EUROPEAN GUIDE
TO GOOD PRACTICE
FOR SMOKED AND/OR SALTED AND/OR MARINATED FISH

GLOSSARY

GEN – General
MNG – Management
SUP – Support
OPE – Production process
FPO – Food Processing Operators
OPRP – Operational Prerequisite Program
CCP – Critical Control Points

GENERAL REQUIREMENTS

GEN 1 – SCOPE

The present guide is applicable to cold or hot smoking and/or salting and/or marination (pH>4,5) of raw fish (salmonids and other fishes), with a shelf life period exceeding 5 days[1] at a controlled temperature (chilling, freezing or deep freezing), and suitable for immediate consumption, i.e ready-to-eat.

The Guide applies to approved fish processing operators (FPO) processing fish originating from marine or freshwater fishing, and from marine or land-based aquaculture which may be served whole, as fillets, in slices, pieces, etc.

Generally, the products are raw (except for hot smoking), salted or not, smoked or not, with or without the addition of vinegar or a light marinade, with or without the addition of aromatic herbs such as dill, spices, thin slices of carrots, slices of lemon, etc. The shelf-life exceeds 5 days.

The products defined in this guide underwent at least one of the following three operations: smoking, salting, or marination.

Retail trade activities are de facto excluded.

The professional selects the appropriate measure, as defined below, in accordance with the size (processed quantities and types, the number of persons employed in the enterprise, etc.) and activity of the enterprise.

Labelling of these products must comply with relevant EU and/or any national rules where sold.

Examples of products concerned:

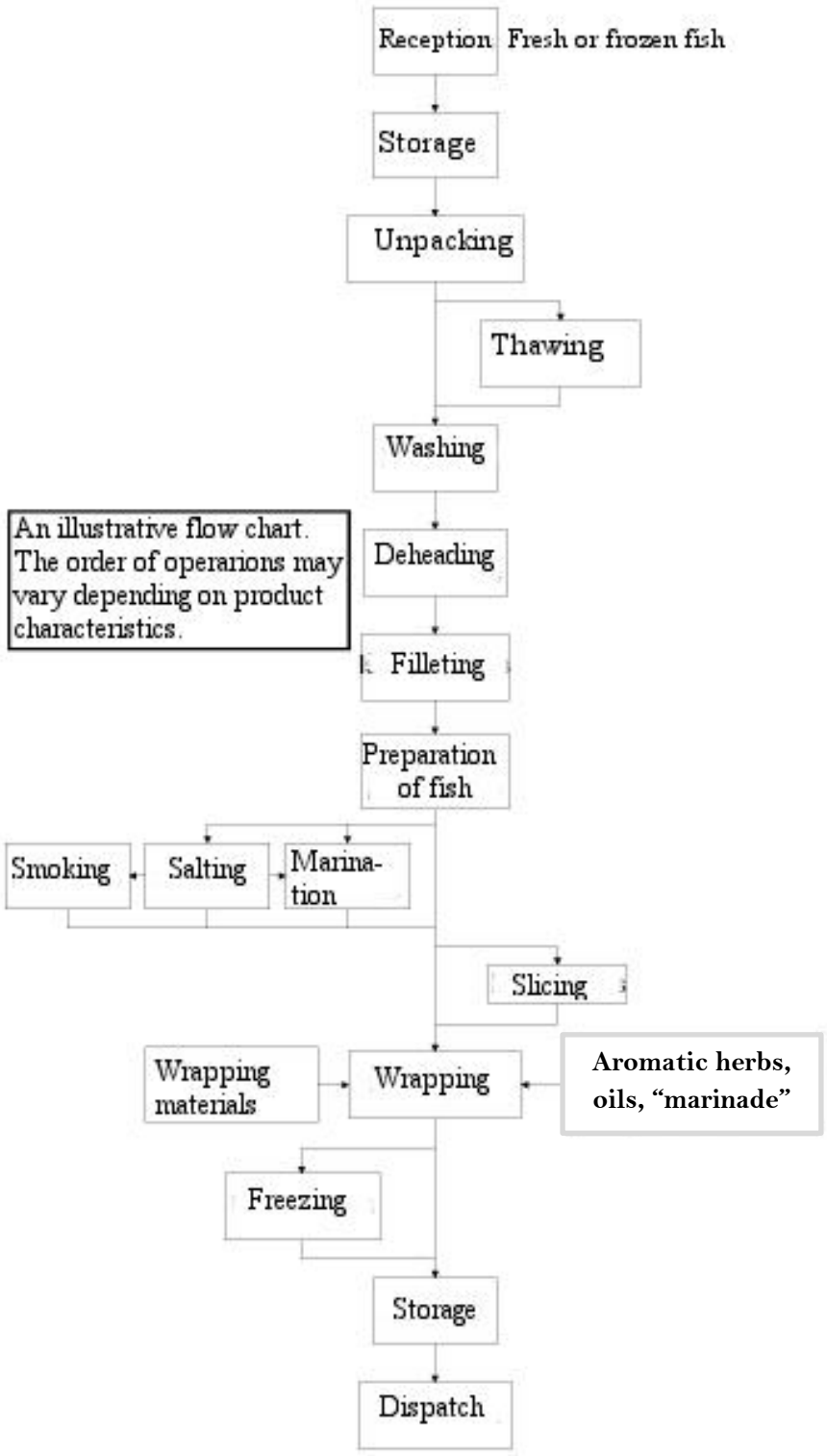
- smoked salmon or trout,
- smoked halibut, tuna, etc.
- smoked mackerel,
- Raw fish fillets salted, smoked or not, with or without light marinade
- Raw fish fillets salted, smoked or not, with or without vinegar
- fish carpaccio with light marinade,
- salted smoked herring,
- herring roll mops etc.

[1] As defined in Regulation 2073/2005.

GEN 2 - PRINCIPLE STAGES OF PRODUCTION

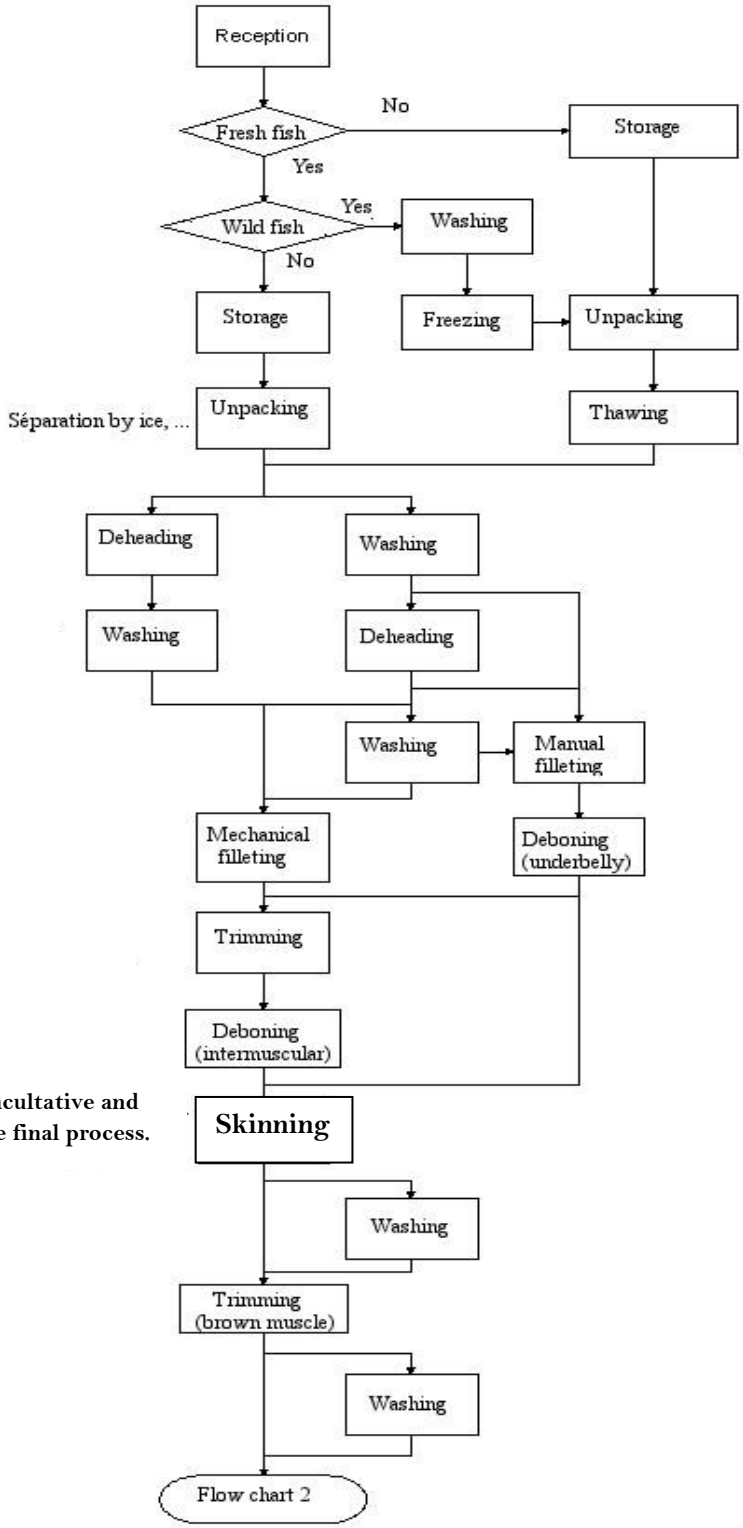
Principle stages are indicated below. To determine and implement own HACCP plans, each professional must establish flow charts (or a description) displaying distinct process stages (or sets of similar activities, identical hazards, identical operations, identical uses, etc.).

Illustrative flow chart



1 - Smoked salmon and trout (cold smoking)[2]

Illustrative flow chart (1)

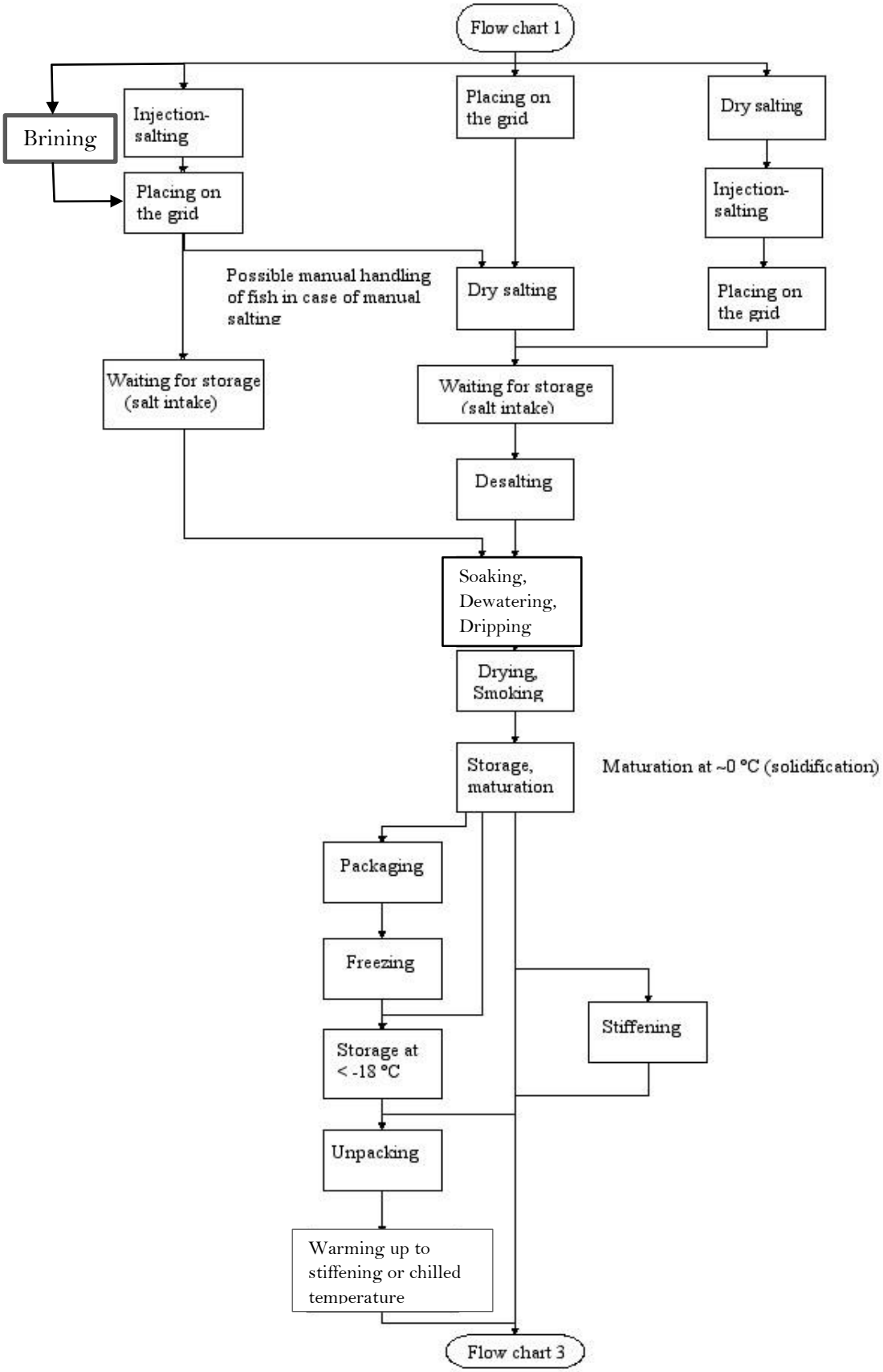


Skinning is facultative and depends on the final process.

Processing of raw fish

[2] For parasite management please see GEN 4 – Principal Hazrds – Preventive Measures : 1.1. Biological Hazards (Parasites)

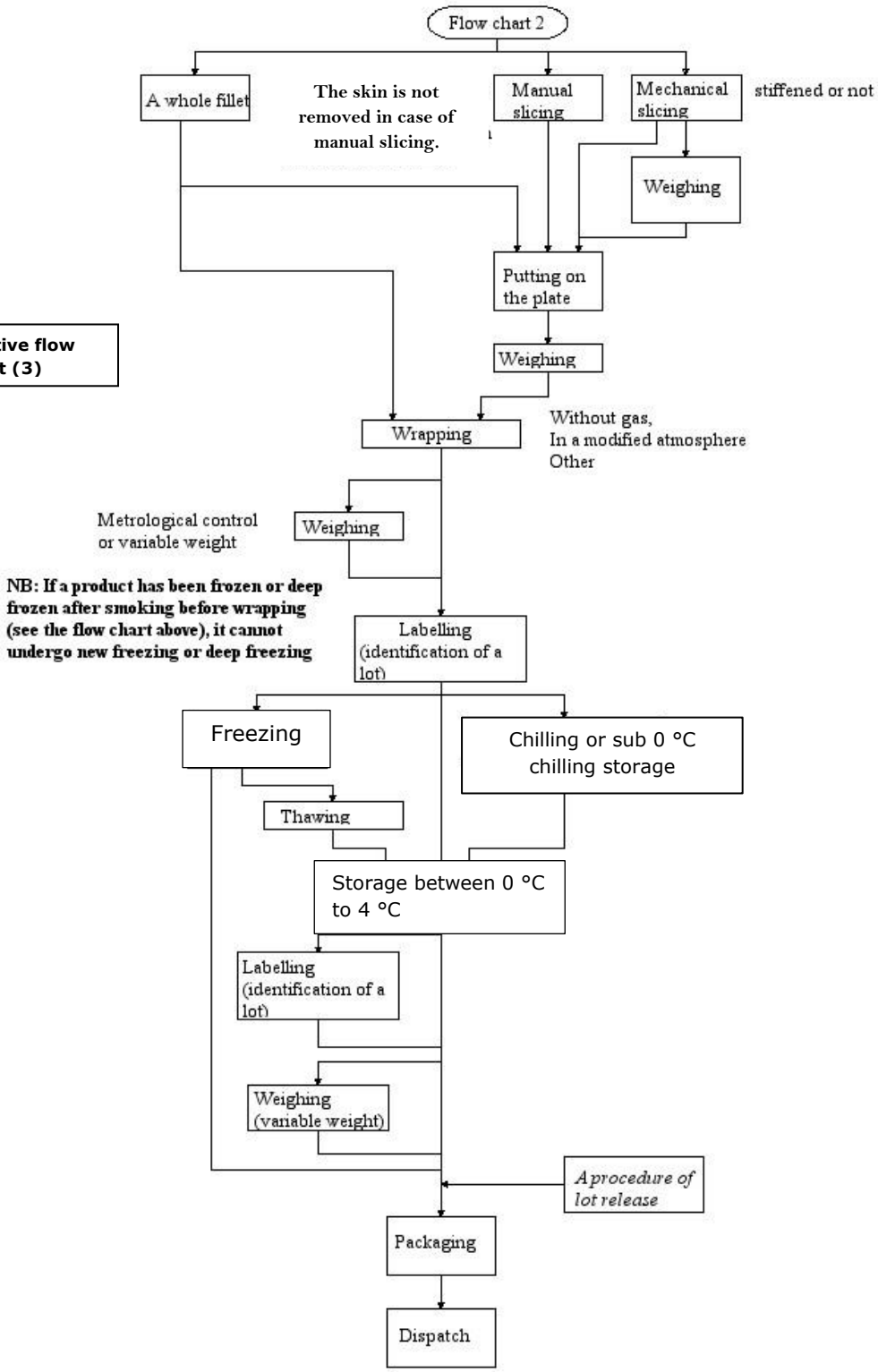
Illustrative flow chart (2)



[3]

[3] For parasite management please see GEN 4 – Principal Hazrds – Preventive Measures : 1.1. Biological Hazards (Parasites)

Illustrative flow chart (3)



[4]

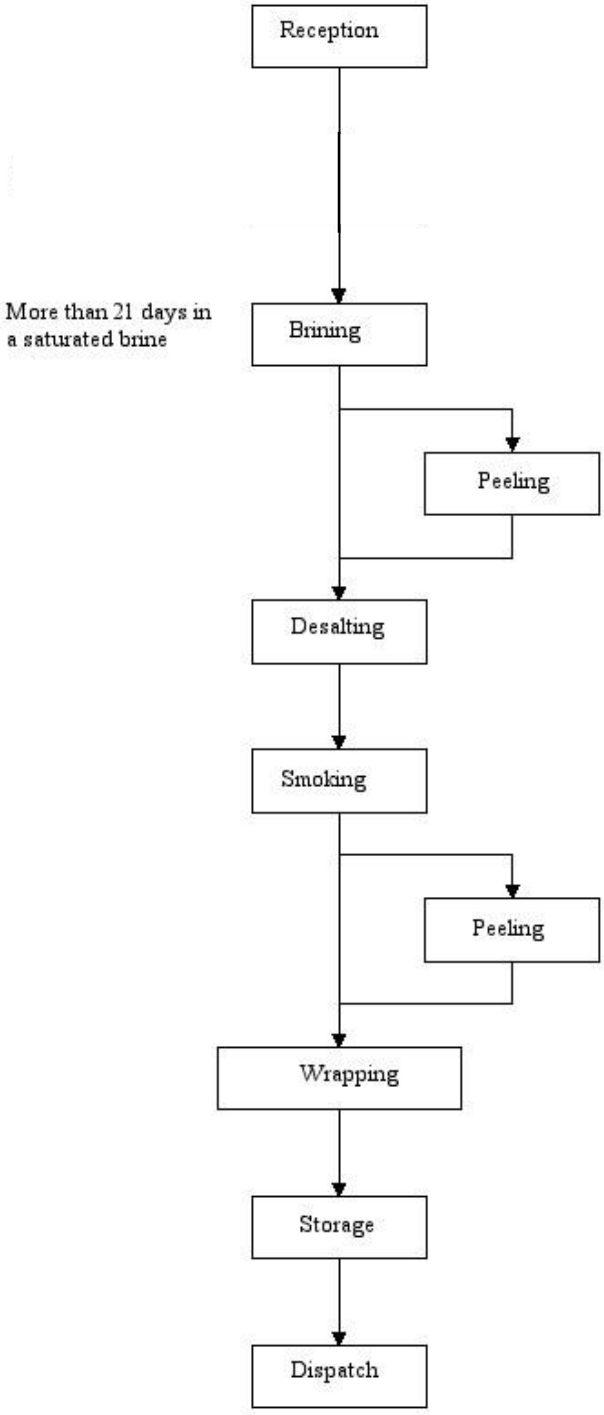
[4] For parasite management refer to GEN 4 – Principal Hazrds – Preventive Measures : 1.1. Biological Hazards (Parasites)

2 - Other species

2.1 Traditionally salted smoked herring fillet

Salting of herring fillet in brine that is permanently saturated by salt for at least 21 days.

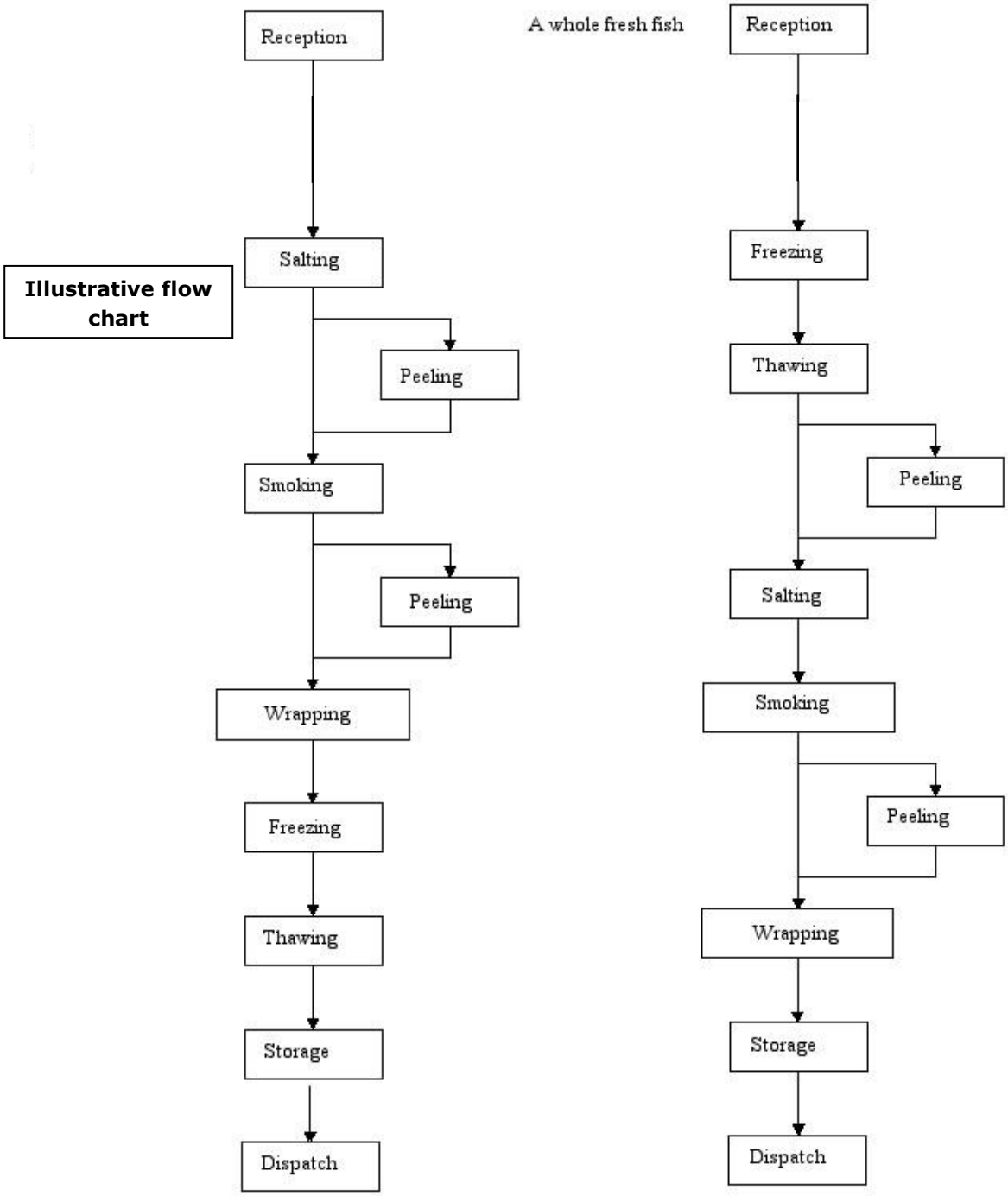
An illustrative flow chart



2.2 Other fish fillet

Mandatory freezing according to Regulation 853/2004 and subsequent consolidated versions concerning parasites[5], for ready-to-eat products.

Illustrative flow chart



[5] Regulation 853/2004 and subsequent consolidated versions concerning parasites and Regulation 1276/2011, amending Annex III to Regulation 853/2004 of the European Parliament and of the Council as regards the treatment to kill viable parasites in fishery products for human consumption.

GEN 3 - PRINCIPLE LEGAL ACTS

NOTE: The references below (non-exhaustive list) are based on the original texts. They may be supplemented or amended partly by the documents to be published at a later date.

1 - Legal acts related to hygiene

1.1 Principle legal Food Hygiene Acts

Reference	Object
Regulation (EC) No 178/2002 of 2002, January the 8th	The general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) No. 852/2004 of 2004, April the 29th	The hygiene of foodstuffs.
Regulation (EC) No 853/2004 of 2004, April the 29th	Specific hygiene rules for foods of animal origin. Regulation 853/2004 and subsequent consolidated versions concerning parasites and Regulation 1276/2011, amending Annex III to Regulation 853/2004 of the European Parliament and of the Council as regards the treatment to kill viable parasites in fishery products for human consumption.
Regulation (EC) No 2073/2005 of 2005 November the 15th	Microbiological criteria for foodstuffs.
Regulation (EC) No 2074/2005 of 2005 December the 5th	Implementing measures for certain products under Regulation (EC) No 853/2004 and for the organisation of official controls under Regulation (EC) No 854/2004 and Regulation (EC)No 882/2004l, derogating from Regulation (EC)No 852/2004 and amending Regulations (EC)No 853/2004 and (EC) No 854/2004
Regulation (EC) No 2406/96	Laying down common marketing standards for certain fishery products
R2006/1881 of 2006, December the 19th	Contaminants in food. Maximum levels.

Regulation 396/2005	Pesticide residues in feed

1.2 Legal acts specific to seafood

European legal acts	Object
Council Regulation (EC) No 1224/2009	Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006
IMPLEMENTING REGULATION (EU) No 404/2011 COMMISSION of 2011, April the 8th	Laying down detailed rules for implementing Regulation (EC) No 1224/2009 establishing a Community control system for ensuring compliance with the rules of the Common Fisheries Policy
REGULATION (EU) No 1379/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 2013, December the 11th	On the common organisation of the market in fishery products sector and aquaculture, amending Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Regulation (EC) No 104/2000 from the Council.
IMPLEMENTING REGULATION (EU) No 1420/2013 of the COMMISSION of 2013, December the 17th	Repealing Regulations (EC) No 347/96, (EC) No 1924/2000, (EC) No 1925/2000, (EC) No 2508/2000, (EC) No 2509/2000, (EC) No 2813/2000 (EC) No 2814/2000, (EC) No 150/2001, (EC) No 939/2001, (EC) No 1813/2001, (EC) No 2065/2001, (EC) No 2183/2001 (EC) No 2318/2001, (EC) No 2493/2001, (EC) No 2306/2002, (EC) No 802/2006, (EC) No 2003/2006, (EC) No 696/2008 and (EC) No 248/2009 following the adoption of Regulation (EU) No 1379/2013 of the European Parliament and of the Council on the common organisation of the markets in fishery and aquaculture products sector
Council Directive 96/23/EC of 29 April 1996	*Measures to monitor certain substances and residues thereof in live animals and animal products.*

1.3 Other regulatory legal acts relating to hygiene or health

European legal acts	Object
Regulation (EC) No 183/2005	Requirements for feed hygiene

2 - Legal acts related to labelling

Community legal acts	Object
REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 2011, October the 25th and its amendments	Concerning consumer information on foodstuffs, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council and repealing Council Directive 87/250 / EEC, Directive 90/496 / EEC, Directive 1999/10 / EC, Directive 2000/13 / EC of the European Parliament and Council directives 2002/67 / EC and 2008/5 / EC and Regulation (EC) No 608/2004
R 2006/1924 and amendments	Nutritional health claims made on food

3 - Various regulatory laws

European legal acts	Object
Regulation (EC) No 1935/2004	Materials and articles intended to come into contact with food
Regulation (EC) No 2065/2003	Smoke flavourings used or intended for use in or on foods
COMMISSION IMPLEMENTING REGULATION (EU) No 1321/2013 of 10 December 2013	*establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings*
R 2008/1334 and its modifications	Food flavourings

European legal acts	Object
R2008/1333 of 2008, December, the 16th and its modifications.	Food additives
R2008/1332 and its modifications	Food enzymes
R2008/1331	Authorization procedures additives, enzymes and flavorings
COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006	*Good manufacturing practice for materials and articles intended to come into contact with food* should be included in page 17.

4 - Legal acts for related activities

European legal acts	Object
Directive 2006/88	Minimum Community measures for the control of certain fish and aquaculture diseases.
Directive 2002/32/EC	Undesirable substances in animal feed
Regulation (EC) 2009/1069	Health rules concerning animal by-products not intended for human consumption

5 - Other references

- *Recommended international practice codex – General Food Hygiene Principles (CAC/RP 1- 1969, rev. 4 – 2003) covering the Analysis System of Risk Factors, management of Critical Control Points (CCP) and application of implementation directives* Appendix to CODEX Alimentarius Comission (CAC/RP 1- 1969, rev. 4 – 2003)
- *Codex Alimentarius - Code of practice for fish and fishery products CAC/RCP 52-2003*
- *Processing parameters needed to control pathogens in cold smoked fish - Journal of Food Science (2001)*
- *Fishery Food Industry – Marcel Sainclivier (1983)*
- *Food safety management systems- Requirements for any organisation in the food chain* (NF EN ISOO 22000 – October 2005)
- *Food safety management systems- Guidelines relating to application of ISO 22000: 2005(ISO/TS 22004:2005).*

- *Food and feed hygiene - Methodology for preparing guides to good hygiene practices and applying the principles of HACCP* (AFNOR NF V01-001 March 2006)
- *Traceability in the food chain - General principles and and basic requirements for system design and implementation (ISO 22005, currently undergoing the acceptance procedure)*
- *Guide to good hygiene practices applicable to plastic and composite flexible packaging coming in contact with foodstuffs (April 2001 – Publishing house of official journals)*
- *Traceability guide for packaging* (SEFEL – January 2006)
- *Effect of delayed processing on changes in histamine and other quality characteristics of 3 commercialy canned fishes* (R. Jeya Shakila, Geevarethinam Jeyasekaran, S. Aunto Princy Vyla and R. Saravana Kumar - Journal of Food Sciences - Vol 70 ,Nr 1, 2005)
- *The quality of fresh fish and its development* (Technical document No 348 of The Food and Agriculture Organisation of the United Nations)
- *Scientific opinion on risk a assessment of parasites in fishery products; EFSA Panel on Biological Hazards (BIOHAZ); EFSA, Journal 2010; 8(4): 1543*
- *Guidelines on Sampling the Food Processing Area and Equipment for the detection of Listeria monocytogenes.*
- *EURL Lm Technical Guidance Document for conducting shelf-life studies on Listeria monocytogenes in ready-to-eat foods*

GEN 4 - PRINCIPAL HAZARDS - PREVENTIVE MEASURES

The following hazards might occur:

- **biological**: parasites, pathogenic bacteria, toxins, viruses[6],
- **chemical**: residues of pesticides, veterinary medicine, dioxins, polychlorinated biphenyl , radionuclides, heavy metals
- **physical:** foreign materials, etc.
- **allergens**

The hazards to be considered while establishing any HACCP plan depend on the product produced, the origin of the ingredients used and whether those products are ready to eat or must be sent for further processing.

To define *controllable* hazards, it is necessary to identify them, evaluate the probability of their emergence (incidence) and the severity.
In order to ensure that hazards are managed as appropriate under HACCP, it is essential to distinguish between:

- Contamination (pollution) which can originate from:
  - the presence of a Potentially harmful element in raw material (food, packaging materials...). **The level of potential contamination may be closely related to fish origin (i.e. level of contamination in the water body) and how the fish has been handled or prepared before receiving by the processor.**
  - the introduction of such a hazard within the course of the production activity can be due to cross-contamination, **when carrying out various works related to fish preparation (filleting, trimming, particularly slicing).**
- Proliferation (multiplication), is the development of a dangerous element present in the product. **Temperature control and time/activity management, amount of salt, particularly smoking quality are vital to minimise the multiplication process.**

FPOs do not have any de-contamination processes in factories.

1 - Main hazards

1.1 Fish (wild or farmed)

Fish may be obtained directly from ships, auctions, or farmed fish, or may be fish that has been processed previously (slaughterhouses, fish trade,...). FPO controls should reduce or eliminate hazards to acceptable levels and should be reviewed regularly while preparing the supplier's technical documentation.

[6] The reproduction of viruses is restricted to live cells, only initial contamination control (for example, fresh vegetables) should be considered.

Processing procedures may not completely decontaminate products due to, for example, the absence of a thermal treatment (except for hot smoking). Professionals should put all effort into reducing any initial contamination through supplier selection, into controlling proliferation (by maintaining the temperature of fish as close as possible to 0^{o} C) and by preventing cross-contamination.

	HAZARDS		ORIGIN	HEALTH IMPACT	PREVENTIVE MEASURES
Biological hazards	Parasites	Nematodes, including *Anisakis spp.* *Capillaria spp.* *Gnathostoma spp.* *Pseudoterranova spp*	Transmitted by feeding with fish or crustacean.	Acute dyspepsia that might require, in rare cases, surgical intervention.	A quick and efficient evisceration is a necessary practice to avoid or minimize the presence of parasites. For wild fish and farmed fish when the FPO cannot guarantee absence of parasites according to regulation 853/2004 control measure must be assured by: a) freezing of fish (According to Regulation 853/2004 and subsequent consolidated versions concerning parasites), for 24 hours at ≤ - 20° C or -35° C for not less than 15 hours in all parts of the fish. b) heating process (at least 1 min. at ≥60° or 15 seconds at 74° C (microwave) c) hot smoking (at ≥60° C for 1 minute) d) resting in salt for more than 21 days (salted herring). For farmed fish when the FPO can guarantee absence of parasites according to regulation 853/2004 control measure must be assured by net control as a preventive measure to be taken plus the compliance with the prevention and market fishery conditions for FPO established in Regulation 853/2004.
		Cestodes (taenias), including *Diphyllobothrium latum*	Mainly in freshwater and diadromous fish including salmonids	Kidney damage	
		Trematodes (flukes), including *Clonorchis* and *Ophisthorchi* (liver flukes), *Paragonimus* (lung flukes), *Heterophyes* and *Echinochasmus* (intestinal flukes)	Endemic contamination in certain regions, particularly in Asia and the South East Mainly freshwater fish		
	Pathogenic bacteria	*Aeromonas hydrophila*		Gastroenteritis, especially for infants, older or immunocompromised people.	

	HAZARDS		ORIGIN	HEALTH IMPACT	PREVENTIVE MEASURES
		Clostridium botulinum	Present "normally" in the aquatic environment . Present mainly on the skin, gills or in the digestive tract of the fish.	Nausea and vomiting, then central nervous system affected: eyes (double vision, difficult accommodation), the digestive tract (difficulty swallowing), later, in serious cases, respiratory paralysis and death Neither fever nor diarrhoea.	Knowing fishing or rearing areas[7] Rapid chilling (reduces proliferation) Good evisceration (Viscera should not contaminate the flesh and peritoneum is not damaged) Compliance with good hygiene practice
		Vibrio parahaemolyticus with hemolytic genes (THD or TDR)	Dependant on fish origin	Watery diarrhea , sometimes low-grade fever, colic, nausea	
Biological hazards	Pathogenic bacteria	*Listeria monocytogenes*	Present "normally" in the aquatic environment Present mainly on the skin, gills or in the digestive tract of the fish. Contamination during suppliers' operation (slicing, evisceration, filleting, etc.)	Meningitis, encephalitis, septicaemia, abortion	Selection of the slaughtering centres Rapid chilling (to moderate proliferation) Good evisceration (avoid cross-contamination) *Cleaning* and *disinfection* of facilities (especially slaughterhouses) Personal hygiene Fish handling conditions during slicing and evisceration Compliance with good hygiene practice
		Salmonella spp.	Contamination of environment by domestic and industrial waste	Febrile syndrome : exhaustion, predominance of fever >38 °C, with diarrhoea and colic Vomiting occurs rarely Without respiratory disorders	Knowledge of fishing and fish farming areas (coastal areas and river mouths are more contaminated) Rapid chilling (to moderate

[7] Fishing or economic zones might be objects of monitoring (contaminants, etc.). It is necessary to be sure that the products come from zones that do not present any risk of contamination of fish.

	HAZARDS		ORIGIN	HEALTH IMPACT	PREVENTIVE MEASURES
		Shigella	Present mainly on the skin, gills or in the digestive tract of the fish. Depending on fish origin	Profuse watery diarrhoea, sometimes with blood and purulence, fever	proliferation) Good evisceration (should not contaminate the flesh and peritoneum is not damaged) Compliance with good hygiene practice
		Vibrio cholerae *serogroup C or O139, or with cholera toxin gene* non O1/O139 *V. cholera*		Watery diarrhoea, vomiting, dehydration	
		Escherichia coli O 157		Hemolytic syndrome	
		Edwardsiella tarda *Pleisomonas shigeloides* *Yersinia enterocolitica*		Acute watery diarrhoea, fever, headache	

	HAZARDS		ORIGIN	HEALTH IMPACT	PREVENTIVE MEASURES
Biological hazards	Biological toxins	Scombrotoxin (histamine)	In the muscles of certain fish rich in histidine, for example, tuna, mackerel, swordfish, ..., Indicative of poor chilling post catch	Skin rash, redness, swelling of face, hot flashes, nausea, vomiting, diarrhoea, headache, dizziness, taste of pepper in the mouth, burning sensation in the throat, stomach upsets, itching, tingling of the skin, palpitations.	Rapid refrigeration after capture Early evisceration of fish Precautions while handling Compliance with good hygiene practice
		Mycotoxins	Vegetables used as ingredient or cereals in fish feed and meal	Allergies, Gastric problems, kidney problems, reduced resistance to infectious diseases for immunosuppressed people	Rapid refrigeration after capture Early evisceration of fish Precautions while handling Compliance with good hygiene practice
		Phycotoxin	Farming enviroment, ALGAE used as ingredient or in fish feed and/or meal	Diarrhoea, PSP[8], ASP[9]	
		Ciguatoxin[10] and other potential tropical toxins[11]	Shallow-water carnivorous fish living in or around tropical coral reefs	Acute gastroenteritis, tingling in extremities, nervous system and respiratory symptoms	Avoid potentially toxic species
		Staphylococcal toxin	Handling (supplier) and internal	Vomiting, diarrhoea	Compliance with good hygiene practice

[8] Paralysis Shellfish Poisoning
[9] Amnesic Shellfish Poisoning
[10] Ciguatoxins is a phycotoxin that can produce intoxication on humans after consumption of contaminated carnivorous tropical and subtropical fishes.
[11] There are also other types of intoxication caused by marine animals that are less frequent, for example, clupeotoxin (Clupeidae fish family), tetrodoxin (Tetraodintidae, Molidae, Diodontidae and Canthisgasteida fish families), carchatoxin (sharks, mainly of the types Carcharhinus and Sphyrna), chelotoxin (hawksbill sea turtle (Eretmochelys imbricata) hallucinary intoxication ("a drunk female") (Siganus fish family). Avoid the potentially toxic species during risk periods.

	HAZARDS		ORIGIN	PREVENTIVE MEASURES
Chemical hazards	Phytosanitary residues	Disinfectants, pesticides, herbicides, algicides, fungicides, etc.	Environmental contamination Contamination during handling process	Selection of fishing/aquaculture areas Compliance with good hygiene practice
	Veterinary residues	Antibiotics, growth hormones, other fish feed additives	Fish feed (farmed fish) Environmental contamination	Selection of fish farms Observing the withdrawal period prior to slaughtering
	Heavy metals, dioxins PCB (polychlorinated biphenyl), …	Heavy metals leached from soil, industrial waste, sewage water or droppings of animals	Environmental contamination	Selection of fishing/aquaculture areas
	Hydrocarbon.	Contamination by fuel, gas or oil in the water etc...	Environmental contamination in the growth area	Selection of fishing/aquaculture areas Hygienic fish handling on board Compliance with good hygiene practice
Physical dangers	Radioactivity		Environmental contamination	Selection of fishing/aquaculture areas
	Boxes, plastic pieces, etc.		Hygienic fish handling	Compliance with good hygiene practices during supply and processing

1.2 Other raw materials

The initial contamination level is the main hazard.

Proposed controls[7] are intended to reduce initial contamination levels received on products from the supplier and should be reviewed regularly while preparing the supplier's technical documentation.

	HAZARDS	PREVENTIVE MEASURES
Water and ice	Pathogenic bacteria Chemical contamination	Use of potable water Maintenance of water pipes
Wrapping materials **Packing gases** **Storage containers**	Microbiological contamination Chemical contamination Physical contamination (foreign bodies)	Confirmation of suitability for contact with foodstuffs Compliance with manufacturer's good hygiene practice for packaging and wrapping materials Delivery of wrapped packaging
Smoking wood	Chemical contamination (PAH during combustion)	Wood type used (conifers with high level of lignin should be avoided)[12] Temperature of combustion chamber (≤ 400 °C)
Other ingredients (aromatic herbs, spices, salt, sugar, vinegar, etc.)	Microbiological contamination (spices) Viral contamination[13] (aromatic herbs and fresh vegetables) Allergens Chemical contamination (pesticides PAH, ...)[14] Physical contamination (foreign bodies)	Conditions of agricultural production (good agriculture practice) Supplier's good hygiene practice Supplier's technical documentation Decontaminated spices (ionisation[15], etc.) Ready-to-use vegetables

[12] CODE OF PRACTICE FOR THE REDUCTION OF CONTAMINATION OF FOOD WITH POLYCYCLIC AROMATIC HYDROCARBONS (PAH) FROM SMOKING AND DIRECT DRYING PROCESSES (CAC/RCP 68-2009)
[13] The quality of irrigation water and the possibility of using sewage sludge are also factors which need to be taken into account
[14] CODE OF PRACTICE FOR THE REDUCTION OF CONTAMINATION OF FOOD WITH POLYCYCLIC AROMATIC HYDROCARBONS (PAH) FROM SMOKING AND DIRECT DRYING PROCESSES (CAC/RCP 68-2009)
[15] Directive 1999/2/EC on the irradiation of foods and food ingredients

A list of allergy-causing ingredients defined by regulations (Regulation (EU) No 1169/2011 on the provision of food information to consumers)

- Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products made from these grains.
- Crustacean and crustacean products.
- Eggs or egg-based products
- Fish or fish-based products
- Peanuts and peanut-based products
- Soya and soya-based products.
- Milk and milk-based products (including lactose)
- Nuts, i.e. almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoiesis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia nuts and Queensland nuts (Macadamia ternifolia), and products thereof
- Celery and celery-based products
- Mustard and mustard-based products
- Sesame seeds and products thereof.
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO2
- Lupins
- Molluscs

1.3 Processing operations

Risks associated with cross-contamination and the growth of microbial pathogens need to be managed from the moment raw materials arrive on site, throughout the production process and through to final consumption.

Processing procedures are unlikely to result in complete decontamination of products (for example, absence of thermal treatment, except for hot smoking). Professionals should therefore put all effort into:

- minimising initial contamination: through selection of suppliers, notably the ability to meet good hygiene practices, maintenance of the cold chain during transportation (carriers' technical documentation)
- preventing cross-contamination of the products during operations through control of the working environment and personnel training
- preventing the development of biological hazards: the management of delays and product temperature are of paramount importance (maintaining fish temperature as close as possible to 0 °C throughout fish preparation processes
- minimising potential for decomposition or development of toxins during operations
- controlling of sealings of packaging, where appropriate

- developing the procedures and shelf-life of products compatible with product safety and security to consumers under normally predictable conditions of distribution: transport conditions, the cold chain, in particular.

CAUSE	HAZARDS	PREVENTIVE MEASURES
Viscera Mucus	Pathogenic bacteria *Listeria monocytogenes,* Spoilage bacteria Biogenic amine precursor bacteria	Early and good evisceration (Evisceration quality control) followed by rinsing with clean water Washing of fish before use Early skinning (or salting by using dry or mixed salt, sufficient amount of salt on the skin) Personnel training Working instructions (prevent skin to flesh contact) Visual Control of the fish to evaluate gutting quality
Water Ice	*E. coli* Chemical contaminants	Water quality monitoring Maintenance of water distribution facilities
Various ingredients	Pathogenic bacteria	Storage conditions
	Allergens	Special storage area (Separation in space or time)
Premises Environmental	*Listeria monocytogenes*	One-way flow Effectiveness of cleaning and disinfection (cleaning and disinfection procedures)
	Allergens	Air circulation Cleaning and disinfection procedures
uipment and tools	*Listeria monocytogenes* Allergens	One-way principle Ability to clean/disinfect Cleaning and disinfection procedures (training of staff is necessary)
	Physical or chemical contamination (foreign bodies,oils, glass, …)	Preventive maintenance Material selection (training of staff is necessary)
Personnel	*Staphylococcus aureus* *E. coli* *Salmonella*	Personnel hygiene (training of staff is necessary)
Processing operations	Pathogenic bacteria Spoilage bacteria Chemical contaminants[16] Physical contaminants	Organisation of premises (one-way principle ,...) Training of personnel on the work performed Working procedures and instructions

[16] If combustion temperature is > 400°C during smoking operation, there is a risk of contaminating the products with benzopyrene.

CAUSE	HAZARDS	PREVENTIVE MEASURES
Wrapping (materials, sealing, …)	Chemical contaminants Physical contaminants Pathogenic bacteria Spoilage bacteria Chemical migration	Technical documentation (approved for contact with food) Selection of suppliers Storage conditions for wrapping materials Cleaning of containers before use Set-up of the sealing machine Qualified personnel (training of staff is necessary) Closure control
Non-integrity of wrapping	Pathogenic bacteria Spoilage bacteria	Wrapping material specification Product storage conditions
Contaminated raw materials	Parasites	Freezing of fish (24 hours at ≤ - 20 °C or at -35 ºC for not less than 15 hours) (raw or partially cooked fish) Completely cooked (1 min. at ≥60° or 15 seconds at 74° C (microwave) Hot smoking (at ≥60 °C for 1 minute[17]) Resting in salt more than 21 days (salted fish)
Breaking the cold chain	Pathogenic bacteria *Listeria monocytogenes, …* Spoilage bacteria *(Enterobacteriaceae)* and production of toxins (histamine) (staphylococcal toxin)	Maintenance of glazing before transportation of the raw material Management of delays, Final shelf-life ... Room temperature of production facilities Performance of refrigeration with volume, maintenance
Absence of physical or thermal decontamination steps (except for hot smoking)	Pathogenic bacteria *Clostridium botulinum*[18], *Listeria monocytogenes, …* Spoilage bacteria *(Enterobacteriaceae)* and production of toxins	Production methods Salting, smoking, pH management Shelf-life Storage temperature, notably before dispatching

2 - Smoked salmon and trout (cold smoking)

This section concerns the production of cold smoked smoked salmon or trout. The raw material can be fresh or frozen, wild caught or farmed. End products may be served whole (with or without skin), as fillets, in slices, chunks, dice etc. The fish may contain spices (for example, "dill", etc.)

2.1 Identification of hazards

Note: GHP/PRP = a good hygiene practice or prerequisite program necessary to ensure control. OPRP/CCP = a specific measure necessary to ensure control

[17] When trimatod is identified the treatment should be 70 °C for 30 minutes according to EFSA opinion (EFSA Journal 2010; 8;(4):1543).

[18] The management of growth risk to Clostridium botulinum may be ensured by: 1. Salt levels that exceed the 3.5 % in the aqueous phase for Chilling conservation; 2. Alternative control factors as pH < 5.0 or Water Activity (Aw) under 0.97 (Johnson 2007 (Johnson EA (2007). Clostridium botulinum. In: Doyle MP, Beuchat LR and Montville TJ (eds) Food Microbiology, Fundamentals and Frontiers. 3rd edition, pp 401-421. ASM Press, Washington DC.),

beyond GHP/PRP; operational prerequisite program (OPRP) or critical control points (CCP).

The dangers pertaining to the production of smoked salmon or trout are highlighted in grey. They should be managed either by GHP/PRP (generally for purchasing) or by OPRP/CCP, and are subject to monitoring (for example, control at reception).

HAZARDS		ORIGIN	SEVERITY	FREQUENCY[19]	MANAGEMENT
Biological	*Listeria monocytogenes*	Fish Management (personnel, premises and equipment)	Very high (population at risk)	High	OPRP/CCP
	Salmonella	Fish Management (personel, premises and equipment)	Very high	Low (only 1 case identified, without definitive conclusion)	GHP/PRP
	Clostridium botulinum	Fish	Very high	Low	OPRP/CCP
	Clostridium perfringens	Fish	High	Low	*The same as for Clostridium botulinum*
	Vibrio cholerae, *parahaemolyticus and vulnificus*	Fish	High	None[20]	GHP/PRP
	E. coli O157 H7 and other verotoxins	Fish	Very High	None (same)	GHP/PRP
	E. coli other (indicator of hygiene)	Handling (personnel)	Low	None (same)	GHP/PRP
	Staphylococcus aureus (indicator of hygiene) Staphylococcal toxins	Handling (personnel)	High	Low	GHP/PRP
	Yeast and Moulds	Handling Environment	Low[21]	None	GHP/PRP
	Parasites	Wild fish	Very High	High	OPRP/CCP

[19] Identified frequency of presence
[20] Up to now no case has been reported.
[21] The risk is low for packaged fish. For non-packaged products, this risk must be evaluated within the HACCP plan.

HAZARDS		ORIGIN	SEVERITY	FREQUENCY[19]	MANAGEMENT
Biological	Toxins (phycotoxin, scombrotoxins, mycotoxins)	Fish	High	None[22]	GHP/PRP
	Virus	Raw vegetables, fish and acquatic environment	Low	Low	GHP/PRP
Chemical	Dioxins and polychlorinated biphenols	Feed Fishing zone (wild fish)	High	High	GHP/PRP
	Heavy metals[23]	Feed Fishing zone Marine (Sea) salt	High	High	GHP/PRP
	Antibiotic residues, veterinary residues	Feed	Low	Low	GHP/PRP
	Phytosanitary residues	Location of farms	Low	Low	GHP/PRP
	Cleaning-product residues	Materials and equipment	Low	Low	GHP/PRP
	Migration from packaging materials	Packaging materials	Low	Low	GHP/PRP
	PAH *benzo[a]pyrene, benzo(a)antracene, benzo[b]fluoranthene, and chrysene)*[24]	Feed oils Smoking (wood quality and high smoking temperature) Accidental environmental pollution	Low	Low	OPRP/CCP

[22] The studies and research show that histamine content of salmon or trout is low, well below the regulatory threshold.

[23] The bio concentration potential for certain marine fish: (TABLE)

Species	cadmium	lead	mercury
Fish	low	low	from average to high
- Herring/sardine	low	low	low
- Plaice/sole	low	low	average
- European seabass/catshark	average	average	average
- Swordfish/tuna	average	average	high

Source: INERIS / AFSSA / CNRS - Synthèse OPECST (Rapport 261 (2000-2001)

[24] Opinion of EFSA - *Polycyclic Aromatic Hydrocarbons in Food. Scientific Opinion of the Panel on Contaminants in the Food Chain (Question N° EFSA-Q-2007-136) Adopted on 9 June 2008*

HAZARDS		ORIGIN	SEVERITY	FREQUENCY[19]	MANAGEMENT
Chemical	Wood treatment products, antifouling, malachite green and other external treatments	Fish	Low	Low	GHP/PRP
	Lubricants , rodenticides, ...	Handling	Low	Low	GHP/PRP
Physical	Impurities present in salt	Salt	Low	Low	GHP/PRP
	Metal contamination	Equipment	High	Low	GHP/PRP and/or OPRP/CCP
	Glass, plastic and other foreign bodies	Handling	Low	Low	GHP/PRP
Physical	Hair, ...	Handling	Low	Low	GHP/PRP
	Radioactivity	Fish	Low	Low	GHP/PRP

2.2 Management of significant hazards

Only hazards underlined in grey in the preceding table are considered, other hazards do not require specific monitoring measures.

a) Biological hazards

RELEVANT HAZARDS		PREVENTIVE MEASURES
Listeria monocytogenes	Initial contamination	Evaluation of farms and slaughter centres and selection on the basis of technical documentation and performance Time from slaughter to evisceration, reception and start of production Quality of evisceration Fish temperature (the presence of ice) Control at reception: status of glaze, freshness of fish Removal of mucus from skin Washing during processing operations

RELEVANT HAZARDS		PREVENTIVE MEASURES
	Cross-contamination during processing operations	Instructions for product handling and personnel training: avoid transfer due to direct contact between potentially contaminated parts (skin, gills, ...) and flesh, or by indirect contact (contaminated equipment) Flow control (people, product, waste) Personnel hygiene Cleaning and disinfection procedures for premises, equipment, especially during slicing Cleanliness of the air flow system, including compressed air
	Growth (during and after processing operations, including time to Use By date after placing on the market)	Maintain the fish at the lowest temperature possible: premises with controlled temperature, management of delays during operations Humidity control after smoking Process control (salting, drying, smoking) Storage conditions and maintenance of refrigeration equipment Product shelf-life Integrity of wrapping
Clostridium botulinum	Initial contamination Contamination during evisceration, Proliferation	Quality of evisceration Salt content (≥ 3 % in the aqueous phase, ≥ 3.5 % – if shelf-life exceeds 30 days[25]) Management of the cold chain Shelf-life
Staphylococcal toxins	Initial contamination Cross-contamination (*S. aureus*) Proliferation (*S. aureus*)	Quality of evisceration, early evisceration Staff hygiene Management of the cold chain
Parasites (wild fish)	Contamination	GEN4 Principle Hazards – Preventive Measures 1. Main Hazards 1.1. Fish (wild or farmed) – Hazards (Parasites).
Parasites (farmed fish)	Contamination	

NB: Calculation of salt content

The moisture content of smoked salmon or trout (after salting) is approximately 63-66%, with variations, dependable on the part of fish and process.

x = salt % in the aqueous phase, y = salt % in the end product (salted), h = moisture content % in the end product (salted) ➔ **y = x (h/100)**

[25] However we acknowledged that in UK and Ireland, guidance from the competent authorities recommends a salt content of 3.5 % in the aqueous phase for products with a shelf-life exceeding 10 days.

Moisture Content of the end product	Salt % in the aqueous phase	Salt % in the end product	Salt % in the aqueous phase	Salt % in the end product
62	3.00%	1.86%	3.50%	2.17%
64	3.00%	1.88%	3.50%	2.24%
66	3.00%	1.94%	3.50%	2.31%
68	3.00%	2.00%	3.50%	2.38%

b) Chemical hazards

HAZARDS	CAUSES	PREVENTIVE MEASURES
Dioxins and PCBs	Oil and flour quality in fish feed Farming and fishing areas	Evaluation and supplier's technical documentation
Heavy metals	Fish flour quality Farming and fishing areas	Supplier's technical documentation
PAH *benzo[a]pyrene, benzo(a)antracene, benzo[b]fluoranthene, and chrysene)*	Vegetable oils used in feed	Supplier's technical documentation
	Smoking	Wood supplier's technical documentation (conifers with high level of lignin should be avoided[26]) Combustion temperature (< 40 0 °C)
Veterinary residues	Non-compliance with withdrawal periods	Supplier's technical documentation

c) Physical hazards

HAZARDS	CAUSES	PREVENTIVE MEASURES
Metals	Needle ends (Injection-salting) Various metal pieces	Maintenance of equipment and materials Metal detection
Foreign materials	Glass, plastic, scales, fish bones	Staff training Good practice

3 - Other products (other fish and/or other treatments)

The main hazards identified for smoked salmon and trout apply for other fish.

[26] CODE OF PRACTICE FOR THE REDUCTION OF CONTAMINATION OF FOOD WITH POLYCYCLIC AROMATIC HYDROCARBONS (PAH) FROM SMOKING AND DIRECT DRYING PROCESSES (CAC/RCP 68-2009)

Account must be taken of the fish in use (for example, *Vibrio* risk, parasites, histamine*),* production processes, hygiene practices implemented in accordance with recommendations laid down in this guide.

The points below require particular attention by the professional for these manufactured products.

3.1 - Salted herring

As far as cold smoking is concerned, parasite control is described in GEN4 Principle Hazards – Preventive Measures 1. Main Hazards 1.1. Fish (wild or farmed) – Hazards (Parasites).

In addition, significant control elements are similar to those for cold smoked salmon or trout.[27]

3.2 - Products marinated, salted or not

Depending upon the type of fish, the same hazards exist as for salmon or trout and additionally more specific hazards may be present (*Vibrio*, histamine content, etc.) Whether the product is lightly salted or not must be considered.

To kill parasites refer to GEN4 Principle Hazards – Preventive Measures 1. Main Hazards 1.1. Fish (wild or farmed) – Hazards (Parasites).

Microbiological safety of raw materials is crucial, including marinade safety depending on the level of pH (marinated with a pH over 4.4 are more sensitive to the proliferation of microorganisms.) as per Regulation 2073/2005.

Bacterial growth control in end products is assured by the following combination of factors: marinade pH and storage temperature (≤ 4 °C). The marinade composition is a very important element; production (or purchase) control requires specific control measures (an OPRP or CCP), if product safety is to be ensured by the marinade) (see MNG 2.2).

3.3 - Products in oil, with or without addition of herbs or other spices

Apart from the fish in use, the specialist must be vigilant about the biological quality of plant ingredients added, particularly chemical contaminants in oil (notably the amount of PAH).

In order to avoid cross-contamination during operations at risk, the products should be prepared in a separate room or specially designated area (or at a specific point in time: separation in time followed by cleaning).

3.4 - Fish naturally rich in histidine

For example, fish species of the families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae such as tuna, swordfish, marlin, etc (warm water fish).

[27] Moller H (1989) Nematode problems in North Atlantic Fish, International Council for the Exploration of the Sea, Kiel

For fish rich in histidine, cold chain management ensures control of histamine from the harvest. [28]

According to the research *Effect of Delayed Processing on Changes in Histamine and Other Quality Characteristics of 3 Commercialy Canned Fishes* (R. Jeya Shakila, Geevarethinam Jeyasekaran, S. Aunto Princy Vyla and R. Saravana Kumar - Journal of Food Sciences - Vol 70, No.1, 2005), for fish held at 30 °C for 6 hours, the content of histamine remains low. According to technical document No. 348 of the FAO, the production of histamine in yellowfin tuna starts exponentially after 36 hours at 20 °C.

Special attention should be given to the control of histamine risks (OPRP in general), notably:

- The quality of raw materials (histamine content ≤ 50 ppm, preferably ≤ 10 ppm); this requires technical documentation for purchases, including fishing conditions and on board storage;

  NB: If knowledge on supply is insufficient (storage temperature, time to land after fishing, etc.), a CCP may by applied during reception of raw materials. The sampling plan may be increased to more than simple regulatory sampling and is applicable pursuant to batch size, homogeneity, etc.
- Prevention of contamination with spoilage bacteria that foster the production of histamine;
- Management of delays[29] and product temperature control: (production of histamine is significant at ≥ 10 °C).
- Supervision of control measures during production by analysing the end products (see OPE 3.2).

3.5 - Products with filling or with other ingredients

The management of cross-contamination risks pertaining to allergenic substances (for example, celery) should be taken into consideration. Control is ensured by organising and separating operations in time and space, cleaning procedures, etc.

3.6 - Products packed in a modified atmosphere

Good performance of packaging operations has an impact upon the microbiological quality of the end product.

Wrapping materials and gases should not cause microbiological contamination (the technical documentation acceptable from the supplier is significant (see SUP 1).

For packagings preformed outside the factory, the absence of foreign bodies will be checked before their usage.

[28] An EFSA Scientific report on "Scientific and technical assistance on the evaluation of the temperature to be applied to pre-packed fishery products at retail level" provides some useful data"

[29] According to the article (Potential Hazards in Cold-Smoked Fish: Biogenic Amines - Journal of Food Science Supplementa au Vol 66 n° 7 -2001), it seems that salting and smoking can suppress or inactivate bacteria capable of producing biogenic amines. But then, given the product temperature, atmospheric conditions, etc., the production of biogenic amines may occur.

In all cases, wrapping operations should be performed rapidly. It is necessary to avoid an increase in temperature of the product. Procedures to manage delays should therefore be established.

Sealing and quality of wrapping and the quality of the gas injected should be monitored and preventive maintenance for wrapping facilities should be in place.

The growth of pathogenic or spoilage flora may be either fostered or suppressed depending on gas composition[30].

3.7 - By-products

By-products may include split fish, fish pulp after filleting[31], etc. When producing such by-products, it is necessary to follow the same requirements as for other prime products, particularly temperature management (glazing, delays). A specific *HACCP plan* is required for each by-product.

[30] For example, the gas mixture of 60 % CO_2/40 % N_2 encourages the production of histamine for fresh tuna wrapped in a modified atmosphere under the temperature close to 2° C, whereas the mixture of 40 % CO_2/60% O_2 suppresses it (Significant histamine formation in tuna (Thunnus albacares) at 2°C - effect of vacuum and modified atmosphere-packaging on psychotolerant bacteria - International Journal of Food Microbiology 1001 (2005) 263-279).

[31] While preparing the pulp, the producer should act in compliance with the requirements laid down in Regulation (EC) 853/2004, Appendix II, Chapter II-C: Requirements for mechanically separated fishery products.

FOOD SAFETY MANAGEMENT PROCESS

MNG 1 - Definition of food safety control measures

Mandatory conditions throughout implementation of operations

1. Premises suitable for activities (space, temperature, etc.)
2. Simple and precise working instructions
3. Organised in a way that prevents cross-contamination (for example, operations that may cause cross-contamination separated in time and space)
4. Organised in a manner to prevent proliferation (temperature control during production, management of delays, etc.)
5. Minimal handling after smoking.
6. Training personnel in the tasks and in good hygiene practice
7. Documented management criteria for individual operations
8. *Monitoring* operations and recording monitoring details (OPRP and CCP)
9. Precise instructions in the event of a non-conformance (OPRP and CCP).
10. Regular verification of the efficiency of operational control measures (see MNG 2.3)

General procedures to avoid cross-contamination and proliferation throughout implementation of operations

1. During transportation, storage and preparation, it is necessary to take efficient measures to prevent foodstuffs from contamination resulting from either direct or indirect contact with raw materials, products undergoing processing, and waste.
2. Inside the company:
   - Different zones are identified with respect to required hygiene level.
   - Flow (personnel, products, waste and equipment) organised in a manner to prevent working back against the flow causing cross-contamination.
3. Where there is the possibility of contamination, personnel wash their hands thoroughly between handling operations.

   Persons handling raw materials or work in progress products that might contaminate the end product do not touch the materials until appropriate measures have been taken to prevent such contamination.
4. All equipment which has been in contact with raw or contaminated materials, should be fully disinfected and rinsed if necessary before contact with products in preparation (for example, handling containers).
5. All production stages should be executed without delay and under conditions preventing any possibility of contamination, deterioration and bacterial growth and proliferation.

   During all processing stages, critical micro-organism proliferation temperatures should be avoided and should be resolved rapidly.

   Work in progress products while waiting, should be held in a special cooling zone.

6. Raw materials of separate origin (vegetables, fish, etc.) should be prepared in different rooms or areas. If this is not possible, these operations should be executed at different times after cleaning and disinfection.

   The movement of product flow is organised to protect against cross-contamination (moving forwards, in particular) (see SUP 2.1).

1 - Planning of a food safety management system

HACCP, and Risk Analysis when necessary, assure that the objectives defined by the management and written in the quality and safety objectives and actions regarding the implementation of the management system (PRP, Hazard analysis, OPRP and CCP), are well planned in order to achieve the food safety objectives.

The planning also includes regular, systematic review of the management system in addition to review following a non-conformance.

1.1 Prerequisite program

The prerequisite program is the basic conditions and activities necessary to maintain a hygienic environment throughout the food chain, suitable for the production, handling and provision of safe end products and safe food for human consumption. It comprises the following elements:

This program covers everything useful for the enterprise activity (or everything that is not particular to a specific activity). During lot release (see MNG 2.5), correct application of a prerequisite program occurs throughout processing rather than specifically for each individual product lot.

- Infrastructural and equipment requirements,
- Requirements for raw materials,
- Safe handling of food (including packaging and transport),
- Food waste handling,
- Pest control procedures,
- Sanitation procedures (cleaning and disinfection),
- Water quality,
- Maintenance of the cold chain,
- The health of staff,
- Personal hygiene,
- Training.

The prerequisite programme ensures compliance with basic regulatory requirements defined in Regulation (EC) 178/2002 and "Hygiene package" and relevant Appendices to Regulations (EC) 852 and 853/2004, and if the enterprise seeks ISO 22000 certification, the requirements described in chapter 7.2 of the standard.

Implementation of the prerequisite program (regulations for good hygiene practice) is necessary for the control of hazards. This provides the foundation for effective HACCP implementation.

The HACCP plan ensures that such measures are implemented properly and achieve the expected control of the hazards.

If the company adheres to the recommendations defined in this guide, particularly SUP 1 to SUP 4, the controls implemented will be considered as compliant with the requirements of the regulations and ISO 22000 standard, since this guide has been validated officially. Therefore, the enterprise is obliged to demonstrate that it operates in line with the recommendations of this guide.

Certain elements relevant to the prerequisite program (see SUP 1 to 3) are subject to extensive recording[32], such as room temperature, especially storage temperature, pest control, maintenance operations, application of the cleaning and disinfection plan, personnel training, cold chain control, etc. These records should be handled in accordance with the procedural rules applicable to documents and records (see MNG 3), and to information system (SUP 4).

Compliance with the recommendations in this guide defined in the chapter on support processes permits the implementation of good hygiene practice (PRP or GHP) when adhering to the requirements laid down in legal acts.

2 - Preparation for hazard analysis

Hazard analysis is a regulatory requirement. It might be effective only after implementing good hygiene practice (prerequisite program, see below).

Prior to carrying out hazard analysis and to ensure effectiveness, it is necessary to follow a systematic process[33]:

1. Define the scope of the hazard analysis.
2. Build a team bringing together all required competencies, team members having sufficient knowledge and experience (it should be confirmed in the records), comprising specialists from diverse areas of expertise (including not only production and quality/safety services, but also sales, marketing, finance (if there is a need for investment after completing the analysis, etc.).
3. Define the product, particularly the ingredients, physico-chemical characteristics, production methods, wrapping, etc. This stage is usually implemented within the design phase (see OPE 1.1 to 1.4), in case of new products.
4. Define expected conditions of distribution and use. Conformance with this description and information displayed for users (for example, distribution conditions, product specifications) or consumers (for example, labelling) needs to be ensured.

If the activity of the enterprise is covered in the scope of this guide and if the enterprise is in compliance with the requirements of this guide, the creation of this team is not required however, the enterprise must demonstrate that it follows the requirements of this guide.

Nevertheless, it is useful to include all persons responsible for product safety with control of safety, notably through management review.

[32] Production lots cannot be released (see OPE 3.2) if it appears that one of the elements of the prerequisite program has not been applied. A clearly identified person, who is often in charge of product safety (HACCP), or under the responsibility of it, with decision-making authority unrelated to production and commercial activity, is obliged to evaluate a product safety "non-conformance" before eventual release.

[33] See ISO 22000 standard 7.3 §, as well as the Recommended International Code of Practice -General Principles of Food Hygiene (CAC/RCP 1-1996, rev. 4-. 2003), in particular Appendix designated for HACCP.

5. Create a production flow chart, including interactions between stages, outsourced stages and if necessary, introduction points of ingredients, etc. During each stage, existing measures (or those that will be implemented for new products) are specified.
6. Verify on-site if this flow chart is realistic and conforms with current procedures, or is compatible with "any products or processes being implemented at the current moment" (new products).

The HACCP process is documented: Records will be handled in accordance with the procedural rules applicable to documents and records (see MNG 3) and information systems (SUP 4). Records should be updated as often as necessary, notably when changing existing or developing new processes, wrapping, conditions of use, etc. The hazard analysis (see below) is then reviewed.

3 - Hazard analysis

To conduct the hazard analysis, the enterprise can rely on information provided in this guide (chapter GEN4): important hazards, acceptable levels.

Depending on the product manufactured and product use, the enterprise may eventually be forced to consider hazards other than those defined in this guide.

To carry out the hazard analysis, the team responsible:

1. identifies hazards while establishing, particularly in the production flow diagram, the stages at which they could occur, equipment and environmental hazards that might be related
2. establishes acceptable levels (see GEN 4) for end products, taking account of the regulatory requirements, client expectations and expected use
3. evaluates the effectiviveness of controls for hazards, considering the occurrence and severity of hazard, production methods, expected use
4. Identifies, selects, and defines (equipment, training, operations, etc.) relevant preventive measures, with regard to their effectiveness, ability to be monitored, location in the production process and potential synergistic impact between several measures, etc.
5. Where necessary, defines if the measures being implemented are OPRP or CCP.

The hazard analysis can lead to a product in production without a CCP.

The hazard analysis should be revised if any element has been modified.

The analysis (the original or revision) is documented in records that will be handled in accordance with the procedural rules applicable to documents and records (see MNG 3) and information systems (SUP 4).

If the identified control measures, acceptance levels, monitoring procedures, etc., are in compliance with the measures defined in this guide, this is sufficient to prove application, without any obligation to conduct this analysis, demonstrating that the product sanitary safety is under control.

4 - Establishment of operational prerequisite program (OPRP)

Operational prerequisite programs[34] (OPRP) identified by the hazard analysis are essential to control the likelihood of introducing food safety hazards and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment (FDIS - ISO 22000 - 2005).

If the activity of the enterprise falls within the scope of this guide and if the enterprise applies the measures defined in this guide, the enterprise does not have to justify that it has already established and validated these measures.

For each OPRP, the following elements should be established:

- potential hazards involved
- control measures
- monitoring activities that demonstrate implementation of control measures, this may be monitoring of control parameters
- *corrections* and *corrective actions* in case of a "non-conformance";
- responsibility and monitoring authority in addition to the solution in the event of a non-conformance
- monitoring records, handled in accordance with the procedural regulations of documents and records (MNG 3) and information systems (SUP 4).

If during monitoring it is found that the OPRP has not been applied (in case of a non-conformance), then analysis is performed to:

- evaluate the impact upon product safety
- identify the reason(s) for non-conformance and evaluate the effectiveness of the OPRP.

This may require hazard analysis and review of control measures.

5 - Establishment of Critical Control Points (from the HACCP plan)

If the activity of the enterprise is within the scope of this guide and if the enterprise applies the measures defined in the guide, the enterprise does not have to justify the selection of CCP or associated control measures.

A CCP[35] is a step at which:

- a control measure can be applied and a **food safety hazard** can be prevented, eliminated or reduced to an acceptable level
- one control measure might be specifically implemented to ensure the control of one (or several) hazard(s) where control is necessary for product safety
- a critical limit might be established.

For each CCP, the following elements should be determined:

- Hazards controlled by the CCP

[34] Production lots cannot be released (see OPE 3.2) if it has been unveiled that one of the elements of the prerequisite program has not been applied. A clearly identified person (who is often in charge of product safety), with decision-making authority unrelated to production and commercial activity, is obliged to evaluate "non-conformance" pertaining to product safety before potential release.

[35] During lot release, it is advisable to be ensured that the critical limits for all products have been taken into consideration. Release is limited to products whose compliance with the critical limit can be proven. For other products, only risk analysis will enable reaching a decision on their future (repair, destruction, other designation, etc.)

- Control measure(s)
- Critical limits
- Monitoring action(s) assuring the compliance with critical limits on the basis of different management parameters
- Action(s), corrections and/or corrective actions in the event of failure to comply with a critical limit
- Officials and authorities responsible for monitoring and making decisions where a critical limit has been exceeded
- monitoring record(s) handled in accordance with the documentation system (see MNG 3).

If a critical limit has been breached for a CCP, affected products are isolated and a decision is required on further use (destruction, re-processing, new intended use, etc). The analysis of root cause helps to determine if:

- the non-conformance is related to an abnormality within the course of operations
- it is required to review the hazard analysis and to modify control measures, etc.

6 - Updating the information on control measures

Having defined the control measures (PRP, OPRP, and CCP if required), the team responsible ensures that information related to product characteristics, intended use, flow charts, process stages and control measures is consistent with decisions made during this analysis.

If necessary, certain elements should be amended after review and evaluation of modifications.

Records of review should be handled in accordance with the procedural regulations of documents and records (MNG 3) and information systems (SUP 4).

MNG 2 – VALIDATION, VERIFICATION AND IMPROVEMENT SYSTEM

Conditions assuring the efficiency of control measures

1. validate *(qualification*) control measures[36] in place:
   - Good general hygiene practice
   - Define operational control measures after carrying out the hazard analysis (OPRP/CCP)

Register the results of such validations.

2. *Assure the monitoring of defined measures realisation of (see MNG 2.5)*
3. Verify (*re-qualification*) if measures put in place remain effective.

- Plan verification actions, for example, audit, control, specific analyses, etc.
- Record the results of verification.

4. Improve the product safety management system.

- Use the results of monitoring actions, handling of non-conformances, verifications, etc.
- Re-validate, if applicable, control measures in the event of deviation, notably during verification.

1 - General organisation

HACCP ensures that all product safety measures have been validated before implementation and that all elements available (results of monitoring, verification, customer complaints, etc.) are used for improving the product safety management system.

It is the responsibility of the producer:
- to define the organization to carry out the HAACP study.
- to demonstrate that measures in place assure the production of safe and healthy products as stipulated in regulations.

To do so, a planning exercise is carried out, especially to verification implemented measures[37].

It is necessary to establish verification of the effectiveness of the control measures adopted throughout the process.

Food business operators shall perform testing as appropriate against the microbiological criteria established by European legistlation* (Reg 2073/2005, Article 4), when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.

Food business operators shall decide the appropriate sampling frequencies (except when a minimum is establish by Regulation), in which case the sampling frequency shall be at least as it is indicated by law. Food business operators should make

[36] If the measures put in place are consistent with the requirements stipulated in this guide, they are considered as validated, since this guide has been officially acknowledged.
[37] See 7.8 § of ISO 22000 standard.

this decision in the context of their procedures based on HACCP principles and good hygiene practice, taking into account the instructions for use of the foodstuff.

The frequency of sampling may be adapted to the nature and size of the food businesses, providing that the safety of foodstuffs will not be endangered.

Reminder for distinctive types of criteria and corrective actions

Please refer to: Article 7 (Regulation 2073/2005):

When testing against food safety criteria set out provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002 (Responsibilities for food: food business operators)

However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.
The food business operator may use the batch for purposes other than those for which it was originally intended, providing that this use will not suppose a risk and providing that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority.
In the event of unsatisfactory results as regards process hygiene criteria, it should be follow the actions establish in Reg 2073/2005 (Annex I, Chapter 2.4 Fishery products).

Examples of microbiological criteria useful for validation or verification

During validation or verification, (n=5, m – threshold value, M – limit value).

Analysis of	Micro-organism	Criterion	Type of criterion
Raw materials	*Listeria monocytogenes*	Absence at reception[38]	Indicative standard
End products	*Listeria monocytogenes*	≤ 100 cfu/g, Products placed on the market during their shelf-life	Mandatory standard[39]

[38] If presence at reception, specific control measures are required (as the choice of the enterprise), for example: production of that batch at the end of the day (for example, before cleaning and disinfection), cleaning and disinfection after lot monitoring, enforced control measures, selection and monitoring of suppliers, etc.
[39] This criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life.

		Absence in 25 g	Mandatory Standard[40].
Food contact surfaces[41]	*Listeria monocytogenes* or *Listeria* spp	Absent after cleaning and disinfection[42]	Indicative standard
Environment	*Listeria monocytogenes* or *Listeria* spp	Absent after cleaning and disinfection[43]	Indicative standard
End products subject to manual slicing or extensive handling[44]	Heat-resistant coliforms (44°C)	≤ 10 cfu /g, at the end of shelf-life	Guidelines (hygiene indicator)
End products	Aerobic mesophilic flora[45] at the end of production	m=10^3 cfu/g M=10^4 cfu/g	Guidelines (monitoring indicator)
	Aerobic mesophilic flora at the end of shelf-life[46]	m=10^6 cfu/g M=10^7 cfu/g	Guidelines (monitoring indicator)

2 - Validation of control measures

Control measures should be validated before they are put in place. The purpose of validation is to demonstrate the control measure achieves the desired outcome. This may be demonstrated using historical data, publications such as this Guide, scientific research, tests, analyses etc.

When performing the different sampling for microbiological analysis, due to the variability of the results that can be obtained, it is necessary to minimize the degree of uncertainty about their guarantee and accuracy. Therefore, the use of accredited laboratories specialized in the required tests is recommended.

The validation concerns:

- Premises, the location
- Equipment and installations used (an approved/ licensed facility)
- A maintenance plan
- A cleaning and disinfection plan
- Personnel competence (qualifications), with particular regard to the CCP

[40] Absence in 25 g before the food has left the immediate control of FPO is applicable if the FPO is not able to demonstrate that the product will not exceed 100 cfu/g. It is possible to place products with Listeria monocytogenes in the market when the manufacter is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life, for example a limit of <10 cfu/gr at delivery date can be considered if the FPO can demonstrate to the competent authority that the product will not exceed the limit of 100 cfu/g at the end of the shelf-life.

[41] Guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes* and Article 5 Regulation (EC) 2073/2005.

[42] Guidelines on Sampling the Food Processing Area and Equipment for the detection of Listeria monocytogenes

[43] Guidelines on Sampling the Food Processing Area and Equipment for the detection of Listeria monocytogenes

[44] Not significant in other cases.

[45] The enterprise can decide upon following this criterion at the end of production and/or shelf-life at 30 °C (ISO 4833).

[46] The enterprise can decide upon following this criterion at the end of production and/or shelf-life at 30 °C (ISO 4833).

- The procedures of evaluation, supplier monitoring, implementation of technical documentation
- Salting (for example, salting diagrams)
- Smoking
- Thermal diagrams (hot smoking)
- Microbiological hurdles deployed (for example, marinades)
- Other operational control measures, etc.

The validation includes the determination of product shelf-life.

The validation is the result of individual measures (acceptance taking into consideration limit values established during the hazard analysis) and combinations of control measures (for example, a set of control measures defined, compliance with existing limit values). The validation assures conformance with regulatory or customer requirements.

Validation actions and records as evidence of validation should be handled in accordance with the procedural regulations of documents and records (MNG 3) and information systems (SUP 4).

3 - Control of monitoring and measuring

When defining monitoring measures, the enterprise ensures that these measures are appropriate, effective, and define the conditions to be followed, in particular measurement, technology tools, to maintain the effectiveness of monitoring.

Monitoring and measuring equipment is subject to continuous calibration (pursuant to the standard) and is defined in a preventive maintenance plan (see SUP 2.3).

Applied to FPO laboratory, the continuous calibration could be done through participation in a PT (Proficiency Testing) scheme.

When a measuring device has a non conformance, all the products monitored by this equipement and produced before the non conformance identification become the object of evaluation (scrapping, new measurement, etc.).

4 - Verifying the effectiveness of measures put in place

The professional verifies (reviews) measures subject to constant implementation to ensure that a set of implemented measures functions well, without any deviations in time. During verification[47], the specialist verifies in particular that:

- PRP have been implemented and are suitable (effective); if the enterprise is compliant with this guide, the enterprise is assured that established elements to demonstrate compliance have been implemented and are pertinent
- Input elements for hazard analysis are updated and remain appropriate
- OPRP and CCP have been implemented and are effective; if the enterprise applies the principles of this guide, the enterprise is assured that the production conditions are consistent with those defined in this guide (for example, scope)

[47] See also 7.8 § of ISO 22000 standard

- Identified hazard levels are updated and conform with regulatory requirements, and if applicable, the internal requirements of the enterprise (for example, those defined in this guide) or customer requirements; the enterprise acting in compliance with this guide possesses the most recent edition of the publication, notably with regard to requirements for end products
- Established control measures dealing with monitoring, traceability, continuous improvement, etc., have been implemented appropriately and are effective.

To do this[48], the professional conducts verification activity on the basis of the results obtained from monitoring actions, non-conformance reviews, etc. Additional measures that should be applied include, for example:

- Internal audit: conduced in accordance with a specified program by a person independent of the activity being audited; these audits ensure the good functioning of a product safety management system. If the enterprise certification of the product safety management system, the internal audits are carried out following a documented procedure. Audit reports are stored in accordance with the procedural regulations of documents and records (MNG 3) and information systems (SUP 4).
- When specific analysies, requiered by regulation, need laboratory controls, those must be conducted and refer to reference methods through accredited external laboratory, or FPO laboratory which follows continuous calibration and could be done through participation in a PT (Proficiency Testing). Specific analysies may concern: raw materials, processing products, end products (according to the requirements established during the validation process - see above), the processing conditions, etc.

For all validated elements, effectiveness of measurement is subject to continuous verification. The frequency and severity of non-conformances determines the performance of such verifications.

During verification if elements are identified as ineffective, actions should be taken to achieve conformance. This may lead to changes in raw material technical documents, prerequisite programs, the definition of OPRP or CCP, procedures, working instructions, sorting, storage, conditions of use, etc. Newly defined measures should be validated before application, following the execution of hazard analysis (see MNG 2.1 and MNG 2.2)

Verification actions are tracked, notably during management review, to validate the efficiency of the measures in place, determine the need for improvement, identify potentially illegal practices, and guide the plan for internal audits, etc.[49]

Verification actions and records as evidence of verification should be handled in accordance with the procedural regulations of documents and records (MNG 3) and information systems (SUP 4).

5 - Continuous improvement of the system

All available data is deployed to define the guidelines for system improvement. This includes, for example:

[48] See also 8.4 § of ISO 22000 standard
[49] See also 8.4.3 § of ISO 22000 standard

- data resulting from internal communication (for example, proposals from personnel)
- data resulting from external communication (for example, customers' demands, sanitary alerts, scientific monitoring, etc.)
- internal audit reports
- management reviews
- results from validation, monitoring or verification actions
- corrective measures put in place, etc.

For continuous improvement to be effective, the team responsible for product safety and targetted with continuous improvement, conducts a review of the product safety management system at fixed intervals using existing data.

All changes in the product safety control system must be revalidated and documented. The records are handled in accordance with the procedural rules applicable to documents and records and information systems.

MNG 3 -TRACEABILITY

Conditions for effective traceability

1. Defined batches or lots with respect to hazards and acceptable risk
2. Ability to identify products on the basis of defined batches or lots
3. Ability to track the information useful for the traceability of batch or lots history
4. Ability to track the information useful for traceability of destination of a batch or a lot
5. Ability to test the reliability and effectiveness of traceability (accuracy, response time, etc.)

Traceability[50] enables establishment of a link between products and information flows. Traceability can provide information on a product, product history, product position in the food chain**.** Traceability contributes to analysing the reasons for a non-conformance and facilitates product recall or withdrawal.
According to the regulatory requirements, it is obligatory to have an effective traceability system: Regulation (EC) 178/2002 Article 18), its subsequent modification Regulation (EC) 931/2011 and Regulation (EC) 1224/2009, article 58.

1 - Methodology for traceability

1.1 - Principles

An effective traceability system is based on verifiable information:
- applied in a consistent manner, notably through the food chain
- result-oriented, i.e. accumulation of useful information
- economically viable, i.e. costs are proportionate to risk, notably as regards product safety (detailed information, for example, lot size)
- practical to apply
- allowing for rapid availability of the data.

1.2 - Objectives

To implement an efficient traceability system, objectives must be established following the principles mentioned above:
- product safety (quality control)
- knowledge on product history or origin
- facilitation of product withdrawal or recall (know your customer and product position in the food chain)
- identify responsibility in the food chain
- facilitate the verification of the specific product information
- report information to parties concerned (customers, official authorities, consumers, etc.)

[50] Relevant documents: AFNOR FD V01-020 and ISO 22005 (see GEN 3 4§ - Other legal references)

1.3 - Design

During implementation of a traceability system, the following stages should be considered:

1. Establish context:
   - Enterprise position in the industry: customers, suppliers, associated enterprises, etc.
   - needs of consumers, customers, official authorities, etc.
   - expected information: what information, from where and for whom, relevance, feasibility, etc.
   - products, flows, hazard analyses, etc.
2. Establish key objectives:
   - why? (see above 1.2 § - Objectives)
   - what is the scope of application?: products, product position in the food chain, etc.
   - Means of communication: what type of communication, for whom, etc.
3. Establish existing elements:

   Based on the context and objectives, identify if existing elements need to be improved, by analysing:

   - The diagram of the product life-cycle
   - Means of data gathering and transmission.
4. Establish procedures (action plan):

   Having analysed the existing elements and after evaluation of all information, the professional defines procedures for:

   - product
   - determination of a lot (see below)
   - identification of a lot (see below)
   - information management
   - responsibility for seizure and quarantine
   - associated documentation, records
   - data management methods and tools
   - internal or external communication of information, etc.
5. Organisation of documentation:

   Traceability documentation (analysis, procedures, and records) must be handled in accordance with the procedural regulations of documents and records (MNG 3) and information systems (SUP 4).

1.4 - Implementation

1. Validation:

   It is recommended the enterprise conducts a pilot project before implementation of accepted decisions to be sure of suitability and effectiveness.
2. Planning:

   Establishing a plan for implementation of measures and achieving identified requirements.

3. Training:

   Personnel that might have an impact on traceability systems must be trained and informed of the role of traceability.

4. Monitoring

   The traceability system should be monitored to ensure the application of discussed measures.

1.5 - Evaluation and improvement

1. Simulation/ Traceability Exercises

   It is necessary to conduct traceability simulations to determine the effectiveness: the ability to find certain products, speed, etc. The simulations should be recorded.

   Frequency of simulations is established in a verification plan.

2. Audit:
   Traceability is subject to audit procedures like all other elements of the safety management system. The audit covers application of procedures, compliance with planning, etc.

3. Review:

   Traceability measures are reviewed regularly and consist of:
   - obtained results (simulations, audits)
   - applicable corrective actions
   - changes to a production process
   - regulatory changes
   - changes to the traceability system
   - new traceability requirements, etc.

2 - Application

2.1 - Identification

Mandatory identification of production (for example, the "best before" or "use by" date) permits identification of lots.

Records of information identified during risk analysis related to lot identification is useful for lot management. The records ensure lot identification using the given information.

For products discussed in this guide, different factors impacting upon product safety (raw materials, production lines, salting, smoking, etc.) need to be taken into account.

Documents contributing to traceability of raw materials, especially batch management, need to be introduced for identification and traceability control.

In the event of questionable or defective lots and subsequent recall, traceability based on the identification of lots provides the means to establish who received the affected goods and possibly other related lots.

The identification method for lot identification of end products is the choice of the manufacturer and is reported to enforcement bodies and validated by written regulations. Marking of lots is carried out in the form of an indelible inscription on the packaging making it possible to find the necessary information on withdrawal or recall.

Traceability provision in distribution chains facilitating the recall of products, is determined in advance and lots shipped to the customer should be identified and registered during dispatch. In the event of a non-conformance, the products follow a written recall procedure (see MNG 2.5).

Furthermore, if a lot has been damaged during dispatch, the sender can track the reasons for non-conformance with the help of traceability and withdraw or withhold non-compliant products.

2.2 – Batches or Lots

Batch (Reg. 2073/2005): *means a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period*.

Lot (Directive 2011/91/EU): *The concept of a lot implies that several sales units of a foodstuff have almost identical production, manufacture or packaging characteristics. That concept should, therefore, not apply to bulk products or products which, owing to their individual specificity or heterogeneous nature, cannot be considered as forming a homogeneous batch.*

This Guide uses both batches and lots.

Identification and traceability of batches or lots facilitates traceability.

Each one consists of products "deemed to be identical" at a production stage.

Batches are intermediate identification for:
- raw material, processing
- wrapping, cooking

Lots are intermediate identification for:
- end product packed (or production lots)
- dispatching lots.

Selection and size of batches or lots depends on:
- regulatory requirements
- preliminary evaluation and hazard analysis
- identification of critical points
- means of control and monitoring
- reliability of recall procedure intending to be used
- economic risk that the responsible person in the enterprise would be prepared to accept in the event of product withdrawal or recall, etc.

Each intermediate batch has a specific identification in place, which might be incorporated into the identification of end product batches.
If many end product lots have been grouped together in the dispatched lot (a delivery note, an invoice), each end product lot should be identified.

It is recommended to have several tanks or containers for storing of ingredients (for example, oils, flour) to ensure better traceability of raw materials.
Where this is not possible, and if an ingredient has been taken out of the warehouse due to food safety issue, tracking the use of an ingredient gives the opportunity to address a potential anomaly. However, if this non-conformance has been detected in the uncertainty zone of the raw material batch, the deployment of special control measures is required for end products that might be affected.

A production lot corresponds maximum to a day of end product (closure of a packaging) produced under practically the same conditions.

2.3 - Useful information

Recorded information (that is tracked) is defined during hazard analysis. The information is sufficient to conduct a non-conformance analysis. The information is related to batches or lots and given their identification. Traceability information includes everything that can influence product safety, notably:

- Raw materials, including primary packages (packaging), the traceability for secondary packages is required only if it has been revealed by the hazard analysis that they might trigger a sanitary risk or be useful for traceability, for example, for labels and pre-printed boxes, but primarily for transport boxes
- General hygiene conditions (the prerequisite program): state of premises, equipment and facilities (maintenance, cleaning and disinfections, etc.), personnel hygiene, etc.
- Production operations, operational PRP (OPRP) and, if applicable, CCP
- Treatment facilities (salting, smoking, etc.) and production times, etc.

Examples of ways to ensure identification and traceability - Non-exhaustive list (refer to Article 35 & 38 of Council Regulation 1379/2013)

Level	Traceability documents	Identification Information retained	Other references
Reception	Delivery note	Delivery note reference number Delivery date Name Origin (country, fishing area, ...) Supplier, ship, farm, slaughterhouse, official body validation number Date of fishing, dispatch, etc.	Possible sampling for the analysis Possible observations, etc.
Putting into a cold storage room	A stock sheet or specification document	Stock sheet number Date/hour of putting in a cold chamber Name of fish, crustaceans, molluscs or shellfish Sorting Information from the delivery note Date/hour of the first output Date/hour of final output, etc.	Possible sampling for analysis (a sampling sheet should contain delivery note information) Possible observations, etc.

Level	Traceability documents	Identification Information retained	Other references
Preparation	Preparation records	Customer name and identification number of preparation batch Product name Information from a stock sheet Preparation type (filleting, ...) Date/time of preparation	Potential sampling for analysis Possible observations, etc.
Dispatch	A packaging label	An identification mark Product name Information from a preparation sheet Date of packaging Information as required by EU Regulation	Possible sampling for analysis, ageing tests (tracked) Possible observations, etc.
	Delivery or Dispatch note	Delivery or Dispatch note reference number Customer, etc. Information for preparation note	

3-Traceability of food contact materials (other than packaging materials)

Traceability of different materials coming into contact with foodstuffs is required.[51] However the extent of the traceability and speed at which traceability can be carried out will depend on risk, confidence in suppliers, etc.

The risk incurred is usually managed by means of specifications, evaluation of suppliers and control at reception. Generally, it involves a low level of risk. All food contact materials have to follow Regulation 1935/2004.

Examples of ways to ensure traceability of food contact materials

MATERIAL IN CONTACT	USEFUL DOCUMENT
Equipment	Delivery note Invoice
Gloves (for example, risk of "allergen latex")	Delivery note Invoice Stock control records

[51] Requirements of Regulation (EC) 1935/2004

MNG 4 – CONFORMANCE OF PRODUCTS

Conditions for ensuring compliance with the product safety control system

1. Implementation of a monitoring plan to ensure compliance with control measures[52]:
   - Good general hygiene practice
   - Establishment of operational control measures (operational PRP (OPRP and CCP, if applicable))
2. Monitoring records
3. Identification of non-conforming products
4. Records of non-conformance
5. Treatment of non-conformances
6. Investigations to determine the reasons for non-conformance and implementation of measures to avoid repetition
7. Records of corrective action and corrective measures put in place.
8. A procedure providing the information and decisions required to inform official bodies of the need to recall or withdraw product.

Confidence in product conformance, resulting from the enterprise acting in accordance with the established measures or those laid down in this guide for every product lot, is ensured by:

- Monitoring actions (observation, measures) at various points identified within the course of hazard analysis, in addition to specific points discussed in this guide (ability to demonstrate the pre-defined actions have been adhered to)
- Implementation of product release
- Treatment of non-conformances (execution of actions either to remove non-compliant products from the market or substitute with products that are suitable for placing on the market)
- Existence of a procedure for notification, withdrawal and recall (with reference to Regulation (EC) 178/2002).

Having pre-validated the efficiency of the measures put in place and by performing regular verifications (see MNG 2.3), confidence in product safety can be assured.

1 - Monitoring compliance with control measures

1.1 - General requirements

In order to ensure compliance with the established measures (as defined in this guide), control measures are deployed for execution of monitoring; this may

[52] If the measures are consistent with the requirements stipulated in this guide, the measures are considered as validated, since this guide has been officially acknowledged.

include analysis[53], visual inspection, supervision of one control (for example, temperature) etc.

The monitoring may take place within distinctive phases or moments, for example:

- For purchases, monitoring is carried out during reception to ensure compliance with specification; it is extremely important to execute such monitoring during reception because the specialist does not always have measures to reduce initial contamination of products (for example, caused by heavy metals, pesticides)
- For products during production, to ensure that an important parameter for product safety and health has been achieved, for example, thermal treatment, formulation, salting, smoking, etc.
- For storage temperature and product temperature
- For working environment, notably to ensure that a cleaning and disinfection plan has been met
- For potable water, point of use (changing of sampling locations)
- For personnel hygiene (see SUP 3)
- For release of end product lots (see OPE 3.2): analyses, monitoring measures applied within the course of operations (compliance with PRP, OPRP, possibly CCP).

Monitoring points include:

a) Control points related to Good General Hygiene Practice (PRP) to ensure that application of key prerequisite hygiene measures for the control of product safety: personnel hygiene and training, maintenance plan, cleaning and disinfection plan, room temperature, cold storage rooms, etc. ;
b) Production operational control measures (OPRP) to ensure no non-conformance (non-application of measures identified) was identified;
c) Critical control points (CCP) for product safety to ensure that critical limits are being met.

Monitoring actions (the action performed and frequency) are determined by what is being monitored (production, activity volume, etc. ...), reliability of procedure (technology, event analysis,...), hazard analysis, etc.

1.2 - Monitoring plan

The professional applies a monitoring plan: this is a document that describes the provisions put in place to ensure the compliance with identified measures, PRP, OPRP or CCP.

The following elements should be established for each control:

- where and when it is implemented
- the control criterion or criteria
- the method applied
- the limit value, tolerance and possible critical points (CCP)
- responsibility for control
- frequency of control
- sampling methods, a sampling plan

[53] Since the response time for microbiological analysis, except for certain rapid methods, is very long to execute monitoring "at a present moment".

- actions to be taken in the event of a non-conformance (changes to product or corrective actions to prevent repetition of the same mistakes)
- product release procedures to be taken where product is released before the end of control
- corresponding records.

The monitoring plan is established in terms of hazard analysis and by defining control measures (OPRP and CCP, if applicable). When defining the monitoring plan, the enterprise takes into consideration existing information on events to determine the frequency of monitoring actions (if confidence is demonstrated, the frequency of monitoring measures may be reduced).
If monitoring is through analysis, analysis activities may be performed using in-house methods if the results have been assessed by acknowledged methods and in accredited laboratories (see MNG 2.3).
See below for the examples of control that are an integral part of the monitoring plan.

1.3 - Recording of monitoring actions

All monitoring actions should be recorded (control sheet, analysis report, audit report, etc.), the record should include:

- nature of a monitoring action
- the conditions during production (time, products being produced at a present moment,...)
- the operator
- results (every time the result is assessed: avoid statements such as: "good", "acceptable", "for processing", etc.)
- a reminder that values must conform within the allowable tolerance limits, if necessary
- potential defects: nature, importance
- visits by auditors engaged in control (who is appointed to implement the monitoring plan)

1.4 - Identification of products controlled

All batches controlled should be identified so that operators know if the batch has undergone a verification procedure before the next process stage. This might be implemented in several ways (by following the operation sheet accompanying products during processing, use of colours, storage zones, etc.).

Records help identify the person performing verification who has responsibility for putting compliant product into circulation.

2 - Lots release

Where possible, before dispatch, the professional applies a procedure to prevent dispatch of non conforming lots in terms of regulatory, in-house and customer requirements. If dispatch takes place before final verification of lot release, the enterprise should recall or withdraw products on the basis of a non-conformance identified at any stage of the food chain (logistic platform, customer, consumer, ...).

Such a lot release procedure is applied to ensure that the control measures established by the professional (PRP, OPRP and CCP) have been applied.

For this purpose, the professional deploys available traceability and monitoring measures.

During application of this procedure, the professional is assured that:

- Good General Hygiene Practices (PRP) have been observed: this can be ensured through the management control and through specific records. All of the activities during one or several days have been assessed taking into account the monitoring point and on the basis of the established monitoring plan (see above for the monitoring plan).
- operational control measures (OPRP) have been followed: the person in charge of lot release ensures that no non-conformances have occurred during production of the product lots concerned.
- CCPs (in certain cases) are being followed: the person in charge of lot release verifies all CCP records for the product lot to ensure that critical limits have been achieved.

3 - Control of non-conformances

When the results of the monitoring actions (PRP, OPRP, and CCP) do not comply with acceptance criteria laid down in the monitoring plan, this results in a "non-conformance". Non-conformance falls into three categories:

- **a critical non-conformance:** non-conformities that affect the food safety of the manufactured product. An imperative standard, a criterion requiring product withdrawal (regulatory value or value defined by a manufacturer) or critical limit of the HACCP plan has not been attained; in this case, the sale of product is prohibited; this category includes non-conformances present at points critical for control of product safety and suitability
- **a major non-conformance:** unacceptable for product quality or key operational control, but not having a dangerous effect upon consumer health; this may include certain non-conformances brought about by the application of good hygiene practice, for example, non-conformances arising due to hygiene or personnel training, cleaning, etc., or due to results obtained from a specific operational control (OPRP)
- a minor non-conformance: this concerns mainly special customer demands and is therefore outside the scope of this guide.

The existence of non-conformances is identified by qualified persons who have received relevant training, there are 3 stages:

- identification of non-compliant products (certificate, isolating in a designated area, etc.); it may take place during reception (unacceptable raw materials), preparation (insufficient salting, etc.) or before dispatch (for example, a damaged package)
- description of a non-conformance with respect to product specifications and allowable tolerances
- classification of a non-conformance (critical, major or minor).

Two considerable cases:

- the correction of a non-conformance is limited to achieving acceptability (for example, re-salting); where, appropriate actions have been put in place and product conformance is controlled
- the non-conformance for the market considered cannot be addressed; in this case, the lot is destroyed or redirected to a market with which it is in compliance.

In any case, the analysis of root cause is carried out to prevent repetition of the same non-conformance. If the corrective actions require modification of production conditions, the analysis of causes is conducted to evaluate the effect of such changes. This may lead to new validation of control measures (see MNG 2.2 and MNG 2.3).

The data obtained from the analysis of causes is used during the verification of the product safety management system, improvement procedures, management reviews, etc.

These operations are recorded on a non-conformance document that serves as a record. The authorised person takes the decision about future actions. The decision made is recorded on a non-conformance document with all information on the treatment of the non-conformance. This includes the records for the future of the product, in particular for CCP, in the event of a non-conformance.

When a non-conformance poses a threat to consumer health, competent authorities should be contacted immediately (Regulation (EC) 178/2002).

4 - Procedure of withdrawal or recall

For procedure of withdrawal or recall please refer to Appendix 4: *WITHDRAWAL, RECALL AND NOTIFICATION BY FOOD BUSINESS OPERATORS* extracted from the GUIDANCE ON THE IMPLEMENTATION OF ARTICLES 11, 12, 14, 17, 18, 19 AND 20 OF REGULATION (EC) N° 178/2002 ON GENERAL FOODLAW CONCLUSIONS OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH dated 26. January 2010.

Examples of analysis in application of a monitoring plan

The monitoring plan implemented in the enterprise depends on size, products manufactured, technologies applied, hazard analysis, historical reviews, effective control measures, etc. The table below is a non-exhaustive example of a monitoring plan; it is established by each enterprise on the basis of the enterprise methods, qualification and confidence regarding the application of measures put in place.

If the control produces poor results, corrective action must be applied and new controls established (validation of actions employed).

Object	Type of analysis	Samples	Frequency of monitoring
Potable water (a network)	Bacteriology	Various points of use	≥ 1 analysis of potable water per year (reference local rules)
Drill water (borehole)	Consumption of chlorine/water treatment		On a daily basis
	Chemical (minerals) Bacteriology		(analyses for verification of treatment efficiency) ≥ 1 analysis of drill water per year(reference local rules)
Ice in product contact	Bacteriology	Points of use	≥ 1 analysis per year
Disinfection of surfaces	Bacteriology (surface samples)	Various points of use - work tables, - floors, - walls, - gloves, - aprons, - polyethylene tables, - razor blades, etc.	Several samples per day must be analysed after cleaning
End products (Day 0, D0)	Bacteriology Histamine	Various products Fish rich in histidine	1 or more products per day
End products (final shelf-life)	Bacteriology	Various products	1 or more products per week Any product with detection of *Listeria monocytogenes* D_0[54]
Salting	Homogenate analysis	After desalting and/or on the end product	Identified on the basis of desired salt content trend performance (refer to seasonal variations, raw materials, etc.)
Functioning of the smoke generator (temperature, risk of PAH).	Use of a temperature sensor and/or analysis of PAH on final product.		Every trimester and when there are significant changes on the process

[54] If it is the case with the product frozen after handling that is intended to be sold after thawing, it should be accounted of (conduct a final shelf-life testing after thawing).

Examples of products in compliance with good general hygiene practice

HAZARD MANAGEMENT CONTROL	PREVENTIVE MEASURES	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Safe products Contamination of a product, and cross contamination during distribution (for example, a non-tight package, lost vacuum) or proliferation (no negative effect on physical or chemical properties, poor evaluation of shelf-life, etc.)	Application of identified measures implemented in accordance with the monitoring plan Management of non-compliant products	Regulatory criteria	Production/ Technical Staff controls Monitoring plan Validation procedure for implementation	Rework or repair, alternative use or destruction of products Review of procedures and working instructions	Procedures and working instructions Monitoring records, analysis reports, audit reports, reports of non-conformance meetings etc.

SUPPORT PROCESSES
Good Hygiene Practice

The following pages describe good hygiene practice (the prerequisite program in accordance with ISO 22000 or Codex Alimentarius) that has to be implemented before any production activity. This good practice establishes a framework within which the activity can take place. Certain rules of good hygiene practice are regulatory.

When good hygiene practice is implemented, operations and associated control measures may be defined (see the chapter "Operations" displayed below in this document).

At the bottom of each page is a table showing the key points defining controllable hazards (related to all activities of the company), measures in place, target values and corresponding records (required to demonstrate that good hygiene practice is being applied).

SUP 1 - PURCHASES

Objectives	Justifications
Controllable hazards: initial contamination, efficiency of external services Raw material supplies are managed to ensure that the raw material is safe and suitable for intended use. - avoid keeping supplies in zones where the environment presents a significant threat to product safety - ensure that supplies are not the source of contamination (raw materials are suitable for contact with foodstuffs, water quality, etc.) - ensure that service providers do not pose any threat to product safety.	Reduce the probability that hazards related to initial contamination could have a negative impact upon food safety and suitability for use.

Conditions of good hygiene practice to be complied with during purchasing

1. Working with reputable or evaluated suppliers (products or services).
   - An evaluation procedure for suppliers
   - A tracking procedure (quotation) for suppliers
2. Defined specification requirements acceptable to suppliers.
   - Conditions of glazing for fresh fish, freshness condition of fish, freezing conditions and storage of frozen fish,
   - Quality of ice and potable water
   - Suitability of packaging materials for contact with foodstuffs
   - Suitable cleaning products with known conditions of usage
   - Services meeting the requirements, etc.
3. Established transportation conditions, notably the vehicle temperature (for materials and end products)
4. Controlling purchases during reception: the processor is liable for raw materials used in production (see. OPE 2.1)
   - Control of the transport vehicle (cleanliness, temperature, etc.)
   - Fish temperature, glazing
   - Condition of fish freshness
5. Placing purchased raw materials into storage without delay to maintain optimal condition (see. OPE 2.2)
   - Specialised storage zones
   - Observing "first-in, first-out" (FIFO)
6. Monitoring external service provider performance (behaviour, efficiency)

1 - Purchases

1.1 - Working with well-known or assessed suppliers

Since the sanitary safety of raw materials is very important for end product safety, the professional should purchase supplies from providers acting in accordance with the requirements.

> When buying fish from non-yet-evaluated vendors a specific procedure of validation and verification has to be applied.
> Fish should be purchased from reputable suppliers managing the whole chain (eggs, farms, feed, boats, processing center.)

This applies to all purchases, whether the purchase of products (fish, packages cleaning agents, etc.) or services (maintenance, transport, etc.).

To do this, the professional performs supplier selection and ensures the supplier performance is monitored (conformance of goods supplied, legal disputes, etc.).
Two categories of suppliers are identified:

1. Regular suppliers with whom the professional maintains an established relationship: a relationship history is a very important factor for selection and monitoring (maintenance of commercial relations).
2. New suppliers: the professional takes various measures to obtain the appropriate confidence level (see the box below). Traceability of products from suppliers is one essential validation point.

Examples of criteria for validation of suppliers

- Ability to meet specification requirements, in particular those related to safety, suitability, and traceability (it is important to know the origin of potential contamination)
- identification of whether the supplier has an established quality system, control procedures, a HACCP plan, etc.
- history of relationship with suppliers
- visits and audits of the supplier
- examination of samples, etc.
- Reviewing overall supplier performance data

In some cases, the evaluation of suppliers can be difficult. **As such, the professional has to consider the risk related to such purchases (for examples, enforce additional control during reception).** It is not advisable to purchase from supplier who has not been evaluated.

Evaluation and monitoring of suppliers of farmed fish

The supply chain should be assessed over 3 levels:

- feed supplier (notably a risk of dioxins and antibiotics)
- rearing farms
- fishery product establishments, important for controlling the risk of *Listeria monocytogenes*

A single on-site assessment of a slaughterhouse is not sufficient.

It may be useful to perform evaluations on farms, in particular:

- location, radioactivity, renewal of water, etc.
- feed,

To conduct this evaluation, the supplier may be provided with a questionnaire requesting information such as:

- the HACCP plan in place (stages, control procedures and measures)
- selection of the hatchery
- feed and amount and type of fish oil
- traceability.

For new suppliers (a new slaughterhouse site), there should be enforcement of control at reception (notably the systematic analysis of *Listeria monocytogenes* at reception) until the supplier is approved.

Monitoring of "approved" (evaluated) suppliers (slaughterhouses) is ensured by performing product analysis (amount of fat by breeding farms, *Listeria monocytogenes,* etc.) delivered from the same slaughterhouse using random selection (possibly systematically for *Listeria monocytogenes*). In the event of a non-conformance, the control enforced is applicable to all batches delivered from every slaughterhouse, from this supplyer. In the event of other non-conformances (notably with regard to *Listeria monocytogenes*), it is recommended to cease buying from this supplier.

Evaluation of slaughterhouses for farmed fish

During evaluation of slaughterhouses, slaughter conditions in particular are subject to examination and the probability of contamination, especially with that of *Listeria monocytogenes* is established. Monitoring points include:

- stress of fish during slaughter (impact on meat quality after this process)
- evisceration quality
- fish rinsing technique (prohibit fish rinsing in stationary tanks filled with water)
- fish accumulation in slaughter lines
- management of delays
- fish temperature before placing into boxes
- observation during evisceration, filleting, etc.

To ensure monitoring, suppliers are always informed of the results of analyses and delivery control.

Control results are also deployed for renewal of supply contracts.

If other non-conformances (in particular *Listeria monocytogene*s) have been identified after the implementation of the enforced control (related to new suppliers or due to poor results of reception control for suppliers that have already been approved), it is recommended to cease purchasing from this supplier.

1.2 - Establishing specification requirements

Specifications define the relationship between the professional and the supplier. The specification must be sufficiently accurate but not necessarily exhaustive; they define important elements in particular regulatory and acceptance criteria.

Purchase specifications facilitate resolution of legal disputes.

To enforce compliance, the specification should be agreed between the enterprise and the supplier.

Examples of specification elements

- a list of documents that should accompany goods on delivery (a delivery note, etc.)
- specifications (regulatory requirements, the condition of freshness, packaging, services provided, transportation conditions, ...), and target values and tolerances: acceptance values or rejection criteria for raw materials or services
- transportation conditions for a consignment when implemented by the supplier
- potential controls for the supplier or during reception including: the nature and frequency of the control, who performs the control (the supplier, sender or the third party, buyer), the sampling method and methods of analysis used
- actions that need to be taken in the event of a non-conformance
- in the event of a dispute, liability limits, between the buyer and the supplier, etc.

Examples of specification elements for the production of smoked salmon or trout (including legal requirements and additional company requirements)

OBJECT		CONTENT OF TECHNICAL DOCUMENTATION
Fish	Microbiological criteria	*Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus*, coliforms, etc.
	Fish feed	The feed is assessed and analysed during evaluation of suppliers. – Absence of contamination from terrestrial animals and of waste from processing companies – Amount of dioxin and PCB in feedstuff. – Growth hormones, including very small quantities of antibiotics that have an impact upon the growth of salmon. – Nutritional composition (animal feed regulations) – Traceability
	Rearing	Fish history on a rearing monitoring sheet[55]. – Date of release into the sea – Veterinary treatment and dates, – Foodstuffs used, fat content (impacts upon fat content of fish, smoking process and salt intake) – Duration of non-consumption of food before slaughter (related to water temperature), etc.
	Slaughterhouse	– Presence of a HACCP plan, notably with regard to the risk of *Listeria monocytogenes.* – Absence of disinfection agents used for fish rinsing or any other non-authorised treatment – Cooling of fish (< 4 °C) before icing. – Ice quality and amount, nature of ice – Use of single or multi-use boxes (when applying cleaning/disinfection procedures)
	Freshness[56]	– Delay between slaughter and evisceration – Delay between slaughter and delivery
	Other	Controls implemented by the supplier
Salt		- Granulometry - Regulatory amount of impurities It is recommended that salt is purchased in a double package, the external layer is removed before entry into the preparation workshop.
Sawdust and timber		- beech, oak, vine stalk,... - Avoid the use of coniferous trees with high level of lignin[57], - Do not use processed woods
Packaging		- Suitability for contact with foodstuffs

[55] In application of Regulation (EC) 852/2004, all farms should submit rearing registration records at the customer's request

[56] See below the table displaying the recommended duration for operations (9 §).

[57] CODE OF PRACTICE FOR THE REDUCTION OF CONTAMINATION OF FOOD WITH POLYCYCLIC AROMATIC HYDROCARBONS (PAH) FROM SMOKING AND DIRECT DRYING PROCESSES (CAC/RCP 68-2009)

OBJECT		CONTENT OF TECHNICAL DOCUMENTATION
Transportation Logistics	Raw materials	- Trucks must be clean and have refrigeration equipment - "Use reserved" for transportation of fish/foodstuffs - Load only clean and undamaged crates
	End products	- Trucks that are clean and have refrigeration equipment - Transportation temperature ≤ 4° C for chilled products or ≤ -18° C for frozen products

2 - Provision of supplies

2.1 - Requirements

2.1.1 - Fish supplies

Fish intended for use is classified into the categories of extra fresh, A, and B. **It is not recommended to use the fish from category B (purchases of fresh fish) or frozen fish from category B (purchases of frozen fish). This would require a specific hazard analysis to be carried out for this category of fish, taking into consideration the reason for this classification.**

For purchases made directly in auctions or through professional intermediaries, the products have to be classified in advance by level of freshness and are under the control of producer organisations and veterinary authorities. **This does not exempt the professional from implementing verifications during reception.**

When purchasing other fish (reared in farms, in particular), the specialist defines the requirements of the enterprise (microbiological, chemical, etc.) that exceed simple adherence to regulations, depending upon the procedures deployed, product in use, etc.

To ensure organoleptic and hygiene quality, fish is kept at a temperature of melting ice. It is recommended to use ice or an alternative method having equivalent impact.

Fish temperature (icing), condition of freshness, evisceration quality (notably integrity of peritoneum), are the key characteristics during reception.

<u>Icing of fish</u>

During dispatch, there must be maximum 3/4 fish and minimum 1/4 ice, split equally among fish. Proportion of ice may be reduced or increased depending on transportation conditions (local transportation by an isothermal truck), ambient temperature, destination of product, duration of transportation, etc.

Fish fillets should not come into direct contact with ice (use a plastic film to separate fillet from ice).

2.1.2 - Supplies of water and ice[58]

An adequate supply of potable water should be available for use to ensure that foodstuffs are not contaminated.

Clean water may be used with whole fishery products; clean water may also be used for external washing. When clean water is used, adequate facilities and procedures must ensure that such use is not a source of contamination for the foodstuff.

Ice which comes into contact with food or which may contaminate food, must be made from potable water or, when used to chill whole fishery products, clean water.

Clean water: clean seawater[59] and fresh water of a similar quality.

Potable water: water meeting the minimum requirements laid down in Council Directive 98/83/EC on the quality of water intended for human consumption.

Water used in workshops should come from a network or drill[60] (borehole) on condition that the requirements for potable water have been adhered to (see SUP 2.1).

Utilisation of marine water is forbidden[61].

2.1.3 - Wrapping and packages

Use of packaging materials (plastic boxes, polystyrene, films, etc.) is restricted to those approved for contact with foodstuffs.

2.1.4 - Cleaning and disinfection procedures

Products designated for cleaning and/or disinfection of installations that come into contact with food must be approved.

Only authorized products[62] should be used, for which the supplier can provide the required documentation, in addition to the technical instruction sheet (the professional should keep these sheets), the scope of application for disinfection agents or any proof of inclusion into an official list of detergents.

It is important to be aware of the potential non-compatibility of cleaning and disinfection agents (efficiency) and installations (corrosion).

The selection of disinfection agents is based on microbes, the environment and the activities. To avoid resistance of microbiological flora, to reduce the growth of the micro-organism community and limit the creation of biofilms, it is advisable to change regularly the disinfectants used (with alternative disinfection functionality), or rotate the use of different products, taking into account the results obtained by studying the bacteriological surfaces, in order to verify the effectiveness of cleaning/disinfection.

---

[58] Refer to Appendix V – Supplies of water and ice for elaborated information.
[59] For clean seawater definition refer to Regulation 852/2004 Article 2 – Defiinitions.
[60] Borehole requires a prior permission.
[61] As indicated by Regulation 853/2004. SECTION VIII: FISHERY PRODUCTS CHAPTER I: REQUIREMENTS FOR VESSELS II. HYGIENE REQUIREMENTS Point 5: "Ice used to chill fishery products must be made from potable water or clean water".
[62] For disinfectants Regulation (EU) 528/2012 including a reference to REACH Regulation (EC) 1907/2006 for detergants: local authorisations.

Cleaning and disinfection agents are selected on the basis of potential impact on environment.

Principle information useful when purchasing cleaning and/or disinfection products

- approval number or proof of inclusion into an official list
- incompatibility of cleaning and disinfection products with facilities
- conditions of use: application time, mechanical operation, product concentration, temperature of use
- environmental effect (destruction conditions, etc.)

2.1.5 - Other products

Various ingredients can be used, for example, salt, sugar, wood for smoking, oil, aromatics, vegetables or spices, but also grease used for maintenance (alimentarity), etc.

Dependant on the product and methods used, the professional determines its requirements (microbiological, chemical, etc.) that may exceed simple adherence to the regulations.

2.2 – Reception of raw materials

To prevent the possibility of cross-contamination during reception, different raw materials[63] are received in distinctive zones or at different times. Reception premises should be suitable for the products received (temperature, etc.) (see SUP 2.1) – Working environment).

Raw materials undergo inspection procedures during reception. Reception is very important for product safety as there is no decontamination of products in the forthcoming process stages (except for hot smoking).

Sampling for microbiological and physical as well as chemical analyses is carried out at reception if it has been established in the monitoring plan (MNG 2.5). Sampling for analyses can also be conducted in case of doubts on the products quality.

During the first reception or one of the first receptions from a new supplier, the producer should examine carefully all delivered raw materials (immediate examinations, sampling for analyses).

The personnel carrying out the reception must be prepared and evaluated, with particular regard to assessing organoleptic properties of raw materials (freshness of fish, etc.)

2.3 - Control at reception

The control at reception permits the monitoring of adherence to specification requirements nd the control is defined in the specification.

N.B. If suppliers have not been evaluated, the control at reception allows assessment of the suitability of raw materials in respect of the results of of the hazard analysis (absence of knowledge of the measures taken by the supplier).

[63] For example, fish, various ingredients, cleaning agents, packaging, etc.

Such is the case when purchasing fish rich in histidine without knowledge of supply measures (the cold chain, time period between fishing and chilling of fish, etc.). Reception can therefore be a CCP. Control is ensured for batch release after histamine analysis by applying an enhanced sampling plan that exceeds the regulatory requirements (see OPE 1.1 and OPE 2.1).

2.3.1 - Immediate controls

Immediate controls determine acceptance or rejection of the batch at reception.

In addition to the execution of regular controls between products delivered and a delivery note (quantities, specifications), it is advisable to perform immediate verification before accepting the batch.

Information useful for the batch (salmon or trout)
(minimum required):

- Slaughterhouse details (*Listeria monocytogenes*)
- Rearing conditions (fat content ⇔ influences smoking)
- Date of slaughter ⇔ salting control
- Delivery date
- Fish size

- condition of transportation: vehicle cleanliness, temperature, etc.
- a delivery note, associated documents that are indicated in specifications acceptable to the supplier
- integrity of packages and raw material packaging
- labelling of raw materials
- condition of glazing (fresh fish)
- product temperature (≤ 2 C for fresh fish, ≤ -18 °C for frozen products)
- the presence of foreign matter (visual check)
- evisceration quality for eviscerated fish (absence of damage to peritoneum) and the degree of potential infestation with parasites
- level of freshness
- fish size that is important for smoking and salting (an identical batch) and *Listeria monocytogenes*.

Fish not covered by ice is not acceptable, unless the temperature is ≤ 2 °C.
The presence of ice is a mandatory condition.
Fish freshness reveals if the fish has been stored in good conditions, notably temperature. This examination is performed by a qualified assessor.

Examples of sampling for controlling trout or salmons at reception
- Condition of ice: 1 % of boxes,
- condition of freshness: 2 fish 2 % of boxes

Causes for the rejection of a batch (a non-conformance):
- loading conditions,
- temperature of the truck,
- condition of glazing: rejection due to absence of ice if the quantity of ice is very small, fish temperature (≤ 2 °C) and condition of freshness are verified.
- damage to peritoneum,
- excessively long transportation time (freshness)

2.3.2 - Other controls

In addition to immediate controls (see above), other controls are applied in a systematic or random manner. The number and frequency depends upon confidence in the supplier. For example, the verifications may be reduced given the history of relations with the supplier and depending on the presence of a quality assurance system, or when the supplier guarantees, with documented evidence, the control of the products supplied.

The controls at reception, applied by the supplier or producer in accordance with the provisions of the agreed specification might include for example:

- freezing data (frozen raw materials) provided by the supplier
- microbiological or physical-chemical analysis (for example, histamine[64], TVB-N analysis[65]) of food raw materials conducted by the supplier and/or producer, with regard to *Listeria monocytogenes.* In particular at reception of salmon or trout, the presence and absence of contamination and the frequency of contamination is monitored.

According to Regulation 853/2004 and subsequent consolidated versions concerning parasites), for 24 hours at ≤ -20° C or -35° C for not less than 15 hours in the whole fish

- fat: a measure of humidity or use of fat meter is an indicator for fat content[66]; fat monitoring is not always performed at reception, it may be carried out before salting/smoking. The batches may be separated by the supplier if there is a need to purchase batches with a fat content specific for a smoking process

Control method with regard to *Listeria monocytogenes* (for fish or trout)

Sampling with a sponge or cloth used for mucus, gills, abdominal wall is applied for 5 fish.

Analysis is performed regularly, but not necessarily in a systematic way (1 cloth per analysis), and analysis may be reinforced (5 sponges or cloths per analysis) in the presence of a new or "risky" supplier.

- monitoring of raw material data (fishing area, farms, rearing registers, fish feed, etc.), such basic knowledge and rearing conditions of raw materials provide relevant information on radioactivity, heavy metals, PCB and dioxins; monitoring analyses may be carried out which will depend on confidence in the supplier, previously established results, etc.
- results of analysis of packaging materials and product packages, in particular suitability for contact with foodstuffs, technological fitness (resistance, weldability, etc.), etc.

All criteria have established acceptance levels (limit values, tolerances). Unacceptable raw materials should be identified and separated from other products.

Controls are performed before raw materials have entered the production process. However, if the control cannot be performed at reception or if the results of controls cannot be determined before use of the raw material, the raw material lot is identified to facilitate product recall in the event of a non-conformance. For a new supplier, the lot should be processed last.

The records of observations and control of sampling selected at the reception constitute proof of control at this important stage.

The controls are used for supplier monitoring.

2.4 - Placing/storage of raw materials

After reception, fish and other food raw materials should be placed into storage as soon as possible in premises that will maintain preservation.

[64] This concerns the conformance criterion at the moment of consumption; manufacturer's acceptance criteria at the reception should be reduced, given the nature of products.
[65] TVB-N analysis is suitable for evaluating fish freshness, except for certain categories of white fish.
[66] For non-processed fish, fillet fat + humidity = value is close to 80 %.

Packages, cleaning and disinfection agents etc., are placed in appropriate zones (reception premises are not designated for storage).

Fresh fish is kept below a temperature as close as possible to 0 °C, under ice, or by applying a method generating an equivalent effect (for example, in a cold chamber with controllable humidity). Frozen fish is kept below ≤ –18 °C

During storage, different products are stored in conditions to prevent deterioration and to prevent contamination, notably cross-contamination. For example:

- do not mix packed and non-packed foodstuffs
- storage areas in all premises are defined for storage of specific materials
- Stored ice must be protected from any contamination and storage conditions must ensure preservation of ice quality (for example, absence of block formation, clumping)
- plastic pallets, films, etcshould be stored in a manner which protects from accumulation of dirt (in a specific area, elevated storage, etc.)
- Salt is stored in dry premises avoiding cross-contamination
- chemical agents (notably cleaning and disinfection) are stored in designated areas where foodstuffs are not handled.

Good management of supplies ensures renewal of raw materials and helps prevent prolonged storage (application of FIFO method, "first in, first out").

Raw materials with a final or optimal shelf-life are used within the shelf life.

3 - Delivery of services

3.1 - Transportation

Conditions of transportation are defined in the specification. During transportation, raw materials and end products are protected from contamination or sources of contamination.Fresh fish is transported at a temperature as close to 0° C as possible. Chilled end products are transported at a temperature of ≤ 4 °C. Frozen products are transported at a temperature of ≤ –18 °C.[67] Whatever materials are transported, in addition to regulatory requirements, special transportation requirements may be established for loading conditions, journey duration, etc.

3.2 - Laboratory

When using a laboratory, internal or external, it is advisable for such a laboratory to be accredited for the field of activity in which it operates and that the testing should be carried out within the scope of the accreditation. In the absence of accreditation, the laboratory should participate in an inter-laboratory PT scheme – Proficiency Testing. In this case, it is advisable to conduct similar analysis in separate laboratories to validate the reliability (see supplier information).

3.3 - Other services

This applies to all external service providers that are included in the enterprise activity that could influence product safety, for example:

- company dealing with work clothing, room cleaning, etc.

[67] Regulation (EC) 853/2004 permits short-term fluctuations of this temperature during transportation or reloading; however the temperature fluctuation cannot exceed 3°C.

- company specialized in pest management
- storage company
- company responsible for maintenance (preventive or corrective), etc.

Services, conditions of intervention, etc. are also defined in the specification. Service provider personnel must follow the hygiene requirements established specifically for that provider (see SUP 3).

3.4 - Subcontracting production processes

When production processes are subcontracted, requirements established by hazard analysis are applied for such subcontracting.

The measures defined in this guide should be followed by the contractor, except for cases where the contractor can prove that measures applied attain the expected safety level of the products concerned.

3.5 - Subcontractor monitoring

Monitoring the conformance of products supplied against the specification, for example, effectiveness of cleaning, efficiency of pest management, behaviour, work clothes, etc., independent interested parties, efficiency of interventions, etc is carried out through analyses and monitoring of the the enterprise activities.

Monitoring is recorded and reported to the subcontractor (supplier monitoring).

4 - Purchases of equipment

In conducting hazard analysis, equipment should be also taken into consideration. All purchased equipment should undergo hazard analysis linked to its function. In addition to production requirements, the results of this analysis are used to define equipment specifications. Within the course of this analysis, it it necessary to consider production, technical maintenance, cleaning and disinfection, personnel security, etc.

When the equipment is designed for a specific activity, design stages should be implemented by the equipment manufacturer[68].

Example of specification element for equipment purchase

- equipment characteristics, in particular: performance, precise description of various components (technical documentation), suitability for dismantling and cleaning, work safety and ergonomics;
- compliance with sanitary requirements, for example: risk of foreign matter, cleaning properties (equipment used, liquid leakage, etc.), risk of chemical contamination (fat, etc.) ;
- cleaning procedure;
- personnel training on operation and cleaning of equipment;
- technical maintenance conditions regarding the acceptance, installation, launch of equipment, and compliance with sanitary regulations during these operations.

[68] See Chapter 7.3 § of I ISO 9001-2000 standard

Note: When purchasing second-hand equipment (or upon site transfer), special attention should be paid to cleaning and disinfection.

Examples of good general hygiene practice for purchases

HAZARD ASSURANCE CONTROL	PREVENTIVE MEASURES	*LIMIT VALUE*	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Initial contamination of raw materials, packaging **Efficiency** of cleaning products, external services (in particular due to the possibility of cross-contamination)	Assessed and monitored suppliers	Criteria for acceptance of suppliers	Supplier audit Reception control Evaluation	Supplier action plan Supplier visit Delist supplier	Supplier results
	Specification or technical data sheets	Regulatory or specific requirements	Reception control (immediate or delayed) Efficacy testing Management	Request to the supplier Special treatment or lot rejection Modification of specifications	Specifications or technical data sheets Delivery note Acceptance record Analysis reports, etc.
Proliferation or contamination during transportation (raw materials)	Transportation specification	Maintenance of storage temperature Non-mixing of foodstuffs, etc...	Reception control (cleanliness, vehicle temperature, etc.)	Request to the supplier Special treatment or lot rejection	Technical documentation (transportation conditions) or technical data sheets Delivery note Acceptance record
Cross-contamination during or after the reception	Separate zones depending on raw materials (acceptance zones, storages zones)	Compliance with defined zones	Production / Technical staff controls	Sorting, special treatment or lot rejection Personnel training	Delivery note Acceptance record Storage record
Proliferation during or after the reception	Relevant temperature in reception and storage premises Storage within the shortest time possible	Relevant temperature (≤ 2 °C or ≤ −18 °C, etc.) Immediate storage	Measurement of product temperature Production / Technical staff controls	Special treatment or lot rejection Staff training	Acceptance record Storage record Temperature records

HAZARD ASSURANCE CONTROL	PREVENTIVE MEASURES	***LIMIT VALUE***	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Proliferation or cross-contamination during or after subcontractor interventions during transportation of end products	Subcontractor specifications, transportation of end products, etc.	Special requirements (for operations, temperature, cleanliness, etc.)	Analyses Production / Technical staff controls	New subcontractor Supplier intervention Delist supplier	Analysis reports Monitoring reports, etc.

SUP 2 – WORKING ENVIRONMENT - PEST CONTROL – FACILITIES AND EQUIPMENT – TECHNICAL MAINTENANCE – LABELLING AND CALIBRATION

1 Water (including ice)

1.1 - Risks

Water is a vector for potential contamination by food borne pathogens including *Listeria monocytogenes.*

Practices or processes involving water should be evaluated in terms of potential sources and routes of contamination, e.g. animal and human waste.

Only potable water should be used during processing.

Measures should be put in place to limit the possibility for waterborne contamination and to ensure that water quality is appropriate for the intended use.

Sources of water used for any purpose should be identified, and the microbial and chemical quality assessed with regard to suitability for intended use and the measures to prevent or minimise contamination (e.g. from livestock, birds, other animals, run-off from heavy rainfall).

In general, the risk of contamination is greatest for surface water supplies, less for ground water supplies, and significantly less for municipal (potable) water supplies.

Where water is stored, a risk assessment should be carried out considering the risk of contamination by pathogens during storage.

Equipment used for the application and storage of water must be regularly inspected for cleanliness and cleaned as appropriate.

Ice must be protected from exposure to condensation and must be stored in clean containers.

Non-compliant ice must not be used in direct contact with fish to be used for the production of Ready To Eat food.

1.2 - Analysis

Microbial analysis is important for producing data for assessment of to environmental cleanliness.

Frequency and sampling methodology should be defined for each water risk identified.

It should be noted that testing only reflects water quality at the time of sampling.

Harvest locations should arrange periodic testing of the wellboat chilling water and ice for microbial contamination, the frequency based on risk assessment. This must be documented.

Testing for total *E. coli* is recommended to estimate the risk of faecal contamination.

Additional micro-organisms, such as pathogens of major concern (Salmonella, *Enterococcus*, protozoa etc.), may be tested for if there is a potential or suspected hazard.

1.3 - Temperature control

A high performance chill chain is required to minimise microbiological growth.

Appropriate temperature control will limit the potential for growth of any contaminating micro-organisms, maintaining quality over shelf life.

Refer to the appropriate process steps section for guidance on temperature control.

The manufacture and volume of ice must be closely controlled.

Where water is used as an integral part of a cooling system it should originate from a potable source. Due regard should be paid to the risk of contamination of recirculated water in cooling systems.

2 - Fish Contact Surfaces

Each processor should implement a hygiene policy with due consideration of the points detailed below.

2.1 - Cleaning and Hygiene

Equipment handling fish during chilling should be clean and sanitary.

Poor sanitation and handling practices at any of the process steps can significantly increase the risk of contaminating fish.

Fish for human consumption must not be stored outdoors unless under cover and at an acceptable temperature.

Facilities should be designed and constructed in such a way as to minimise damage to fish, avoid access by pests, minimise the potential for cross-contamination and to minimise the opportunity for potential contamination from physical objects such as glass, wood, metal etc.

Pathogenic micro-organisms may be found on any food contact surface including conveyors, packaging in addition to floors, walls, ceilings and drains.

Checks made at start up and after deep cleaning must be recorded and should include visual inspection of contact surfaces and environmental sampling.

Damaged or visually dirty containers should be repaired, cleaned or discarded in order to reduce possible microbial contamination of fish.

Appropriate protective clothing should be provided.

Key hazards to be managed in the cold-smoked salmon production chain are:

· Contact with waste
· Feed contamination

· General hygiene
· Cross-contamination from other fish

Containers and associated equipment and materials coming into contact with fish and fish products should be designed and constructed to facilitate adequate cleaning, disinfection and maintenance and should not be stored directly on the ground or floor.

Containers for waste and inedible or dangerous substances should be clearly identifiable of suitable construction and, where appropriate, made from impervious material. They must not be used for carrying fish or fish products at any stage of the lifecycle.

All food contact equipment must be kept clean and tidy and in good working order at all times, in particular:

· Control of physical, microbiological and chemical contamination
· Realistic and rigidly applied cleaning schedules with detailed procedures must be implemented and the efficacy tested on a regular basis.
· All equipment should be free from obvious contaminants (such as mud, diesel, grease, oil, waste fish and debris etc.)
· All knives must be cleaned and stored appropriately when not in use.
· All knives must be accounted for and checked for damage after gill cutting, and appropriate action taken to deal with any defects.
· Hygiene schedules must be implemented for automated and semi automated systems
· Packaging must be kept clean and separate from any sources of contamination, including foodstuffs
· Cleaning chemicals must be suitable for cleaning food contact surfaces and should be stored in a locked area during processing.

2.2 - Equipment & machinery

A documented procedure for preventive maintenance schedules and frequency should exist, detailing all items of equipment used in the production process.

For machinery used to process food Directive 2006/42/EC on machinery, and amending Directive 95/16/EC states that machinery suppliers are required to meet certain essential hygiene design requirements and to declare conformance to the Directive. Food processing machinery should carry the CE mark.

Health and Safety Executive: Catering Information Sheet No 24[69] lists the following general design points. For each item of equipment, establish whether the food safety risk can be eliminated by state of the art design and construction methods.

[69] Health and Safety Executive: Catering Information Sheet No 24

If this is not possible, reliance must be placed on cleaning and disinfection regimes. The regimes must be provided by the supplier to the user and the machine should be designed to allow easy and effective cleaning;
In addition, limits need to be stated in instructions to the user on use of the machine (temperature, product,etc).

Some Key Do's:

- ⇨ Ensure permanent joints are smooth.
- ⇨ Ensure dismantlable joints have a true and hygienic fit.
- ⇨ Ensure projections, edges and recesses are kept to a minimum.
- ⇨ Ensure internal curves allow thorough cleaning, and, where necessary, disinfection.
- ⇨ Ensure shafts and seals are self- lubricating or use food grade lubricants
- ⇨ Ensure appropriate biocides are used in condenser trays to prevent contamination build up.
- ⇨ Ensure that air cooling systems are designed and maintained to avoid contaminating fish. They must be clean and the cool air free from microbiological contaminants.
- ⇨ Consideration should also be given to the health and safety risk from Legionella due to the creation of aerosols.

Some Key Don'ts:

- ⇨ Don't allow dead spaces or bends in pipework in the food area which allow product to accumulate – if this is unavoidable then ensure good drainage and cleanability.
- ⇨ Don't use screws, screw heads and rivets in contact with food.
- ⇨ Don't allow condensate and defrost water from evaporator type cooling systems (e.g. cold rooms) to drip onto fish.

The Chilled Food Association recommend that equipment should be designed for:

- ⇨ Ease of strip down and rapid release (design principles should be according to European Hygienic Equipment Design Group (EHEDG) guidance[70] and Chilled Food Association (CFA)'s Hygienic Design Guidelines[71])
- ⇨ Compliance with user requirements and specifications

Equipment installation must be carried out hygienically.

- ⇨ Engineers should be trained in hygiene principles and follow specified procedures
- ⇨ Pre-installation hygiene of second hand/rented equipment and history including pre-use storage requires particular attention
- ⇨ Effective pre-installation cleaning must be carried out
- ⇨ Handover procedures to production must be specified and followed.

Equipment should be sited away from sources of contamination, e.g. drain flows, evaporators, air flows from raw material intake

[70] European Hygienic Equipment Design Group (EHEDG) guidance
[71] CFA's Hygienic Design Guidelines

3 - Pest Control

Each Company must produce and implement a Pest Control Policy specific to the individual process in operation within the business.

The Policy should include:

- ⇨ Level and Type of Pest Control Service Contract employed including:
  - A. Number of inspections
  - B. Pests Covered, e.g. rats, mice and insect species
  - C. Emergency Contacts following any report of a problem
  - D. External Biologist audits
- ⇨ Type of Monitoring
  - A. Tamper-proof plastic rodent baits should be used throughout buildings with the exception of production areas.
  - B. External bait stations, should be used at strategic locations and monitored for rodent activity.
  - C. For the purposes of Health and Safety, all bait stations must be clearly labeled and all monitors dated at time of inspection.
- ⇨ Recording

Records should include the following information:

- Contract specifications, contact names and telephone numbers
- Summary Reports
- Checklist detailing type and location of monitors.
- Monitor location plan.
- Technician service and treatment reports.
- Biologist service and treatment reports.
- Rodenticide Usage Chart.
- Technical Data Sheets.
- Duty of Care Certificate

- ⇨ Corrective Action
  - A. Inspection reports should provide details of defects found in the course of the inspection and provide recommendations for future compliance.
  - B. Should a defect be reported, a designated responsible individual should decide what best course of action can be taken to remedy the problem. Once the problem has been rectified, the corrective action details (action taken, completion date, instigators signature) should be recorded on the original inspection sheet.

The contracted Pest Control service provider should be responsible for ensuring the implementation of the action plan

4 - Definition of the different working areas in the factory

Definition of working areas within the facility are arranged according to the risk of contamination or the risk of proliferation or degradation of products (choice of temperature of rooms).

Generally separated into three main areas:

- **Zone A:** areas where the products are not protected from external contamination such as foreign bodies, pollution and microbial contamination, where the products are susceptible to degradation caused by enzymatic and microbial activity. It is possible to separate this area into three sub-zones:
  A1 = zone prior to smoking, A2 = curing, smoking and pre-slice storage/ stiffening and A3 = slicing zone

- **Zone B:** areas where the products are packaged and protected from external contamination. In addition, the equipment washing areas except for small equipment (knives, etc.) which are washed in the area of use.

- **Zone C** : waste storage and handling areas

Example of classification of work areas for the production of salmon or smoked trout:

WORK AREA	ZONE	Recommended Temperature, °C
➢ **Reception areas :**		
○ food commodity chilled and frozen	B	≤ 12 ° C
- other food raw materials, packaging and other non-food materials (cleaning / disinfection)	B	
➢ **Storage areas / storage :**		
○ Raw food (chilled, frozen and ambient temperature)	B	depending on the material
○ Semi-finished products (work in progress, maturation after smoking)	A	≤ 4° C
○ products in saturated brine	B	≤ 10° C
○ products under salt, curing and maturation before smoking	A	≤ 8° C
○ finished products	B	≤ 4° C
○ finished goods "sub 0° C chilling"	B	<-2° C and ≥ -3° C
○ packaging,	B	
○ clean or dirty material	A or B	
○ cleaning products	B	
➢ **Fish preparation areas:**	A1	
○ Unpacking	A1	≤ 12 °C
○ Thawing	A1	[72]

[72] Room temperature during thawing must be managed to keep products at ≤ 2 ° C (≤ 4 ° C for finished products)

WORK AREA	ZONE	Recommended Temperature, °C
○ filleting, sorting, washing, skinning etc.	A1	≤ 12 °C
➢ **Processing Zones**	A1	
○ Salting	A1	≤ 12 °C
○ Smoking	A2	
➢ **Area of slicing and packaging of fish**	A3	≤ 10 °C
➢ **Picking areas and shipping finished products**	B	≤ 10 °C
➢ **Washing area (cash handling, etc.)**	B	
➢ **Waste area, located so as not to contaminate other areas**	C	
○ dry waste	C	
○ wet waste	C	≤ 4° C [73]

[73] Except Daily removal

SUP 3 – CLEANING AND DISINFECTION

Objectives	Justification
Hazards to be controlled: cross-contamination (from premises or equipment) or during operations Establish efficient systems for: - maintenance of adequate and appropriate cleaning; - Pest management; - Waste disposal; - Monitoring of cleaning and disinfection; - Verifying the efficiency of cleaning and disinfection procedures.	Facilitating efficient and continuous control of hazards, materials that might ultimately contaminate premises, facilities, and foodstuffs Maintaining cleanliness to prevent cross-contamination

Conditions of good general hygiene practice for cleaning and disinfection

1. Define and apply the cleaning and disinfection plan
2. Do not clean and disinfect in the presence of products (or protect them to prevent from contamination)
3. Select cleaning and disinfection agents with reference to to efficiency and compatibility; modify products to prevent creation of resistant strains, biofilms
4. Trained personnel (competence and behaviour)
5. Monitor cleaning and disinfection operations
6. Keep records of cleaning and disinfection and control.
7. Monitor efficiency of cleaning and disinfection

The purpose of cleaning and disinfections is two-fold:

- cleaning eliminates food residues and dirt that can be a source of contamination, ensuring protection and management of bacteria (use of detergents)
- disinfection kills bacteria

These may be implemented separately or simultaneously after systematic removal of gross soil. Cleaning, when combined with disinfection, is not as effective as separate operations. Separate cleaning and disinfection is therefore recommended.

Rinsing with potable water or vapour removes traces of detergents and disinfectants.

Cleaning and disinfection methods and substances depend on the nature of the enterprise.

Cleaning and disinfection is performed in the absence of products (to prevent cross-contamination from splashes). If this is not possible, products should be protected. Products in cold storage rooms should not be placed directly on the floor to facilitate the cleaning process. If products are to be placed unpacked in cold storage rooms, the rooms need to be emptied before cleaning and disinfection.

1- Cleaning and disinfection agents

Cleaning and disinfection agents are handled and used in accordance with manufacturer's instructions (dosage, temperature, intermediate rinsing, etc.) to reduce the risk of contamination of food and environment.

Cleaning and disinfection agents chosen for equipment in contact with foodstuffs must be approved.[74]

- a precise list of detergents,
- an approval for disinfectants.

Cleaning and disinfection agents must be stored in appropriate premises in accordance with storage specifications provided by the supplier (storage temperature, final shelf-life)

During use, attention should be drawn to potential incompatibility between detergent and disinfectant (efficiency), in addition to between detergent, disinfectant and equipment (corrosion).

Cleaning and disinfection agents are chosen on the basis of efficiency (anti-bacterial) for the task at hand, compatibility with equipment, materials and installations, etc. To prevent creation of microbial resistance, regular change or rotation of disinfectants is required (containing different active materials).

It is necessary to consider the elements above when selecting the chemical supplier (specifications, etc.).

Reminder of mode of action of cleaning and disinfection agents

1. Effect of a detergent (used for cleaning): The detergent may be useful for:
   - chemical effect: takes place because of product concentration,
   - temperature: accelerates cleaning,
   - mechanical: reinforces detergent contact with dirt,
   - time: chemical reaction between cleaning solution and dirt is not immediate, a minimal contact time is required.

2. Effect of a disinfectant: for effective disinfection, three factors should be considered:
   - concentration
   - time
   - temperature

[74] For disinfectants Regulation (EU) 528/2012 including a reference to REACH Regulation (EC) 1907/2006 for detergants: local authorisations.

Key cleaning/sanitising agents

A list of the most common active antimicrobial substances (for disinfection):

- alcohol
- acids (peracetic, others)
- chlorine
- aldehydes
- quaternary ammonium compounds

The spectrum of action for each active substance is different; it is advisable to rotate the use of disinfectants in order to extend the spectrum of action.

Ideal properties of a detergent:

- wetting (tension active)
- emulsifying
- dissolving
- saponifying
- dispersing
- good rinsability
- Anti-scaling, anti-corrosive

Since all these properties are difficult to obtain in a single detergent, rotative use of detergents, complemented by other properties to ensure cleaning effectiveness, is recommended

Examples of products:

- For cleaning: alkaline (sodium or potassium hydroxide), chlorine (sodium hypochlorite[75] = active chlorine), foaming; enzymatic products
- For disinfection: solutions containing the active principles of the following type: Glutaraldehyde and benzalkonium chloride or acetic acid and Laurylpropylene diamine, or quaternary ammonium compounds;
- Regular disinfection in risk zones (for example, slicing): quaternary ammonium compounds, for example;
- Regular descaling with acid detergent which is either foaming or not: phosphoric or sulfamic acid;
- Disinfection of surfaces without rinsing during production: alcohol (ethanol, isopropyl alcohol,...).

In all cases, the professional must have safety data sheets and follow the manufacturers guidelines for use.

2-Methods

Cleaning can be carried out by the separate or combined use of physical methods such as scrubbing, turbulent flow and chemical methods using detergents, alkalis, acids or enzymes.

[75] Sodium hypochlorite also acts as a disinfectant.

The use of sponges, foam brushes, reusable cloths, and mops is not permitted. If necessary (for cleaning work tables, walls, floors, etc.), the specialist can use disposable cloths, easy-to-clean brooms with rubber, or brush-brooms, etc. Reusable cleaning and disinfection equipment must be cleaned and disinfected frequently (for example, after each use) and renewed regularly.

3 - The cleaning and disinfection plan

A permanent cleaning and disinfection plan must be established covering the full extent of the business operations. The plan should also cover the cleaning and disinfection of the cleaning and disinfection equipment.

The application of the cleaning and disinfection plan is a prior condition for any activity (The prerequisite program) and is carried out by specially trained personnel.
The plan may include cleaning and disinfection operations tied to production activity (for example, washing knives during product preparation), which is traditionally carried out by production personnel. Frequency and nature of cleaning and disinfection is directly related to production (operational PRP-OPRP) activity (volume, product) (see Chapter Operations that is provided later in this document).

Cleaning and disinfection of slicing and packaging zones is extremely important for controlling *Listeria monocytogenes*.

Regular inspection of surface contamination is carried out and actions taken to prevent formation of biofilms (cleaning/disinfection by an acidic product).

To avoid contamination of products, all machines and tools are cleaned, disinfected and rinsed as often as necessary, in particular before and after each working day. Removable parts coming into contact with foodstuffs, particularly knives and trays are separated, cleaned, disinfected and rinsed at the end of operations.

After the daily work is completed or as scheduled, the walls and floors of product handling zones are thoroughly washed.

Cleaning and disinfection plans define :

- cleaning zones, equipment, and tools
- the nature of detergents and disinfectants, dosage, the required contact time of detergents and disinfectants
- responsibility and competences regarding the implementation of various cleaning tasks
- methods and frequency of cleaning and disinfection
- temperature/time for optimum efficency
- order of cleaning operations
- monitoring procedures, ...

The cleaning and disinfection plan also incorporates intermediate cleaning operations that can occur during the day (for example, when changing raw materials for preparation).

Examples of cleaning and disinfection procedures

1. Cleaning and disinfection carried out separately: operations take place successively:

- Pre-wash: store equipments, where possible dismantle, scrape and sweep up equipment or premises to remove debris visible on surfaces; this action is carried out at low pressure to prevent splashes; the pressure can be somewhat higher for equipment that is difficult to clean (for example, a slicer)
- Cleaning: detergent solution is applied for a contact time(hot water is used with detergent at the optimal temperature for detergent), and mechanical action is carried out (for example scrubbing) to separate bacteria from the surface and to contain the bacteria in solution or under pressure.
- Intermediate rinsing: rinse with potable water to remove dirt and detergent residue (in particular if this is recommended by the detergent manufacturer). Use of equipment with low pressure can facilitate rinsing.
- disinfection: apply aqueous disinfection solution and leave for the recommended contact time
- final rinsing: rinse with potable water to eliminate disinfectant residue

2. Cleaning and disinfection combined (not as effective as the first method)

- use of mixed products (mixture of detergent and disinfectant).
- operations: pre-wash, cleaning/disinfection and rinsing

Example of a cleaning and disinfection plan

OBJECT	DETAILED CLEANING PLAN (PREREQUISITE PROGRAM (PRP)) (carried out by cleaning personnel)		PRECISE OPERATIONS (OPERATIONAL PREREQUISITE PROGRAM - OPRP) (realised by operators)	
	IMPLEMENTED OPERATION	**FREQUENCY**	**IMPLEMENTED OPERATION**	**FREQUENCY**
The elements proposed below are only examples. Cleaning-disinfection plans are enterprise specific, they depend*, inter alia*, on product nature, equipment used, ... and are defined in advance hazards analysis. Depending on disinfectants used, cleaning and disinfection may be carried out simultaneously or separately.				
Individual equipment - knives - sharpen tool - metal gloves	- washing under water jet, - brushing - soak in a disinfectant bath (≥ 15 minutes) - rinsing before use	At the end of production (once per day)	- washing under water jet, - brushing - soak in a disinfectant bath (≥ 15 minutes) - rinsing before use	During each break If food residuals are present After a " critical" lot
- circular blades	- cleaning and disinfection with disassembly	At the end of production (once per day)		
	- cleaning and disinfection without disassembling (scrubbing) (in wet area) - application of alcohol before use	During each break		
Other mechanical equipment				
- bone remover - skinner	Cleaning and disinfection with disassembly	At the end of production (once per day)		
	Cleaning without disassembly (in the absence of products)	During each break After a "critical" lot		

OBJECT	DETAILED CLEANING PLAN (PREREQUISITE PROGRAM (PRP)) (carried out by cleaning personnel)		PRECISE OPERATIONS (OPERATIONAL PREREQUISITE PROGRAM - OPRP) (realised by operators)	
	IMPLEMENTED OPERATION	**FREQUENCY**	**IMPLEMENTED OPERATION**	**FREQUENCY**
- salt spreader	Cleaning and disinfection Maintaining the condition of needles for salting equipment	At the end of production (once per day)		
- slicer	Cleaning and disinfection with disassembly	At the end of production (once per day)		
	Waste disposal (without water use) (dry zone)	between each lot		
<u>Working surfaces</u> - table made from stainless steel - polyethylene boards - conveyor belts	Cleaning and disinfection	At the end of production (once per day)	In a wet zone (in the absence of products): pre-wash, rinsing In a dry zone: elimination of waste without water use	If residuals are present
	In a wet zone (in the absence of products): pre-wash and rinsing In a dry zone: elimination of waste without water use	During each break		
<u>Environment</u>				
- floors of working rooms	Cleaning and disinfection	At the end of production (once per day)		
	In a wet zone: rinsing of floor (in the absence of products and when products are protected) In a dry zone: elimination of waste without water use	During each break		

OBJECT	DETAILED CLEANING PLAN (PREREQUISITE PROGRAM (PRP)) (carried out by cleaning personnel)		PRECISE OPERATIONS (OPERATIONAL PREREQUISITE PROGRAM - OPRP) (realised by operators)	
	IMPLEMENTED OPERATION	**FREQUENCY**	**IMPLEMENTED OPERATION**	**FREQUENCY**
- walls (within human reach)	Cleaning and disinfection	1 or two times per week		
- ceilings	Cleaning and disinfection	once per week (depending on the height of ceilings)		
- protection grids - ventilators - evaporators	Cleaning and disinfection	once per trimester (at the same time as ceilings)		
- drainage	Cleaning and disinfection	At the end of production (once per day)		
	Alkaline treatment	once a week		
- cloakrooms	Cleaning	once per day		
	Cleaning and disinfection	once a week		

3 – Validation of a cleaning and disinfection plan

The cleaning and disinfection plan must be validated to assure the efficiency of control measures put in place (see MNG 2.3) to reduce risk and prevent cross-contamination: microbiological analyses, DNA testing (allergens), etc.

Validation results are archived (see MNG 3).

4 – Realisation of cleaning and disinfection operations

Premises, installations (illumination of workshops, pipework in workshops, drains and pipes, etc.), equipment (cold storage rooms and cooling units, etc.), and materials should be cleaned regularly and, if necessary, disinfected in accordance with the cleaning plan.

After daily work, before restarting and if the circumstances so require, floors and walls are thoroughly washed in product handling zones.

Records must be kept .

If cleaning and disinfection services are provided by a service provider[76], the provider must undergo evaluation, and specifications must be established including all of the control elements defined in this guide, taking into account the risk laid down in advance in the hazard analysis(see SUP 1).

5 – Cleaning monitoring

The application of cleaning and disinfection is monitored considering variables such as temperature, pressure, product concentration, selection of products used, etc. The control performed may be:

- During cleaning: visual control, application of biuret testing (recognition of peptide bonds), ATP testing
- During disinfection: microbiological analyses.

The frequency of control is defined based on hazard analysis to monitor compliance with cleaning and disinfection instructions, etc. (MNG 2.2 and MNG 2.3). Records must be kept.

[76] The professional, who prepares specifications designated for industrial cleaning services, can refer to the standard NF X50-791 Septembre 2006.

Examples of monitoring of premises and installations

Object	Type of control	Method
Walls Table surfaces Floors	Application of a cleaning method Application of a disinfection method Total flora (typical) *Listeria monocytogenes*[77] or spp	Visual control Contact boxes, Swabs Cloths, Napkins, etc.
Cleanliness of ventilation/aeration systems	Air quality Cleanliness of exchangers and ventilators	Calculation of particles Visual analysis Swabs Cloths, Napkins

6 - Verification of cleaning efficiency

The cleaning-disinfection program is reviewed periodically; trending of monitoring results aids verification of the efficiency of the cleaning-disinfection plan and evidence required to adapt the plan if necessary.

The verification details are recorded (reports, meeting report, etc.).

[77] Guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes* and Article 5 Regulation (EC) 2073/2005.

Examples of good general hygiene practice for cleaning and disinfection

HAZARD ASSURANCE CONTROL	PREVENTIVE MEASURES	LIMIT VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Decontamination of premises and equipment	Selection of cleaning products Rotation of cleaning products The cleaning and disinfection plan Trained personnel	Destruction of bacteria identified in hazard analysis Avoid resistant strains and biofilms	Visual inspection (cleanliness) ATP testing Microbiological or chemical analysis Audit	Improved cleaning-disinfection Change of cleaning-disinfection products Modification of the cleaning plan Personnel training	Cleaning records Technical data sheets Cleaning-disinfection plan Audit report
Cross-contamination (for premises and equipment)	"General" cleaning and disinfection plan (daily and periodic)			As above	Cleaning records
Cross-contamination during operations	Completion of the cleaning and disinfection plan for operations	Destruction of bacteria identified in hazard analysis	Visual inspection[78] Production / Technical staff controls	As above	Production records Cleaning records

[78] To proceed with validation (qualification) and verification (requalification) of efficiency of the method, these examinations have to be conducted.

SUP 4 – Hygiene and training of personnel

Objectives		Justification
Personal hygiene and health	**Controllable hazards: contamination** Ensure that people having direct or indirect contact with products can not contaminate the products by: - Maintaining the appropriate level of personal hygiene - Behaving in an appropriate manner. - Being in a good state of health that will not affect product safety	People failing to comply with sanitary safety, suffering from certain diseases or ailments, or whose inappropriate behaviour could contaminate foofstuffs and transmit disease to consumers.
Training and qualification	**Controllable hazards: proliferation or further contamination,** the absence of decontamination Operators having direct or indirect contact with foodstuffs receive training from the company and have instructions regarding the product hygiene operations they have to perform. All persons whose activity is related to product preparation, are trained and/or receive the instructions for work they have to perform.	Training is vital for product safety (appropriate performance of operations, compliance with working instructions). Training helps the operator understand why and how hazards arise or increase.

Conditions to be followed by personnel acting in compliance with good hygiene practice

1. Good state of health and clean personnel
2. Work clothes are clean and used only in working zones (and possibly also in resting zones)
3. Personnel trained to complete tasks and aware of their responsibility for product safety
4. Presence of training programs
5. Special training for personnel working at a CCP
6. Personnel monitoring
7. Personnel records

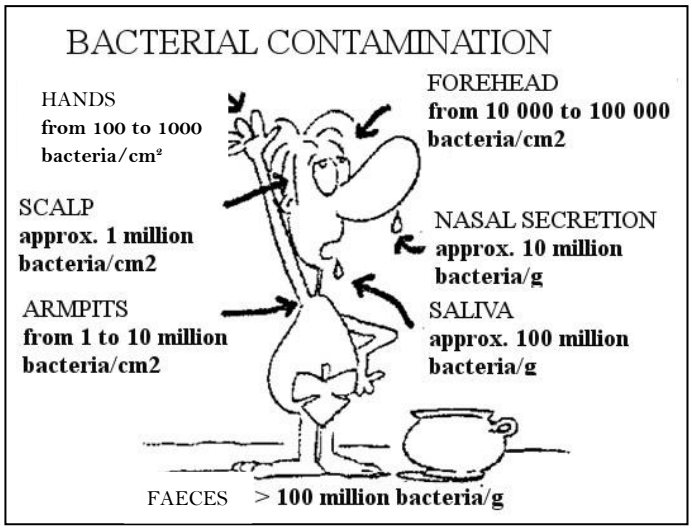
Personnel behaviour and training are key elements for product safety

Personnel handling foodstuffs can be an important source of contamination, due to either poor state of health or because of non-compliance with basic hygiene

regulations. Therefore, personnel hygiene monitoring must be undertaken, and existing personnel should be trained to understand the consequences of their behaviour.Personnel play an important role in product safety and must be trained to maintain product safety.

1- State of health

1.1 - Risk of contamination



No persons afflicted with communicable diseases or having ailments (infected wounds, skin infections or irritations, diarrhoea, ...) that may contaminate foodstuffs can be involved in direct handling of products for a period within the course of which they can be potentially hazardous. Any person infected with this kind of disease should inform the responsible person of the company.

However, these persons can maintain their positions in exceptional cases where precautions have been taken to tackle the ailment (for example, waterproof plaster in the case of injury to the hand).

1.2 - Medical examinations

It is recommended that any person coming into contact with foodstuffs (employed permanently or under a temporary contract) receives a regular medical examination, to determine their suitability to work with foodstuffs:

- before beginning their duties,
- at least once every 2 years (or according to local regulations)
- as many times as deemed necessary.

2 – Personnel hygiene

The measures described below are important due to uncertainties linked to actual control of personnel health (notably in relation to the Labour Law).

2.1 - Work clothes

The personnel handling foodstuffs should maintain their personal hygiene and wear appropriate protective clothes. Special clothes for personnel and visitors are essential to prevent microbial contamination in workshops.

2.1.1 - Clothes

Clothes, preferably light coloured (to facilitate cleanliness check), should be issued and collected in cloakrooms and stored separately from other clothes. Workers in zones A cannot exit the factory premises wearing working clothes. A risk analysis will determine the type of clothes to be used.

Cap and hood cover and hold tightly all hair.

Wearing of jewellery (bracelets, rings, watches, etc.) and badges attached to clothes is not permitted. Any derogation to this, needs to be sufficiently justified. The frequency of changing workclothes depends on the risk of cross-contamination given the workplace. In some cases, clothes should be changed at least every day and more often, if necessary, especially for persons working in zone A.
For each working zone, it would be useful to differentiate the colours of clothes; it would help to identify persons that not permitted in a certain zone (due to the risk of cross contamination).

Examples of clothes with respect to a working zone

Clothes for	Protection Cap or hood	Mask	Gloves	Special boots or shoes	Special clothes
Zone A1(Before Smoking)	Obligatory	Recommended	Recommended	Obligatory(Boots)	Obligatory
Zone A2(from smoking to stiffening)	Obligatory	Recommended	Recommended	Obligatory	Obligatory
Zone A3(slicing)	Obligatory	Recommended	Recommended	Obligatory	Obligatory
Zone B	Recommended			Obligatory	
Zone C	Recommended			Recommended	Recommended
Maintenance people	Obligatory from the moment entering zone A	Recommended in production zones	Recommended in production zones	Obligatory	Obligatory
Visitors	Necessary from the moment entering zone A	Obligatory		Necessary	Necessary

2.1.2 – Maintenance and cleaning of clothes

To prevent contamination or proliferation of microbes, control of protective clothing is given careful consideration.

Aprons are cleaned and disinfected on a daily basis or more often, if necessary.

A policy for maintenance and cleaning of clothes is required to ensure:

- renewal and replacement of damaged clothes
- cleaning, using establishing procedures and preferably in specialised laundry facilities
- supply and distribution.

The use of disposable clothes removes some of the constraints of maintenance and cleaning.

2.2 - Gloves

If gloves and sleeves are used during product handling, these should display the desired characteristics of strength, cleanliness, and hygiene and must be made from a non-porous and non-absorbing material that does not increase the risk of contamination (they must be approved for contact with food, allergens (latex), in particular).

The wearing of gloves does not exempt from thorough washing of hands before putting the gloves on.

It is recommended to pour disinfection solution on gloves before entering the workshops (zone A).

It is recommended to use disposable gloves; which are changed as many times as necessary.

When reusable gloves are worn, these must be washed and disinfected as many times as necessary (like hands).

Knitted metal gloves (chainmail) or equivalent (for example, made from synthetic fibres), required in certain workplaces for health and safety reasons, are particularly difficult to clean and disinfect due to the texture. Careful cleaning, followed by heating and prolonged immersion in disinfectant, is necessary (rinse with potable water before use).

When disposable gloves are used, particular attention should be paid to the issue of training personnel how to wash them.

Wearing of gloves is required if a bandage or plaster has been applied.

2.3 - Hand cleanliness

It is necessary, in particular, to ensure the cleanliness of hands, forearms, and nails. Nails must be as short as possible and well taken care of.

Example of hand washing instructions

- firstly, wet your hands
- pour some disinfection liquid soap
- soap carefully
- if required, brush nails
- rinse with warm water
- wipe your hands with a single-use towel
- throw out the towel in the container set up for this purpose
- apply alcohol/ hand disinfectant

Personnel should wash their hands at the following times:

- when starting or resuming work
- immediately after using the toilet (signs placed on exit doors and in appropriate positions remind personnel of the obligation to wash their hands)
- after blowing your nose
- after a potentially contaminating activity (washing of boots, working with soiled or dirty objects, ...)
- when handling materials capable of transmitting micro-organisms (in particular pathogens– see Chapter 4).

Personnel must wash their hands thoroughly using a product suitable for washing under running potable water. It is recommended to use warm water for more efficient hand washing.

2.4 - Footwear cleanliness

Footwear cleaning is necessary:

- before entering a production workshop (zone A)
- after use in order to remove organic material residues.

2.5 - Personnel behaviour

Persons handling foodstuffs should avoid potentially contaminating activities.

Eating, drinking, smoking, chewing, spitting in premises in which products are prepared is forbidden. Coughing and sneezing are tolerated where products will not be contaminated.

Maintenance personnel must implement the level of hygiene required for the specific zone within which they operate.

The rules of movement of production staff on the site must be defined by limiting as much as possible the passage from one production area to another. Within the fish processing factories, depending on the work activities, there are areas of greater risk of contamination.

To avoid cross-contamination caused by operators, factory personnel must:

A) Access only to the specific work areas of their activity.
B) The displacements should be made through the accesses enabled for it.

2.6 - Visitors, contractors

Precautions need to be taken to prevent visitors from contaminating foodstuffs; visitors must wear protective clothing and comply with business requirements regarding clothing and personnel behaviour[79]

The circulation of visitors must be controlled; the visit sequence should progress from the cleanest zones to the most contaminated. A health questionnaire is recommended to be completed by visitors to protect products from exposure to

[79] It can be carried out, for example, by submitting the document to the visitors before each visit. The drivers can enter the reception or dispatching premises for a period necessary to deliver or collect the goods, however, entrance into the food processing zones is forbidden.

the contamination risk, and visitors are required to sign a statement that they will abide by the business hygiene regulations.

Example of basic hygiene rules to be displayed

Appropriate and clean clothing

Hand washing before work, after leaving the toilet, blowing your nose, contaminating activities, at the end of work

Do not eat, drink, smoke, spit in production premises

Do not cough or sneeze on products

3 - Training

3.1 - Information and responsibility

The business executives and responsible persons must have the necessary knowledge on principles and food hygiene practice to evaluate a potential risk and take the necessary actions to eliminate or control such risk.

Where necessary, the business appoints a person responsible for ensuring compliance with requirements in a certain area, specially trained in food hygiene.

All persons have to be aware of their roles in relation to food hygiene.

Persons handling foodstuffs have to be conscious of their role in food hygiene, and have the knowledge necessary to perform the works in a hygienic manner.

Displaying the main hygiene rules is useful for keeping personnel informed.

Training must cover personal and clothing hygiene, hygiene methods for food processing, responsibility of persons working in this area. Such training must be conducted for new hires and repeated on a day-to-day basis. Training is delivered in writing with illustrations to demonstrate the principles of hygiene rules.

Any person involved in either fish or product handling must receive appropriate training. In zone A, the personnel (including persons responsible for cleaning, and maintenance personnel) are specially selected, trained, and instructed in the highest levels of personal hygiene at all times.

Personnel in charge of cleaning and disinfection must receive training in safe usage of chemical agents (detergents and disinfectants).

3.2 - Training programs

Each manager identifies the need for personnel training taking into consideration the following factors:

- nature of products handled
- food handling and packaging procedures, including the risk of contamination
- transformation steps
- product storage conditions
- product shelf-life

Training programs are subject to periodic evaluation and renewal when necessary.

The measures are put in place to ensure that food handlers have been informed of all necessary procedures for maintaining product safety and quality of foodstuffs[80].

[80] For example, operation procedures at work, pictograms, etc.

Training records are maintained which comprise individual training records for each member of staff and their professional experience and previous training received; this is very important for those staff working at a CCP, relevant training records must be available.

4 - Workers monitoring

4.1 - Monitoring of workers hygiene

Compliance with general personnel hygiene rules must be monitored. This includes, in particular:

- control of work clothing (visual inspection, ...)
- control of correct wearing of clothing (the role of engineering and technical personnel)
- control of personnel behaviour in the workplace (compliance with the rules of work procedures, hygiene, ...)
- control of personnel health (medical examination) and personal hygiene; handswabs do not need to be taken regularly, but can be useful for monitoring personnel handwashing or glove washing.

Records should be maintained of monitoring activities.

4.2 - Monitoring of workers qualification

The qualification of the personnel and compliance with working procedure rules must be monitored for activities which play an important role in quality of the products dispatched (notably persons responsible for cleaning and or maintenance, salting,smoking and other CCPs)

Records should be maintained of monitoring activities.

4.3 - Personal File

The file must comprise individual records showing:

- initial training of a person
- his personal experience
- his employment contracts
- training attended, especially for persons working at a CCP
- medical certificate for capacity to handle foodstuffs.

Examples of good general hygiene practices for personnel

HAZARD	PREVENTIVE MEASURES	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Contamination	State of health Personnel awareness	Absence of diseases transmitted through foodstuffs Personnel awareness	Engineering-Technical personnel	Training and staff awareness	Personal file
	Protective clothing Personnel training	Appropriate clothing worn only in the work place	Engineering-technical personnel	Changing procedures Personnel training	
	Cleanliness Personnel training	Handwashing, footwear, etc. before entering workshops	Engineering-technical personnel Hand swab	Handwashing, footwear, etc. Personnel training	Personal dossier Analysis report
	Personnel training (behaviour)	Do not eat, drink, smoke, spit, etc. in workshops	Engineering-technical personnel	Personnel training	
Proliferation Non decontamination	Training for task	Compliance with work procedures and regulations	Engineering-technical personnel	Personnel training	Personal file

PRODUCTION PROCESS DESIGN

OPE 1.1 – VALIDATION OF OPERATIONS

The efficiency of control measures put in place to ensure product safety and quality must be demonstrated. This is accomplished by prior validation of established measures (qualification) and verifying that the measures remain effective (see MNG 2.3).
The validation is carried out during product design stage, taking into consideration the established hazards and control measures (OPRP or CCP) on the basis of GHP/PRP in place (see from SUP 1 to SUP 4).

1- A reminder of basic regulations applicable to all production

General conditions for operations

1. Organize work in a way to minimise product waiting time/ delays
2. Do not allow fish temperature to increase during operations
3. Separate either in time or space operations that can cause cross-contamination
4. Record the criteria for verification and management of different operations
5. Monitor operations and record monitoring elements
6. Verify the efficiency of operational control measures

The temperature of whole fish should never exceed 2 °C during reception at the production workshop.
The temperature of filleted fish should not exceed 5 °C before salting (except in a few cases: ≤ 7 °C if there is a way to cool fillet rapidly).
Smoked fish product is stored below a temperature of 4 °C

All stages of production should be performed without unnecessary delay and under conditions that will prevent the possibility of contamination, deterioration and the growth of bacteria. Personnel should be trained in the operations they have to perform.

1.1 – Production planning

The quality of end products is closely related to the quality of raw materials; production planning must minimise the accumulation of raw materials (process fresh fish as soon as possible).

1.2 - Management of delays

Management of delays in the process is of paramount importance. Delayed products should be placed in a special refrigeration zone.

Management of chilled temperature in premises makes it possible to control the proliferation of bacteria, the production of histamine (for example, for smoked tuna) or quality changes in fish.

Example of delays
(production of smoked salmon from fresh fish)

- Slaughter to filleting
- Deboxing to the beginning of smoking
- the end of smoking to the the end of maturation
- the end of smoking to the slicing

Such delays must be considered when determining the product shelf-life.

A period of ≤ 15 minutes is recommended before the production phase (deboxing) and salting (for salmon, trout, etc.); the period may be extended to 30 minutes if fish temperature remains ≤ 5 °C.

1.3 - Compliance with basic organisation rules

To limit the risk of cross-contamination (see SUP 2.1):

- Raw materials of distinctive origin (marine products, flavourings, vegetables, etc.) should be prepared in different rooms or places. When this is not possible, these operations should be carried out with time segregation, followed by cleaning and disinfection implemented between.
- Operations are performed in a way to avoid the cross-contamination of foodstuffs at different production stages ("a step forward")

1.4 - Use of "barriers/ hurdles"

Microbial growth depends on suitable environmental conditions, i.e. the gaseous atmosphere, nutrients, amount of water, absence of inhibitors, for example acids, potential oxidation-reduction, storage temperature and duration. One or all of the barriers can be used to limit microbial growth.

For chilled products, chilling is a primary safety barrier, if used together with high quality raw materials. To control microbial growth, additional factors can be deployed, for example, packing in a modified atmosphere, or use of acids, such as for marinated products (pH barrier).

Examples of barriers/ hurdles

- pH of product (marinades etc.)
- a_w
- Packaging gases
- Salt content
- Smoke level
- Preservatives etc.

Appropriately selected barrier combinations can be used to mitigate the growth/survival of micro-organisms in a product. The presence of more than one of the barriers inhibiting micro-organisms may be synergistic so requiring less input from each barrier to control.

The barrier combination is selected on the basis of the product composition, production methods and storage conditions.

Analysis as to the effectiveness of the barriers at inhibiting or minimising pathogenic organisms during product design, and the presence of synergies, is carried out during the design stage and will be verified regularly. The deployment of predictive microbiology models can be helpful for this analysis.

Details on the establishment of barriers should be recorded (see MNG 3).

The results of the analysis are used when preparing work instructions (product documentation, etc.) for relevant operators.

1.5 - Validation of control measures

The control measures put in place by the professional are validated (qualified) before application. The purpose of such validation is to demonstrate the efficiency of the control measure put in place.

For this purpose, the professional can rely on the history of own activity, publications and scientific research (individual or collective), experimental analyses, etc. In the case of analyses, particularly microbiological, the sampling plan should be carried out with respect to the risk of variability [81]; laboratories in charge of such analyses should have an established competence for those analyses, i.e. they should, preferably, be accredited or, if this is not the case, be capable of performing quality procedures, and included in a network of inter-laboratory comparative research. The validation concerns, in particular:

- Premises, the location (within the framework of sanitary agreement)
- Equipment and installations used (installation qualification procedure)
- Maintenance plan
- The cleaning and disinfection plan
- Personnel competence (qualification procedure)
- Procedures for evaluation and monitoring of suppliers, implementation of specifications
- Other operational control measures, etc.

The validation also concerns the determination of shelf-life (see OPE 1.4).

All validation should be recorded and the records kept as the evidence of the validation.

Examples of validation (qualification)

Principal criteria that influence the intake of salt:

- Size and physiological state of the fish (depending on season in particular)
- Fat content
- Salting technique: dry salt (nozzles or fluidised bed), injections, mixed (dry salt and injection)
- Salting equipment (defining the quality of salt used)

[81] For examples, when validating on *Listeria monocytogenes,* at least 10 units shall be taken, 5 for analyses on day 0 and 5 for analyses at the end of shelf-life.

- The temperature of the salting room, etc.

Establishment of salting diagrams when taking account of these factors that give the ability to achieve a desired salt content by calculating salt content in different parts of the fish fillet (notably in a collar/ shoulder, centre, tail) in the course of salting (determination of salting period), and after maturation as well as rinsing (in the event of excessive salting).

Example of validation (qualification) of cold smoking

Main criteria having impact upon smoking

- Size and physiological state of the fish (depending on season in particular)
- Fat content
- Smoking method: hot or cold smoking
- Smoke generator
- Smoking room/ equipment (eg kiln)
- Smoke temperature, etc.

Knowledge on distribution of smoke in a room/ equipment,

Establish smoking programs:

- Define the distribution of product in the smoke room/ equipment
- Define the duration of the drying phase(s) considering the desired result
- Define the duration of the smoking phase(s), etc.
- Measure the flavour (analyse phenol or organoleptic testing)
- Monitoring of PAH content

Example of validation (qualification) of hot smoking

In addition to the elements of cold smoking, the thermal scale should also be validated by taking into account the fact that the temperature of 10 °C to 63 °C should not be maintained for a period exceeding 2 hours, notably:

- The microbial flora and the maximum quantity of bacteria in raw materials
- Expected cooking value
- Initial product temperature before thermal treatment
- Temperature homogeneity in the thermal treatment room/ equipment
- The size of products smoked
- The quantity of product treated (the size of the lot smoked)
- Distribution of product in the smoking room
- The reduction level (log) of micro-organism (s) to be achieved
- The thermal scale required to achieve the desired level of product safety, etc.

OPE 1.2 – Determination and monitoring of shelf-life

It is the professional's responsibility to determine the product shelf-life. The professional must prove that under normal or other conditions of use, reasonably foreseeable by the specialists, the products display the level of safety that can be reasonably expected and does not pose any harm to consumers health (Regulation (EC) 178/2002) before the end of the product shelf-life.

This obligation implies that the specialist should justify:

- how the shelf-life was determined in accordance with the safety requirement → shelf-life determination protocol.
- how the shelf-life chosen ensures the safety requirement → shelf-life monitoring protocol.

Combination of criteria influencing the shelf-life of products

- **phenol content,**
- **salt content,**
- **storage temperature,**
- physical-chemical characteristics (A_w, pH)
- manufacturing procedure, ...

1 Determination of shelf-life[82]

The professional determines the microbiological shelf life taking into account the risk of Listeria monocytogenes. He can use durability studies (ageing tests), challenge studies (growth tests) and/or predictive microbiological models.

The professional must consider the other relevant dangers defined in the HACCP.

The shelf-life can vary according to the hazard that is considered. The shelf-life indicated on the label should be the shortest determined.

For safety reasons, the professional must substract 2 days to the validated shelf-life when the shelf-life is ≥ 10 days, or 1 day when the shelf-life is < 10 days. This means the professional will qualify a 30 days shelf-life for a product that will be sold with 28 days.

FPO will establish and guarantee the shelf-life of end products in accordance with food safety criteria established by regulation, ensuring its safety – during its distribution, storage and use - when the conditions of conservation and use - indicated on the packaging - are strictly respected.

1.1 – Durability studies

The foodstuffs are placed under the conditions of time and temperature that correspond with "reasonably foreseeable" conditions of transportation, distribution, and consumption of final purchaser. The recommendations for carrying out durability studies are provided in Guidance Document on Listeria

[82] Guidance Document on Listeria monocytogenes shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

monocytogenes shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

In case of specific rules in certain countries the processors will have to respect the local rules according to where the product is sold. At the end of the microbiological shelf-life, the micro-organisms that are likely to be present will be verified to determine that they do not exceed threshold levels.

Initial quantification of contamination level and monitoring during the ageing testing are possible if the frequency of contamination with Listeria monocytogenes is high (≥ 20%, which is not often the case).

However, the accumulation of results from the ageing testing performed in accordance with the sanitary quality maintenance plan provides useful information on the condition that the professional can prove that:

- **the measures defined are applied for production conditions (Good Hygiene Practice, OPRP control, CCP control)**
- **the history of results is in line with similar production conditions.**

1.2 - Challenge tests

"These tests give a possibility to monitor the quantitative development of a bacterial species added into the foodstuff over time. The growth test allows us to evaluate quantitatively bacterial growth sensu stricto" (Technical guidance document on shelf life studies for listeria monocytogenes in ready to eat food)

However, although these tests do provide useful information, they do not reveal the actual growth of bacteria in the end product (notably evaluation of the lag phase[83]).

1.3 - Predictive microbiology

"Mathematical equations have been developed to simulate and foresee the behaviour of pathogenic flora which triggers off diseases in foodstuffs according to diverse conditions" (Report No. 2003-SA-0352 of the AFSSA and Guidance Document on Listeria monocytogenes shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs) on the basis of results obtained from foodstuffs or following the curves displaying the growth in a liquid medium (not necessarily representing what is happening in a solid medium).
Such models are particularly interesting only when they have been established on the basis of kinetics in a solid medium.

[83] "Latent phase" is the time, in the course of which the consecutive transition into a changed environment of bacterial population takes place (for example, the inoculation of micro-organisms into a sterile broth in a laboratory, stress-causing phase for micro-organisms present in a foodstuff, etc.). During this phase, bacterial multiplication is either totally lacking (latency in the strict sense) or progressive (an acceleration phase) until the beginning of exponential growth has been reached." (Report No. 2003-SA-0352 of the AFSSA and Guidance Document on Listeria monocytogenes shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs). In the event of weak manifestation of bacterial population, the lag phase is usually greater than that in the case of strong initial populations.

2 - Shelf-life testing

These tests can be used for different purposes;

- To validate[84] the product shelf-life having carried out the HACCP analysis for the product, in particular due to the risk of *Listeria monocytogenes*
- Establish the growth curve of *Listeria monocytogenes* for the product analysed, if the initial contamination is high and significantly quantifiable.
- In any case, at the end of shelf-life, monitor the application of control measures for products manufactured.

Having regular ageing tests performed is vital for products that are produced under similar conditions of raw materials, production, and storage.

2.1 - Taking into account of different production processes

The product shelf-life is evaluated and monitored by uniting all procedures applied in the enterprise (for example, if different salting technologies are applied, the ageing tests are conducted for each salting technology when making an assumption that the remaining part is constant. If the waiting time varies between each stage of production, the time selected for testing products (validation of the shelf-life) is the longest period of time (the most unfavourable situation).

If the enterprise changes production and packaging (vacuum, MAP, etc.) processes or storage conditions, it should re-evaluate the product shelf-life.

Validation or monitoring of the shelf-life for each type of wrapping (4 slices, 12 slices, etc.) is not required. However, the shelf-life of a product sliced or not, with or without the skin, may be different and should be evaluated and monitored.

The different possibilities of process use are as follows (indicative, but incomplete list, because different installations can have a distinctive impact upon the shelf-life even with the same process):

Raw materials	Frozen or fresh Fillet or eviscerated fish,…
Salting	The procedure: dry salt, injection, mixed Salt content (salting duration, … for example, salted, smoke-flavoured/light-flavoured fish, ...
Smoking	Type of smoke room/ equipment Firewood (beech, oak …) Cold smoking, hot smoking, …

[84] It is possible only if initial population is abundant and frequent enough to measure the level of initial contamination (D_o) during durability studies ageing testing.

Stiffening	None Technology (cryogenic frost, mechanical, mixed) Temperature and duration
Slicing	None Manual Machine (stiffened or not)
Wrapping	Under vacuum, in a modified atmosphere, Presence of "barriers/ hurdles", With or without skin, …
Storage before dispatch	Freezing "Sub 0°C Chilling" (≤ -2°C and ≥ -3°C) Chilled (from 0°C to 4°C)
Type of distribution	Sale to the final consumer Public catering (out-of-home) Industry, …

2.2 - Conditions of conservation

To perform the ageing test, the professional must consider temperature under which the product is kept, according to local usage, logistic organization, consumer equipement and regulation.

2.3 - Specific cases

Note 1: In case of Sub 0°C Chilling , storage below a temperature of ≤ -2°C and ≥ -3°C (the temperature interval at which the salmon is cooled, not frozen) does not lead to the growth of *Listeria monocytogenes*. During testing, the maximum duration of "sub 0°C chilling" needs to be taken into account to determine the total shelf life.

Note 2: Storage of frozen products (≤ -18°C), does not lead to the growth of *Listeria monocytogenes*. The research carried out by the enterprises shows that there can be changes in the growth of *Listeria monocytogenes* when stored between 0°C and 4°C (traditional storage), in particular a more rapid growth at a positive temperature, for example during a freezing/thawing procedure.

During testing, the time at various temperatures should be as representative of the total process, including freezing/ thawing, as possible.

2.4 - Samples for analysis

It is recommended to take 5 samples at the begining of the shelf life and 5 samples at the end of the shelf life for analysis to have representative data.

Some samples can be taken during the shelf life to understand the microbiolocal kinetics. Rules for testing and sampling are established in Reg 2073/2005 (Art 5).[85]

[85] Refer to ISO 6887 Microbiology of the food chain -- Preparation of test samples, initial suspension and decimal dilutions for microbiological examination (mainly Part 1: General rules for the preparation of the initial suspension and decimal dilutions and Part 3: Specific rules for the preparation of fish and fishery products).

3 - Records

Testing records should include:

- Origin of raw materials (farm and slaughterhouse, reared fish, the date of fishing, slaughter, reception, etc.)
- The condition of raw materials at the reception (fresh or frozen, index of freshness), possible contamination with *Listeria monocytogenes*
- Production date (wrapping)
- Methods used (salting, maturation, slicing, etc.) together with the duration of each stage
- Firewood used for smoking (for smoked fish)
- Test results for the start of the shelf-life D_0=day$_0$ with, if possible, a characterisation of the strain
- The results of analysis for at least D_1, D_2, D_3, D_4 or more, if the enterprise desires to monitor the analyses when going beyond the established shelf-life
- The content of salt and phenol (for smoked fish), also a_w for the products analysed.

4 - Smoked salmon and trout specificities

As it is indicated by regulation, absence of listeria in 25 g before the food has left the immediate control of the food business operator is the mandatory standard. In case of presence in the end product, the food business operator may fix intermediates limits if they are able to demonstrate (Chapter 1, Footnote 5 of Regulation 2073/2005), to the satisfaction of the competent authority, that the product will not exceed the limit 100 ufc/g throughout the shelf-life.

This option (intermediate limits) must be defined and demonstrated by each food business operator. An intermediate limit of <10 ufc/g has already been qualified in most facilities that have implemented this option and follow good practices which have inspired the present guidance, including a qualification by their health authorities of the monitoring of the global listeria prevalence in the plant (raw material & ingredients, semi products, finish products and environmental).

In the case that FPO uses the intermediate limit of <10 ufc/g and when the results of the analysis implemented at the end of production reveal the level of contamination with *Listeria monocytogenes* of ≥10 cfu/g, the FPO cannot put the product on the ordinary market of distribution (or to recall, if it has been already dispatched). In compliance with the Regulation 2073/2005, the professional can also:

- shorten the final shelf-life to ensure that the limit of 100 ufc/g (for listeria monocytogenes) will be respected. In that case prior validation is required.
- use the products with further processing by treatement that will eliminate the risk of *Listeria monocytogenes* respecting Article 7 of Regulation 2073/2005.

5 - Controlling the conformance of the category

The processor should demonstrate that they are compliant with this guide. Furthermore, it must prove that the verifications are accurate and that maximum process delays are managed.

PRODUCTION PROCESS MANUFACTURING

This section describes measures applied during the processing operations, **considering that general good hygiene practice is put in place (PRP).**

Only OPRP measures are considered.

If for some products a CCP is applicable, the notion of target value is complemented with a critical limit for a monitoring measure in respect of a management process.

The only measures taken into account are the ones related to production activity (measures directly related to this production activity), which are highlighted with grey in the following tables.

"Operation" documentations indicated below cover two parts:

1. Description of appropriate measures, if applicable
2. A table for facilitating the implementation of the HACCP in the establishment; in these tables, the most important hazards subject to control during each operation are written in bold.

A critical control point is not indicated as it depends on the product, its consumption, etc. However, information is provided for certain products.

The corrective measures defined in these tables should be applied for a specific hazard analysis, which can be performed as the result of a -non-conformance (referring to the hazard analysis in the tables).

The indicated records should be maintained with documentation for non-conformance management (see MNG 2.5).

OPE 2.1 - RECEPTION

See SUP 1

1- Eviscerated fish or fish fillet, other ingredients

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Initial contamination with pathogenic bacteria	Product temperature	OPRP	Presence of ice (Fish of fresh fish fillet) Temperature ≤ 2°C	Visual inspection Temperature measurement if case of insufficient glazing	Batch rejection if temperature is > 2°C or due to the absence of ice	Reception documentation
			Temperature ≤ 4°C (Other chilled products, except for fish)	Measurement of temperature for vehicle and products	Batch rejection if temperature is > 4°C	
			Temperature ≤ -18°C (Deep frozen products)		Batch rejection if temperature is > -15°C	
Initial contamination with pathogenic bacteria	Specifications and selection of suppliers (including transportation)		Fish: Type of freshness condition – extra or A Criteria defined during hazard analysis	Inspections carried out by a qualified person during reception	Batch rejection (fish with the type of freshness condition – B, etc.)	Reception documentation
			Listeria monocytogenes ***Absent***	Sampling for analysis	Batch/Lot rejection and specific monitoring	Analysis report
Parasites (anisakis)[86]	Specifications Frozen raw materials (in certain cases)	OPRP	Fish or fillet without obvious contamination	Visual	Batch rejection	Reception documentation
Histamine (no regulation for salmonids)	Specifications Fish temperature	OPRP/CCP	≤ 50 ppm (indicative limit for salmonids)	Analysis	Rejection of inappropriate lot	Reception documentation Analysis report

[86] In compliance with Regulation 1276/2011

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Initial chemical contamination (heavy metals, dioxins and PCB, phytosanitary residues, residues of veterinary medicine, nuclear contamination...)	Known area of origin Specifications Animal feed specifications (for reared fish)	OPRP	Regulatory criteria or specifications	Knowledge of official monitoring in production zones Rearing documentation and feeding plan	Lot rejection (non-conformance of specifications)	Reception documentation
				Analysis (according to specifications)		Analysis reports
Initial physical contamination (plastic pieces, …)	Specifications	OPRP	Absence of foreign matter	Visual	Elimination of foreign matter before production	Reception documentation
Reception of appropriate products	Working instructions	OPRP	Integrity of packages Order conformance	Visual and in accordance with criteria (see above)	Rejection of punctured packages and in accordance with other criteria (see above)	Reception documentation

N.B.: For fish rich in histidine, in the absence of knowledge on supply control measures (for example, unevaluated supplier, "spot" purchases), this stage can be a CCP. Raw material lot release after analysis under the enforced sampling plan is regarded as a control measure; the lot is subject to rejection if the amount is > 50 ppm. These analyses can be carried out by the enterprise laboratory by using rapid use kits on condition that the laboratory participates in a network of inter-laboratory comparative research. The batches are released into production if the results are favourable. The monitoring is ensured by the person responsible for product safety, taking into account the results of comparative research obtained by the laboratory.

2- Salt

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Initial physical and chemical contamination	Compliance with specifications	OPRP	Regulatory requirements	Analysis	Supplier intervention	Reception documentation Analysis report
Reception of suitable products	Working instructions	OPRP	Integrity of packages Order conformance	Visual inspection (integrity of packages)	Rejection of specific products	Reception documentation and/or delivery documents

3- Smoking wood

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Chemical contamination	Compliance with specifications	OPRP	Non-treated wood, non-use of softwood	Sensory examination (visual, odour)	Lot rejection	Reception documentation and/or delivery documents
Reception of suitable products	Working instructions	OPRP or CCP	Integrity of packages Order conformance	Visual inspection (integrity of wrapping)	Rejection of inappropriate products	Reception documentation and/or delivery documents

4 - Other ingredients

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Initial physical and chemical contamination	Compliance with specifications	OPRP	Regulatory requirements	Analysis	Supplier intervention	Reception documentation Analysis report
Reception of suitable products	Working instructions	OPRP	Integrity of packages Order conformance	Visual inspection (integrity of packages)	Rejection of specific products	Reception documentation and/or delivery documents

5 - Wrapping materials

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Contamination (bacteriological, chemical, physical)	Compliance with specifications	OPRP	Suitability for contact with foodstuffs Mesophilic flora ($\leq$ 10 cfu/cm^2)	Agar plates (once or twice per year)	Supplier intervention Lot rejection	Analysis report
Reception of suitable products	Working instructions	OPRP	Integrity of packages Order conformance	Visual inspection (integrity of a package)	Rejection of specific products	Reception documentation and/or delivery documents

6 - Cleaning/disinfection agents

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Non-decontamination **Inefficiency**	Selection of products (specifications) and suppliers	OPRP	Compliance with specifications	Reading of labels Visual inspection (at reception or during use)	Lot rejection Supplier intervention	Reception documentation and/or delivery documents

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Reception of suitable products	Working instructions	OPRP	Integrity of packages Order conformance	Visual inspection (integrity of packages)	Rejection of unsuitable products	Reception documentation and/or delivery documents

OPE 2.2 – STORAGE

See SUP 1 and SUP 2.1

Individual products should be stored separately as soon as possible after reception.

The method "First in, First out" (FIFO) should be applied.

Good hygiene practice should be applied when controlling the room temperature:

- fish or fish fillets should be stored below a temperature of ≤ 2°C (tolerance to+ 5°C), preferably under ice
- other chilled products (including vacuum packed products – ≤ 4°C)
- frozen products – ≤ -18°C. Failure to follow the cold chain specification should lead to evaluation of the future of some batches.

Conditions of conservation	Action needed to be taken in the event of the break in the cold chain
Fish and fresh fish fillet: maintain when covered with ice at ≤ 2°C	Cooling of the lot, when temperature is > 2°C and ≤ 5°C, Evaluation of freshness condition when temperature is > 5°C and ≤ 7°C, and dispensation of the lot depending upon the results, by applying special monitoring or destruction
Chilled products, except for fish or fish fillet stored at ≤ 4°C	Cooling of the batches, when temperature is > 8°C and the products are unchanged, otherwise – destruction
Fish or frozen products stored at ≤ -18°C	Immediate thawing for entering into production if the temperature is higher

To prevent cross-contamination, separate products are stored in specific room zones (GHP/PRP).

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Good management of storage operations	Work instructions	OPRP	Immediate storage Storage in an initial wrapping Observing storage conditions	Production / Technical staff controls	Based on observations (see above)	Storage documentation

OPE 2.3 – UNPACKING-UNWRAPPING

Raw material unpacking operations (removal of delivery packages that may have been soiled/ damaged) should be performed carefully to reduce the risk of contamination and/or proliferation (in the case of an increase in temperature of chilled products).

If unpacking areas are not physically separated from reception zones or preparation zones, unpacking should be carried out in a defined and prepared zone enabling direct disposal of waste (packages, pallets, etc.), without crossing paths. In the zone dedicated for unpacking of fish, other types of fish handling cannot be carried out; however, head removal and washing can be performed in certain areas of the zone, if such operations are not carried out by the personnel dealing with unpacking of fish, and if hygiene measures have been put in place (hand washing, etc.)

Removal of ice

We cannot use water for the ice removal (We recommend grid usage).

If the establishment does not have any specific area to perform this operation, unpacking is performed before other operations and the unpacking area is cleaned/disinfected before using it for other types of food preparation.

During unwrapping and unpacking of allergy-causing products, measures need to be taken to mitigate the risk of cross-contamination (air, contact). It is advisable to have a special room for storing and unpacking of allergenic products.

Fish boxes should be emptied above a grid to remove contaminated ice; empty boxes are removed against the direction of product flow.

The temperature should be regulated in unpacking areas (recommended ≤ 12°C), the areas should be cleaned and disinfected (cleaning and disinfection plan (GHP/PRP)).

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Cross contamination, microbiological, chemical, physical contamination	Pulverized allergens are unwrapped and prepared in specific zones	OPRP	Absence of contamination	Production / Technical staff controls	Specific use of relevant ingredients Labelling of end products	Production documentation
	Working instructions		Ice removal Waste disposal		Additional washing of fish	
Proliferation of microbes (temperature of fish and other chilled ingredients)	Control of product temperature	OPRP	Fish and fresh fish fillet: temperature of ≤ 2°C Presence of ice	Control of temperature in case of any doubt	Cooling of lot, if temperature is > 2°C	Production documentation
			Chilled products, except for fish temperature of ≤ 4°C		Immediate use or cooling	
			Frozen fish: temperature of ≤ -18°C		Immediate thawing	
	Waiting time management		Time between unpacking and salting ≤ 15 minutes (≤ 30 minutes, if temperature of fish remains ≤ 5°C)	Production / Technical staff controls Measurement of temperature of fish in case of any doubt	See above, if waiting time has been exceeded	Production documentation (for example, note down the time)
Hygienic unpacking	Working instructions		Absence of contamination Absence of proliferation Absence of contact between fish/waste Work without delay	Production / Technical staff controls	Washing or destruction of fish (referring to hazard analysis) Washing, rinsing with water for fillets	Production documentation

OPE 2.4 – THAWING OF RAW MATERIALS

If thawing is not performed in separation from storage and handling, it should take place in a special area and in accordance with defined procedures to have thawing water removed without contaminating other products, and to avoid the creation of conditions favouring multiplication/ proliferation of micro-organisms.

Thawing can take place in accordance with one of the following technologies:

- in a cold storage room
- under running water or by applying any other method that has been validated

Thawing facilities should be maintained perfectly clean. In certain cases, there should be the possibility to connect the thawing exudates directly to drain.

The thawing method is subject to prior validation. It will be applied to products undergoing thawing under strict control by the professional. The parameters of time/temperature are selected to prevent proliferation of micro-organisms and production of histamine. After thawing, the temperature of products should not exceed +2°C. If the products reach 4°C then during subsequent operations the temperature of fish must not exceed 5°C (validation is required).

When unwrapped products are thawed in water, the water must not be recycled. Products should be positioned during thawing to prevent leakage of exudates from one product to another.

Thawed raw materials waiting for preparation should be stored under the same temperature conditions as refrigerated products.

Thawing facilities should be included in the cleaning and disinfection plan (GHP/PRP) to reduce the risk of cross-contamination.

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	LIMIT VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Proliferation of microbes	Application of a validated thawing method	OPRP	Thawed fish or fish fillet: temperature of ≤ 2°C (see above) Other ingredients: temperature of ≤ 4°C	Measurement of temperature in a thawing room Measurement of temperature of fish or products in case of any doubt	Cooling of lot if temperature is > 2°C (for fish) if temperature is > 4°C (for other products) or immediate placement into production (by applying lot monitoring), storage below ≤ 5°C(except in a few cases during preparation operations)	Time/temperature records Production documentation
Cross-contamination (unwrapped products)	Control and management of thawed products (avoid leakage of exudate from one product to another)		Absence of contamination with exudates	Visual examination	Washing or destruction if visibly contaminated Specific lot monitoring in the event of any doubt regarding contamination[87]	Non-conformance documentation Thawing or production documentation
Non-alteration of products during thawing	Work instructions		Thawing parameters Handling conditions	Production / Technical staff controls	Washing or destruction if visibly contaminated Specific lot monitoring in the event of any doubt regarding contamination[88]	Thawing or production documentation

[87] For example, beginning of production before cleaning and disinfection, and monitoring of a relevant lot (analysis, particular orientation, etc.).
[88] For example, beginning of production before cleaning and disinfection, and monitoring of a relevant lot (analysis, particular orientation, etc.).

OPE 2.5 – PREPARATION OF FISH

This chapter defines operations after unpacking and, if applicable, thawing, as well as those preparing for salting and smoking. These operations are carried out at a certain pace leading to a rapid handling of consecutive batches during production under conditions preventing contamination, alteration, deterioration or proliferation of infectious or toxic organisms. If waiting time between various operations is too long, products should be kept cold or under ice (time between unpacking and salting ≤ 15 minutes, tolerance of 30 minutes is acceptable if fish have been stored under the temperature of ≤ 5°C during all operations).

During various washes, the temperature of water (as low as possible) is one of the factors helping avoid the elevation of fish temperature within the course of preparation process.

Raw fish should be washed thoroughly with potable water[89] before handling and immediately after handling operations, for example: evisceration, head removal, skinning, etc.

For washing of fish, it not advisable to use a container.

Evisceration, deheading, skinning, bone removal, filleting and trimming operations etc. should be carried out according to cleanliness and hygiene regulations.

The order of operations depends on the organisation. For example, when producing manually sliced smoked salmon, the fillet may retain the skin until slicing, in this case, measures need to be taken to prevent the skin from becoming a source of contamination with *Listeria monocytogenes* (always keep fish with skin side down on the table, conveyor belt, etc. to avoid overlapping of fillet, salt the skin with dry salt, etc.)

Fish waiting at preparation handling zones should be kept under ice or put into a cold storage room in the event of extended waiting time (>15 minutes or >30 minutes if fish are retained at a temperature of ≤ 5°C). If not during this time, appropriate temperature may not be maintained.

Within the course of fish preparation operations, the flesh must not be placed in contact with viscera and skin.

The quantity of fish without ice and waiting for preparation should be reduced to the necessary minimum for proper running of operations.

Heavily parasites contaminated fish are removed from the process.

In the case of production of smoked fish (salmon or other), it is advisable to carry out all preparation operations handling the fish before smoking in a manner that reduces handling after smoking; ideally, smoking should be followed only by slicing and wrapping.

[89] The use of any substance other that potable water to remove surface contaminateion is not permitted (Regulation 853/2004, Article 3(2)). The use of acetic acid is recognized as a processing aid to wash the fish in some countries it can be used in line with Appendix II of this Guide in these countries. If another substance is recognized as a processing aid Appendix II will be updated.

1 Washing of raw fish

During this stage, washing should be carried out to remove the mucus on the fish skin (source of contamination with *Listeria monocytogenes*. See Appendix II.

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Efficiency of elimination of mucus	Validated procedure Working instructions	OPRP	Absence of mucus flow from one fish to another Absence of mucus on the skin	Control of the pressure and the flow of water Visual examination of mucus after washing Occasional microbiological tests	Facility repair Washing of fish	Production documentation

2 Deheading/Evisceration

The skin, gills and intestines are the most contaminated parts of the fish. During deheading or evisceration, direct contact between flesh and the skin of other fish or waste (viscera, heads) should be avoided. Fish are placed on the conveyor belt with skin against the belt at a speed preventing accumulation of fish. Early evisceration is vital to prevent contamination of the flesh with parasites or any bacterial proliferation. Incomplete evisceration can also be a source of contamination. The results of this operation are used for supplier monitoring.

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Microbiological cross-contamination	Cleanliness of machines, knives and conveyors Cleaning during production	OPRP	Clean facilities	Monitoring performed by production or technical staff	Cleaning during production In the event of any doubt, monitoring of a specific lot[90]	Cleaning documentation (for large facilities) Production documentation

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Proliferation	Waiting time management	OPRP	Time between unpacking and salting ≤ 15 minutes (≤ 30 minutes, if temperature of fish remains ≤ 5°C)	Production / Technical staff controls Measurement of temperature of fish in case of any doubt	Examination of personnel If necessary, cooling of fish (temperatures of > 5°C and ≤ 7°C)	Production documentation
Well-performed deheading/ evisceration	Working instructions	OPRP	Waste disposal Absence of contact between flesh/skin or flesh/waste	Visual inspection Production / Technical staff controls	Washing or fish destination to low risk usage production, or destruction due to fish spoilage	Production documentation

[90] Monitoring of a relevant batch (analysis and specific usage of such a batch etc.)

3 Filleting/Cutting/Skinning/Trimming[91]/Deboning[92] (intramuscular bones)

To prevent contamination with pathogenic bacteria (particularly *Listeria monocytogenes*), contact of fish flesh to the skin (source of contamination) or waste should be avoided during operations,

It is recommended to use shower heads for continuous washing of tables and belts on condition that water jets or splashes do not touch the products under preparation.

Skinning should take place as early as possible to mitigate the contamination of flesh (from the skin) by *Listeria monocytogenes* during various handling processes. Alternatively, measures need to be put in place to limit the risk of contamination (positioning of fillet with the skin side to the belt, avoid overlapping of fish, dry salting, etc.)
Filleting tools (filleting machine, knives, etc.) are cleaned and disinfected as many times as required and at least once before each shift change.

These operations can be performed manually (in this case, washing takes place at the end of preparation of the salmon fillet) or mechanically (combined with washing).

If circular knives are used, these should be cleaned regularly (see SUP 2.5).

Within these operations, specially trained personnel can perform inspections to evaluate supplier performance and to determine use of the fish in production.

- Appearance of flesh
- Hematomas and blood spots
- "Gapping" (tearing of muscles).

There criteria are not directly related to hygiene but permit monitoring of supplier performance, notably the ability of the supplier to provide products complying with specification, including aspects of product safety and quality.

At the end of these operations, the fish fillet is ready for smoking. It is recommended that preparation operations be as effective as possible to prevent additional fillet handling or interventions (penetrations to flesh can result in fish being contaminated with *Listeria monocytogenes*).

[91] Trimming comprises removal of peritoneum, fins, belly fat, hematomas, belly bones, brown muscles, skin, gill pieces, etc.

[92] Deboning can be carried out manually or mechanically (clean, disinfect and wash regularly the deboning machine (see GHP 6). In the latter case, deboning can be complemented by manual intervention (with tweezers or pliers). This operation should preferably be carried out before smoking.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Cross contamination, microbiological, chemical, physical contamination	Facility cleaning and disinfection plan Maintenance plan	OPRP	Clean and functioning facilities	Production / Technical staff controls	Demand for cleaning or technical management during production	Documentation of facilities Cleaning documentation Documentation of maintenance Production documentation
Proliferation	Waiting time management	OPRP	Time between unpacking and salting ≤ 15 minutes (≤ 30 minutes, if temperature of fish remains ≤ 5°C)	Production / Technical staff controls Measurement of temperature of fish in case of any doubt[93]	Examination of personnel If applicable, cooling of fish (temperature of > 5°C and ≤ 7°C)	Production documentation
Non decontamination (bone residues after deboning)	Working instructions	OPRP	Absence of bone residues[94] (for whole products, in particular)	Production / Technical staff controls	New deboning Personnel training	Production documentation

[93] The procedure has been validated and the personnel have been trained for work; hence, the temperature of fish should not need to be verified.
[94] It is not always easy to remove intramuscular bones ("pin bones") (for example, when removing with tweezers or pliers). It is preferable to leave a small bone than to penetrate into the flesh posing the microbial risk. Fewer cuts is better

Well-performed preparation	Working instructions Washing of small tools	OPRP	Work without delay Absence of contact between fish and waste Absence of contamination with tools Trimming as good as possible (avoid repeated trimming after smoking)	Visual inspection Production / Technical staff controls	Immediate salting (after washing) Washing, other use or destruction of fillet (referring to hazard analysis) Additional trimming	Production documentation

4 Washing

Fish are washed before and after preparation operations and before salting and smoking stages. It is advisable to use cold water (qualification of procedure). Only potable water can be used, use of baths is not recommended.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Proliferation of microbes	Waiting time management	OPRP	Time between unpacking and salting ≤ 15 minutes (≤ 30 minutes, if temperature of fish remains ≤ 5°C)	Production / Technical staff controls Measurement of temperature of fish in case of any doubt[113]	Examination of personnel Cooling of fish, if applicable	Production documentation
Well-performed washing	Working instructions	OPRP	Clean fish	Production / Technical staff controls	Re-washing of fish	Production documentation

OPE 2.6 - SALTING

Reminder: the process from thawing to salting is continuous. Where this is not the case, the fish fillet is stored below a temperature of < 2°C. When the process is continuous, salting is carried out after 15 minutes and not more than 30 minutes following thawing (if the temperature of fillet remains ≤ 5°C or in few cases ≤ 7°C over the entire period until salting).

In certain markets where the product shelf-life exceeds a period of 30 days, salt content is vital for the control of *Clostridium botulinum* (non-proteolytic) (≥ 3,5% in the aqueous phase); hence, salting is a CCP. A validated procedure applied by qualified personnel should ensure that the minimum required salt content has been attained; the target values of the control parameter will be as high as the variability of results, in particular due to variety of raw materials). When determining control (notably duration of salting) parameters , it is necessary to consider several factors:

- fish characteristics (weight, fat content, etc.)
- physiological state of fish (based on season, farming conditions, etc.)
- salting equipment and facilities (dry salt, injections, mixed, etc.)
- salt quality (size, additives, moisture content, etc.)
- salting conditions (temperature of the salt room, etc.)
- other ingredients used (eg. sugar).

Elements of CCP monitoring, which ensure the applicability of the defined method and demonstrate that the critical limit has not been reached, differ from elements of process control which are applied at this stage. For example, salt content analysis before the end of salting (dry salting).

It is desirable that the salt content in products where the shelf-life is close to 28 days would be 3% in the aqueous even if the salt content is only one of the factor of *Clostridium botulinum* control.

This stage comprises 4 phases:

- loading onto a grid before or after salting, given the enterprise equipment
- salting (adding salt)
- salt penetration – maturation
- desalting in the event of excessive salting

1 - Loading onto a grid

The placing of a fillet on the grid is defined. The professional should consider salting technology, dewatering after rinsing, smoking conditions (if the grid is not moved before smoking, etc.). Fillet with the skin is laid with the skin side to the grid. In this case, it is advisable to treat skin with dry salt.

The grids should be made from materials approved for contact with food (stainless steel), and be clean (a cleaning and disinfection plan).

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Proliferation of microbes	Fish temperature	OPRP	Storage of fillet under the temperature of ≤ 5°C	Measurement of temperature	Cooling or immediate salting, if required, special monitoring (analysis, alternative use) of products, given the prolonged duration of temperature and temperature attained	Temperature readings
	Delay management	OPRP	Time between unpacking and salting ≤ 15 minutes (≤ 30 minutes, if temperature of fish remains ≤ 5°C)	Production / Technical staff controls		Production documentation (for corrective measures)
Salting efficiency (and smoking[95])	Working instructions	OPRP	Defined placing of fillet on the grid	Production / Technical staff controls	Re-placing on the grid	Production documentation
			Handling without contamination		Washing or elimination of altered fillet (for example, falling on the ground)	
			Work without delay			

2 - Salting

Different salting techniques can be used. Control of salting is very important to control a_w and further growth of *Listeria monocytogenes* or *Clostridium botulinum* (see OPE 1.2).

The risk of contamination with salt is managed by control of purchasing and the salt storage procedure. (see above "Reception").

The amount of salt added is at least equal to the salt content that is required in end product. Since the thickness of the fillet is not the same along the full length, the content is calculated in relation to expected content in the thickest part of the fillet. On this basis, particularly in case of dry salting, the amount of salt added is higher than theoretical quantity. The quantity added is determined when defining the salting process verification and salting procedures.

When salting is a CCP, the quantity of salt added is monitored, but the critical paramter is mainly the uptake of salt into the fillet.

[95] If smoking is carried out without transferring fish onto another grid, restrictions related to smoking should be applied for placing of fish on the grid.
If salting is a CCP, the quantity of salt added should be monitored, however, the most important factor is the real intake of salt (see below).

Wet salting

The quantity of salt in the brine and the frequency of brine renewal is defined within the hazard analysis and validation of the process.[96]

Injectors are cleaned and disinfected every day. Needles are subject to preventive maintenance.

In the event of any doubt about broken needles, knife debris (during preparation), end products should be controlled for the presence of foreign matter with a metal detector.

Dry salting

Must be carried out by specially trained personnel. It is advisable to apply salt to both sides of a fillet (for example, by salting in a fluidized bed). In the case of fillet with skin, it is necessary to consider that salt intake time cannot be determined for salt penetrating through the skin, although this operation is useful to mitigate the microbial growth on the skin within operations.

Mixed salting

Comprises both injection and dry salting.

In case of injection-salting, needles should undergo preventive maintenance.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Physical contamination (injection needles of brine)	Preventive maintenance of needles	OPRP	Undamaged needles	In the event of any doubt, metal detection	Destruction of unsuitable products	Maintenance documentation Production documentation
Microbiological contamination (*Listeria monocytogenes*) (injection-salting with closed brine circuit)	Salt content in brine Renewal of brine	OPRP	Salt content of brine Renewal at a pre-defined frequency	Density of brine Visual inspection	Addition of salt Renewal of brine	Production documentation

[96] The renewal depends on the technology, the temeperature, the production volume etc. It is defined by FPOs.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Further proliferation (*Clostridium botulinum, Listeria monocytogenes)* (given the shelf-life of products, production technologies, etc.) (see introduction to this operation)	Appropriate equipment Preventive maintenance	OPRP	Smooth functioning	Production / Technical staff controls	Ongoing preventive maintenance Re-salting	Maintenance documentation Production documentation
	Validation of salting procedure Working instructions Time/ temperature management of brine	OPRP or CCP[97]	Amount of salt added to reach expected salt content in end products (defined during validation of the salting procedure)	Brine saturation, brine temperature and quantity injected Quality of salt in use	Re-salting Renewal of brine	Production documentation

3 - Salt uptake

The waiting time for salt uptake is linked to salting technique, size of salt, size of fish, fat content, temperature, presence of other ingredients and brine composition. Salt intake is carried out in a workshop with adjustable temperature; when determining the temperature, a number of factors need to be considered: efficiency of salt uptake, duration of this phase, etc.

Given the process and reliability of pre-established schemes, salt content should be measured regularly (for example, chloride homogenate analysis in end products) to identify optimal waiting time and to verify or modify salting technique. When this point is a CCP, monitoring actions (for example, de-salting analysis), , are carried out to ensure the actual uptake of salt. In this case, it is not sufficient to carry out simple salt analyses in end products.
Premises should be cleaned (a cleaning and disinfection plan)

[97] For certain products, it can be a CCP due to the risk of *Clostridium botulinum* if the shelf-life is ≥ 30 days or for herring salted in a traditional way. Personnel carrying out this operation should be specially qualified.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Further proliferation (*Clostridium botulinum, Listeria monocytogenes)* (given the shelf-life of products, production technologies, etc.) (see introduction to this operation)	Validation of salting procedure Work instructions	OPRP or CCP	Amount of salt added to reach expected salt content in end products	Measurement of salt applied (salting step or before smoking) Measurement of salt content in final products Production / Technical staff controls	Re-salting Alternative use of products (eg. change of use by date) Revision of procedure	Production documentation

4 - De-salting (optional)

In the case of excessive salting (notably by using dry salting or mixed techniques), specially qualified personnel should carry out desalting by using shower heads or ramps[98]. During this operation the fish needs to be dripped to ensure that excess water is not taken inot the kilns. After this operation, dewatering can be carried out (for example, by using inclined trays).

The objective of this phase is organoleptic (to prevent excessive saltiness).

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Microbiological (drainage of de-salting water), chemical cross-contamination	Validation of technique (positioning of fillet, washing of the trolley from top to bottom) Work instructions	OPRP	Absence of water splashes from floor Properly washed fish (elimination of surface crystals)	Production / Technical staff controls	Washing of fish or elimination of affected fish (based on the hazard analysis)	Production documentation
Good removal of salt	Work instructions		Compliance with work instructions	Visual inspection Production / Technical staff controls	Repeat de-salting	Production documentation

[98] A jet used should be weak (of low pressure) as not to alter fish flesh and avoid water splashes.

OPE 2.7 – SMOKING MATURATION

Control of smoking and salting combined with product storage temperature and shelf-life are very important for the control of proliferation of *Listeria monocytogenes*

Post smoking processing should be minimised to limit the risk of contamination with *Listeria monocytogenes*. Most processes should be carried out before smoking.

The temperature in the kiln smoke generator is essential for the control of PAH[99] production (smoke generator temperature ≤ 400°C)[100].

The smoking technique should be verified in advance taking into account fish size, origin, and fat content (see OPE 1.2).

This operation should be implemented by qualified personnel.

During smoking, fish with and without skin, should not be mixed together.

This stage is divided into several phases: drying, smoking, cooling, storage/maturation.

1 - Drying/Smoking

Drying is often carried out in a smoking or drying area where cold air circulates through an exchanger. The duration of this phase is related to original physical-chemical characteristics of the product and humidity and desired residual humidity. Within this drying phase, 5 to 10% of weight is lost depending on product, technique, etc.

Smoke is produced in a smoke generator separated from production premises, the temperature in the smoke generator (automatic regulation) remains at ≤ 400°C to prevent production of (PAH) benzo[a]pyrene, benzo(a)antracene, benzo[b]fluoranthene, and chrysene) .

Smoke quality control is important; utilization of an opacimeter for periodic monitoring of smoke quality is possible but difficult; as soon as it becomes blackened by smoke, it should be cleaned.

Size and humidity (when water is added) of the particles of wood sawdust and cuttings depend on the smoke generator; they should be supplied as regularly as possible so that the smoke generator is fed constantly (due to gravity).

Control factors during smoking depend on the size of the smoking room, in particular:

- smoking temperature, notably for hot smoking (effect on bacteria, parasites)
- air humidity and temperature (smoke-drying)
- the speed of circulation in the smoke room (number of mixed m^3 per hour), etc.

During this operation, drying and smoking phases can be alternated. Smoking with liquid smoke (in kiln) can be used in accordance with *Codex Alimentarius CAC/RCP/52/2003 and Regulation (EU) 1321/2013 of 10 December 2013.* Time and temperature of regenerated smoking should be equivalent to the traditional smoking. The labelling of the final product must mention the use of non-traditional methods.

[99] Regulation (EC) No 835/2011
[100] EFSA Scientific Opinion June 2008

The objective of smoking is to reach a phenol content between 0.4mg and 2mg/100g of meat.

Nevertheless, during validation or verification of smoking method, it is useful to associate phenol content analysis to organoleptic analysis.

Smoking can be carried out cold (when the temperature approaches 28°C or less) or hot, given the products manufactured.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Subsequent microbial proliferation[101]	Validation of procedure weight loss (due to water, in particular)	OPRP	Weight loss defined during validationof procedure	Measurement of weight loss	Continuation of smoking, new smoking, or divert product	Non-conformance documentation Production documentation
	Validation of procedure smoke density		Phenol content defined during validation of procedure	Organoleptic testing Visual inspection		
Chemical contamination (by smoke)	Wood quality Validation of procedure	OPRP	Amount of PAH complying with regulatory requirements Temperature in kiln ≤ 400°C [102]	Combustion monitoring	Immediate extinction of kiln and resumption of smoking	Production documentation
Non-decontamination (parasites) (Hot smoking of unfrozen raw material)	Validation of procedure	OPRP or CCP	Temperature inside the product (≥60°C for 1 minute[103]	Temperature of the smoking room	New smoking or freezing	Production documentation

[101] The risk of microbial proliferation occurring during cold smoking is negligible as it takes place in dry, then smoke atmosphere.
[102] EFSA Scientific Opinion June 2008.
[103] When trimatod is identified the treatment should be 70 °C for 30 minutes according to EFSA opinion (EFSA Journal 2010; 8;(4):1543).

2 Cooling/Storage/Post smoke maturation

The products removed from the smoke room should be cooled to a temperature of ≤ 4°C. Cooling is performed in a chilled room or in a stiffening room. During this phase, equilibration of smoke in the product is reached (this equilibration can also be carried out within final wrapping of end products). The duration varies depending upon the process in the enterprise, size, smoking, etc.

During the cooling phase, the temperature of ≤ 10°C needs to be reached as rapidly as possible. It is usually implemented within 2 hours, with some exceptions eg large fish.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Microbial proliferation (cold smoking)	Temperature in maturation room (cold smoking) Validation of time and temperature of storage Selection and maintenance of facilities	OPRP	Room temperature ≤ 4°C Validated time included in use by date Product temperature of ≤ 10°C[104] reached as rapidly as possible	Room temperature Fish fillet temperature in cases where any doubt exists.	Room temperature regulation, also ongoing maintenance Fillet cooling	Temperature readings Production documentation
Subsequent microbial proliferation (maturation control)	Validation of procedure	OPRP	Phenol content measurement	Organoleptic testing Production / Technical staff controls	Continuation of maturation	Production documentation
Good realisation of maturation	Work instructions	OPRP	Compliance with defined criteria	Organoleptic testing Production / Technical staff controls	Continuation of maturation of divert of product	Production documentation

[104] The speed of temperature decrease, within a reasonable limits, does not generate hazards in less than 2 hours, but avoid, if possible, the beginning of growth of bacteria, in particular *Clostridium,* between 30 and 55°C during smoking.

OPE 2.8 – SLICING BUILDING OF SLICES

After smoking handling of fillets and slices has to be minimised. All operations between smoking and wrapping generate the risk of contamination and proliferation with Listeria monocytogenes.

Slicing is high risk of cross-contamination with *Listeria monocytogenes for* Smoked Salmon.

1 Manual slicing

To prevent from cross-contamination with *Listeria monocytogenes* as the result of the contact with flesh/skin, fillet cannot be placed on each other, they should always be laid with skin side (if present) to the table.

Cleaning and disinfection of cutting tables, conveyors, knives or mechanical slicers should be implemented in a strict manner.

Slicing zones should be dry.

Do not use an air blower in slicing rooms, except for cases where measures are put in place to protect the product.

Packing boards, pouches etc which may have come into contact with food, for example, those that have been placed on slicing lines, cannot be returned to the packaging storage room.

2 Mechanical slicing

2.1 - Without stiffening

The product is sliced at temperature between -2°C and +2°C.

2.2 - With stiffening

The products can undergo stiffening before slicing (before certain mechanical slicing processes take place) (see Appendix III).

To prevent refrigeration installations from the risk of leakage, preventive maintenance should be used. If leakage is detected during production of fish, the fish should be destroyed.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Effective stiffening	Work instructions	OPRP	Compliance with stiffening target time and temperature	Product temperature Duration	Continuation of stiffening	Production documentation

3 Mechanical slicing and building slices on the tray/ board

Mechanical slicing can be performed on both stiffened and non stiffened fish. In the latter case, an increase in fish temperature should be avoided (as a result of slicing method, a mechanical disk or knife and waiting time) to avoid any risk of bacterial proliferation, notably *Listeria monocytogenes*.

A slicer should be cleaned regularly, during the production process. If possible it is recommended to clean without water i.e. by removing any waste that has built up.

Zones where slicing is carried out should be clean and the personnel must act in compliance with special rules of behaviour (clothing, etc.) (see SUP 2.1 and SUP 3).

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Cross-contamination (notably *Listeria monocytogenes*)	Regular cleaning of slicing facilities and equipment (manual or mechanical slicing)	OPRP	Frequency of equipment cleaning established during validation of method, given the volumes treated	Monitoring of good practices	New cleaning	Documentation of cleaning
Foreign materials (mechanical slicing)	Preventive maintenance	OPRP	Undamaged materials (e.g.blades, needle bed/belt)	Visual inspection Monitoring of good practice	Ongoing maintenance, OR equipment inspection	Maintenance documentation
					OR pass the product through metal detector (after final examination)	Production documentation

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Microbial proliferation	Selection of the cutting system (avoid overheating) Room temperature Waiting time management	OPRP	Temperature of fillet or slices ≤ 4°C No waiting time for products	Room temperature	Rapid cooling of products or divert product in accordance with hazard analysis	Room temperature readings Production documentation
Good operation of slicing and slice manipulation	Work instructions	OPRP	Cleaning of small equipment, if applicable Recommendation to remove waste from a mechanical slicer without water during production Hand washing or changing gloves when necessary Avoid manual handling as much as possible Work without delay Compliance with defined instructions	Monitoring of good practices	Control measures	Production documentation

OPE 2.9 – PREPARATION OF MARINADES, LIQUID MEDIUM/LIQUIDS

Preparation zones should be separated and maintained in a state of cleanliness (a cleaning and disinfection plan) to mitigate the risk of cross-contamination.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Subsequent proliferation	Composition of marinades Quantity added	OPRP or CCP[105]	pH value defined Quantity defined during validation of method	Measurement of pH Control of quantities used	Rectification of marinade composition or quantity added	Production documentation
Good realisation of the process stage	Work instructions	OPRP	Cleaning. Compliance with defined instructions	Monitoring of good practices	Control measures	Production documentation
Cross-contamination(allergen, ingredients,etc)	Work instructions	OPRP	Cleaning. Time planning solution or physical separation.	Monitoring of good practices	Control measures and/or product redirection(with adapted labelling)	Production documentation

[105] If the composition of marinade gives the possibility to ensure the stability of product over the entire shelf-life, given the cold chain, then this preparation can be a CCP. The personnel preparing this marinade should be specially qualified.

OPE 2.10 – WRAPPING

Wrapping is performed immediately after slicing, without any delay (continuous flow, avoiding accumulation of sliced fish in a workplace). In case of incidents, products should be kept cold. Addition of marinades or liquid medium, if applicable, takes place at this time.

Tightness of wrapping packaging is controlled by checks at the end of production. Non tight packaging can be re-wrapped on condition they have been kept cold and will be re-wrapped maintaining traceability with the production lot.

Wrapping procedures (selection of materials, vacuum level, gas mixture, residual quantity of oxygen, etc.) should be verified during the design process (see OPE 1.1 and 1.2) to reduce contamination or proliferation after wrapping within distribution

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Microbial or chemical contamination	Clean facilities (for example, reversal or blowing of rigid packages) Protection of packaging	OPRP	Clean wrapping	Visual Surface inspections	Isolation of suspicious packaging for evaluation	Production documentation
Microbial proliferation	Waiting time management	OPRP	No waiting time for products	Room temperature Monitoring of good practice	Rapid cooling of products	Production documentation
Subsequent contamination (non tightness of wrapping) or proliferation (modified atmosphere, non tightness of wrapping)	Appropriate equipment Preventive maintenance	OPRP	Tightness of wrapping Atmosphere control (in vacuum or gas)	Atmosphere analyses	Setting the sealing machine Re-wrapping (if noticed immediately) or with revised use by date or destruction of relevant products	Non-conformance documentation Production documentation
Good wrapping performance	Work instructions	OPRP	Wrapping criteria (tight wrapping, vacuum level, gas mixture, residual gas level (0,5 mbar), etc.) Detection of leaks	Visual inspection Monitoring of good practice	Re-wrapping (if noticed immediately) or with revised use by date or destruction of relevant products	Production documentation

OPE 2.11 - FREEZING (SEMI-FINISHED OR END PRODUCTS)

If products are frozen (as intermediate or end product), freezing procedures should be evaluated in advance, given the type of product frozen.

Freezing requires application of a validated method, with defined criteria, for example, temperature in the freezing room, speed of a moving belt, product temperature, etc. and equipment used, for which preventive maintenance is carried out to avoid contamination with refrigerants.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
When freezing of the final product is considered as CCP for parasite management (refer to GEN4 Principle Hazards – Preventive Measures 1. Main Hazards 1.1. Fish (wild or farmed) – Hazards (Parasites))						
Good freezing practice	Work instructions	OPRP	Compliance with freezing procedures	Temperature of the freezing room Speed of movement on a conveyor belt (continuous freezing) Product temperature Duration Absence of refrigerant leakage	Re-freezing or divert product	Production documentation

OPE 2.12 - THAWING (PRE-PACKED END PRODUCTS)

Where products are sold after thawing (product labels should indicate the relevant information), methods used should maintain the product below a temperature of ≤ 4°C. Methods should undergo prior validation.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Cross-contamination	Wrapped products Handling conditions	OPRP	Tightness of wrappings	Monitoring of good practice Visual inspection	Elimination of non tightened wrappings	Production documentation
Prevention of quality degradation of products during thawing	Working instructions	OPRP	Thawing targets Fillet temperature of ≤ 4°C after thawing Handling conditions	Monitoring of good practice	On the basis of findings (hazard analysis) for example, cooling of lot when temperature is > 4°C, or divert product or destruction (temperature > 8°C) or prolonged duration, when temperature is between 4°C and 8°C	Thawing documentation

OPE 2.13 – DETECTION OF FOREIGN BODIES

In the absence of a special detection system (the risk of foreign matter is low for sliced products), a specialised HACCP is performed to address this hazard. Several principle rules help to mitigate the risk of foreign matter, especially the risk of metal particles:

- Items present above production lines eg lights should be protected in case of damage
- Knives should be sharpened away from production lines
- Preventive maintenance to reduce the risk of parts or metal pieces (for example, needles from injection-salting).

Furthermore, detection of foreign matter should be carried out:

- If there is any doubt about the presence of foreign matter (broken needles in a salting machine when performing repair, etc.)
- If dropped during slicing, etc.

The method should be validated; the detector subject to constant calibration.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Absence of foreign matter	Work instructions Monitoring of customer complaints and of missing parts in equipment.	OPRP	Detection of foreign matter in products belonging to a risk group.	Auditof passing through a metal detector Monitoring of good practice	Repeat detection(after final calibration) Elimination of contaminated products	Production documentation

Detection of foreign matter is intended essentially for monitoring if supply control measures, notably during maintenance operations, have indeed been applied. This stage is not considered to be a CCP due to the fact that the use of metal packaging (smoked salmon or trout), for example, limits the application of the foreign matter detector for wrapped products.

OPE 2.14 – STORAGE

Refrigerated products should be stored immediately after wrapping, frozen products after freezing.

1 - Chilled and sub 0°C chilling products

Chilled should be stored at a temperature between 0°C and 4°C

Sub 0°C chilling should be stored at a temperature between - 3°C and -2°C. This specifically apllies to smoked salmon where crystalisation starting temperature is below -3°C.

Labelling of these products will be according to local rules where the product is sold and is the responsibility of the processor.

2 - Frozen products

Should be stored below a temperature of ≤ -18°C

Control of the cold chain is necessary (GHP/PRP). If the cold chain is broken, the consequences for product stored is determined to decide upon further actions (for example, reduction of shelf-life, divert product, rapid cooling, etc.).

Labelling of these products will be according to local rules where the product is sold and is the responsibility of the business operator.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Cross-contamination	Storage conditions	OPRP	Tightness of wrappings	Production and Technical Staff	Elimination of unsuitable products, or divert products	Storage documentation
Proper storage of goods	Working instructions		Immediate placing in a cold room Compliance with conditions of cold room control		Sorting of products when they are wrapped Sorting and destruction of contaminated products	

PRODUCTION PROCESS DISPATCH

Dispatch concerns a set of operations carried out after storage of products. Certain operations defined in this stage, in particular product labelling, can be carried out at the same time as wrapping.

OPE 3.1 – LABELLING

The wrapping or packaging should contain information according to current EU Regulations:

Regulation 1379/2013 specific to fishery products (this list is non-exhaustive)[106]:

- scientific name, when applicable
- production method, caught or farmed
- fishing gear, when applicable
- Country of origin or place of provenance if its absence might mislead the consumer

Regulation 1169/2011 for all food products (this list is non-exhaustive)

- the name of the food, including the method of processing
- list of ingredients(preservatives when used), and the quantity of certain ingredients (added water when applicable)
- net quantity
- the durability date (indication of the "use by date" of consumption for chilled products or "best before date" for frozen products)
- shelf-life is expressed in day/month/year
- name oand address of the operator/ business under which the food is marketed
- identification mark
- nutrition declaration
- allergen declaration
- additional information (packaged in a protective atmosphere)
– fishing area or aquaculture country , when applicable
- instructions for use and special conditions of use, if applicable (for example, conditions of conservation in the consumer refrigerator).

If applicable, information on thawing before placing on the market. Regulation 1169/2011 and Regulation 1379/2013 the word "defrosted" should be used, i.e. the defrosted should be stated on the label.

If marking (for example, lot number, date of minimum durability) is not applied immediately at wrapping, products must be stored in identified containers, enabling the lot number to be traced.

[106] The full list of is set out in Articles 35 and 38 of EU Regulation 1379/2013 on the common organisation of the markets in fishery and aquaculture products

APPENDIX for LABELLING (non-exhaustive list)

Description of the process	Labelling information
Washing gutted fish with water/ acetic acid + rinsing with water + control – no acetic acid residue (only when permitted by national authorities)	**No specific labelling (used as processing aid)**
Addition of authorised additives at any stage of the process	**Declare the additives used in the ingredient list**
Fish smoked with liquid smoke	**For labelling refer to Regulation (EU) No 1379/2013 or specific national rules**
Fillet stiffened in continuous way (tunnel) or static, with a maximum delay of 96h (exceptionally)	**The product does not need to be labelled defrosted**
For storage (over 96 hours) product must be kept at -18°C	**The product must be labelled: defrosted product**
Fillet smoked only with wood	**The product can be labelled: Traditional smoking**

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Proliferation of microbes	Validation of shelf-life Compliance with the production conditions established during the determination of shelf-life	OPRP	Safety and suitability for health of products reaching the end of shelf-life (for frozen products = ”Best before date” for chilled products = ”Use by date”	Product monitoring tests	Modification to final shelf-life	Test results
				“Use by date” or “Best before date” is applied, given the date of production or freezing	New labelling (when there is no risk of confusion for users) Divert product	Production documentation
Appropriate labelling	Work instructions	OPRP	Durability (shelf-life) is applied in relation to validation test.	Conformance of labelling Production and Technical staff control	New labelling (when there is no risk of confusion for users) Divert product	Production documentation

OPE 3.2 – LOT RELEASE

See MNG 2.5

A formal procedure should be put in place for batch or lot release to ensure compliance with regulatory and customer requirements.

To facilitate this, traceability and monitoring measures should be used.

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
General conditions of appropriate work (GHP/PRP)	Compliance with GHP/PRP	GHP/PRP	No non-conformance identified	Inspection of the results of analysis Inspection of GHP records	Modification of shelf-life, divert product or destruction of relevant products	Production documentation (may be general information indicating if GHP established is correct)
Correctly performed operations	Measures determined for various operations (OPRP) Review of records	OPRP	Absence of non-conformances posing threat to product safety	Inspection of operation records	Product recall, divert product or destruction, Recall or withdrawal of relevant products (potential lots, customers, etc.)	Production documentation (information on production activity provided from time to time) Documentation regarding withdrawal or recall

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
	Identify CCP (if applicable) Revision of monitoring actions	OPRP	Compliance with critical limits	Inspection of CCP records	Destruction of products (unless there is an opportunity of retreatment or diversion) Recall or withdrawal of relevant products (potential lots, customers, etc.)	Production documentation indicating critical limits and target values Documentation regarding withdrawal or recall

OPE 3.3 - TRANSPORTATION, STORAGE AND DISTRIBUTION

End products and semi products should be handled, stored and transported in a manner to protect from damage and below the following temperatures: for chilled products 0 to 4°C, for frozen products ≤ -18°C[107] until use (the time of purchase by the customer or other consumer).

The temperature should be controlled in the vehicles intended for transportation purposes. Before loading, it is necessary to ensure the temperature and cleanliness of a truck.

During dispatch, the temperature of products may be < 0°C, when they are dispatched immediately after slicing/wrapping with stiffening, or if products have been stored with sub 0°C chilling or if they have been thawed. Thawing should not take place place during transportation.

Particular attention should be paid to loading and unloading and these processes should be carried out as rapidly as possible by air conditioned chambers.

[107] Short temperature increases not exceeding 3 °C are tolerated during handling operations

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Proliferation	Carrier specifications Validated shelf-life taking into account the actual cold chain Respecting the cold chain Information about storage conditions on the wrapping and packaging	OPRP	Temperature ≤ 4°C (for refrigerated products) Temperature ≤ -18°C (for frozen products)	Utilisation of sensors	Verification of the carrier Cooling of products, modification of shelf-life or recall, or destruction of lot New training or verification of a carrier	Temperature readings Delivery documents
Cross-contamination	Handling, vehicle driving instructions, etc.	OPRP	Absence of changes in wrappings or packaging	Production and Technical Staff control		Delivery documents

HAZARD	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Delivery of products suitable for consumption	Work instructions	OPRP	No products waiting at ambient temperature Integrity of packaging and wrapping Appropriate product temperature (≤ 4°C for refrigerated products and ≤ -18°C for frozen products)	Measurement of temperature in the transport vehicle before loading When in doubt, measurement of product temperature	Cooling of the transport vehicle before loading Cooling of products, modification of shelf-life or recall, or destruction of lot	Delivery documents

APPENDIX

APPENDIX I - PRINCIPAL MICROBIOLOGICAL HAZARDS PERTAINING TO FISH

Food-borne diseases are caused by toxins (T) and/or by significant exposure to microbes though digestion (I = Infection). Cricital levels are described in several different regulations and documents[108]

MICROBE UNDER CONSIDERATION
Shigella
Salmonella
Vibrio parahaemolyticus
Clostridium perfringens
Clostridium botulinum - proteolytic A, C, B, F
- non-proteolytic E, B, F
Listeria monocytogenes
Staphylococcus aureus - Proliferation aerobic / anaerobic - Production of toxins (staphylococci)

[108] Guidance Document on Listeria monocytogenes shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. FDA's Bad Bug Book, Regulation (EC) 2073/2005. ICMSF 1980- 1988 and Microbiological Basics to Food Hygiene (ROZIER etc.)

APPENDIX II - UTILISATION OF ACETIC ACID AS A PROCESSING AID FOR WASHING THE FISH WHERE AUTHORISED AS A PROCESSING AID

The use of acetic acid for the washing of the fish should be submitted for authorisation to the national authorities. Note: For instance the notice of 22 July 2005 published by the AFSSA authorised the use for French processors of acetic acid as a processing aid to wash raw fish.

1 Objectives

The objective of using an acetic acid process is to enhance the quality and safety of products, smoked salmon and trout by flocculating mucus immediately after unpacking of fish.

Acetic acid is an approved additive included in the EU Regulation 1333/2008.

Acetic acid is used to wash the fish at the very early stage of the production process.

Acetic acid is rinsed right after its use with potable water to eliminate it. There is no detection in the final products. Therefore, acetic acid may be regarded as a processing aid.

2 Principles of use

Products intended for processing are fresh, eviscerated and deheaded fish before filleting. The temperature should not exceed 5°C, spray nozzles should be adjusted for the size of fish.

The processing consists of:

- ✓ a phase of full exposure of fish to spraying (fine drops) with dilute acetic acid (water + acetic acid: pH = from 2.8 to 3, maximum dose 5%)
- ✓ a phase of rinsing with potable water that begins approximately 30 seconds after spraying.

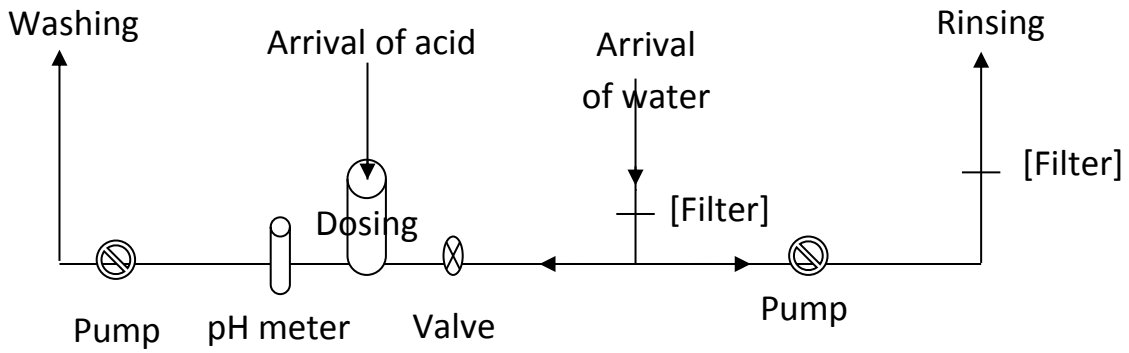
Acetic acid flocculates mucus on the skin, and eliminates dirt from abdominal cavity of fish. Hence, rinsing with water helps to remove these compounds.

The washer is divided into two zones:

- ✓ the first: spraying the mixture of water + acetic acid by spray nozzles
- ✓ the second: rinsing with water.

Dosing of mixture is carried out automatically by using a validated management system (pH meter,...). Water should be filtered to avoid clogging of spray nozzles.

Diagram of the principle



Functioning of the washer is verified before use, the control system should verify the conformance of the start-up mixture and that for the very first fish, the processing is implemented in the correct manner.

3 Parameter control

Checking the pH of the acetic solution (or management measures)

According to the graph *"Evaluation of pH for acetic solution based on its concentration",* optimum functioning of pH is determined between 2.8 and 3.

Monitoring of pH or a management measure is carried out in the same workshop.

Examination of correct functioning of spray nozzles

Examination of potentially clogged spray nozzles is carried out several times per day (approximately every two hours).

Note: Fish washers, like any other equipment, should be examined by maintenance personnel (frequency: at least once a day).

Examination of correct functioning of rinsing facilities

pH analysis of the surface of the fish can be carried out to ensure effective rinsing.

Procedure to control washing with acetic acid

ASSURANCE OF HAZARD CONTROL	PREVENTIVE MEASURES	OPRP or CCP	TARGET VALUE	MONITORING ACTIONS	CORRECTIVE MEASURES	RECORDS
Efficiency of flocculation and elimination of mucus	Validated procedure Working instructions	OPRP	pH = 2,8 to 3 Absence of mucus flow from one fish to another Absence of mucus on the skin Rinsing wih water Absence of acetic acid	Measurement of pH of the washing solution Visual examination of mucus after washing Measurement of pH on the fish surface after rinsing	Facility repair Washing of fish	Production documentation

In case of detection of acetic acid in the final product the FPO will have to declare it as an additive in the ingredient list.

APPENDIX III - DIFFERENT PROCEDURES FOR STIFFENING

In order to meet production requirements and to deliver a product of consistent quality, the industry sector deploys machines that slice and can build the slices again by using automatically placed interleaving sheets. In this case, the product is partially toughened or covered with a crust (this is not freezing, because the temperature varies from -7°C to -14°C from case to case).

In addition, it seems that this technology increases the lag phase in the *Listeria monocytogenes* growth curve (Research: 1999 by the ADRIA[109] according to the AQS programme).

Products stiffened as defined here are classified as Never Frozen products.

1 Stiffening in a cold room

This is the most popular technology. After smoking or maturation, fish is placed in a cold room to reduce the temperature as rapidly as possible to approx. -7°C to -8°C. The fish is then transferred into a stabilisation room to allow the temperature of fillet to homogenize to approx. -11°C. Depending on the stiffening equipment and the objective of the stiffening temperature, related to the type of a slicer being used, the kinetics of stiffening will not be the same.

Given the batch nature of the process, it is crucial that the core product temperature is reached and maintained homogenously throughout the whole product.

The technological time to achieve the best temperature is up to 24h.

Due to the organisation of work (for examples situations such as week-ends/bank holidays), products may have to be maintained at stiffening temperature for some time, which should however be as short as possible, less than 96 hours.

Stiffening temperature cannot be used for storage or transportation.

2 Continuous stiffening

Some processors carry out the stiffening procedure in a continuous tunnel using cryogenic or mechanical cooling facilities, without storing the products in a cold room. The entire operation lasts for 1 hour (approx. 40 minutes while the temperature decreases, and 20 minutes until the temperature homogenizes). The objective is to achieve approx. -7°C to -8°C, but no colder than -12°C. As soon as practicable after exiting the stiffening tunnel, products should be sliced.

It is the responsability of each processor to integrate the stiffening step into the shelf life validation of the use by date and to respect local rules in terms of product labelling.

[109] ADRIA: Agro Industry Technical Institute (ITAI). Partner in the European Regulation WG 2073/2005

APPENDIX IV - GUIDANCE ON THE IMPLEMENTATION OF ARTICLES 11, 12, 14, 17, 18, 19 AND 20 OF REGULATION (EC) N° 178/2002 ON GENERAL FOODLAW CONCLUSIONS OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH - 26 January 2010

IV. ARTICLE 19

WITHDRAWAL, RECALL AND NOTIFICATION BY FOOD BUSINESS OPERATORS

Article 19

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

IV.1. Rationale

• Article 19 aims at mitigating the problems caused when foodstuffs that do not meet the food safety requirements have left a food business's control and at preventing, reducing or eliminating the risk, when a business has placed on the market food which may be injurious to health.

• The obligation to withdraw, recall or notify unsafe food under Article 19 arises when the food is or may be unsafe under Article 14 of Regulation 178/2002.

• Food business operators must apply the criteria in Article 14 for determining whether food is unsafe and action should be taken under Article 19.

• The notification of competent Authorities by food business operators enables those authorities to monitor whether the business operators have taken the appropriate measures to address the risks posed by a food placed on the market and to order or take additional measures if necessary for avoiding the risks.

IV.2. Implications

• Article 19 imposes specific obligations from 1st January 2005 on food business operators to withdraw from the market food that does not meet the food safety requirements and to notify this to competent authorities. Where the product may have reached the consumer, the operator shall inform the consumer and if necessary recall from consumer products already supplied to them.

• Article 19 provides for the necessary cooperation between operators in different parts of the food distribution chain, so as to ensure the withdrawal of unsafe food from the market.

• Article 19 also imposes an additional obligation on the food business operator to inform the competent Authorities should they consider or have reason to believe that a food which it has placed on the market may be injurious to health.

• It provides a general obligation on food business operators to co-operate with competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

IV.3. Contribution/ Impact

IV.3.1. Article 19 (1)

i) Obligation to withdraw

Article 19 (1) imposes the specific obligation on food business operators to withdraw from the market a food which has left their immediate control and that does not meet the food safety requirements, and inform the competent authorities thereof.

Withdrawal is not defined in Regulation (EC) 178/2002, but is commonly understood to be the process by which a product is removed from the supply chain, with the exception of a product that is in the possession of consumers. The definition in Directive 2001/95/EC on General Product Safety is useful, as it indicates that withdrawal is aimed at preventing the distribution, display or offer of a product 25

It should be emphasised that under Article 19:

- The withdrawal from the market may take place at any step along the food chain and not only at time of delivering to the end consumer;

- The obligation to notify a withdrawal to the competent Authorities is a consequence of the obligation to withdraw;

- The obligation to withdraw from the market applies when the following two cumulative criteria are met:

- *the food in question is considered unsafe by the operator as not being in compliance with the food safety requirements*

Article 14 of Regulation 178/2002 specifies the food safety requirements to be used in deciding whether the food is unsafe.

- ☐ *a food is on the market and has left the immediate control of the initial food business.*

So Article 19(1) does not apply where a food business operator has placed the food on the market (and thus is considered as the initial food business) but it is still in their immediate control.

A food is considered to have left the immediate control of a food business operator when it has been sold or supplied free of charge or otherwise transferred so that the initial operator no longer has the legal right to the food, for example when they have sent it to a wholesaler or it is with any other operators later in the distribution chain.

ii) Notification of the withdrawal to the competent authorities

When a food business operator withdraws a food in accordance with Article 19 (1), it shall notify this withdrawal to the competent authority, which has enforcement responsibility for the operator's establishment, and the national authority.

It is up to the national authority to issue the RASFF as in point III.3.5 if necessary.

If the product is removed before being placed on the market or if it is under the immediate control of a particular food business operator, there are no notification obligations under Article 19 (1).

iii) Methods of the notification to competent authorities

It is for competent authorities in individual Member States to decide what methods of notification are appropriate.

iv) Recall and information to the consumers

When a withdrawal is necessary and the product may have reached the consumer, Article 19 (1) requires the food business operators:

- to inform the consumer accurately and effectively of the reason for withdrawal

and,

- if necessary to recall from consumers products already supplied to them - i.e. to take "any measure aimed at achieving the return of an unsafe product that has already been supplied or made available to consumers by a food business operator". A recall will mean asking consumers to take the product back to the place of purchase or to destroy it. The recall is necessary when other measures are not sufficient to achieve a high level of health protection.

v) Responsibility for application of Article 19 (1)

All food business operators who have imported, produced, processed, manufactured or distributed a food are covered by the provisions of Article 19 (1) (withdrawal and/or recall and notification). This may include retailers, when they have sent the product on to another retailer or have recall obligations because they have sold or supplied the product to consumers.

Cooperation between each level of the food chain will be necessary to achieve the objectives of Article 19 (1) – please see the obligations in Article 19(2).

IV.3.2. Article 19 (2)

Article 19 (2) places a requirement on food business operators responsible for retail15 or distribution activities, which do not affect the packaging, labelling, safety or integrity of food (i.e. retailers and distributors of branded food). The

purpose of this provision is to ensure that these food business operators also play their part in withdrawal of food not in compliance with food safety requirements, and in passing on relevant information. For example, when a producer withdraws/recalls a food for which it is responsible, the distributor and/or the retailer is/are required to participate as necessary. It also compels them to let the manufacturer know if there is a safety problem, so that the manufacturer can co-ordinate the withdrawal.

IV.3.3. Article 19 (3)

Article 19 (3) places a specific, stronger requirement on food business operators when they consider or have reason to believe that a food that they have 'placed on the market' may be 'injurious to health. In this case, they must immediately inform the competent Authorities and detail the action taken to prevent the risk.

16 'Placing on the market' is defined in Article 3.8 as 'the holding of food (or feed) for the purposes of sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves'

Article 19(3) does not impose systematically a withdrawal but provides for immediate information of the competent authorities of a potential risk and the action taken to prevent it.

The following conditions need to be met to trigger the application of Article 19 (3):

- The food in question is placed on the market. 'Placing on the market' also covers food products which have already been produced by food business operators or imported and are being held with a view to sale or supply free of charge. It does not include food products which are still under processing, or raw materials provided by suppliers.

and

- The food in question may be injurious to health.

The objective of this Article is to ensure that the competent authorities are informed in case of a potential risk for health for a product which is placed on the market, even if the product is under the immediate control of the operator.

Article 19 (3) can be applied in different types of cases such as:

- the operator definitely knows that the food is injurious to health and it is still in his/her possession.

- New information in possession of the operator leading to consider the food as injurious to health but this information diverges from other information. For example, when an operator withdraws internally an unsafe food and informs thereof the supplier of this food, the supplier might consider that the information sent contradicts other information in its possession.

- Information that the product is likely to be injurious to health, but this information is not yet completely confirmed; this could originate from consumer complaints or batches placed on the market where sampling had proved satisfactory where other batches had not.

- Information of an emerging risk.

The aim of this provision is to enable the competent Authorities not only to be aware of definitely unsafe food, but to receive early warnings or to identify

potential (possibly emerging) risks in order to ensure the most efficient and proportionate ways to manage it.

In some cases, for example when further or more validated information confirms that the product is injurious to health and the product has left the immediate control of the initial food business operator, the withdrawal and recall obligations set up in Article 19 (1) will also apply.

The operator responsible for providing the information to the competent Authorities is the operator that has placed the product on the market.

The second part of Article 19 (3) is designed to prevent food business operators from discouraging their employees and others from cooperating with competent Authorities where this may prevent, reduce or eliminate a risk arising from food.

IV.3.4. Article 19 (4)

This paragraph requires that the food business cooperates with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

For example, food business operators should contact the competent authorities when they need help in determining how to fulfil their obligations.

In accordance with the general objective of prevention set up in Article 19 (3), operators, in particular small operators should be encouraged to contact the competent authorities in case of uncertainty on the risk at stake.

Assistance should be given by the competent authorities when operators contact them in the framework of Article 19.

IV.3.5. Notification to the Rapid Alert System for Food and Feed (RASFF)

A clear distinction should be made between the RASFF and the obligation of notification provided by Articles 19 and 20. The RASFF involves only competent Public Authorities (Commission, Member States and EFSA). Food operators have an obligation, under certain circumstances (see part III on notification), to notify only the competent authorities (at appropriate level depending on Member States rules) and not the RASFF.

APPENDIX V – SUPPLIES OF WATER AND ICE

Clean water and clean seawater and potable water are defined in Regulation 852/2004 Article 2 as:

> *clean water: clean seawater[110] and fresh water of a similar quality.*
>
> *potable water: water meeting the minimum requirements laid down in Council Directive 98/83/EC on the quality of water intended for human consumption;*

Regulation 852/2004, Annex II, Chapter VII permits clean water to be used to clean and to make ice to chill fishery products:

> *1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;*
>
> *(b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When clean water is used, adequate facilities and procedures are to be available for its supply to ensure that such use is not a source of contamination for the foodstuff.*
>
> *2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.*
>
> *3. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.*
>
> *4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.*
>
> *5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.*
>
> *6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.*

Regulation 853/2004 Annex III, Section VIII states:

[110] For clean seawater definition refer to Regulation 852/2004 Article 2 – Defiinitions.

Clean seawater may be used for the handling and washing of fishery products, the production of ice used to chill fishery products and the rapid cooling of crustaceans and molluscs after their cooking.