CONFEDERATION OF TANZANIA INDUSTRIES (CTI)

Analysis of Regulatory and Fiscal Challenges in the Food Processing, Textile and Pharmaceutical Value Chains in Tanzania

FINAL REPORT

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Abbreviations and Acronyms

ASDS	Agricultural Sector Development Strategy
BRELA	Business Registration and Licensing Authority
CTI	Confederation of Tanzania Industries
EAC	East African Community
EIA	Environmental Impact Assessment
GCLA	Government Chemist Laboratory Agency
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
ISO	International Standards Organization
LATRA	Land Transport Regulatory Authority
LGA	Local Government Authority
MDAs	Ministries, Departments and Agencies
MEMARTS	Memorandum and Articles of Association
MSD	Medical Stores Department
NEMC	National Environment Management Council
NGO	Non-Governmental Organization
NSGRP	National Strategy for Growth and Reduction of Poverty
OECD	Organization of Economic Cooperation and Development
OSHA	Occupation Health and Safety Administration
PSO	Private Sector Organization
SADC	Southern African Development Cooperation
SIDP	Sustainable Industrial Development Programme
SMEs	Small and Medium Enterprises
TAFOPA	Tanzania Association of Food Processors
TAEC	Tanzania Atomic Energy Commission
TAMPA	Tanzania Milk Producers Association
TEGAMAT	Textile and Garment Manufacturers Association of Tanzania
TEOSA	Tanzania Edible Seeds Association
TBS	Tanzania Bureau of Standards
TCB	Tanzania Cotton Board
TDB	Tanzania Dairy Board
TIC	Tanzania Investment Centre
TMDA	Tanzania Medicines and Medical Devices Authority
TPI	Tanzania Pharmaceutical Industries
TRA	Tanzania Revenue Authority
TVI	Tanzania Vaccines Institute
TZS	Tanzania Shillings
UNIDO	United Nations Industrial Development Organization
USD	United States Dollar
VAT	Value Added Tax

VC	Value Chain
WMA	Weight and Measures Agency
WRBWB	Wami Ruvu Basin Water Board

Executive Summary

The main objective of this value chain analysis of three value chains (textile, food processing and pharmaceuticals) was to identify key fiscal and regulatory policy' constraints facing these value chains and recommend policy options to address them. Further to this, to provide recommendations on potential linkages and technology transfer for targeted companies from the value chains to scale up production, enhance competitiveness and grow their exports. The study entailed desk review of the regulations and legislations concerning food processing, textile and pharmaceutical value chains, interviewing value chain actors both direct and indirect, and officials from regulatory authorities. This document is the report of the study findings and proposed policy actions for desirable change.

Generally, regulations governing the food processing, textile and pharmaceutical value chains are amenable and have a number of benefits such as ensuring public safety, protecting the environment, correcting market failures and promoting fairness. However, excessive regulations increase the costs of value chain actors, mainly due to duplication of the regulatory functions and fees charged by the regulators. In particular, the study indicates that:

There are at least 22 different laws and 15 different regulators regulating food processing, textile and pharmaceutical value chains. These has created overlaps and duplication of regulatory functions to businesses. Businesses are charged fees for similar functions like registration, inspection or health checkups by different regulators.

Over-regulation has created burdens to businesses in terms of monetary costs to pay fees, taxes, charges, and consultants, production down-time to attend inspectors, preparation of documentations, follow-up on regulatory issues and attending mandatory trainings. The time taken in waiting for the necessary permits and licenses during start-up is estimated to be a minimum of 39 person-days and in the operational phase, at least 167 person-days.

Based on data from businesses and existing regulations, cost of compliance for a food-processor is during the start-up phase is estimated reach at least TZS 6,482,600/= while at operational phase direct compliance cost is estimated to reach at least TZS 15,513,000/= per year while the indirect cost estimate for labour, transport, communication and loss productivity is TZS 9,271,666.67/=. In the textile and pharmaceutical value chains, compliance cost is estimated at TZS 67,378,666.7/=.
From the analysis done in this study, the main regulatory issues that require policy attention and that guide the recommendations made in this proposal are as follows;

- Multiplicity of regulations where at least 22 laws and 15 regulators governing the value chains, overlaps and overregulation characterized by duplication of regulatory functions, compliance requirements and fees charged
- Business registration and licensing process which is overly long with at least 19 processes for food processor, textile and pharmaceutical manufacturer to follow to

accomplish the compliance. This takes at least 39 person-days in registration for start-up and at least 167 person-days per annum for compliance.

- Supporting compliance and enforcement capacity of the Regulatory Authorities which is weak, fragmented and ineffective.
- Harmonization of national policies with regional integration policies particularly on common external tariffs as agreed in EAC
- Rent-seeking behavior (unbearable penalties, fees and charges) which is witnessed by overemphasis on enforcement more than compliance done by most regulators.
- Unfriendly and unsupportive attitude of regulatory agencies staff
- Lack of education and awareness of compliance requirements and procedures among the business community

Based on the findings, the following are proposed policy actions to address the challenges. Generally:

a) CTI to advocate and promote reform of the current regulatory system and improvement of harmonization and coordination of the regulatory tasks

b) Coordination of EIA and inspection of environmental compliance stipulated in Environmental Impact Assessment Act, 2004, section 8, Industry and Consumer Chemicals Act, 2003, the Sugar Industry Act, 2002, section 47 and the Fisheries Act, 2003, section 52, the Public Health Act, 2009. NEMC should be mandated to conduct an EIA and carry out inspections for environmental compliance in consultation with other relevant authorities.

c) Harmonisation of business registration and licensing activities stipulated in: the Business Licensing Act, of 1972Cap 208, [R.E, 2002]; Business Names Registration Act (Cap 213); Industrial Licensing and Registration Act, 10 Cap 46 [R.E, 2002];Tanzania Medicines and Medical Devices Act of 2019, Section 18; The Explosives Act,56 Cap 45,[R.E 2002]; Fisheries Act, 22 of 2003; the Cashew Nut Industry Act, 2009, section 12(1); the Coffee Industry Act, 2001, section 12(1); and the Tea Act, Cap 251, [R.E, 2002]. Business registration and business licensing can be harmonised through cross-referencing, whereby food processors are registered only by BRELA and TBS after complying with the requirements of the industrial licence, EIA and quality control that ensure good manufacturing practices.

d) Harmonisation and coordination of product testing. The laws establishing the agencies involved in product testing provide for the establishment of "a system of consultation and cooperation" as stipulated in the Standards Act, 2009, Section 4 (2) (b); Protection from Radiation Act, Section 1983, section 14(10); and the Dairy Industry Act, 2004, section 10 (r), (s). The following ways could be used to improve product testing: a) TBS, GCLA and TFDA to conduct product testing concurrently; b) TBS to focus on setting the quality standards for products, with TFDA enforcing the

quality standards and setting safety standards; and c) once the product has been tested by one of the regulators, the result should be shared with all the regulators.

e) Improve the capacity of Regulatory Agencies to undertake their tasks more effectively by allocating adequate budget and employing more human resources
f) Design and implement public awareness and education campaigns targeting specific businesses and policy makers on compliance matters and their rationale
g) The private sector should build relationship and take part in the policy making processes as a proactive stance towards coming up with good policies

On Food Processing Value Chain

- Harmonize and enhance coordination of licenses and permits that relate to food hygiene and premises and introduce cross-referencing and amend laws to allow recognition of permit from one authority by other authorities for similar functions.
- Regulators to have frequent consultations with enterprises to provide them with coaching and guidance on how to comply with quality and safety requirements in the entire process of processing and preparing food for human consumption.
- Regulators to prescribe exactly what actions regulated entities must take to improve their performance and share the checklist of actions with enterprises.
- Invest in educational programs and capacity building to inform and empower all actors within the value chain.

On Textile Value Chain

- Smuggling, under-invoicing and under-declaration of textiles and clothing should be stopped or controlled. All borders and shoreline should be strictly managed against smuggling business
- Harmonize Import duties with the common external tariff agreed among the EAC members. Similarly, harmonize tariffs between Tanzania Bara Ports and Zanzibar Port.
- Apply the EAC Customs Management Act approved unit of verification for textiles and garments imports which is using weight in kilograms
- Make further modification to tax reform on imported yarn from the current 25% to 10%.
- Trucks and small operations vehicles for ginners and textile industries be categorized as "tax free" goods.
- The tariffs for utilities like electricity, water, petrol, and others to be reviewed to attract more investment in the textile industry.

On Pharmaceutical Value Chain

- Restructure trade, tax, and credit policies to favor local producers over importers.
    - Impose duties on imports of finished pharmaceuticals particularly those similar with local availability;

    - List only pharmaceuticals which can be imported only if local manufacturers cannot supply reliable quality at acceptable prices;
    - Lay down proper identification of pharmaceutical inputs needed for investment in production, and exempt them from duties;
    - Remove VAT on inputs to pharmaceuticals;
- Reduce imports of medicine and medical equipment from 70% to less than 50% to promote market for locally manufactured medicines and medical devices.
- Reform public procurement policy and regulations to raise the local preference rate to at least 50% from local manufacturers.

CHAPTER ONE

INTRODUCTION

1.1 Background

This report presents analysis of textile, food processing and pharmaceuticals value chains in Tanzania with a special focus on the regulatory and fiscal regimes to discern growth and development challenges and recommend policy reforms. These value chains create opportunities for economic growth in developing countries and particularly in Tanzania. Existing evidence shows that, food processing, textiles and pharmaceuticals value chains are integral to many developing countries to achieve growth, employment creation and poverty reduction objectives. Linkages in both upstream and downstream deserve policy attention both domestic and global for their crucial role in creating international competitiveness. The competitiveness of the individual firm depends upon the competitiveness of the value chain to which it belongs. Competitive pressure to achieve efficiency gains obliges companies to interact more closely with partners upstream and downstream in the value-adding process.

Evidence from other countries shows that, being competitive internationally requires an effective domestic value chain. However, value chain actors argue that, these value chains are plagued by unbearable challenges and that, the regulatory environment in Tanzania is unfriendly to private enterprises relative to other countries. For instance, the World Bank's 2019 Ease of Doing Business Report ranked Tanzania the 36th out of 48 sub-Saharan African countries for ease of starting a business. This is below regional counterparts such as Kenya (25th), Rwanda (4th), Burundi (5th) and Democratic Republic of Congo (7th). Overall rank is 141 out of 190 countries world-wide. Although there are many factors that may account for the deterioration of these value chains, "inappropriate" regulation leads to excessive compliance requirements and low competitiveness of the value chains hence unable to unleash job creation, poverty reduction and export growth (Urassa, 2014). This raises a question on what regulatory and fiscal challenges which have locked growth and export potentials of these value chains in Tanzania? What relationships and linkages that are needed for effective technology adoption among the value chain actors? What policy reforms which need to be made to address these challenges?

The term value chain refers to the various business activities and processes involved in creating a product or performing a service. A value chain can consist of multiple stages of a product or service's lifecycle, including research and development, sales, and everything in between. To address any challenges across value chain and ensure smooth performance of value chains requires a value chain analysis. This is a framework of assessing all the relevant activities and processes by disaggregating them into step by step and discrete activities as they are involved in creation and delivery of products to the market. Value chain analysis is especially a useful framework as it allows taking stock of the processes that comprise industry value chain. This helps to understand what goes into or affects each transaction in terms of who is involved, what inputs and what affects cost (materials, compliance, etc.). Ways for integrating the value chain together with improving efficiency and effectiveness

can be better understood and mobilized to gain competitive advantage locally and internationally.

In Tanzania, the value-chain development approach has been adopted by many development organizations, non-governmental organizations (NGOs), research institutions and government programs (Tarimo et al., 2012). The focus of most of these value-chain interventions has been on facilitating smallholder farmers' links to the market, in order to increase profit and reduce poverty. However, much less attention has been paid on the impact of regulatory framework on domestic value chains especially on their competitiveness, technology transfer and adoption and linkages along the value chain actors. This report presents therefore, empirical evidence of the regulatory and fiscal challenges encountered in the food processing, textile and pharmaceutical value chains in Tanzania, thereby proposing policy reforms to address these challenges.

1.3 Objectives of the Study

The main objective of this value chain analysis of three value chains (textile, food processing and pharmaceuticals) was identify key fiscal and regulatory policy' constraints facing the value chains and recommend policy options to address them. Further to this, to provide recommendations on potential linkages and technology transfer for targeted companies from the sub-sectors to scale up production, enhance competitiveness and grow exports.

Specifically, the study intended:

i. To identify the major constraints facing the value chains of textile, pharmaceutical and food processing sectors in Tanzania.
ii. To suggest ways that will enhance growth of the key players present in the textile, pharmaceutical and food processing sectors in Tanzania.
iii. To provide recommendations on potential linkages and technology transfer for targeted subsector in pursuit to scale up production.

2.0 Approach and Research Methodology

2.1 Value Chain Approach

The approach employed in undertaking this study is value chain approach. This is a holistic approach to analysis which includes consideration of direct actors, indirect actors and external influences. The United Nations Industrial Development Organization (UNIDO)(2009) describes a value chain as the entire range of activities that take place to bring a product from the initial input-supply stage, through the various phases of processing, to its final market destination, including its disposal after use.

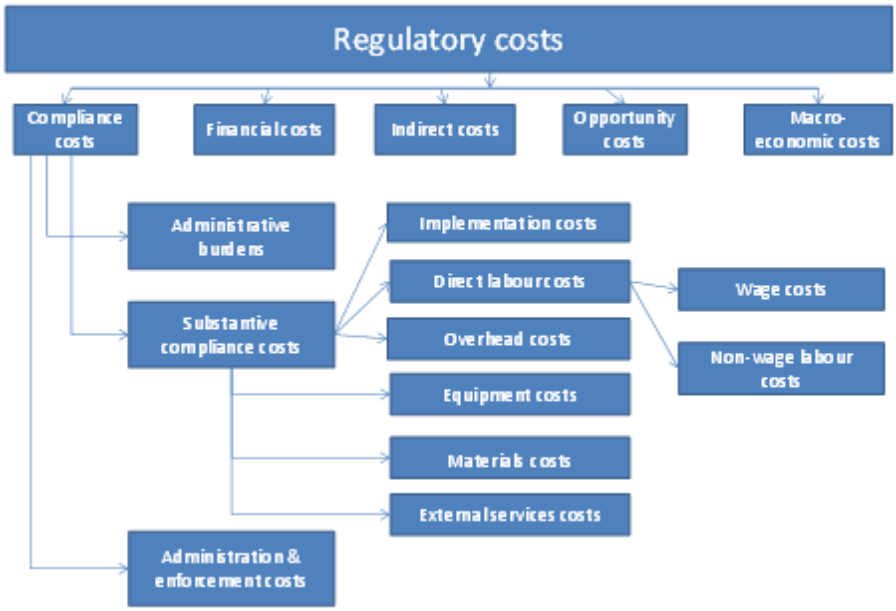
According to Kaplinsky and Morris (2012) there are four aspects of value-chain analysis which make it a particularly useful technique to apply to business development. These include, systematic mapping of the actors participating in the production, distribution, marketing, and sales of a particular product (or products) in terms of their characteristics, profit and cost structures, flows of goods throughout the chain, employment characteristics, and the destination and volumes of domestic and foreign sales. Secondly, distribution of benefits between actors in the chain to determine who benefits from participation in the chain and which actors could benefit from increased support or organization. Thirdly, upgrading which

involves looking for improvements in quality and product design or diversification in the product lines served, through assessment of the profitability of actors within the value chain as well as information on limitations that are currently present. Lastly, governance in the value-chain, which can be internal or external. Governance within a value-chain refers to the structure of relationships and coordination mechanisms that exist between actors in the value-chain.

Based on the objectives and scope of this study, value chain approach has been used considering three aspects of analysis namely, value chain mapping, upgrading and governance. Systematic mapping was done to be able to identify actors, direct and indirect in the particular value chain and treat them as unit of analysis as well as to define unit of enquiry from whom data was collected. Upgrading as an aspect of analysis was considered to critically assess and unveil limitations towards technology adoption, growth of the actors and their competitiveness locally and internationally. Governance was analyzed from the external point of view to discern regulatory and fiscal challenges encountered by value chain actors so as to recommend policy actions for improvement.

In making analysis of regulatory costs the Organization for Economic Cooperation and Development (OECD)'s conceptual framework and taxonomy of regulatory costs (OECD, 2014) was adopted.

Figure 1: Taxonomy of Regulatory Costs



OECD, 2014

2.2 Population, Sampling and Sample Size

The analysis was conducted for three value chains namely, food processing, textile and pharmaceuticals in the selected regions of Dar es Salaam, Mwanza, Tanga, Kilimanjaro, Arusha, Manyara, and Morogoro. These regions were selected based on the concentration of businesses engaged in these three value chains so that findings may be a highlight of

what exists elsewhere in Tanzania. Since, food processing is broad, four value chains within food processing which include maize, fruits, dairy and sunflower processing value chains were selected and examined. The selection of these four VCs was informed by their contribution to GDP, employment and potentials available for growth and competitiveness domestically and internationally. This was decided based on available statistics. Actors direct and indirect in the three value chains and corresponding VCs within food processing in the selected regions together with officials from regulatory agencies relevant to the industry formed the population of this study.

In this study, convenience and judgmental sampling methods were employed to get respondents for the survey. The choice of these two methods was considered appropriate given the objectives of the study and limitation in getting a full register of businesses in the particular value chain and regions. Respondents were picked based on the convenience of their availability and the judgement of the researcher of their ability to supply the required information based on their active involvement in the particular business and complying with required regulations in the given industry. Prior information on their availability and involvement was obtained from CTI regional/zonal managers. The CTI officials worked on the preliminaries of ensuring the target respondents are located and booked for taking the survey.

A total of 46 respondents from both the private and public sector were involved in the study.

Table 1: Sample Size and Distribution

Value Chain	Number of Respondents (Direct Actors)	Number of respondents Indirect Actors/Regulators
Food processing	21	3
Textile	6	3
Pharmaceuticals	6	3

2.3 Data Collection

Given the nature of the study, both primary and secondary data were collected.

2.3.1 Primary Data Collection

Primary data collection for this study was mainly done through interviews with selected members and non-members of CTI, regulators, informed experts and other stakeholders to gather their opinions on the issue of regulatory and fiscal challenges in the three value chains. Interviews were conducted in Dar es Salaam, Mwanza, Morogoro, Tanga, Manyara, Kilimanjaro and Arusha. The consultant worked closely with CTI to identify the stakeholders interviewed. CTI played an important role in linking the consultant with its members. The interviews were unstructured and qualitative in nature to enable deeper understanding of the issue to be gained and to allow respondents to express their opinions freely. However, any quantitative data available were collected to provide evidence of the issues raised in the

study. The sampling approach was therefore purposeful, targeting selected respondents who could provide the desired information.

2.3.1 Desk Review

Relevant national policies, strategies and laws together with existing literature on regulatory and fiscal issues relevant to this analysis were extensively reviewed. In the review, important information was identified and gathered. This review was meant to gain an understanding of existing national policies and regulations focusing on the private sector, regulatory reform in the national context, national policies and institutions for regulatory reform, the progress that has been made on regulatory reform and the challenges and impact of the regulatory framework on the competitiveness of the food processing, textile and pharmaceutical value chains.

CHAPTER TWO

POLICY AND REGULATORY FRAMEWROK IN TANZANIA

3.1 Overview of National Policies and Strategies

This section presents analysis of the policies and strategies established and implemented by the government through its ministries, agencies and departments (MDAs). These were developed in support of the development of the private sector in the country. Most of these policies were developed in consideration of the Tanzania Development vision 2025 and the National Strategy for Growth and Reduction of Poverty (NSGRP II). The vision 2025 aims to transform the country's agriculture-based economy into a competitive and dynamic semi-industrial economy. Three key objectives guide the realization of the Vision 2025 namely; achieving quality and good life for all; good governance and the rule of law; and building a strong and resilient economy that can effectively withstand global competition. One of the basic guidelines on the implementation of the Vision include undertaking reviews and reforms of existing laws and structures of various institutions in order to ensure that they meet the requirements of implementing the objectives of this Vision. Thus far, it is expected that all policies, regulations and strategies formulated should focus towards realization of the TDV 2025.

Nonetheless, NSGRP II proposes the strategic intervention of instituting measures to promote a conducive and enabling business environment and to reduce the cost of doing business, by reforming the regulations governing the business environment, easing registration and licensing requirements to encourage both domestic and foreign investors, and improving market facilities and business infrastructure for small–scale enterprises. It also proposes improving the business environment further in order to reduce the cost of doing business for both large-scale manufacturers and SMEs. Different strategies including agricultural sector development strategy and sustainable industrial development are relevant in as far as food processing, textile and pharmaceutical value chains are concerned. Further to that are policies such as the National Environment Policy and National Health Policy.

The Agricultural Sector Development Strategy (ASDS) was developed to create an enabling and conducive environment for improving the profitability of the agricultural sector so that farm incomes are improved and rural poverty alleviated. On the other hand, the Industrial Development Policy (SIDP 1996-2020) was developed to provide an overall framework for Tanzanian's future industrial development and lists specific national objectives, including making the industrial sector contribute more broadly and evenly to the creation of employment opportunities. The policy states that the government will put more emphasis on the development of industries by strengthening the capacity to support the industrial sector and improving the legal and regulatory framework as well as access to finance. The government will position itself to encourage investment in the sector by ensuring that trading practices and competition are fair, as well as to develop the social and economic infrastructure, including industrial support institutions. Although most policies focus largely on promoting the private sector, some highlight the rationale for regulating the sector and

promoting product quality and safety standards as well as promoting sustainable environment management practices.

The National Environment Policy (1997), underscores the need to ensure the sustainability, security and equitable use of resources to meet the basic needs of the present and future generations without degrading the environment or risking health or safety. It focuses on preventing the degradation of land, water, vegetation and air, which are important for life. It highlights the need to conserve and enhance the biological diversity of the unique ecosystems of Tanzania, to raise awareness of the relationship between the environment and development, and to promote individual and community participation in environmental action.

The National Health Policy (2007) aims to provide direction for improving and sustaining the health status of all the people, by reducing disability, morbidity and mortality, improving nutritional status and raising life expectancy. The policy established the Tanzania Food Drugs and Cosmetics Act, 2003 to regulate, inter alia, food and food products manufactured and/or imported into the country.

The Food and Nutrition Policy (1992) covers extensively the issue of food hygiene and insists categorically that food quality standards must be maintained. To ensure that processed food meets nutritional requirements, the policy raises the need to control food quality standards. This implies that there should be effective supervision of foodstuff to ensure that it meets the standards before being distributed and consumed. The policy recognises however that food and nutrition issues require a multi-sector approach. While the roles of various Ministries are recognised in the policy, one of the roles of the Ministry of Industry and Trade is to effectively control the quality of food produced in the country and that imported from outside the country so that it meets the standards. The Local Government is responsible for ensuring that the food is sold in a clean environment. This shows that the issue of regulating the food, textile and pharmaceutical value chains is well articulated in the policy framework.

3.2 Laws and Regulations Governing Food Processing, Textile and Pharmaceutical Value Chains

Tanzania has a number of laws and regulations governing food processing, textile and pharmaceutical value chain in the areas of production, consumer protection, environmental protection and quality control. Some regulations are directed at all value chains while others apply differently to food processing, textile and pharmaceutical value chains. These regulations vary from one value chain to another depending on the manufacturing complexity of the value chain and the sub-sector to which it belongs. An analysis of the regulations and compliance requirements in relation to the three value chains shows that the regulatory system in Tanzania is complex with several overlapping laws and a duplication of the functions of regulators. In total over 22 laws are directly or indirectly directed at the value chains.

Laws and Regulations Governing the value chains in Tanzania

i) Tanzania Medicines and Medical Devices Act, of 2019
ii) Environmental Management Act, No.20 of 2004
iii) Standards Act, Act.No.2 of 2008
iv) Dairy Industry Act, No.8 of 2004

v) Fair Competition Act, No. 8 of 2003
vi) Industrial and Consumer Chemicals (Management and Control) Act, No.3 of 2003
vii) Sugar Industry Act, Cap 251 [R.E.2002]
viii) Fisheries Act, No. 22 of 2003
ix) Local Government (District Authorities) Act, Cap 287 [R.E.2002]
x) Local Government (Urban Authorities) Act, Cap 288 [R.E.2002]
xi) Local Government (Finance) Act, Cap 290 [R.E.2002]
xii) Income Tax Act, No.11 of 2004
xiii) Merchandise Marks Act Cap 85 [R.E.2002]
xiv) Business Licensing Act No. 25 of 1972 (Cap 208 R.E 2002)
xv) Business Activities Registration Act, 2006
xvi) Public Health Act of 2009
xvii) Cashew nut Industry Act of 2009
xviii) Occupational Health and Safety Act No.5 of 2003
xix) Atomic Energy Act, 2002
xx) Weights and Measures, 1982
xxi) Fire and Rescue Force Act, No.14 of 2007
xxii) The Executive Agency Act, 1997

Although most laws apply to manufacturing firms in general, the laws reviewed below have a direct impact on food processors, textile manufacturers and pharmaceutical industries.

The Tanzania Medicines and Medical Devices Act of 2019

This Act provides for the control of drugs, medical devices, cosmetics, herbal drugs and poisons. The law established the Tanzania Medicines and Medical Devices Authority as a regulatory body responsible for national-wide compliance and enforcement of regulations and laws governing medicines and medical devices.

Section 5 empowers the Authority among other things to:

i) regulate all matters relating to quality and safety of drugs, herbal drugs, medical devices and poisons;
ii) regulate in accordance with this Act, the importation, manufacture, labelling, marking or identification, storages promotion, sell of drugs, herbal drugs and medical devices or any materials or substances used in the manufacture of products regulated under this Act.
iii) approve and register products regulated under this Act, manufactured within or imported into, and intended for use in the United Republic;
iv) examine, grant, issue, suspend, cancel and revoke certificates and licences or permits issued under this Act;
v) appoint inspectors and order inspection of any premises;

TMDA under section 21 has powers to issue manufacturing licenses, wholesale licenses, retail licenses or any other license or permit as it deems fit, and it can vary any provision, suspend or revoke any license issued under the Act as provided under section 25.

The Authority has the power to inspect any premises for the purpose of Good Manufacturing Practice (GMP), distribution and routine inspection after the product has been in the market (post-marketing surveillance).

The main issue is that the Act provides for the payment of many fees as almost all applications under the law must be accompanied by a fee. For instance, Sections 18 and 20 show businesses in pharmaceutical value chain will have to apply for registration of premises and later for license of permit. While both apply for same business, they are paid for each independently to the same authority. This calls for harmonization of the application fees. In this regard, sections 18 and 20 need to be harmonized to consolidate the requirements for applications and payment of fees.

Section 5 of the Regulations obliges persons involved in business operations (product dealers) to pay many fees in US Dollars (13 charges) as indicated below. The fees shown in the Schedule to these regulations shall be paid by a product dealer in connection with the following matters: -

Table 2: Services Chargeable Fee by TMDA

i) Laboratory sample analysis;	ii) Product evaluation and registration;
iii) Pre-registration GMP inspection;	iv) Annual medical representative permits;
v) Certification of export;	vi) Annual dealers license/permit;
vii) Approval of product advertisement;	viii) Annual retention for registered products;
ix) Product alteration;	x) Duplicate certificate, permit or license;
xi) Trade fair permit;	xii) Restoration of licenses certificates or permits
xiii) Training fees.	

Schedule 5 of the regulations requires pre-registration GMP inspection fees:

Table 3: Fees for Drug Registration and GMP Inspection

Compliance Action	Variation	Cost in USD	Duration
Drug Registration	Normal	2000	12 months
	Fast Track	4000	6 months
	GMP Inspection	6000	
	Annual retention	300	
Human, Veterinary Medicines and Biologicals (Imported)			
Registration	Normal	2000	
Registration-biological	Normal	3500	
Retention	Normal	300	
Variation-Major	Normal	1000	
Variation-Minor	Normal	300	
Duplicate certificate	Normal	100	
GMP Inspection	East Africa	4000	
	SADC	4500	

	Rest of Africa	5000	
	Asia	6000	
	Europe	6500	
	America, Australia	7500	

The Standards Act, Act.No.2 of 2009

This Act provides for the standardization of the specifications of commodities and services, the re-establishment of the Tanzania Bureau of Standards and an improvement in the provisions for the functions, management and control of the Bureau, as well as repealing the Standards Act, Cap130.The law established the Bureau of Standards with the following powers and functions;

i. undertake measures to control the quality of commodities, services and the environment of all descriptions;
ii. promote standardisation in industry and trade approve, register and control the use of standard marks in accordance with the provisions of this Act;
iii. provide for the inspection, sampling and testing of locally manufactured and imported commodities with a view to determining whether the commodities comply with the provisions of this Act or any other law dealing with standards relevant to those commodities;
iv. assist industries in setting up and enforcing quality assurance and environmental management systems and procedures.

The Tanzania Bureau of Standards (TBS) sets standards and acts as a member of ISO providing International Standards to companies. The Agency certifies the imports and new company's products introduced into the market for a fee. The Act confers powers on the Bureau of Standards to issue a license for standard marks. Any mark approved by the Bureau for any commodity or for the manufacture, production, processing or treatment of any commodity will be a standard mark in respect of it and TBS may, in like manner, cancel or amend that mark.

The law further provides that the issuance of a license shall be at the discretion of the Bureau or the person acting under its authority, and the license may be issued subject to conditions to be specified in it and subject to the payment of any fees which may be prescribed. The law has provisions that overlap other laws, such as the Tanzania Food, Drugs and Cosmetics Act.

The Government Chemistry Laboratory Agency is also empowered to perform quality analysis of foodstuff produced by companies. The Agency inspects chemicals that are imported, particularly the raw materials used in the production process. This calls for harmonization through cross-referencing to reduce the overlapping and unnecessary bureaucracy in relation to business. These laws need to be amended to create a one-stop compliance centre for TBS, and the Government Chemistry Laboratory Agency.

The Environmental Management Act, No.20 of 2004:

This Act provides for a legal and institutional framework for the sustainable management of the environment; it outlines the principles for management, impact and risk assessment; it provides for the prevention and control of pollution and waste management; it establishes environmental quality standards, compliance and enforcement; and provides for implementation of the National Environment Policy. This is the main law for all issues relating to the environment and health.

Section 81 of the Act imposes an obligation to undertake an Environmental Impact Assessment (EIA) for several projects, including industries involved in processing and manufacturing. A permit or license to carry out any project or undertaking in accordance with any written law shall not entitle the proposed developer to undertake a project or activity without an environmental impact assessment certificate issued under this Act.

The Act empowers the Minister responsible to make a recommendation to the licensing authority that the project should not be licensed or, where the license has been issued, be cancelled if the project or undertaking does not comply with the environmental standards set by the Act.

The law's provisions overlap those of other laws, such as the Standards Act, the Industrial and Consumer Chemicals (Management and Control) Act, and the Fisheries Act. Additionally, there are statutes that have provisions governing environmental issues. For example, the Industrial and Consumer Chemicals (Management and Control) Act,2003, has introduced the concept of Environment Management Plan, which outlines the activities to be undertaken to prevent and control any adverse effects to health and the environment. This means that manufacturing industries governed by this Act are subject to environmental matters stipulated by the Environment Management Act,2004.

In addition, there are no cross-references among the related provisions of these laws. The Act just mentions any written law without specifying any law in particular. This could also create confusion and the overlapping of powers among TBS, Local Government Authorities, NEMC and TMDA, which seem to have similar powers and functions as regards regulating the quality of food, pharmaceuticals, health and the environment and other related commodities. The laws therefore need to be amended to create a one-stop compliance centre for all institutions that require environmental compliance for manufacturing food, textiles and pharmaceuticals.

The Dairy Industry Act, No.8 of 2004

This Act, which repeals the Dairy Industry Act, 1965, provides for the production, regulation and promotion of the dairy industry, the establishment of the Tanzania Dairy Industry Board and other related matters. This Act applies to milk and milk products intended for sale. Dairy is defined to mean the premises used for the production, processing, or manufacture of milk and milk products for sale. The Tanzania Dairy Board was established by this Act and is vested with the functions relevant to the effective implementation of the Act. The Act provides the Board with the power to inspect, provide certificates and charge fees. For example, i) Section 17 provides that a person who deals with milk or milk products must register with the Board to undertake milk production, processing or marketing, or to import or export milk or milk products, as well as dairy inputs suppliers, manufacturers or importers and retailers

14ii) Regulation 7 of 2007 provides for the issuance of a Certificate of Registration upon payment of the registration fee. The certificates issued under these regulations remain valid for one-year subject to renewal. iv)Section 20(1) provides that on registering the persons specified under the Act, renewals of registration are issued upon payment of the fees prescribed in the Fourth Schedule of Regulation 9 of the Dairy Industry (Registration of Dairy Industry Stakeholders) Regulations. v)The Board has powers to appoint inspectors and has put in place the Dairy Industry (Duties and Powers of the Inspectors and Analysts) Regulations of 2007

The Fair Competition Act, No. 8 of 2003
This Act promotes and protects effective competition in trade and commerce, and protects consumers from unfair and misleading market conduct. It regulates restrictive trade practices such as anti-competitive agreements, the misuse of market power, mergers and acquisitions. The law further protects consumers through regulating misleading and unfair business practices, deceptive and unconscionable conduct, conditions implied in consumer contracts, manufacturers' obligations, product safety and product information and other related matters. It established the Fair Competition Commission with the power to study government policies, procedures and programmes, legislation and proposals for legislation so as to assess their effects on competition and consumer welfare and to publicise the results of such studies. Section 49(I) of the Act provides for restrictions on the supply of unsafe goods. The provision prohibits the supply of goods that are intended to be used, or are of a kind likely to be used, by a consumer if the goods are of a kind in respect of which there is a prescribed consumer product safety standard and which do not comply with that standard. This provision is likely to be in conflict with the provisions of other laws such as the medicines and medical devices act 2019.
The Industrial and Consumer Chemicals (Management and Control) Act, No.3 of 2003
The Industrial and Consumer Chemicals (Management and Control) Act,2003 established the National Chemist Laboratory with the power to ensure that any chemical producer complies with the GMP and undertakes EIA before undertaking operations. This act also empowers the Chemical Laboratory Agency to issue a license for producing, transporting, importing, exporting, storing and dealing in chemicals for a prescribed fee. This overlaps the provisions of other Business Licensing Authorities. The procedure for applying for a license seems to be cumbersome without a clear and short-term framework. There is no cross-reference between this law and other laws such as the Environmental Management Act that provides for Environmental Impact Assessments. In addition, there is no coordination between the regulatory bodies established under this law and other bodies mandated to do related tasks
The Sugar Industry Act, Cap 251 [R.E.2002]
This Act makes provisions for the establishment of the Sugar Board of Tanzania and the National Sugar Institute, to provide for the improvement, development and regulation of the sugar industry and matters related thereto. The Act established the Sugar Board of Tanzania. This Board is basically responsible for all matters pertaining to the improvement, development and regulation of the sugar industry in Tanzania. The Board is mandated to issue licenses to sugar manufacturers and small plant operators and to register exporters, importers and industrial users of sugarcane, etc. It has also the power to issue sugar import

and export licenses. All licenses are issued subject to the payment of various fees, whose amount is not indicated in the parent Act. Penalties for contravening the law are a fine of thirty million shillings or three years' imprisonment.

The Fisheries Act, No. 22 of 2003

Section 22 of the Act prohibits persons from fishing, collecting, gathering, processing or manufacturing fish products or the products of aquatic flora; selling or marketing fish, fish products, aquatic flora or the products of aquatic flora; and importing or exporting fish, fish products, aquatic flora or the products of aquatic flora, unless he applies for and is granted by the Director or any other authorised officer a license in respect of such activity. Section 24 provides for standards for the quality and management of fish and fish processing and for monitoring quality management programmes and the application of Hazard Analysis and Critical Control Point (HACCP). Section 52 of this Act prohibits persons from undertaking any development activities, without undertaking an Environmental Impact Assessment in accordance with any other written laws of Tanzania. Additionally, the Act empowers the Minister responsible to impose the mandatory licensing and registration all fishing vessels, which could also be registered under the Business Licensing Act.

The Local Government (District Authorities) Act, Cap 287 [R.E.2002]

Local Governments (District Authorities) are entrusted with immense powers to make by-laws to regulate various matters including the manufacture of food and the payment of fees and levies. In particular, sections 153-162 empower local governments within districts to make by-laws for their area of jurisdiction, which entails the payment of fees and levies by food manufacturers.

The Local Government (Finance) Act, Cap 290 [R.E.2002]

This Act makes provision for sources of revenue and the management of the funds and resources of local government authorities and for matters connected with or incidental to securing the proper collection and sound management of finances in the local government system. The Local Government (Finance) Act and Local Government (District Authorities) Act empower LGAs to make by-laws to regulate various matters, including the payment of fees and levies for the manufacture of food in their area of jurisdiction. More specifically, section16 empowers LGAs to impose taxes and rates. This section mandates LGAs to make by-laws imposing such rates to be paid by the inhabitants, or such categories of inhabitants, for or in connection with such services, things, matters or acts as the authority may describe or specify in the by-laws in question. Sections 7, 8 and 9 provide for Sources of revenue of district councils, sources of revenue of township authorities and sources of revenue of village councils. These provisions empower LGAs to impose so many taxes, fees and other charges on any business, including those producing and manufacturing food within their jurisdiction. Therefore, there is a need to amend sections7, 8, 9 and 16 of the Act to simplify the taxes, charges and other fees and related tax laws through centralising all charges and taxes in a one-stop centre.

The Income Tax Act, No.11 of 2004

This Act makes provision for the charging, assessment and collection of income tax as well as ascertaining the amount to be charged and matters incidental thereto. Generally, this law and other tax laws provide for compulsory registration. The 4thSchedule of the Act specifies

the transactions for which a Taxpayer Identification Number (TIN) is required. This requirement means that upon incorporating or registering a business the party concerned must immediately register with the TRA and produce the TIN prior to securing a licence to undertake the business for which the entity was established. Such a complicated and cumbersome requirement discourages informal enterprises from formalizing their businesses. The Value Added Tax (VAT) obliges person whose taxable turnover exceeds, or the person has reason to believe will exceed, the turnover prescribed in the regulations made under the Act, to make application to be registered within thirty days. Apart from this Act, there other tax laws administered by different institutions which give overlapping powers to tax manufacturers and place an unnecessary burden on businesses, especially those of food manufacturers. Thus, the tax laws need to be amended to simplify the taxes, charges and other fees and to harmonize them with other tax laws through centralizing all charges and taxes in a one-stop centre.

The Merchandise Marks Act Cap 85 [R.E.2002]

This Act provides for controlling the use of marks and trade descriptions in relation to the merchandise mark. The Act is also relevant to businesses related to food products and the food manufacturing sector as it controls counterfeits and provides for the offences of forgery and the deceptive application of trademarks. It is implemented using the Merchandise Marks Regulations,2008, which mainly focus on controlling counterfeit and sub-standard goods, including food products. However, the Act defines neither counterfeit nor sub-standard goods. There is no clear provision as to whether the persons who sell counterfeit or sub-standard goods commit an offence. There is no clear cross-border provision under the law. The inspectors under the Fair Competition Commission are given immense discretionary powers by the law and regulations to inspect and seize impound or destroy or any goods and products they think are sub-standard or counterfeit. In this case, there is a need to review and amend the laws to clearly address the counterfeiting of goods and the sale of sub-standard goods. The Act should define "Counterfeiting" to include, but not limited to, manufacturing, producing, packaging, repackaging and labelling. The Law needs to address the question of how to deal with businesses that import products from foreign countries where the production of counterfeit goods is not strictly regulated. There is a need to introduce a clear provision for a criminal offence, specifically for counterfeiting the origin of food products.

The Business Licensing Act No. 25 of 1972 (Cap 208 R.E 2002)

This is the main Act that provides for the licensing of all businesses and for related matters. The Act prohibits any business from operating without a license. The function of the Act is threefold: i) to regulate businesses; ii) to raise revenue from licensing; and iii) to gather and retain information on businesses. The regulatory objective of the Act is fulfilled through the use of pre-approval. The system of licensing is applied to all firms and individuals, regardless of the size and nature of the business being undertaken. The regulatory function of the Act is duplicated by the licensing provisions contained in more than 634 sector-specific statutes that regulate certain economic activities that are perceived as prejudicing public interests in some way. Tanzania has a universal business licensing regime enforced by the Business Licensing Act (Act No. 25 of 1972) as amended by the Business Licensing (Amendment) Act (Act No.9 of 1980). The Business Licensing Act (1972) gives effect to a universal pre-

conditional approval to operate a business in Tanzania, which places the burden of proof of compliance with standards on the individual entrepreneur and vests considerable discretionary power on government officials, particularly at the local government level. The Act creates a multiplicity and duplication of processes, including the cumbersome pre-approval system that acts as a barrier to business growth. The Act provides for a business licensing regime which creates the potential for a great deal of overlapping and duplication in the licensing process among Regulatory Authorities using cross-cutting legislation. There is a need to repeal the Business Licensing Act, No. 25 of 1972, Cap 208[R.E 2002] and limit licensing to sector-specific areas of necessity. There is also a need to implement the Business Activities Registration Act, 2007, which could replace the Business Licensing Act. The proposed business regulatory regime under the Business Activities Registration Act, 2007 needs to reflect other related laws administered by Regulatory Authorities such as TMDA, TBS, OSHA, TRA, LGAs and others. This could be effectively done by creating provisions that cross-refer to other related laws. There is also a need to provide a legal provision that will remove the requirement for businesses that are licensed under sector laws to obtain a licence under the Business Licensing Act.

The Business Activities Registration Act, 2007

This is an Act that provides for the establishment of a business activities registration system, business registration centre and other related matters to provide for the following.

- Section 8(a) of the Act provides that the regulatory function of the Centre is to register all business undertakings, business entities and enterprises in the area of its jurisdiction.
- Compliance by regulated and unregulated businesses: Under section 11(1), it shall be necessary to obtain a certificate of registration from the Registration centre in respect to every business.
- Issuance of Certificate of Registration: Section 11(2) requires any business not regulated under any written law shall upon application be issued with a certificate of registration.
- Inspection: Section 26(1) of the Act empowers the Minister responsible for local government to appoint such number of officers of the local authority to be inspectors for the purpose of the Act.

Therefore, there is a need to implement the Business Activities Registration Act, 2007 by preparing effective and simplified regulations under the Act. The proposed business regulatory regime under this Act needs to reflect other related laws administered by Regulatory Authorities such as TMDA, TBS, OSHA, TRA, Local Government Authorities and others. This could be effectively done by creating provisions that cross-refer to other related laws.

The Cashew Nut Industry Act of 2009

This Act provides for the establishment of the Cashew Nut Board to regulate the production, grading, and processing of cashew nuts, to market the kernels and to provide for other related matters. The Act is also relevant to the food manufacturing sector as it obliges every cashew nut dealer, whether a buyer, processor, importer, exporter, warehouse owner or operator, to register with the Cashew Nut Board. Section 15 obliges any person registered as

a cashew nut buyer, seller, processor, exporter, importer, warehouse owner or operator to apply for a license. The decision of the Minister under section 15 is final and this is contrary to the principles of natural justice under the Constitution of the United Republic of Tanzania. The dealers in cashew nuts are also obliged to obtain a business licence under the Business Licensing Act.

The Public Health Act of 2009

The main objective of the Act is to provide for the promotion, preservation and maintenance of public health with a view to ensuring the provision of comprehensive, functional and sustainable public health services to the general public and to provide for other related matters. The Act provides that the District/Urban Authority shall ensure that food is not manufactured except on premises registered in accordance with the relevant laws. The Authority shall ensure that all premises registered for food manufacturing maintain and adhere to the prescribed public health standards throughout the duration of registration. The Act empowers the Authority to make by–laws, among other things,

- prohibiting the manufacturing and sale of adulterated food,
- ensuring milk products intended for human consumption comply with the prescribed standards
- ensuring that the transport, storage, packaging and marketing of any food intended for public consumption is done in strict observance of sanitary and clean conditions and practices and using wholesome methods
- ensuring that prescribed cases of food poisoning are reported
- ensuring the inspection and control of infected food
- furnishing the authorised officer with general powers to examine and seize any food which is, or which appears to him to be, unfit for human consumption
- requiring any person to comply with any order calling for information regarding the composition of substances in food
- prescribing the general provision for the good performance and effective carrying out of the provisions of the Act.

Some provisions of this Act are very similar to the Environmental Management Act, 2004 as both laws require inspection for environmental compliance, which might cause duplication and overlapping powers among the institutions implementing these laws.

Occupational Health and Safety Act No.5 of 2003

The main objectives of the Act are to repeal the Factories Ordinance, to make provision for the safety, health and welfare of persons at work in factories and other places of work, to provide for the protection of persons other than persons at work against hazards to health and safety arising out of or in connection with the activities of persons at work, and to provide for connected matters. Section 15 the Act provides for the registration of factories or workplaces. The Chief Inspector is given discretionary powers to enter such particulars in relation to every factory and workplace as he may consider necessary. The Act obliges the owner or occupier of a factory or workplace to register such factory or workplace and obtain a certificate of registration or compliance license. The Act established the Occupational Health and Safety Agency (OSHA), which checks the company's premises and inspects the health, safety and dwelling of workers and of workplaces. It inspects the

working environment and the equipment used in operational activities. OSHA is responsible for coordinating the provision of health services for employees of these institutions, with technical support from the Regional Secretariat and Ministry of Health. The procedures for obtaining a certificate of registration and compliance license appear to be cumbersome and time consuming. Additionally, the provisions of this Act overlap other laws such as the Environmental Management Act, No.20 of 2004, the Standards Act, Act.No.2 of 2008, the Dairy Industry Act, No.8 of 2004 and the Industrial and Consumer Chemicals (Management and Control) Act, No.3 as all these laws give discretionary powers to inspectors to inspect premises at any time and take legal action over non-compliance.

The Atomic Energy Act, 2002:

This Act established the Tanzania Atomic Energy Commission(TAEC)and provides for its functions in relation to controlling the use of ionising and non-ionising radiation sources and promoting the safe and peaceful use of atomic energy and nuclear technology. The Commission is empowered to issues various licenses upon application being made to the Commission on the prescribed form and the prescribed fee being paid, subject to such conditions or limitations as may be deemed fit or necessary to impose. Section 5 empowers TAEC to regulate the safe and peaceful use of atomic energy, promote and expand the contribution of atomic energy and nuclear technology to health and prosperity throughout the United Republic of Tanzania. Section 30 provides for the mandatory requirement for any manufacturer, importer and exporter of foodstuffs specified in the relevant regulations to obtain a radioactivity analysis certificate from the Commission before the said food is imported into the country or exported from the country or distributed for human and animal consumption. The headquarters of the Commission are in Arusha and the Commission is not decentralised to other regions. This leads to unnecessary costs and consumes the time of those complying with this law. Part four of the Act deals with controlling the radioactivity in foodstuffs and section 28 provides that the provisions of this part shall be read together with the Tanzania Food, Drugs and Cosmetics Act, 2003.This provision is one of the best provisions of the laws and regulations that regulate food production, food processing and business in food as it provides for cross-referencing with the provisions of other laws. Other related laws need to provide provisions like this to harmonise and simplify the implementation of laws. For instance, section 29 further provides that "Save as is provided for under this Act, the Commission shall, in consultation with the Tanzania Food and Drugs Authority and other competent institutions, establish a system designated for the control of radioactivity in foodstuffs".

The Fire and Rescue Force Act, 2007:

The Fire and Rescue Force Act provides the Commissioner or any fireman or other person authorised by him in writing the right to enter any premises and inspect the fire safety standards. The Act also states that an applicant to the fire and rescue service shall pay the Commissioner for the services of any fireman and for the use of equipment fees as may be prescribed by the Minister. The provisions of this Act overlap other laws due to the fact that each law requires the inspection of premises to be done by inspectors who have discretionary powers to inspect premises at any time and take legal action over non-compliance.

The Weights and Measures Act, 1982

This Act revises and consolidates the laws relating to weights and measures and provides for the introduction of the International System of Units (SI) and related matters. Section9 empowers the Minister to procure and cause to be maintained standard equipment, which he may from time to time determine as being proper and necessary for the verification of standards of weights and measures. The duties of an assizer shall be: (a) to carry out verification of weights, measures, weighing and measuring instruments; (b) to care for and maintain any working standards which may be entrusted to his care; (c) to keep records and make such reports as the Commissioner may require;(d) to give effect to the directions of the Commissioner; and (e) generally to exercise such other powers and duties as may be conferred or imposed by this or any other Act or by regulations made under this Act.

The reviewed regulations imply that, for a manufacturing business in the food processing, textile or pharmaceutical value chain, there are about 19 process requirements for licensing the manufacturer as stipulated in table 4.

Table 4: Process Requirements to Establish Manufacturing Business in Food Processing, Textile or Pharmaceutical Value Chain

i.	Apply for clearance of the proposed company name at BRELA
ii.	Incorporate the Company with BRELA so as to obtain a business license
iii.	Apply to TRA for the Tax Identification Number and PAYE scheme
iv.	Apply for a business licence from the regional trade officer or from the Ministry of Industry and Trade (depending on the nature of the business)
v.	Premise Registration Certificate. In order to obtain this certificate, premises are inspected by TMDA through the Local Authority Health Officers
vi.	Apply for Food Manufacturing License. This requires the manufacturing plant to be inspected so as to ensure that it has the correct layout of facilities and the necessary machines, etc.
vii.	Apply to the local Government authority for site inspection and building permit.
viii.	Divisional or district Local Government Authority's Health Officer inspects premises on which food is to be manufactured
ix.	Inspection by NEMC to check environmental compliance and the Environmental Impact Assessment.
x.	Inspection by the Fire and Rescue Force
xi.	Chemical inspection by Government Laboratory Agency for radiation

xii.	Inspection and registration of the factory by the Ministry of Labour after which the factor obtains a certificate of registration or compliance license, valid for twelve months
xiii.	The Ministry of Labour uses inspection agencies to check on machinery layout, occupational health and safety, light intensity and proper ventilation, noise, fire appliances and boilers.
xiv.	TMDA tests for product safety and quality and registers it.
xv.	Inspection by OSHA to check compliance with labour standards
xvi.	Inspection of weights and measures
xvii.	The health status of employees is checked on a quarterly basis.
xviii.	TBS tests each product to ensure that it meets minimum standards.
xix.	Registration of staff with the NSSF.

3.3 Synthesis of the Policy and Regulatory Framework Governing Food Processing, Textile and Pharmaceutical Value Chain in Tanzania

- The policy and regulatory framework has been designed for regulating various sectors and industries to safeguard public interests, consumers and businesses at various capacities.
- The policy framework has been designed with an intent to attain greater performance of the private sector while at the same time maintaining good business practices.
- Most regulations affecting the private sector and the mandates of regulators are therefore drawn from the country's policy framework.
- However, the regulatory framework is fragmented and uncoordinated resulting into regulatory functions overlaps and deviating from the TDV 2025
- Regulatory overlaps have resulted into over-regulation of businesses with a corresponding appalling compliance costs
- Therefore, the key challenge is to rationalise the way in which the sector is regulated without overlaps and avoiding unnecessary costs and too many burdens on the private sector while ensuring that good business practices are attained.
- There is a need for an in-depth analysis and crafting of proper intervention by engaging both the private and public sector through innovative partnerships, harmonize regulations and ensure a smooth cost effective compliance to the regulatory requirements.

CHAPTER THREE

STUDY FINDINGS

3.1 Introduction

The analysis of the regulatory and fiscal challenges facing the three value chains of food processing, textile and pharmaceutical was done considering general issues affecting all value chains and disaggregation to discern specific value chain challenges. In this section of findings, the general issues are presented followed by value chain specific issues.

3.1.1 Burdens in Accessing Regulatory Services

The number of procedures to follow in compliance, processing time (issuance of licenses, registration certificate, inspections etc.), requirements (environment impact assessment report, audited statements, MEMARTs, etc.), bureaucracy and corrupt practices have been earmarked as common regulatory challenges faced by businesses. These have been considered not only as triggers to dissatisfaction with regulatory service delivery but also reasons for rising cost of compliance and detest to comply among businesses. Similarly, in the three value chains analyzed, respondents have indicated their experience with these in compliance with various regulations. Findings reveal that, processing time (40.7%), bureaucracy and corrupt practices (37%) and permit or license requirements (14.8%) as the most common challenges in the process as depicted in Table 5.

Table 5: Compliance Burdens

Compliance Burden	Frequency	Percent
Processing time	11	40.7
Permit/license requirements	4	14.8
Bureaucracy, paper work and corrupt practices	10	37.0
Total	**27**	**100.0**

These findings imply that, there is a feeling that the processing time of certificates and licenses by regulatory authorities is burdensome and leads to loss of productive time for businesses. Time is an important resource to businesses as it translates to effectiveness and efficiency. Similarly, bureaucracy which is closely connected to elongated processes, paper work and corrupt practices are still perceived as a burden to business in the context of regulatory compliance.

3.1.2 Time Spent in Regulatory Compliance

Delays and elongated processes in getting certifications, licenses and permits have been an area of complain from value chain actors. They lament that, their time which would have been used in production is used in following up for compliance issues. This is contributed by inefficient systems and people, distance between actors and regulatory offices, poor customer services, lack of correct information to clients and inefficient service provide. The findings of the study indicate average number of days spent from the application to receiving particular compliance document like license, certificate or permit. Getting certification and license take the longest at average of 29 and 7 days respectively.

Respondents claimed that, despite efforts by the government to establish online platforms for application and processing of these licenses and permits, delays have always been experienced as response from the system takes long. They further claimed that delays have been explained as resulting from system being down, power cuts, internet problems and some of the actions in the system need approval which takes long. Figure 1 shows average number of days taken to accomplish some of compliance processes.

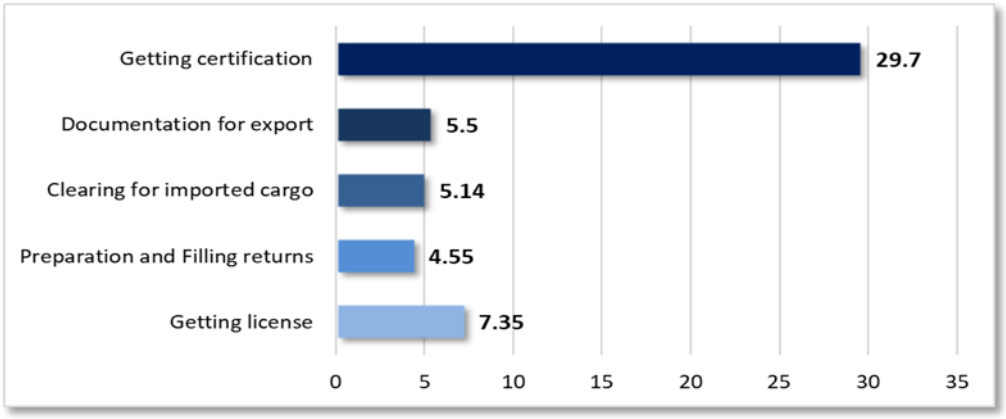


Figure 2: Time Spent in Days to Comply to Regulations

3.1.3 Business Permit Issuers

Figure 2 indicates that top 5 issuers are LGA, TBS, OSHA, NEMC and Tanzania dairy board. Additionally, Figure 3 shows top 5 issuers who provide expensive permits; these are OSHA, WMA, WRBWB, TBS and NEMC.

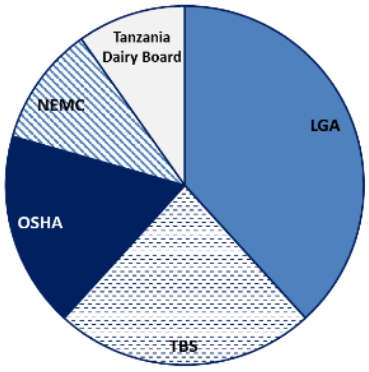


Figure 3: Top Five Highly Reported Regulators

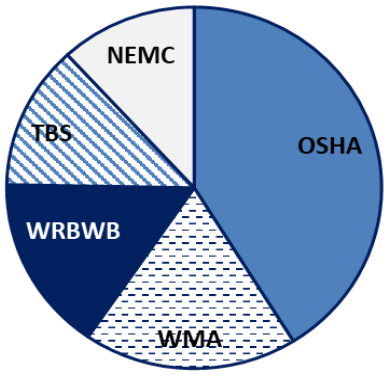


Figure 4: Top Five Most Expensive Regulators

All respondents reported that they were required to conduct an inspection before and after granting the permit/license; however, 55.6% said it is required once per year and 25.9 % said twice per year, and the rest were unsure.

3.1.4 Supporting documents to Permit Application

There were various documents required for the license application; these were (i) tax clearance certificate, (ii) introduction letter from Village/ward leader (iii) MEMARTS, and (iv) expert certificates. On average, they reported to comply approximately six (6) authorities; some reported up to 8 authorities. Unfortunately, even though the business owners have to comply to these authorities, it brought several burdens to the business operators. Figure 3 indicates that majority reported that bureaucracy, paper work, and corrupt practices were the biggest issue. It was followed by another major issue of lengthy *processing time* for permit and other required documents.

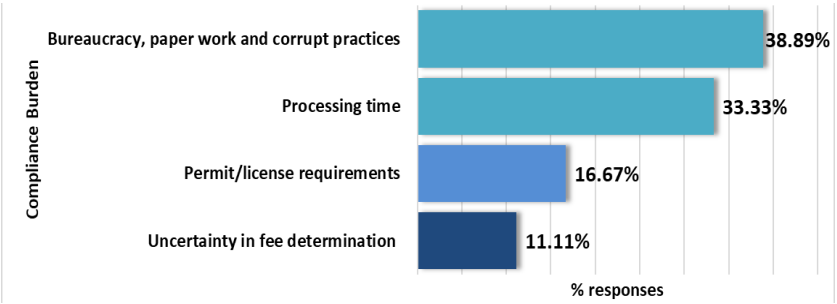


Figure 3: Burdens experienced during Processing documentation for Compliance

Other issues that created burdens in complying with these permits or licenses were; the presence of multiple regulatory authorities doing the same function and high amount of fees. The respondents also indicated the number of days spent on getting licenses, preparation of tax return documents, filling the returns, cargo clearance, preparation of documentation for exporting, and getting certification. Majority of them reported that on getting business certificates from TBS, TMDA etc. takes many days and on average it can take 7 to 8 days.

Table 6: Days Spent to Complete Compliance Process

Activity	Number of Days		
	average	Min	Max
(a)Getting license	7.35	2	14
(b)Preparation and Filling returns	4.55	1	7
(c)Clearing for imported cargo	5.14	3	7
(d) Documentation for export	5.50	4	7
(e)Getting certification	29.70	3	90

3.1.5 Coordination Challenges in the Value Chains

Challenges relating to Forward Coordination/Linking	
Transportation	high cost of transportation which impacts transport coordination problems

	and the overall efficiency of the value chain
Multiple Actors Issuing Several Permits	Multiple authorities issuing permits can lead to bureaucracy, delays in distribution, increased administrative burdens, and potential compliance issues. It impacts the forward flow of products in the value chain from processing to distribution.
Poor linkage among actors	Poor linkage can lead to inefficiencies, delays, and misunderstandings at various levels in the chain, affecting both raw material sourcing (backward) and processed product delivery (forward). It delays the smooth flow of information, products, and feedback along the whole value chain.
Compliance costs	Meeting regulatory compliance requirements can be costly and time-consuming. Furthermore, price competition from informal, unregulated businesses may affect the profitability of registered and regulated businesses.
Inadequate infrastructure	Inadequate infrastructure networks directly impact the transportation and distribution of processed products.
Unreliable power supply	unreliable power supply which directly impacts the machinery operations, processing equipment, and maintaining proper storage conditions for processed products.
Lack of storage facilities	The availability of storage facilities directly impacts the processing and distribution phases of the grain value chain. This challenge pertains to the storage of processed products before they are distributed to customers. A lack of storage facilities can lead to issues such as post-processing delays, increased distribution costs, and potential product quality degradation due to inadequate storage conditions
permit for transporting products	Acquiring permits for product transportation is a step in the forward direction, related to product distribution
price variation/ price volatility	Price fluctuations can impact pricing strategies for the respective products in the businesses.
Quality and reliability from the supply side	It is challenging to ensure that the suppliers consistently provide raw materials at a prescribed quality.
	Challenges relating to Backward Coordination/Linking
Substandard	There are issues reported about the authenticity of the raw materials supplied by farmers, importers/retailers, or wholesalers. There might be attempts to pass off lower-quality materials, impacting the value or quality of the final processed products.

Poor quality of raw materials	This challenge which is mostly common in food processing and textile value chains impacts the quality of the final products, high processing costs, greater product loss, and decreased customer satisfaction.
Distance from the market challenge	It is logistically difficult to transport processed goods across great distances to clients or marketplaces. Long distances may result in higher transportation costs, delayed deliveries, and potential quality problems

The respondents were asked to state the challenges hindering technology adoption and use of modern technology in their firms. The following points were mentioned:

- High charges in import duties significantly increase the cost of importing modern technologies, making it financially difficult for businesses to acquire the necessary facilities.
- The initial cost of investment required to fix modern technologies in factories can be substantial. It includes additional costs in installation, training, and maintenance.
- Limited financial resources and a shortage of skilled human resources pose challenges in adopting and utilizing the modern technologies brought in the business.
- Establishing incentives for local manufacturers to produce technological equipment in Tanzania. This can support the growth of local industries and influence the affordability of the technology.

In conclusion, several strategies can be implemented to alleviate value chain challenges. Firstly, government support in the form of policy adjustments is crucial; this includes the review of import taxes on technology-related imports and the granting of exemptions for such imports. Secondly, efforts should be directed toward enhancing and fortifying local technological capabilities. This measure will counteract the issue of limited local capacity. Lastly, financial support, such as loans and assistance, should be provided to businesses and individuals looking to invest in technology. In this case Local Government Authorities (LGAs) can play a pivotal role. These combined strategies aim to foster technology adoption and bolster the overall resilience of the value chain.

3.2Food Processing Value Chain

One of the tasks of the consultant was to assess the regulatory and fiscal challenges in the food processing value chain in Tanzania. The findings from the assessment are presented in this section.

3.2.1 Factors for Over-regulation in Food Processing Value Chain

It is widely acknowledged that regulations in the food processing value chain are important in safeguarding the interests of the public in health and safety, environmental safety and addressing market failures. However, it is also acknowledged that, there are challenges to businesses arising from the implementation of the policies and regulations. Specifically, the value chain is burdened by regulatory and fiscal challenges as follows:

i) The food processing value chain is plagued regulatory overlaps related to: inspection of premises (TDB, TMDA, TBS, NEMC, FRF, LGA); production (TDB, TMDA, TBS, weights and measures); product transportation (TDB, TMDA; Veterinary Department under the Ministry of Livestock Development); inspection of premises and equipment (TMDA, TBS, LGA, NEMC, OSHA etc.); labelling (TMDA, TDB, WMA); registration (TDB, BRELA); and licensing (TMDA, TBS, LGA, Relevant Ministry). There are at least 22 laws and 15 regulators each spending an average of 5 hours to conduct inspection of premises, machinery or health check-up to employees. On average 9-10 days are lost for inspection in each calendar year. This is aggravated even further for firms with multiple production premises, since inspection is done in all factory premises and employees. Mounting cost is incurred to facilitate transport and accommodation of inspectors, pay consultants and in preparing reports.
ii) Lack of harmonization among the regulatory bodies and corresponding regulations has resulted into duplicate of services, inefficiencies and mounting compliance costs among value chain actors. For instance, in the dairy sector, if a processor has 20 shops around the country, then he will need to obtain 20 certificates of registration and 20 business licenses. The Registry will receive 20 repeated data on the business. If the same processor places the 20 shops within one LGA, he will still need to register all of them, obtain 20 certificates of registration.
iii) There are reported inconsistencies in application of regulations. Different regulators performing more or less regulatory function like inspection have been charging differently for the same business. For instance, while OSHA makes health checkup for all employees at entry, on work and during exit at a rate of 50,000/ per staff, the LGA does the same at a rate of 10,000/= per staff twice a year. On average, businesses pay at least 70,000/= per staff for health checkup annually.
iv) There has been significant variation of compliance cost charged by same organization at different times whose explanation for such variation is not normally provided. For instance, one respondent in Moshi claimed that, they used to be charged 600,000/= inspection costs by OSHA prior 2022. Surprisingly, in 2022, the cost shot to 1,800,000/= which is three times more than the previous year. In 2023, the cost hiked again to 1,900,000/=. However, there are no expansion made in the factory of whatsoever.
v) The necessary infrastructure for the proper functioning of the value chain is either non-existent or in bad condition. This includes warehousing, machinery and transportation infrastructure which has to be created and maintained by the government. It is fragmented, disconnected to key producing areas and inaccessible throughout. This has been the reason for rising costs of production compromising competitiveness of locally processed products in the local and regional markets.
vi) Excessive bureaucracy and unfriendly attitude of regulatory authority's staff, result into waste of enterprises' time and resources, delays, corruption, frustration and unnecessary inconvenience which are found to affect the operations of enterprises significantly.
vii) Rent-seeking behavior is common among most regulatory agencies. The reasons being inadequate resource allocation to regulatory agencies. Besides that, the

government's use of regulation as a source of revenue has resulted into prioritizing compliance facilitation to enforcement. Compliance costs in terms of fees, processing charges and penalties have been imposed businesses in regardless of their ability to pay and sustainability. For instance, OSHA charges a penalty of 5% on the amount unpaid daily after deadline. This has resulted into some businesses closing.

A Case Story about OSHA

This is a case of a business dealing with maize processing in Moshi. This is about an incidence of this year 2023 where normal inspection was done by OSHA and the inspectors promised to issue report for the same and invoice for the annual inspection via the system in three days' time. Three days went by but the report was not in the system and after several log ins, the client made a follow up call. He was told to wait as the system was not ok. After some weeks, the client found the report and invoice amounting six (6) million Tanzanian shillings. The client was surprised by figure and had to physically visit OSHA offices to air out his concerns. This resulted into lowering down the fee to 1.9M down from 6M. The reasons for the alarming figure were that the system was new and automatically sets the figures.

Once they had agreed on the correct annual inspection fee, they promised to issue control number to effect the payment via their system in a day. The client tried to access the system for control number several times but it was not yet generated. Follow up was made via phone call and the client was notified that there was a problem with the system and would be contacted once the system was back to normal functioning. This was May 2023, and there was no any notification up to June when the client decided to make a physical follow up. This time the client went to follow up for training certificates not issued after training and the control number. The client was told his issue of control will be taken to IT expert and will be notified. About the certificates, he was told to be called once ready. In July 2023, the client was called to collect certificates and upon arrival at OSHA offices was informed of outstanding fee of 3M which is the fee plus penalty for delay. The following Saturday, unknown person dispatched a letter notifying the same.

This is a case from a regulatory agency established to facilitate business operations to foster growth and competitiveness. Regulatory services should be timely, user-centric and efficient. Conversely, ineffective communication, lack of transparency, inconsistency and costly compliance framework have characterized the atmosphere of compliance. Businesses have been complaining about time wasted, loss of productivity, high and unrealistic fees and other charges, cumbersome procedures as impediments towards smooth compliance and doing business.

Table 7: Different Fees and Charges to Dairy Processors

Regulatory Body	Required Compliance	Amount	Period Covered
NEMC	Environmental Audit for Premise Certification	4,500,000	Once
	Annual Fees	450,000	Annually
TBS	Premise Registration Fees	831,600	Once

	Machines & equipment Calibration (Minimum Costs)	1,300,000	Annually
	Service Charges during Inspection of Machines & Equipment	450,000	Annually
	Product Registration Fees - Mtindi	2,100,000	Annually
	Product Registration Fees - Yogurt	2,700,000	Annually
	Product Registration Fees - Fresh Milk	2,380,000	Annually
	Re-testing Fees for Failed Product	760,000	
	ISO certification across border	11,840,000	Once
OSHA	Premise Registration Fees	250,000	Once
	Premise General Inspection Fees (Minimum Cost)	1,202,000	Annually
	Service Charges during Inspection Premise General Inspection	730,000	Annually
	Training Fees per Person (Requirement 2-Persons)	600,000	Annually
	Medical Check-up Costs (Per Person)	25,000	Annually
TDB	Premise Registration Fees	300,000	5-Years
	Sales Outlets (Shops) Registration Fees	5,000	Annually
	Milk Carriage (Distribution Vehicles) Registration Fees @	35,000	Annually
Fire	Fire Safety Inspection Fees	500,000	Annually
	Sales Outlets (Shops) Fire Safety Inspection Fees	40,000	Annually
Weight & Measure	Packed Products Inspection Fees	500,000	Annually
GS1	Barcodes Fees	1,300,000	Annually
LGA	Business License	101,000	Annually
	Health Check-up (Per Person)	20,000	Annually
LATRA	Distribution Vehicles - Transportation Fees @	65,000	Annually
Other Fees Based on the Revenue Income			
	Service Levy	0.3%	Gross of Income
	TRA - Income Tax	30%	Of Net Profit
	WCF	0.5%	Employee Gross Salary
	NHIF	3%	Employee Basic Salary

	NSSF	10%	Employee Gross Salary

viii) Based on the data obtained from the enterprise records and from the regulators, the cost of compliance by a food-processing plant during the start-up phase is Tanzanian shillings 6,482,600/=. Recurrent compliance costs exceeded Tanzanian shillings 15,513,000/= per year. The time taken in waiting for the necessary permits and licenses during start-up was estimated to be a minimum of 39 person-days, though in practice it could be less because some activities are done simultaneously. In the operational phase, compliance takes 167 person-days to which include cc The cost estimate for all the 167 days which includes transport, communication and loss productivity is Tanzania shillings 9,271,666.67/=. Therefore, total compliance cost estimates (direct and indirect) is 31,267,266.7/=.

3.3 The Textile Value Chain in Tanzania

Existing industry reports and government strategic documents reveal that, the textile value chain has huge poverty-reducing potential, given that more than 500,000 smallholders, concentrated in some of the poorest and least fertile regions of Tanzania grow cotton. However, cotton yields have remained below expectations at an average of 283,600 tones (five years' average) where 80% of this cotton is exported in raw form. Projections indicate that, Tanzania has the potential to be a leading producer of textiles and garments for domestic, regional and global markets, generating hundreds and thousands of decent jobs and doubling the incomes of more than 500,000 cotton farmers. This is subject to doing reforms to address regulatory and fiscal challenges in the cotton & textiles value chain. This is expected to unlock potentials embed in the value chain including lifting 650,000 people out of poverty in cotton-growing areas by doubling household incomes from the current US$540 per year; creating 50,000 decent textile and garment jobs; and increasing textile and garment export revenues six fold to US$800 million.

3.3.1 Regulatory and Fiscal Challenges in Textile Value Chain in Tanzania

It is widely acknowledged that regulations in the textile value chain are important in safeguarding the interests of the public in health and safety, environmental safety and addressing market failures. However, it is also acknowledged that, there are challenges to businesses arising from the implementation of the policies and regulations. Specifically, the value chain actors are burdened by regulatory and fiscal challenges as follows:

i. The charges on imported textile industry spear parts and machinery are high and the rates are often uncertain. Textile manufacturers import machinery, spare parts, dye and color for use in their production process. Tax rates for some spare parts and machinery are not in the established list in the revenue authority where the officials are at a discretion to subject the items to either 10% or 25% tax rate. However, common tendency is opting for the higher tax rate of 25% which in turn raises compliance cost and inhibiting ability to import modern machinery by textile mills. Worse still, when textile mills negotiate for these taxes, the decisions take long affecting storage costs.

ii. Presence of sub-standard imported textiles sold alongside the domestically-produced quality but higher priced textiles. Although laws do exist, loopholes make the import of these low-priced goods possible because of smuggling and under-valuation of imports for tax determination with dire consequences for the domestic manufacturing enterprises. Market for locally manufactured textiles and garments has been lost to cheap imports with consequent closure of factories and loss of government revenues. Since 1992, out 35 textile mills and garments manufacturing industries 23 have closed down. Worse still, all mills except the two under EPZ are operating on average at 30-50 % Capacity utilization.

iii. The infrastructure related to textile industry including transport and storage is not fully supportive of the value chain. While the road network linking regions and districts in the raw material producing areas is generally very good, village (feeder) roads where majority of raw materials are sourced are not generally good. Analysis of costs of production, reveals that transport costs alone account for about 32% of the total costs.

iv. Presence of numerous taxes and fees paid to both the central and local governments. The multiplicity of taxes is a disincentive to taxpayers, as numerous taxes and fees increase the related taxation processes as well as costs for the firms, and frustrate their operations. For instance, firms in Tanzania pay a 3.5 per cent levy on private company payroll for skills and development, 0.3 per cent of annual turnover as city service levy, 5 percent crop levy charged on farm gate prices, and many other compliance fees as stipulated in Table 8. The cumulative levies, taxes and fees have significantly increased the cost of doing business and reduced competitiveness in both domestic and external markets.

v. Most regulations and regulators in the textile value chain are just a duplicate of each other. They are unnecessary burden leading machine and employee down time, high compliance costs and associated stringent requirements. In the textile value chain premises inspection is conducted by NEMC, TBS, OSHA, LGA, Fire and Rescue, TIC and WMA. Further to this, a typical textile manufacturer is required to be registered and licensed by TIC, TCB and BRELA. This duplicates the number and frequency a textile actor needs to interact with regulators to comply to regulations. Number of working hours are lost to a tune of 8 hours per regulator per annum factory wide and 64 working days of an employee to follow up compliance.

vi. It is established that, there are fiscal challenges emanating from not abiding with the common external tariff agreed in the EAC. While the agreed common evaluation and verification of garments imported in EAC is to be based on weight measured by kilogram, in Tanzania that has not been adopted and the same is by meter or pieces. This is rather difficult to do verification which results into under-valuation of imports. Further to that, across all countries worldwide, kitenge/Kanga is valued at 1 USD CIF whereas the same is valued at 0.4 USD CIF value. This results into less tariff for imported garments and low prices in the market. The locally produced textiles are relatively expensive and less competitive in the market.

vii. The regulatory authorities in the textile value chain are under-resourced which results into weaknesses in discharging their regulatory functions. Cotton production is

regulated by the Tanzania Cotton Board to ensure quality of output. TCB as the key regulator of the industry, lacks both the human and financial resources to effectively conduct its full range of regulatory activities. Currently, the board is staffed with only about 30 District inspectors who cover 5,500 to 8,500 buying posts located in 34 districts. This bottleneck in turn leads to quality and consequent competitiveness problems to downstream actors including textile mills. Further to that, textile mills are supposed to buy all the consignment of cotton for the whole production year right at the beginning. This ties up huge capital and forces textiles to succumb to exorbitant credit facilities from financial institutions. Worse still, prices for cotton are arranged based on world market prices and quoted in USD. Fluctuation of global prices impacts predictability of local price and ultimately, the economics of the yarn and textile industry. Government intervention in setting higher prices of farmers impact local industries. This adds exchange rate challenges making costs unreflective of the local markets.

viii. Textile factories heavily depend on imported inputs (machinery, spear parts, dye, chemicals, polyester, etc.) apart from cotton which is sourced locally. Key challenge is high tariffs on such inputs which drive up costs of production.

ix. There is over-reliance on imported inputs for textile industry. The textile industry imports non-cotton inputs (e.g. dyes, chemicals, polyester), which ultimately increases cost of production. This is one of the key reasons of losing markets to cheap imports despite the potentials inherent in the industry in job creation, poverty alleviation and contribution to foreign exchange. This has resulted into dropping of the number of textile factories in the country 17 textile factories in 2000 to only eight factories. Worse still, the existing factories are currently operating at 40 to 60 per cent capacity due to lack of markets caused by uneven competition from imported clothing.

Table 8: Different Fees, Charges and Taxes on Textile Industry

Regulatory Body	Required Compliance	Amount	Period Covered
Cotton Board	**License**	**550,000**	**Once**
NEMC	Environmental Impact Assessment for Premise Certification	4,500,000	Once
	Environmental Audit Annual Fees	2,500,000	Annually
TBS	Service Charges during Inspection of Machines & Equipment	720,000	Once
	Certification	180,000	Per consignment
OSHA	Premise Registration Fees	250,000	Once
	Premise General Inspection Fees (Minimum Cost)	19,000,000	Annually
	Service Charges during Inspection Premise General Inspection	730,000	Annually

	Training Fees per Person (Requirement 2-Persons)	600,000	Annually
	Medical Check-up Costs (Per Person)	75,000	Annually
Fire	Fire Safety Inspection Fees	3,000,000	Annually
	Training fees	20,000	Per person
Weight & Measure	Packed Products Inspection Fees	1,500,000	Annually
	Inspection of weighing scales	4,500,000	Annually
	Inspection of trucks (per truck)	650,000	Annually
GCLA	Certification	.5% of CIF	Annually
LGA	Health Check-up (Per Person)	10,000	Annually
Pangani Water Basin	Water disposal fee	304,000	Annually
	Discharge permit	1,000,000	For 5 years
	Discharge fee	900,000	Annually
Other Fees Based on the Revenue Income			
	Service levy	0.3%	Gross of Income
	TRA - Income Tax	30%	Of Net Profit
	WCF	0.5%	Employee Gross Salary
	NHIF	3%	Employee Basic Salary
	NSSF	10%	Employee Gross Salary
	Work Permit + facilitation fee	1100 USD	Two years
	Resident Permit +facilitation fee (10%)	2255USD	Two years

Total cost 67,378,666.7

3.4 The Pharmaceutical Industry in Tanzania

While Tanzania's pharmaceutical market is among the largest in Sub-Saharan Africa, the industry is still nascent with huge untapped potentials. There is a total of 42 medical products manufacturing facilities of which 18 are engaged in manufacturing pharmaceutical products and 24 medical devices. The first pharmaceutical industry which is Mansoor Daya Chemicals Limited was established in 1962. From 1962 up to 2015, there were only 9 facilities that were established and in operation. Beginning 2015 there has been an upsurge of pharmaceutical and medical devices manufacturing facilities in the country of which 32 have been constructed. Almost all of the existing and newly constructed industries are privately owned except five (5) which are partly owned by the Government of Tanzania through the Treasury Registrar. These are Keko Pharmaceutical Industries (1997) Ltd, Tanzania

Pharmaceutical Industries Ltd (TPI), Medical Stores Department (MSD) (Keko), MSD (Idofi), and Tanzania Vaccines Institute (TVI).

The industry's capacity is limited in range of products and primarily produces only generics. Accordingly, Tanzania remains a net importer of its pharmaceutical products, where evidence from the United Nations COMTRADE database on international trade shows in 2021 80% of pharmaceutical products worth US$458.77 million were imported. This is daunting as it indicates a declining trend from 33% in 2009 to between 10% and 20% in 2022. This implies that, while the market has been growing at an estimated annual rate of 9%, the domestic product's value share in the market ranges between 10 and 20 percent.

There is a need to revamp the situation by increasing investment in domestic production which will not only enhance local production but also reduce the country's reliance on the importation of medicines, save much-coveted foreign currency, and create jobs for the majority of Tanzanians. The government envisages increasing domestic production of pharmaceutical products in order to reach 60 percent market share by the end of 2027. Different policies and strategies including the National Health Policy 2017, the Tanzania Food, Drugs, and Cosmetics Regulations 2015 which was repealed into Tanzania Medicines and Medical Devices Act of 2019, and the Pharmaceutical Sector Action Plan 2014-2020 have been developed in the pursuit of this target. Previous reports reveal that, the pharmaceutical industry in Tanzania is plagued by various challenges, including registration delays, unfavorable tax laws, labor shortages, poor infrastructure, and rising power prices. Thus far, these challenges need to be examined carefully, mitigation strategies established and implemented to create a conduce investment climate that will foster growth and development of the domestic industry for uptake of domestic and regional/export market potentials.

3.4.1 Regulatory and Fiscal Challenges in the Pharmaceutical Value Chain

The pharmaceutical industry in Tanzania faces several regulatory and fiscal challenges. Findings from the analysis conducted depict the following as key challenges. Study findings reveal that, the existing tax rules disfavor local manufacturers and encourage imports. Specifically:

i. Pharmaceutical manufacturers argue that, duties and tariffs are directed at incentivizing imports whereby imported medicines are exempt from duties. This has consequently created problematic tax rules for local manufacturers. For instance, VAT on inputs (with slow reimbursement), combined with difficulties pharmaceutical manufacturers experience in obtaining exemption from duties for some imported inputs, undermines local competitiveness. Rules also appear unclear and unstable, discouraging investment in the pharmaceutical industry by both local and foreign investors.
ii. There are delays associated with registration of firms entering into pharmaceutical manufacturing in Tanzania. It is noted that, there are about 1.5–2-year delays by TMDA in testing and registering products. To register with TMDA which follows after

a prospective manufacturer has cleared with TIC, BRELA and NEMC, four different functions and registration steps need to be followed to be cleared for production. This includes:

a. Premises inspection to acquire premise registration certificate
b. Product registration to acquire business license
c. Product registration to acquire product registration certificate and,
d. When both premises and products are qualified to get Business Permit

This is a very lengthy process unnecessarily which seriously discourages business establishment and it is costly in terms of time and resources used. The systems and operations of TMDA have not been designed to serve the purpose of regulating the industry while upholding the interest of business of effectiveness and efficiency for profitability.

iii. There regulatory overlaps in the pharmaceutical industry. This creates multiple inspections by different regulators such as TMDA, OSHA, LGA, NEMC, Fire and Rescue, TBS, etc. There are also multiple licensing and permits for the same business from different regulators with imperceptible difference. A pharmaceutical manufacturer or dealer needs to acquire license/permit from TIC, BRELA, TBS, LGA and TMDA. Behind this, are costs of meeting requirements, lost time to follow up, and staff employed to perform these functions. This is a disincentive to investing in pharmaceutical manufacturing in Tanzania.

iv. Appalling compliance cost during registration and operation of manufacturing business. Over regulation in the pharmaceutical industry arising from duplication of regulations, stringent compliance requirements, delays and bureaucracy amount to inhibitive costs of compliance. For instance, it costs roughly TZS 8,991,251.51 to register with TMDA during initial business registration in manufacturing. Table 8 and 9 provide indicative costs of compliance for a manufacturer in the pharmaceutical industry. These costs exclude meeting prior requirements for particular registration like consultants' fees, labour, and other non-financial resources.

v. There are minimal chances for local manufacturers to win large tenders of medical supplies. Respondents argued that, MSD's working relationships with local suppliers are problematic. It has been pointed out that, there is financial risk from rising payments delays, lack of clear delivery dates, and failure to complete contracted purchases, plus low probability of winning (expensive) tenders. MSD is perceived as giving preference to imports, by providing trade credit only to overseas suppliers and buying supplies 'bundled' by local importers. MSD itself faces serious financing delays and complains of quality and delivery problems from local suppliers.

vi. Unfriendly government policy to local pharmaceutical manufacturers. There is a build-up of mutual mistrust which has undermined local tendering. Manufacturers argue that government policy currently undermines investment and innovation in their industry. A lack of 'joined up' support across the key Ministries of Health, Industry, and Finance (at worst, active hostility) contrasts with active support elsewhere. South Africa, Ghana, Sudan, Ethiopia, and Morocco all now actively protect and support local producers, as did India, resulting in investment and diversification of local production.

vii. Unfavorable market access conditions for local manufacturers. While local manufacturers depend on imports of some of the machinery and inputs, there is high tax rate charged to these imports as compared with imported medicines and medical devices. This has largely undermined competitiveness of local manufacturers thereby limiting their growth and expansion to regional markets.

Table 9: Compliance Costs in Pharmaceutical Industry

Regulatory Body	Required Compliance	Amount Tshs/USD	Period Covered
TMDA	**Business Permit**	**TZS 700,000**	**Once**
	GMP Facility inspection within East Africa	**USD 3,000**	
	New Product Registration	**USD 300**	
	Premise Inspection fee	**TZS 300,000**	
	Good Manufacturing Practice GMP Inspection fees per year	**TZS 150,00**	
	Training Fees		
BRELA	**Business License**	**600,000**	**Once**
NEMC	Environmental Impact Assessment for Premise Certification	4,500,000	Once
	Environmental Audit Annual Fees	2,500,000	Annually
TBS	Endorsement	2,000,000	Once
OSHA	Premise Registration Fees	250,000	Once
	Premise General Inspection Fees (Minimum Cost)	19,000,000	Annually
	Service Charges during Inspection Premise General Inspection	730,000	Annually
	Training Fees per Person (Requirement 2-Persons)	600,000	Annually
	Medical Check-up Costs (Per Person)	75,000	Annually
Fire	Fire Safety Inspection Fees	3,000,000	Annually
	Training fees	20,000	Per person
Weight & Measure	Packed Products Inspection Fees	1,500,000	Annually
	Inspection of weighing scales	4,500,000	Annually
	Inspection of trucks (per truck)	650,000	Annually
GCLA	Certification	.5% of CIF	Annually
LGA	Health Check-up (Per Person)	10,000	Annually
Other Fees Based on the Revenue Income			
	Service levy	0.3%	Gross of Income

	TRA - Income Tax	30%	Of Net Profit
	WCF	0.5%	Employee Gross Salary
	NHIF	3%	Employee Basic Salary
	NSSF	10%	Employee Gross Salary
	Work Permit + facilitation fee	1100 USD	Two years
	Resident Permit +facilitation fee (10%)	2255USD	Two years

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

4.1 Conclusion

The analysis reveals that, regulations in the food processing, textile and pharmaceutical value chains are indispensable. The government through regulatory and fiscal approaches intends to ensure public safety, protect the environment, correct market failures and promote fairness among all the actors in the value chain for sustainable economic development. However, there are challenges emanating from either weakness in the existing regulations or the way they are implemented. This is manifested by overlaps, unbearable compliance costs and inefficiencies among the regulators emanating from excessive number of regulations, duplication of regulatory functions and the fees charged by the regulators.

The findings of the study result into key conclusions;

- There are at least 22 laws and 15 regulators governing the value chains. While acknowledging that regulations are necessary for ensuring health and safety, environmental protection and health competition, overregulation resulting from duplication and the associated fees remain stumbling block among actors.
- There is an application of 25% in Tanzania compared to 10% common agreed tariff among the EAC members in edible oil industry for imported inputs, this has serious implications on competitiveness of the local manufacturers in the local and regional markets. For the past six years starting from 2017, edible oil local production has been costly leading to closure of oil refinery industries in the country as they succumbed to cheap imports from neighboring countries and smuggling.
- Similarly, the use of inefficient garment and textile imports verification and consequent valuation has negatively impacted local textile manufacturers and government incomes. Currently, textiles and garment imports are verified by length (meters or yards) or pieces which is difficult to implement as opposed to international good practice of using weight (kilograms). This has created undervaluation of imported cargo thereby low taxes collected. This has created rampant competition to locally produced textiles and loss of government revenue.
- Most regulators actions are biased to enforcement other than compliance which is why providing education and facilitating compliance are not a priority. There is a tendency of putting high penalties and stringent conditions in order to maximize collections from enterprises. Some regulators charge fees in dollars which becomes a burden to business in the face of unfavorable exchange rates.
- Misalignment of policies and regulations with the national development vision together with frequent change in positions of Permanent Secretary (PS) has not only lost institutional memory but also left most policies and regulations not harmonized. For instance, between 2015 and 2023, there has been 9 different PS serving in the Ministry of Industry, trade and Marketing. Duplicate in policies and regulations has

been a burden to burden to businesses in terms multiple registration, licensing, inspection and fees.

- Overregulation which raises cost of doing business, has impacted performance and competitiveness of businesses domestically and globally. Businesses have lost markets to cheap imports and others have closed down operations.
- There enforcement capacity of the Regulatory Authorities is weak, fragmented and ineffective. Most Regulatory Authorities have limited human resource capacity, poor infrastructure and limited outreach. Nonetheless, no clear mechanism for harmonizing and sharing the roles and responsibilities of regulators which has created a lot of inefficiencies. Apart from paying fees for licenses, certificates and permits granted, the cost of inspection in terms of transport to the premises, per diems etc. are paid by businesses.
- There is unfriendly business atmosphere between businesses and regulators. This comes from the poor attitude among staff of the regulators. The attitude of staff contributes to unnecessary delays, bureaucracy and wastage of time which negatively impacts businesses through increased cost of follow up, corruption and reduction in willingness to comply.
- Communication between regulators and businesses is ineffective. Inspections are not done transparently to involve businesses to discuss challenges together. The fashion has been inspect-report- invoice for payments. As a result, most business enterprises lack adequate information on the requirements for compliance.

4.2 Recommendations

4.2.1 General Recommendations

Food processing, textile and pharmaceutical value chains' regulations emanate from multiple ministries and local government authorities. There is no clear and well-established mechanism for coordination and harmonization. This created overlaps and over-regulation with mounting compliance costs. It is therefore recommended:

i) To harmonize overlapping regulations to mitigate burdens to businesses. Areas for harmonization include the following:

Inspection of Premises

Table 10: Laws on Inspection of Premises

Premises inspection	Tanzania Medicines and Medical Devices Act-2019 The standards act -2009 The Dairy industry act 2004 Occupational Health and Safety Act, 2003 Business Registration Act, 2007 Local Government District Authorities Act (Cap 287, R.E 2002) Local Government Urban Authorities Act (Cap 288, R.E 2002) Environmental Management Act Public Health Act of 2009

Two ways are recommended for harmonization:

- Create a committee comprised of experts from all the regulators who will work together to conduct inspections as per criteria established by regulator. By this, multiple inspections with multiple production down time and idleness of labour will be avoided.
- Assig all health check-ups and inspections formal manufacturers to OSHA. All other health check-ups and inspection to informal businesses be assigned to LGAs. The registration and inspection of factories/premises used for food processing to be done by TBS in consultation with other relevant regulatory authorities.

Business registration and licensing activities

The following laws and regulations which govern business registration and licensing need to be harmonized.

Table 11: Laws on Business Registration and Licensing

Business Registration and Licensing Activities	Business Licensing Act, of 1972Cap 208,[R.E,2002]; Business Names Registration Act (Cap 213) Industrial Licensing and Registration Act, 10 Cap 46 [R.E, 2002]; Tanzania Medicines and Medical Devices Act, 2019, Section 18; The ExplosivesAct,56 Cap 45,[R.E 2002]; Fisheries Act, 22 of 2003 The Cashew nut Industry Act, 2009, section 12(1); The Coffee Industry Act, 2001, section 12(1) The Tea Act, Cap 251, [R.E, 2002]

It is recommended as follows:

Business registration and licensing should be harmonised through cross-referencing:

- Food processors should be registered by BRELA and TBS; Pharmaceuticals by BRELA and TMDA textile manufacturers by BRELA and TBS.
- Businesses before being registered should have complied with the requirements for industrial licence, EIA and quality requirements that ensure good manufacturing practices.

ii) The Regulatory Authorities should be supported to undertake some joint registration and licensing processes electronically.

iii) The government to allocate adequate funding to strengthen the Regulatory Agencies and avoid Rent-seeking behavior.

iv) Regulatory Authorities should prioritize facilitating compliance over enforcement by providing education to businesses, simplify compliance processes by strengthening online systems and training their staff to be responsive and empathetic.

v) One-stop centre and one-online system for key regulators where enterprises accomplish all the necessary processes for compliance should be established. Online systems minimize face to face interactions and prevalence of corrupt practices.

vi) Regulatory authorities should design and implement a comprehensive strategy for educating and sensitizing compliance to both businesses and policy makers. A monitoring and evaluation framework should be designed and put into practice to get feedback on the effectiveness.

vii) Regulatory agencies should design and sustainably implement capacity building program to their staff. Emphasis should be on areas such as attitude change, effective communication, time management, and customer experience management. Workforce analysis should be conducted to identify capacity deficiencies which should be filled by employing new staff.

viii) Ensure preservation of institutional memory by ensuring stability of tenure in Ministries through the Permanent Secretary incumbents. This is the custodian of Ministry policies. This ensures alignment of regulations and policies to National Development Vision which in a way reduces complications arising from the fragmentation of institutions dealing with policies in the country.

ix) The government should amend the procurement policies of the country to establish a minimum amount of local made goods and services to be procured in any government procurement of goods and services. This will preserve a share for the local manufacturers which lays base for growth and development on one hand and preserves forex, local jobs and competitiveness of local firms.

x) Encourage enforced self-regulation to support standards management

- The government should identify PSOs that could facilitate self-regulation in their specific sub-sectors and build their capacity to regulate their members. These include, for example, TAMPA in the dairy sector, Tanzania Association of Food Processors (TAFOPA) in the SME sector, Tanzania Edible Seeds Association (TEOSA), TEGAMAT for textile manufacturers and CTI for large manufacturers.
- Promote self-regulation at the company level, whereby the laboratories of capable food processors are accredited by the regulators and audited from time to time. This would enhance the capacity of food processors to comply with the regulations and would lead to fewer inspections that would ultimately reduce their costs.
- Train enterprises, especially SMEs, in the food safety and food hygiene requirements, and encourage them to comply voluntarily.

xi) Promote public-private dialogue and Public-Private Partnership

- PSOs in the food processing, textile and pharmaceuticals value chain to establish a working group of stakeholders, who will undertake continuous dialogue with the private and public sector. The role of PSOs will be to continuously inform the government about the regulatory challenges, to provide feedback to their members on the changes happening in the regulatory system and to participate in facilitating the implementation of good practices.

- Regulators should explore ways of effectively accrediting and working with private laboratories to perform basic analyses of samples.

xii)Engage the government into reform

- CTI should initiate the process of consulting with the regulators and facilitate the preparation of draft bills (layman's Draft Bills) to be submitted to the ministries responsible. These ministries would then submit them to the Attorney General (Chief Parliamentary Draftsman) for refinements and finalization before signing and gazette them.
- The processes that do not require a change in the law should be implemented immediately by the regulators responsible. Regulators dealing with food processing, textile and pharmaceutical value chains should meet and discuss the strategies they could use to enhance collaboration among them. Initial forums could be organized by CTI and other PSOs in the sector so that the regulators are able to come together.
- Each regulator to read the report and identify the issues that are within their control and start addressing them.
- CTI to ensure that the recommendations given in this report are discussed in dialogue session with stakeholders from the public sector

xiii) Harmonize taxation systems between Tanzania mainland and Zanzibar as a way to curb smuggling and tax evasion among traders

4.2.2 Recommendations on Food Processing Value Chain

4.2.2.1 On Regulatory and Fiscal Challenges

- Harmonize and enhance coordination of licenses and permits that relate to food hygiene and premises. Introduce cross-referencing and amend laws to allow recognition of permit from one authority by other authorities for similar functions. For instance, the permits and certificates issued by TBS, TDB, could be recognized by GCLA and LGAs.
- Regulators should have frequent consultations with enterprises to provide them with coaching and guidance on how to comply with quality and safety requirements in the entire process of processing and preparing food for human consumption.
- Regulators need to prescribe exactly what actions regulated entities must take to improve their performance and share the checklist of actions with enterprises. This could be done through frequent forums organized between regulators and the regulated.
- Invest in educational programs and capacity building to inform and empower all actors within the value chain. This includes training farmers, processors, and regulators on modern practices and compliance.

4.2.2.2 On Innovation, Growth and Export

- The LGAs, Ministry of Agriculture (MoA), Ministry of Transport and Ministry of Industry and Trade (MIT) should improve the storage and transportation infrastructure, including roads and warehouses. This will enhance the efficiency of the supply chain and reduce post-harvest losses and quality deterioration.
- The Local Government Authorities (LGAs) should institutionalize in the LGAs budget to provide for funds to build storage warehouses and cold rooms, particularly in areas with high amount of food processors.
- The Ministry of Finance should tackle specific issues like the high cost of importing machinery that hinder local production by offering import duty exemption.
- Issue input subsidies to farmers and offer educational programs to enhance their agricultural practices, leading to product quality and improved yields.
- Implement measures to stabilize forex rates to reduce the impact of currency fluctuations on pricing and production costs.

4.2.3 Recommendations on Textile Value Chain

4.2.3.1 On Regulatory and Fiscal Challenges

- Illegal imports of textiles and clothing should be stopped or controlled. All borders and shoreline should be strictly managed against smuggling business
- The government through the Ministry of Finance to harmonize Import duties with the common external tariff agreed among the EAC members. Similarly, harmonize tariffs between Tanzania Bara Ports and Zanzibar Port.
- Apply the EAC Customs Management Act approved unit of verification for textiles and garments imports. The EAC common external tariff unit of measure for chapters 51 to 65 is weight in kilograms and not length in meters. This is the best international practice. The application of kilograms as a unit of quantity on imports of textiles and garments will SOLVE the problems of under valuation, under-invoicing and simplify verification of imports.
- Further modification to tax reform is recommended especially on imported yarn from the current 25% to 10%. Tax rates have to be reviewed and synchronized to reduce multiple procedures, to lower compliance costs, and to eliminate all nuisance taxes.
- Trucks and small operations vehicles for ginners and textile industries be categorized as "tax free" goods. They are capital goods which deserve tax exemption as it was before the recent tax reforms.
- The tariffs for utilities like electricity, water, petrol, and others to be reviewed to attract more investment in the textile industry. The tariffs must reflect the actual costs of production and must compete with the world tariffs.
- An advocacy campaign should be developed to address upstream value chain challenges including LGAs license and advance cess payments prior to the start of buying season which affects actors' cash flows. The arrangement does not only make it difficult for buyers and ginners to secure a loan facility for advance seed cotton cess payment but also erodes their profit margins. The costs emanating from such an

arrangement are added in the computation of final seed cotton prices ultimately making seed cotton farmers to receive low farm gate prices.

4.2.3.2 On Innovation, Growth and Export

- The Government of Tanzania could play a pivotal role in addressing some of the main barriers to investment and innovation reported by firms, such as high cost of finance, and excessive and inefficient bureaucracy and red tape.
- The government through Ministry of Industry and Trade, Ministry of Finance, and Tanzania Cotton Board (TCB) should design and negotiate with TIB and TADB on the adoption of a ring-fencing business model for ginners, cotton oil mills, spinning and textile industries. In this model, financial institutions, will inject funds for installation of more efficient machines, gin stands and for working capital. Under this model, the Bank and borrower have to enter into an agreement of a business which ensures that the two entities are benefiting from mutual engagement and recruitment of qualified staff for the management and operations of the business with repayment being operation – dependent and the management operations and cash flows closely monitored by the financier till when the project pays back for the loan facility.
- Promote regional trade to enhance market access by adopting Common External Tariff (CET) on imports of inputs to textile industry
- Measures need to be taken to promote the consumption of domestic goods so as to build a tradition of consuming Tanzanian-made products and thus expand the market for local articles.
- Financial reforms have to be continued. Attention needs to be directed on lowering financial risks in the market to help reduce interest rates. This is pertinent to decreasing the cost of capital.
- Dedicated efforts from Ministry of Agriculture and Livestock Development, TCB, LGAs should be applied to improving yarn quality and efficiency. Employ enough extension officers and equip them with farm access facilities like motorbikes to provide education and guidance to cotton producers to ensure quality output. If this is achieved, then the yarn could be an attractor for knit fabric producers to manufacture for the garment industry in Tanzania.
- Further promotion to get market access should be done through active and focused participating in international trade fairs and exhibitions to attract both investors and buyers of Tanzania textile products. Export promotion initiatives, marketing campaigns, and branding efforts can help raise awareness and create demand for Tanzanian textiles in both domestic and international markets.

4.2.4 Recommendations on Pharmaceuticals

4.2.4.1 On Regulatory and Fiscal Challenges

- It is recommended policy actions to be taken to restructure trade, tax, and credit policies to favor local producers over importers. This is to activate local production of

pharmaceuticals and encourage investment in the value chain. Thus far, the following actions are recommended:

- Impose duties on imports of finished pharmaceuticals particularly those similar with local availability;
- List only pharmaceuticals which can be imported only if local manufacturers cannot supply reliable quality at acceptable prices;
- Lay down proper identification of pharmaceutical inputs needed for investment in production, and exempt them from duties;
- Remove VAT on inputs to pharmaceuticals;

- The government to take action to reduce imports from 70% to less than 50% to promote market for locally manufactured medicines and medical devices.
- Reform public procurement policy and regulations to raise the local preference rate to at least 50% from local manufacturers.

4.2.4.2 On Innovation, Growth and Export

- The government should invest on the development of skills and capabilities to promote innovation. Talent management strategies should be developed to push the heights of the pharmaceutical industry.
- The government through the Ministry of Health should foster private-public partnership to promote investment in pharmaceutical manufacturing in the country.
- The government should consider to make arrangements to provide financial support, technical assistance, and access to markets for pharmaceutical manufacturers by reviewing procurement policies to provide a threshold for procurement of locally produced medicines and medical devices.

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Annexes

Annex 1: Questionnaire

QUESTIONNAIRE FOR BUSINESSES IN THE VALUE CHAIN

Dear respondent, I am…… On behalf of the Confederation of Tanzania Industries (CTI) we are taking this survey to identify regulatory and fiscal challenges in the value chain so that policy proposal can be developed to influence policy changes. We request you to spear less than 10 minutes to respond to this questionnaire. The answers you provide will be strictly used for the sole purpose of this study and will be treated with high degree of confidentiality.

Thank you in advance for taking this survey!

<table>
<tr><td colspan="5">1. Name of the respondent…… Contacts……..</td></tr>
<tr><td colspan="2" rowspan="3">2. Name of the value chain</td><td>Food Processing</td><td colspan="2"></td></tr>
<tr><td>Pharmaceuticals</td><td colspan="2"></td></tr>
<tr><td>Textile</td><td colspan="2"></td></tr>
<tr><td colspan="2" rowspan="7">3. Function performed by your firm in the value chain</td><td>Production</td><td colspan="2"></td></tr>
<tr><td>Wholesale trade</td><td colspan="2"></td></tr>
<tr><td>Retail trade</td><td colspan="2"></td></tr>
<tr><td>Processing</td><td colspan="2"></td></tr>
<tr><td>Storage</td><td colspan="2"></td></tr>
<tr><td>Export</td><td colspan="2"></td></tr>
<tr><td>Other</td><td></td><td>Name it</td></tr>
<tr><td colspan="2" rowspan="2">4. List all the permits/license needed to run your business</td><td rowspan="2">Issuer</td><td colspan="2" rowspan="2">Cost for getting the permit</td></tr>
<tr></tr>
<tr><td>1</td><td colspan="4"></td></tr>
<tr><td>1</td><td colspan="4"></td></tr>
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2	
3	
4	
5	
6	

5. What are the conditions/ requirement for granting the permit/licenses (state all)……
……
……
……

6. Are there any inspections needed before and after granting the permit/license?	Yes	No

7. If the answer above is yes, how many times? How often is the permit or license renewed?

It is valid indefinitely	
Issued once	
Renewed every after…….	

8. Specify amount of fees charged for the issuance of the license/permits/certificates
……
……..

9. What is the percent of compliance cost to the total revenue/cost of your business?

10. Please list any supporting documents required for the license application……
……
……
……

11. How many Authorities do you have to comply to as a business?.....

12. What creates burden in complying with these permits or licenses?	
a) Processing time	
b) Fees	
c) Permit/license requirements	
d) Frequency of renewal	
e) Bureaucracy, paper work and corrupt practices	
f) Any other burden, please specify ……..	
13. How many days do you spend to comply with the following…….	
a) Getting license	
b) Preparation and Filling returns	
c) Clearing for imported cargo	
d) Documentation for export	
e) Getting certification	
f) Please identify any other compliance issue and time…… …….	
14. How many documents required to fill online/hard copy for compliance? Any cost?	

15. Do you (as a business) have representation during budgeting cycles?	
16. Do you think your views are taken seriously during budgeting?	
17. What are the challenges related to coordination/linking forward and/backward in the value chain?	
18. What do you think are the reasons for such challenges?	
19. What is/are your opinion(s) on how to mitigate such challenges?	
20. What do you suggest to be done to upgrade the functioning of the value chain and the actors?	
21. What are challenges hindering adoption and use of modern technologies in your sub-sector/firm?	
22. What do you suggest to alleviate the challenges?	
