



KEMENTERIAN KESIHATAN MALAYSIA

MALAYSIAN CERTIFICATION SCHEME (MCS) FOR *HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP)*



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Food Safety and Quality Division
Ministry of Health Malaysia

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1.0 INTRODUCTION

The Malaysian Certification Scheme for Hazard Analysis and Critical Control Point system (MCS HACCP) describes procedures which apply to food establishment in gaining HACCP certification. The scheme is administered by the Ministry of Health (MOH), which requires the food establishment to setup and implement a HACCP system that meets the MCS HACCP criteria, followed by the application and granting of the certification. The certification process includes adequacy, compliance and follow-up audit(s) by appointed and certified auditors. The MOH will verify the maintenance of the certified HACCP system through surveillance audit.

2.0 OBJECTIVE

This MCS HACCP is used as a guideline for food establishment in Malaysia to obtain HACCP certification from Ministry of Health (MOH).

3.0 SCOPE

This scheme is applicable to food establishment in order to obtain and maintain the HACCP certification from MOH. The certification is granted for specific food product and is not a blanket certification for all types of food product within a food establishment.

The certification reference documents are;

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

4.0 DEFINITIONS

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

4.1 Audit

An independent, systematic examination of objective evidence, performed by trained personnel, to determine whether the activities of the HACCP systems and the related results comply with planned arrangements and whether these arrangements are implemented

effectively and are suitable to achieve food safety objectives.

4.2 Auditor

A person formally appointed by MOH with technical competency in the HACCP system and audit, including food processing technology.

4.3 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.

4.4 Corrective Action Request (CAR)

Non-conformity was documented request by the auditor which must be satisfactorily addressed or corrected by the auditee. All CAR(s) must be closed before a recommendation for the HACCP Certification can be made.

4.5 Food Establishment

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.

4.6 HACCP Manual

The written documents describe the implementation of HACCP and PRP elements.

4.7 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.

4.8 Non-conformity (NC)

The absence or the failure to implement and maintain one or more required system element or situation which would on the basis of available objective evidence or evaluation raise doubt as to the safety of food.

4.9 Serious

A severe deviation from planned requirements MS1480, 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.

4.10 Major

A significant deviation from planned requirements MS1480, 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.

4.11 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.

4.12 Observation

A recommendation given to affect an improvement.

5.0 BENEFITS

The benefits of a certified MOH HACCP system are as follows;

- 5.1** To facilitate and expedite the issuance of Health Certificate which is not depend on the end product testing;
- 5.2** To reduce the frequency of regulatory inspection on food establishment and sampling;
- 5.3** To enhance safety of food produced by food establishment;
- 5.4** To fulfill global requirements on food safety including the application for Approval Number for the exporting of fish and fishery products to European Union;

- 5.5 To promote the acceptance, both in Malaysia and international, of food produced from establishment with certified HACCP system;
- 5.6 To improve marketability of the certified product; and
- 5.7 To gain recognition by use the HACCP logo upon certification.

6.0 GENERAL REQUIREMENTS FOR APPLICATION

Food establishments applying for HACCP Certification shall fulfill the following requirements;

- 6.1 Establishments shall be registered with Ministry of Health Malaysia via online system at <https://fosim.moh.gov.my>;
- 6.2 Establishment is registered with the Companies Commission of Malaysia(Suruhanjaya Syarikat Malaysia (SSM)
- 6.3 Establishments shall be licensed with local authorities;
- 6.4 Establishments processing Packaged Drinking Water, Natural Mineral Waterand Ice shall obtain valid licensed from MOH prior to application;
- 6.5 The HACCP system shall be developed based on the Malaysian Standard MS1480 and any other requirements imposed by the importing country(s);
- 6.6 PRP system shall be in place and documented based on the MS 1514 forfood and/or any other requirements imposed by the importing country(s);
- 6.7 The HACCP and PRP Manual shall be available as stated in **Appendix 1**. The Manual shall be duly signed and dated by the company management with executive responsibility; and
- 6.8 The HACCP system and PRP system should have been 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/ additional product(s) certification shall be made via online system (<https://fosim.moh.gov.my>) refer to fsq.moh.gov.my.
- 7.2 The applicant shall submit the documents according to the checklist as in **Appendix 1** via FoSIM.
- 7.3 MOH will review and verify the application and documents. Upon completeness of application, quotation will be issued to the applicant via FoSIM
- 7.4 For **compliance audit (new application) and additional product(s)**, MOH shall seek approval from Finance Department for Trust Fund approval. Meeting for approval will be conducted twice (2) a year. Refer to **Appendix 2**.
- 7.5 The criteria to determine the number of application will depend on the food category and the complexity of the process type. Refer to **Appendix 3**.

Note :A registered company can have more than one establishment. The address can be the same or different from one another. Choose only the establishment(s) that needs to apply for HACCP Certification.

8.0 FEES AND AUDITOR EXPENDITURE

The applicant shall pay the fee as follow within **one (1) month** from the quotation date. Payment for certification fee and auditor expenditure fee shall be made **through FoSIM** (<https://fosim.moh.gov.my>). Detail on fee schedule is shown in **Appendix 4**. All payment made is **NOT REFUNDABLE**.

9.0 APPOINTMENT OF AUDITOR

- 9.1 Upon received payment from the applicant, MOH will appoint at least two (2) auditors for the audit.

- 9.2 The names of the auditors will be made known to the food establishment.
- 9.3 Audit arrangements will be mutually agreed upon by the lead auditor and the applicant. The lead auditor will send out an audit plan to the food establishment.

10.0 AUDITING PROCEDURE

10.1 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. Flow chart for compliance audit is shown in **Appendix 5**.

10.2 Adequacy audit

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

10.3 On-site audit

10.3.1 An audit that is conducted at the food establishment and will be carried out after adequacy audit has been done. All the document and record shall be readily available during on-site audit. Establishment shall conduct actual processing within the applied HACCP scope during on site audit.

10.3.2 The auditors will present audit finding during the closing meeting. 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 auditee is required to take corrective action for each non-conformity documented based on CAR(s) issued.

10.3.3 The establishment shall respond to CAR(s) issued within **two (2) weeks** after the on-site audit to the lead auditor. The establishment

shall rectify the CAR given and submit the updated document within **six (6) months** from the onsite audit for follow up if applicable.

- 10.3.4 For compliance and additional products audit, the establishment is given a **maximum of one (1) year** from the first on-site audit for all the audit process to be completed and all corrective action to be closed out after follow up audit has been conducted. If the one (1) year period is exceeded, the application is deemed to be automatically void and food establishment has to reapply (unless valid justification can be provided).

10.4 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. Follow up audit shall be carried out within **two (2) weeks** after all CARs have been rectified by the establishment. The establishment shall respond to unsatisfactorily corrective action on previous CAR(s) and new CAR(s) issued (if any) within **two (2) weeks** after the follow up audit.

10.5 Final audit report

Final a u d i t report will be submitted to the HACCP and GMP Technical Committee after all CARs have been satisfactorily closed out.

10.6 Evaluation process

The HACCP and GMP Technical Committee will conduct a meeting once (1) a month or when the need arises. Upon satisfactory verification and resolution of the non-conformity raised, a recommendation will be made to the HACCP and GMP Technical Committee to award the certification of HACCP.

10.7 Issuance of certificate

HACCP certification will be awarded together with covering letter upon approval.

10.8 Surveillance audit

All certified establishments shall be subjected to at least once (1) surveillance audit within the validity period of HACCP Certification. In exceptional cases, additional surveillance audits shall be carried out annually. The audit will be conducted by State Health Department to

determine HACCP system is being effectively maintained.

The establishment is given a **maximum of six (6) months** from the first on- site audit for all the audit process to be completed and all CAR(s) to be closed out. If the period is exceeded without valid justification, the certification shall be suspended, revoked, or terminated. Flow chart for surveillance audit can refer **Appendix 6**.

11.0 RENEWAL OF CERTIFICATION

Application for renewal of certification shall be made as early as **six (6) months** prior to certificate's expiry date. Once certification is expired, the application is treated as new application. Flow chart for renewal audit can refer **Appendix 7**.

12.0 FAST TRACK FOR GMP AND MeSTI CERTIFICATION

12.1 The HACCP certification will automatically certified with GMP & MeSTI by Fast Track without any payment and audit process.

12.2 The validity of the certificate awarded shall follow as HACCP certification.

13.0 ADDITIONAL PRODUCT(S)

Added product in certificate shall be applied as additional product application. Flow chart for application of additional product(s) is described in **Appendix 2**. Applicant shall submit supporting documents as follows:

- a. Process Flow Diagram
- b. Product Description, Intended Use and Potential Consumer
- c. Plant Layout refer MS1480
- d. Hazard Analysis Worksheet
- e. HACCP Summary Plan
- f. Certification Information Form
- g. PRP Manual

Validity for Additional Product shall follow as existing certification validity date.

14.0 CERTIFICATION VALIDITY

The validity of HACCP Certification is **three (3) years**. It will varies when it comes to additional products and under certain conditions.

15.0 REPRINT OF CERTIFICATE

15.1 Charges RM100 will be imposed for reprint of certificate. Request to reprint the certificate shall be in written with valid justification via online system (<https://fosim.moh.gov.my>).

15.2 The original certificate shall be returned to MOH .

16.0 CANCELLATION OF APPLICATION

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

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

16.2. The applicant delay more than three (3) months on the proposed on-site audit date without valid justification;

16.3. The establishment not ready to be audited after appointment of audit team; or

16.4. The applicant did not provide any feedback required by the audit team for the purpose of on-site audit.

17.0 SUSPENSION/ REVOCATION/ TERMINATION OF CERTIFICATION

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

17.1 The certified establishment has manufactured products that are not in compliance with the Food Act 1983 and its regulations;

17.2 The certified establishment's HACCP system has persistently or seriously failed to meet the certification requirement;

- 17.3** The certified establishment does not allow surveillance audit to be conducted at the required frequency;
- 17.4** The certified establishment has failed to take corrective actions on non-conformity(ies) raised within the specified period;
- 17.5** The certified establishment has incorrectly make reference to its certification status or used the certificate, logo or audit reports in misleading manner;
- 17.6** The establishment are moved to a different location/ address or ceased operations;
- 17.7** The certified establishment has voluntarily requested suspension of the certificate ;
- 17.8** The maximum period of suspension of certificate is up to three (3) months before it will be revoke; or
- 17.9** The establishment not operated more than 6 months without valid justification.

In the event of suspension, the certified establishment shall take necessary action within three(3) months. Failure to take necessary action within the specified period may result in the termination of the certification.

A certified establishment dissatisfied with the decision on suspension/ termination has the right to file a written appeal within 14 working days of the date of suspension/ termination.

18.0 APPEAL

The HACCP and GMP Technical Committee will be empowered to make decisions on any appeal lodged against any application or certification. The committee will consists of members who are independent of the certification process, to ensure impartiality and prevent conflict of interest.

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 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 Audit.

20.0 OTHER CONDITIONS

All the food establishments are subjected to the following condition:

- 20.1.** Any changes to the name or address of the food establishment, certification scope, any major renovation is 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 establishment shall at all times be subject to inspection, monitoring and enforcement conducted either by MOH;
- 20.3.** The food establishment 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 that is being produced in the establishment as stated in the 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 establishment request additional certificate under different name, the food establishment shall pay the

certification fee as new application without audit process. A written request and a copy of documents from Companies Commission of Malaysia (SSM) shall be submitted to MOH;

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.

21.0 Further information on this scheme can be obtained from:

**Food Safety and Quality Division,
Ministry of Health Malaysia,
Level 4, Menara Prisma
No 26, Jalan Persiaran Perdana
Presint 3, 62675 Putrajaya
Tel: 03-8885 0797
Fax: 03-88850769
Website :<http://fsq.moh.gov.my>**

22.0 REFERENCES

- 22.1** *Codex Basic Food Hygiene Texts/Annex to CAC/RCP1-1969, Rev.3 CodexAlimentarius (1997).*
- 22.2** *Food Act 1983, Food Regulations 1985 and Food Hygiene Regulations 2009, Malaysia.*
- 22.3** Malaysian Standard MS 1480. *Food Safety According to Hazard Analysis and Critical Control Point (HACCP) System.* Department of Standards Malaysia.
- 22.4** Malaysian Standard MS 1514. *Good Manufacturing Practice (GMP),* Department of Standards Malaysia.

**HACCP CERTIFICATION SCHEME
NEW / ADDED PRODUCT / RENEW APPLICATION CHECKLIST**



| SECTION A : CHECKLIST FOR NEW APPLICATION FORM /ADDITIONAL PRODUCT(S) | | Please tick *Yes (√) / No (X) | |
|---|---|----------------------------------|---------|
| | | Applicant | Officer |
| 1 | Online application via https://fosim.moh.gov.my | | |
| 2 | SSM Certificate (Suruhanjaya Syarikat Malaysia) | | |
| 3 | Premise License from Local Authority | | |
| 4 | Latest Company Audited Account (if any) | | |
| 5 | HACCP Manual (Refer to Annex A below for content of HACCP Manual). The manual shall be duly signed and dated by the company management with executive responsibility; | | |
| 6 | PRP/GMP Manual (Refer to Annex B below for content of PRP/GMP Manual). The manual shall be duly signed and dated by the company management with executive responsibility; | | |
| 8 | Certification Information Form* | | |

| SECTION B : CHECKLIST FOR RENEWAL APPLICATION FORM | | Please tick *Yes (√) / No (X) | |
|--|--|----------------------------------|---------|
| | | Applicant | Officer |
| 1 | Online application via https://fosim.moh.gov.my | | |
| 2 | Latest Company Audited Account (if any) | | |
| 3 | HACCP Manual & GMP Manual (if any amendment) | | |
| 4 | Certification Information Form* | | |

Note: All the documents must be upload to FoSIM

| Annex A. | CHECKLIST FOR MINIMUM CONTENTS OF HACCP MANUAL AND SUPPORTIVE DOCUMENTS | | Please tick *Yes (✓) / No (X) | |
|----------|---|-------------------------------|-------------------------------|---------|
| | | | Applicant | Officer |
| 1. | Company & Food Safety Policy | Company profile | | |
| | | Organization chart | | |
| | | Food safety management policy | | |
| | | Plant layout | | |
| 2. | HACCP Team & Responsibilities | | | |
| 3. | Scope of HACCP Plan | | | |
| 4. | Food Safety Objective(s) | | | |
| 5. | Product Description & Intended Consumer | | | |
| 6. | Process Flow Chart | | | |
| 7. | Hazard Analysis Worksheet | | | |
| 8. | HACCP Plan Summary | | | |
| 9. | Overall Verification Activities & Schedule | | | |
| 10. | Summary of Pre-requisite Programmes | | | |

Note: Document shall be tagged according to numbering in the Annex A checklist

| Annex B. | CHECKLIST FOR CONTENTS OF PRP/GMP MANUAL | | Please tick *Yes (✓) / No (X) | |
|----------|--|--|-------------------------------|---------|
| | | | Applicant | Officer |
| 1. | Establishment : Design and Facilities a. Location b. Premises and rooms c. Equipment d. Facilities | | | |
| 2. | Control of Operation a. Control of Food Hazards b. Key aspects of hygiene control systems c. Incoming Materials requirements d. Supplier assurance programme e. Packaging and storage f. Water, steam and ice g. Management and supervision h. Documentation and records i. Customer feedback and complaints j. Recall procedures and traceability | | | |

| | | | |
|-----|---|--|--|
| 3. | Establishment : Maintenance and sanitation a. Maintenance and cleaning b. Cleaning programmes c. Chemical control d. Pest Control e. Waste Management f. Sanitation systems | | |
| 4. | Establishment : Personal Hygiene a. Health Status b. Illness and injuries c. Personal cleanliness d. Personal behavior e. Visitors and workmen | | |
| 5. | Transportation and Distribution a. General b. Requirements c. Use and maintenance | | |
| 6. | Product information and consumer awareness a. Batch Identification b. Product information c. Labelling d. Consumer education | | |
| 7. | Training a. Awareness and responsibilities b. Training programmes | | |
| 8. | Internal Inspection | | |
| 9. | Management Review | | |
| 10. | Legal Requirements | | |
| 11. | Forms related for each elements describe on HACCP and PRP Manual | | |

Note: All the documents must be upload to FoSIM

Certification Information Form*

| No | Product Category | Type of Products | Regulation No | List of Products |
|-------------|------------------------------------|---|---------------|--|
| E.g. | | | | |
| 1. | Vinegar, Sauce, Chutney and Pickle | Tomato Sauce or Tomato Ketchup or Tomato Catsup | 343 | 1. Tomato Ketchup Brand A 2. Tomato Ketchup Brand B |
| 2. | Edible Fat and Edible Oil | Sesame seed Oil or Gingelly Oil | 205 | 1. Sesame oil Brand A |

Products category and type shall refer Food Regulation 1985.

1.0 FLOW CHART FOR APPLICATION OF NEW CERTIFICATION/ ADDITIONAL PRODUCT(S)



2.0 FLOW CHART FOR APPLICATION OF RENEW CERTIFICATION



APPLICATION FOR CERTIFICATION

a. Application for certification shall be under the same food category for example;

1. Food Additives and Added Nutrient
2. Cereal, cereal product, starch and bread
3. Malt and malt extract
4. Food aerating substance
5. Milk and milk product
6. Sweetening substance
7. Confection
8. Meat and meat product
9. Fish and fish product
10. Egg and egg product
11. Edible Bird's nest and EBN Product
12. Edible fat and edible oil
13. vegetable and vegetable product
14. Soup and soup stock
15. Fruit and fruit product
16. Jam, fruit jelly, marmalade and seri kaya
17. Nut and nut product
18. Tea, coffee and chicory
19. Cocoa and Cocoa Product
20. Milk shake
21. Salt and spice
22. Vinegar, sauce, chutney and pickle
23. Soft drink
24. Natural mineral water
25. Packaged drinking water
26. Alcoholic beverage
27. Shandy
28. Special purpose food
29. Use of Water, Ice or Steam
30. Miscellaneous
31. Food Services

b. Application for certification also can be categorized as follows;

One food group category from 3 maximum processes. e.g. Freezing,
Canning, Smoked : Or ;

Various of food group category with one process

Note : The above groupings are only guides and the final decision will be made by Ministry of Health, Malaysia.

HACCP CERTIFICATION FEE

| Item | BI (RM) ¹ | SMI (RM) ² |
|-----------------------|---------------------------|-----------------------|
| New application** | 5,400.00 | 4,000.00 |
| Renewal | 4,000.00 | 3,000.00 |
| Additional Product** | 2,750.00 | 2,550.00 |
| Surveillance | 1800.00 | 1800.00 |
| Item | Peninsular Malaysia, (RM) | Sabah & Sarawak, (RM) |
| Auditor expenditure** | 3,420.00 | 4,040.00 |
| Reprint Certificate | 100.00 | |

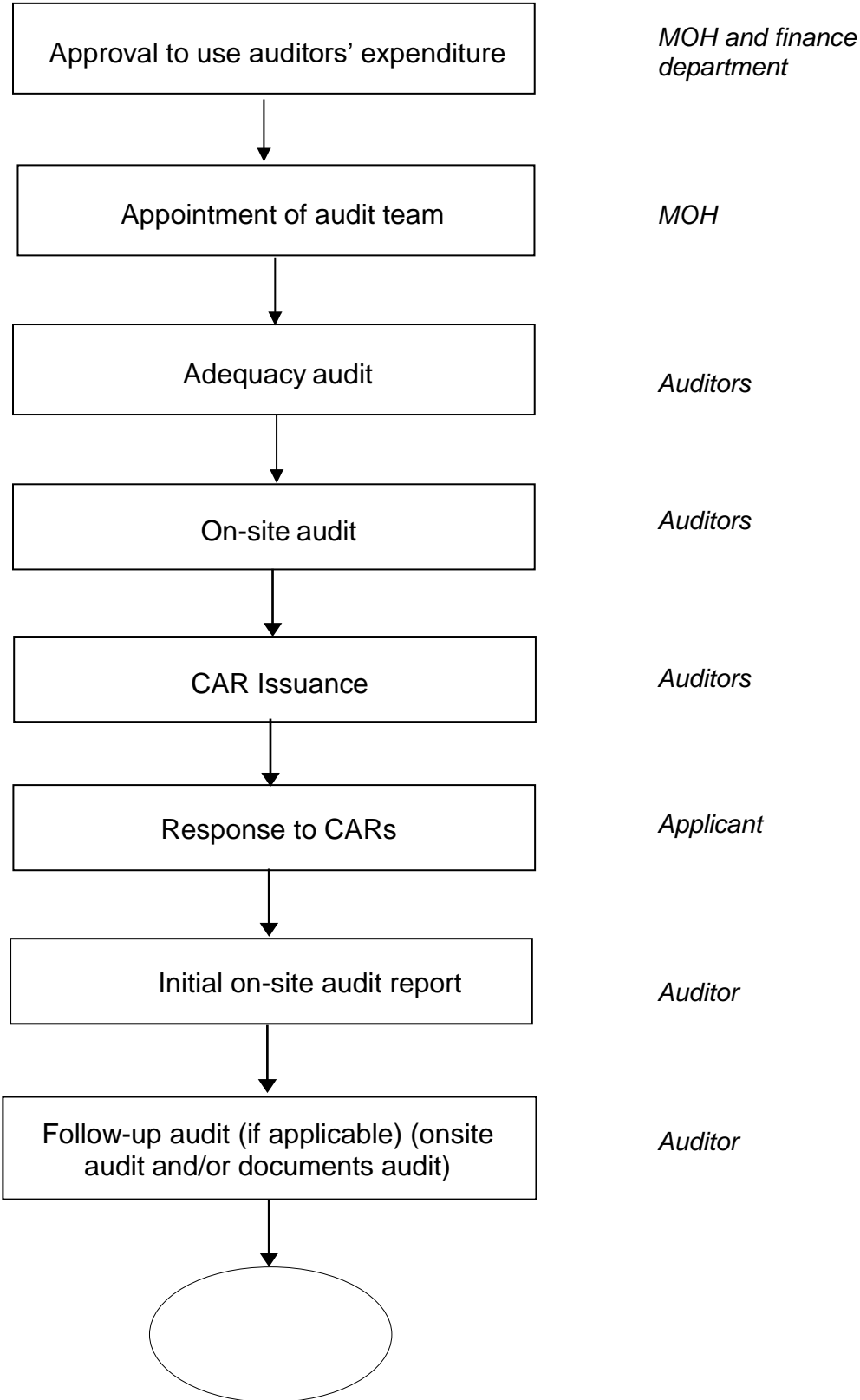
Definition:

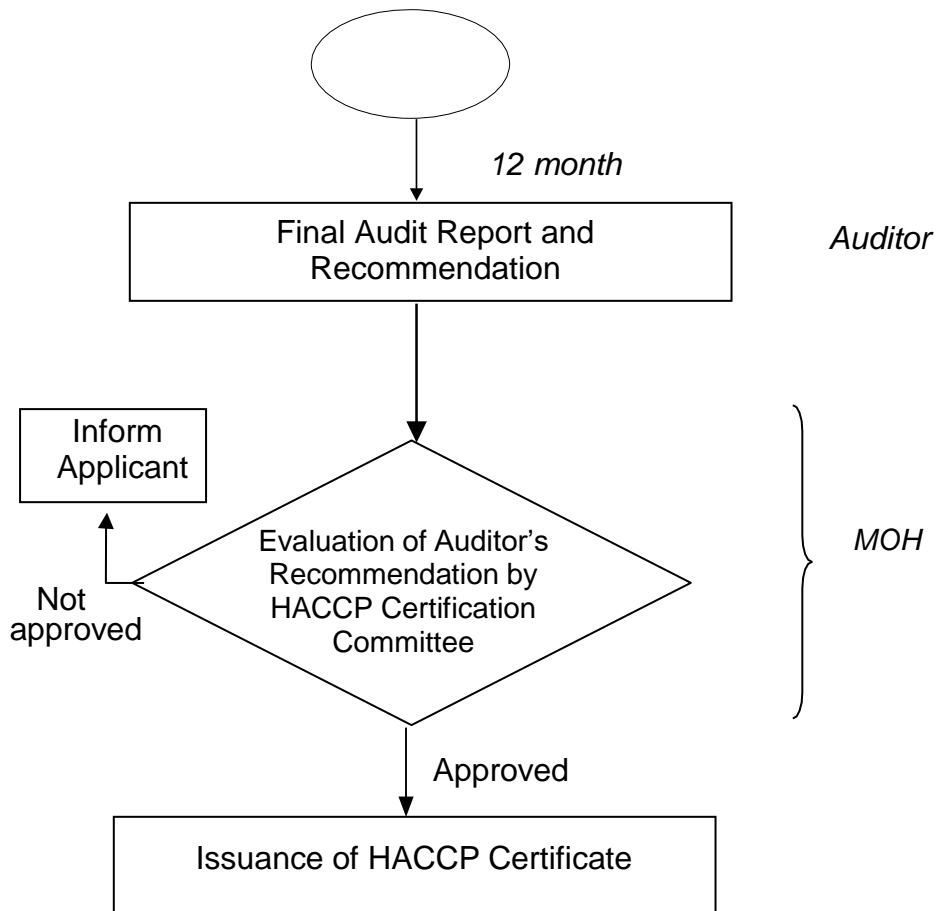
1. Big Industry (**BI**) Comprises 150 full time workers with an annual sale turn-over of RM25 million
2. Small and Medium Industry (**SMI**) Comprises less than 150 full time workers with an annual sale turn-over of not more than RM25 million

Note:

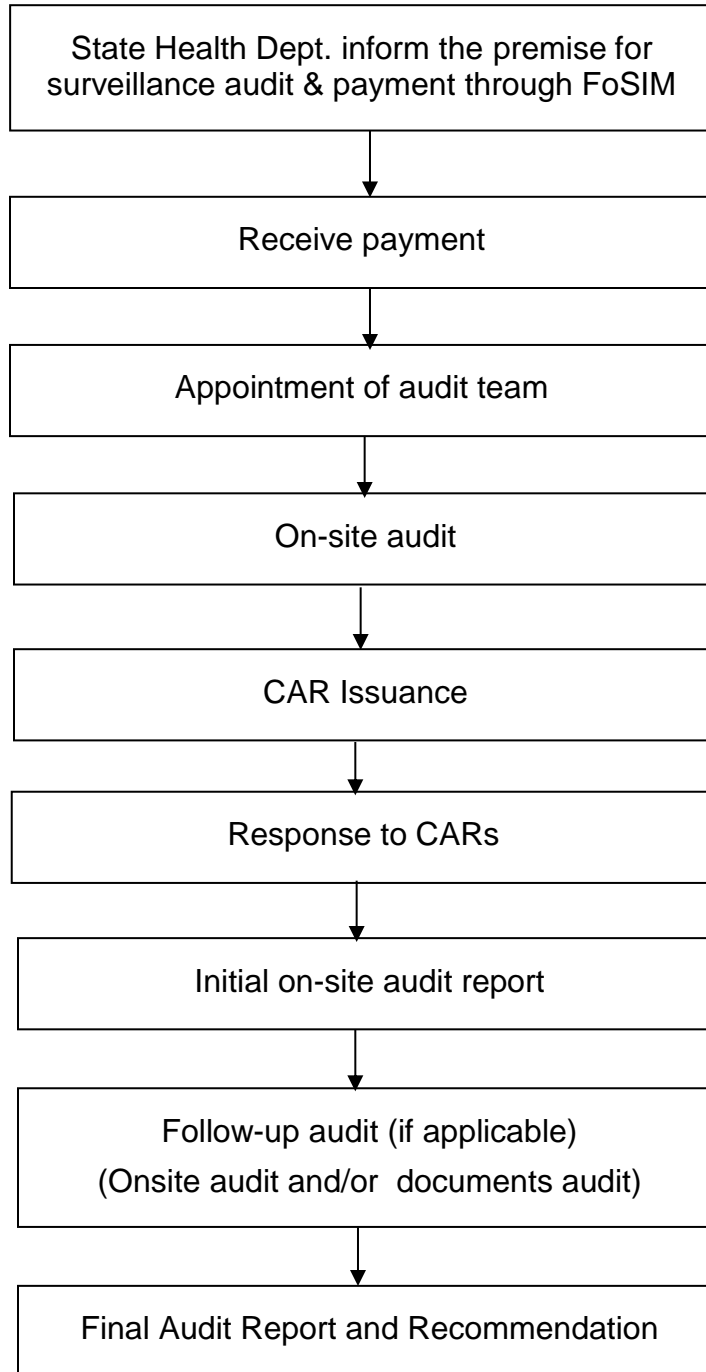
(**) Auditor expenditure is applicable for new application and certification for additional products. It's includes airfares, food, accommodation, mileage and other costs incurred by the auditor such as follow-up audit.

FLOW CHART FOR COMPLIANCE AUDIT





**FLOW CHART FOR SURVEILLANCE AUDIT
(STATE HEALTH DEPARTMENT)**



FLOW CHART FOR APPLICATION OF RENEWAL CERTIFICATION

