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MINISTRY OF HEALTH MALAYSIA

GUIDELINE FOR MALAYSIAN CERTIFICATION SCHEME FOR HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) AND GOOD MANUFACTURING PRACTICE (GMP)

Food Safety and Quality Division
Ministry of Health Malaysia
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1.0 INTRODUCTION

The guideline for Malaysian Certification Scheme for Hazard Analysis and Critical Control Point (HACCP) and Good Manufacturing Practice (GMP) describes the requirements for HACCP and GMP application under the HACCP and GMP certification scheme. This scheme is administered by the Food Safety and Quality Programme, Ministry of Health (MOH), which requires the food manufacturing premises to implement a HACCP and /or GMP system that meets the requirements, followed by the application and granting of the certification. The certification process includes adequacy audit, compliance audit and follow-up audit(s) by appointed auditors. Maintenance of the HACCP/GMP system by the certified food manufacturing premises will be verify through surveillance audit.

2.0 OBJECTIVE

These guidelines outline the procedure and requirements for HACCP and GMP certification from Ministry of Health Malaysia

3.0 SCOPE

3.1 This certification scheme is applicable to food manufacturing premise registered under Category P1 and P2 (for certain premises such as central kitchen, hospital etc). HACCP certification is granted based on specific food category following the Food Act 1983 whilst GMP certification is granted for the entire food manufacturing premises.

3.2 Reference documents are:

i. Food Act 1983 and its Regulations.
ii. Malaysian Standard (MS) 1514 Good Manufacturing Practices;
iii. Malaysian Standard (MS) 1480 Hazard Analysis Critical Control Point;

4.0 DEFINITIONS

For the purpose of this guideline, the following definitions shall apply:

4.1 Food Manufacturing Premises

Any premises comprising groups of people and facilities used for or in connection with food preparation, preservation, processing, reprocessing, manufacturing, packaging, repacking, conveyance, relabeling, reconditioning, storage, distribution, handling or offering for sale or supply in any sector of the food chain intended for human consumption.

4.2 Audit

An independent, systematic examination of objective evidence, performed by trained personnel, to determine whether the activities of the HACCP and/ or GMP systems and the related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve food safety objectives.

4.3 Auditor

A person formally appointed by MOH with technical competency in the HACCP and / or GMP system and audit.

4.4 Conformity

Conformity means activities are carried out in accordance to the required system element as laid out in the HACCP plan and the PRP documents.

4.5 Non-Conformity (NC)

Non-fulfillment of requirement.

4.6 Corrective Action Request (CAR)

Non-conformity issued by the auditor to the auditee.

4.7 HACCP / GMP Manual

Document prepared by the food manufacturing premises in accordance with the HACCP / GMP principles to ensure control of hazards significant for food safety in the product under consideration and its intended use.

4. 8 Pre-Requisite Programs (PRP)

Universal steps or procedures that control the operational conditions within a food establishment allowing for environmental conditions that are favorable to the production of safe food as describe in the MS1514 or other related document.

4.9 Good Manufacturing Practice

A set of requirements that controls the operational conditions within a food manufacturing premises allowing for the production of safe food.

4.10 Compliance Audit

Compliance audit consist of adequacy and on-site audit which applicable to new application and additional product(s). Compliance audit is conducted by means of an independent, impartial and objective audit to ascertain full compliance with criteria and requirements of MS 1480 and / or MS 1514.

4.11 Adequacy Audit

Upon receipt of the complete documentations, the auditors conduct an adequacy audit on the HACCP Manual and / or PRP/GMP Manual. The lead auditor collates comments on the adequacy audit and prepares the report.

4.12 Renewal audit

An audit conducted to verify compliance with the requirements and to determine whether the certification can be renewed.

4.13 Surveillance audit

An audit conducted at least **once (1) audit** within the validity period**.** The aim is to verify compliance with the requirements applicable at the time.

4.14 Follow-up audit

Follow up audit is conducted to obtain evidence of non-conformity has been satisfactorily corrected and implemented. The audit will be conducted by verification of document and / or on-site audit.

4.15 Serious

A severe deviation from planned requirements, such that maintenance of safety is impacted. Serious non-conformity represents a very significant to mission or failure in the food safety system, one that has a direct and adverse effect on the safety of the product.

4.16 Major

A significant deviation from planned requirements, such that maintenance of safety is inhibited. Major non-conformity represents an unacceptable safety risk without constituting an overall system failure in the area concerned.

4.17 Minor

A deviation of the system relative to HACCP/GMP 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.

4.18 Observation

A recommendation given to affect an improvement.

5.0 BENEFITS

The benefits of a MOH HACCP/GMP certification are as follows;

5.1 To facilitate the issuance of Health Certificate and export listing

5.2 To fulfill importing country requirements on food safety

5.3 To promote the product acceptance, both in Malaysia and international, of food produced from certified food manufacturing premises

5.4 To improve marketability of the certified product. HACCP and / or GMP logo can be used on food label.

5.5 Fast track for *Makanan Selamat Tanggungjawab Industri* (MeSTI) and / or GMP certification

5.6 To facilitate the industry to obtain incentive or other forms of financial assistance

6.0 GENERAL REQUIREMENTS FOR APPLICATION

Food manufacturing premises applying for HACCP or GMP certification shall fulfill the following requirements;

6.1 Food manufacturing premises shall be registered with Ministry of Health Malaysia (MOH) via online system at (*http://fosim.moh.gov.my*); [1]

6.2 Food manufacturing premises is registered with the Companies Commission of Malaysia (Suruhanjaya Syarikat Malaysia (SSM) except for government facilities;

6.3 Food manufacturing premises shall be licensed with local authorities or from the relevant government agencies except for government facilities;

6.4 Food manufacturing premises shall provide audited account or bank statement for company less than 1 year;

6.5 Food manufacturing premises processing Packaged Drinking Water, Natural Mineral Water and Ice shall obtain valid licensed from MOH prior to application;

6.6 The HACCP system shall be developed based on the Malaysian Standard MS1480 or any other requirements imposed by MOH;

6.7 GMP/PRP system shall be in place and documented based on the MS 1514 for food and/or any other requirements imposed by MOH;

6.8 The minimum document of HACCP and GMP Manual as stated in ***Appendix 1*** shall be available during submission of the application***.*** The Manual shall be duly signed and dated by the company management with executive responsibility; and

6.9 The HACCP and/or GMP system shall be implemented , records are available and maintained for a **minimum of three (3) months** prior to application.

7.0 APPLICATION PROCESS

7.1 The application for new / renewal of HACCP or GMP certification and additional product(s) (for HACCP) certification shall be made via online system at (*http://fosim.moh.gov.my*);

7.2 The application for renewal of certification shall be made at least **six (6) months** before expiry date. Application made after the expiry date will be rejected and the applicant need to re-apply as **new application**.

[1] *Note: A registered company can have more than one food manufacturing premises. The address can be the same or different from one another. Choose only the food manufacturing premises(s) that needs to apply for HACCP or GMP Certification.*

7.3 The application for renewal of certification will be rejected if the surveillance audit is not carried out **six (6) month** before the expiry date without any valid justification or agreed by MOH.

7.4 Only **one (1) application** can be applied at a time.

7.5 MOH will review and check the application and documents. Upon completeness of application, quotation will be issue to the applicant via FoSIM.

8.0 CERTIFICATION FEES

Payment must be made **within one (1) month** from quotation issuance date. If payment is not received within that time, application will be canceled. All payment made is **NOT REFUNDABLE**.

8.1 HACCP CERTIFICATION FEE

8.11 Certification fee for HACCP application is subject to the number of food category and the complexity of the process type involved. Detail on the fee is as in **Appendix 2** .

8.12 For new and additional product application, all payment will be submitted to MOH Trust Account for approval before appointment of the Auditor. Meeting for approval will be conducted by Finance Department **twice (2) a year.**

8.2 GMP CERTIFICATION FEE

Details on the GMP certification fee schedule is as in **Appendix 3.**

9.0 APPOINTMENT OF AUDITOR

9.1 MOH will appoint at least two (2) auditors for the audit. Details of auditors will be made known to the applicant via email / notification from the system.

9.2 Audit arrangements will be mutually agreed by the Lead Auditor and the applicant. Audit plan will be informed to the applicant by the Lead Auditor.

10.0 AUDITING PROCEDURE FOR COMPLIANCE AND ADDITIONAL PRODUCT AUDIT

10.1 Consist of adequacy and on-site audit which applicable to new application and additional product(s). Flow chart for compliance audit is shown in **Appendix 4**.

10.2 Auditor will conduct an adequacy audit on the HACCP and GMP Manual and all comments will be submitted to the applicant. The applicant shall respond to the comment (s) issued to the lead auditor before or during the on-site audit.

10.3 On-site audit will be carried out to verify the implementation of HACCP and / or GMP system. All document and record shall be made available during on-site audit. Food manufacturing premises shall conduct actual processing within the applied certification scope during on site audit.

10.4 Applicant are responsible to ensure all the processing activity within the certification scope are available during the onsite audit. Mock production is not allowed. Failure to do so could cause onsite audit to be postponed or applications to be cancelled and MOH will not responsible on any implication involved due to this.

10.5 Corrective Action Requests [CAR(s)] will be issued if there is any non-conformity. The non-conformity shall be classified as either observation, minor, major and serious. The food manufacturing premises is required to take corrective action for each non-conformity documented based on CAR(s) issued.

10.6. The food manufacturing premises shall respond to CAR(s) issued within **two (2) weeks** after the on-site audit to the lead auditor.

10.7 For **serious** non-conformances, corrective action shall be taken immediately and satisfactory closed by Lead Auditor **within two (2) weeks** from the onsite date. Serious non-conformances may result the application to be cancelled if corrective action is not satisfactory taken.

10.8 A **maximum of one (1) year** from on-site audit is given to the food manufacturing premises to complete the audit process by rectify all CAR(s) and satisfactory closed by Lead Auditor except for serious non-conformances

10.9 If the one (1) year period is exceeded, the application is deemed to be automatically void and food manufacturing premises has to reapply.

10.10 Follow up audit will be carried out when necessary.

10.11 Final audit report will be submitted by Lead Auditor to the Secretariat after all **CARs have been satisfactorily closed out. In certain cases, lead auditor may submit the final report at any point based on the Lead Auditor jurisdiction.** Final report will be discuss in the Committee Meeting and the committee will decide the approval status of the application. HACCP/GMP certificate will be granted upon approval.

11.0 AUDITING PROCEDURE FOR RENEWAL AND SURVEILLANCE AUDIT

11.1 Onsite audit will be carried out to verify the implementation of HACCP/GMP system. All the document and record shall be made available during on site audit. Food manufacturing premises shall conduct actual processing within the applied certification scope during on site audit.

11.2 Applicant are responsible to ensure all the processing activity within the certification scope are available during the onsite audit. Mock production is not allowed. Failure to do so could cause onsite audit to be postponed or applications to be cancelled and MOH will not responsible on any implication involved due to this.

11.3 Corrective Action Requests [CAR(s)] will be issued if there is any non-conformity. The non-conformity shall be classified as either observation, minor, major and serious. The food manufacturing premises is required to take corrective action for each non-conformity documented based on CAR(s) issued.

11.4 The food manufacturing premises shall respond to CAR(s) issued within two (2) weeks after the on-site audit to the lead auditor. A maximum of **six (6) months** from on-site audit is given to the food manufacturing premises to complete the audit process by rectify the CAR and satisfactory closed by Lead Auditor.

11.4 For **serious** non-conformances, corrective action shall be taken immediately and satisfactory closed by Lead Auditor within **two (2) weeks** from the onsite date. Serious non-conformances may result the application to be cancelled if corrective action is not satisfactory taken.

11.5 If the six (6) months period is exceeded, the application is deemed to be automatically void and food manufacturing premises has to reapply.

11.6 Follow up audit will be carried out when necessary.

11.7 Final audit report will be submitted by Lead Auditor to the Secretariat after all **CARs have been satisfactorily closed out. In certain cases, lead auditor may submit the final report at any point based on the Lead Auditor jurisdiction.** Final report will be discussed in the Committee Meeting and the committee will decide the approval status of the application. HACCP/GMP certificate will be granted upon approval.

11.8 For surveillance audit the final report will be reviewed and endorsed at State Health Department. However, if the compliance status is deemed to be unsatisfactory, the State Health Department may suggest to the Headquarter that the certificate be suspended or terminated. Final report will be discussed in the Committee Meeting and the committee will decide on the status of the certificate.

11.9 Flow chart for renewal and surveillance audit as in **Appendix 4** and **Appendix 5**

12.0 FAST TRACK FOR GMP AND MeSTI CERTIFICATION

12.1 All HACCP or GMP Certified premises will automatically obtain GMP and/ or MeSTI certification without any payment and audit process.

12.2 Any amendment on GMP and/ or MeSTI certification obtain through this process is not allowed.

12.3 The validity of the certificate shall follow the HACCP / GMP certification.

13.0 CERTIFICATION VALIDITY

13.1 The validity of HACCP/GMP Certification is **three (3) years** except for certification received through fast-track process.

13.2 For additional products, the validity of the certificate will follow the current HACCP certificate.

14.0 REPRINT OF CERTIFICATE

14.1 The application for reprint of certificate shall be made via online system at (*http://fosim.moh.gov.my*);

14.2 RM100 fee will be charged for each certificate reprint.

14.3 The original certificate shall be returned to MOH before received reprint certificate.

15.0 CHANGES / AMENDMENT OF CERTIFICATE

15.1 Any changes or amendment made on the certification are **not allowed** except:

15.1.1 Changes on the name of the food manufacturing premises
15.1.2 Changes on the name of existing products

16.0 CANCELLATION OF APPLICATION

MOH shall cancel any application if the applicant fails to the following conditions:

16.1 The amended application and supporting document not submitted within 14 working days after the applicant is notified of the document feedback

16.2 The certification fee and auditor expenditure are not paid within one (1) month from the issuance date of quotation;

16.3 The applicant delay more than two (2) months on the proposed on site audit date without valid justification.

16.4 The applicant not ready to be audited after appointment of the auditor

16.5 The applicant did not provide any feedback required by the audit team for the purpose of the onsite audit

16.6 Food manufacturing premises are found to be unprepared in terms of documentation, competency, infrastructure or other matters based on the assessment of the audit team during on-site audit.

16.7 The applicant fails to comply with any clause mentioned in this Malaysian Certification Scheme (MCS) for Hazard Analysis and Critical Control Point (HACCP) and Good Manufacturing Practice (GMP)

17.0 SUSPENSION AND TERMINATION OF CERTIFICATION

MOH has the right to suspend or terminate the certification under the following circumstances:

17.1 Products produced on the certified food manufacturing premises do not adhere to the Food Act of 1983 and its Regulations;

17.2 The certified food manufacturing premises HACCP and / or GMP system has persistently or seriously failed to meet the certification requirement;

17.3 The certified food manufacturing premises does not permit surveillance audit to be conducted at the required frequency;

17.4 The certified food manufacturing premises has failed to take corrective actions on non-conformity raised within the specified period;

17.5 The certified food manufacturing premises has misrepresented the status of its certification or has used the certificate, logo or audit reports in deceptive manner;

17.6 The food manufacturing premises are moved to a different location/ address or ceased operations;

17.7 The certified food manufacturing premises has voluntarily request for withdrawal of its certification; or

17.8 The certified food manufacturing premises not operated more than six (6) months without valid justification.

17.9 In the event of suspension, the certified food manufacturing premises shall take the corrective action within three (3) months. Failure to take the satisfactory corrective action within the specified period, may result in the termination of the certification.

17.10 The certified food manufacturing premises fails to comply with any conditions or requirement imposed by MOH from time to time.

18.0 APPEAL

18.1 The certified food manufacturing premises has 14 working days from the date of suspension or termination to file any appeal in writing.

18.2 To avoid conflicts of interest, all appeals will be reviewed by a committee consists of members who are not involved in the certification process

19.0 CONFIDENTIALITY

It is the policy of the MOH to require its staff members and auditors to maintain confidentiality of information and documentation belonging to any organization. The auditor shall not 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 Code of Ethics for Auditors.

20.0 OTHER CONDITIONS

All the food manufacturing premise are subjected to the following condition:

20.1 Any changes to the name of the food manufacturing premise or any major renovation carried out on the structure or design of the building or anything related there/to shall be informed in writing to the MOH for further action;

20.2 The food manufacturing premise shall at all times be subject to inspection, monitoring and enforcement conducted by MOH;

20.3 The food manufacturing premise shall be held responsible for any abuse or misappropriation of the Certificate. Any loss or damage of the Certificate shall immediately be informed in writing to the MOH;

20.4 The use of the certificate is subject to the laws and regulations that are currently in force in the country, which is related;

20.5 The certificate remains the property of MOH. The certificate may be withdrawn or terminated at any time if there is violation of any laws or regulations that are currently in force;

20.6 The use of the logo is only allowed for food product :

a. produced in the food manufacturing premises as stated in the MOH HACCP and/or GMP Certificate;
b. registered in the FoSIM system ; and
c. listed in the HACCP certificate (not applicable for GMP Certificate).

20.7 The color of logo shall follow color coded which required by MOH. The logo maybe reproduced in black and white or in the predominant color of packaging;

20.8 In the case where certified food manufacturing premises requests additional certificate at the same address but under a different name, the applicant shall submit a new application and pay the certification fee with exemption on the audit process.

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20.9 Food establishment shall control the Original Equipment Manufacturing (OEM) products produced and shall be responsible for any violation of the Food Act 1983 and it's regulations thereunder.

****MOH has the right to make any changes to this guideline's requirements at any time.**

Appendix 1

Minimum Content of HACCP Manual

The HACCP manual shall contain but not limited to

1. Background

    1.1 Company profile
    1.2 Plant layout

2. Management Responsibility

    2.1 Organization chart
    2.2 Food Safety Policy
    2.3 Food Safety Objective
    2.4 Scope of HACCP Plan
    2.5 HACCP team and responsibilities
    2.6 Product Description and intended consumer
    2.7 Process Flow Diagram

3. HACCP Plan

    3.1 Hazard Analysis Worksheet
    3.2 HACCP Plan Summary
    3.3 Validation
    3.4 Internal Audit
    3.5 Management Review

4. Operation, maintenance of the HACCP system

    4.1 Control of non-conforming products
    4.2 Traceability
    4.3 Notification and Recall
    4.4 Control of measuring equipment and methods
    4.5 Maintenance

5. Overall Verification activities and schedule

6. Summary of Pre-Requisite Programmes

***All document shall be submitted via FoSIM**

Minimum Content of GMP Manual

The GMP manual shall contain but not limited to :

1. Background

    1.1 Company profile
    1.2 Plant layout

2. Design and facilities

    2.1 Location
    2.2 Premises and rooms
    2.3 Equipment
    2.4 Facilities

3. Control of operations
    3.1 Control of hazards
    3.2 Key aspects of hygiene control system
    3.3 Incoming materials
    3.4 Packaging materials
    3.5 Non-conforming materials
    3.6 Water

4. Maintenance, cleaning and sanitation
    4.1 Cleaning and sanitation
    4.2 Preventive and corrective maintenance
    4.3 Pest control
    4.4 Waste management programme

5. Personal hygiene
    5.1 Health Status
    5.2 Illness and injuries
    5.3 Personal Cleanliness
    5.4 Personal Behaviour
    5.5 Control of visitors

6. Training
    6.1 Awareness and Responsibility
    6.2 Management and Supervision
    6.3 Training Programmes

7. Product information and traceability
    7.1 Lot or batch identification
    7.2 Product information and labelling
    7.3 Traceability
    7.4 Recall procedures

8. Transportation

9. Internal inspection
   9.1 Self-inspection
   9.2 Internal audit

10. Management review

11. Documentation and records

***All document shall be submitted via FoSIM**

Appendix 2

HACCP CERTIFICATION FEE

Certification Fee	BI (RM)	SMI (RM)
New application[1]	5,400.00	4,000.00
Renewal	4,000.00	3,000.00
Additional Product[1]	2,750.00	2,550.00
Surveillance	1800.00	1800.00
Reprint Certificate	100.00	100.00

Auditor Fee	Peninsular Malaysia, (RM)	S&S, WPL (RM)
Auditor expenditure[1]	3,420.00	4,040.00

The above fi is for one application. One application is based on the following criteria:

a) One (1) food category from 3 maximum process or;
b) Various food category with one (1) process;

Determination of the food category is based on the Food Regulations 1985.

The final quotation will be based on the number of food category and the complexity of the processing / activity involved.

Definition:

1. Big Industry (**BI**) — Comprises 150 full time workers with an annual sale turn-over of RM25 million
2. Small and Medium Industry (**SMI**) — Comprises less than 150 full time workers with an annual sale turn-over of not more than RM25 million

Note : The above criteria are only guides and the final decision will be made by Ministry of Health, Malaysia. 50% HACCP Certification Fee reduction applicable for application from government agency other than MOH.

[1]Auditor expenditure is applicable for new and additional products application only

Appendix 3

GMP CERTIFICATION FEE

Item	BI (RM)	SMI (RM)	MICRO (RM)
New	4700.00	3500.00	2300.00
Renewal	3500.00	2600.00	1800.00
Surveillance	1600.00	1600.00	1600.00
Reprint Certificate	100.00	100.00	100.00

Definition:

1. Big Industry	Comprises more than 150 workers with an annual sale turnover of RM 25million
2. Small and Medium Industry	Comprises 5-150 full time workers with an annual sales turnover between RM250,000 to RM25 million
3. Micro-enterprise	Comprises less than 5 full time workers with an annual sales turnover less than RM250,000

Note : 50% GMP Certification Fee reduction applicable for application from government agency other than MOH.