

**DRAFT HARMONIZED CRITERIA FOR
REGISTRATION AND CERTIFICATION OF PROCESSED AND PRE-PACKAGED
FOOD FOR INTRA-EAST AFRICAN COMMUNITY (EAC) TRADE**

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INTRODUCTION

The East African Community (EAC) has developed a Framework for facilitating cross border trade in food and cosmetic products. The framework aims to enhance intra-EAC trade in processed and pre-packaged foods and cosmetics products without medicinal claims by removing or minimising the impediments / non-tariff barriers (NTBs) created by standards, technical regulations and conformity assessment.

The EAC Standardization, Quality Assurance, Metrology and Testing (SQMT) and Sanitary and Phytosanitary (SPS) frameworks provide for development and harmonization of procedures, guidelines and frameworks to enhance efficiency and effectiveness in achieving product safety and quality for consumer protection, as well as trade facilitation. The EAC has developed and harmonized a number of standards that have been adopted and implemented by Partner States in their food control systems and for trade facilitation. The EAC Partner States also recognize results of their respective conformity assessment processes among their respective National standards Bodies (NSBs) whereby goods certified by the NSB of one Partner State are recognized as meeting quality and safety requirements and move freely across the borders.

Development and implementation of a clear transparent harmonized criteria for registration, approval and verification of processed and pre-packaged foods in the region will help achieve broader cooperation and collaboration, among the different competent authorities within the SPS/TBT space in order to enhance trade facilitation and ensure frugal use of the limited resources for achieving the public policy goal for consumer protection.

Within the EAC region the key control tools or activities undertaken by competent authorities for processed and pre-packaged food control include:

- Licensing of establishments (manufacturing/processing premises);
- Product Registration;
- Product Certification;
- HACCP/FSMS Certification;
- Import and Export Inspection/Verification
- Inspection and market monitoring.

These activities help ensure processed and pre-packaged foods placed in the market meet safety and quality requirements.

- *Licensing of establishments (manufacturing/processing facilities)*

Establishments engaged in the manufacture of processed and pre-packaged foods are assessed to ensure that facilities, equipment, personnel and all operational practices meet prescribed standards for food safety before they are approved to process or handle food meant for sale/distribution to the public. Registration of stakeholders and licensing of food establishments is majorly undertaken by the specific commodity competent authorities such as those responsible for the control of coffee, tea, dairy, sugar, meat and fish sectors and by the local health authorities.

- *Product Registration*

Product registration is conducted for purposes of establishing that the food product complies to quality and safety requirements as prescribed in the specific product or general subject standards. Laboratory tests are performed on food product samples to ascertain conformance to physical, microbiological and chemical quality and safety parameters as prescribed in standards.

- *Product Certification*

The National Standards Bodies (NSBs) audit/evaluate the manufacturing facility and production processes to verify that the production and quality assurance processes are capable of consistently producing products that meet specified requirements. The products are also evaluated for conformance to the quality and safety requirements specified in the relevant product standards. For a Product Certification Mark to be issued, the products must conform to the requirements of the specified standards and the food establishment must demonstrate its ability to consistently manufacture safe products.

- *Verification of Implementation of Hazard Analysis and Critical Control Points (HACCP) / ISO 22000 Food Safety Management Systems (FSMS)*

Competent authorities may audit the food safety (management) systems, procedures and processes to verify the manufacturer's ability to identify and control food safety hazards as per requirements of HACCP or ISO 22000 FSMS. This level of food product safety assurance is particularly required for high risk foods because of their ability to support the growth of pathogenic micro-organisms.

- *Import and export inspection/verification*

Competent Authorities verify processed and pre-packaged foods at the ports of entry through physical inspection of products, examination of accompanying documents, and in some cases sampling and testing to ascertain conformance to specified safety and quality requirements before clearance of such goods into the country. Processed and pre-packaged foods bearing a notified Product Certification Mark are deemed to meet safety and quality requirements set in standards and therefore not subject to sampling and laboratory testing before clearance.

Importers/exporters apply to the relevant competent authority to import/export food consignments prior to importation/exportation. Importers of certain foods particularly those of animal or plant origin will require to obtain an import permit accompanied with a health certificate or phytosanitary certificate respectively from the country of origin prior to importation. This is for purposes of controlling entry, spread and establishment of diseases and pests that may be brought into the country with these food products.

- *Inspection and market monitoring.*

Routine inspection of processing facilities and monitoring of the products on the market is conducted by competent authorities to assess continued conformance of the registered/licenced establishments and products to prescribed requirements.

The harmonised criteria is the basis on which regulatory control or conformity assessment bodies will assess manufacturing entities for purposes of Product registration and establishment approval; Product Certification and Verification of compliance at the port of entry.

The application of these harmonized criteria will help strengthen the implementation of a standards based regime for food control in the EAC region, help transition from the product registration to the notification system and enhance collaboration among competent authorities to facilitate trade within the EAC common market.

The application of these criteria shall form a basis upon which the EAC Partner States accept the results of each others' control systems for processed and pre-packaged foods as providing the the same level of protection.

1. SCOPE

This document outlines the criteria to be used in the licensing, registration and certification of processed and pre-packaged food products and verification of conformity and clearance of pre-packaged foods across the EAC borders.

The application of this document shall be limited to processed and pre-packaged food which is processed food as defined in this document. This criteria does not cover unprocessed products.

2. TERMS & DEFINITIONS

In addition to the terms and definitions in the SQMT Act the following shall apply:

Audit is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.

Certification means the issue of a written statement by a third party based on a decision following review that products, processes, systems or persons have fulfilled specified requirements.

Codex Alimentarius Commission is a subsidiary body of the Food and Agriculture Organization of the United Nations and the World Health Organization. The Commission is entrusted with the elaboration of international standards of food to protect the health of consumers and to ensure fair practices in the food trade.

Competent Authority means a body that is mandated by law in the respective Partner State to certify, license, register, inspect the products covered within this criteria document.

Equivalence - The process of recognition that enables the measures employed in one country to be deemed equivalent to those of a second country, trading in the same product manufactured within the EAC Partner State, although different control measures are being practised.

Food Fortification ó It is the addition of specific amounts of one or more essential micronutrients (vitamins and/or minerals) to foods that are commonly eaten, regardless of whether they occur naturally in food or not, to improve the nutritional quality of the overall diet of the consumer and community, leading to the reduction and prevention of micronutrient deficiencies in a country, or correcting a demonstrated deficiency in the population.

Food Inspection refers to the examination of food, food production facilities or establishments, including the examination of documents to verify compliance with legal requirements by an agency mandated to perform food safety regulatory and/or enforcement functions.

Food Product Registration means official recognition or approval by a competent authority for food products to be marketed or distributed for human consumption.

Food Supplement ó refers to a processed food product intended to supplement the diet that contains vitamins, minerals, amino acids, herbs, or other dietary substance of botanical, animal, artificial, or natural origin to increase the daily nutrient intake in amounts conforming to agreed minimum daily requirements. These are usually in the form of capsules, tablets, liquids, gels, powders, or pills and are not presented for use as conventional food or as the sole item of a meal or diet or a replacement for drugs or medicine.

Food Surveillance - The continuous monitoring of the food supply to ensure consumers are not exposed to components in foods, such as chemical contaminants or biological hazards, which pose a risk to health.

Good Manufacturing Practices (GMP) means measures or practices undertaken to ensure that the food produced, manufactured or processed is of good quality and safe for human consumption.

HACCP System - Hazard Analysis Critical Control Point system (HACCP) is a scientific and systematic way of enhancing the safety of foods from primary production to final consumption through the identification and evaluation of specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. It identifies, evaluates and controls hazards which are significant for food safety at critical points during a given stage in the food supply chain.

Health certificate for food products of animal origin means an official document issued by the competent authority responsible for bio-security or veterinary services of the country of origin from which an animal product originates certifying that the animal product is substantially free from animal diseases and also meets the health import requirements of the importing country and also complies with the relevant requirements of the exporting country.

Licensing means the process of approval of an application to operate or set up an establishment prior to engaging in the manufacture, importation, exportation, offer for sale, distribution or sale of a processed and pre-packaged food product.

Processed and Prepackaged Food means the product, resulting from the application of physical, chemical or biological processes to a "primary food commodity", and such food is packaged or made up in advance in a container and is intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing or for catering purposes.

Product Certification Mark means a distinctive mark, owned by the certification body, and appropriately protected by legislation as defined in section 24 of the SQMT Act, applied to products to indicate compliance with a specified standard;

Product Certification Permit/License means a formal authorization granted to a person to apply the product certification mark of the certification body to a product or range of products as defined in the permit/license

Product Registration Certificate means an instrument for official approval for the food product to be marketed or distributed in the country.

Requirements are criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair-trading.

3. HARMONIZED CRITERIA FOR REGISTRATION AND CERTIFICATION OF PROCESSED AND PRE-PACKAGED FOOD

This criteria below shall be used by competent authorities involved in regulating processed and prepackaged foods to license, register, certify and verify that the requirements are met.

3.1 General Requirements

3.1.1 Information on Food Establishments

Knowing who is involved in the manufacture, export and import of processed and pre-packaged foods is an important foundational aspect in designing and achieving effective food safety control. For purposes of establishing an inventory of regulated activities and to aid in sharing of regulatory information within the Partner States, Competent Authorities shall establish and regularly update a register of business entities engaged in the manufacture, import or export of processed and prepackaged food.

The information to be captured shall include:

- Business details including the name of the entity, physical address and contact (telephone, emails)
- List of products produced, with their brands and/or common names;
- Business category of importer/exporter, manufacturer
- Relevant licences from local health authorities;
- Permits/certificates issued and their validity

This information shall be updated regularly to take into consideration any changes in physical location or ownership, including any relevant information to ensure traceability in case of need to take any regulatory actions.

3.1.2 EAC Harmonized Standards for Good Manufacturing Practices (GMP) / Good Hygiene Practices (GHP)

In determining compliance of the food establishments to Good Manufacturing/Hygiene (GMP/GHP) requirements for purposes of product registration or product certification the competent authority shall conduct GMP/GHP inspection/audit of the manufacturing facility and ascertain that the manufacturing operations for such food complies with the EAC harmonised standard EAS 39 - Code of practice for hygiene in the food and drinks manufacturing industry.

The licensing/registration of premises shall be conducted by the competent authority in the respective Partner States in accordance with the GMP/GHP requirements in EAS 39. Food establishments that are certified using this criteria shall be deemed to have met the requirements for establishment licensing. Information on licensed/registered and certified establishments shall be shared with the competent authorities in the different Partner States, upon request.

The license/registration status of an establishment based on this harmonised criteria will be deemed sufficient to meet the licensing/registration requirements of the importing country and such licensing/registration shall be recognised by the importing country for purposes of listing such establishment on their register without further assessment.

3.1.3 EAC Harmonized Labelling Requirements

A processed and pre-packaged food shall bear clear labels with complete information as per the labeling requirements specified in EAC harmonised standard for that product or the following East African Standards:

- EAS 38, Labelling of pre-packaged foods - General requirements
- EAS 803, Nutrition labelling - Requirements
- EAS 804, Claims on food - Requirements
- EAS 805, Use of nutrition and health claims - Requirements

Processed and pre-packaged food products shall in addition bear the notified product certification mark.

Processed and pre-packaged food shall not be described or presented on any label or in any labelling manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character or nature in any respect. Any claim included on the food label, presentation or advertising must not mislead the consumer; and it should be clear, accurate and based on scientific evidence.

3.1.3.1 Standards on Food Additives

A processed and pre-packaged food product may contain food additives as prescribed in EAC harmonised standard for that product or in the latest *Codex General Standard For Food Additives (GSFA)*.

3.1.3.2 Standards on Contaminants and Toxins

Limits of contaminants or toxins in a processed and pre-packaged food product shall be as set in the EAC Harmonised standards for that product or CODEX STAN 193, *Codex General Standard for Contaminants and Toxins in Foods (GSCTF)*.

3.1.3.3 Limits of Pesticide Residues

Limits of pesticide residues in a processed and pre-packaged food product shall be as set in the EAC Harmonised standards for that product or CAC/MRL2, *Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for residues of veterinary drugs in foods*.

3.1.3.4 Limits of Veterinary Drug Residues

Limits of veterinary drugs residues in a processed and pre-packaged food product shall be as set in the EAC Harmonised standards for that product or in Codex Alimentarius online resources (data bases) for residues of veterinary drugs

3.1.3.5 Specific Product Quality & Safety Requirements

Processed and pre-packaged foods shall comply with the relevant quality and safety requirements specified in the applicable harmonized EAC Standards or international standard or national standard equivalent to an international standard.

Processed and pre-packaged food products shall be evaluated against the specific product standards to verify compliance with the set food safety, quality and labeling requirements.

Food establishments shall be required to comply with the requirements of the **food fortification** laws of Partner States, as appropriate and with the requirements of the specific fortification product standards including:

- EAS 35 Fortified food grade salt
- EAS 767 Fortified wheat flour
- EAS 768 Fortified milled maize (corn) products
- EAS 769 Fortified edible fats and oils

3.2 EAC Requirements for Verification of Export/Import of Processed and Pre-packaged Foods

3.2.1 Products with Harmonized EAC Standards

Where a processed and prepackaged food product has been registered or certified by a competent authority of an EAC Partner State based on harmonised EAC standards, then the products shall be allowed unhindered access into another importing EAC Partner State.

A valid product certification permit shall be the primary requirement for cross border clearance of processed and pre-packaged foods. On arrival at a border post, a prepackaged and processed food bearing a notified product certification mark by a competent authority of the exporting country shall not be subjected to sampling and testing before clearance. The receiving country shall verify the documents submitted and may conduct physical inspection of the processed and pre-packaged food products to confirm that there is no misrepresentation or false declaration prior to release.

Where Partner State food control laws require processed and pre-packaged food products registration before placement in the market, and where such a processed and pre-packaged food that has been registered and/or certified in the country of origin as per the harmonised registration and/or certification criteria, a valid product certification permit shall be sufficient to clear the consignment at the port of entry. The competent authority responsible for the product registration in the Partner State shall, for all processed and pre-packaged food products manufactured and certified in other Partner States, deem the products, including the manufacturing facilities to have complied with all relevant requirements as specified in this criteria.

The manufacturer and the relevant product(s) shall be listed, as applicable, based on their certification permit without re-evaluation (pre-registration site inspection and/or product testing).

3.2.2 Products with International Standards or National Standards adopted from International Standards

Processed and pre-packaged food products certified based on international standards (CODEX, ISO) or national standards adopted from international standards shall be treated as those in Section 3.2.1 of these criteria, provided there are no EAC harmonised standards for such products.

Partner States shall initiate the process of harmonization of the said standard under the fast tracking provisions of the EAC procedures.

3.2.3 Products with Indigenous National Standards

Where there are no EAC harmonized standards and/or international standards and the Partner State has developed an indigenous national standard, the following pre-export arrangements shall be undertaken by the competent authority to facilitate exports for such processed and pre-packaged food products to other Partner States:

- Notify the Partner States and provide the full text of the standard(s);
- The Partner States will provide feedback on the results of their evaluation, on whether such products may be accepted in their country as providing an acceptable level of protection;

Such products shall be treated as in Section 3.2.1 of these criteria above

Where the volume of trade in such products is substantial within the region, then such product standards shall be considered for harmonisation.

3.2.4 Products without specific standards

Cognizant that the procedures for standards development may not match the rate of food product innovation within the region, it is likely that novel products may be allowed access to the local markets based on general standards for microbial and chemical contaminants and labelling requirements or other criteria.

Such products could also find market in another Partner State. In such cases:

- i. The manufacturer shall be required to prove the fitness of each consignment against the set quality and safety requirements by conducting laboratory tests using a laboratory recognised by a competent authority in the country of origin

- ii. The products may, on request of the exporter, be subjected to **batch certification** for each consignment by the National Standards Body of the country of origin. The evaluation of such products shall be done using objective and transparent criteria which shall be declared on the certificate.
- iii. Such consignments may be detained, sampled and tested and only released upon confirmation of conformance by the importing Partner State. The importing country shall implement its clearance procedures that achieve appropriate level of protection.
- iv. Such products cannot be certified and cannot bear the notified product certification marks.

4. PEER ASSESSMENT AMONGST COMPETENT AUTHORITIES

The competent authorities in the EAC Partner States shall conduct Peer Assessment activities amongst themselves every 2 years or as may become necessary, to give confidence of equivalence of systems and to foster mutual recognition.

5. SURVEILLANCE AND PRODUCT MONITORING

Surveillance and product monitoring may be conducted by the relevant authorities in respective Partner States based on the risks presented by the processed and pre-packaged food products.

During routine monitoring and inspection, if the products are found not complying or in violation of requirements, then such actions shall be taken as prescribed in the applicable local legislation. The respective authorities in the country of origin shall be informed to take such other action as provided for in the local legislation and relevant procedures.