FOOD SAFETY AND QUALITY DIVISION

MINISTRY OF HEALTH MALAYSIA

ACTIONS TO BE TAKEN BY COMPETENT AUTHORITY FOLLOWING THE OCCURRENCE OF RED TIDE

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.	7 April 2010	01	Para 12 The original Para 12 is deleted and replaced with a new para. New Para 13, 14, 15 and 16 New Para 13, 14, 15 and 16 are included. Appendix 1 ***"Contaminant to be Monitored under for Marine Biotoxins"*** is included. Appendix 2 **"Request Form for Analysis of Samples Taken For Monitoring of Export of Fishery Products"** is included. Appendix 3 **"List of Official Laboratory for Monitoring of Marine Biotoxins"** is included. Appendix 4 **"Compilation Of Analytical Results Of Samples Taken Under Capture Fishery And Fishery End Products Monitoring Plans Year _____"** is included. Appendix 5 **"Contravention Report Fishery Products Monitoring Programmes For Export To EU"** is included. Appendix 6 **"European Union Requirements For Marine Biotoxins"** is included.

1. Red Tide or Harmful Algal Blooms (HABs) in Sabah are caused by *Pyrodinium bahamense var. compressum*, a marine dinoflagellate , which effectuate fatalities to human and fish due to the marine biotoxin it produces. The biotoxin produced can cause Paralytic Shellfish Poisoning (PSP). During the occurrences of red tide, small planktinovorous fish and molluscan shellfish are known to be affected. Red Tides were frequently reported in Sabah seawater since it was first detected in 1976. The Sabah State Fishery Department and Sabah State Health Department have established monitoring procedures for the management of red tides and paralytic Shellfish Poisoning in Sabah as in "*Manual Prosedur Kerja Pemantauan Dan Pengurusan Kejadian Air Merah Di Negeri Sabah*" (Work Procedure Manual for the Monitoring and Management of Red Tide in Sabah).

2. In the event of red tide occurrence, it is the responsibility of the export establishment to take necessary action to ensure that fishery raw materials are not obtained from farms or fishing areas affected by the red tide.

3. The Department of Fisheries, Head Quarters [DOF (HQ)] shall immediately alert in writing to the Ministry of Health, Head Quarters [MOH (HQ)] on the occurrence of red tide. Upon receiving such an alert, MOH (HQ) shall immediately suspend the approval of the export establishment.

4. MOH (HQ) shall immediately notify the export establishment in writing of the occurrence of red tide and request for information on the preventive measures taken to address the possible contamination of fishery raw materials by biotoxin. The measures should include own checks on biotoxin in fishery raw materials. The frequency of the own checks is to be risk-based.

5. MOH (HQ) shall immediately notify the State Health Department in writing of the occurrence of red tide and request the State Health Department to investigate the possible contamination of fishery raw materials obtained by the concerned export establishment.

6. The designated officers in the State Health Department shall conduct joint investigation with the State Fisheries Department and carry out follow-up actions as follows:

   6.1 Review of traceability records on sources of the fishery raw materials i.e. farm and/or fishing area;

   6.2 Sampling of suspected fishery raw materials for biotoxin analysis;

   6.3 Conduct follow-up investigation to verify the implementation of the control measures by the export establishment, where necessary;

6.4 The Head of Food Safety & Quality Unit of the State Health Department shall forward the investigation report to MOH (HQ) within 7 working days from the date of notification.

7. If MOH (HQ) is not satisfied with the investigation findings, the MOH (HQ) may take the following action where appropriate:

   a. Seek further clarification from the State Health Department; or

   b. Request for further investigation; or

   c. Request for additional remedial measures to be undertaken by the export establishment.

8. A meeting is to be held at HQ level to discuss the findings of the investigation carried out by the State Health Department on the export establishment and State Fisheries Department on the farms and/or fishing areas.

9. The suspension of approval of the export establishment will only be lifted when the MOH (HQ) is satisfied that there is no possible contamination of the fishery raw materials with marine biotoxin.

10. Once the suspension of the approval has been lifted, the State Health Department shall take samples from five (5) subsequent consignments of fishery products for purposes of issuance of Health Certificate in order to verify that the fishery products are not contaminated with biotoxin.

11. The State Health Department shall monitor the biotoxin level in fishery raw materials at the export establishment. The monitoring frequency is to be risk-based.

12. Minimum sample weights to be taken according to the parameter of analysis are as stated in Appendix 1.

13. 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.

14. Official laboratory providing analytical service for parameter biotoxin is as in Appendix 3.

15. Official laboratory shall have quality assurance programme based on ISO/IEC 17025 and performance of analytical methods shall be in compliance to Commission Decision 2002/657/EC.

16. Reporting of Analytical Results

i. 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. In the event of non-compliance of the TAT, reasons are to be submitted to the CA by the laboratories.

ii. Analytical results shall be reported in compliance to the requirements under clause 5.10 of ISO/IEC 17025.

iii. 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.

iv. The laboratory shall issue results of analysis to the sampler with a copy to the State Health Department, State Fisheries Biosecurity Unit, DOF (HQ) and MOH (HQ) within 3 working days from the date of reporting.

v. 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.

vi. 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, State Fisheries Biosecurity Unit, DOF (HQ) and MOH (HQ).

vii. The State Health Department shall take appropriate follow-up action at the establishment within three (3) working days after preliminary reports.

viii. All analytical results are to be kept for at least 3 years.

17. Follow-up Action

i. 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:

a. To notify in writing the contravention to the establishment.

b. To ensure the food business operators take immediate corrective actions to address the non-conformance and ensure that the non-conformance does not recur.

c. 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.

d. 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:

- Re-sampling of the remaining products in the processing establishment;
- To increase the control activities such as inspection & monitoring

e. To suspend or withdraw the identified establishment from the National Approved List, depending on the seriousness of the contravention.

ii. 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.

18. References

i. Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results;

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. ISO/IEC 17025- General requirements for the competence of testing and calibration laboratories

19. Supporting documents

Appendix 1 : Contaminant to be Monitored under for Marine Biotoxins

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 : European Union Requirements For Marine Biotoxins

Appendix 1

Contaminant to be Monitored under for Marine Biotoxins

Group	Parameters	Minimum sample size
Marine Biotoxins	Paralytic Shellfish Poison (PSP)	1 kg whole

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 : _____

Appendix 3

List of Official Laboratory for Monitoring of Marine Biotoxins

No.	Full Address of Agency	Contact person / Tel. / Fax / e-mail	Scope/Analyte
1.	Pusat Penyelidikan Perikanan 89400 Likas Kota Kinabalu Sabah	Mr. Boniface Jintony Ms. Aina Buyong Tel: 088-425677, 088-428415/416, 088-424810 Fax: 088-425890 Email: fish.dept@sabah.gov.my	PSP Toxin

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	CONTRAVENE	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)

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	☐ Capture Fishery Raw Material (C) ☐ Capture Fishery End Product (FA) ☐ Aquaculture End Product (FA)
6.	Type of sample	☐ Finfish ☐ Crustacean ☐ Cephalopod ☐ 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	

NO.	DESCRIPTION	
14.2	Result of analysis	
14.3	EU Standard	
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 • Local source of raw material: - Name and address of farm/ vessel/ landing site - Date of harvesting • Imported raw material: - 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: • Date of instructions • Summary of instructions • Time period for corrective actions committed by establishment (attach a copy of the instruction e.g. letter, email)	

NO.	DESCRIPTION	
16.2	Instructions to other agency (if applicable) (state the name of the agency): • 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)	
17.	**Corrective Actions**	
17.1	Corrective actions committed by establishment: • 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: • 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): • Date of re-sampling • Result of re-sampling	
18.2	Corrective actions taken by establishment: • Date of report on corrective actions taken by establishment • Summary of corrective actions taken by establishment	

NO.	DESCRIPTION	
	(attach a copy of the report)	
18.3	Corrective actions taken by other agencies: • 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	
20.	General comment	

Prepared by: …….
(Signature)

Name : …….

Designation : ……..

State Health Department : ……

Date : ……

Appendix 6

EUROPEAN UNION REQUIREMENTS FOR MARINE BIOTOXINS

REGULATION (EC) NO 853/2004

Annex III, Section VII, Chapter V, 2

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