No: 1600 /MOH



# Lao People Democratic Republic Peace Independence Democracy Unity Prosperity

**Ministry of Health** 

### **Regulation on Food Registration**

Pursuant to: The Notice of the Ministerial Office of the National Assembly No 1675/Cab.NA, dated 5/12/91 on the declaration of using the Food control regulation of the Food and Drug Committee

Pursuant to: The Prime Minister Decree on the organization of the Ministry of Health No 73/PM, dated 10 May 1993 on the adoption of the National Drug policy of Lao PDR.

# The Minister of Health hereby issued Regulation on Food Registration as follows:

#### Part I GENERAL PROVISIONS

**Article 1:** The registration of food products and drinks, herewith called Food Registration, means a declaration of the food formula in written form by stating a list of food ingredients, weight or volume of each item clearly.

**Article 2:** The objective of the food registration is to collect data for statistical purpose and control the circulation of the product, import, export, sale, distribution of domestic and imported food products, to facilitate the authority to monitor and control the quality and safety of food products and their formula according to the law in order to protect the health of consumers and the copyrights of the owner of the formula.

**Article 3**: The owner of a food formula that was produced in the country or imported for the purpose of production and sale of food products in Lao PDR shall register with the Food and Drug Department of the Ministry of Health in order to avoid the adulteration of the product with others.

#### **Article 4**:

- 1. Food products to be registered are processed products and semi-processed products that have had a permit from the Ministry of Industry and have an import permit from the Ministry of Commerce and Tourism, respectively.
- 2. For products that have no representative in Lao PDR, the mother company shall file the registration or give a letter of power of attorney to any person or entrepreneur to file the registration.

# Part II SUPPORTING DOCUMENTS FOR REGISTRATION

#### **Article 5: Supporting Documents for Registration of Food domestically produced**

- 1. Application for food formula registration (application form Food/1)
- 2. Food processing details (procedures of food processing);
- 3. Label of the products
- 4. The business license from industry sector;
- 5. Samples of products in the original package (the number of the samples depends on the analysis parameters, see Annex I)
- 6. Analysis result of the products from the recognized laboratory in case by case basis.

#### Article 6: Supporting Documents for Registration of Imported Food

- 1. Application form for Food registration, formula of food productions (application form Food/2)
- 2. Food Safety certificates from recognized laboratory competent authority of exported country
- 3. Certificate of analysis from recognized laboratory of the competent authority of exported country such as:
  - Certificate of Analysis (COA)
  - Microbiology Certificate
  - Dirt and Extraneous Matter certificate
  - Sanitary Certificate
  - Mycotoxin Certificate
  - Heavy Metal Certificate
  - Phytosanitary Certificate
  - Certificate of Age
    - The above certificates are dependent on the type of food
- 4. Free sales certificate of producing or exporting country;
- 5. Samples of products in the original package (the number of the samples depends on the analysis parameters, see Annex I)
- 6. Label of the product in Lao with the registration number of Lao PDR

### Part III Registration Fees

**Article 7**: The registration fee for domestic products is calculated according to the bill of the official laboratory plus 5,000 kips

**Article 8**: The registration fee for imported product is calculated according to the bill of the official laboratory plus 20,000 kips

#### **Article 9**: Fees for Renewal of registration.

- For domestic products = 2,500 kips
- For Imported products = 10,000 kips.

# Part IV Time Period for Issuing a Registration Certificate

- **Article 10**: Registration will be considered for issuing after all document are submitted as stipulated in articles 5 and 6 of this regulation or when the owner of product has supplied all data completely according to the steps prescribed.
  - 1. For domestic product the certificate will be issued within 60 days from the date of receipt of the application by the Food and Drug Department
  - 2. For imported food products the certificate will be issued within 120 days from the date of receipt of the application by the Food and Drug Department.

# Part V Withdrawal and Renewal of Certificate of Food Registration

- **Articles 11:** The Food Registration Certificate is valid for two years from the date of signature.
  - 90 days before expiry date, the owner of the product shall submit an application for renewal.
- **Article 12:** The registration of any food may be revoked in any of the following:
  - The owner did not submit an application for renewal within 30 days of expiry date;
  - The test results showed that the quality of the product does not comply with the registered standards;
  - The product is unsafe for consumers notified by the producing country or international org anization;

# Part VI Prohibition and Measures against Violation

- **Article 13**: It is prohibited for individuals and legal persons to counterfeit the registered food formulas.
- **Article 14**: It is prohibited for individuals and legal entity to produce finished or semi-finished food for sale without permission of the Industry and without registering with the Food and Drug Department.

**Article 15**: It is prohibited for individuals and legal entity to import – export finished or semi-finished food for sale without permission of Commerce and without registering with the Food and Drug Department.

**Article 16**: Any individual or legal entity that violates the provision in articles 13,14 or 15 of this regulation shall face the following measures:

- First violation: a warning will be given;
- Second violation: a warning will be given and a fine 50,000 kips per item and the products shall be confiscated.
- Third violation: a warning will be given and a fine 50,000 kips per item. The products shall be confiscated and the business shall be closed and the case will be referred to the court.

### Part VII Enforcement

**Article 17**: The Food and Drug Department shall be responsible for controlling, monitoring and implementing this regulation.

**Article 18**: Only the Food and Drug Department has the right to issue a Food formula Registration.

**Article 19**: This regulation enter into force from the date of signature.

Vientiane, 25/11/1994

Minister of Health

Dr Khamphay Latsamy