



FOOD SAFETY AND QUALITY DIVISION

MINISTRY OF HEALTH MALAYSIA

STANDARD OPERATING PROCEDURE FOR MONITORING OF FISHERY END PRODUCTS

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Title: **STANDARD OPERATING PROCEDURE FOR MONITORING OF FISHERY END PRODUCTS**

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Approved by:	
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Designation:	Director for Compliance and Industry Development Food Safety and Quality Division Ministry Of Health Malaysia
Date:	7/8/2012

NO.	DATE OF AMENDMENT	REVISION NO.	AMENDMENT REFERENCE
1.	30 July 2012	04	<p><u>Para 6.1 (iv) a</u> The phrase- "Re-sampling of the remaining products in the processing establishment" is changed to "Re-sampling of the products in the processing establishment after corrective actions have been taken"</p> <p><u>Appendix 1</u> Parameter "Formaldehyde and Hydrogen Peroxide " is removed from Additives.</p> <p><u>Appendix 3</u> Formaldehyde and Hydrogen Peroxide is deleted from "scope/analyte" column</p> <p><u>Appendix 6</u> "Formaldehyde and Hydrogen Peroxide" is deleted from Parameter of Analysis</p> <p><u>Appendix v</u> Annex II – List of substances not subject to maximum residue limit COUNCIL REGULATION (EEC) NO 2377/90 to be excluded</p>

1. INTRODUCTION

Malaysia exports fishery products to the European Union (EU). In line with the EU requirements, a monitoring programme for contaminants and additives in fishery end products is being implemented. This monitoring programme provides useful information in assuring the quality and safety of Malaysian fishery products.

Ministry of Health (MOH) designs the programme, determines and manages the operational process, which include product sampling, identification and dispatch to laboratories, data management and analysis and initiation of traceabilities.

2. SCOPE

All fishery end products including crustaceans and cephalopods for export to the EU or intended for export to the EU.

3. OBJECTIVE

To provide a monitoring programme in compliance with the Regulation (EC) No 853/2004, 854/2004, Commission Regulation 1881/2006, 1883/2006, 333/2007, 2073/2005, 2074/2005, Council Regulation (EEC) No 2377/90, Council Regulation (EC) No 2406/96, Council Directive 95/2/EC and 2006/52/EC.

4. SAMPLING

4.1 General

Sampling of fishery end products are carried out randomly at processing establishment to ensure compliance with the following legislation:

- Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
- Commission Regulation (EC) No 1883/2006 (Sampling and analysis of dioxins and dioxin-like PCBs in certain foodstuffs);
- Commission Regulation (EC) No 333/2006 (Sampling and analysis of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs);
- Commission Regulation (EC) No 2073/2005 and 1441/2007 (Microbiological criteria for foodstuffs);
- Commission Regulation (EC) No 2074/2005 (Implementing measures for certain products under Commission Regulation (EC) 853/2004 and 854/2004;
- Council Regulation (EC) No 2406/96 (Marketing standard for fishery products).

4.2 Number of samples

- i. The number of samples to be taken shall be based on the sampling programme prepared by MOH (HQ) for sampling at the establishment.
- ii. Implementation of sampling plan shall be monitored by State Health Department. Every State Health Department has to achieve the sampling targets that have been determined according to the parameter of analysis.

4.3 Sampling Method

Samples should be handled, packaged and delivered accordingly to the laboratory requirements to maintain the integrity of the samples.

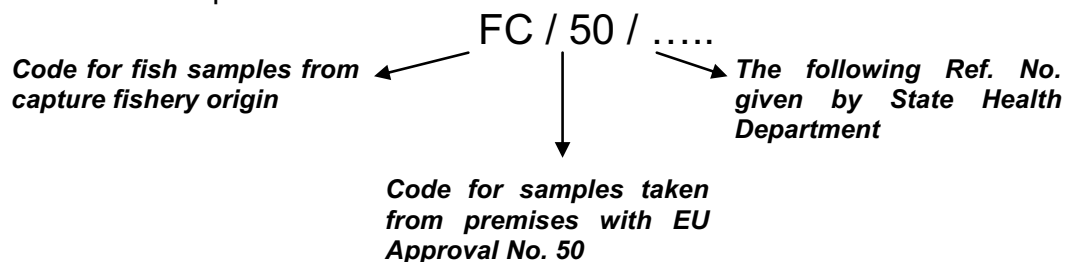
- i. Samples are to be taken for monitoring tin (for canned products);

- ii. microbiological contaminants (for cooked products); dioxin; PCBs; benzo(a)pyrene and food additives.
- iii. Samples to laboratories shall be maintained at appropriate temperature.
- iv. When there is a need for samples to be stored overnight at the office before sending to the laboratory, samples shall be placed in appropriate secured place and at appropriate temperature.
- v. Transportation of samples to the laboratory will be either through courier service or by the designated officers.
- vi. Minimum sample weights to be taken according to the parameter of analysis are as stated in Appendix 1.
- vii. The samples sent to the laboratory are to be accompanied with the Request Form for Analysis of Samples Taken Under Monitoring of Export of Fishery End Products as in Appendix 2.

4.4 Labelling of sample

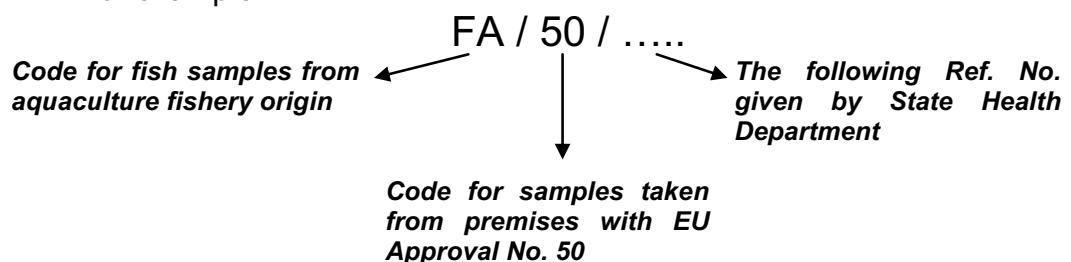
- i. Collected samples shall be packed in sealed plastic bags and labelled with unique sample identification number. The sample number for capture fishery end products taken from establishment shall be as follows:

For example:



- ii. The sample number for aquaculture fishery end products taken from establishment shall be as follows:

For example:



4.5 Analysis Request Form

Analysis Request Form as in Appendix 2 shall be completed and submitted together with the samples to the laboratory.

4.6 Delivery of samples

Samples should be delivered to the identified laboratories according to the determined sampling schedule.

5. LABORATORIES

5.1 Official Laboratories

Official laboratories providing analytical services by parameters of analysis are as in Appendix 3.

Official laboratories shall have quality assurance programme based on ISO/IEC 17025.

5.2 Analytical Methods

Performance of analytical methods shall be in compliance to Commission Decision 2002/657/EC.

Performance criteria for method of analysis shall be in compliance Commission Regulation (EC) No 1883/2006 and Commission Regulation (EC) No 333/2006.

5.3 Reporting of Analytical Results

- i. The Fishery End Products Monitoring Programme has a defined performance criterion for timeliness of analysis and reporting of results.
- ii. Turnaround time is defined as time taken between the receiving of samples at the laboratory and the date of reporting which shall be within 14 working days for chemical and microbiological analysis, and 30 working days for PAH, dioxins and PCBs analysis. In the event of non-compliance of the TAT, reasons are to be submitted to the CA by the laboratories.
- iii. Analytical results shall be reported in compliance to the requirements under clause 5.10 of ISO/IEC 17025.
- iv. It is the responsibility of the State Health Department to follow-up with the relevant laboratory if analysis results are not received and TAT has been exceeded.

- v. The laboratory shall issue results of analysis to the sampler with a copy to the State Health Department and MOH (HQ) within 3 working days from the date of reporting.
- vi. The State Health Department shall submit to MOH (HQ) the summary of analytical results according to the format as in Appendix 4 on a weekly basis.
- vii. In the case of suspected contravening results, the laboratory shall report the preliminary results immediately via e-mail or facsimile to the sampler with a copy to the State Health Department and MOH (HQ).
- viii. The State Health Department shall take appropriate follow-up action at the establishment within three (3) working days after preliminary reports.
- ix. All analytical results are to be kept for at least 3 years.

6. FOLLOW-UP ACTION

- 6.1 Follow-up action shall be taken by the designated state officer for all analytical result that does not comply with the EU standard. The follow-up actions are as follows:
- i. To notify in writing the contravention to the establishment operator.
 - ii. To ensure the food business operators take immediate corrective actions to address the non-conformance and ensure that the non-conformance does not recur.
 - iii. To conduct joint investigation, such as verification of records including traceability records and additional sampling where necessary, to identify the source/cause of the contamination.
 - iv. To identify the appropriate actions that should be taken to avoid recurrence of the contamination. Such actions will depend on the risk associated with the identified contaminant which include the following:
 - a. Re-sampling of the products in the processing establishment after corrective actions have been taken;
 - b. To increase the control activities such as inspection & monitoring
 - iv. To suspend or withdraw the identified establishment from the National Approved List, depending on the seriousness of the contravention.

6.2 The State Health Department shall forward a preliminary contravention report to MOH (HQ) within 14 working days from date of completion of the investigation by completing No. 1-17 of Contravention Report Fishery End Products Monitoring Programmes For Export To EU as in Appendix 5. Final Contravention Report is to be submitted to MOH (HQ) within 7 working days after all corrective actions have been taken.

7. YEARLY REPORT OF MONITORING PROGRAMME

MOH (HQ) shall compile, analyse and evaluate the implementation of the monitoring programme and prepare a yearly report.

8. RE-EXAMINATION OF SAMPLING PROGRAMME

Sampling programme is reviewed on the yearly basis based on the evaluation findings of the previous year's implementation of the monitoring programme.

9. SUPPORTING DOCUMENT

- Appendix 1 : Contaminants and Additives to be Monitored Under Fishery End Products Monitoring Programme
- Appendix 2 : Request Form for Analysis of Samples Taken Under the Fishery End Products Monitoring Programme
- Appendix 3 : List of Official Laboratories Approved By the CA
- Appendix 4 : Compilation of Analytical Results of Samples Taken Under Fishery End Products Monitoring Programme Year _____
- Appendix 5 : Contravention Report Fishery End Products Monitoring Programmes for Export to EU
- Appendix 6 : Summary of European Union Requirements for Fishery End Products

10. REFERENCE

- i. Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results; Regulation (EC) No 853/2004 (laying down specific hygiene rules for food of animal origin);
- ii. Regulation (EC) No 853/2004 (laying down specific hygiene rules for food of animal origin);
- iii. Regulation (EC) No 854/2004 (laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption);
- iv. Commission Regulation (EC) No 1881/2006 (setting maximum levels for certain contaminants in foodstuffs);
- v. Commission Regulation (EC) No 1883/2006 (laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs);

- vi. Commission Regulation (EC) No 333/2007 of 28 March 2007 (laying down the methods of sampling and analysis for the official control of the level of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a) pyrene in foodstuffs);
- vii. Commission Regulation (EC) No 2073/2005 (on microbiological criteria for foodstuffs);
- viii. Commission Regulation (EC) No 2074/2005 (laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004;
- ix. Council Regulation (EEC) No 2377/90 (laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin;
- x. Council Regulation (EC) No 2406/96 (laying down common marketing standards for certain fishery products);
- xi. Council Directive 95/2/EC (on food additives other than colours and sweeteners);
- xii. Council Directive 2006/52/EC (amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs).
- xiii. ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories

Appendix 1

Contaminant and Additives to be Monitored Under Fishery End Products Monitoring Plan

Group	Parameters	Minimum sample size
Contaminants	Tin (Sn)	500 g edible portion (excluding head, bone, tail etc)
	PCBs	
	Dioxin	
	Benzo(a)pyrene	
Additives	Benzoic Acid and Sorbic Acid	500 g edible portion (excluding head, bone, tail etc)
	Polyphosphate	
	Sulphites	
	Citrates	
	Triphosphates	
	Calcium Disodium EDTA	
	Sorbitol / Mannitol / Maltitol / Lactitol / Xylitol	
Erythritol		
Antioxidant	4-Hexylresorcinol	
Microbiology	<i>Salmonella spp., E.Coli and Coagulase Positive Staphylococci</i> <i>Listeria Monocytogenes</i>	250 g whole
Others	TVB-N	500 g edible portion (excluding head, bone, tail etc)

**Please refer to Summary of Testing Requirement for the detail of analysis.

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Appendix 2

Request Form for Analysis of Samples Taken For Monitoring of Export of Fishery End Products

Laboratory: _____ Date of Sampling: _____

Competent Authority: _____

Name and Address of Establishment : _____

Monitoring program: Fishery End Product

Importing Country: EU US Others _____

No.	Sample Reference No.	Type of product	Batch No.	Substance or group of substances for examination

Particulars of Sampling Officer :

Signature : _____

Name : _____

Designation : _____

Office : _____

Date : _____

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Appendix 3

List of Officials Laboratories for Fishery End Products Monitoring Programme

No.	Full Address of Agency	Contact person / Tel. / Fax / e-mail	Scope / Analyte
1.	National Public Health Laboratory Ministry of Health Malaysia Lot 1853, Kg. Melayu 47000 Sg. Buloh Selangor, Malaysia	Ms. Tosiah Abdullah Tel: 603-61565109 Fax: 603-61402249 E-mail: tosiahabdullah@moh.gov.my	Microbiology Tin Benzoic Acid and Sorbic Acid Sulphites (SO ₂) Polyphosphates Triphosphates Citrates
2.	Public Health Laboratory Ipoh Ministry of Health Malaysia Lot 39052 Jalan Jelapang 30020 Ipoh Perak, Malaysia	Ms. Noraliza Mohd Akhir Tel: 05-5287829 Fax: 05-5287836 E-mail: noraliza2@moh.gov.my	Microbiology Benzoic Acid and Sorbic Acid Sulphites (SO ₂)
3.	Public Health Laboratory Kota Kinabalu Ministry of Health Malaysia Bukit Padang, Jalan Kolam 88850 Kota Kinabalu Sabah, Malaysia	Ms. Afiedah Munir Tel: 088-250710 / 243230 Fax: 088-243210 / 243211 E-mail: afiedah@sbh.moh.gov.my	Microbiology Benzoic Acid and Sorbic Acid Sulphites (SO ₂)
4.	Public Health Laboratory Johor Bahru Ministry of Health Malaysia Jalan Persiaran Tanjung Tampoi, 81200 Johor Bahru Johor, Malaysia	Ms. Valarmathi Kanapathy Tel: 07-2387162 Fax: 07-2387215 E-mail: valar@moh.gov.my	Microbiology

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No.	Full Address of Agency	Contact person / Tel. / Fax / e-mail	Scope / Analyte
5.	Food Safety and Quality Laboratory Penang Penang State Health Department Jalan Bagan Luar 12000 Butterworth Penang, Malaysia	Mr Fadzil Othman Tel: 04-3324924 Fax: 043334097 E-mail: fadzilmkak@moh.gov.my	Microbiology Benzoic Acid and Sorbic Acid Sulphites (SO ₂)
6.	Food Safety and Quality Laboratory Sarawak Sarawak State Health Department Jalan Tun Abang Haji Openg 93590 Kuching Sarawak, Malaysia	Mr. Eraou Batang Tel: 082-242675 Fax: 082-258849 E-mail: eraou@srwk.moh.gov.my	Sulphites (SO ₂) Benzoic Acid / Sorbic Acid Microbiology
7.	Food Safety and Quality Laboratory Selangor Laboratory Selangor Block C, Jalan Langat, Bandar Botanik ,41200 Klang Selangor, Malaysia	Mr. Abdul Ghani Abu Samah Tel: 03-33718822 / 33723361 Fax: 33737154 E-mail: abdulghani@sel.moh.gov.my	TVB-N/TMA-N
8.	Doping Control Centre, Universiti Sains Malaysia 10800 Minden Penang, Malaysia	Prof. Aishah A. Latiff Tel : 04-6595605 Fax : 04-6569869 E-mail : aishah@dccusm.com	Dioxin PAH (Benzo(a)pyrene) PCBs
9.	Department of Chemistry Malaysia Jalan Sultan 46661 Petaling Jaya Selangor, Malaysia	Ms. Zaiton Ariffin Tel : 03-79853000 Fax : 03-79556764 E-mail: zaiton@kimia.gov.my	Calcium disodium EDTA Sorbitol, Mannitol, Maltitol, Lactitol, Xylitol Erythritol 4-Hexylresorcinol

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Appendix 5

CONTRAVENTION REPORT CAPTURE FISHERY/ FISHERY END PRODUCTS MONITORING PROGRAMME FOR EXPORT TO EU

NO.	DESCRIPTION
1.	State Health Department (SHD)
2.	Name of the processing establishment
3.	Sample name
4.	Batch number and production date of product
5.	Category of sample <input type="checkbox"/> Capture Fishery Raw Material (C) <input type="checkbox"/> Capture Fishery End Product (FC) <input type="checkbox"/> Aquaculture End Product (FA)
6.	Type of sample <input type="checkbox"/> Finfish <input type="checkbox"/> Crustacean <input type="checkbox"/> Cephalopod <input type="checkbox"/> Surimi
7.	Where product will be sold: Local/ Export (state the name of the country)
8.	Sample reference number
9.	Date of sampling
10.	Date of receipt of samples by official laboratory
11.	Name of official laboratory
12.	Date of analysis report
13.	Date of receipt of analysis report by SHD
14.	Contravention
14.1	Parameter of analysis
14.2	Result of analysis
14.3	EU Standard

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NO.	DESCRIPTION	
15.	Investigation	
15.1	Date and place of investigation	
15.2	Joint investigation (state the name of other agencies)	
15.3	Investigation findings: Source of raw material <ul style="list-style-type: none"> • Local source of raw material: <ul style="list-style-type: none"> - Name and address of farm/ vessel/ landing site - Date of harvesting • Imported raw material: <ul style="list-style-type: none"> - Name of processing establishment, country of origin and EU Approval Number - Batch number and production date of raw material • Date of receiving raw materials by establishment • Quantity of raw materials received 	
15.4	Other information:	
16.	Follow-up Actions by SHD	
16.1	Instructions given to establishment to conduct investigation and corrective action: <ul style="list-style-type: none"> • Date of instructions • Summary of instructions • Time period for corrective actions committed by establishment (attach a copy of the instruction e.g. letter, email) 	
16.2	Instructions to other agency (if applicable) (state the name of the agency): <ul style="list-style-type: none"> • Date of instructions • Summary of instructions • Time period for corrective actions committed by other agencies (attach a copy of the instruction e.g. letter, email) 	

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NO.	DESCRIPTION	
17.	Corrective Actions	
17.1	Corrective actions committed by establishment: <ul style="list-style-type: none"> • Date of report on corrective actions committed by establishment • Summary of corrective actions committed by establishment (attach a copy of the report) 	
17.2	Follow-up actions committed by other agencies: <ul style="list-style-type: none"> • Date of report on follow-up actions committed by other agencies • Summary of follow-up actions committed by other agencies (attach a copy of the report) 	
18.	Follow-up On Corrective Actions To be completed after corrective actions have been taken by establishment/other related agencies and follow-up inspection has been carried out by SHD)	
18.1	Re-sampling (after corrective actions have been undertaken): <ul style="list-style-type: none"> • Date of re-sampling • Result of re-sampling 	
18.2	Corrective actions taken by establishment: <ul style="list-style-type: none"> • Date of report on corrective actions taken by establishment • Summary of corrective actions taken by establishment (attach a copy of the report) 	
18.3	Corrective actions taken by other agencies: <ul style="list-style-type: none"> • Date of report on corrective actions taken by other agencies • Summary of corrective actions taken by other agencies (attach a copy of the report) 	
19.	Other additional information	

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NO.	DESCRIPTION	
20.	General comment	

Prepared by:
 (Signature)

Name :

Designation :

State Health Department :

Date :

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Appendix 6

SUMMARY OF EUROPEAN UNION REQUIREMENTS FOR FISHERY END PRODUCTS

Official control	EU Requirements	Purpose	Type of Food	Sampling Point	Parameter of Analysis	EU Standard
Organoleptic examination	Council Regulation (EC) No 2406/96	Determine freshness category of fish & fishery product	Fishery Products	Processing establishment	a) Freshness Ratings b) Size category	Appendix i
Freshness Indicators	Commission Regulation (EC) No 2074/2005	Freshness criteria for fish & fishery product	Fishery Products	Processing establishment	TVB-N	Appendix ii
Parasites	Commission Regulation (EC) No 2074/2005	Determine fish infested to parasites are not released for human consumption	Fishery Products	Processing establishment		
Microbiological Criteria	Commission Regulation (EC) No 2073/2005	Microbiology criteria for foodstuff	Cooked crustaceans and molluscan shellfish	Processing establishment	a) <i>Listeria monocytogenes</i> b) <i>Salmonella</i> c) <i>E.coli</i> d) Coagulase-positive <i>Staphylococci</i>	Appendix iii
Contaminants	Commission Regulation (EC) No 1881/2006	Maximum level for certain contaminants in foodstuffs	Fishery End Products	Processing establishment	a) Tin b) Dioxins & PCBs c) PAH (polycyclic aromatic hydrocarbons) – benzo(a) pyrene	Appendix iv
Additives	Council Directives 95/2/EC, 2006/52/EC	Additives	Fishery End Products	Processing establishment	a) Benzoic Acid b) Sorbic Acid c) Polyphosphate d) Sulphites e) Citrates f) Triphosphates g) Calcium disodium EDTA	Appendix v

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Official control	EU Requirements	Purpose	Type of Food	Sampling Point	Parameter of Analysis	EU Standard
	Council Regulation (EEC) No 2377/90				h) Sorbitol / Mannitol / Maltitol / Lactitol / Xylitol / i) Erythritol	

ORGANOLEPTIC EXAMINATION

COUNCIL REGULATION (EC) NO 2406/96

Article 4: Freshness categories

- Extra, A or B in the case of fish, selachii, cephalopods and Norway lobsters
- Extra or A in the case of shrimps

Annex I: Freshness Ratings

- A. Whitefish
Haddock, cod, saithe, Pollack, redfish, whiting, ling, hake, Ray's bream, anglerfish, pouting and poor cod, bogue, picarel, conger, hurnard, mullet, plaice, megrim, sole, dab, lemon sole, flounder, scabbard fish
- B. Bluefish
Albacore or longfinned tuna, bigeye tuna, blue whiting, herring, sardines, mackerel, horse mackerel, anchovy, sprat
- C. Selachii
Dogfish, skate
- D. Cephalopods
Cuttlefish
- E. Crustaceans
Shrimps & Norway lobster

A. Whitefish

	Criteria			Not admitted
	Freshness category			
	Extra	A	B	
Skin	Bright, iridescent pigment (save for redfish) or opalescent; no discolouration	Pigmentation bright but not lustrous	Pigmentation in the process of becoming discoloured and dull	Dull pigmentation
Skin mucus	Aqueous, transparent	Slightly cloudy	Milky	Yellowish grey, opaque mucus
Eye	Convex (bulging); black, bright pupil; transparent corneo	Convex and slightly sunken; black dull pupil; slightly opalescent cornea	Flat; opalescent cornea; opaque pupil	Concave in the centre; grey pupil; milky cornea (2)
Gills	Bright colour; no mucus	Less coloured; transparent mucus	Brown/grey becoming discoloured; thick, opaque mucus	Yellowish; milky mucus

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Peritoneum (in gutted fish)	Smooth; bright; difficult to detach from flesh	Slight full; can be detached from flesh	Speckled; comes away easily from flesh	Does not stick (2)
Smell of gills and abdominal cavity - whitefish other than plaice - plaice	Seaweedy	No smell of seaweed; neutral smell	Fermented; slightly sour	(2) Sour
	Fresh oily; peppery; earthy smell	Oily; seaweedy or slightly sweetish	Oily; fermented; stale, slightly rancid	Sour
Flesh	Firm and elastic; smooth surface (3)	Less elastic	Slightly soft (flaccid), less elastic; waxy (velvety) and dull surface	Soft (flaccid) (2); scales easily detached from skin, surface rather wrinkled

Extra criteria for headed anglerfish

Blood vessels (vental muscles)	Sharp outline and bright red	Sharp outline; darkening of the blood	Diffuse and brown	Totally (2) diffuse, brown and yellowing of the flesh
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B. Bluefish

	Criteria			Not admitted
	Freshness category			
	Extra	A	B	
Skin	Bright, pigmentation, bright, shining, iridescent colour; clear distinction between dorsal and central surfaces	Loss of lustre and shine; duller colours; less difference between dorsal and ventral surfaces	Dull, lustreless, insipid colours; skin creased when fish curved	Very dull pigmentation; skin coming away from flesh
Skin mucus	Aqueous, transparent	Slightly cloudy	Milky	Yellowish grey, opaque mucus
Consistency of flesh	Very firm, rigid	Fairly rigid, firm	Slightly soft	Soft (flaccid)
Gill covers	Silvery	Silvery, slightly red or brown	Brownish and extensive seepage of blood from vessels	Yellowish
Eye	Convex, bulging; blue-black bright pupil; transparent 'eyelid'	Convex and slightly sunken; dark pupil; slightly opalescent cornea	Flat; blurred pupil; blood seepage around the eye	Concave in the centre; grey pupil; milky cornea (3)

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Gills (2)	Uniformly dark red to purple. No mucus	Less bright colour, paler at edges. Transparent mucus	Becoming thick discoloured opaque mucus	Yellowish; milky mucus (3)
Smell of gills	Fresh seaweed; pungent; iodine	No smell or seaweed, Neutral smell	Slightly sulphureous (4) fatty smell, rancid bacon cuttings or rotten fruit	Rotten sour (3)

C. Selachii

	Criteria			Not admitted
	Freshness category			
	Extra	A	B	
Eye	Convex, very bright and iridescent; small pupils	Convex and slightly sunken; loss of brightness and iridescence, oval pupils	Flat, dull	Concave yellowish (2)
Appearance	In rigor mortis or partially in rigor, small quantity of clear mucus present on skin	Beyond rigor stage; no mucus on skin and especially in mouth and grill openings	Some mucus in mouth and on gill openings; slightly flattened jaw	Large quantities of mucus in mouth and on grill opening (2)
Smell	Seaweed	No smell or very slight stale but not an ammonia smell	Slight ammonia; sour	Pungent ammonia smell (3)

Specific or additional criteria for skate

	Criteria			Not admitted
	Freshness category			
	Extra	A	B	
Skin	Bright, iridescent and shiny pigmentation, aqueous mucus	Bright pigmentation, aqueous mucus	Pigmentation in the process of becoming discoloured and dull, opaque mucus	Discolouration, skin creased, thick mucus
Texture of the flesh	Firm and elastic	Firm	Soft	Flaccid
Aspect	Edge of the fins translucent and curved	Stiff fins	Soft	Drooping
Belly	White and shiny with a mauvish edge around the fins	White and shiny with red patches limited to around the fins	White and dull, with numerous red or yellow patches	Yellow to greenish bellies red patches in the flesh itself

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D. Cephalopods

	Criteria		
	Freshness category		
	Extra	A	B
Skin	Bright pigmentation, skin sticks to flesh	Dull pigmentation; skin sticks to flesh	Discoloured; easily detached from flesh
Flesh	Very firm; pearly white	Firm; chalky white	Slightly soft; pinky white or slightly yellowing
Tentacles	Resistant to removal	Resistant to removal	More easily removed
Smell	Fresh; seaweed	Slightly or no smell	Ink smell

E. Crustaceans

1. Shrimps

	Criteria	
	Freshness category	
	Extra	A
Minimum requirements	<ul style="list-style-type: none"> - Surface of shell; moist and shiny - Shrimp must fall out separately when transferred from one container to another - Flesh must be free from any foreign odour - Shrimps must be free from sand, mucus and other foreign bodies 	The same as for Extra category
Appearance of: 1) Shrimp with shell 2) Deep-water prawn	<p>Clear reddish-pink in colour with small white flecks; pectoral part of shell predominantly light in colour</p> <p>Uniformly pink</p>	<ul style="list-style-type: none"> - ranging in colour from slightly washed-out reddish-pink to bluish-red with white flecks; pectoral part of shell should be light coloured tending towards grey - pink with possibility of start of blackening of head
Condition of flesh during and after shelling	<ul style="list-style-type: none"> - shell easily with only technically unavoidable losses of flesh - firm but not tough 	<ul style="list-style-type: none"> - shell less easily with small losses of flesh - less firm, slightly tough
Fragments	Occasional fragments of shrimp allowed	Small quantity of fragments of shrimp allowed
Smell	Fresh seaweed, slightly sweet smell	Acidulous, no smell of seaweed

2. Norway lobster

	Criteria		
	Freshness category		
	Extra	A	B
Shell	Pale pink or pink to orange-red	Pale pink or pink to orange-red; no black spots	Slight discolouration; some black spots and greyish colour, particularly on shell and between tail segments
Eye and gills	Shiny black eyes; pink gills	Eyes dull and grey/black; gills greyish	Gills dark grey or some greenish colour on dorsal surface of shell
Smell	Characteristic mild shellfish smell	Loss of characteristic shellfish smell. No ammonia smell	Slightly sour
Flesh (tail)	Translucent and blue in colour tending towards white	No longer translucent but not discoloured	Opaque and dull in appearance

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Appendix ii

FRESHNESS INDICATORS: LIMIT FOR TOTAL VOLATILE BASIC NITROGEN (TVB-N)

COMMISSION REGULATION (EC) NO 2074/2005: ANNEX II

Food category	Limit
<i>Sebastes</i> spp., <i>Helicolenus dactylopterus</i> , <i>Sebastichthys capensis</i>	25 milligrams of nitrogen/100 grams of flesh
Species belonging to the <i>Pleuronectidae</i> family (with the exception of halibut: <i>Hippoglossus</i> spp.)	30 milligrams of nitrogen/100 grams of flesh
<i>Salmo salar</i> , species belonging to the <i>Merlucciidae</i> family, species belonging to the <i>Gadidae</i> family	35 milligrams of nitrogen/100 grams of flesh

MICROBIOLOGICAL CRITERIA**COMMISSION REGULATION (EC) NO 2073/2005, 1441/2007****Annex I, Chapter 1: Food Safety Criteria**

Food category	Microorganisms/ toxins/ metabolites	Sampling plan ⁽¹⁾		Limit ⁽²⁾		Stage where the criterion applies
		n	c	m	M	
1.2 Ready to eat food able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g	Absence in 25 g	Products placed on the market during their shelf-life Before the food has left the immediate control of the food business operator, who has produced it
1.3 Ready to eat foods unable to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purpose ^{(4) (8)}	<i>Listeria monocytogenes</i>	5	0	100 cfu/g		Products placed on the market during their shelf-life
1.16 Cooked crustaceans and molluscan shell-fish	<i>Salmonella</i>	5	0	Absence in 25 g		Products placed on the market during their shelf-life

Footnotes:

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.

(2) For points 1.1-1.16 m = M.

(4) Regular testing against the criterion is not useful in normal circumstances for the following ready to eat foods:

- those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (e.g. products heat treated in their final package),
- fresh, uncut and unprocessed vegetables and fruit, excluding sprouted seeds,
- bread, biscuits and similar products,
- bottled or packed water, soft drinks, beer, cider, wine, spirit and similar products,
- sugar, honey and confectionery, including cocoa and chocolate products,
- live bivalve mollusks.

(8) Products with pH ≤ 4.4 or aw ≤ 0.92, products with pH ≤ 5.0 and aw ≤ 0.94, products with a shelf life of less than 5 days are automatically considered to belong to this category

Interpretation of the test results

i. *L. monocytogenes* in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

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- ii. *L. monocytogenes* in other ready-to-eat foods and *E. coli* in live bivalve molluscs:
 - satisfactory, if all the values observed are \leq the limit,
 - unsatisfactory, if any of the values are $>$ the limit.
- iii. *Salmonella* in different food categories:
 - satisfactory, if all the values observed indicate the absence of the bacterium,
 - unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

Annex I, Chapter 2: Process Hygiene Criteria

Food category	Microorganisms/ toxins/ metabolites	Sampling plan ⁽¹⁾		Limit ⁽²⁾		Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M		
2.4.1 Shelled and shucked products of cooked crustaceans and molluscan shellfish	E.coli	5	2	1/g	10/g	End of the manufacturing process	Improvements in production hygiene
	Coagulase- positive staphylococci	5	2	100 cfu/g	1000 cfu/g		

Footnotes:

- (1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
- (2) The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

- i. *E. coli* in shelled and shucked products of cooked crustaceans and molluscan shellfish:
 - satisfactory, if all the values observed are \leq m,
 - acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are \leq m,
 - unsatisfactory, if one or more of the values observed are $>$ M or more than c/n values are between m and M.
- ii. Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:
 - satisfactory, if all the values observed are \leq m,
 - acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are \leq m,
 - unsatisfactory, if one or more of the values observed are $>$ M or more than c/n values are between m and M.

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Appendix iv

CONTAMINANTS IN FOODSTUFFS

COMMISSION REGULATION (EC) NO 1881/2006

Section 3: Metal

Foodstuffs		Maximum levels (mg/kg wet weight)	Performance criteria for sampling and for the method of analysis
3.4	Tin (Inorganic)		Reg. 333/2007
3.4.1	Canned foods other than beverages	200	LOD : 1/10 maximum level Reg. 1881/2006 LOQ: 1/5 maximum level

Section 5: Dioxins and PCBs ⁽³¹⁾

Foodstuffs	Maximum levels		Performance criteria for sampling and for the method of analysis
	Sum of dioxins (WHO-PCDD/F-TEQ) ⁽³²⁾	Sum of dioxins and dioxin-like PCBs(WHO-PCDD/F-PCB-TEQ) ⁽³²⁾	
5.3 Muscle of fish and fishery products and products thereof, excluding eel ⁽²⁵⁾ ⁽³⁴⁾ . The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>)	4,0 pg/g wet weight	8,0 pg/g wet weight	Reg. 1883/2006 Upperbound concentration: upperbound concentration are calculated on the assumption that all values of the different congeners below limit of quantification are equal to the limit of quantification
5.4 Muscle meat of eel (<i>Anguilla anguilla</i>) and products thereof	4,0 pg/g wet weight	12,0 pg/g wet weight	

Footnotes:

(31) Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent using the WHO-toxic equivalency factors (WHO-TEFs)) and sum of dioxins and dioxin-like PCBs (sum of PCDDs, PCDFs and polychlorinated biphenyls (PCBs), expressed as WHO toxic equivalent using the WHO-TEFs). WHO-TEFs for human risk assessment based on the conclusions of the WHO meeting in Stockholm, Sweden, 15

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to 18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106 (12), 775).

- (32) Upperbound concentrations: Upperbound concentrations are calculated on the assumption that all the values of the different congeners below the limit of quantification are equal to the limit of quantification.
- (34) Foodstuffs listed in this category as defined in categories (a), (b), (c), (e) and (f) of the list in Article 1 of Regulation (EC) No 104/2000 with the exclusion of fish liver falling under code CN 0302 70 00.

Section 6: Polycyclic aromatic hydrocarbons

Foodstuffs		Maximum levels (µg/kg wet weight)	Performance criteria for sampling and for the method of analysis
6.1.	Benzo (a)pyrene ⁽³⁵⁾		Reg. 333/2007
6.1.3	Muscle meat of smoked fish and smoked fishery products ⁽²⁵⁾ ⁽³⁶⁾ , excluding bivalve molluscs. The maximum level applies to smoked crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>)	5,0	LOD <0.3 µg/kg LOQ < 0.9 µg/kg
6.1.4	Muscle meat of fish ⁽²⁴⁾ ⁽²⁵⁾ , other than smoked fish	2,0	
6.1.5	Crustaceans, cephalopods, other than smoked ⁽²⁶⁾ . The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>)	5,0	
6.1.6	Bivalve molluscs ⁽²⁶⁾	10,0	

Footnotes:

(35) Benzo(a)pyrene, for which maximum levels are listed, is used as a marker for the occurrence and effect of carcinogenic polycyclic aromatic hydrocarbons. These measures therefore provide full harmonisation on polycyclic aromatic hydrocarbons in the listed foods across the Member States.

(36) Foodstuffs listed in this category as defined in categories (b), (c), and (f) of the list in Article 1 of Regulation (EC) No104/2000.

FOOD ADDITIVES

COUNCIL DIRECTIVES 95/2/EC, 94/35/EC, 2006/52/EC

Additives	Foodstuff	Maximum level	
Calcium citrates (citrates)	Unprocessed fish, crustaceans and molluscs, including such product frozen and deep frozen	GMP – in line with good manufacturing practices	Annex II
Benzoic or Sorbic Acid *	Semi preserved fish products including fish roe products	2000 ppm	Annex III, Part A
	Salted, dried fish	200 ppm	
Sorbic Acid	Analogues of fish, crustaceans and cephalopods	2000 ppm	
Benzoic or Sorbic Acid *	Cooked crustaceans and molluscs	2000 ppm	
Benzoic acid		1000 ppm	
Sulphites **	Dried salted fish of the "Gadidae" species	200 ppm	Annex III, Part B
	Fresh, frozen & deep-frozen crustaceans and cephalopods	150 ppm	
	Crustaceans: <i>Penaeidae</i> , <i>Solenoceridae</i> , <i>Aristaeidae</i> family: - up to 80 units - between 80 and 120 units - over 120 units	150 ppm 200 ppm 300ppm	
	Crustaceans and cephalopods - cooked - cooked crustaceans, <i>Penaeidae</i> , <i>Solenoceridae</i> , <i>Aristaeidae</i> family: - up to 80 units - between 80 and 120 units - over 120 units	50 ppm 135 ppm 180 ppm 270 ppm	
Boric acid	Sturgeons' eggs (Caviar)	4 g/kg expressed as boric acid	Annex III, Part C
Erythorbic acid / sodium erythorbate	Preserved and semi-preserved fish products	1500 ppm expresses as erythorbic acid	Annex III, Part D
4-Hexylresorcinol	Fresh, frozen and deep-frozen crustaceans	2 mg/kg as residues in crustacean meat	Annex III, Part D

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Additives	Foodstuff	Maximum level	
Triphosphates ***	Surimi	1000 ppm	Annex IV
	Fish and crustaceans paste	5000 ppm	
Polyphosphates ***	Fillet of unprocessed fish, frozen and deep-frozen	5000 ppm	
	Unprocessed and processed molluscs and crustaceans frozen and deep-frozen	5000 ppm	
	Canned crustaceans products	1000 ppm	
Calcium disodium ethylene diamine tetra-acetate (calcium disodium EDTA)	Canned and bottled crustaceans, molluscs	75 ppm	
	Canned and bottled fish	75 ppm	
	Frozen and deep-frozen crustaceans	75 ppm	
Sorbitol, Mannitol, Isomalt, Maltitol, Lactitol, Xylitol, Erythritol	Frozen unprocessed fish, crustaceans, molluscs and cephalopods (for purpose other than sweetening)	GMP	

Notes:

* benzoic acid and sorbic acid maybe used singly or in combination. If used in combination, total both additives may not exceed the limit shown.

** Maximum levels are expressed as SO₂ in mg/kg or mg/l as appropriate and relate to the total quantity, available from all source. All SO₂ content of not more than 10 mg/kg or 10 mg/l is not considered to be present

***The indicated maximum levels of phosphoric acid and the phosphates E 385, 451, 452 may be added individually or in combination (expressed as P₂O₅)