TRAINING

Visit of a Processing Establishment

Name of Trainee : .....

Intervention Details

Scope of the diagnosis and risk analysis
Targeted elements of the diagnosis and risk analysis
Targeted processing lines on their risk analysis

Activity of the Establishment

Number of employees:	Women :	Men :
Activity (processes and products) Type of Raw materials: Species: Source (Wild/Farmed):		
Production Capacity:		
Diagnostic and risk analysis Grids:		

PE 01 : Surroundings and Construction – All facilities
PE 02 : Construction Requirements in Areas Where Food is Handled– All facilities
PE 03 : Implementation of Pre-requisite Programmes
PE 04 : Specific Process Design Criteria and Control
PE 05 : Health Standards for Fishery Products
PE 06 : Assessment of HACCP Plans

PRATICALY SPEAKING UNDER THE COLUM “OBSERVATION” THE TRAINEES CAN ADD THE RISK ASSESSMENTM ANALYSIS AND MANAGEMENT WITH ITS MITIGAITON PROCEDURES HE UNDERSTANDS

Elements shown in these diagnosis grids are personal observations made by the trainee. They do NOT reflect the opinion of any competent authority of any third country or EU member state. They CANNOT be considered as the results of an official inspection and do not reflect the opinion of the European Commission.

The information contained is PERSONAL and CONFIDENTIAL and CANNOT be used for any other purpose than the training programme referred to in the header of these documents.

The checklist proposed in these diagnosis grids are training tools prepared by independent experts. They are NOT mandatory requirements to be followed by third countries towards approving food establishments for exports to the EU.

PE 01: Surroundings and Construction

Elements to be checked	Objective of the legislation and references	Observations
1. Surroundings, Constructions and Layout 1.1. External environment hygienic and kept clean 1.2. Surroundings maintained to prevent access and harbourage of pest 1.3. Establishments designed to prevent admission of pests 1.4. Establishments that exclude contamination with materials such as accumulated dirt, condensate, mould or other undesirable particles 1.5. Conditions in areas for handling and processing are appropriate to store, handle and process under sanitary and hygienic conditions? 1.6. Conditions suitable to allow storage, handling and processing at adequate temperatures 1.7. Layout and appropriate product flow to preclude cross-contamination from less clean to clean areas 1.8. Establishments kept clean	Ensure that design, construction, location and size of the food premises allow for adequate control of food hygiene and safety Reg 852/2004, Annex II, chapter I-1, 2a-2d. Ref. also to Item 23, 26 and 47 below	
2. Ventilation 2.1. Sufficient and suitable for the operation 2.2. Mechanical airflow ensure flow from clean to less clean area 2.3. Allowance made for ease of maintenance and cleaning	To reduce the risk of contamination of the products. Reg 852/2004, Annex II, chapter I-5	
3. Staff facilities 3.1. The number of lavatories is adequate 3.2. Presence of flushable lavatories that are connected to effective drainage system 3.3. Lavatory facilities that do not open directly into processing areas 3.4. Number of hand washing basins is adequate. 3.5. Hand washing basins are suitably located 3.6. Hand washing basins are suitable designed (non-hand operated) 3.7. Hand washing basins have adequate facilities for efficient hand washing (hot and cold running water, soap and hygienic drying facilities). 3.8. Hand washing basins that are designated for the purpose only 3.9. Lavatory facilities have adequate ventilation 3.10. Changing facilities are adequate for the operation	To ensure that the adequate conditions are in place to ensure implementation of personal hygiene rules in the establishment. Reg 852/2004, Annex II, chapter I-3, 4, 6, 9	

PE 01: Surroundings and Construction

Elements to be checked	Objective of the legislation and references	Observations
4. Light 4.1. Premises have adequate light for operations	Reg 852/2004, Annex II, chapter I-7	
5. Drainage system 5.1. Constructed to avoid risk of contamination with flow of waste water from less clean to clean areas 5.2. Adequate for the operation	To make sure that the drainage system is not a source of contamination of the establishment. Reg 852/2004, Annex II, chapter I-8	
6. Storage of Chemicals 6.1. Adequate storage facilities allow for safe storage of cleaning and disinfection agents in areas where food is not handled	To ensure that dangerous cleaning and disinfecting chemicals can not contaminate food Reg 852/2004, Annex II, chapter I-10 Ref. also to point 22 below	

PE 02: Construction Requirements in Areas Where Food is Handled

Elements to be checked	Objective of the legislation and references	Observations
7. Floors 7.1. Made of impervious, non-absorbent, washable and non-toxic Materials 7.2. Surfaces maintained in sound condition so they are easy to clean and disinfect 7.3. Surfaces allow adequate surface drainage **8. Walls** 8.1. Made of impervious, non-absorbent, washable and non-toxic Materials 8.2. Surfaces maintained in sound condition so they are easy to clean and disinfect **9. Ceilings and light fittings** 9.1. Constructed and finished to prevent accumulation of dirt, growth of moulds, shedding of particles and minimize condensation. **10. Windows and other openings** 10.1. Constructed so to prevent accumulation of dirt 10.2. Fitted with insect proof screens if to be opened to the outside 10.3. Insect screens in windows and other openings are easy to remove for cleaning. **11. Doors** 11.1. Made of appropriate materials (smooth and non-absorbent) 11.2. Easy to clean and disinfect **12. Surfaces in contact with food** 12.1. Made of appropriate materials (smooth, washable, non-corrosive, non-toxic) 12.2. Maintained in sound conditions which allow for easy cleaning and disinfection	To ensure that the design of facilities shall permit good hygiene practices including protection against contamination between and during processing operations Reg. 852/2004, Annex II, chapter II-1a-1f	

PE 02: Construction Requirements in Areas Where Food is Handled

Elements to be checked	Objective of the legislation and references	Observations
13. Cleaning of working utensils 13.1. Facilities for cleaning, disinfecting and storage of working utensils and equipment adequate 13.2. Facilities for cleaning, disinfecting and storage of working utensils constructed of easy to clean and maintain materials 13.3. Facilities for cleaning, disinfection of working utensils shall have adequate supply of hot and cold water	To ensure that work utensils can be efficiently cleaned Reg 852/2004, Annex II, chapter II-2	
14. Facilities for washing food 14.1. Designed for the purpose 14.2. Provided with potable water 14.3. Kept clean	To avoid contamination of the food Reg 852/2004, Annex II, chapter I-4 Reg. 852/2004, Annex II, chapter II-3	
15. Articles, fittings and equipment 15.1. Installing allow adequate cleaning of both equipment and surrounding area. 15.2. Constructed of materials and maintained to minimize risk of contamination. 15.3. Constructed of materials and maintained to enable cleaning and disinfection. 15.4. Effectively cleaned and disinfected at sufficient frequency to avoid risk of contamination 15.5. Additives for corrosion protection used in accordance with good practices 15.6. Equipment shall be fitted with appropriate control devices (e.g. cookers, freezers, cold stores, chilling rooms)	Articles, fittings and equipment in contact with food shall be constructed and maintained in good order to avoid any risk of contamination. Reg. 852/2004, Annex II, chapter V 1-3	

PE 03: Implementation of Pre-requisite Programmes

Elements to be checked	Objective of the legislation and references	Observations
16. Raw materials, Ingredients, packaging and other input materials What to check ? 16.1. Are controlled at receiving 16.2. Are rejected if known or reasonably expected to be contaminated with food safety hazards which can not be eliminated through normal sorting, preparation or processing 16.3. Are stored to prevent deterioration 16.4. Are stored to protect from contamination How to check ? 16.5. Quality and safety criteria defined and adequate to ensure food is safe and fit for consumption 16.6. Traceability criteria adequately defined 16.7. Monitoring, corrective actions and internal verification adequately planned according to defined criteria 16.8. Monitoring, corrective actions and internal verification implemented as planned 16.9. Monitoring and internal verification effective to control food hazards and to ensure food is fit for consumption 16.10. Documents on raw material supply system adequate and updated (e.g. Supplier approval program, system of traceability)	Control at receiving and good handling practices at storage and at all processing steps shall ensure that the final products are fit for human consumption and are not injurious to human health. References: Reg. 852/2004, Annex II, chap. IX 1-2 Reg. 852/2004, Annex I, part A III-7, 8 HACCP Guidance document Annex II ch. 5	
17. Wrapping and packaging material 17.1. Materials selected not to be a source of contamination 17.2. Materials stored so they are not exposed to contaminants 17.3. Wrapping and packaging operations designed to avoid contamination of products 17.4. Integrity of container's construction and cleanliness ensured where relevant (e.g. sterilized cans and glass jars products) 17.5. Re-used packaging materials are easy to clean and disinfect	Wrapping and packaging materials shall not present any risk for contamination of the food. References: Reg. 852/2004, Annex II, chapter X 1-4 Ref also to item 35 below	

PE 03: Implementation of Pre-requisite Programmes

Elements to be checked	Objective of the legislation and references	Observations
18. Water What to check ? 18.1. Adequate supply of potable water in all areas where necessary 18.2. Supply of clean seawater adequate in all areas where allowed (if applicable only) 18.3. Non-potable water circulated in separate pipe system, designed to prevent backflow to potable water system 18.4. Pipe system for non-potable water duly identified 18.5. Recycled water potable or of adequate quality for the purpose used (if applicable only) **19. Ice** What to check ? 19.1. Ice in contact with fishery products made from potable water or clean water 19.2. Protected from contamination during production, handling and storage **20. Steam** What to check ? 20.1. Steam used in contact with food is clean and does not present any hazards to fishery product. How to Check ? 20.2. Quality criteria adequately defined 20.3. Process criteria adequately defined (Chlorine, uv-treatment etc.) 20.4. Monitoring, corrective actions and internal verification are adequately planned against defined criteria 20.5. Monitoring, corrective actions and internal verification implemented as planned 20.6. Documents on water supply system adequate and updated (Map of supply system, monitoring plan, results of analysis)	Water supply system shall ensure that only potable or clean water can be used in contact with fishery products. References: Reg. 852/2004, Annex II, chapter VII 1-6 EC Directive 98/83 Annex II table A and B (Note: clean water ice can only be used for chilling whole fishery products)	

PE 03: Implementation of Pre-requisite Programmes

Elements to be checked	Objective of the legislation and references	Observations
21. Food waste and other refuse What to check ? 21.1. Removed quickly from rooms where food is present (not allowed to accumulate) 21.2. Deposited in closable containers or other appropriate waste disposal systems 21.3. Containers constructed of materials that allow easy cleaning and disinfecting 21.4. Facilities for waste deposit are appropriate constructed, maintained and easy to clean. 21.5. Provisions for waste storage and disposal designed and managed to allow cleaning and protection from entrance of pest. 21.6. Waste eliminated in a hygienic and environmentally friendly way (in accordance with EU regulation/National regulation) How to check ? 21.7. Procedures are efficient (objective evidence)	Food waste and other refuse shall be kept away from products and hygienically handled and stored in order to minimize risk for cross-contamination to products References: Reg. 852/2004, Annex II, chapter VI 1-4	
22. Hazardous and/or inedible substances (feed, disinfectants, cleaning agents, etc.) 22.1. Adequately labelled 22.2. Stored in separate a and secure containers	To control chemical hazards. Reg. 852/2004, Annex II, chapter IX , 8 Ref. also to Item 6 above	
23. Pest Control 23.1. Procedures for controlling pests such as insects, mice, rats, and domestic animals, etc. in establishment surroundings are planned and implemented 23.2. Procedures for controlling pests such as insects, mice, rats etc. in processing areas are planned and implemented 23.3. Procedures are effective (objective evidence)	To control (prevent and eliminate) pests from contaminating product as per Reg. 852/2004, Annex II, chapter IX 4 Ref. also to Item 1 above	

PE 03: Implementation of Pre-requisite Programmes

Elements to be checked	Objective of the legislation and references	Observations
24. Personal Hygiene What to check ? 24.1. All staff members wear suitable protective clothing 24.2. Protective clothing are clean and maintained in a clean condition 24.3. All staff members maintain a high degree of personal cleanliness How to check ? 24.4. Laundry facilities and procedures for cleaning protective clothing are adequate 24.5. Procedures for changing of dirty protective clothes are adequate and efficient 24.6. Facilities and procedures for hand washing adequately designed, implemented and monitored 24.7. Use and control of boot baths adequately designed, implemented and monitored	The risk for transmission of human pathogenic microorganisms, and other hazards which may be carried by staff who handle food shall be minimized. Reference Reg. 852/2004, Annex II, chapter VIII 1	
25. Staff health What to check? 25.1. Staff who may carry diseases that can potentially be transmitted through food or have afflictions such as infected wounds, skin infections, sores or diarrhoea are not allowed to handle food How to check? 25.2. Procedures for staff reporting of diseases and afflictions are planned, implemented and effective 25.3. Procedures for monitoring staff health are planned, implemented and effective	To ensure that food handlers are not a source of contamination. Reference Reg. 852/2004, Annex II, chapter VIII 1	

PE 03: Implementation of Pre-requisite Programmes

Elements to be checked	Objective of the legislation and references	Observations
26. Sanitation (cleaning and disinfection) What to check ? 26.1. Procedures for cleaning and disinfection of processing facilities and equipment before, after and during processing are adequately described and implemented effectively. 26.2. Procedures for cleaning and disinfection of staff facilities are adequately described and implemented effectively. How to check ? 26.3. Sanitation products technical specifications are available and known by responsible staff 26.4. Criteria for sanitation are adequately defined 26.5. Effectiveness of sanitation is monitored 26.6. Objective evidence is available to show that sanitation procedures are effective	To ensure that processing facilities and equipment in contact with the product is not a source of contamination as per Regulation Reference: Reg. 852/2004 Annex II Ref. also to Items 1 and 15 above	
27. Traceability, Withdrawal and Recall Procedures 27.1. Procedures for recall adequate described and communicated to team as relevant 27.2. Identification Marks correct applied on products before leaving the establishment 27.3. Raw materials from aquaculture and bivalve mollusks are traceable to identified primary producer unit 27.4. Suppliers of raw materials from aquaculture and bivalve mollusks comply with specific criteria to record keeping and labelling	To prevent risks to the final consumer and collaborate with competent authorities in risk management Reference: Reg. 178/2002, Art. 3, 15 and Art. 18 Reg. 178/2002, Art.19 Reg. 853/2004 Art. 5, 6 and Annex II Reg. 852/2004 Annex I, Part A III-7,8 Reg. 853/2004 Annex II, VII ch. 1 Ref. also to Item 16 above and specific Diagnosis Grids on Bivalves and Aquaculture.	

PE 04: Specific Process Design Criteria and Control

Elements to be checked	Objective of the legislation and references	Observations
28. Procedures <u>designed to protect food</u> at all stages of production, processing and distribution 28.1. Food protected against contamination that may render the product unfit for human consumption or injurious to health 28.2. Raw materials, intermediary food materials and finished products (not frozen) are kept at temperatures approaching that of melting ice throughout the cold-chain (except when practicalities of handling require otherwise). 28.3. Ready to eat products are cooled down immediately to temperatures approaching that of melting ice after final processing stage (e.g. cooked and smoked products) 28.4. Thawing processes are designed to minimize the risk of pathogenic microorganisms growth or the formation of toxins 28.5. Thawed products treated like raw materials (kept at temperatures approaching that of melting ice) 28.6. Run off water from thawing is properly drained to prevent cross-contamination	To minimize the risk of product contamination from pathogenic micro-organisms, chemical and physical hazards and to minimize the risk for growth of pathogenic micro-organisms. References: Reg. 852/2004, Annex II, chapter IX 3, 5,6,7 Ref also to point 29, 31, 33 below	
29. Fresh Products – raw materials handling 29.1. Stored under ice if not immediately distributed or processed 29.2. Melt water can drain away from the product/container 29.3. Facilities for storage are appropriate to help maintain temperatures approaching that of melting ice 29.4. Raw materials received from vessels or aquaculture are stored in cooled water or in ice at arrival 29.5. Headed and gutted raw materials are cleaned, especially in the belly area 29.6. Heading and gutting (pre-processing) in the factory carried out under hygienic conditions 29.7. Live fish are kept at temperatures that do not adversely affect their viability or food safety	To avoid contamination and growth of pathogens, good handling and manufacturing practices imply that: Fresh fishery products (raw materials) shall be kept at temperature approaching that of melting ice and handled and stored to avoid contamination and or spoilage of the materials Reg. 853/2004, Annex III, section VIII, chapter III A1, A4, A5 Reg. 853/2004, Annex III, section VIII, chapter. VII-1, 3	

PE 04: Specific Process Design Criteria and Control

Elements to be checked	Objective of the legislation and references	Observations
30. Fresh Products - Filleting and cutting of fresh products 30.1. Carried out hygienically 30.2. Tools used are clean (procedure described and implemented) 30.3. Products removed from the worktables without delay 30.4. Products appropriately chilled without delay	Reg. 853/2004, Annex III, section VIII, chap. III A2, A3	
31. Frozen Products What to check ? 31.1. Capacity of freezing equipment is sufficient to rapidly achieve core temperature of not more than -18C. 31.2. Capacity in cold stores are sufficient to maintain product temperature at least –18 C 31.3. Cold store equipped with easy to read temperature recording device 31.4. Sensors for temperature recording in cold stores are placed in the area with highest temperature 31.5. Fish stored in brine at least -9 C are used for canned products only How to check? 31.6. Evidence of temperature control is available 31.7. Corrective actions in case of non-compliance with requirements are adequate	Good handling and manufacturing practices imply that: Products shall be frozen rapidly to -18 C or less in the core and kept at at -18C or lower. Storage temperatures shall be monitored and documented. References: Reg. 853/2004, Annex III, section VIII, chapter III B (ref: section VIII, ch. 1 part 1, C1, C2) Reg. 853/2004, Annex III, section VIII, chapter. VII-2 Ref. also to Item 15.6 above	

PE 04: Specific Process Design Criteria and Control

Elements to be checked	Objective of the legislation and references	Observations
32. Mechanically separated Fishery Products 32.1. Raw materials for mechanical separation include whole fish and bones after filleting, and must exclude all gut material 32.2. Separation process carried out immediately after filleting or cutting (if applicable) 32.3. Further processing takes place immediately (freezing or otherwise processed)	Good handling and manufacturing practices imply that: Mechanically separated fishery products shall be produced from fresh materials excluding guts, and frozen or further processed without delay References: Reg. 853/2004, Annex III, section VIII, ch. III C1, C2.	
33. Cooked Products (crustaceans and molluscs) 33.1. Cooled immediately and rapidly in potable water or clean seawater after cooking 33.2. Cooled down to temperatures approaching that of melting ice or frozen immediately to at least -18 C after cooling 33.3. Shucking or shelling procedures are carried out hygienically	Good handling and manufacturing practices imply that: Cooked crustaceans and molluscs shall be hygienically handled, rapidly cooled in potable water down to temperatures approaching that of melting ice or immediately frozen References: Reg. 853/2004, Annex III, section VIII, ch. IV-1,2,3.	

PE 04: Specific Process Design Criteria and Control

Elements to be checked	Objective of the legislation and references	Observations
34. Heat Sterilized products What to check ? 34.1. Does the process conform to international recognized standard? 34.2. Does the process ensure that time-temperature parameters are specified and complied with? 34.3. Are relevant process parameters monitored by the use of automatic device? 34.4. Does the process prevent contamination of the product 34.5. Sealing operation is appropriately controlled How to check ? 34.6. Are thermometers and other measuring devices calibrated? 34.7. Are heat distribution tests made? 34.8. Are heat penetration tests made for each product? 34.9. Are organoleptic tests made for each product? 34.10. Are adequate placing of cans, trays and racks monitored? 34.11. Are proper functioning of the equipment checked during heating process? 34.12. Are time-temperature parameters checked in the (autoclave) retort recorder? 34.13. Are microbiological sampling and testing carried out for each finished product 34.14. Are can integrity adequate controlled? 34.15. Is cooling water for heat treated containers a possible source of contamination	Good handling and manufacturing Practices and control of hazards for heat treated, long-term stable products imply that: Products shall be rendered free of microorganisms capable of growing in hermetically sealed containers when kept at ambient temperatures References: Reg. 852/2004, Annex II, chapter XI 1-3 Reg. 852/2004 Art. 5 Reg. 852/2004, Annex II, chapter VII, 6 Codex Alimentarius: Low-Acid and Acidified Low-acid Canned foods (CAC/RCP 23-1979, Rev. 2 (1993)	

PE 04: Specific Process Design Criteria and Control

Elements to be checked	Objective of the legislation and references	Observations
35. Wrapping and Packaging (of raw materials) 35.1. Handling containers for fresh fish and ice are water resistant 35.2. Handling containers for fresh fish and ice and ensures that melt-water does not remain in contact with product (efficient drainage) 35.3. Block frozen raw materials are adequately packed 35.4. Packaging materials for block frozen raw materials are not a source of contamination	Good handling and manufacturing practices imply that: Suppliers of raw materials or semi-manufacture from vessels shall ensure hygienic handling and storage conditions and use only clean materials of food grade quality. Ref: Reg. 853/2004, Annex III, section VIII, ch. VI-1, 2, 3 Ref. also to Item 17 above	
36. Transport conditions for Fishery Products 36.1. Transported fresh fishery products, thawed unprocessed products and cooked chilled products are maintained at temperature approaching that of melting ice 36.2. Melt water drains away efficiently from products 36.3. Frozen fishery products kept at temperatures of at least -18 C in all parts, with upward fluctuations limited to a maximum of 3 C 36.4. Live fish kept at temperature which do not affect adversely their viability or food safety	Good handling and manufacturing practices imply that: Temperatures under transport shall be so to minimize risk for growth of pathogenic bacteria, and deterioration by microbiological growth or enzymatic degradation. Reference: Reg. 853/2004, Annex III, section VIII, ch. VIII-1, 2, 3, 4	
37. Training 37.1. All staff trained to properly carry out their responsibilities and activities 37.2. Training complies with national laws concerning training of staff in the food or fishery sectors.	To ensure that staff shall be instructed and trained in food hygiene, appropriate to properly carry out their responsibilities and activities as food handlers. References: Reg. 852/2004, Annex II, chapter XII 1-3 Ref. also to Item 57 below	

PE 05: Health Standards for Fishery Products

Elements to be checked	Objective of the legislation and references	Observations
38. Organoleptic examination 38.1. Carried against specified freshness criteria	Products placed on the market shall meet minimum freshness criteria in order to be deemed fit for human consumption. References: Reg. 853/2004, Annex III, section VIII, ch. V-A Reg. 2406/1996, Article 3 and Annex I.	
39. Freshness and histamine 39.1. Levels of histamine complies with requirements in all products of the specie families of: Scrombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scrombresosidae 39.2. Sampling plan includes 9 samples per lot (if sampling is applied) 39.3. Histamine content - does not exceed 200 ppm in any of 9 samples per lot and - is below 100 ppm in at least 7 of the same 9 samples and - average of 9 samples is below 100ppm	Monitoring and Internal verification of Prerequisite and HACCP programmes shall include sampling and testing for compliance with certain process and product standards References: Reg. 2073/2005 and 852/2004 Art. 4, 3a and 3e Reg. 853/2004, Annex III, section VIII, ch. V-B Reg. 2073/2005, Annex I, chapter 1, 1.25	

PE 05: Health Standards for Fishery Products

Elements to be checked	Objective of the legislation and references	Observations
39.4. Products are tested for TVB-N or TMA-N if organoleptic assessment indicates problems with freshness 39.5. Fishery products with TVB-N > 30 are not placed on the market.	Freshness tests shall be carried out to complement organoleptic assessment if this reveals any doubts about freshness. References: Reg. 853/2004, Annex III, section VIII, ch. V-C Reg. 2074/2005 Annex 2, section II, chapter I and II	
40. Parasites 40.1. Are fishery products visually examined for visible parasites 40.2. Fishery products with visible parasites are not placed on the market	Fishery Products obviously contaminated with parasites shall not be placed on the market. Ref: Reg. 853/2004, Annex III, section XIII, ch. V-D Reg. 2074/2005, Annex 2, section I, chapter I and II	
41. Toxic species 41.1. Species of Tetraodontidae, Molidae, Diodontidae and Canthigastridae or other known toxic species are not placed on the market. 41.2. Species of family Gempylidae (Ruvetus petriosis and Lepidocybium flavobrunneum) are placed on the market only in wrapped packed form 41.3. Species of family Gempylidae (Ruvetus petriosis and Lepidocybium flavobrunneum) are appropriately labelled with scientific name and information about specific related risks.	Fish species poisonous to humans shall not be placed on the market. Fish species with mildly adverse effects such as family *Gempylidae* are appropriately packaged and labelled References: Reg. 853/2004, Annex III, section XIII, ch. V-E. Reg. 2074/2005 Annex VII, 2c	

Grids used for training in requirements of EU Regulation 852/2004, 853/2004, 2073/2005 and 2074/2005, including the application of HACCP and Prerequisite programs.

PE 05: Health Standards for Fishery Products

Elements to be checked	Objective of the legislation and references	Observations
42.Microbiological criteria 42.1. Shelled and shucked products of cooked crustaceans and molluscs comply with requirements for salmonella, E Coli and Coagulase + staphylococci.	Monitoring and Internal verification of Prerequisite and HACCP programs shall include sampling and testing for compliance with certain process and product standards References: Reg. 2073/2005 and 852/2004 Art. 4, 3a and 3e Reg. 2073/2005, Annex I, chapter 2.4.1	

PE 06: Assessment of HACCP Plans

Elements to be checked	Objective of the legislation and references	Observations
43. Management Commitment and Preliminary Steps. 43.1. All prerequisite programmes and HACCP Plan documents are up-to-date and approved by management 43.2. Are modifications to documentation / implementation communicated to relevant staff members 43.3. HACCP team up-to-date in regard to members and responsibilities	Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market Reg. 852/2004, Art. 5, pt. 1, 3, 4	
44. HACCP Team 44.1. Made up of multi-disciplinary and multi-divisional members 44.2. Team leader is appointed 44.3. Scope of HACCP Plan is adequately defined 44.4. All team members have skills and knowledge about hazards, process, hygiene, product and raw materials characteristics, appropriate to the product. 44.5. Team members have received adequate training in application of HACCP principles	HACCP Guid.Doc. Annex 1 ch. 1.1 Reg. 852/2004 Annex II, ch. XII, 2	
45. Product description What to check ? Includes adequate information on: 45.1. Description of products 45.2. Characteristics of raw materials and end products 45.3. Composition (raw materials, ingredients, additives etc.) 45.4. Processing technologies used 45.5. Packaging method and materials 45.6. Storage and distribution conditions 45.7. Required shelf life 45.8. Instructions for use 45.9. Applicable microbiological and chemical criteria How to check ? 45.10. Are product descriptions up-to-date, accurate and in compliance with requirements	HACCP Guid.Doc. Annex 1 ch. 1.2	

PE 06: Assessment of HACCP Plans

Elements to be checked	Objective of the legislation and references	Observations
46. Identification of intended use 46.1. Normal or expected use by intended customers or consumer target groups are defined 46.2. Suitability for particular vulnerable groups /consumers has been considered (YOPI)	HACCP Guid.Doc. Annex 1 ch. 1.3	
47. Flow diagram What to check ? 47.1. Cover all steps in the process operation including delays during or between steps 47.2. Consider raw materials prior to receiving and product following processing at the plant (if company is in charge) 47.3. Flow diagram is backed up by adequate technical data on planning and conducting the operations (eg. in Lay Outs/Blue prints, GMP and SSOP documents) How to check ? 47.4. Flow diagram is up- to- date, accurate and in compliance with requirements.	*Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market* References: Reg. 852/2004, Art. 5, pt. 1, 2 HACCP Guid.Doc. Annex 1 ch. 1.4	
48. Confirmation of flow diagram 48.1. HACCP team has conducted on-site confirmation that each processing step in the plant is accurately included in the flow diagram during operation hours.	*Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market* References: Reg. 852/2004, Art. 5, pt. 1, 2 HACCP Guid.Doc. Annex 1 ch. 1.5	

PE 06: Assessment of HACCP Plans

Elements to be checked	Objective of the legislation and references	Observations
49. Hazard analysis 49.1. Conducted for each step in the verified flow diagram 49.2. Identification of hazards are specific 49.3. Likely occurrence hazards considered 49.4. Severity identified and considered 49.5. Risk considered 49.6. Significance evaluated 49.7. Effective control measures for each significant hazards are identified	*Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market* References: Reg. 852/2004, Art. 5, pt. 1, 2 HACCP Guid.Doc. Annex I ch. 1.6	
50. CCP determination 50.1. Based on the Decision Tree or a similar systematic approach 50.2. Assessment conducted for each step where a significant hazard was identified 50.3. CCPs are appropriate and correctly identified	*Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market* References: Reg. 852/2004 Art. 5 HACCP Guid.Doc. Annex I ch. 2	
51. Critical Limits (CL) 51.1. Established for each identified CCP 51.2. Parameters and criteria scientifically validated (i.e. research, literature, monitoring data etc. justify that effective control is achieved) 51.3. Applicable for real-time observable or measurable parameters by an operator 51.4. Correspond to extreme values acceptable to product safety that separate acceptability from unacceptability 51.5. Target levels (i.e. more narrow operational limits) are identified where relevant.	*Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market* References: Reg. 852/2004, Art. 5, pt. 1, 2 852/2004 Art. 5 HACCP Guid.Doc. Annex I ch. 3	

PE 06: Assessment of HACCP Plans

Elements to be checked	Objective of the legislation and references	Observations
52. Monitoring Procedures Requirements: 52.1. Procedure established for each CCP/CL 52.2. Procedures are accurate, implemented and able to detect loss of control for timely corrective action to be taken without delay 52.3. Location for monitoring is appropriate 52.4. Frequencies, schedule, sampling plan are adequate 52.5. Responsible operator is appropriately trained and competent 52.6. Monitoring Records are associated with each CCP 52.7. Monitoring Records are signed by operator and verified by identified official(s) of the company. Implementation : 52.8. Monitoring at each CCP are carried out as planned 52.9. Corrective actions in case of deviations from specified limits are carried out as planned without delay. 52.10. Corrective actions in case of deviations from specified limits are effective to control food safety	*Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market* References: Reg. 852/2004, Art. 5, pt. 1, 2 HACCP Guid.Doc. Annex I ch. 4	
53. Corrective actions (CA) Requirements: 53.1. Established and defined specifically for each CCP/CL 53.2. Responsible operator is identified 53.3. Responsible operator is appropriately trained and competent 53.4. Isolation and treatment of non-conforming product specifically defined 53.5. Written records of CA measures available. Implementation: 53.6. Corrective actions are implemented as planned 53.7. Corrective actions are adequate to control food safety	*Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market* References: Reg. 852/2004, Art. 5, pt. 1, 2 HACCP Guid.Doc. Annex I ch. 5	

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Elements to be checked	Objective of the legislation and references	Observations
54. Verification procedures <u>Requirements: CCP verification</u> 54.1. Adequate methods and procedures are described and implemented for each CCP/CL, e.g. -record reviews (records for monitoring, corrective action, calibration, sampling and analysis, etc.) - staff monitoring - calibration of instruments - sampling and analysis 54.2. Responsible operator is identified for each specific verification activity who is appropriately trained and competent 54.3. Results of verification activities are themselves verified 54.4. Corrective actions in case of non-compliance is identified for each verification activity <u>Requirements: System verification</u> 54.5. System audits are planned and implemented at appropriate frequencies 54.6. System audits includes Pre-requisite programmes and HACCP plan 54.7. Scope of system audits links to assessment of the efficiency of applied parameters, criteria, procedures and method to control food safety 54.8. Review of whole system or relevant parts are carried out at appropriate intervals or when changes in product, process conditions, packaging or intended consumers takes place or when new information about hazards reveals 54.9. Responsible operator for planning and conducting system audits are appropriately trained and competent.	*Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market* References: Reg. 852/2004 Art. 5 HACCP Guid.Doc. Annex I ch. 6	

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Elements to be checked	Objective of the legislation and references	Observations
<u>Requirements: Validation</u> 54.10. Validation activities planned at appropriate frequencies to efficacy of all elements of the HACCP plan 54.11. Validation activities include at least confirmation of established Critical Limits parameter and other scientific and technical parameters as appropriate to ensure food safety 54.12. Validation activities reviewed when changes occur (e.g. to raw materials, processing equipment, new information on hazards, etc). 54.13. Responsible operator for planning and conducting validation activities are appropriately trained and competent. <u>Implementation of Verification:</u> 54.14. Carried out as planned, including: - Validation of critical limits (and other scientific and technical parameters as appropriate to ensure food safety) - calibrations of equipment - product sampling and testing - records review - Internal audits - Reviews when there are relevant changes - System reviews (in addition to internal audits) conducted at appropriate frequencies 54.15 Corrective actions in case of deviation from requirements are efficient to control food safety	*Procedures based on HACCP principles shall be documented, implemented and maintained to ensure safety of food placed on the market* References: Reg. 852/2004 Art. 5 HACCP Guid.Doc. Annex I ch. 6	

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Elements to be checked	Objective of the legislation and references	Observations
55. Training 55.1. HACCP team members trained specifically in the application of HACCP principles 55.2. Training needs identified for all staff working at CCPs 55.3. Training conducted and documented	To ensure that staff shall be instructed and trained in food hygiene as relevant to their responsibility and activity with food. References: Reg. 852/2004 Art. 5 Reg. 852/2004, Annex II, chapter XII 1-3 HACCP Guid.Doc. Annex I ch. 8	