



FOOD SAFETY AND QUALITY DIVISION

MINISTRY OF HEALTH MALAYSIA

STANDARD OPERATING PROCEDURE FOR MONITORING OF CAPTURE FISHERY PRODUCTS

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

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Approved by:	
Name:	WEE BEE WAH
Designation:	Deputy Director (Export) Food Safety And Quality Division Ministry Of Health Malaysia
Date:	

NO.	DATE OF AMENDMENT	REVISION NO.	AMENDMENT REFERENCE
1.	11 March 2010	02	<p><u>Para 1</u> The word “<i>plan</i>” changed to “<i>programme</i>”.</p> <p><u>Para 3</u> The original statement is deleted and the new statement “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, 1441/2007, 2074/2005, and Council Regulation (EC) No 2406/96” is included.</p> <p><u>Para 4.1</u> “Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results” is included EC No “1441/2007” is included.</p> <p><u>Para 4.2 (ii)</u> The statement “and DOF for sampling at landing site level” is deleted. The new statement – “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”. is included</p> <p><u>Para 4.3</u> i. The new statement – “Samples of raw material</p>

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			<p><i>are to be taken for monitoring of histamine and contaminants</i>". is included</p> <p>vi. The phrase - "Request Form for Analysis of Samples Taken Under the Capture Fishery Monitoring Plan" is changed to "Request Form for Analysis of Samples Taken For Monitoring of Export of Fishery Product"</p> <p><u>Para 5.1</u> The word "involved" is deleted. The word "Official" is included.</p> <p>The new statement – "Official laboratories shall have quality assurance programme based on ISO/IEC 17025" is included.</p> <p><u>Para 5.2</u> The original statement is deleted and replaced with "Performance of analytical methods shall be in compliance to Commission Decision 2002/657/EC</p> <p>The new statement - "Performance criteria for method of analysis shall be in compliance Commission Regulation (EC) No 1883/2006 and Commission Regulation (EC) No 333/2006." is included</p> <p><u>Para 5.3</u> i. The original statement is deleted and replaced with statement – "The capture fisheries monitoring plan has a defined performance criterion for timeliness of analysis and reporting of</p>

NO.	DATE OF AMENDMENT	REVISION NO.	AMENDMENT REFERENCE
			<p>results.”</p> <p>ii. The original statement is deleted and replaced with statement - “Turnaround time is defined as time taken between the arrival 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 dioxins and PCBs analysis. In the event of non-compliance of the TAT, reasons are to be submitted to the CA by the laboratories.”</p> <p>iii. The new statement – “Analytical results shall be reported in compliance to the requirements under clause 5.10 of ISO/IEC 17025.” is included</p> <p>iv. The new statement – “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.” is included</p> <p>v. The phrase – “to the sampler with a copy to the State Health Department and MOH (HQ) within 3 working days from the date of reporting.” is included</p> <p>vi. The New statement – “The State Health Department shall submit to MOH (HQ)</p>

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			<p><i>the compilation of analytical results according to the format as in Appendix 4 on a weekly basis.</i> is included</p> <p>vii. The phrase – “<i>after preliminary reports</i>” is included</p> <p>ix. The new statement – “<i>All analytical results are to be kept for at least 3 years.</i>” is included.</p> <p><u>Para 6.1</u></p> <p>i. The phrase “<i>landing site operator</i>” is deleted.</p> <p>ii. The new statement “<i>To ensure the food business operators take immediate corrective actions to address the non-conformance and ensure that the non-conformance does not recur</i>” is included.</p> <p>iv. The phrase “<i>without delay</i>” is included.</p> <p>v. The phrase “<i>fishing vessel</i>” is deleted.</p> <p><u>Para 6.2</u> The original statement has been deleted and new statement “<i>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 Products Monitoring Programmes For Export To EU as in Appendix 5. Final Contravention Report is</i></p>

NO.	DATE OF AMENDMENT	REVISION NO.	AMENDMENT REFERENCE
			<p><i>to be submitted to MOH (HQ) within 7 working days after all corrective actions have been taken</i>" is included.</p> <p><u>Para 7</u> The word "programme" is included.</p> <p><u>Para 10</u> "Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results" is included</p> <p>EC No "1441/2007" is included.</p> <p>"ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories" is included</p> <p><u>Appendix 1</u> Group, parameters and minimum sample size for Marine Biotoxins is deleted.</p> <p><u>Appendix 2</u> The original form is deleted and replaced with a new form (Rev 1)</p> <p><u>Appendix 3</u> The column for "Method and Technique" is deleted.</p> <p>Contact person / Tel. / Fax / e-mail for related agencies are included.</p> <p><u>Appendix 4</u> New appendix "COMPILATION OF ANALYTICAL RESULTS OF SAMPLES TAKEN UNDER CAPTURE FISHERY AND</p>

NO.	DATE OF AMENDMENT	REVISION NO.	AMENDMENT REFERENCE
			<p><i>FISHERY END PRODUCTS MONITORING PLANS</i> is included.</p> <p><u>Appendix 5</u> New appendix <i>“CONTRAVENTION REPORT FISHERY PRODUCTS MONITORING PROGRAMMES FOR EXPORT TO EU”</i> is included.</p> <p><u>Appendix 6</u> Sampling point at <i>“landing site”</i> is excluded from the list.</p> <p>Official control for <i>“Toxic and Poisonous Fishery Product”</i> is deleted.</p>
2.	31 March 2010	03	<p><u>Para 5.3 (ii)</u> The word <i>“PAH”</i> is included.</p>
3.	12 May 2010	04	<p><u>Para 4.3 (ii)</u></p> <p>New statement <i>“Samples for histamine analysis are to be taken from species of fish associated with high level of histamine”</i> is included.</p> <p><u>Appendix 3</u></p> <p>The original <i>“List of Officials Laboratories for Capture Fishery Products Monitoring Plan”</i> is replaced by a new <i>“List of Officials Laboratories for Capture Fishery Products Monitoring Plan”</i></p>

1. INTRODUCTION

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

Ministry of Health (MOH) designs the plan, determines and manages the operational process, which include product sampling, identification and dispatch to laboratories, data management and analysis and initiation of trace-back activities.

2. SCOPE

All capture fishery 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, 1441/2007, 2074/2005, and Council Regulation (EC) No 2406/96

4. SAMPLING

4.1 General

Sampling of capture fishery products are carried out randomly at processing establishment and landing site level 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 plan prepared by MOH for sampling at establishment level.
- 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

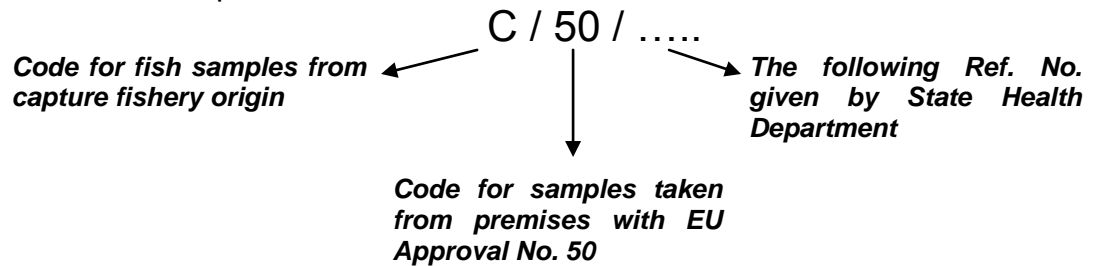
Samples should be handled, packaged and delivered accordingly to the laboratory requirements to maintain the integrity of the samples.

- i. Samples of raw material are to be taken for monitoring of histamine and contaminants.
- ii. Samples for histamine analysis are to be taken from species of fish associated with high level of histamine.
- 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 an appropriate and secured place and at appropriate temperature.
- v. Transportation of samples to the laboratory could 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 For Monitoring of Export of Fishery 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 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 capture fisheries monitoring plan has a defined performance criterion for timeliness of analysis and reporting of results.
- ii. Turnaround time is defined as time taken between the arrival 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 compilation 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.
 - 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 without delay 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 remaining products in the processing establishment;
 - 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 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 PLAN

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

8. RE-EXAMINATION OF PLAN

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

9. SUPPORTING DOCUMENT

- Appendix 1 : Contaminants to be Monitored Under Capture Fishery Products Monitoring Plan
- Appendix 2 : Request Form for Analysis of Samples Taken For Monitoring of Export of Fishery Products
- Appendix 3 : List of Official Laboratories Approved for Capture Fishery Products Monitoring Plan
- Appendix 4 : Compilation of Analytical Results of Samples Taken For Capture Fishery and Fishery End Products Monitoring Plans Year _____
- Appendix 5 : Contravention Report Fishery Products Monitoring Programmes for Export to EU
- Appendix 6 : Summary of European Union Requirements for Capture Fishery 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 854/2004 (laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption);
- iii. Commission Regulation (EC) No 1881/2006 (setting maximum levels for certain contaminants in foodstuffs);
- iv. 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);
- v. 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);
- vi. Commission Regulation (EC) No 2073/2005 and 1441/2007 (on microbiological criteria for foodstuffs);
- vii. 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);
- viii. Council Regulation (EC) No 2406/96 (laying down common marketing standards for certain fishery products);
- ix. ISO/IEC 17025- General requirements for the competence of testing and calibration laboratories

Appendix 1

Contaminant to be Monitored under Capture Fishery Products Monitoring Plan

Group	Parameters	Minimum sample size
Microbiology	Histamine	250 g whole
Contaminant	Mercury (total mercury)	1 kg whole
	Lead & Cadmium	
	Dioxins	500 g edible portion(excluding head, bone, tail etc)
	PAH	
	PCBs	
Others	TVB-N	500 g edible portion (excluding head, bone, tail etc)

**Please refer to Summary of European Union Requirements for the detail of analysis.

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**Appendix 2
Rev.1**

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

Laboratory: _____

Competent Authority: _____

Date of Sampling: _____

Name and Address of Establishment : _____

Monitoring program: Capture Fishery 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 Capture Fishery Products Monitoring Plan

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 / Ms. Zalilah Nasir Tel: 603-61565109 Fax: 603-61402249 E-mail: tosiahabdullah@moh.gov.my zalilah.nasir@moh.gov.my	Lead Cadmium Total Mercury
2.	Public Health Laboratory Ipoh Ministry of Health Malaysia Lot 39052 Jalan Jelapang 30020 Ipoh Perak, Malaysia	Ms. Kalai Vaani Vengrasalam Tel: 05-5287829 Fax: 05-5287836 E-mail: kalai@moh.gov.my	Total Mercury
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	Total Mercury
4.	Food Safety and Quality Laboratory Selangor Level 1 and 2 Bangunan Hospital Lama Poliklinik Aneka Jalan Istana 41000 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
5.	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	Histamine
6.	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 PCBs

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Appendix 4

**COMPILATION OF ANALYTICAL RESULTS OF SAMPLES TAKEN UNDER CAPTURE FISHERY AND FISHERY END PRODUCTS MONITORING
PLANS YEAR _____
(Ministry of Health Malaysia)**

STATE	EXPORT ESTABLISHMENT	SAMPLE NAME	CATEGORY (C/FA/FC)	TYPE (CRUSTACEAN / FISH / CEPHALOPOD / SURIMI)	BATCH NO. & PRODUCTION DATE OF SAMPLE	SOURCE OF RAW MATERIAL (LOCAL / IMPORTED)	NAME AND ADDRESS OF SUPPLIER OF RAW MATERIAL	SAMPLE REFERENCE NO.	SAMPLING DATE	DATE SAMPLE RECEIVED AT LAB	LABORATORY	DATE OF CERTIFICATE OF ANALYSIS (CoA)	DATE RECEIPT OF ANALYSIS RESULT BY STATE HEALTH DEPARTMENT	LAB NO.	PARAMETER OF ANALYSIS	RESULT OF ANALYSIS	LOD/LOQ	EU DECISION LIMIT	CONTRAVENTE	REMARK	TAT (14/30 DAYS)	TAT *	TAT (C/ NC)	

Note:
 CATEGORY (C/FA/FC) : C - Capture Fishery Raw Materials, FC - Capture Fishery End Products, FA - Aquaculture End Products
 TAT : Turn Around Time (time taken from date sample received at lab to date of Certificate of Analysis (CoA))
 TAT (C/NC) : TAT (Comply / Non-comply)

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Appendix 5

**CONTRAVENTION REPORT
FISHERY PRODUCTS MONITORING PROGRAMMES 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 (FA) <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	

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) 	

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	
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 :

Appendix 6

SUMMARY OF EUROPEAN UNION REQUIREMENTS CAPTURE FISHERY 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	a) Processing establishment	a) Freshness Ratings b) Size category	<i>Appendix i</i>
Freshness Indicators	Commission Regulation (EC) No 2074/2005	Freshness criteria for fish & fishery product	Fishery Products	a) Processing establishment	TVB-N	<i>Appendix ii</i>
Parasites	Commission Regulation (EC) No 2074/2005	Determine fish infested to parasites are not released for human consumption	Fishery Products			
Histamine	Commission Regulation (EC) No 2073/2005	Microbiology criteria for foodstuff	Fishery Products	Product placed on the market during shelf-life	Histamine	<i>Appendix iii</i>
Contaminants	Commission Regulation (EC) No 1881/2006	Maximum level for certain contaminants in foodstuffs	Fishery Products	a) Landing Site b) Processing establishment	a) Lead b) Cadmium c) Mercury d) Dioxins & PCBs e) PAH (polycyclic aromatic hydrocarbons) – benzo(a) pyrene	<i>Appendix iv</i>

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	Seaweedly	No smell of seaweed; neutral smell	Fermented; slightly sour	(2) Sour
	Fresh oily; peppery; earthy smell	Oily; seaweedly 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 (ventral 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

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	Clear reddish-pink in colour with small white flecks; pectoral part of shell predominantly light in colour	<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
2) Deep-water prawn	Uniformly pink	
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

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 miligrams of nitrogen/100 grams of flesh
Species belonging to the <i>Pleuronectidae</i> family (with the exception of halibut: <i>Hippoglossus</i> spp.)	30 miligrams 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 miligrams 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	
1.25 Fishery products from fish species associated with high amount of histidine ⁽¹⁶⁾	Histamine	9 ⁽¹⁷⁾	2	100 mg/kg	200 mg/kg	Products placed on the market during their shelf-life
1.26 Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with high amount of histidine ⁽¹⁶⁾	Histamine	9	2	200 mg/kg	400 mg/kg	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.

(17) Single sample may be taken at retail level. In such case the presumption laid down in Article 14(6) of Regulation (EC) No. 178/2002, according to which the whole batch should be deemed unsafe, shall no apply.

Interpretation of the test results

i. Histamine in fishery products from fish species associated with a high amount of histidine:

— satisfactory, if the following requirements are fulfilled:

1. the mean value observed is $\leq m$,
2. a maximum of c/n values observed are between m and M,
3. no values observed exceed the limit of M,

— unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are $> M$.

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
3.1	Lead		Reg. 333/2007
3.1.5	Muscle meat of fish ⁽²⁴⁾ ⁽²⁵⁾	0.30	
3.16	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>) ⁽²⁶⁾	0.50	LOD : 1/10 maximum level Reg. 1881/2006 LOQ: 1/5 maximum level
3.1.7	Bivalve molluscs ⁽²⁶⁾	1.5	
3.18	Cephalopods (without viscera) ⁽²⁶⁾	1.0	
3.2	Cadmium		Reg. 333/2007
3.2.5	Muscle meat of fish ⁽²⁴⁾ ⁽²⁵⁾ , excluding species listed in 3.2.6 and 3.2.7	0.050	LOD : 1/10 maximum level Reg. 1881/2006 LOQ: 1/5 maximum level
3.2.6	Muscle meat of the following fish ⁽²⁴⁾ ⁽²⁵⁾ : anchovy (<i>Engraulis species</i>) bonito (<i>Sarda sarda</i>) common two-banded seabream (<i>Diplodus vulgaris</i>) eel (<i>Anguilla anguilla</i>) grey mullet (<i>Mugil labrosus labrosus</i>) horse mackerel or scad (<i>Trachurus species</i>) louver or luvar (<i>Luvarus imperialis</i>) sardine (<i>Sardina pilchardus</i>) tuna (<i>Thunnus species</i> , <i>Euthynnus species</i> , <i>Katsuwonus pelamis</i>) wedge sole (<i>Dicologlossa cuneata</i>)	0.10	
3.2.7	Muscle meat of swordfish (<i>Xiphias glasius</i>) ⁽²⁴⁾ ⁽²⁵⁾	0.30	
3.2.8	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of the lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>) ⁽²⁶⁾	0.50	
3.2.9	Bivalve molluscs ⁽²⁶⁾	1.0	
3.2.10	Cephalopods (without viscera) ⁽²⁶⁾	1.0	
3.3	Mercury		Reg. 333/2007
3.3.1	Fishery products ⁽²⁶⁾ and muscle meat of fish ⁽²⁴⁾ ⁽²⁵⁾ , excluding species listed in 3.3.2. The maximum level applies to crustaceans, excluding the brown meat of the	0.50	LOD : 1/10 maximum level Reg. 1881/2006

	Foodstuffs	Maximum levels (mg/kg wet weight)	Performance criteria for sampling and for the method of analysis
	crab and excluding head and thorax meat of the lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>)		LOQ: 1/5 maximum level
3.3.2	Muscle meat of the following fish ⁽²⁴⁾ ⁽²⁵⁾ : anglerfish (<i>Lophius species</i>) atlantic catfish (<i>Anarhichas lupus</i>) bonito (<i>Sarda sarda</i>) eel (<i>Anguilla species</i>) emperor, orange roughy, rosy soldierfish (<i>Hoplostethus species</i>) grenadier (<i>Coryphaenoides rupestris</i>) halibut (<i>Hippoglossus hippoglossus</i>) marlin (<i>Makaira species</i>) megrim (<i>Lepidorhombus species</i>) mullet (<i>Mullus species</i>) pike (<i>Esox lucius</i>) plain bonito (<i>Orcynopsis unicolor</i>) poor cod (<i>Tricopterus minutes</i>) Portuguese dogfish (<i>Centroscymnus coelolepis</i>) rays (<i>Raja species</i>) redfish (<i>Sebastes marinus</i> , <i>S. mentella</i> , <i>S. viviparous</i>) sail fish (<i>Istiophorus platypterus</i>) scabbard fish (<i>Lepidopus caudatus</i> , <i>Aphanopus carbo</i>) seabream, Pandora (<i>Pagellus species</i>) shark (<i>all species</i>) snake mackerel or butterfish (<i>Lepidocybium flavobrunneum</i> , <i>Ruvettus pretiosus</i> , <i>Gempylus serpens</i>) sturgeon (<i>Acipenser species</i>) swordfish (<i>Xiphias gladius</i>) tuna (<i>Thunnus species</i> , <i>Euthynnus species</i> , <i>Katsuwonus pelamis</i>)	1.0	

Footnotes:

- (24) Fish listed in this category as defined in category (a), with the exclusion of fish liver falling under code CN 0302 70 00, of the list in Article 1 of Council Regulation (EC) No 104/2000 (OJ L 17, 21.1.2000, p. 22) as last amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ L 236, 23.9.2003, p. 33). In case of dried, diluted, processed and/or compound foodstuffs Article 2(1) and 2(2) apply.
- (25) Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish.
- (26) Foodstuffs falling within category (c) and (f) of the list in Article 1 of Regulation (EC) No 104/2000, as appropriate (species as listed in the relevant entry). In case of dried, diluted, processed and/or compound foodstuffs Article 2(1) and 2(2) apply.

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 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.

Appendix v**TOXIC AND POISONOUS FISHERY PRODUCT****REGULATION (EC) NO 853/2004****Annex III, Section VIII, Chapter V (E), 1****a) Poisonous Fish**

Fishery products derived from poisonous fish of following families must not placed on the market :

- 1) *Tetraodontidae*
- 2) *Moridae*
- 3) *Diodontidae*
- 4) *Canthigasteridae*

Annex III, Section VII, Chapter V, 2**a) Marine Biotoxins**

Toxin	Tolerance
Paralytic Shellfish Poison (PSP)	800 µg/kg
Diarrhetic Shellfish Poison (DSP)	Okadaic Acid, Dinophysistoxins and Pectenotoxins together – 160 µg/kg of okadaic acid equivalents Azaspiracids – 160 µg/kg of azaspiracid equivalents
Amnesic Shellfish Poison (Domoic Acid) (ASP)	20 mg/kg of domoic acid
Yessotoxins	1 mg/kg of yessotoxins equivalents