



FOOD SAFETY AND QUALITY DIVISION

MINISTRY OF HEALTH MALAYSIA

PROCEDURE FOR INTERNAL AND EXTERNAL AUDITS ON COMPETENT AUTHORITIES

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Title: **PROCEDURE FOR INTERNAL AND EXTERNAL AUDITS ON COMPETENT AUTHORITIES**

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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. | 22 February 2010 | 02 | <p><u>Para 1</u> The original statement is deleted and the replaced with new statement.</p> <p><u>Para 3</u> New Para "Frequency of Audits" is included.</p> <p><u>Para 4</u> Word "external" is included. For responsibility, "CCA/CA" changed to "HQ". Word "external" is included. The original statement is changed to "g". For Actions to be taken, the new statement "Prepare a preliminary report on the internal/external audit findings and submit the report to HQ with a copy to relevant CA and MOH (HQ)" is included. "Lead auditor" is included in Responsibility column. The original statement is changed to "h". The original statement is changed to "i". The original statement is deleted and changed to "Prepare a preliminary report on the internal/external audit findings and submit the report to HQ with a copy to relevant CA and MOH (HQ)". The original statement is changed to "j". For Actions to be taken, the new statement "The audit reports will be presented and discussed during technical committee</p> |

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|-----|-------------------|--------------|---|
| | | | <p><i>meeting involving all Competent Authorities to ensure continuous improvement are made in the official control system</i>” is included. <i>“MOH (HQ)”</i> is included in <i>Responsibility</i> column.</p> <p><u>Para 6 ii)</u> The reference <i>“Commission Decision 94/256/EC”</i> is deleted.</p> <p><u>Appendix 3</u> No. 9 <i>“Recommendation on action to be taken if status of overall compliance is partial compliance (PC) and non-compliance (NC)”</i> is deleted.</p> |

1. Introduction

Internal audits are carried out on the Competent Authority at state level by designated officers of the same Competent Authority from HQ level and from other states.

In addition, external audits are carried out on one Competent Authority by other Competent Authorities, both at HQ level and state level.

2. Purpose

To ensure the official controls being carried out by the Competent Authorities are in accordance with the relevant EC Regulations, Commission Decisions, protocols and standard operating procedures.

3. Frequency of Audits

Audits are carried out once a year.

4. Actions to be taken

| | Actions to be taken | Responsibility |
|----|---|-----------------------|
| a. | Prepare a schedule for internal/external audit. | HQ |
| b. | Inform the relevant Competent Authority (CA) of the date of audit. | Lead Auditor |
| c. | Conduct opening meeting with the officers of the relevant CA explaining the scope and objective of the audit. | Lead Auditor |
| d. | Carry out the internal/external audit using the checklist in Appendix 1 as a guide. | Audit Team |
| e. | Conduct closing meeting and issue Corrective Action Requests (CARs) using the format in Appendix 2. | Lead Auditor |
| f. | Prepare a preliminary report on the internal/external audit findings and submit the report to HQ with a copy to relevant CA and MOH (HQ). | Lead Auditor |
| g. | Follow-up on CARs to ensure corrective actions are taken without delay. | Lead Auditor |
| h. | Receive the report on the action taken on the CARs issued and close them out if the corrective action taken is satisfactory. | Lead Auditor |

| | Actions to be taken | Responsibility |
|----|--|-----------------------|
| | Follow up with the CA if the action taken is not satisfactory and where necessary carry out an onsite follow-up visit. | |
| i. | Prepare a final report on the internal/external audit findings and submit the report to HQ with a copy to relevant CA and MOH (HQ). | Lead Auditor |
| j. | Keep a copy of audit report in the relevant file. | Lead Auditor |
| k. | The audit reports will be presented and discussed during technical committee meeting involving all Competent Authorities to ensure continuous improvement are made in the official control system. | MOH (HQ) |

5. Records

| | Type of record | Duration to be kept |
|------|-------------------------------------|----------------------------|
| i. | CARs issued | 3 years |
| ii. | Evidence of corrective action taken | 3 years |
| iii. | Audit report | 3 years |

6. References:

- i. Regulation (EC) No. 882/2004
- ii. National Approval And Listing Protocol
- iii. Protocol For Issuance of Health Certificate For The Export of Fishery Products To The European Union
- iv. Official Verification Protocol
- v. Action To Be Taken By Competent Authority Following RASFF Notifications/Other Alerts
- vi. SOP For Monitoring Capture Fisheries
- vii. SOP For Monitoring of Water & Ice Used in The European Union Supply Chain
- viii. SOP For Monitoring of Fisheries End Product
- ix. SOP For Aquaculture Residue Monitoring Plan



Appendix 1

Checklist for Internal / External Audit on Competent Authorities

| | |
|-------------------------------------|-------|
| Audited Competent Authority: | |
|-------------------------------------|-------|

Details:

| | |
|--|---|
| Date of Internal / External Audit *: | |
| State Representative sand Designation : | |
| Number of Staff Performing Official Control: | |
| Auditors: | |
| Scope of Audit: | The internal audit is carried out based on EU requirement to ensure competent authority achieving the requirement set in EU commission requirement. (Reg. 882/2004, Title II, Chapter II, Article 4, 6). These include export establishment and sources of raw materials and ice. |
| Audit Checklist: | |
| CL 01: Competent Authorities CL 02: Sampling & Analysis CL 03: Official Control System | |

*Delete where not related

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CL 01: COMPETENT AUTHORITIES

| Elements to be checked | Legislation and references | Findings/Observation | Status Compliance (Yes/No) |
|---|--|-----------------------------|-----------------------------------|
| <u>1. Competent Authorities & Operational Criteria</u> 1.1 Officers are designated to carry out official control. 1.2 Market Access Group formed and functioning in regional level and central level. | Reg. 882/2004, Article 4 | | |
| <u>2. Competency of Staff Performing Official Control</u> 2.1 Officer appropriately trained on EU requirement. 2.2 Officer trained and aware of HACCP requirement 2.3 Training records on EU export requirements 2.4 Qualification of the officer sufficient to carried out official control 2.5 Officer understand protocols and SOPs | Reg. 882/2004, Annex II, Chapter I Reg. 882/2004, Chapter III, Article 51 | | |
| <u>3. Control and verification procedures (control activities , method and technique)</u> 3.1 Protocols and SOPs available at operation level <ul style="list-style-type: none">- National Approval and Listing Protocols- Health Certificate Issuance Protocol for The Export of Fishery Products to the EU- Official Verification Protocol- Standard Operating Procedures for Malaysian Aquaculture Residue Monitoring Plan- Sampling Plan for Captured Fishery Products | Reg 882/2004, Title II, Chapter V, Article 14 | | |

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| Elements to be checked | Legislation and references | Findings/Observation | Status Compliance (Yes/No) |
|--|-----------------------------------|-----------------------------|-----------------------------------|
| <p>for EU Market</p> <ul style="list-style-type: none">- Actions To Be Taken By Competent Authorities Following RASFF Notification- Other relevant procedures <p>3.2 Official control is carried out using appropriate control method, techniques and tools (auditing, verification, monitoring, surveillance, sampling and analysis)</p> <p>3.3 Verification of establishment based on checklist accordance to EU legislation</p> <p>3.4 Detailed reports of official control carried out and properly documented</p> <p>3.5 Timely closed-out of CARs and records</p> | | | |

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CL 02: SAMPLING AND ANALYSIS

| Elements to be checked | Legislation and references | Findings/Observation | Status Compliance |
|--|--|----------------------|-------------------|
| <p>1. <u>Method of Sampling & Analysis</u></p> <p>1.1 Determined the need of sampling and testing accordingly to the assess safety of the product and process.</p> <p>1.2 Sampling carried out according to sampling plan:</p> <ul style="list-style-type: none">- ARMP- CFMP- Water & Ice- Organoleptic examination- Food additives- Freshness indicator- Microbiological checks- Poisonous Fishery Product (PSP, Biotxin etc)- Parasites | <p>Reg. 882/2004, Title II, Chapter III, Article 11</p> | | |
| <p>2. <u>Testing Laboratories</u></p> <p>2.1 List of laboratories carrying out analysis by parameters and accreditation</p> | <p>Reg. 882/2004, Title II, Chapter III, Article 12</p> | | |

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CL 03: Official Control System

| Elements to be checked | Legislation and references | Findings/Observation | Status Compliance |
|---|--|----------------------|-------------------|
| <p><u>1. Implementation of Official Controls</u></p> <p>1.1 Annual verification schedule available and documented</p> <p>1.2 Verification frequency should be programmed regularly based on the Verification Protocol</p> <p>1.3 Verification should include various outlet:</p> <ul style="list-style-type: none">- Refrigerated store,- Factory Vessel,- Transport vehicles,- Processing establishment, and- Ice factories <p>1.4 Checklist available for various outlets.</p> <p>1.5 Reports of verification are available and documented</p> <p>1.6 A list of the approved establishment, raw material, ice factories and etc available</p> <p>1.7 Action of non-compliance clearly drawn up and documented. The officer understand the structure and procedures in term category of non-compliance.</p> <p>1.8 Effectiveness of evaluation/assessment of the programme been carried out</p> <p>1.9 To keep records of fish entering/leaving the farms and to record/report cases of increased mortality; and are properly documented; (DOF)</p> <p>1.10 Restrictive measures are applied without delay in case of suspect or outbreak of infectious diseases of fish. (DOF)</p> | <p>Reg. 882/2004, Chapter V, Article 14</p> <p>Reg. 882/ 2004, Chapter VII, Article 31</p> <p>Reg. 882/2004, Title VII, Chapter 1, Article 54</p> | | |

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|--|---|--|--|
| <p><u>2. Official Certification Requirement</u></p> <p>2.1 FExCIS database available 2.2 Health certificate with security features 2.3 Traceability of the certificate – unique and consistent numbering to trace back the certificate 2.4 Certificate and stamps should kept in secured place. 2.5 Effective records kept of distribution of health certificate 2.6 Health Certificate should be issued according to Certification Protocol 2.7 Random checking on consignment carried out</p> | <p>Reg. 882/2004, Title II, Chapter VII, Article 30 – 31</p> | | |
| <p><u>3. Management of Rapid Alert</u></p> <p>3.1 Rapid alert procedure available 3.2 Report on follow-up action taken</p> | <p>Reg. 882/2004, Title II, Chapter IV, Article 13</p> | | |

| | | |
|-----------------------------|-------------------|------------------|
| Signature | Signature : | Signature: |
| Name of CA Representative : | Name of auditor : | Name of auditor: |
| Date : | Date: | Date: |

CORRECTIVE ACTION REQUEST (CAR) FOR INTERNAL / EXTERNAL AUDITS

| | | |
|---|----------|-------|
| Audit No: | CAR No.: | Date: |
| Audited CA: | | |
| Address/Tel. No.: | | |
| CA representative(s): | | |
| Auditor(s): | | |
| Non-Conformance Report : Partial Compliance (PC) <input type="checkbox"/> Non-Compliance (NC) <input type="checkbox"/> | | |
| Signature:..... Name: <i>CA Representative</i> | | |
| Signature: Name:..... <i>Auditor</i> | | |
| Corrective Action required to fix and prevent recurrence: (To be completed by the audited CA) Completion target date: Signature:..... Name:..... Date: <i>CA Representative</i> | | |
| Signature: Name: Date: <i>Lead Auditor</i> | | |
| Follow-up audit comments Date CAR Closed Out:..... Signature: Name: <i>Lead Auditor</i> | | |

Appendix 3

VERIFICATION REPORT

1. Audited Competent Authority (CA):
2. Address :
3. Date of Audit :
4. Scope of Audit :
5. CA Representative(s) :
6. Auditor(s) :
7. Results and Observations¹ :

| NO. | NON-CONFORMANCE | CATEGORY PC / NC | CORRECTIVE ACTION TAKEN | DEADLINE | CLOSED- OUT |
|-----|-----------------|---------------------|----------------------------|----------|----------------|
| | | | | | |

¹ Fill up the table below

8.

(a) Status of Overall Compliance of CA (please tick where relevant):

Compliance (C) :

Partial Compliance (PC) :

Non-Compliance (NC) :

(b) Reasons for Status of Overall Compliance :

Signature :

Name of Lead Auditor :

Position :

Date :