EAST AFRICAN COMMUNITY

FRAMEWORK TO FACILITATE EAST AFRICAN COMMUNITY CROSS BORDER TRADE OF FOOD AND COSMETICS PRODUCTS

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0 Introduction

0.1 Background to the development of the framework

The East African Community (EAC) has made substantial and steady achievements in its integration process, progressing from a Customs Union in 2005 to a Common Market in 2010. At the heart of these milestones, is the quest for the full liberalization of intra-EAC trade by progressively transforming into a single market and increasing its share of trade in the global market for the socio-economic transformation of her people.

Promotion of intra-regional trade remains a key cornerstone as the EAC Partner States move towards the full realization of the benefits of the integration. Statistics show that intra-EAC trade remains low at about 12% (EAC trade and investment report, 2018) compared to other economic blocks such as SADC where Intra-regional trade is at approximately 46% and EU at approximately 67%. This is mainly as a result of non-tariff measures or barriers (NTBs) in form of restrictive trade policy measures and technical requirements.

Among the key sectors greatly impacted by NTBs are the food and cosmetics products. In all the six Partner States, these products are subjected to multiple conformity assessment and regulatory control requirements by multiple regulatory institutions, often with a similar goal to enhance products safety and protect consumer health. This multiplicity in regulation and inconsistencies in the conformity assessment and regulatory controls across borders creates a great deal of uncertainty for the business community, increases the cost of doing business in the region and limits trade. In some cases, the delays cause substantial cost increase to the extent, that some businesses abandoned exporting to some Partner States due to the restrictive requirements and multiple fees that made their products less competitive by the time they entered the market.

Regulatory cooperation and coordination between Partner States and regulatory institutions presents a significant opportunity to reduce NTBs and facilitate increased intra-EAC trade flows.

It is therefore necessary to establish a framework that clearly outlines the principles, requirements, processes, and a coordination mechanism that ensures close collaboration among Partner States regulatory and conformity assessment institutions in enhancing safety and free flow across borders of food and cosmetics products within the EAC region. The framework is aimed at integrating the implementation of regulatory controls and measures for processed pre-packaged food, non- medicated cosmetics products and herbal cosmetics without medicinal claims to facilitate trade in the EAC region.

0.2 Establishment of the task force

The East African Standards Committee (EASC), at its 21st meeting of April 2018, while recognizing the value of mandatory requirements for food and cosmetics products, safety controls, conformity assessment policies, practices in achieving adequate protection of people, the environment, and other essential interests of society, noted that it was necessary to ensure these were less restrictive to trade.

The EASC recommended the establishment of the task force composed of the TBT and SPS experts/other regulators and the private sector to develop a framework for facilitating cross border trade for food and cosmetics products, while

at the same time providing for food and cosmetics products safety and consumer protection. The Task Force was constituted in August 2018 and undertook the development of this regulatory framework.

Members of the task force were drawn from each of the Partner States institutions shown below with coordination from the EAC Secretariat:

- National standards bodies (NSBs);
- Agencies responsible for control of safety of cosmetics and foods;
- Ministries responsible for trade;
- Manufacturers' associations;
- NTB Monitoring committee;
- East African Business Council (EABC); and
- EAC Secretariat

0.3 Key findings from the national consultations in the Partner States

The taskforce undertook national consultations in all six Partner States following a methodology given in Annex A. A summary of the regulatory institutions and conformity assessment processes subjected to food and cosmetics products in each Partner State is summarised in the regional matrix given in Annex B.

Overall, it was noted that the private sector was dissatisfied with the multiple agencies with duplicated mandatory conformity assessment and regulatory controls imposed on food and cosmetics products within the context of intra-EAC trade. The private sector reported delays of up to three months in meeting conformity assessment requirements and movement of goods from the country of origin to the destination country.

The following key challenges were identified:

(i) an overlap and lack of clarity of mandates that has resulted into duplication of roles in respect to registration, licensing, sampling, testing, inspection and market surveillance in all the Partner States in food and cosmetics products;

(ii) various fees charged by the different authorities for sampling, testing and certification activities, inspection, licensing, permits, etc;

(iii) high costs of doing cross-border trade for food and cosmetics products;

(iv) inadequate information exchange amongst regulatory institutions and between the private sector and regulatory institutions;

(v) delays in clearance at the border points;

(vi) lack of harmonized standards for some products;

(vii) lack of timely review and update of laws;

(viii) weak enforcement of laws and regulations due to inadequate human and financial resources and awareness;

(ix) weak collaboration and coordination amongst the regulatory authorities within the region; and

(x) weak collaboration between the regulatory authorities and the private sector

0.4 Legal background to the framework

The legal framework for regulatory cooperation for purposes of promoting intra-EAC trade is provided for in the SQMT Act 2006, East African Customs Management Act (EACMA) 2004, One Stop Border Posts (OSBP) Act, 2016 and other relevant laws, and protocols such as the Common Market Protocol, the Customs Union Protocol and trade policies, Tripartite, AfCFTA in addition to the Multilateral Agreements such WTO SPS and TBT Agreements.

Harmonization, equivalence and mutual recognition are the two main forms of regulatory cooperation used in EAC both to enhance the quality and safety, including the free flow of food and cosmetic products across borders. The cooperation and coordination among the NSBs of the EAC Partner States has progressed steadily with the harmonization of the various conformity assessment procedures, recognition of certification marks and implementation of peer assessment. These arrangements have been driven and coordinated by the East African Standards Committee and its technical sub-committees of quality assurance, testing, standards and metrology.

The EAC SQMT and SPS frameworks provides for development of procedures, guidelines and frameworks to facilitate the implementation of the SQMT Act to enhance efficiency effectiveness in achieving product safety and quality for consumer protection, as well as trade facilitation.

1 Scope

The scope of the framework is to enhance the free flow of trade across the borders, while maintaining an appropriate level of consumer protection, of processed pre-packaged food products, non-medicated cosmetics and herbal cosmetics without medicinal claims.

The framework does not apply to products imported from outside the EAC.

2 Objectives

The overall objective of the framework is to provide a comprehensive harmonized approach to implement regulatory safety controls for food and cosmetics products based on the principles of risk-based preventive controls, equivalence, harmonization, mutual recognition and adherence to ISO/IEC standards requirements while still achieving the twin critical goals of improved consumer protection and facilitating trade.

The framework will further help to achieve the following specific objectives:

a) enhance cooperation and coordination in ensuring safety and quality of pre-packaged processed food and cosmetics products among conformity assessment and regulatory bodies;

b) promote mutual recognition of conformity assessment/regulatory control activities and results among conformity assessment bodies and regulatory institutions to minimise technical barriers to intra-EAC trade; and

c) facilitate free flow of safe food and cosmetics products within the EAC Common Market and achieve efficient cross-border trade by reducing operational and financial burden on private sector.

3 Terms, definitions and abbreviations

3.1 Terms and definitions

3.1.1

certification

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

3.1.2

conformity assessment

demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. Typical examples of conformity assessment activities include sampling, testing, inspection, certification, etc.

3.1.3

consumer

person or group of persons within the target range of the producer or manufacturer or packer of goods, and include the market within the anticipation of such producer, manufacturer or packer

3.1.4

confidentiality

securing information or data to safeguard it from access by unauthorised persons and to ensure that the information is not used inappropriately for personal gain or in a manner detrimental to the legitimate interests of the source

3.1.5

designated authority

public institution nominated by the government as the main organization coordinating other conformity assessment bodies/regulatory agencies in the implementation of this framework and clearance of goods at entry/exit points

3.1.6

competent authorities

bodies that are mandated by law in the respective Partner States to regulate, certify, license or register the products covered within this framework

3.1.7

harmonisation

process of establishment of common standards, procedures, etc. among the Partner States with the result that Partner States recognize, establish and apply the same measures

3.1.8

herbal cosmetics without medicinal claims

preparation which contains ingredients from one or more plants but without therapeutic claims or other human health benefit

3.1.9

importer

person or legal entity that places a product from one member country into another country’s market in which he or she is resident or established.

3.1.10

inspection

examination of a product design, product, process or installation, and determination of their conformity with specific requirements or, on the basis of professional judgement, with general requirements

3.1.11

manufacturer

person or legal entity responsible for designing and or manufacturing a product or brand owner of a product and whose intention is to place it on the market. Manufacturer includes any person or entity that produces, processes, treats, installs, tests, operates, prepares, compounds, formulates, fills, refines, transforms, packs, repackages and labels a product with the intention of placing it in the market.

3.1.12

market surveillance

action which is carried out in order to check whether the product is in conformity with the relevant standards when placed on the market

3.1.13

notification

process of informing of a proposed measure, reacted upon by parties and dialogued for adoption

3.1.14

products

goods designed to be released or launched into a market

3.1.15

Partner States

country granted membership to the East African Community under Article 3 of the Treaty for the establishment of the EAC

3.1.16

designated testing laboratory

public or private testing laboratory approved by a Partner State based on an established criteria as being competent in conducting testing within a given scope

3.1.17

product certification mark

notified mark, owned by a Partner State certification body, and appropriately protected by legislation as defined in section 24 of the SQMT Act 2006, applied to products to indicate compliance with a specified standard

3.1.18

standard

document approved by a recognised body that provides for common and repeated use, rules, guidelines or characteristics, of products and their related processes or production methods, with which compliance is not mandatory and may cover terminology, symbols, packaging, or labelling requirements as they apply to a process or production method;

3.1.19

East African Standard (EAS)

standard approved by the East African Standards Committee (EASC) and declared as such by the Council of Ministers of the EAC established by article 9 of the Treaty

3.1.20

cosmetics product

any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs or with the teeth and mucous membranes of the oral cavity) with a view to exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours without having any medicinal effects

3.1.21

pre-packaged processed food

food which is packaged or made up in advance in a container or package, ready for offer to the consumer

3.1.22

equivalence

Equivalent is defined as the state wherein sanitary or phytosanitary measures applied in one Partner State, though different from the measures applied in another Partner States, are achieved, as demonstrated by the one Partner State and recognized by another Partner State"

3.2 List of abbreviations and acronyms

- AfCFTA - Africa Continental Free Trade Area
- AFA - Agriculture and Food Authority
- CA - Conformity Assessment
- CAB - Conformity Assessment Body
- CODEX - Codex Alimentarius Commission
- DDA - Dairy Development Authority
- EABC - East African Business Council
- EAC - East African Community
- EACMA - East African Customs Management Act
- EASC - East African Standards Committee
- EAS - East African Standard
- EU - European Union
- GMP - Good Manufacturing Practices

- HACCP - Hazard Analysis Critical Control Point
- IEC - International Electrotechnical Commission
- ISO - International Organization for Standards
- KDB - Kenya Dairy Board
- KEBS - Kenya Bureau of Standards
- NDA - National Drug Authority
- MOH - Ministry of Health
- NSB - National Standards Body
- NTB - Non-Tariff Barrier
- OSBP - One Stop Border Post
- PPB - Pharmacy and Poisons Board
- QATSC - Quality Assurance Technical Sub Committee
- RIA - Regulatory Impact Assessment
- SADC - Southern Africa Development Community
- SMC - Standards Management Committee
- SPS - Sanitary and Phyto-Sanitary
- SQMT - Standardisation, Quality Assurance, Metrology and Testing
- TBS - Tanzania Bureau of Standards
- TBT - Technical Barriers to Trade
- TFDA - Tanzania Food and Drugs Authority
- TMDA - Tanzania Medicines and Medicinal Devices Authority
- UCDA - Uganda Coffee Development Authority
- UNBS - Uganda National Bureau of Standards
- WTO - World Trade Organization

4 Principles

The framework is based on the following common guiding principles and best practices for establishing effective regulatory and conformity assessment processes and systems.

4.1 Consumer protection

The primary goal for a food and cosmetics safety regulatory and control system is to ensure safe products for the consumers. Priority therefore in the design and implementation of the regulatory and conformity assessment framework for the control of food and cosmetics products shall always be given to protecting consumers from unsafe products.

4.2 Use of certification marks for trade facilitation

A good and effective regulatory control system for food and cosmetics products should be the least restrictive to trade while protecting the health of consumers.

Partner States shall recognise each other's notified quality certification marks for purposes of facilitation of transfer of goods across borders in line with the provisions of the EAC standardization and conformity assessment framework. Food and cosmetics quality and regulatory safety requirements or measures specified in relevant East African standards shall be the primary basis for issuing quality certification marks. In the absence of East African standard, the international or national standard shall be used as the basis for product certification.

A valid quality certification mark permit or batch certificate issued by the designated conformity assessment body in the country of origin shall be the primary requirement for cross border trade in processed pre-packaged foods, non-medicated cosmetics and herbal cosmetics without medicinal claims.

4.3 Collaboration and coordination between competent agencies

Partner States shall ensure coordination and sharing of information and best practices among regulatory and conformity assessment bodies in order to promote consistency in their conformity assessment processes, mutual recognition and minimise duplication and trade restrictions.

The Partner States shall designate a single regulatory agency that shall be the principal regulatory agency to coordinate the clearance of processed and pre-packaged foods and non-medicated cosmetics and herbal cosmetics without medicinal claims at the entry points.

The designated conformity assessment body shall collaborate with the other competent authorities to ensure that the products meet all the requirements at country of origin before certification and transfer to the other Partner States.

The competent authorities involved in the regulation of food and cosmetics products should collaborate to minimise duplication and reduce costs and turnaround time for conformity assessment through harmonisation of criteria and recognition of each other's results for the various components of conformity assessment processes for the same objective.

The Partner States shall strengthen and build capacity of the designated regulatory agencies that shall serve as reference institutions for conformity assessment processes and procedures in foods, non-medicated cosmetics and herbal cosmetics without medicinal claims.

4.4 Transparency and notifications

In order to attain transparency and convergence of harmonised standards and measures, a Partner state is obliged to notify other Partner States of any new or proposed changes in requirements that affect trade in processed pre-packaged foods, non-medicated cosmetics and herbal cosmetics without medicinal claims. The notifications shall be done at least six months prior to the implementation of the changes.

CABs shall publish and make publicly available information on existing requirements and draft proposed requirements before implementation. CABs shall use online systems, including the EAC online information system portal, for information sharing on policies, standards, laws, regulations, procedures, certified products, suspended products and banned products.

Clear documentation and timely communication, as well as exchange or sharing of information between competent authorities where non-compliances have been identified shall be encouraged in order to facilitate timely implementation of appropriate corrective and preventive actions.

Regulatory agencies shall carry out sensitization of the stakeholders on requirements and conformity assessment procedures.

4.5 Impartiality and consistency

The regulatory framework for the control of food and cosmetics products shall be applied consistently and impartially to all products produced within the EAC domestic market.

4.6 Risk based approach

Risk assessment shall be an integral part of the conformity assessment of products. The level of food and cosmetics safety regulatory and control requirements should be proportionate to the level of risk associated with the food or cosmetics products or ingredients.

Implementation of standards and risk-based conformity assessment procedures shall form a foundation for establishing and implementing controls to address risk factors that could put products at risk.

Partner States shall establish harmonised risk assessment guidelines for selected products and processes for effective quality and safety control within the EAC.

4.7 Mutual recognition

Partner States shall recognize each other's food and cosmetics conformity assessment and regulatory control systems or components as deemed to provide the same level of consumer protection in accordance with the EAC standardization and conformity assessment framework.

CABs shall accept and recognise the conformity assessment results that have been issued by CABs from other Partner States issued in accordance with harmonised standards and conformity assessment processes.

In the absence of harmonised standards, Partner states shall accept each other's CA results based on International or national standards as long as they have been carried out using harmonised CA processes that attain similar quality and safety objectives.

Where there is lack of a valid quality certification mark, a batch certificate (certificate of conformity) issued by the designated CAB based on an East African standard or national standard shall be accepted in lieu of the notified quality mark permit for that particular consignment.

CABs shall demonstrate effectiveness and adequacy of their conformity assessment programs to give confidence to each other and allow for approximation of such control systems by adhering to relevant ISO/IEC standards and peer assessment processes.

4.8 Harmonisation of standards and conformity assessment processes

Conformity assessments shall be based on harmonised standards, CA procedures and criteria to promote mutual recognition In Partner States.

Stakeholders shall be engaged to enhance effective participation in standards harmonization activities to ensure that all applicable regulatory requirements are covered in the harmonized standards.

In the absence of harmonised standards, Partner states shall accept each other's CA results based on International or national standards as long as they have been carried out using harmonised CA processes that attain similar quality and safety objectives.

The EAC Secretariat shall publish the most current and updated catalogue of all EAC harmonised standards and conformity assessment procedures and upload them in the EAC website to enhance compliance.

4.9 Confidentiality

Partner States shall ensure that the confidentiality of information about products originating in the territories of other Partner States supplied in connection with such conformity assessment procedures is respected and safeguarded in the same way as for domestic products and in such a manner that legitimate commercial interests are protected.

5 The Framework

This framework establishes a Single Integrated Multi-Agency Mechanism for cross border control of food and cosmetics products through collaboration and coordination of conformity assessment activities. This framework will also serve as a trade facilitating tool to build trust between different regulatory systems and contribute to facilitating acceptance of results of conformity assessment. It aims at providing a high level of confidence as regards to conformity of products, while avoiding imposing heavier procedures than necessary and minimizing the burden on businesses.

The principles enshrined in this framework are in tandem with current global trends in finding effective mechanisms for achieving efficient and effective food control regulation and trade facilitation by integrating and taking into consideration the various conformity assessment activities such as product and system certifications, inspection and testing.

5.1 One harmonized standard

Conformity Assessment shall be undertaken based on East African standards. Where an East African Standard is not available, a national standard or a mutually agreed upon objective transparent criteria may be used as long as they provide acceptable level of consumer protection and do not impede trade.

5.2 One certification and one quality mark

A valid quality certification mark permit issued by the designated conformity assessment body in the country of origin shall be the primary requirement for cross border trade in processed pre-packaged foods, non-medicated cosmetics and herbal cosmetics without medicinal claims.

Certification shall be based on one set of harmonized conformity assessment criteria based on quality and safety requirements specified in relevant EAS or mutually agreed upon criteria in coordination among relevant regulatory institutions and conformity assessment bodies.

Partner States shall recognise each other's quality certification marks as the primary requirement for purposes of facilitation of intra-EAC trade in food and cosmetics products in line with the provisions of the EAC standardization and conformity assessment framework.

5.3 One designated Conformity Assessment Body

Each Partner State shall designate a single conformity assessment body with the overall responsibility to coordinate conformity assessments and clearance of goods at entry points with regard to quality and safety of processed pre-packaged foods, non-medicated cosmetics and herbal cosmetics without medicinal claims.

The designated CAB shall collaborate and coordinate with the other competent authorities within Partner States to ensure that the products meet all the requirements before certification and transfer to the other Partner States.

Competent authorities involved in the regulation of food and cosmetics products should collaborate to minimise duplication and reduce costs and turnaround time for conformity assessment through harmonisation of criteria and recognition of each other's results for the various components of the conformity assessment process.

The designated authority shall:

a) Coordinate with other Regulatory Authorities to ensure products certified for quality and safety meet the requirements of the standard and any other requirements specific to other regulatory authorities such as registration and licensing.
b) Establish a coordination mechanism with other competent regulatory authorities to ensure effective coordination of conformity assessment activities.
c) Ensure verification and clearance of goods at ports of entry for processed pre-packed foods, non-medicated cosmetics products and herbal cosmetics with no medicinal claims.
d) Coordinate other regulatory authorities to harmonise their conformity assessment criteria and accept each other's conformity assessment results where there is duplication to reduce regulatory burden on the business community.
e) Recognize registration, licencing and other conformity assessment activities undertaken by competent authorities based on defined criteria that may be harmonized for purposes of mutual recognition.
f) Undertake testing of products for compliance to the requirements of the standards and/or mutually recognize and accept as equivalent test reports from other designated test laboratories for meeting the same objective based on the same criteria.
g) Undertake targeted joint inspection at the national level with other regulatory agencies where necessary for compliance to the requirements of the standards.
h) Issue permit/license as certificate of conformity according to the regulations to use the notified product Quality Mark.
i) Receive, document and effectively address complaints related to certified products in a timely manner.
j) Share information on detected non-compliance related to certified products with other regulators in a timely manner taking into consideration the requirement for confidentiality and level of risk associated with the products.
k) Ensure conformity assessment criteria, procedures and processes are easily accessible to the business community and other stakeholders.
l) Notify the counterpart regulatory authorities of any changes in the conformity assessment regime/criteria/policies.

5.4 One set of harmonized Conformity Assessment Criteria

The EASC to establish a clear, transparent, non-discriminatory and coherent criteria for the products conformity assessment to ensure that cosmetics and processed pre-packaged foods made available in the market conform to essential requirements set out in the relevant quality and safety standards and other

requirements in relevant legislation to protect the relevant public objectives. In addition to the specific requirements in the standards, the harmonized criteria should take into consideration specific sector registration and licensing requirements, where applicable.

The results of conformity assessment undertaken in accordance with the harmonized criteria shall be accepted by other Partner States for automatic registration and licensing of food and cosmetics' products.

5.5 One standardized risk-based Conformity Assessment/Certification approach/system

The main conformity assessment activities include inspection, testing, product certification and market surveillance. These activities can be used to assess and certify both product quality and safety.

The level and extent of conformity assessment shall be based on the level of risk associated with the firm and the product i.e. the level of food and cosmetics safety regulatory and control requirements should be proportionate to the level of risk associated with the food or cosmetics products or ingredients.

CABs shall demonstrate effectiveness and adequacy of their Conformity assessment programs to give confidence to each other and allow for approximation of such control systems by adhering to international standards for conformity assessment bodies, including: ISO/IEC 17065; ISO/IEC 17021; ISO/IEC 17020; ISO/IEC 17025 and EAC product certification peer assessment processes.

CABs shall carry out their conformity assessment processes in accordance with relevant ISO/IEC standards in order to enhance confidence, trust and establishment of equivalence and mutual recognition of each other's conformity assessment results and product certification marks.

CABs shall accept and recognise the conformity assessment results that have been issued by CABs from other Partner States issued in accordance with harmonised standards and conformity assessment processes.

6 Implementation of the framework

An enabling environment and arrangements are necessary to support effective and efficient implementation of the framework, including collaboration with various stakeholders from government, industry and consumers.

6.1 Designated authorities

Partner States shall designate Competent Authority as the coordination agency in the implementation of conformity assessment within this framework.

The designated authority shall undertake roles as listed below:

a) Coordinate with other Regulatory Authorities to ensure products certified for quality and safety meet the requirements of the standard(s) and any other requirements specific to other regulatory authorities such as registration and licensing;

b) Establish a coordination mechanism with other competent regulatory authorities to ensure effective coordination of conformity assessment activities;

c) Ensure verification and clearance of goods at ports of entry/exit for processed and pre-packaged foods, non-medicated cosmetics products and herbal cosmetics with no medicinal claims;

d) Recognize the registration, licencing and other conformity assessment activities undertaken by competent authorities based on defined criteria for purposes of mutual recognition;

e) Mutually recognize and accept as equivalent, test reports from other designated test laboratories for meeting the same objective based on the same criteria;

f) Undertake targeted joint inspection at the national level with other regulatory agencies, where necessary, for compliance to the requirements of the standards.

g) Issue permit(s)/license(s) as certificate of conformity according to the regulations to use the notified product Quality Mark; and

h) Undertake joint cross border sensitization.

6.2 Coordination committee

6.2.1 Regional coordination committee

The East African Standards Committee (EASC) shall establish a Regional coordination committee to monitor and ensure smooth implementation of this framework.

The composition of the Regional Coordination Committee shall be made up of representatives drawn from the Partner States as follows:

- One representative from each of the Partner States NSBs (6 persons)
- One private sector representative from each Partner State (6persons);
- One representative from regulatory institutions [6 persons]; and
- The EAC Secretariat SQMT Liaison office.

The EASC Quality Assurance Technical Sub-Committee (QATSC) shall develop ToRs for the Coordination Committee for approval by the EASC.

6.2.2 National coordination committee

Each Partner State shall constitute a national coordination committee that shall consist of:

- NSB (Secretariat);
- Other regulatory authorities in the food and cosmetics products;
- Private sector representatives from both food and cosmetics products sectors;
- Manufacturers' association representatives; and
- Any other relevant institution.

The national coordination committee shall monitor the implementation of the framework at national level and its deliberations shall inform discussions of the Regional Coordination Committee.

6.3 Harmonization of standards and procedures

To support the implementation of this framework, the following aspects shall be considered:

a) The Regional Coordination Committee shall identify commonly traded foods and cosmetics products for which standards have not been harmonized and bring them to the attention of the EAC Standards Management Committee (SMC) for harmonization.

b) Stakeholders shall be engaged to enhance effective participation in standards harmonization activities to ensure that all applicable regulatory requirements are considered when harmonizing standards.

c) The respective regulatory authorities in the Partner States shall actively participate in standards harmonization process to ensure that all their regulatory requirements with respect to quality and safety are addressed when harmonizing standards.

d) NSBs shall adopt harmonised standards within the stipulated timelines in the SQMT Act 2006 to facilitate the process of conformity assessment.

e) Partner States shall promote and support fast tracking of harmonisation of standards for commonly traded products and conformity assessment processes.

f) EAC Secretariat shall publish the most current and updated catalogue of all EAC standards and conformity assessment procedures and upload them on the EAC website to enhance compliance.

g) EAC Secretariat shall coordinate the harmonization of conformity assessment procedures to facilitate mutual recognition.

6.4 Exchange of information/information sharing

The designated authorities shall share information on certified products using the EAC harmonized template for sharing information on certified products, to facilitate faster clearance of goods at the ports of entry.

Partner States shall establish a harmonized online system to ensure real time access to conformity assessment procedures, harmonized standards, permits/certificates and other information.

Partner States shall share relevant information relating to conformity assessment criteria and procedures with the business community in a transparent and timely manner to promote compliance.

Partner States shall notify to the EAC Secretariat, at least 60 days before implementation, any other measures outside the standards and the harmonized criteria that may affect cross border trade of food and cosmetics products.

6.5 Peer assessment

EAC Secretariat shall design and implement peer assessment program, at least once every two years, covering product certification, inspection and market surveillance activities in the Partner States.

6.6 Capacity building

EAC secretariat shall design, coordinate and monitor annual capacity building program to enhance competence, trust and mutual recognition of conformity assessment activities. These include:

a) Training of peer assessors, auditors and inspectors for participating CABs.

b) Sensitization of stakeholders on conformity assessment procedures.

c) Digitalization of standards harmonization and conformity assessment processes such as certification process, issuance of digital certificates and e-permits.

7 Monitoring and evaluation

The monitoring and evaluation plan will guide periodic performance reporting on implementation of this framework.

7.1 Data to be collected

The Regional Coordination Committee shall annually collect data on the following aspects to assess effective implementation of the framework:

a) Designation of a single authority by Partner States to manage entry points (within one year);

b) Turnaround time for clearing of goods (improvement attributed to changes proposed in the framework);

c) Number of traded food and cosmetics products without harmonised standards;

d) Harmonised procedures for conformity assessment (and non-harmonised procedures that require to be harmonised);

e) Meetings conducted amongst agencies – intra- and inter- Partner States aimed at enhancing the clearing of goods at ports of entry;

f) Number and nature of complaints received for delayed clearance from Partner regulators and traders;

g) Number of certified products manufactured and traded within the region;

h) Number of consignments with a valid certification permit denied entry into EAC Partner States (and reasons);

i) Number of stakeholder engagements conducted to sensitise on clearance procedures;

j) Any SQMT legislation made/revised in Partner States to improve intra-EAC trade;

k) Level of automation of conformity assessment services;

l) Information exchange platforms (active websites and portals, newsletters, etc.) created

m) Capacity building trainings, benchmarking visits conducted for auditors and inspectors to improve service delivery;

n) Number of peer assessments conducted in the year;

o) Responsiveness to issues raised in peer assessments and corrective interventions for improvement;

p) Data on volume of intra-EAC trade trends – outcome indicator;

q) Level of participation of regulators in standards development; and

r) Regulatory impact assessment (RIA) from the private sector.

7.2 Reporting

The Regional Coordination Committee shall annually report to the QATSC on the progress of implementation of the framework based on set objectives and comparing planned outputs with results obtained.

The results may be published on the respective websites of the NSBs, Regulatory Authorities, EAC Secretariat, EABC and private sector associations.

When results are not forthcoming as planned, investigations shall be carried out and the root cause analysis used for corrective action.

The QATSC Chairperson shall provide annual briefs to the EASC on the implementation of the framework and progress made with regard to trade facilitation.

Annex A

Methodology

A.1 Establishment of a taskforce

The task force was established and had its first meeting from 14th to 16th August 2018, where it developed a roadmap for activities leading to a framework for integrating the implementation of regulatory controls and measures for food and cosmetics, based on international good practices.

Members of the task force were drawn from each of the Partner States institutions shown below with coordination from the EAC Secretariat:

a) NSBs;

b) Agencies responsible for control of safety of cosmetics and foods;

c) Ministries responsible for trade;

d) Manufacturers' associations;

e) NTB Monitoring committee;

f) East African Business Council (EABC); and

g) EAC Secretariat

As part of the roadmap, the taskforce established a Working Group comprising two delegates from each Partner State to undertake national consultations. The Working Group was constituted of the regulatory authorities responsible for standards and drugs, food and cosmetics from each Partner State, private sector and the EAC Secretariat.

A.2 Activities

National consultations were undertaken between November 2018 and April 2019, in all the six Partner States to develop a national position on the Regulatory Framework.

Presentations were made by the regulatory authorities highlighting the applicable laws, activities and details of the operations undertaken by each authority in respect of food and cosmetics control. The private sector presentations gave the practical experiences and challenges encountered in the cross border trade on food and cosmetics products.

The Working Group met on 12th to 16th August, 2019 in Dar es Salaam and from 26th to 30th August, 2019 in Kampala to review and analyse the national consultation reports and came up with a regional matrix that highlighted the existing regulatory framework for food and cosmetics products in the EAC.

A.3 Overview of good practices in regulation of food and cosmetics in EAC

During the consultations, the following good practices were shared by the respective Partner States.

(i) The decision by the government of the Republic of Kenya to reduce the number of regulatory Agencies from 28 to 4 and designate one regulatory agency (Kenya Bureau of Standards) to represent other regulatory agencies in clearing consignments at the Mombasa Port of entry has led to significant reduction of time taken to clear goods from the port.

(ii) The government of the United Republic of Tanzania recently made changes in the control of food and cosmetics products and vested the powers to Tanzania Bureau of Standards (TBS) as of July 2019, which functions were formerly under Tanzania Food and Drug Authority (TFDA) and this was replaced by the now, Tanzania Medicines and Medicinal Devices Authority (TMDA).

(iii) The collaborations between the agencies in certification and regulation of products in Uganda, particularly the Uganda National Bureau of Standards (UNBS), National Drug Authority (NDA), Dairy Development Authority (DDA) and Uganda Coffee Development Authority (UCDA).

The framework has been developed after undertaking a critical assessment and analysis of the current regulatory regimes in Partner States and best practices in the EAC.

Annex B

Summary of the legal framework and basic principles of regulatory cooperation within the EAC Partner States

B.1 Legal framework

The legal framework for regulatory cooperation for purposes of promoting intra-EAC trade is provided for in the SQMT Act 2006, East African Customs Management Act (EACMA) 2004, One Stop Border Posts (OSBP) Act, 2016 and other relevant laws, protocols such as the Common Market Protocol, the Customs Union Protocol and trade policies. The cooperation and coordination among the NSBs of the EAC Partner States has progressed steadily with the harmonization of the various conformity assessment procedures, recognition of certification marks and implementation of peer assessment. These arrangements have been driven and coordinated by the East African Standards Committee and its technical sub-committees of quality assurance, testing, standards and metrology.

The above said legal framework requires streamlining of requirements among the various conformity assessment bodies and regulatory agencies implementing mutual recognition, equivalence, harmonization principles, to enhance efficiency effectiveness in achieving product safety and quality for consumer protection, as well as trade facilitation.

B.2 Basic principles of regulatory cooperation currently in use in the EAC

There are two main forms of regulatory cooperation used in the EAC both to enhance the quality and safety of food and cosmetics products and promote free flow of these products across the EAC Partner States borders. These include harmonization and mutual recognition. Furthermore, multilateral standards setting bodies continue to promote the principle of one standard, one certification as a basis for ensuring enhanced product safety and quality and trade facilitation globally.

B.2.1 Harmonization

Harmonization of standards, rules, laws, processes, procedures and practices is at the very heart of the EAC frameworks for cooperation in the areas of quality infrastructure. It is one of the key principles that underpins international and regional standardization, and bilateral and multilateral trade arrangement and cooperation. The objective of harmonization is to ensure, as far as practicable, that uniform rules such as standards and/or conformity assessment procedures are applied across trading partners' regulatory control systems. The EAC through the East African Standards Committee (EASC) has put in place a mechanism for harmonization of standards and conformity assessment procedures in the region in order to enhance consumer protection and promote intra-EAC trade in goods and services.

B.2.2 Mutual recognition

The principle of mutual recognition involves an arrangement between Partner States to recognize or accept the results of regulatory controls or conformity assessment procedures implemented by the other Partner States. This principle is enshrined in the EAC SQMT legal framework and plays a critical role in the promotion of the free flow of goods across borders and improving intra-EAC trade. As far as SQMT and trade in the EAC is concerned, and in order to ensure confidence and trust in Partner States' quality infrastructure for effective implementation of mutual recognition arrangement, mutual recognition is founded on four pillars: -

- Use of harmonized standards;
- Adoption of conformity assessment procedures consistent with international standards;
- Implementation of peer assessment programs; and
- Use of designated laboratories for product evaluation.

Ongoing initiatives at the global stage and by various economic blocks for good regulatory practices, adoption of IT to enhance collaborations in conformity assessment and regulatory controls, and networking provide a framework to learn from as the EAC seeks to integrate into the global value chain. In the EU for example, the use of harmonized technical regulations serves to provide an integrated approach for implementing standards for control of product safety and quality and using a risk-based approach to ensure conformity assessment procedures and regulatory controls are appropriate to provide an acceptable level of consumer protection while ensuring trade facilitation. The Asian economic block has adopted harmonized food and cosmetics standards as basis for regulatory controls and trade facilitation.

CODEX has been working on a broader framework for integrating conformity assessment activities (certification, inspection and testing) from conformity assessment bodies into the food safety control systems to enhance efficiency and effectiveness in food control regulation and trade facilitation.

Similarly, the USFDA implements a system of facilities approvals and certification for food establishments to food safety standards (HACCP/GMP and product standards) as adequate to meet food control requirements.

B.2.3 Key areas of convergence among Partner States regulatory systems

Regulatory cooperation in the EAC is aimed at minimising or eliminating NTBs by streamlining compliance requirements for enhanced intra-EAC trade while maintaining appropriate levels of consumer protection. Based on existing arrangements, there are already vital areas of convergence within Partner State regulatory systems that should make it much easier to establish and achieve effective cooperation regarding regulatory control and conformity assessment of food and cosmetics products. These areas of convergence include use of harmonized EAC standards and international standards both for product and process evaluations, including the setting up of conformity assessment processes. Whereas the institutional arrangements may be different among Partner States, the regulatory controls and conformity assessment activities/ processes are similar and are based on harmonized and international standards.

Annex C

Report on regulatory practices among Partner States

Annex D

Regulatory bodies in the different Partner States

Regulatory Agency	Applicable law(s)	Mandate
BURUNDI		
Burundi Bureau of Standards (BBN)	Law N°1/03 of 4/1/2011 on national system of Standardization, Metrology Quality Assurance & Testing	Standardization and conformity assessment services
Department of Pharmacy, Medicines and Laboratory (DPML)		Quality control of medicines
Animal Health Department (DSA)		Veterinary products, fresh non- processed animal products
Plant Protection Department (DPV)	Law N°1/23 of 23/11/2017 on Plant Health Protection	Plant health surveillance for non-processed food products
KENYA		
Kenya Bureau of Standards (KEBS)	Standards Act CAP 496	Standardization and conformity assessment services
Ministry of Health (MoH)	Public Health Act, Cap 242	Port Health Services
Kenya Dairy Board (KDB)	Dairy Industry Act Cap 336	Quality and safety in dairy produce
Agriculture and Food Authority (AFA)	AFA Act 2016	Regulate, production, processing and marketing of agricultural products
Pharmacy & Poisons Board (PPB)	Cap 244	Pharmaceutical products; Medicinal devices & food supplements
Pest Control Products Board (PCPB)		Pesticides
Kenya Plant Health Inspectorate Services (KEPHIS)	Act, No. 54 of 2012	Plant protection; Phytosanitary services
Kenya Veterinary Board (KVB)	Veterinary Surgeons and Veterinary Para-Professionals (VSVP) Act No.29 of 2011	Professional animal health services provision
Directorate of Veterinary Services (DVS)	Animal Disease Act Cap. 364; Meat Control Act Cap. 356	Animal health
RWANDA		
Rwanda Standards Board (RSB)	Law No. 50/2013 of 28/06/2013	Standardization and conformity assessment services
Rwanda Agriculture and Livestock Inspection Service (RALIS)	No law?	SPS Issues

Regulatory Agency	Applicable law(s)	Mandate
SOUTH SUDAN		
South Sudan National Bureau of Standards (SSNBS)	National Bureau of Standards Act, 2012	Standardization and conformity assessment services
Drug and Food Control Authority (DFCA)	Drug and Food Control Authority Act no. 37, 2012	Cosmetics (since 2019), not handling food yet.
Ministry of Agriculture and Food Security	Constitution of South Sudan	Facilitate legislative framework to ensure proper plant protection Establish surveillance system to detect and identify pests (insects, diseases, weeds and birds) Facilitate field pest control Prevent introduction and establishment of exotic pests; Undertake domestic quarantine measures to prevent proliferation of and spread of pests; Safeguard stored agricultural produce; Facilitate safe global trade in agricultural trades by providing technical competent and reliable phytosanitary system that meets the requirements of trading partners; promote integrated pest management approaches; Register and manage pesticides; build capacity of staff; train farmers in safe use and handling of pesticides; establish and strengthen plant protection structures
Ministry of livestock and fisheries	Decree of 2005	Animal and fisheries genetics and service delivery Monitoring of disease control; Monitor SPS, Standard Methods and procedures for in labs and production; Transboundary disease control
Ministry of Trade	Import and Export Act, 2012	Promote and facilitate trade with other EAC partner states
TANZANIA		

Regulatory Agency	Applicable law(s)	Mandate
Tanzania Bureau of Standards (TBS)	Standards Act, Act.No.2 of 2009	Standardization and conformity assessment services
Zanzibar Food and Drug Agency (ZFDA)	Zanzibar Food, Drugs and Cosmetics Act, No. 2 of 2006	Regulating the quality and safety of food, drugs, cosmetics and medicinal devices
The Government Chemist Laboratory Authority (GCLA)	Industrial and Consumer Chemicals (Management and Control) Act, No.3 of 2003	Testing of food, drugs, industrial and consumer chemicals and forensic sciences services
Tanzania Atomic Energy Commission (TAEC)	Atomic Energy Act No. 7 of 2003	Responsible for all atomic energy matters
Ministry of Livestock and Fisheries	The Fisheries Act, No. 22 of 2003	Regulation of the fish industry
The Sugar Board of Tanzania	The Sugar Industry Act, Cap 251	Regulation of the sugar industry
Plant Health Services	Plant Protection Act, No. 13 of 1997	Control of crop pests
Tanzania Diary Board (TDB)	The Dairy Industry Act, No. 8 of 2004	Regulation of the dairy industry
Tanzania Meat Board (TMB)	Animal Diseases Act, No. 17 of 2003	Regulation of the meat industry
Tanzania Tea Board (TTB)	Tea Act of 1997	Regulation of the tea industry
Tanzania Coffee Board (TCB)	Tanzania Coffee Industry Act N0. 23 of 2001	Regulation of the coffee industry
UGANDA		
Uganda National Bureau of Standards (UNBS)	Uganda National Bureau of Standards Act 1983, (2013)	Standardization and conformity assessment services
National Drug Authority (NDA)	National Drug Policy & Authority Act, Cap. 206, 1993 (2000)	Regulating the quality and safety of drugs, cosmetics and medicinal devices
Dairy Development Authority (DDA)	Dairy Industry Act, 1998	Regulation of the dairy industry
Uganda Coffee Development Authority (UCDA)	UCDA Act, 1991	Regulation of coffee
Ministry of Agriculture, Animal Industry and Fisheries		Fresh food products – plants, animals, fisheries and Agrochemicals (SPS issues)

Annex E

Certification criteria for food and cosmetics product

Certification criteria	Processed pre-packaged food	Cosmetics
Product standards: East African, National, International	x	x
GMP requirements	x	x
GHP requirements	x	x
Factory audits/Inspection to assess of production and quality assurance processes	x	x
Pesticide residues	x	x
Heavy metal/chemical contaminants	x	x
Microbial contamination	x	x
Labelling & Marking	x	x
Ingredients	x	x
Additives	x	x
Nutritional claims	x	x
Packaging	x	x
Pre-package control	x	x
Banned substances	x	x
Radiation contamination	x	x
Drug/antibiotic residues	x	x

Bibliography

[1] EAC SQMT Act 2006,

[2] East African Customs Management Act (EACMA) 2004,

[3] One Stop Border Posts (OSBP) Act, 2016

[4] Customs Union Protocol

[5] Common Market Protocol

