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Ministry of Health
Department of Food and Drug Administration, Food Division, Domestic/Market Section

Procedure for Domestic Food Businesses for Applying for a Food Manufacturing Recommendation via E-Submission

January 2026

Introduction

The Food and Drug Administration is developing an Inspection and Certification System that aligns with Codex standards, ASEAN standards, and conforms to the National Food Safety Policy.

Starting from June 2022, domestic food businesses can now submit applications for Domestic Food Manufacturing Recommendation (New Business/Renewal) processes through the E-Submission System on the Food and Drug Administration's website, www.fda.gov.mm.

Rationale

To ensure that consumers/the public in Myanmar consume quality and safe food, to ensure domestically produced foods are safe and meet quality standards, and to make the application process for Food Manufacturing Recommendations easier, faster, and smoother, aiming to develop a more robust inspection system, supervision will be carried out in accordance with the procedures for applying for Food Manufacturing Recommendations for domestic food businesses. Domestic food businesses are scrutinized and processed according to the following procedures.

Basic Principles for the Procedure

(1) Risk-Based Assessment,

(2) Data-based assessment,

(3) Scrutinizing by prioritizing the development of domestic food businesses,

(4) Scrutinizing based on a system that fosters and encourages the responsibility and accountability of domestic food businesses,

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(5) Facilitating easier and faster connections with international organizations and relevant departments,

(6) Scrutinizing based on an Inspection and Certification System that aligns with Codex standards, ASEAN standards, and conforms to the National Food Safety Policy.

→ References to laws, regulations, orders, and directives related to applying for Domestic Food Manufacturing Recommendation, issued based on the National Food Law, are provided in Annex (1).

Standard Operating Procedure (SOP) for a Domestic Food Manufacturing Recommendation

1. Applicability

- Businesses dealing with "Labelled Bottled Water" and "Labelled Edible Oil," which are designated as Controlled Foods by Order No. (524/2021) of the Myanmar Food and Drug Authority, must mandatorily apply for a Domestic Food Manufacturing Recommendation from the Food and Drug Administration in accordance with the National Food Law. (Notification No. (524/2021) Designating Controlled Foods)
- Food businesses operating due to business requirements may voluntarily apply for a Domestic Food Manufacturing Recommendation from the Food and Drug Administration.

2. Application Process

(a) Submitting Online Application

- First, access esubmission.fda.gov.mm and apply following the "Applicant User Guide for Food Manufacturing Recommendation" (Reference Link - https://esubmission.fda.gov.mm/userguides/food/Food Local_Manufacture_UserGuide_V2.pdf)
- Depending on the location of the food manufacturing factory, the application must be submitted by selecting the relevant Region/State Food and Drug Administration Branch Office.

(b) Mandatory Documents to Submit

- Product Label or Artwork
- Food/Drinking Water Manufacturing Process Steps (The manufacturing process steps must be described in text, and if necessary, must be described with a Flow

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Diagram. For renewal businesses, complete documentary photos of the manufacturing process steps must be submitted.)

- Quality Assurance Operational Methodology
- Factory Land Area/ Layout of Buildings within the Premises and Structure by Process Stages
- Factory Room Layout
- Map showing Factory Location
- Product Specifications

Note: Regarding Product Specifications, they must be submitted in accordance with the mandatory orders described in Annex (2).

→ For Health Supplements manufacturing/repackaging businesses, Hazard Analysis and Critical Control Point (HACCP) plans must be attached.

(c) Documents that may be submitted if already obtained

- Trademark Registration issued by the Intellectual Property Department
- Valid ISO/ HACCP/ GMP & Other Food Safety Certificate

3. Application Screening and On-Site Inspection

(a) Initial Application Screening

- Businesses that have submitted applications via the E-Submission System and paid the Assessment Fee will undergo initial screening by the relevant Region/State office.
- If there are deficiencies, the business will be notified via the registered email account and In-system Notification. The business must resubmit the required completions to the relevant Food and Drug Administration office within the specified period (1) month. If not submitted within the specified period, the application will be Auto-Cancelled by the system.

(b) Factory On-Site Inspection

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- Factory on-site inspection will only be conducted after the business pays the Pre-inspection Fee.
- If the Pre-inspection Fee is not paid beyond the specified period (2) weeks, the application will be Auto-Cancelled by the system.
- The scheduled date for the on-site inspection will be notified to the business via Email and In-system Notification. If there is a discrepancy between the scheduled inspection date and the actual inspection date, this must be noted and recorded in the system. If the Department cannot inspect on the specified date (or) the business cannot undergo inspection on that date, the relevant Region/State officers must coordinate with the business.
- During the on-site inspection, the announced "Minimum Compliance Points for Food Businesses" [Notification (15/2025) on Minimum Compliance Points for Food Businesses] will be used, and a business grade will be assigned based on the score obtained. [Directive (4/2023) regarding using the new Checklist for on-site inspection of food businesses starting from 19-6-2023]
- After the on-site inspection, if the business obtains Grade A or Grade B and completely addresses the corrective actions within the timeframe set by the Food Inspector for corrections, the business will be assigned a Risk Profiling of Food Businesses level.
- If Grade C is obtained during the on-site inspection, and the business completely addresses the corrective actions within the timeframe set by the Food Inspector for corrections, a re-inspection will be conducted. [Directive (14/2025) on Risk Profiling of Food Businesses]
- If the business does not submit the corrective actions for the points identified after the on-site inspection within the specified correction period, the recommendation will be rejected as per Section (5).
- After the risk level is assigned and the factory on-site inspection fee is paid, a One-Page report must be prepared and submitted through the appropriate channels.

4. Issuance of Recommendation and Registration

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- For businesses obtaining Grade A or B, risk levels (High, Medium, Low) will be classified. If the scrutiny is complete, the Domestic Food Manufacturing Recommendation will be issued.
- The validity period of the recommendation is (3) years from the date of issuance.
- After obtaining the recommendation, the product scrutiny fee for each product type applied for in the E-Submission System must be paid, and the recommendation can then be downloaded. [Directive (14/2022) announcing that from 1-11-2022, a fee of 2000 Kyats per product item (PR 1) will be collected for product lists with issued recommendations in the Local E-Submission.]

5. Rejection of Recommendation

- If the business does not submit the corrective actions for the points identified after the on-site inspection within the specified correction period, the business will be rejected.
- Businesses that obtain Grade C during the on-site inspection and again obtain only Grade C during the second re-inspection will also be rejected.
- Food Inspectors have the authority to recommend rejection for businesses that obtain Grade D during the on-site inspection.

6. Sampling and Testing Based on Risk Level

(a) Sampling and Testing

Sampling and testing will be conducted as follows:

High-Risk Food Businesses

- Once at (4) months, (12) months, (21) months, (30) months from the date of issuance of the recommendation, total (4) times.

Medium-Risk Food Businesses

- Once at (4) months, (17) months, (30) months from the date of issuance of the recommendation, total (3) times.

Low-Risk Food Businesses

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- Once at (4) months, (24) months from the date of issuance of the recommendation, total (2) times. [Decision of the Food and Drug Administration Management Committee Meeting (8/2025)]

Note: For seasonal businesses (e.g., sugar factories), for sampling, businesses must retain samples and submit them according to the specified schedule for sample submission.

(b) Submitting Representative Samples

- For sample submission according to risk level, notifications will be sent via Email and In-system Notification once (1) month before the specified deadline and again once (1) fifteen days before the deadline.
- Based on the Food Category and GSFA Online Food Category [Information Notification No. (1/2023) on Food Category and Food Group Classification (Draft)], the system will randomly select one (1) item per food sub-category, specifying the final sample submission date, required sample quantity, and the laboratory to which the sample must be submitted.
- Businesses must submit the food samples required for laboratory testing to the relevant laboratory before the final deadline for sample submission specified by the system. [Directive (15/2020) on Designating Laboratories for Submitting Food Samples for Laboratory Testing from Drinking Water Businesses Applying for Drinking Water Manufacturing Recommendation and Directive (16/2020) on Designating Laboratories for Submitting Food Samples for Laboratory Testing from Food Businesses Applying for Food Manufacturing Recommendation]
- Required sample quantities are:
  - -- By food type and production batch: if solid or powder, 1000 grams; if liquid,
  - -- Health Supplements: Net weight 150 grams and 1 unit of original packaging.
  - -- Food Additives: 200 grams / 200 milliliters.
- If the original packaging is larger than the required sample quantity, the sample must be repackaged according to the specified quantity without compromising the original quality of the food item. The repackaged sample must be properly

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labeled by affixing a sticker or printing in accordance with the provisions of Chapter (3), Section (5) of the "Order on Labeling of Prepackaged Foods" [Notification No. (8/2022)].

- If the foods require storage at a specified temperature, they must be submitted properly under conditions that maintain the specified temperature.

(c) Payment of Laboratory Testing Fees [Notification No. (6/2022) on Setting the Rates to be Collected for Applying for Domestic Food Manufacturing Recommendation via E-Submission]

→ Details regarding the payment of laboratory testing fees are described in Annex (3).

(d) Review of Laboratory Results

- If the results comply with the laboratory specifications, the process will continue according to Section (6) (a).
- If the results do not comply with the laboratory specifications:
  - -- The concerned production batch must be recalled from the market.
  - -- If the business is High Risk, a re-inspection will be conducted, and after corrective actions are completed, a second sample submission and testing is required.
  - -- If the business is Medium or Low Risk, a second sample submission and testing is required.

7. Suspension and Revocation of Recommendation

(a) Suspension of Recommendation

- If a sample is not submitted by the final deadline specified by the system for sample submission, the recommendation will be suspended. Furthermore, the business will be announced as a business that failed to submit a sample on the Food and Drug Administration's website, www.fda.gov.mm.
- According to the sampling and testing procedure based on risk level, if the business submits a sample for testing within (2) months after the final submission deadline, the

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suspension will be lifted. If no sample is submitted, the recommendation will be revoked as per Section (7) (b).

- If the first laboratory test results for samples submitted by Medium and Low Risk food businesses do not comply with specifications, the business will be notified via Email and In-system Notification to submit a second sample. Businesses that do not submit a sample within (2) weeks will have their recommendation suspended.
- Businesses whose second test results also do not comply with laboratory specifications will have their recommendation suspended.
- Such suspended businesses will be notified via Email and In-system Notification. Furthermore, the status of the business's obtained recommendation will show as "Suspend" in the Certificate Status under Validation Check on the publicly accessible website https://esubmission.fda.gov.mm/.
- Businesses whose second test results do not comply with specifications will be re-inspected within (2) weeks by an inspection team directed by the Food and Drug Administration (Head Office).
- During such re-inspection, if the inspection team cannot inspect within (2) weeks (or) the business cannot undergo inspection, the relevant Region/State officers must coordinate with the business to confirm an inspection date, not exceeding a delay of (1) month.
- If, after the re-inspection, the business does not submit corrective actions for identified points within the specified correction period, or if during the re-inspection the business obtains Grade C or D, or if after the factory re-inspection and subsequent sample submission the laboratory results do not comply with specifications, the business's recommendation will be revoked as per Section (7) (b).
- If Grade A or B is obtained and corrective actions are completed, the sampling and testing process according to the procedure will continue.

(b) Revocation of Recommendation

- Businesses that fail to submit samples within (2) months after the deadline according to the risk-based sampling and testing procedure, businesses that fail to submit a second sample within (4) weeks after first test non-compliance, businesses that obtain Grade C or D during re-inspection, businesses that do not submit corrective actions for points

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identified after inspection within the specified correction period, and businesses whose subsequent sample submissions fail laboratory testing after factory re-inspection, will have their Domestic Food Manufacturing Recommendation revoked. These businesses will be notified via Email and In-system Notification. Regarding this revocation, a notification letter will be sent to the relevant Region/State Food and Drug Supervisory Committee. Businesses whose recommendation is revoked must re-apply as a new business, and if they are Controlled Foods, market surveillance will be conducted to check for manufacturing/distribution/sales activities.

8. Responsibilities

(a) Responsibilities of Domestic Food Manufacturing Businesses

- Responsible for the food safety and quality of the product according to the "Minimum Compliance Points for Food Businesses".
- Responsible for preparing and operating in accordance with the "Guideline for Food Hygiene" issued by the Food and Drug Administration.
- Responsible for complying with relevant laws, regulations, and guidelines issued by relevant departments.
- Responsible for complying with the provisions of the "Order on Labeling of Prepackaged Foods (8/2022)" for the product's label.
- Responsible for accurately following this procedure.

(b) Responsibilities of the Food and Drug Administration

- Food Inspectors are responsible for conducting systematic scrutiny according to the Minimum Compliance Points for Food Businesses and the Risk Profiling of Food Businesses.
- The Review & Revise Team is responsible for amending, supplementing, and changing the Minimum Compliance Points for Food Businesses and the Risk Profiling of Food Businesses every (3) years, or as needed by submitting to the Director General.

Risk-Based Domestic Food Manufacturing Recommendation Issuance System

[Graph omitted.]

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Actions Based on Laboratory Test Results in Issuing Domestic Food Manufacturing Recommendation

[Graph omitted.]

9. Annexes

Annex (1) Laws, Regulations, Orders, and Directives related to applying for Domestic Food Manufacturing Recommendation, issued based on the National Food Law

(a) "National Food Law" (1997) and "Law Amending the National Food Law" (2024)

(b) "Order on Labeling of Prepackaged Foods" Notification No. (8/2022)

(c) "Order on Marketing of Formulated Foods for Infants and Young Children" Notification No. (22/2014) and "Notification Amending the Order on Marketing of Formulated Foods for Infants and Young Children" (5/2024)

Annex (2) Microbiological Reference Criteria (MRC) pertaining to Prepackaged Foods

(a) Order No. (1/2026) on Setting Microbiological Reference Criteria pertaining to Prepackaged Foods

Annex (3) Scrutiny Fees to be paid when applying for Domestic Food Manufacturing Recommendation

- Applying businesses must pay the following scrutiny fees:

  (1) Assessment Fee (Data Scrutiny Fee) - 50,000 Kyats

  (2) Factory On-site Inspection Fee

  -- Before conducting factory on-site inspection - 200,000 Kyats

  -- Additional payment required for businesses conforming to Good Manufacturing Practice (GMP) - 500,000 Kyats

  (3) Food Item Registration Fee - 20,000 Kyats (per item)

  (4) Laboratory Testing Fee

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-- First time (per item) - 200,000 Kyats

-- Second time

Microbiological Test Fee - 50,000 Kyats

Chemical Test Fee - 50,000 Kyats

Annex (4) Extraordinary Circumstances

Businesses applying for a recommendation that encounter extraordinary circumstances beyond the ordinary (e.g., experiencing flooding, business suspension due to unforeseen events, etc.) will be handled on a case-by-case basis as exceptional cases.

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