



REPUBLIC OF THE PHILIPPINES  
**DEPARTMENT OF HEALTH**  
**BUREAU OF FOOD AND DRUGS**  
Civic Drive, Filinvest Corporate City  
Alabang, Muntinlupa City



07 April 2005

**BUREAU CIRCULAR**

No. 09 s. 2005

**TO :** ALL FOOD MANUFACTURERS (LARGE)

**SUBJECT :** Submission of Site Information File

To facilitate the evaluation and inspection of food manufacturers' compliance to current Good Manufacturing Practices (cGMP) and other related regulations, you are hereby directed to submit your current site information file.

A Site Information File (SIF) is a document prepared by the manufacturer containing specific and factual information about the production and/or control of manufacturing operations carried out at the site and any closely integrated operations at adjacent and nearby buildings. If only part of a manufacturing operation is carried out on the site, the site information file need describe only those operations, e.g. repacking.

The SIF should be concise and must not exceed 25 pages in A4 size paper excluding annexes. See attached format.

All food manufacturers must submit the necessary documents to Regulation Division II on or before 14 October 2005.

Foy your information and guidance.

  
**PROF. LETICIA BARBARA B. GUTIERREZ, M.S.**  
Director IV

**SITE INFORMATION FILE  
(FOOD MANUFACTURER/REPACKER)**

**1. General Information**

- 1.1 Brief Information (Name and Address of the Establishment, Name and Business Address of Owner/President of the Corporation, telephone numbers/s, fax number, e-mail address, if applicable)
- 1.2 Description of Quality Policy/Credo, if any
- 1.3 License to Operate, Date Issued, Expiry Date
- 1.4 Permit and/or other licenses
- 1.5 Type/s of food products manufactured/repacked in the site
  - 1.5.1 variant
  - 1.5.2 net weight/volume
  - 1.5.3 brand name/trade name
  - 1.5.4 ingredients
  - 1.5.5 packaging shelf-life
- 1.6 Any other (except food products) manufactured/repacking activities carried out in the site (e.g. premix)
- 1.7 Name/s and address/es of suppliers including goods/materials supplied (e.g. raw materials, packaging materials)
- 1.8 Name/s and address/es of client/s including services offered
- 1.9 Short description of the site
  - 1.9.1 location and immediate environment (e.g. residential, commercial, industrial, identify nearby industries)
  - 1.9.2 size of the site (in sq. m)
    - 1.9.2.1 total land area
    - 1.9.2.2 total covered area
- 1.10 Number of employees in the following areas
  - 1.10.1 production
  - 1.10.2 quality assurance or quality control

- 1.10.3 storage or distribution
- 1.10.4 technical and engineering support services
- 1.10.5 laboratory
- 1.10.6 other areas

1.11 Use of outside services or technical assistance in relation to manufacture (e.g. laboratory analysis)

- 1.11.1 name and address of the company
- 1.11.2 telephone/fax number

## 2. Specific Information

### 2.1 Personnel

- 2.1.1 Management has the authority and the resources needed to discharge duties adequately
- 2.1.2 Organizational chart showing the arrangements for quality assurance including production and quality control
- 2.1.3 Qualification, experience and responsibilities of key personnel
  - 2.1.3.1 Brief details of academic qualifications (production and quality control)
  - 2.1.3.2 Who is in-charge of Food Fortification
  - 2.1.3.3 Who is in-charge of checking GMP compliance
- 2.1.4 Training: outline of procedures for basic and in-service training and how records are maintained
  - 2.1.4.1 Details of training relative to GMP requirements
  - 2.1.4.2 Description of how training needs are identified and by whom
  - 2.1.4.3 State the form of training (e.g. in-house, external, frequency and how practical is gained
  - 2.1.4.4 Explain how the effectiveness of the training/appraisal is assess (e.g by giving questionnaires) to determine if further training is needed
  - 2.1.4.5 Give brief detail of records kept
- 2.1.5 Hygienic Practice
  - 2.1.5.1 Are there procedures for disease control (e.g. regular examination) and clear instruction for all personnel to report health conditions to supervisors?



2.1.5.2 Are there clear procedures and work instructions for maintaining cleanliness in all areas?

- Is the clothing suitable for the activity undertaken? Briefly describe
- Are outer garments (e.g. hairnet, headband, cap, beard cover or other hair restraints, gloves, apron, masks) including working shoes provided?
- Are there clear instructions on how protective clothing should be used and when it should be changed? Storage of clothing or other personal belongings?
- Is in-house or external laundry used?
- Are there suitable washing, changing and rest areas?
- Is hand washing procedures provided?
- Are there clear instructions on eating food, chewing gum, drinking beverages or using tobacco in areas where food manufactured may be exposed?

## 2.2 Premises

### 2.2.1 Grounds

2.2.2.1 How is it constructed?

2.2.2.2 What are the methods implemented for adequate maintenance? (e.g. good housekeeping, operating systems for waste treatment and disposal)

### 2.2.2 Plant Construction and Design

2.2.2.1 Simple plan or description of manufacturing areas with dimensions

- Provide master floor plan identifying each area with corresponding dimensions; include support systems if any
- size, design and construction per section/area
  - receiving
  - storage
  - production
  - packaging/labeling
  - other areas
- types of buildings/number of floor levels

2.2.2.2 Nature of construction and finishes; include all processing and critical storage areas

- Description of floors, walls, ceilings, windows and other openings, doors, drains, stairs, lift cages and auxiliary structures such as platforms, ladders and chutes, lighting fixtures and ventilation

## 2.3 Equipment

2.3.1 List and briefly describe equipment in :

2.3.1.1 Major productions and quality control facilities

- Description of surface, parts and usage, installation
- Description of planned preventive maintenance programmes and recording system
- Who is responsible for maintenance and servicing?
- Are there written procedures and contractual details for outside work?
- Are records kept for the type and frequency service check, details of service repairs and modifications?
- Are reports made known to the users?

2.3.1.2 Laboratory equipment

2.3.2 Qualification and calibration, including the recording system

- Briefly describes the company's general policy and records kept

2.3.3 Cleaning and Sanitation procedures for manufacturing areas and all equipment

## 2.4 Sanitation and Hygiene

2.4.1 Description of sanitary facilities available

- 2.4.1.1 Water supply (potable and from approved sources sufficient and with adequate pressure in all areas)
- 2.4.1.2 Effluent and waste disposals
- 2.4.1.3 Toilet Facilities
- 2.4.1.4 Hand washing facilities – Accessibility to works provided with adequate supply and soap/detergent
- 2.4.1.5 Disinfection facilities
- 2.4.1.6 Facilities for storage of waste and inedible material
- 2.4.1.7 Eating facilities

#### 2.4.1.8 Pest Control Measures

### 2.5 Documentation

*Note: This section refers to all documentation used in manufacture. Manufacture involves all activities relating to production and control of food products.*

- 2.5.1 Procedures for the preparation, revision and distribution of necessary documentation for manufacture (e.g. batch records, SOPs)
  - 2.5.2.1 Description of the documentation system
  - 2.5.2.2 Who is responsible for the preparation, revision and distribution of documents?
  - 2.5.2.3 Where are the master documents stored?
  - 2.5.2.4 Is there a standard format and instruction of how documents are to be prepared? Are there documents for:
    - Raw materials (specification, batch records, results of analysis)
    - Product process specification
    - Packaging component specification
    - Standard process instruction including packaging
    - Batch production records including packaging
    - Records for finished product
    - Records for returned products
    - QA release procedures
    - Laboratory control
    - Records for major equipment used, cleaning, sanitation and/or sterilization and maintenance
  - 2.5.2.5 How is the documentation controlled?
  - 2.5.2.6 For how long documents are kept after the release of the batch?
- 2.5.2 Any other documentation related to product quality (e.g. microbiological controls on air water)
  - 2.5.2.1 Production equipment specification
  - 2.5.2.2 Standard operating procedures
  - 2.5.2.3 Quality Control Procedures
  - 2.5.2.4 Training Procedures
  - 2.5.2.5 Computer program specifications, if applicable
  - 2.5.2.6 Documentation control of process deviations
  - 2.5.2.7 Calibration and test documents
  - 2.5.2.8 Validation documents



- 2.5.2.9 Reconciliation of batches of raw materials, major packaging components (e.g. product contact and printed materials)
- 2.5.2.10 List and briefly explain the use of any additional standard documentation used routinely

2.5.3 Batch numbering system

## 2.6 Production

2.6.1 Detailed description of manufacturing procedure and identification of critical control points. Include production schedule.

2.6.2 Procedures and work instruction for the handling of:

- 2.6.5.1 Raw materials
- 2.6.5.2 Packaging materials
- 2.6.5.3 Bulk and finished products including sampling, quarantine, release, storage and rework items
- 2.6.5.4 Equipment and utensils for manufacturing operations
- 2.6.5.5 Identification of supplier's lot number with the company's lot number
- 2.6.5.6 Sampling plan
- 2.6.5.7 Labeling (e.g. by using labels or by computer)
- 2.6.5.8 Issue of materials to manufacture and package
- 2.6.5.9 In-process checks
- 2.6.5.10 How are materials being used for manufacture identified and released?
- 2.6.5.11 Storage
- 2.6.5.12 Suitability of packaging materials
- 2.6.5.13 Finished products' compliance with standards

2.6.3 Packing

- 2.6.5.1 Release of bulk, semi-finished products, packaging materials
- 2.6.5.2 Confirmation of identity and line clearance checks
- 2.6.5.3 In-process checks

2.6.4 Quarantine and release of finished products

2.6.5 Procedures and work instructions for the handling of rejected materials and products

- 2.6.5.1 Are rejected materials and products clearly labeled?
- 2.6.5.2 Are they stored separately in restricted areas?
- 2.6.5.3 Describe the arrangements for sentencing the materials and their disposal. Is destruction recorded?

## 2.7 Quality Control

- 2.7.1 Description of the quality control system and the activities of the quality control department
- 2.7.2 Quality control procedures for the different activities
  - 2.7.2.1 Sampling
  - 2.7.2.2 Inspection and testing of raw materials, in-process, intermediate, bulk and finished products
  - 2.7.2.3 Review of batch documentation
  - 2.7.2.4 Sample retention program
  - 2.7.2.5 Stability studies
  - 2.7.2.6 Product complaints
  - 2.7.2.7 Product recall
  - 2.7.2.8 Maintaining correct specification of materials and products

## 2.8 Distribution/complaints and product recall

- 2.8.1 Procedures and recording system for distribution
  - 2.8.3.1 Is the warehouse secure?
  - 2.8.3.2 Is it environmentally controlled?
  - 2.8.3.3 How are the materials are stored (cool room)?
  - 2.8.3.4 How is the status of the product controlled (e.g. by computer, by label)?
  - 2.8.3.5 What are the methods of distribution to customers?
  - 2.8.3.6 Does the dispatch order ensure first-in first-out method and identify the lot number?
- 2.8.2 Security of stocks: defective stocks, market returns or complaint goods
- 2.8.3 Procedures for handling complaints and product recalls
  - 2.8.3.1 Complaints
    - Is there a written complaint procedure?
    - Who is responsible for:
      - Logging
      - Classifying



- Investigating complaints
- Are written reports prepared?
- Who review reports?
- For how long are complaints' records kept?

#### 2.8.3.2 Procedure recalls

- Is there a written procedure for Product Recall which describes the sequence of actions to be followed including:
  - Retrieval of distribution of data
  - Notification customers
  - Receipt segregation of returned products
  - Investigation/reporting cause
  - Reporting corrective action
- Who is responsible for coordinating product recalls?
- Who notifies BFAD of the complaints?
- Is BFAD involved in complaints and decision to recall?
- Traceability of records of raw materials, packaging materials, processing date ad laboratory results
- Storage condition of retention samples

### 2.9 Sub-contracting of manufacture

- 2.9.1 Describe the way in which the GMP compliance of the contract manufacturer is assessed.
- 2.9.2 Written agreements with all contract acceptors, stipulating duties and responsibilities

### 2.10 Self-inspection

- 2.10.1 Short description of the self-inspection system
  - 2.10.1.1 Describe how the self-inspection system verifies that those activities that have a bearing on quality comply with the planned procedures and work instructions
  - 2.10.1.2 Are there documented procedures for the self-inspection system and for the follow-up actions?
  - 2.10.1.3 Does the system ensure that those responsible for the area or activity take timely corrective action on the deficiencies found?