10th Seminar on Nutrition Labeling, Claims and Communication Strategies
August 28 – 29, 2018
Renaissance Hotel, Kuala Lumpur, Malaysia

Ministry of Health and Sports
Department of Food and Drug Administration

28-8-2018
Dr. Ohnmar Soe Win
(Deputy director-Food, Yangon Branch Office)

Formation of and Drug Department of Food Administration

Policy
➢ To act as one of the supporting units to National Security.

Vision
➢ Systematic monitoring of safety, efficacy, quality of Food, Drug, Cosmetics and Medical Device is protective to people and supportive to National Security.
Organizational Setup of Department of Food and Drug Administration

Dept. of Food and Drug Administration composed of (6) Divisions at Nay Pyi Taw

(a) Food Division
(b) Drug Division
(c) Cosmetics / Medical Devices Division
(d) Laboratory Division
(e) Administration Division
(f) Planning/ Inspection Division

States & Regions

(a) Yangon branch office
(b) Mandalay branch office
(c) Other State / Region level -FDA office (12)
(d) District level -FDA office(75)
(e) Border Trade Station (15)

Promulgated Law/ Directive / Order/ Regulation

- Public Health Law (1972)
- National Drug Law (1992)
- Amendment of National Drug Law (2014)
- National Food Law (3-3-1997)
- Amendment of National Food Law (13-8-2013)
- New Food Law has been drawn Since 2015
- Cosmetics Directive (2011)
- Drawing the Medical Devices Law
- Order of Marketing of Breast- Milk Substitute for Infant & children under 2 years old (24-7-2014)

FDA Activities

- Pre market Assessment
- Post market Assessment
- Risk Assessment
- Trainings/ workshops
- Health Education
- Co-operation & Collaboration with related concerning departments / organizations - NGO / INGO

<table>
<thead>
<tr>
<th>Site</th>
<th>Commodities</th>
<th>Control Authority</th>
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<tbody>
<tr>
<td>1. Primary production</td>
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<tr>
<td>(a) Field &amp; farm</td>
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<td>(b) Fishery</td>
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<td>Raw produces,</td>
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<tr>
<td>- Agricultural products</td>
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<td>- Livestock &amp; Fishery products</td>
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<tr>
<td>- Dept. of Agriculture</td>
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<td>- Dept. of Livestock &amp; Fisheries</td>
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<tr>
<td>2. Primary Food processing</td>
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<tr>
<td>Semi finished products – sugar, rice, flour, oil, on diaries, abattoirs, grain mills</td>
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<tr>
<td>- Ministry of Industry</td>
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<td>- City Development Committee (CDC)</td>
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<td>3. Secondary Food processing</td>
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<td>Ready to eat food – canning, brewing, juice, jelly, snacks etc.</td>
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<tr>
<td>- Ministry of Health</td>
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<td>- Ministry of Industry</td>
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<td>- CDC</td>
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<td>- Dept. of Development Affairs (DDA)</td>
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<td>- Dept. of Co-operative</td>
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<td>4. Food Importation</td>
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<td>Raw for processing</td>
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<tr>
<td>Ready to eat food</td>
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<tr>
<td>- Ministry of Health</td>
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<td>- Dept. of Trade</td>
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<td>- Dept. of Customs</td>
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<td>5. Retail handlers</td>
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<tr>
<td>Prepared food</td>
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<td>- Ministry of Health</td>
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<td>- CDC</td>
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<td>- DDA</td>
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<tr>
<td>6. Home</td>
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<td>Prepared food</td>
<td></td>
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<tr>
<td>- Self Health Knowledge</td>
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</tbody>
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**Food Chain (From Farm to Table) and Control Activities**

**Food Chain**

- Raw materials
- Primary production
- Processing/ production
- Packaging
- Transportation/ Distribution
- Retailing/ Preparation
- Consumption

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**Health Recommendation for Local Food Manufacturing business requires**

- Food manufacturing facility must apply for Prepackaged food manufacturing recommendation to DFDA

- The application should include -
  - Foods to be produced (kind of food, brand name, type & size of packaging etc.)
  - Organogram of the business
  - Localization map (area map)
  - Factory layout (measurement, door, window)
  - List of employees and their duties and function, qualification
  - Health (fit) certificate of employees (from Town Ship PHD)
  - List of machines and specifications
  - List of ingredients (formula) and specifications (raw material)
  - Production process (time, temperature)
  - QC/QA procedure
  - Photo records of production process
  - Label and copy of label registration document
  - Halal Certificate, Bar Code explanation, Data for Nutrition table (if shown on label)
  - Copies of other licenses/Registrations (e.g. Municipal, Private Industry Registration, if any)
The Inspection procedure and guidelines refer to Codex Alimentarius Commission (General principle for Food Hygiene)

- GMP (Good Manufacturing Practice) - 2 years validity
- GHP (Good Hygienic Practice) - 1 year validity

**Import Recommendation**

**Required Documents**

1. Import Recommendation Form
2. Product Specification
3. Ingredients List (If not described on label)
5. Photo of product / label (2 sets)

**Remark:** for the purpose of getting the Import Licence, Import Recommendation is valid for 2 years.
**Import Health Certificate**

**Required Documents**
1. Application (Manual or MACCS)
2. Assessment (Documents & Label)
3. Laboratory Analysis (Chemical & Microbiological)
5. MACCS
6. Analysis Report to FDA Nay Pyi Taw
7. Approval / Disapproval via online by the Director (Yangon Branch)
8. Issue Import Health Certificate

- IHC is required for every shipment, for the purpose of Custom clearance.

*MACCS (Myanmar Automated Cargo Clearance System - started on 12th Nov 2016)*

**Export Recommendation**

**Required Documents**
1. Application
2. Assessment (Documents & Label)
3. Laboratory Analysis (Chemical & Microbiological)
4. Process continue at FDA, Nay Pyi Taw
5. Analysis Report to FDA, Nay Pyi Taw
6. Issue Export Recommendation

- Export Recommendation is valid for 2 years
**Export Health Certificate**

Required Documents

1. Export Health Certificate Form
2. Export Recommendation copy
3. Bill of Lading
4. Invoice
5. Packing List
6. Export Declaration
7. Buyer’s Specification
8. Photo of product and label (2 sets)
   - If the good is rice/ maize/ beans- fumigation, phytosanitary, aflatoxin certificate from DoA are necessary. EHC for every shipment.

For Export

- Export recommendation is no longer required for local food products which already have food production certificate from FDA( FDA approval No. received), as of 18 April 2018.
- Informed Department of Trade under the Ministry of Commerce on 11 April 2018.

**Labelling Requirements**

1. Brand Name
2. Kind of Food
3. Net Weight/ Net Content
4. Ingredients (descending order)
5. Manufacturer Name & Address
6. Country of Origin
7. Date Marking - Expiry Date (or) Manufacture Date/ Shelf Life, Batch Number (or) Lot Number
   - Storage instruction, Direction for use, Allergen information (if necessary)

- Order of Marketing of Breast- Milk Substitute for Infant & children under 2 years old (24-7-2014)- label must be Myanmar Language.
- FDA control the infant & baby food(under 2 years) to inline with the labelling under chapter 3 & marketing under chapter 4 of BMS code of marketing.
- FDA hold the labelling guideline concerning workshops collaborate with other government agency, stakeholders. Now FDA has been drawing the labelling Regulation and submit to higher level for approval.
Trade Facilitation

For Import

- For Codex GSFA on line listed Food Additives – Import Recommendation is not required. (informed to Dept. of Trade.)
- For low risk food items (1008 items)- both Import Recommendation and Import Health Certificate is not required. (informed to Dept. of Trade, Customs Department on 15th Feb 2017, Low risk food items list (1008 items) can be searched online on FDA Official website -www.fdamyanmar.gov.mm)

Post-market surveillance

- Regular market surveillance on priority basis conducted for quality and safety of marketed food / food on shelves.
- Post Market Surveillance with Monthly Work plan on priority basis according to consumption e.g., rice noodle, chilli powder, shrimp paste, edible oil and Bottled Drinking Water.
- Market Surveillance according to complaint
- Ad hoc survey
- PMS - buy market food by FDA resemble as customer
  - buy market food by FDA with Township Food & Drug Supervisory Committee, Dept. of consumer affairs.

Cont.

- Customs Department will give import/ export clearance.
- FDA has requested Customs Department to regulate importer companies about sending imported food items list to FDA
- Future Plan: Import Online Notification will be applied. (Instead of Import Recommendation by manual)
  - food matrix group based on risk categorization (Low. Medium, high risk) is setting through workshops participating the stakeholders, relevant government organizations.
  - more emphasize on high & medium risk food items.
  - low risk food items are controlled by Post Market Surveillance.

Findings on scrutinize the label of Infant & Baby food (under two years old) in Markets

<table>
<thead>
<tr>
<th>States &amp; Regions</th>
<th>No. of samples</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>conform</td>
</tr>
<tr>
<td>Yangon, Mandalay, Nay Pyi Taw, Ayawady, Bago, Sagaing, Magway, Thanintharyi, Kayin, Kachin, Kayar, Chin, Mon, Rakhine, Shan, Border Trade cities</td>
<td>630</td>
<td>371</td>
</tr>
</tbody>
</table>

* 2017, June 1st & 2nd week
Thank You for your attention

(www.fdamyanmar.gov.mm)