FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE ESTABLISHMENT OF A FOOD STORAGE FACILITY

Document No. :	**FDA/FID/CP-DFW/2020/01**
Date of First Adoption:	1st February 2013
Date of Issue:	21st May 2020
Version No.:	02

TABLE OF CONTENTS

1.0 INTRODUCTION

In exercise of the powers conferred on the Food and Drugs Authority (FDA) by Part Seven, Section 148, Sub-section 2(g) of the Public Health Act, 2012, Act 851, this guideline applies to the storage of food products in order to ensure their safety and quality. This guideline is for the establishment of food storage facilities for food products that are:

a) Locally manufactured/produced/processed
b) Imported and are intended for human and animal consumption, distribution or to be offered for sale in Ghana. This guideline is also intended to provide prepackaged food manufacturers, producers, processors and food importers with the requirements of the FDA. This guideline is hereby promulgated for information, guidance and strict compliance by all concerned.

2.0 GLOSSARY

The definitions provided below apply to the words and phrases used in these guidelines. Although an effort has been made to use standard definitions as far as possible, they may have different meanings in other contexts and documents.

Agreement
Arrangement undertaken by and legally binding on parties.

Batch
A defined quantity of food products processed in a single process or series of processes so that it is expected to be homogeneous.

Batch number
A distinctive combination of numbers and/or letters which uniquely identifies a batch.

Best-before date
The suggested date before which the full quality of the product, as marketed, can be enjoyed.

Consignment
The quantity of food products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include food products belonging to more than one batch.

Container
The material employed in the packaging of a food product. Containers include primary, secondary and transportation containers.

Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.

Contamination

The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or food product during handling, production, sampling, packaging or repackaging, storage or transportation.

Contract

Business agreement for the supply of goods or performance of work at a specified price.

Counterfeit food product

A food product which is deliberately and fraudulently mislabelled with respect to identity and/or source.

Cross-contamination

Contamination of a starting material, intermediate product or finished food product with another starting material or product during production, storage and transportation.

Distribution

The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of food products.

Expiry date

The date given on the individual container (usually on the label) of a food product up to and including the date on which the product is expected to remain within wholesome, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.

First expiry/first out (FEFO)

A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used.

Good Distribution Practices (GDP)

That part of quality assurance that ensures that the quality of food product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded food products.

Labelling

Process of identifying a food product including the following information, as appropriate: name of the product; ingredient(s), batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier.

Manufacture

All operations of purchase of materials and products, production, packaging, labelling, quality control, release, storage and distribution of food products, and the related controls.

Marketing authorization

A legal document issued by the competent regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety and quality. Once a product has been given marketing authorization, it is included on a list of authorized products — the register — and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product licence”.

Product recall

A process for withdrawing or removing a food product from the food distribution chain because of defects in the product, concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency.

Quality assurance

A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that food products are of the quality required for their intended use.

Quality system

An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

Quarantine

The status of food products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

Sampling

Operations designed to obtain a representative portion of a food product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments or batch release.

Sell-by date

Refers to a product's shelf life in-store – the recommended time in which it should be sold to retain marketed quality.

Shelf-life

The period of time during which a food product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.

Standard Operating Procedure (SOP)

An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection).

Storage

The storing of food products up to the point of use.

Supplier

A person or entity engaged in the activity of providing products and/or services.

Transit

The period during which food products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.

Use-by

The date after which food will perish, and will no longer retain the marketed quality.

Vehicles

Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey food products.

3.0 REQUIREMENTS

3.1. **Organization and management**

3.1.1 A designated person shall be appointed within the organization, who has defined authority and responsibility for ensuring that a quality system is implemented and maintained.

3.1.2 Managerial and technical personnel must have the authority and resources needed to carry out their duties and to set up and maintain a quality system, as well as to identify and correct deviations from the established quality system.

3.2 Personnel

3.2.1. All personnel involved in distribution activities shall be trained and qualified in the requirements of Good Distribution Practices (GDP), as applicable. Training shall be based on written standard operating procedures (SOPs). Personnel shall receive initial and continuing training relevant to their tasks, and be assessed as applicable, in accordance with a written training programme. In addition, training of the personnel shall include the topic of product security, as well as aspects of product identification, the detection of counterfeits and the avoidance of counterfeits entering the supply chain. A record of all training, which includes details of subjects covered and participants trained, shall be Kept.

3.2.2 Key personnel involved in the distribution of food products shall have the ability and experience appropriate to their responsibility for ensuring that food products are distributed properly.

3.2.3 There shall be an adequate number of competent personnel involved in all stages of the distribution of food products in order to ensure that the quality of the product is maintained.

3.2.4 Personnel involved in the distribution of food products shall wear garments suitable for the activities that they perform.

3.2.5 Appropriate procedures relating to personnel hygiene, relevant to the activities to be carried out, shall be established and observed. Such procedures shall cover health, hygiene and clothing of personnel.

3.2.6 Procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access to food products must be designed and administered to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.

3.3 Quality system

3.3.1. There shall be a documented quality policy describing the overall intentions and requirements of the distributor regarding quality, as formally expressed and authorized by management.

3.3.2. The quality system shall include an appropriate organizational structure, procedure, processes and resources and systematic actions necessary to ensure adequate confidence that a product or service and its documentation will satisfy given requirements for quality. The totality of these actions is described as the quality system.

3.3.3. Where electronic commerce (e-commerce) is used, i.e. electronic means are used for any of the distribution steps, defined procedures and adequate systems shall be in place to ensure traceability and confidence in the quality of the food products concerned. Electronic transactions (including those conducted via the Internet), relating to the distribution of food products, shall be performed only by authorized persons or entities.

3.3.4. Distributors shall from time to time conduct risk assessments to assess potential

risks to the quality and integrity of food products. The quality system shall be developed and implemented to address any potential risks identified. The quality system shall be reviewed and revised periodically to address new risks identified during a risk assessment.

3.4. Traceability of food products

3.4.1. Distributors shall foster a safe, transparent and secure distribution system which includes product traceability throughout the supply chain. This is a shared responsibility among the parties involved. There shall be procedures in place to ensure document traceability of products received and distributed, to facilitate product recall.

3.4.2. Measures shall be in place to ensure that food products have documentation that can be used to permit traceability of the products throughout distribution channels from the manufacturer/importer to the entity responsible for selling or supplying the product to the patient or his or her agent. Records including expiry dates and batch numbers may be part of a secure distribution documentation enabling traceability.

3.5. Premises, warehousing and storage

Storage areas

3.5.1. Precautions must be taken to prevent unauthorized persons from entering storage areas. Employees shall comply with the company policies to maintain a safe, secure and efficient working environment.

3.5.2. Storage areas shall be of sufficient capacity to allow the orderly storage of the various categories of food products, placing physical quarantine shall provide equivalent security. For example, computerized systems can be used, provided that they are validated to demonstrate security of access.

3.5.3. Physical or other equivalent validated (e.g. electronic) segregation shall be provided for the storage of rejected, expired, recalled or returned products and suspected counterfeits. The products and the areas concerned shall be appropriately identified.

3.5.4. Unless there is an appropriate alternative system to prevent the unintentional or unauthorized use of quarantined, rejected, returned, recalled or suspected counterfeit food products, separate storage areas shall be assigned for their temporary storage until a decision as to their future has been made.

3.5.5. Food products shall be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.

3.5.6. A system shall be in place to ensure that the food products due to expire first are sold and/or distributed first (first expiry/ first out (FEFO)). Exceptions may be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.

3.5.7. Broken or damaged items shall be withdrawn from usable stock and stored separately.

3.5.8. Storage areas shall be provided with adequate lighting to enable all operations to be carried out accurately and safely.

Storage conditions and stock control

3.5.9. Storage conditions for food products shall be in compliance with the recommendations of the manufacturer.

3.5.10. Facilities shall be designed and made available for the storage of all food products under appropriate conditions (e.g. environmentally controlled when necessary). Records shall be maintained of these conditions if they are critical for the maintenance of the characteristics of the food product stored.

3.5.11. Records of temperature monitoring data shall be available for review. There shall be defined intervals for checking temperature. The equipment used for monitoring shall be checked at suitable predetermined intervals and the results of such checks shall be recorded and retained. All monitoring records shall be kept for at least the shelf-life of the stored food product plus one year. Temperature mapping shall show uniformity of the temperature across the storage facility. Temperature monitors shall be located in areas that are most likely to show fluctuations.

3.5.12. Equipment used for monitoring of storage conditions shall also be calibrated at defined intervals.

3.5.13. Stock discrepancies shall be investigated in accordance with a specified procedure to check that there have been no inadvertent mix- ups, incorrect issues and receipts, thefts and/or misappropriations of food products. Documentation relating to the investigation shall be kept for a predetermined period.

3.6. Vehicles and equipment

3.6.1. Vehicles and equipment used to distribute, store or handle food products shall be suitable for their purpose and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and to prevent contamination of any kind.

3.6.2. The design and use of vehicles and equipment must aim to minimize the risk of errors and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or dirt and/or any adverse effect on the quality of the food products being distributed.

3.6.3. Where non-dedicated vehicles are used, procedures shall be in place to ensure that the quality of the food product will not be compromised. Appropriate cleaning shall be performed, checked and recorded.

3.6.4. Procedures shall be in place to ensure that the integrity of the product is not compromised during transportation.

3.6.5. Where third-party carriers are used, distributors shall develop written agreements with carriers to ensure that appropriate measures are taken to safeguard food products, including maintaining appropriate documentation and records. Such agreements shall be in line with national and regional regulatory requirements.

3.6.6. Defective vehicles and equipment shall not be used and shall either be labelled as such or removed from service.

3.6.7. There shall be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

3.6.8. Vehicles, containers and equipment shall be kept clean and dry and free from accumulated waste.

3.6.9. Vehicles, containers and equipment shall be kept free from rodents, vermin, birds and other pests. There shall be written programmes and records for such pest control. The cleaning and fumigation agents used shall not have any adverse effect on product quality.

3.6.10. Equipment chosen and used for the cleaning of vehicles shall not constitute a source of contamination. Agents used for the cleaning of vehicles shall be approved by management.

3.6.11. Special attention shall be paid to the design, use, cleaning and maintenance of all equipment used for the handling of food products which are not in a protective shipping carton or case.

3.6.12. Where special storage conditions (e.g. temperature and/or relative humidity), different from, or limiting, the expected environmental conditions, are required during transportation, these shall be provided, checked, monitored and recorded. All monitoring records shall be kept for a minimum of the shelf-life of the product distributed plus one year. Records of monitoring data shall be made available for inspection by the regulatory or other oversight body.

3.6.13. Equipment used for monitoring conditions, e.g. temperature and humidity, within vehicles and containers shall be calibrated at regular intervals.

3.6.14. Vehicles and containers shall be of sufficient capacity to allow orderly storage of the various categories of food products during transportation.

3.6.15. Where possible, mechanisms shall be available to allow for the segregation during transit of rejected, recalled and returned food products as well as those suspected of being counterfeits. Such goods shall be securely packaged, clearly labelled, and be accompanied by appropriate supporting documentation.

3.6.16. Measures shall be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft

or misappropriation thereof.

3.7. Dispatch and receipt

3.7.1. Prior to the dispatch of the food products, the supplier shall ensure that the person or entity, e.g. the contract acceptor for transportation of the food products, is aware of the food products to be distributed and complies with the appropriate storage and transport conditions established. Such procedures shall take into account the nature of the product as well as any special precautions to be observed. Food products under quarantine will require release for dispatch by the person responsible for quality.

3.7.2. Records for the dispatch of food products shall be prepared and shall include at least the following information:

- date of dispatch;
- complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number and names of contact persons;
- complete business name, address (no acronyms), and status of the addressee (e.g. retail pharmacy, hospital or community clinic);
- a description of the products including;
- quantity of the products, i.e. number of containers and quantity per container (if applicable);
- applicable transport and storage conditions;
- a unique number to allow identification of the delivery order; and
- assigned batch number and expiry date (where not possible at dispatch, this information shall at least be kept at receipt to facilitate traceability).

3.7.3. Records of dispatch shall contain enough information to enable traceability of the food product. Such records shall facilitate the recall of a batch of a product, if necessary, as well as the investigation of counterfeit or potentially counterfeit food products.

3.7.4. In addition, the assigned batch number and expiry date of food products shall be recorded at the point of receipt to facilitate traceability.

3.7.5. Methods of transportation, including vehicles to be used, shall be selected with care, and local conditions shall be considered, including the climate and any seasonal variations experienced. Delivery of products requiring controlled temperatures shall be in accordance with the applicable storage and transport conditions.

3.7.6. Care shall be taken to ensure that the volume of food products ordered does not exceed the capacity of storage facilities at the destination.

3.7.7. Food products shall not be supplied or received after their expiry date, or so close to the expiry date that this date is likely to be reached before the products

are used by the consumer.

3.7.8. Incoming shipments shall be examined to verify the integrity of the container/closure system, ensure that tamper-evident packaging features are intact, and that labelling appears intact.

3.8. Documentation

3.8.1. Written instructions and records which document all activities relating to the distribution of food products, including all applicable receipts and issues (invoices) shall be available. Records shall be kept for seven years, unless otherwise specified in national or regional regulations.

3.8.2. Distributors shall keep records of all food products received. Records shall contain at least the following information:

- date;
- name of the food product;
- quantity received, or supplied; and
- name and address of the supplier.

3.8.3. Documents, and in particular instructions and procedures relating to any activity that could have an impact on the quality of food products, shall be designed, completed, reviewed and distributed with care.

3.8.4. All documents shall be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and shall not be changed without the necessary authorization.

3.8.5. The nature, content and retention of documentation relating to the distribution of food products and any investigations conducted and action taken, shall be retained for at least one year after the expiry date of the product concerned.

3.8.6. Documents shall be reviewed regularly and kept up to date. When a document has been revised, a system shall exist to prevent inadvertent use of the superseded version.

3.8.7. Records relating to storage of food products shall be kept and be readily available upon request.

3.8.8. Permanent records, written or electronic, shall exist for each stored product indicating recommended storage conditions, any precautions to be observed and retest dates.

3.8.9. Where the records are generated and kept in electronic form, backups shall be maintained to prevent any accidental data loss.

3.9. Repackaging and relabeling

3.9.1. Repackaging and relabeling of food products shall be limited, as these practices may represent a risk to the safety and security of the supply chain.

3.9.2. Where they do occur, they shall only be performed by entities appropriately authorized to do so and in compliance with the applicable national guidelines, i.e. in accordance with GMP principles.

3.9.3. In the event of repackaging by companies other than the original manufacturer, these operations shall result in at least equivalent means of identification and authentication of the products.

3.10.Complaints

3.10.1. There shall be a written procedure in place for the handling of complaints. All complaints and other information concerning potentially defective and potentially counterfeit food products shall be reviewed carefully according to written procedures describing the action to be taken.

3.10.2. Any complaint concerning a product defect shall be recorded and thoroughly investigated to identify the origin or reason for the complaint (e.g. repackaging procedure or original manufacturing process).

3.10.3. If a defect relating to a food product is discovered or suspected, consideration shall be given to whether other batches of the product shall also be checked.

3.10.4. Product quality problems or suspected cases of counterfeit products shall be documented and the information shared with the appropriate national and/or regional regulatory authorities.

3.11 **Recalls**

3.11.1. There shall be a system, which includes a written procedure, to effectively and promptly recall food products known or suspected to be defective or counterfeit, with a designated person(s) responsible for recalls.

3.11.2.The effectiveness of the arrangements for recalls shall be evaluated at regular intervals. All recalled food products shall be stored in a secure, segregated area pending appropriate action.

3.11.3. The particular storage conditions applicable to a food product which is subject to recall shall be maintained during storage and transit until such time as a decision has been made regarding the fate of the product in question.

3.11.4. All customers and the FDA shall be informed promptly of any intention to recall the product because it is, or is suspected to be, defective or counterfeit.

3.11.5. The progress of a recall process shall be recorded and a final report issued, which includes reconciliation between delivered and recovered quantities of products.

3.12 Returned products

3.12.1 Rejected food products and those returned to a distributor shall be appropriately identified and handled in accordance with a procedure which involves at least:

- the physical segregation of such food products in quarantine in a dedicated area; or
- Other equivalent (e.g. electronic) segregation.

This is to avoid confusion and prevent distribution until a decision has been taken with regard to their disposition. The particular storage conditions applicable to a food product which is rejected or returned shall be maintained during storage and transit until such time as a decision has been made regarding the product in question.

3.12.2. Provision shall be made for the appropriate and safe transport of rejected food products prior to their disposal.

3.12.3. Destruction of food products shall be done in accordance with local requirements regarding disposal of such products, and with due consideration to protection of the environment.

3.12.4. Records of all returned, rejected and/or destroyed food products shall be kept for a predetermined period.

3.13 Self-inspection

3.13.1. The quality system shall include self-inspections. These shall be conducted to monitor the implementation and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures.

3.13.2. Self-inspections shall be conducted in an independent and detailed way by a designated and competent person.

3.13.3 The results of all self-inspections shall be recorded. Reports shall contain all observations made during the inspection and, where applicable, proposals for corrective measures. There shall be an effective follow-up programme. Management shall evaluate the inspection report and the records of any corrective actions taken.

3.14 MISCELLANEOUS

These provisions relating to food storage warehouses are in addition to and not substitute for all other applicable laws or regulations relating to this type of business operation. The FDA shall at any time, when necessary, take other procedures or steps to ensure that food handled, stored, offered for sale for human or animal consumption, is wholesome and unadulterated.

4.0 SANCTIONS

Failure on three counts of caution on non-adherence to this code of practice will result in suspension or revocation of license.

5.0 PENALTIES

Where non-adherence to this code of practice results in exposure of consumers to a food safety hazard, the FDA will impose an administrative fine in accordance with Public Health Act, 2012, Act 851, Section 148, Sub-section 4 & 5.