unfortunately this is not always possible. Microbiological monitoring systems have the disadvantage of having to interpret the results in the light of the known distribution of organisms in the product and are therefore only suitable for verification of CCP's.

3.11 Corrective actions

The HACCP plan should contain written details of:

- Immediate action to be taken when there is (a trend to) loss of control
- Who is to be informed and the type of report to be produced.
- What to do with the product that has been produced.
- Investigations of how loss of control has occurred (prevention of recurrence should be an essential element of any HACCP plan).
- Who is responsible for decision-making.

3.12 Verification

How to verify that the HACCP-system is working effectively:

- Methods that might be used to verify random sampling and analyzing (microbiological analysis and chemical analysis (for example TVB-N) and trend analysis. Reinforced analysis or tests at selected critical control points. Intensified analysis of intermediate or final products. Take surveys on actual conditions during storage, distribution, sale and use of products.

- Verification procedures: Inspection of operations, validation of critical limits, with specialists, experts and standards setting organizations. Review of deviations from the set critical limits and of corrective actions. Audits by consulting agencies or government inspection authorities.

3.13 Documentation

In a HACCP system all activities from production to safety and quality control are described in procedures and instructions, so it will be clear what action is needed at every step of processing and when problems occur. Operating Instructions (OI) cover working activities, whereas Control Instructions (CI) explain which controls have to be carried out, how they are to be carried out and by whom, what to do when control limits are exceeded, what to record. As production data is important for control of production, so is quality and safety data important for control of safe processing. These data are recorded on Registration Forms (RF). Production and quality aspects of raw material, intermediary products, end products, and any material needed for processing (packaging, ingredients) need to be specified in Product Specifications (PS). Documents are identified by an abbreviation of the type of document (OI, CI, RF, PS) and a number, referring to a specific topic. Table 2 shows at which point, which documents are in use.

Operating instructions and Control Instructions have to be available to the persons responsible for the tasks in those instructions. They should be present and accessible at the point where the tasks take place, so they serve as quick reference. Registration forms have to be collected and managed by the Quality Manager.

3.14 Review and update the HACCP plan

When HACCP is completed, it is necessary to review the plan.

It is essential that change to any of the following should automatically act as a trigger for a HACCP review and update:

Change in raw material/product formulation

Change in processing system

Change in factory layout and environment

Modification to process equipment

Change in cleaning and disinfecting programme

Change in packaging, storage and distribution system

Change in staff levels and /or responsibilities

Anticipated change in consumer use

Receipt of information from the market place indicating a health or spoilage risk associated with the product, etc.