LAMPIRAN 1

AUDIT-2/2014

FOOD SAFETY AND QUALITY DIVISION
MINISTRY OF HEALTH MALAYSIA

HACCP AUDIT PLAN

1.0 Objectives:

1.1 To verify that the HACCP and GMP system is effectively maintained

1.2 To verify effective implementation of corrective action on non-conformities rose in the last assessment.

2.0 Date Of Audit : _____

3.0 Location Of Audit : Write down the premise address

4.0 Products : List down the products as in Application Form/Certificate

5.0 Type of Audit:

5.1 Compliance / Surveillance / Renewal /Compliance for Additional product

6.0 Scope Of Audit :

6.1 Cover all the activities in processing from the point of receiving of raw material and packaging material, processing and packing until loading into delivery transport.

7.0 Certification Standard/Criteria/Requirement And Policy:

7.1 Company HACCP Manual and GMP Manual
7.2 Malaysian Certification Scheme for HACCP
7.3 Food Act 1983 & Food Regulations 1985
7.4 Food Hygiene Regulations 2009
7.5 MS 1480:2007 - Food Safety According to HACCP System
7.6 MS 1514:2009 - Good Manufacturing Practice (GMP) for Food.
7.7 Other related standards (if any): _____

8.0 Auditor Members :

8.1 Lead Auditor : _____

8.2 Auditor(s) :

a. _____

b. _____

9.0 Methodology of Audit

Witnessing operations, evaluating documents and records and interviewing of personnel including the management responsible for the area. It shall include an interview session with top management.

10.0 Aspect Of Audit

Document will be selected at random for the last 3 months. On-site inspection will be done through all production line and area.

10.1 Assessment of Documentation :

10.1.1 Clarification of adequacy document comments (If related)

10.1.2 HACCP Documentation

- HACCP manual - Hazard analysis, HACCP Summary Plan etc.
- CCP determination and Critical Limit determination.

10.1.3 Records:

- monitoring logbook/record
- Corrective action
- Verification procedures - Analytical results, complaints, product recall and product rejection, internal audits, Management Review Meeting.

10.1.4 Record on all GMP program.

Please make sure all the related documents ready.

10.2 On-Site Inspection :

10.2.1 Pre-Requisite Program, Verification on Process Flow, Plant Layout, Method of CCP's Recording.

10.2.2 Conduct observations on process, procedures and premises.

10.3 Identify Company representatives: accompanying personnel for onsite inspection- HACCP coordinator.

10.4 Remind the management on the factory to be present during the entry and exit meeting.

11.0 Categories of non-conformance

11.1 Serious

A severe deviation from planned requirements (MS1480: Latest Revision), such that maintenance of safety is impacted. Serious non-conformance represents a very significant omission or failure in the food safety system, one that has direct and adverse effect on the safety of the product.

11.2 Major

A significant deviation from planned requirements (MS1480: Latest Revision), such that maintenance of safety is inhibited. Major non-conformance represents unacceptable safety risk without constituting an overall system failure in the area concerned.

11.3 Minor

A deviation of the HACCP-based system relative to HACCP procedures and facility sanitation or others which are not likely to reduce materially the facility's ability to meet acceptable sanitation requirements or ensure food safety.

11.4 Observation

A recommendation given to affect an improvement.

12.0 Confidentiality Requirements

It is the policy of the Ministry of Health Malaysia to require its auditors to maintain confidentiality of information and documentation belonging to any organization. The auditor must not to disclose any information or documents obtained during the audit to the third party, without the approval of the organization, except as required by the laws. Auditors are also required to abide by the Ministry Code of Ethics for Auditors.

13.0 Working Language : English and Bahasa Malaysia

14.0 Reporting

14.1 Language : English
14.2 Format : Verbal and written

15.0 Facilities and assistance required

15.1 Meeting room.
15.2 Facilities for photocopying / printing/ camera.
15.3 Relevant personal protective equipment and related measuring tools (e.g. probe thermometer, lux meter, UV light etc. if available).
15.4 A representative of the company, acting as a guide to assist each auditor.
15.5 The production activities shall be available during the onsite audit.
15.6 All records shall be available at all time.

16.0 Audit itinerary

Time	**Day 1**
0900	Arrival at the establishment
0915	Entry meeting by Lead Auditor Lead Auditor briefing on audit purpose, audit scope, audit site, methodology and audit related arrangements
0930	Briefing by company's representative on major changes to the HACCP/GMP system since the last audit and the necessary safety / hygiene precautions to be taken during the audit
1000-1300	Commence audit : a. Document audit : • GMP and CCP program/records • HACCP and GMP Manual b. Onsite Inspection : • Verification of the effectiveness of the HACCP/GMP for all sites • Document or records
1300-1400	Breaks/Lunch
1400-1700	Document audit : • GMP and CCP program/records • HACCP and GMP Manual
1700	Finished for day 1
Time	**Day 2**
0900-1300	Arrival at the establishment. Commence audit a. Document audit : • GMP and CCP program/records • HACCP and GMP Manual b. Onsite Inspection (if necessary): • Verification of the effectiveness of the HACCP/GMP for all sites • Document or records
1300-1400	Breaks/Lunch
1400-1600	Document audit : • GMP and CCP program/records • HACCP and GMP Manual
1600-1630	Auditors discussion and report writing
1630-1700	Exit Meeting : Presentation of audit findings and recommendation the management