

Final report

Increasing growth and competitiveness through an enhanced enabling environment

An assessment of the cosmetics sector in Tanzania

New Market Labs

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LIST OF ACRONYMS

ACV	(World Trade Organization) Agreement on Customs Valuation
A-PAD	Assessed Pre-Arrival Declaration
ASEAN	Association of Southeast Asian Nations
ASYCUDA	Automated System for Customs Data
BRELA	Business Registration and Licensing Authority
CAGR	Compound Annual Growth Rate
CFA	Clearing and Forwarding Agent
EACCMA	East African Community Customs Management Act
COA	Certificate of Analysis
COC	Certificate of Conformity
COMESA	Common Market for Eastern and Southern Africa
EABC	East African Business Council
EAC	East African Community
EASC	East African Standards Committee
EMA	Environment Management Act (Tanzania)
EIA	Environmental Impact Assessment
FD&C Act	Food, Drugs, and Cosmetics Act (Tanzania)
FIFO	First in, first out
FOB	Free on Board
FSC	Free Sales Certificate
GCLA	Government Chemists Laboratory Agency
GMP	Good Manufacturing Practices
GNRAS	Generally Not Recognized As Safe
ICCR	International Cooperation on Cosmetic Regulation
ICT	Information and Communications Technology
IGC	International Growth Centre
IQS	Integrated Query System
ISO	International Standards Organization
MAB	Ministerial Advisory Board
MIT	Ministry of Industry and Trade (Tanzania)
MoU	Memorandum of Understanding
NCL	National Chemicals Laboratory
NCR	Non-Conformity Report
NEMC	National Environmental Management Council
NIC	National Insurance Corporation
NML	New Markets Lab
OSC	One Stop Centre
PAD	Pre-Arrival Declaration
P-PAD	Pre-Assessed Pre-Arrival Declaration
PVoC	Pre-Shipment Verification of Conformity
R&D	Research and Development
REC	Regional Economic Community
RFC	Request for Certification

SADC	Southern African Development Community
SADCAS	Southern African Development Community Accreditation Service
SQMT	Standardization, Quality Assurance, Metrology and Testing
SSA	sub-Saharan Africa
SSRA	Social Security Regulation Authority
TAC	Cross-sectoral Technical Advisory Committee
TANSAD	Tanzania Single Administrative Document
TANCIS	Tanzania Customs Integrated System
TBS	Tanzania Bureau of Standards
TBT	Technical Barriers to Trade
TFA	Trade Facilitation Agreement
TFDA	Tanzania Food and Drugs Authority
TFTA	Tripartite Free Trade Area
TIC	Tanzania Investment Centre
TISCAN	Customs Inspection Company (Tanzania)
TISS	Inter-Bank Settlement System
TOR	Terms of Reference
TPA	Tanzania Ports Authority
TRA	Tanzania Revenue Authority
TZS	Tanzania Shilling
UNICEF	United Nations Children's Fund
USD	U.S. Dollar
WTO	World Trade Organization

EXECUTIVE SUMMARY

The enabling environment for business encompasses the system of policies, laws, and regulations that shape an economy, and it has a direct impact on industrial development and the degree to which public policy goals and regulatory objectives can be achieved. The Government of Tanzania clearly recognizes the important role that laws and regulations play in economic development and has been considering ways in which to improve its enabling environment across sectors. For sectors with growth potential, the enabling environment can be particularly important, and both putting the right measures on the books and establishing a system for implementing them in practice will be needed to unlock economic potential.

This study focuses on the cosmetics sector as an example of an emerging growth sector for which the enabling environment is particularly important, and it serves as a pilot project for a broader research agenda on the business enabling environment in Tanzania. The study was supported by the International Growth Centre (IGC) in Tanzania and conducted in close partnership with the Tanzania Investment Centre (TIC), which helped coordinate critical stakeholder meetings and provided invaluable feedback at all project stages. Given the balance between public and private goals in regulatory systems, stakeholder consultations with both the public and private sectors informed the development of this report and contributed to an understanding of how the realized regulatory system impacts cosmetic firms vis-à-vis broader public sector goals such as health and safety standards, consumer and worker protection, job creation, and increased manufacturing.

The cosmetics sector is both of increasing interest to the private sector due to its growth potential and has regulatory, policy, and institutional implications for other priority sectors such as pharmaceuticals and food, making it of an important sector both on its own and in a broader context. This report assesses Tanzania's regulation of cosmetics in the context of investment generation, job creation, and support of regulatory priorities. Within the sector, different policies, laws, and regulations were evaluated to assess how they could be aligned and implemented to enable growth throughout the sector and enhance export potential (including focus on the ingredients needed for the manufacture of cosmetic products and the manufacturing of final cosmetic products themselves). An approach that streamlines laws and regulations both in letter and practice holds promise for both growth in Tanzania's domestic market and for increased regional trade.

Tanzania is one of the few countries in sub-Saharan Africa with a comprehensive system for regulating cosmetics products, which presents both opportunities and challenges. While the current system has notable strengths, such as the existence of a dedicated regulatory body, challenges also arise due to the degree and complexity of regulatory processes that could impact the competitiveness and growth of the cosmetics industry and related sectors. Under Tanzania's current system, a number of regulatory measures are focused on steps prior to market entry. If not carefully considered, these regulatory processes could limit rather than encourage private sector growth, particularly for SMEs, and reduce the availability of quality cosmetics products to consumers. For example, procurement and

manufacture of raw materials into finished products is an important and crucial part of the cosmetics value chain, yet Tanzania has not fully exploited its manufacturing potential in part due to aspects of the enabling environment that function to limit access to inputs.

A number of good regulatory approaches exist that could be instructive as Tanzania considers how to simplify the business enabling environment for cosmetics, achieve its public policy goals, and enhance efficient use of resources. In some cases, good regulatory practices demonstrate how to shift some regulatory functions away from market entry (ex ante regulation) to some combination of regulation at key points in the value chain and more effective enforcement (ex post regulation). Achieving a balance in regulatory approaches could make a significant difference in the cosmetics industry and other growth sectors. In addition, further clarifying and reducing overlapping regulatory mandates, reducing duplicative steps, streamlining regulatory processes, and supporting public-private policy dialogue could help increase understanding of how the system can better support the industry's growth and improve achievement of important public policy objectives.

While the study is primarily focused on Tanzania, the regional and international contexts are important both with respect to growth potential in the cosmetics sector and the broader enabling environment. Tanzania is a member of a number of regional and international institutions, including the East African Community (EAC) and Southern African Development Community (SADC), neither of which has yet developed regional measures specific to cosmetics. The EAC, however, has begun to focus on the sector, and international best practices support some degree of regional cooperation in cosmetics, including in standards, importation, and labeling. Tanzania is also a member of the World Trade Organization (WTO), which has implications for both standards and facilitation of cross-border trade.

Tanzania's national laws and regulations are influenced by regional and international requirements and norms, and further alignment with international standards and good regulatory practices could improve competitiveness and attract investment. For example, streamlining the importation process involving the Tanzania Food and Drugs Authority (TFDA) and Tanzania Bureau of Standards (TBS) and improving implementation of EAC customs rules and trade facilitation measures would help Tanzania take advantage of larger regional markets as well as improve achievement of domestic policy objectives, increase efficient use of resources, and support growth of Tanzania's cosmetics sector. It also would be beneficial for Tanzania to consider how increased harmonization of regional regulatory practices for cosmetics could expand the market regionally and strengthen the industry within Tanzania. Since Tanzania's legal and regulatory system for cosmetics is unique in the region, Tanzania would have a natural leadership role in the development of harmonized standards and rules.

The study assesses the legal and regulatory environment as it pertains to the cosmetics industry in Tanzania, drawing the link between the regulatory system, the realized implementation of this system, its contribution to public policy goals, and the impact of regulation on market opportunities for firms. Particular focus is given to ways in which

regulatory objectives can be achieved that are not too burdensome for the private sector. While balance will be needed, it is possible to find “win-win” solutions that achieve public policy goals while at the same time making it earlier for business opportunities to grow. The study’s recommendations are designed with this approach in mind, and action items are highlighted wherever possible

The study’s findings and recommendations are summarized in Table 1 below. Given the cross-cutting nature of the regulatory aspects governing the cosmetics industry, many of the findings can provide insight into Tanzania’s broader business enabling environment and the effectiveness of its regulatory systems in promoting economic development.

Table 1: Recommendations to Enhance the Enabling Environment for the Cosmetics Industry in Tanzania

Recommendation	Description	Examples of Policy Options
Benchmark Regulatory Options Along the Value Chain Against Good Regulatory Practices and International Standards	<ul style="list-style-type: none"> • Regulation of Tanzania’s cosmetics industry, as is the case with other sectors, is concentrated prior to market entry (ex ante regulation), and important enforcement functions are not fully developed. • Private sector would benefit from greater understanding of how regulatory mandates overlap and are meant to be implemented in practice. • Good regulatory practices for cosmetics provide important insight into regulatory options at different points in the market, such as post-market surveillance and enforcement, that can support policy and regulatory objectives while facilitating growth along the entire cosmetics value chain. 	<ul style="list-style-type: none"> • Conduct a deeper regulatory systems audit that analyzes conflicting regulatory processes and overlapping regulatory mandates for cosmetics. This could also include: <ul style="list-style-type: none"> ○ Assessing alignment with international requirements, guidelines, and standards. ○ Ensuring laws and regulations are open and transparent. • Over time, transition to an ex post, standards-based regulatory approach (including Good Manufacturing Practices (GMP)) headed by a single regulatory authority with oversight of streamlined system.
Apply Global Good Regulatory Practices to Product Registration	<ul style="list-style-type: none"> • The current product registration system is resource intensive and impacts the timely introduction of new products, ingredients, and innovations already 	<ul style="list-style-type: none"> • Transition from product registration system to notification system. <ul style="list-style-type: none"> ○ As an initial step, a review could be undertaken of countries that have transitioned to a notification system, such as Saudi Arabia, in order to learn from

	<p>considered safe and approved for use in other countries, impacting growth and investment as well as consumer choice.</p> <ul style="list-style-type: none"> • A notification system would shift some responsibility for compliance with standards to the entity responsible for the product’s entry into the market, enabling greater regulatory focus on post-market surveillance and enforcement and creating greater responsibility for market actors. • Application of this good regulatory practice could enable regulators to more efficiently allocate resources, particularly within TFDA, which also has regulatory authority over higher-risk products like food and pharmaceuticals, and better achieve public policy goals. • A notification system also could be easily established at the regional level. 	<p>their experiences.</p> <ul style="list-style-type: none"> • In the short-term, reduce the requirement for registration of nonmaterial changes, adding an altered product to an existing registration, or limiting the need for registration renewal.
<p>Enhance Transparency in the Customs Valuation Process</p>	<ul style="list-style-type: none"> • Customs valuation processes are critical to ensuring that imports are valued appropriately, and clearer, more detailed guidelines could help increase compliance and transparency in the process. • Currently, there is concern with improper valuation, and companies report that the implementation of customs valuation procedures is opaque, with inconsistency in the procedures. 	<ul style="list-style-type: none"> • Develop Customs Valuation Guidelines in close consultation with the private sector to ensure they comprehensively address challenges the industry faces with respect to valuation and also take into account critical government priorities of ensuring appropriate valuation. <ul style="list-style-type: none"> ○ Importantly, guidelines could also be useful in helping customs officials collect accurate import revenues. • Publish Customs Valuation Guidelines and ensure they are updated as revisions occur.

<p>Streamline Importation Procedures for Cosmetics</p>	<ul style="list-style-type: none"> • Streamlining importation processes for cosmetics could help increase market demand and investment in domestic cosmetics manufacturing, as well as increase public sector revenue. • Users of Tanzania’s system report that it can be complex, time-consuming, and costly, especially for smaller businesses. 	<ul style="list-style-type: none"> • To help streamline the process for both companies and regulators, TFDA could consider adopting a Pre-Shipment Verification of Conformity (PVoC) program like the one applied by TBS. • TFDA also could develop guidelines with input from the private sector that would increase transparency in the TFDA inspection process to help companies better comply with import requirements.
<p>Enhance Implementation of Exportation Procedures</p>	<ul style="list-style-type: none"> • The World Bank has documented that Tanzanian exporters spend more money to comply with border measures and more time and money to comply with export documentary requirements than do counterparts in sub-Saharan Africa. • In addition to streamlining export processes and reducing documentary requirements, consistent implementation of legal and regulatory processes and requirements is critical for reducing export costs. • Increasing transparency around export procedures would also help reduce the cost for exportation. 	<ul style="list-style-type: none"> • Enhance implementation of export procedures, including regional trade and trade facilitation measures. <ul style="list-style-type: none"> ○ Implementation could be enhanced through entrepreneur case studies and test cases that document the experience of enterprises in navigating export procedures and share findings with policymakers. This could be done in collaboration with the institution discussed in the final recommendation below. • Develop Exportation Guidelines, in close collaboration with the private sector, in order to increase transparency around export requirements and processes to help companies better comply with export rules, increase transparency, and support increased knowledge and dialogue among the different regulators involved. <ul style="list-style-type: none"> ○ Publish Exportation Guidelines, updating them as needed and sharing widely with stakeholders
<p>Lead Harmonization of Regional Regulatory Processes</p>	<ul style="list-style-type: none"> • Tanzania’s well-defined regulatory system for cosmetics is unique in the EAC and SADC, and Tanzania is well-placed to lead the development of a regional framework to regulate cosmetics. • The harmonized system should align with global best 	<ul style="list-style-type: none"> • In the short-term, conduct a study on the development and implementation of multilateral and regional harmonization efforts for cosmetics regulation, including the Association of Southeast Asian Nations (ASEAN) Harmonized Regulatory Scheme and the cosmetics annex to the chapter on Technical Barriers to Trade of the

	<p>practices, perhaps, for example, through a regional notification system, and be consistent with international standards, including ISO good manufacturing practices.</p> <ul style="list-style-type: none"> • Development of a regional framework should include the voice of the private sector, including small- and medium-sized enterprises (SMEs) and women-owned businesses. 	<p>Trans-Pacific Partnership Agreement to inform development and implementation of a regional system in the EAC and SADC.</p> <ul style="list-style-type: none"> • Engage with Tanzanian private sector cosmetics stakeholders, perhaps through a workshop, to inform regional harmonization process, perhaps through the East African Business Council (EABC) or other industry associations as appropriate.
Identify Institution to Facilitate Further Study and Stakeholder Dialogue	<ul style="list-style-type: none"> • An information gap on the business enabling environment exists between the public sector and industry, and an industry association or institution could be identified or created to bring together public and private sector stakeholders across the industry and provide a forum for further research and information exchange. • The institution could focus on ongoing improvements in the business enabling environment and the effective development and implementation of national and regional legal and regulatory frameworks. 	<ul style="list-style-type: none"> • Identify existing industry association or institution to facilitate further study and stakeholder dialogue, including around regional harmonization issues. • Coordinate private sector input to inform policy options listed above, including assisting with development and dissemination of guidelines for trade processes, identifying implementation challenges associated with export requirements, and providing feedback where appropriate on regulatory processes.

Source: *New Markets Lab, 2017*

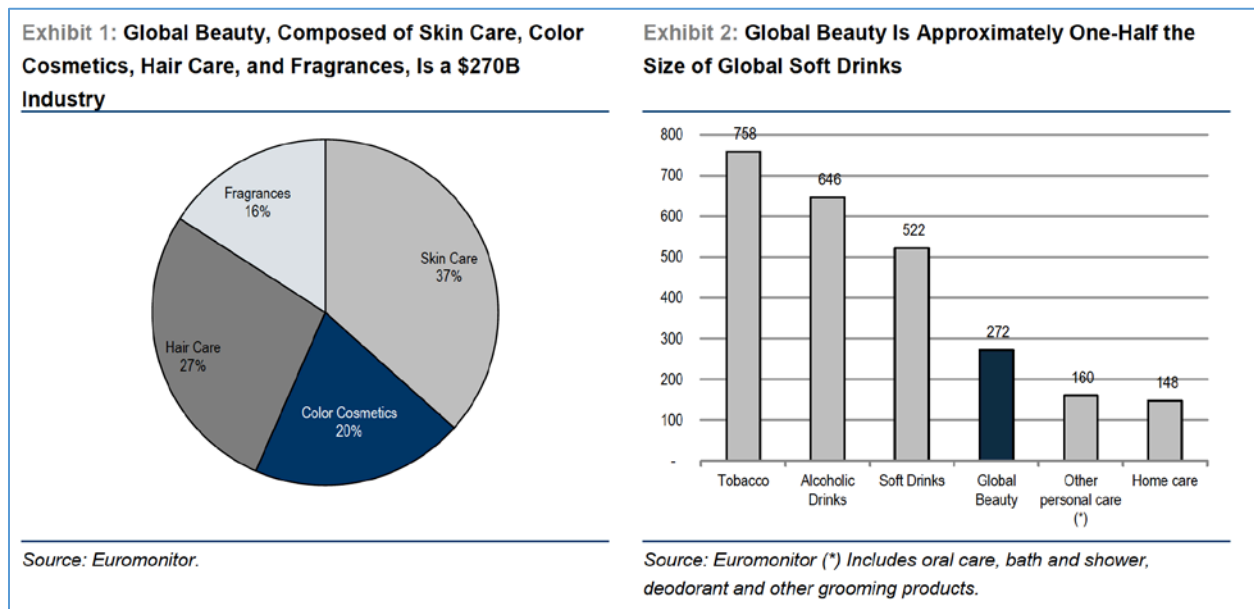
CHAPTER 1: Overview of the Cosmetics Industry

Overview of the Cosmetics Market

Cosmetics is a USD 270 billion global industry, which encompasses a variety of products including skin care, color cosmetics, hair care, perfumes and fragrances, and toiletries. Skin care represents 37 percent of the industry, hair care 27 percent, color cosmetics 20 percent, and fragrances 16 percent (See Figure 1) (Credit Suisse, 2013).

The cosmetics market in Kenya, Tanzania, and Uganda is worth USD 151 million and is projected to grow to USD 231 million by 2018 (Euromonitor International, 2015). Tanzania's expanding middle class is increasingly young and urban, and demand for high quality cosmetics is growing. Many Tanzanians buy their products at high-end supermarkets, beauty stores, pharmacies, online, and abroad.

Figure 1: Size of Global Beauty Industry



Source: Credit Suisse, Global Beauty Industry, November 2013.

In its most recent comprehensive report covering the period 2003-2013, TFDA noted that a total of seven manufacturing facilities had been registered in Tanzania (TFDA, 2013). One of the largest manufacturers is Tanga Pharmaceutical and Plastic Limited, which has registered a number of cosmetic products in its name. Large beauty brands such as Estée Lauder, Unilever, and L’Oreal also have expanded into the Tanzanian market, as have South-South brands like Indian labels Marico and Godrej. These foreign brands have invested in research to tailor products for African beauty needs; for example, researching pigmentation, hair products, and skin products. Simultaneously, local African companies

have emerged with regional beauty brands such as Bannister's Body Cream and Tressa Professional.

In 2014, the value of intra-EAC trade in cosmetics for Tanzania stood at USD three million for exports and USD 8.41 million for imports. A significant portion of cosmetic imports to Tanzania, valued at USD 6.89, come from Kenya (EAC, 2014). This shows a large imbalance in the trade in cosmetic products between Tanzania and its neighbors. Tanzanian industry stands to benefit from domestic and regional demand for cosmetic products, both in terms of untapped domestic production potential and because its agricultural sector produces a number of ingredients commonly used in cosmetics.

Globally, the cosmetics market has experienced a positive annual growth rate over the last ten years, with an increase from 3.6 percent in 2014 to 3.9 percent in 2015 (L'Oréal, 2015). Ingredients, which are segmented into functional ingredients (these are ingredients that affect the cosmetic product, such as preservatives or thickeners) and active ingredients (having a cosmetic effect or claim, such as anti-aging ingredients) (CBI Market Intelligence 2015), show growth as well; the global market for functional ingredients is expected to grow at a compound annual growth rate (CAGR) of 4.7 percent from approximately \$23.8 billion in 2016 to nearly \$30.0 billion in 2021 (BCC Research 2015).

Counterfeiting is common in the Tanzanian cosmetic market, particularly in the Kariakoo market, which is the largest informal market in Dar es Salaam. One estimate shows that 30 percent of cosmeceuticals (cosmetics that have pharmaceutical or medicinal aspects, such as acne or anti-aging creams) in East Africa are counterfeit or have substandard active ingredients (Africa Business Pages, n.d.). Efforts by the United Nations Children's Fund (UNICEF) and the Tanzanian government are improving awareness of hygienic aspects of cosmetics use, but additional education on use of luxury cosmetics often happens through the increasing number of beauty supply stores in cities like Dar es Salaam. The common incidence of counterfeiting in the sector calls for increased focus on the enabling environment, particularly through market enforcement approaches and more effective regulation.

Cosmetics Value Chain

The value chain for cosmetic products can be broadly characterized as having three main steps: (1) processing of raw materials and ingredients, (2) manufacture and packaging of products, and (3) sale and distribution of final products.

Processing of Raw Materials and Ingredients of Cosmetics

Cosmetics products are produced using a variety of ingredients, including vegetable oils, essential oils, botanical extracts, and synthetic chemicals, which may be processed into secondary ingredients. Tanzania produces a number of ingredients in cosmetics, including vegetable oil seed. In addition to vegetable oils, non-timber forest products such as shea

are also a common ingredient in cosmetics and are often cultivated by women, adding an aspect of sustainable gender development to the potential of the cosmetics value chain, even within Tanzania.

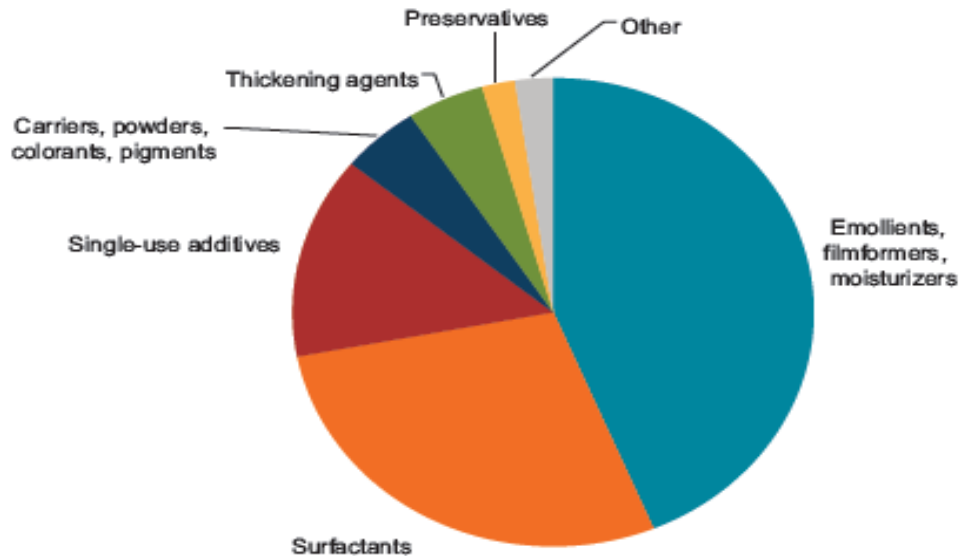
Table 2: Use of Natural Ingredients in Cosmetic Market Segments

Use	Vegetable Oils	Essential Oils	Botanicals
Skin Care	Used in body oils & butters, sun screens and body & face creams; even wider applications when processed into derivatives.	Mostly commonly used as fragrance: either as a fragrance or perfume blend or added directly to the product. Some essential oils are used for efficacy purposes as well (for example, anti-aging) and they are increasingly marketed for their aromatherapy use.	Used in beauty treatment products, serums, and for cooling, soothing, anti-blemish and anti-aging products
Hair Care	Used in most segments, particularly conditioners.	Most commonly used for fragrance purposes.	Botanicals that function as, or support, hair conditioning agents, used by hair care formulators.
Fragrance	Used in small amounts, mostly in scented or fragrance oils.	Largest user of essential oils.	Use of botanicals is limited in fragrances, only as a basis for essential oils or other aromatic by-products.
Toiletry	Used in soap, deodorants and depilatories. Most derivatives used in soaps are based on commodity oils.	Limited use of essential oils in toiletries.	Soap, deodorants and depilatories are significant markets for botanicals.
Decorative Cosmetics	Limited use of vegetable oils.	Limited use of essential oils.	Limited use of botanicals.

Source: CBI Market Intelligence 2015

Chemicals also are common ingredients in cosmetics product. Approximately 1,000 to 1,500 chemical entities are recognized as synthetic cosmetic chemicals worldwide. These chemicals are used for a number of products, and consumption is broken down in the chart in Figure 2, below. Many of these synthetic ingredients are imported, which increases cost of production and may put Tanzanian manufacturers at a disadvantage. Notably, the Guidelines for Submission of Documentation for Marketing Authorization of Domestic Products (Marketing Guidelines) published by TFDA provide a list of prohibited ingredients.

Figure 2: World Consumption of Cosmetic Chemicals



Source: HIS, 2015

Overall, Tanzania’s potential to manufacture raw material and ingredients for domestic and export markets is largely untapped and would need to be more fully explored in order to further develop the sector.

Manufacturing and Packaging of Final Products

As the next step in the value chain, final products are manufactured using raw materials and ingredients as well as packaging materials (Imrie, 2014). Cosmetics manufacturing has two aspects. The first aspect entails manufacturing the raw materials and ingredients, and the second involves using the ingredients to manufacture the final cosmetic product. Packaging, which conveys important information about the product and is a considerable factor in consumer choice, works both as a protector of the product and marketing tool (O'Reilly, 2010). As noted above, manufacturing of cosmetics in Tanzania currently lies well below potential, due in part to challenges in the enabling environment that will be discussed in detail below.

Sale and Distribution of Final Products

Once packaged, cosmetics products are distributed through various channels. These include retail stores such as department stores and drug stores, direct sales to consumers by agents, niche sales to salons and spas, internet sales, and informal sales (including, for example, roadside kiosks). Warehousing can be a crucial function at any point in the distribution chain, especially for those products that are perishable or require refrigeration (Brown, 2014).

CHAPTER 2: Overview of the Enabling Environment for Cosmetics in Tanzania

The cosmetics industry in Tanzania is governed by a number of laws and regulations that cover all aspects of the value chain, from research and development (R&D) of cosmetics products to retail sale and cross-border trade. While some rules are specific to the cosmetics industry, such as regulations on cosmetics product registration, other rules apply to cosmetics as well as a number of other sectors, like regulations on establishing a formal business. As Figure 4 below depicts, a number of the legal and regulatory measures are at the national level (these are shown in blue boxes in Figure 4); however, a number of international measures (shown in yellow boxes in Figure 4) apply as well.

In addition to national level frameworks, regional and international rules and standards also regulate the sector and will impact its growth potential. Tanzania is a member of the EAC and SADC, neither of which has yet developed a comprehensive framework for cosmetics. As evidenced in other regions, regional harmonization, particularly within the EAC, could be beneficial to enhancing competitiveness and attracting investment. For example, the Association of Southeast Asian Nations (ASEAN) has developed a harmonized system for cosmetics comprised of aligned standards, including for good manufacturing practices (GMP), common labeling requirements, common claims guidelines, and harmonized import and export requirements. Given that Tanzania's legal and regulatory system for cosmetics is further developed than other countries in the EAC, Tanzania could be a natural leader to begin discussions to establish regional standards and harmonize regulatory practices.

Tanzania's cosmetics industry is regulated primarily by the **Food, Drugs, and Cosmetics Act (FD&C Act)** and its implementing regulations and guidelines. The FD&C Act provides the legal framework for food, drugs, medical devices, cosmetics, and poisons, and it established the **Tanzania Food and Drugs Authority (TFDA)** in 2003. TFDA is responsible for the control, quality, and safety of cosmetics, as well as food, drugs, herbal drugs, medical devices, and poisons.

The FD&C Act defines "cosmetic" as "any article intended to be used by means of rubbing, pouring, steaming, sprinkling, spraying on or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as component of a cosmetic." Included in this definition are products such as skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product.

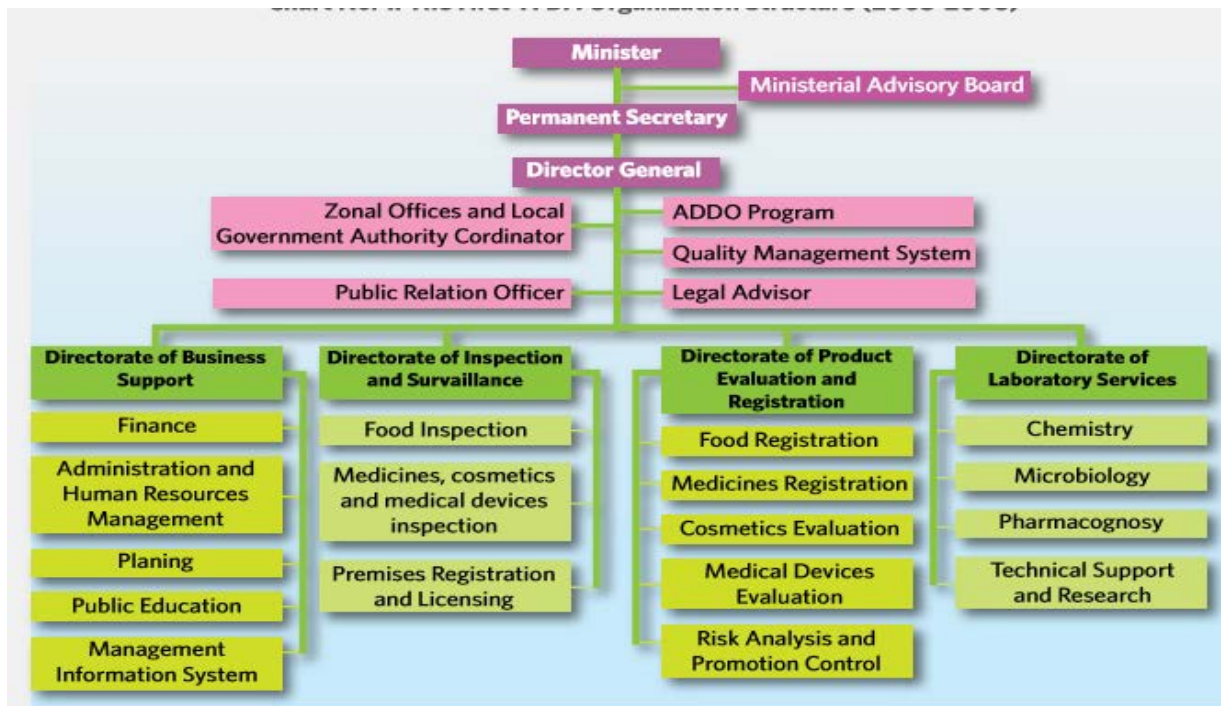
The FD&C Act requires businesses in the cosmetics industry and other sectors regulated by the FD&C to register their premises with the TFDA. The FD&C Act also sets forth requirements for licenses and permits as well as packaging and labeling.

For the cosmetics industry specifically, the FD&C Act:

- Regulates the manufacture, importation, distribution, and sale of cosmetics;
- Establishes prohibited cosmetics ingredient and product lists;
- Establishes rules on counterfeit cosmetics;
- Determines whether to prohibit the manufacture, importation, and distribution of cosmetics; and
- Enforces cosmetics regulations, including through inspections and sampling for analysis.

The structure of TFDA is illustrated in Figure 3 below.

Figure 3: Organizational Structure of TFDA



Source: TFDA 2013

TFDA is headed by a **Director General** (a position created by Section 7 of the FD&C Act), who is responsible for TFDA's day to day operations, the proper management of its funds, property and business and for the personnel management and development. The **Ministerial Advisory Board (MAB)** advises the **Minister for Health and Social Welfare** on the activities of TFDA.¹ The Director General of the TFDA is the Secretary of the MAB. TFDA's zone offices fall under the Director General's office, which provides TFDA services

¹ See Section 9 of the TFDA Act. The MAB consists of the Permanent Secretary in charge of the Ministry of Health, who is also the Chairman; not more than twelve other members appointed by the Minister; and the Director General, who is the Secretary to the Board

in various geographic zones throughout the country and includes the following four Directorates:

- a) *Directorate of Medicines and Cosmetics*: Ensures quality, safety and efficacy of medicines, cosmetics, and medical devices. The directorate evaluates and registers cosmetic products and business premises, and inspects and monitors the quality and safety of products in the market;
- b) *Directorate of Food Safety*: Ensures safety and quality of food by carrying out registration of food products, inspection and surveillance of food in the market;
- c) *Directorate of Laboratory Services*: conducts laboratory analysis of food, medicines and cosmetics to enhance decision-making within the TFDA; and
- d) *Directorate of Business Support*: provides and enhances good management practices by TFDA.

Other functions of the TFDA, as provided under Section 5 of the FD&C Act, include to:

- Regulate the importation, manufacture, labeling, marking, promotion, sale and distribution of cosmetics;
- Approve and register cosmetics manufactured within or imported into, and intended for use in Tanzania;
- Prescribe standards of quality with respect of cosmetics manufactured or imported into or exported from Tanzania; and
- Direct necessary legal measures to complaints made by consumers against manufacturers of products regulated under the FD&C Act.

TFDA's mandate extends to every part of the cosmetics value chain, but other institutions also have important roles. The **Standards Act, 2009** provides for the standardization of specifications of commodities and services and established the **Tanzania Bureau of Standards (TBS)**. The Act gives TBS the power to adopt standards for cosmetics products. The **Industrial and Consumer Chemicals (Management and Control) Act** established the **National Chemicals Laboratory (NCL)**, which governs the manufacture, transport, import, and dealing in industrial chemicals that also are used as ingredients in the manufacture of cosmetic products.

In addition to TFDA and TBS, the **Tanzania Investment Centre (TIC)** operates as a one-stop-shop investment center that coordinates a number of regulatory functions. TIC was established under the 1997 **Tanzania Investment Act** to "coordinate, encourage, promote, and facilitate investment in Tanzania and to advise the Government on investment policy and related matters." TIC works with enterprises with a minimum capital investment of at least USD 500,000 if foreign owned or USD 100,000 if locally owned. TIC helps investors to obtain permits and authorization required by laws to set up and operate investments in Tanzania.

Other relevant statutes and government agencies, all of which coordinate through TIC, include the following:

- The **Tanzania Revenue Act** established the **Tanzania Revenue Authority (TRA)**, which is responsible for collection of business taxes and other fees.
- The **Business Registration and Licensing Authority Act** established the **Business Registration and Licensing Authority (BRELA)**, which issues registration certificates to cosmetics businesses.
- The **National Environment Management Act** established the **National Environmental Management Council (NEMC)**, which regulates manufacturing premises, including for cosmetics products.
- The **Ports Act No. 17 of 2004** created the **Tanzania Ports Authority (TPA)**, which plays a role in regulating the import and export of cosmetics products.

Figure 4, below, depicts the value chain for cosmetic products in Tanzania along with key areas of regulation, legal and regulatory measures, and responsible institutions.

International Frameworks

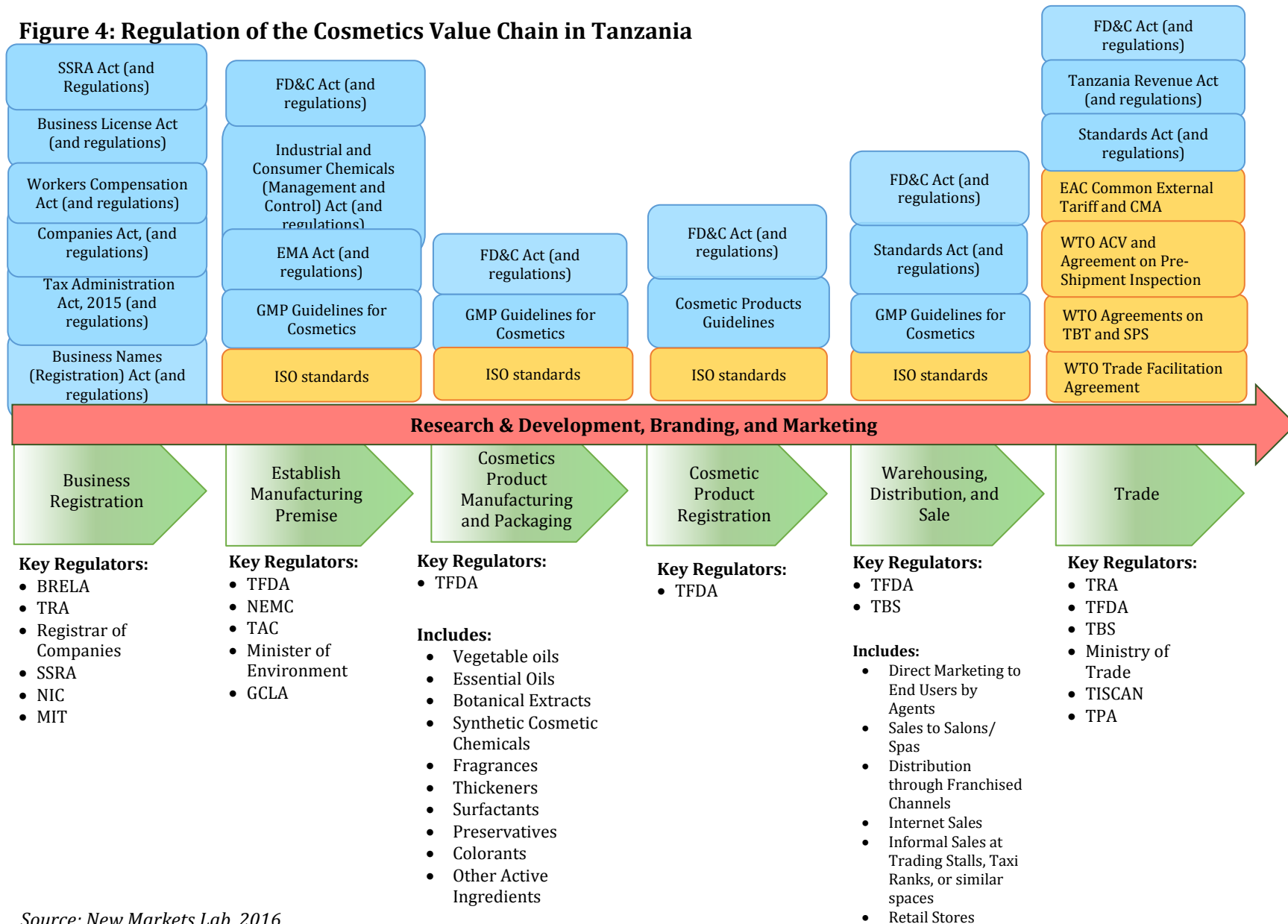
As a Member of the WTO, Tanzania is subject to WTO disciplines. The WTO Agreement on Technical Barriers to Trade (TBT Agreement) is the main international instrument on technical regulations and product standards. The TBT Agreement aims to ensure that technical regulations, standards and testing, inspection and certification procedures do not create unnecessary obstacles to international trade.

The WTO Agreement on Pre-Shipment Inspection and WTO Agreement on Customs Valuation (ACV) are also particularly relevant to the cosmetics sector. In addition, the WTO Trade Facilitation Agreement (TFA), which entered into force on 22 February 2017, binds Members to implement trade facilitation measures, including enhancing transparency, streamlining rules, and increasing automation of customs rules and procedures.

The International Standards Organization (ISO) has developed and published several international standards applicable to cosmetics. There are 20 such international standards, and five relevant reports have been identified as relevant for cosmetics by the International Cooperation on Cosmetic Regulation (ICCR).²

² ICCR is a voluntary international group of cosmetics regulatory authorities from Brazil, Canada, the European Union, Japan, and the United States Report the ICCR Report for the International Cooperation on Cosmetics Regulation, available at http://www.iccrnet.org/files/8314/7038/8801/ICCR_WG_report_International_Standards_2016-07-13.pdf.

Figure 4: Regulation of the Cosmetics Value Chain in Tanzania



Source: New Markets Lab, 2016

Relevant ISO standards concern analytical methods, test methods, microbiology, packaging and labeling, and GMP. For example, ISO 22716:2007 concerns GMP for the cosmetics sector and has its basis in other quality management systems such as ISO 9001. In addition, ISO 22716:2007 gives guidelines for the production, control, storage and shipment of cosmetic products concerning their quality and safety aspects. Such guidelines are based on “the principles of sound scientific judgment and risk assessment to produce products that meet defined characteristics” (ISO, 2011). While ISO 22716:2007 covers the quality and safety aspects of the product, it “does not cover safety aspects of the personnel engaged in the plant, nor [does it] cover aspects of protection of the environment.” With respect to environmental management, the ISO 14000 family of standards provides some practical tools.

The International Cooperation on Cosmetics Regulation (ICCR) is an organization leading efforts to develop international harmonized regulations among member countries. Current membership is made up of Brazil, Canada, the European Union (EU), Japan, and the United States, with participation by a number of developed and developing countries. The organization has collected a number of good regulatory practices from developing and developed countries and is crafting a set of regulatory principles for cosmetics legal and regulatory systems in sub-Saharan Africa that would support growth of the industry while also enhancing the ability of regulators to achieve policy objectives. As regional frameworks develop, these global standards and practices can provide a useful benchmark.

Regional Harmonization

Regional harmonization, which has regulatory harmonization at its core, could significantly expand the market for cosmetic products by unlocking economic efficiencies and economies of scale in trade and helping spur investment. Tanzania is a member of both the EAC and SADC, two major regional economic communities (RECs) that, along with the Common Market for Eastern and Southern Africa (COMESA), form the Tripartite Free Trade Area (TFTA). Both the EAC and SADC have relatively well-developed harmonized trade frameworks and focus on trade facilitation across borders. However, these RECs have not yet developed a harmonized framework specifically for the cosmetics industry.

East African Community

The EAC, which is at the Customs Union stage, is more advanced than other RECs in terms of regional harmonization. The EAC is in the process of developing harmonized standards for certain cosmetics products but lacks a broader framework governing the cosmetic industry. Article 81 of the East African Community Treaty requires cooperation among Partner States in Standardization, Quality Assurance, Metrology and Testing (SQMT). The SQMT Act, 2006 provided for the establishment of the East African Standards Committee (EASC), which consists of representatives of the National Standards Bodies in partner states, together with the representatives from the private sector and consumer organizations. Several Draft East African standards that affect the cosmetics sector have

been prepared in accordance with the EAC Principles and Procedures for harmonization of standards, and await ratification. For example, standard DEAS 841:2015 specifies the requirements and methods of sampling and test for hair oils. In addition, DEAS 846:2015 provides a glossary of terms relating to the cosmetics industry.

Southern African Development Organization

SADC does not regulate cosmetics, but the Southern African Development Community Accreditation Service (SADCAS) is relevant to the sector. SADCAS provides accreditation services to SADC Member States that do not have a national accreditation institution for their laboratories, certification, and inspection bodies. Tanzania, however, already has its own national accreditation body.

Global Good Regulatory Practices

As one of the few countries in the region with a comprehensive legal and regulatory system for cosmetics, Tanzania could play an important leadership role at the regional level, and global good regulatory practices could provide a useful benchmark. Examples of harmonized regional schemes do already exist which could help inform the EAC and SADC. For example, the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme was developed in collaboration with the private sector and seeks to align standards for cosmetics, including for GMP. It also provides common labeling requirements, claims guidelines, and import and export requirements.

More recently, the Trans Pacific Partnership (TPP) Agreement included an annex on cosmetics attached to the chapter on technical barriers to trade (TBT), which was benchmarked against global good regulatory practices.

Aspects of global good regulatory practices for cosmetics include:

- Shifting existing product registration requirements to notification systems (see Figure 11) and post-market inspection;
- Recognizing international standards, including GMP;
- Prohibiting requirements for testing on animals, except when animal testing is the only available means;
- Ensuring regulatory processes are timely, objective, and transparent; and
- Acknowledging that cosmetics products pose a different risk to consumers than pharmaceuticals and medical devices.

The TPP also permits re-labeling to provide more flexibility on packaging requirements for companies.

These good regulatory practices are discussed in greater detail below in the context of the regulatory processes that apply to the cosmetics sector in Tanzania.

CHAPTER 3: LEGAL AND REGULATORY FRAMEWORK FOR THE COSMETICS INDUSTRY IN TANZANIA

The way in which policies, laws, and regulations are designed and implemented directly impacts the growth of businesses, development of sectors, and achievement of public policy objectives. Increasing understanding of the legal and regulatory system and how it is implemented in practice can have a profound impact on economic opportunity and sustainable development. The growing cosmetics industry in Tanzania is regulated along every step of the value chain, often with numerous Ministries and institutions involved (see Figure 4 above). This chapter covers the main regulatory processes for cosmetics, focusing on challenges associated with the establishment of manufacturing premises, product registration, importation and customs valuation, and exportation, which have been identified by stakeholders as priority areas.

Manufacturing, Selling, and Distributing Cosmetics

The cosmetic business in Tanzania encompasses manufacturing, wholesale, and retail, each of which requires an activity license and registration with TFDA. In a significant report highlighting a decade of progress from 2003-2013, TFDA stated that it had registered a total of seven manufacturing facilities, three warehouses, and 1,213 wholesale and retail cosmetics shops (TFDA, 2013).

Although a number of cosmetics-specific licenses and permits ultimately all are issued by **TFDA**, companies first must be registered formally, a process that involves multiple government institutions, such as the **Business Registration and Licensing Authority (BRELA)** and the **Tanzania Revenue Authority (TFA)**. Unlike cosmetics retailers and wholesalers, cosmetics manufacturers also need an Environmental Impact Assessment (EIA) Certificate from the **National Environment Management Council (NEMC)** before applying for a cosmetic manufacturing premise registration and license from TFDA. Depending upon the type of ingredients used in manufacturing the cosmetics products, manufacturers may also be required to register with the **Government Chemist Laboratory Agency (GCLA)**.

The first stage before a cosmetics business license may be sought involves the formation of a formal company and compliance with all general registration requirements. This stage is not unique to a cosmetics company, as it applies to all companies seeking to do business in Tanzania. The process involves several steps, enumerated in Annex I of this report.

The World Bank's Doing Business indicators provide a benchmarking tool for assessing Tanzania's practices in this area vis-à-vis those of other countries. Globally, Tanzania is ranked globally 132 out of 190 by the World Bank with respect to the ease of starting a business (World Bank, 2017). In comparison with sub-Saharan Africa (SSA), Tanzania ranks behind many of its fellow EAC and SADC member countries. The top five global performers in SSA under the Doing Business indicators are all EAC and SADC member

states: Mauritius (global rank 49); Rwanda (global rank 56); Botswana (global rank 71); South Africa (global rank 74); and Kenya (global rank 92) (World Bank, 2017). Continuing to streamline the business registration process, and, importantly, addressing back log challenges, could help increase Tanzania's competitiveness within the EAC and SADC and attract additional investment. Fortunately, this is an area in which Tanzania could improve its practices relatively easily, with significant results likely to flow from doing so.

Cosmetics Manufacturing

In addition to formal business registration, a company wishing to manufacture cosmetics in Tanzania must receive a license and register its manufacturing premise with **TFDA**. This application requires a number of documents, listed below, including an **Environmental Impact Assessment (EIA) Certificate**. While TFDA is the main regulatory authority involved in the licensing and registration process for manufacturing, TFDA is joined by a number of other regulatory authorities in the EIA Certificate process. Due to the number of entities involved, strong coordination is needed in order for the process to become more efficient and less time-consuming for both regulators and manufacturing companies.

EIA Certification Process

All manufacturing premises, not only those engaged in cosmetics production, are required to undergo an EIA under Section 81 of Tanzania's **Environment Management Act, 2004 (EMA Act)**. TFDA's **Good Manufacturing Practice Guidelines for Cosmetics (GMP Guidelines for Cosmetics)** also require that premises for cosmetic manufacturing be suitably located, designed, constructed, and maintained. Additional details regarding the process for obtaining an EIA Certificate are provided under the **Environmental Impact Assessment and Audit Regulations, 2005** and **NEMC Procedures for Carrying Out Environmental Impact Assessment and Audit**.

Obtaining the EIA Certificate is necessary before registering with the GCLA (if required) and securing the final manufacturing permit and premise registration license from TFDA. The **NEMC, Cross-Sectoral Technical Advisory Committee (TAC)**, and **Minister of Environment** are involved in the process of issuing an EIA Certificate. **TFDA** may also play an advisory role through participation in the TAC. According to the EMA Act and Environmental Impact Assessment and Audit Regulations, the process for obtaining an EIA Certificate should take approximately 180 days or about six months. In practice, however, the process may take more than a year to conclude. The process itself contains a number of steps as set forth in Figure 5 (below) and in Annex II.

The EIA itself is a useful tool for companies trying to manage their environmental footprint and increase efficiency, but some companies have stated that there is not enough transparency in the process and that the reports do not always provide them with useful information. In addition, companies are required to engage an expert consultant. However, consultants are not always available who have deep knowledge of cosmetics manufacturing

specifically, and the EIA process may be poorly tailored to the sector as a result. This complicated process for an EIA Certificate could be improved by streamlining the steps involved, providing additional training on sector-specific manufacturing norms for regulators, diversifying the pool of registered expert consultants, and increasing transparency, all of which would help reduce the time to obtain an EIA Certificate. It would also help manufacturers better understand what is required from them and make better use of the EIA results to support sustainable growth.

Registration with GCLA

After receiving an EIA Certificate, the applicant may begin the process for obtaining a license for manufacturing cosmetics and premise registration from TFDA, as well as registration of certain chemicals and the premise with **GCLA**, if required. The Industrial and Consumer Chemicals (Management and Control) Act requires that any entity dealing with certain chemicals and involved in the production, importation, exportation, transportation, and storage of chemicals must register with the GCLA. Therefore, some cosmetics manufacturers may be required to adhere to the registration requirements. GCLA relies upon international classifications and standards where applicable and works closely with TBS and TFDA. The GCLA registration process is independent of obtaining the manufacturing permit and premise registration license from TFDA (described below) and can be conducted concurrently with the TFDA manufacturing license and premise registration process. Notably, there is concern within the public and private sectors alike that GCLA, TFDA, and TBS share some overlap in regulatory mandates. Clarification of roles and greater information sharing with companies could help address this challenge.

Manufacturing License and Premise Registration with TFDA

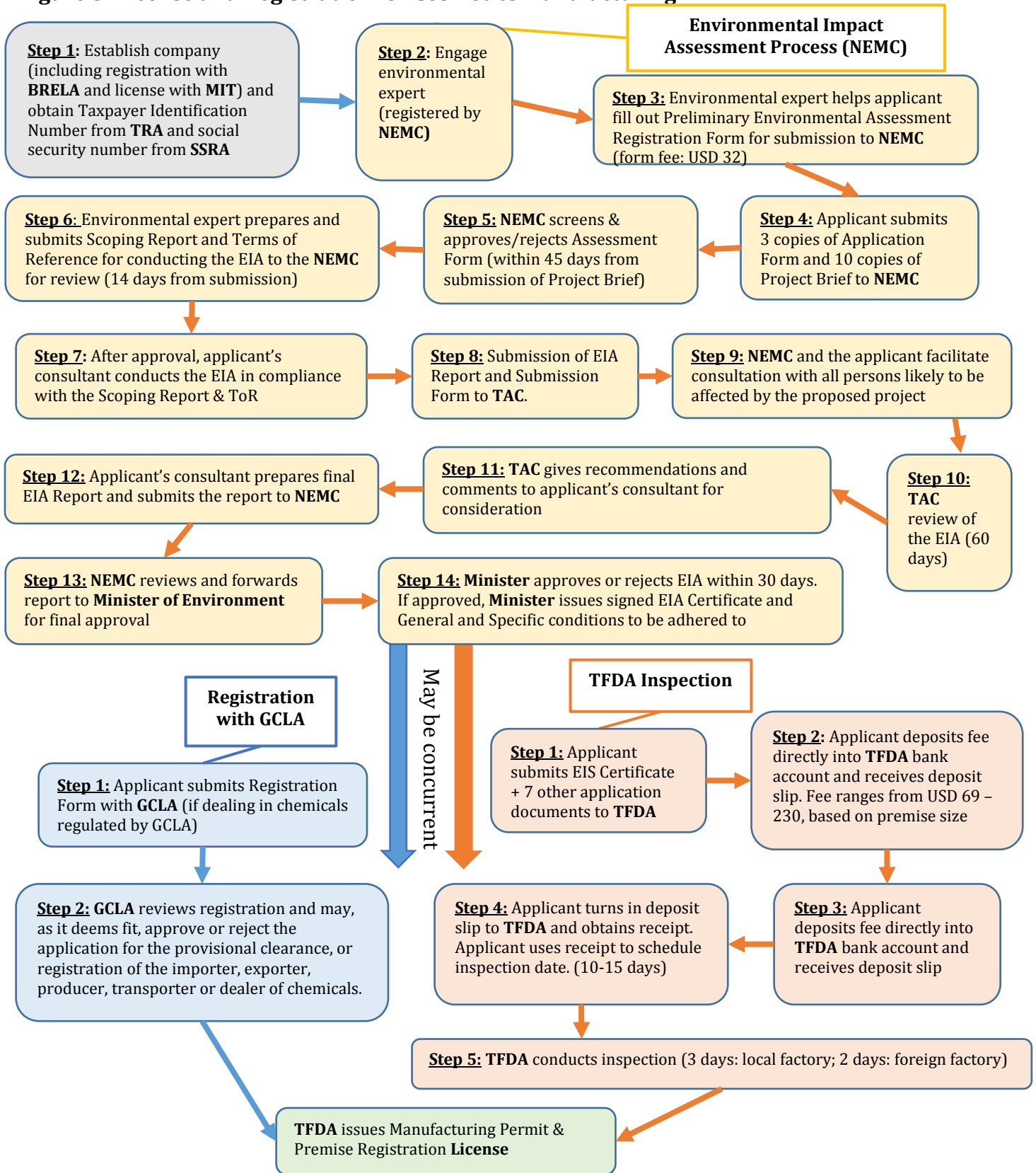
Manufacturers, wholesalers, and retailers must register their business premises with **TFDA** before they engage in the manufacture, storage, sale, or distribution of cosmetics products (Section 8 of the FD&C Act). The FD&C Act makes it a criminal offence to engage in the production, storage, and sale of cosmetics in an unregistered premise. To obtain a manufacturing permit, the entity must first register its business formally and obtain an EIA Certificate from the NEMC, described above, and then commence the following steps:

- *Step 1: Submit Application Documents to TFDA:* A number of application documents must be submitted to **TFDA**:
 - Application for license to manufacture cosmetics (TFDA Form 0003)
 - Application for premise registration (TFDA Form 0001)
 - Memorandum and Articles of Association of the company
 - EIA Certificate from NEMC
 - Factory layout showing the plant layout, air handling systems, and specific locations of equipment
 - Letter of commitment from a superintendent as well as a contract of employment signed between the superintendent and the factory

- Certificate of qualified superintendent
 - Flow chart showing the manufacturing process
- *Step 2: Pay the Application Fees:* Applicants use TFDA's pro-forma invoice to directly deposit its registration fee in the TFDA's bank account and collect a bank deposit slip. The fees that are set forth in the **Food, Drugs, and Cosmetics (Fees and Charges) Regulations, 2015** are based on size of factory. They range from USD 69 to USD 230 or TZS 150,000 to TZS 500,000.
- *Step 3: Schedule Inspection of the Premises:* Applicant will use the receipt of payment to schedule a date for inspection of the premises, which requires a wait time of between ten and fifteen business days. Once scheduled, the inspection for GMP takes between two and three days for a factory owned by locals and one to two days for a foreign-owned factory. The size of the factory is the main determinant for the length of the inspection, and, in practice, most factories can be assessed within one day.
- *Step 4: Issuance of Permit and License:* After application forms are accepted and inspection is completed, TFDA issues a manufacturing permit and premise registration license.

Figure 5 (below) illustrates the processes of registration and licensing for cosmetics manufacturing facilities, including obtaining an EIA Certificate and GCLA registration.

Figure 5: License and Registration for Cosmetics Manufacturing



Source: New Markets Lab, 2016

Key Takeaways: Regulatory Process for Manufacturing

- The application process with TFDA for a manufacturing license and premise registration is straightforward and quick, but, as demonstrated, the process is more involved than just filing the application with TFDA.
- Streamlining the EIA Certification process (Steps 2-14) and increasing collaboration among regulatory agencies would help enhance the ability of companies to engage in the manufacture of cosmetics.
- A number of best practices exist around the world that Tanzania could look to as it seeks to improve the enabling environment to support increased manufacturing and job creation. These include, for example, alignment with ISO GMP practices and development of public-private partnerships to address counterfeit products.
- Shifting to a stronger standards-based system, including around GMP, with more of a focus on enforcement would also help TFDA more efficiently manage its limited resources.

Retail and Wholesale

In addition to the permit and license for the manufacturing of cosmetics, companies intending to engage in retail sale or wholesale, including manufacturers, must obtain a retailer or wholesaler license and register with TFDA. This regulatory process was not flagged as burdensome by the private sector, but it is a process with which companies must comply. Consumers purchase cosmetic products through retailers, including supermarkets and cosmetics shops. Wholesalers import and source cosmetic products from foreign and local manufacturers for sale and distribution to retailer. Both must fill out and submit to **TFDA** an application for an activity license (Form 0003) and premise registration (Form 0001). TFDA's pro-forma invoice can be used to directly deposit the necessary payment for the registration of TZS 70,000 (USD 32.50) for retailers and TZS 300,000 (USD 137.50) for wholesalers into TFDA's bank account. The applicant must then present the bank deposit slip to TFDA to obtain a receipt, which is later submitted to schedule a date for inspection of the premises. Inspection for a retail facility requires a wait time of at least one business day; inspection of a wholesale facility involves a wait time of at least 20 business days. After completion of the inspection, TFDA will present the business permit to the applicant. This process may take only one day for a cosmetics retailer but up to 15 business days for a wholesaler.

Registration of Cosmetics Products

All cosmetic products offered for sale in Tanzania must be registered by the TFDA, and the FD&C Act prohibits the sale and distribution of unregistered cosmetics. The **Guidelines for Submission of Documentation for Marketing Authorization of Cosmetic Products (Cosmetic Products Guideline, 2015)** describes how to register a cosmetic product. For the purposes of registration, the Cosmetic Products Guidelines classify cosmetics into

Category I and Category II. Category I consists of “products that have the potential to be absorbed through the skin or mucus membrane. These products include:

- “Products for application in the area around the eyes (except eye brow products), lips, and oral cavity; [...]
- Hair dyes containing phenylenediamine, toluenediamine, their salts and derivatives; [and]
- Sun tanning products containing topical dyes or tan accelerators” (Cosmetics Products Guideline, 2015, p 6).

Category II cosmetics consist of products that cannot be absorbed through the skin and therefore present a lower risk to the consumer.

An importer or manufacturer of a cosmetic product is responsible for registering the product with the **TFDA**. The applicant must be a Tanzanian resident and be licensed by the TFDA as a cosmetic products dealer. In the event the applicant is not a resident, then the applicant must appoint a local resident or a company incorporated in Tanzania that is authorized by the TFDA to deal in cosmetic products (Cosmetic Products Guideline, 2015). A number of documents may be required along with application, including a Letter of Authorization; a Free Sales Certificate (FSC); a Certificate of Observance to GMP; and a Certificate of Analysis (CoA). The FSC and GMP must be current and from the country of origin, issued by the health authorities or recognized bodies (TFDA may request to see the original). The CoA details the specifications and test results for at least two batches of the finished product (Cosmetic Products Guidelines, 2015). Applications to register a cosmetic product are evaluated on a first in, first out (FIFO) basis according to Standard Operating Procedures for Evaluation.

Applications for registration of a cosmetic product are classified into three categories: new applications, applications for variation of registered cosmetic product, and applications for renewal of registration.

New Applications for Registration of a Cosmetic Product

According to the Cosmetic Product Guidelines (2015), a new application involves the registration of a cosmetic product that will enter the Tanzanian market for the first time. An applicant must submit to TFDA the following:

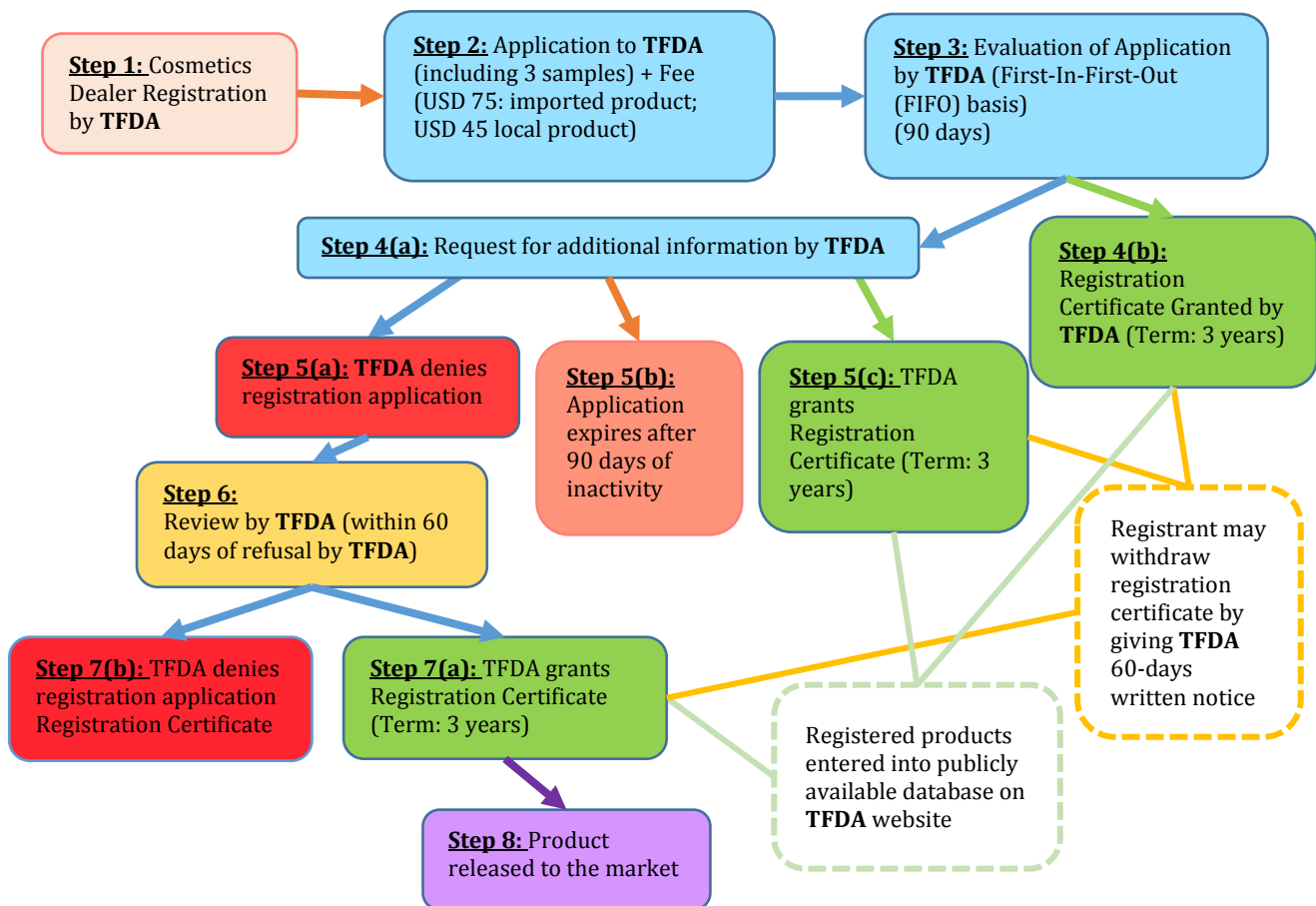
- Cover letter,
- Properly completed application form,
- Copies of referenced information and supporting documents,
- Three samples of commercial pack(s) of the same batch, and
- Non-refundable application fee (USD 100 for imported products and USD 45 for locally manufactured cosmetics).

Decisions on product registration are based on data in the submitted application. The TFDA grants registration of a cosmetic product if it is satisfied that the cosmetic follows:

- a) National Standards, or where there are no National Standards, International Standards; and
- b) Requirements set under the Guidelines.

Figure 6 below illustrates the registration process for a new cosmetic product.

Figure 6: Registration Process for a New Cosmetic Product



Source: New Markets Lab, 2016

Key Takeaways: Regulatory Process for Registration of Cosmetics Products

- o While the regulatory process for registration of cosmetics products does not take as long as other processes (contrast Figures 5 and 6), some stakeholders have flagged that the process for registration often takes longer than officially stated, due to challenges associated with insufficient testing facilities, inexperience concerning new types of products, and high costs of testing facilities. One company found that the evaluation can take up to six months (Mulupi, 2015).

- Increasing the capacity of TFDA staff and laboratories (focus on Steps 2-4) could help reduce the amount of time required to register cosmetics products, and this could be achieved in part through closer collaboration and streamlining of regulatory functions with GCLA and TBS.
- A notification system (See Chapter 4) is a recognized alternative to product registration and shifts some capacity to agencies like the TFDA to focus on enforcement, an important consideration in markets with counterfeiting challenges.

Application for Variation of a Registered Cosmetics Product

This second category involves a registrant notifying and obtaining the approval of the TFDA before making changes relating to a registered cosmetic product. Changes could include compositional change, packaging, labeling, or any other change made to the registered cosmetic product. The notice to the TFDA must include the reasons of for such change. The Authority then assesses the reasons provided in the notice and, if satisfied, approves the changes by issuing an approval notice. If the TFDA is not satisfied with the proposed change, then it will notify the registrant by stating such reasons for rejection.

Application to Renew Registration of a Cosmetics Product

This third category is the application to renew registration of a cosmetic product. The application to TFDA must be made at least 90 days before the expiration of the current registration.

The registration of a cosmetic product is valid for three years, and the TFDA may, after providing justification, revoke or amend a registration. The registrant may also withdraw the registration by giving the TFDA 60 days' notice in writing (Cosmetics Guidelines, 2015). Between June 2003 and June 2013, the TFDA approved a total of 3,968 out of 6,776 evaluated applications.

A product registration system is resource intensive, particularly with strict requirements like re-registration of all products every three years and new registration for even nonmaterial alterations to registered products. An important challenge for TFDA is the lack of sufficient laboratory facilities and personnel. Sometimes TFDA must request laboratory testing by TBS because it does not have the right equipment to test particular products.

Table 3: Cosmetics Applications Received, Evaluated, and Approved by the TFDA between June 2003 and June 2013

Year	Received Applications	Evaluated Applications	Approved Cosmetics
2003/04	0	0	0
2004/05	805	798	787
2005/06	402	340	161
2006/07	1,142	1,279	308
2007/08	512	512	444
2008/08	481	301	34
2009/10	1,119	1,024	505
2010/11	886	886	501
2011/12	1,066	786	422
2012/13	1,095	850	806
Total	7,508	6,776	3,968

Source: TFDA 2013

In addition, TFDA has an insufficient number of inspectors, who must balance other, higher-priority safety investigations on items such as food, medical devices, and pharmaceutical products. In August 2015 TFDA revoked the registration of 31 products, following a routine surveillance that found 36 creams, lotions, and gels with banned ingredients (Tambwe, 2015). Since prices of modern cosmetics are very high, some locals have opted to make their own concoctions of local or homemade cosmetics popularly known as “*Mikorogo*.” Some of these local cosmetics, especially those made of farm produce and allied products, are considered safe, with no health risks to the users. Nevertheless, other local cosmetics may be made of a mixture of various products including chemicals and medicines (TFDA, 2013).

Standards for Cosmetics

TBS is responsible for quality product control measures, standards such as chemical limits, and issuance of a TBS mark for both locally manufactured and imported cosmetics to indicate products that meet its standards. The mark is required to gain market entry, and the process takes approximately one month to complete, with renewal required after one year.

TBS’s mandate is slightly different from TFDA’s mandate, which is focused on health and standards, but there is still overlap in the areas of standards development, testing, and enforcement. For example, TFDA implements TBS standards in the area of GMP. To clarify mandates and address this challenge, TFDA and TBS developed a Memorandum of Understanding (MoU) in 2016. Releasing the MoU to the public was intended to help increase transparency around the different regulatory functions and help address ways in which overlap could be addressed going forward.

Given the expense of testing and limited capacity of laboratory facilities, TBS and TFDA might consider additional collaboration to use resources more efficiently, such as further integrating functions where there is overlap. In addition, shifting to a standards-based system under which more onus is placed on companies to ensure quality and safety of products, with regulators focused increasingly on testing higher risk products and post-market surveillance and enforcement, could improve achievement of important public policy goals.

In addition to product standards, the TBS code TZS 638 (Part 2): 2006(E) sets out a code of GMP for cosmetic industries and lists substances that must not form part of cosmetic products and regarded Generally Not Recognized As Safe (GNRAS). Other TBS codes relevant for the cosmetics industry include TZS 313: 2003 (E) (specification for cosmetic creams, lotions and gels for skin care), TZS 811:2004 (E) (specifications for cosmetics and air freshener aerosols).

TFDA also implements standards on cosmetics and has a quality control laboratory that analyzes cosmetics to ascertain their quality and standards, including for product registration as described above. However, TFDA has limited facilities and sometimes must send products to TBS laboratories to be tested for consumer safety. TFDA Good Manufacturing Practice Guidelines for Cosmetics of January 2016 outline the requirements manufacturers should follow for cosmetic products that are intended to be marketed in the country.

As stated previously, the ISO develops international standards for cosmetic products, and Tanzania recognizes international standards for imported goods. The standards applicable to cosmetic products include ISO/DIS 16128-2.2, which provide guidelines on technical definitions and criteria for natural & organic cosmetic ingredients, and ISO 22716:2007, which provides the guidelines on good manufacturing practices.

Although TFDA seeks to align its cosmetic standards with international standards where ISO standards exist, the private sector has noted that TBS standards are too restrictive and block innovation. In particular, many foreign goods being imported into Tanzania are blocked during pre-shipment verification, discussed in more detail below. More alignment with international standards and mutual recognition, particularly when products come from facilities that maintain internationally recognized GMP standards, could help alleviate bottlenecks around standards while ensuring product and consumer safety is met.

Cross-Border Trade

The movement of goods into and out of Tanzania is regulated by numerous authorities, including the **Customs Department** of the TRA, TPA, the **Customs Inspection Company (TISCAN)**, and MIT. For cosmetics, TBS and TFDA are also involved, with TFDA overseeing the registration of importers and exporters of cosmetic products. The **Guidelines for Importation and Exportation of Cosmetic Products** (the Importation and Exportation

Guidelines) describe the particular importation and exportation process for cosmetic goods.

Customs in Tanzania are largely governed by EAC harmonized rules. Tanzania has made great progress in implementing the EAC Customs Union Protocols, including the **EAC Customs Management Act (as last amended in 2011) (CMA)**, yet enhanced implementation of the CMA, including proper operationalization of the rules of origin (the rules that determine where a product comes from or where value is added), would greatly ease trade with neighboring countries.

Notably, the EAC is exploring ways to simplify its rules so that traders do not have to go through Dar es Salaam, a change that would be especially helpful for smaller businesses and traders. The EAC also has announced a Trade Logistics Information Pipeline, with a new integrated information and communications technology (ICT) data system for information exchange that could help increase competitiveness and spur investment (TradeMark East Africa, 2015).

The process for exportation of cosmetics products is relatively straightforward; however, stakeholders have expressed particular concern about importation procedures that reportedly can be complicated, time-consuming, and expensive. If Tanzania wishes to increase manufacturing in sectors like cosmetics, importation and exportation will be closely linked. The ability to increase exportation of products manufactured in Tanzania will ultimately depend upon the ability to import needed inputs, such as many ingredients used in cosmetics manufacturing.

In addition to importation procedures, which impact stakeholders along the value chain, accurate valuation of imports also is key in order to provide predictability regarding tax liability for companies so that the government can collect accurate import duties. Predictability is important to the private sector as well, particularly for smaller companies. Raw ingredients, machinery for processing and manufacturing, and packaging materials are necessary imports to help build local manufacturing capabilities, and finished goods may also be imported to provide additional product options to consumers and generate greater market demand, which will be important as additional domestic manufacturing comes on line.

Importation of Cosmetic Products

To import cosmetics products, an importer must be registered with and obtain an import permit from TFDA, undertake pre-shipment verification procedures with TBS, conduct pre-arrival declaration, verify the customs value, and secure final clearance of the goods. An overview of this process is contained in Figure 9 below, with additional detail for the process of pre-shipment verification in Figure 8.

All cosmetic products to be imported into Tanzania first must be registered by the TFDA through the processes described above, and importers are required to register their

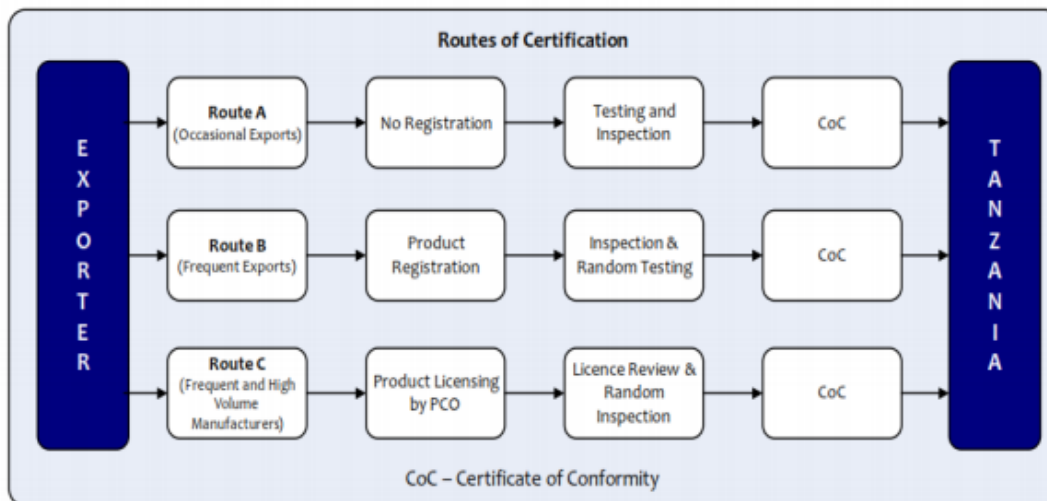
premises, possess a valid license issued by TFDA, and have an import permit for their consignments. Import permit applications can be accessed electronically through the **TFDA** web portal. Applications for importation of cosmetic products are processed within two working days, but this process may take less time. Additional details on the import permit process are included in Annex III of this report.

Pre-shipment Verification by TBS

TBS implements a product conformity assessment program for the control of certain categories of imported goods. Under the PVoC program, all regulated products to be imported to Tanzania must undergo verification and testing in the country of supply, and a Certificate of Conformity (CoC) must be issued to demonstrate that the goods meet the applicable national standards or approved equivalents and technical regulations. The CoC is mandatory for customs clearance.

The guiding principle of the PVoC program is based on Article 5 of the WTO TBT Agreement, which requires that technical requirements (i.e. standards) applied to foreign products also must be applied to domestically manufactured products. Figure 7, below, illustrates the three routes available for certification under the PVoC program, which vary according to the frequency and volume of shipments by the exporter.

Figure 7: Routes of Certification Under the Pre-Shipment Verification of Conformity Program



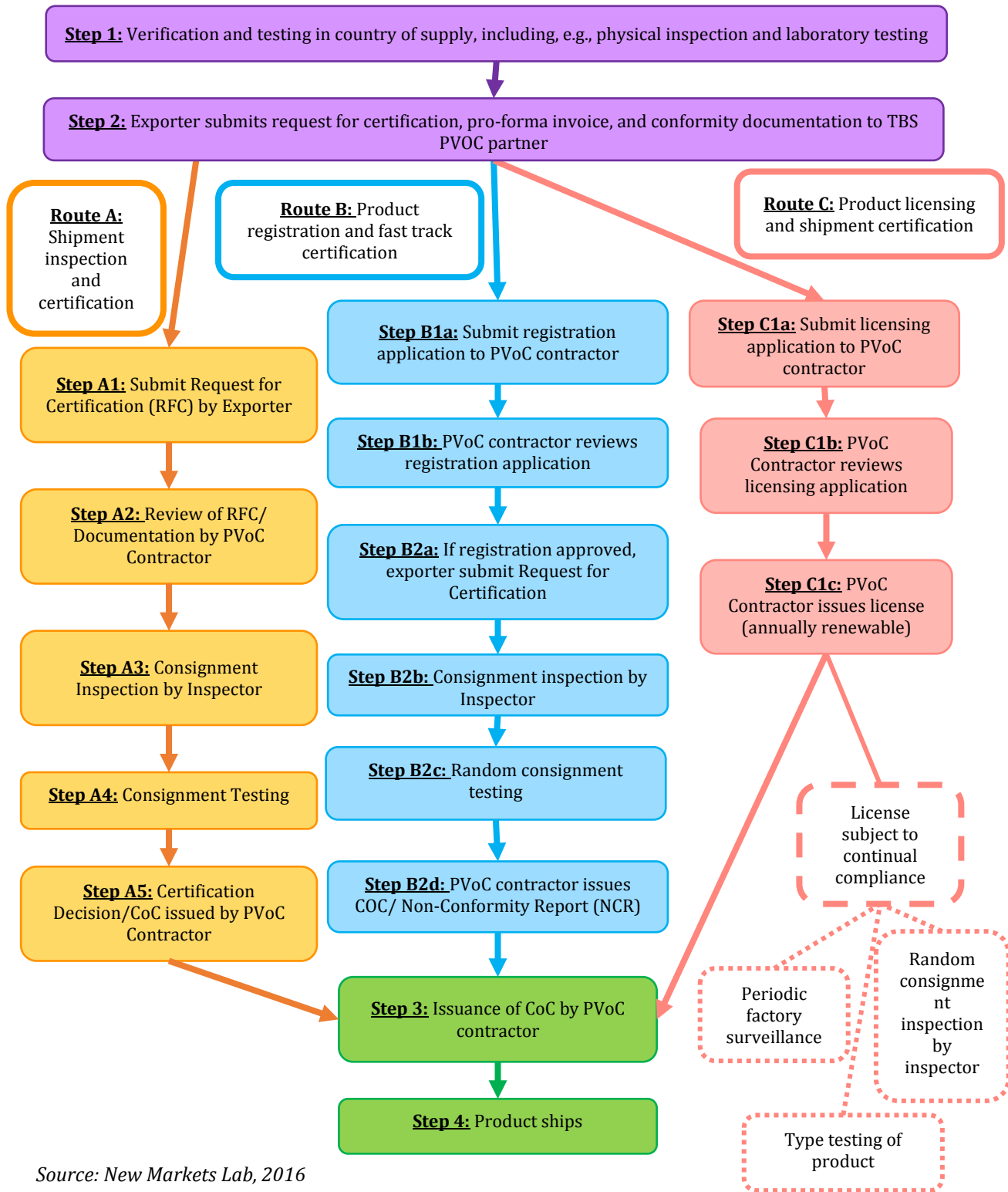
Source: TBS 2016

Under Route A, products are tested and physically inspected to demonstrate conformity to relevant standards, essential requirements, or manufacturer’s specifications. Route B offers a fast track certification process for goods with reasonable and consistent levels of quality through product registration by the PVoC Contractor. Product registration is recommended to exporters having frequent shipments of homogenous products. Route C is open only to manufacturers who can demonstrate existence of a quality management system in their production or manufacturing process. TBS recommends this route for manufactures that

have high frequency or volumes of shipments (TBS, 2016). The pre-shipment verification process is outlined in Figure 8 below and Annex IV of this report; Figure 9 shows the importation process in its entirety.

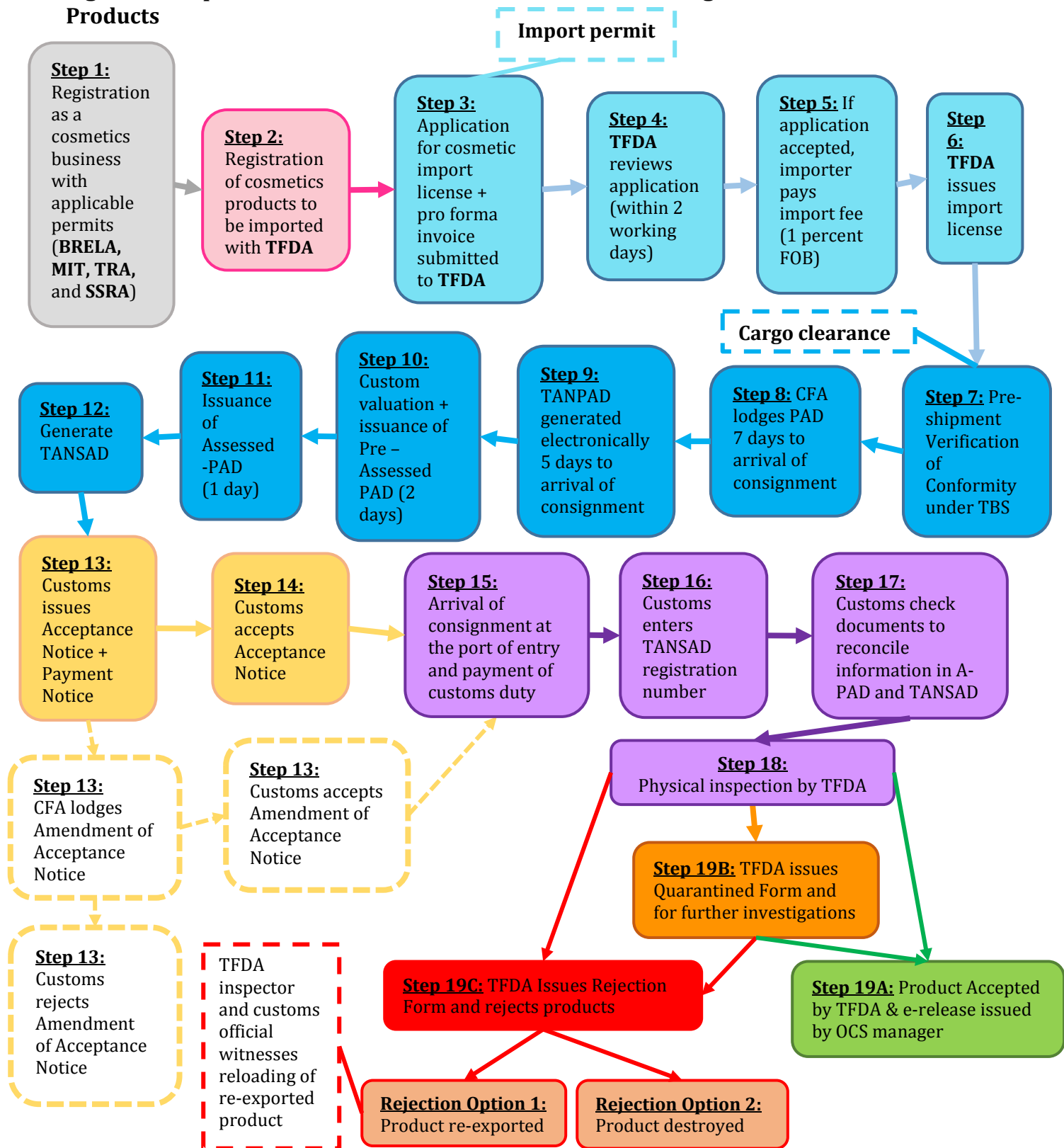
The PVoC program was established in order to reduce clearance delays at the port in Tanzania by eliminating port inspections by TBS. Instead, PVoC ensures that all imported regulated products comply with required standards prior to entry so that products can go directly into the market upon importation, with TBS reserving the right to inspect upon arrival. The program has reportedly helped reduce the time needed to import cosmetics goods; however, there are still implementation challenges. In particular, not all consignments are certified in the country of origin since there may not be TBS agents on the ground, and TBS may not recognize certifications by other authorities, particularly in the case where a product is known to use certain ingredients or be deemed higher-risk. In these instances, TBS takes samples to its laboratory for testing, and the consignment is delayed from being cleared. Not only does this delay cost the importer time and money, but TBS also suffers a resource drain given the expense of running the tests and testing facility capability gaps.

Figure 8: Pre-Shipment Verification of Conformity Procedure



Source: New Markets Lab, 2016

Figure 9: Importation Process for Cosmetic Product or Ingredients for Cosmetic Products



Source: New Markets Lab, 2016

Key Takeaways: Regulatory Process for Importation of Cosmetics Products

- One of the more challenging aspects of importation is due to the parallel processes maintained by TFDA (Steps 3-6; Step 18 in Figure 9) and TBS (Step 7 in Figure 9 as broken out in Figure 8). Despite the PVoC process depicted in Figure 8, TBS may still inspect upon arrival, creating multiple processes for inspection both pre- and post-arrival.
- Some industry representatives have advocated that TFDA be the primary agency involved in importation, but pre-shipment verification of conformity can have advantages. In reality, the process could remain complicated until an assessment is done of where TFDA and TBS are perhaps fulfilling overlapping roles.

Customs Valuation

Customs valuation is central to trade in any product, and, as a key factor in tax liability, it is important to consumers and producers alike. The customs valuation process involves verification by customs officials of the value of a good, which is critical for calculating the duty amount paid by the importer. For SMEs, consistently applied duties can be a significant determinate of whether they can engage in international trade. Tanzania, as a Member of the WTO, grounds its customs valuation process in the principles contained in the ACV (Section 122 and the Fourth Schedule of the CMA). Tanzania's process involves a cursory screening and check on the declared value ("Import Procedures," n.d.). Under the ACV, the value for customs purposes of the imported goods must be based on the actual value on which duty is assessed and should not be based on "arbitrary" or "fictitious" values. Notably, PVoC programs are one way to help improve customs valuation practices, particularly for developing countries (Du Wulf & Sokol, eds., 2005).

Valuation must be determined according to one of the following six methods (Section 122 and the Fourth Schedule to the EACCMA):

- Transaction Value Method (Method 1)
- Transaction Value of Identical Goods Method (Method 2)
- Transaction Value of Similar Goods Method (Method 3)
- Deductive Value (Method 4)
- Computed Value (Method 5)
- Fall-back Value (Method 6)

These methods must be applied in sequence (Method 1- Method 6), starting with Method 1, and authorities may not proceed to the next method unless it is not possible to determine the value under the current method.

An accurate customs valuation is particularly critical for SMEs, who lack the ability to absorb unexpectedly high tax costs. A higher tax liability also translates to higher retail costs for consumers, which influences market demand and impacts the growth of the industry, particularly for a growing sector. Cosmetic companies have stated that the

process around which decisions on customs valuation are made is not sufficiently transparent and lacks consistency. To address this issue and enhance enforcement of valuation rules, clearer guidelines could be developed with input from the private sector that would reduce discretion by agents and help increase transparency. Use of advanced rulings also could be relied upon so that importers better understand the potential tax liability ahead of importation. ASEAN's harmonized rules provide an example of a good regulatory practice that could be tailored to Tanzania's needs and help inform discussions at the regional level.

Exportation of Cosmetics Products

A separate process is in place for exporting cosmetics, although all of the regulatory processes are interconnected as noted above. Exporters wishing to export cosmetics products from Tanzania must comply with general requirements that all exporters must adhere to, as well as several additional requirements particular to cosmetics. Under Section 2 of the **Importation and Exportation Guidelines (2015)**, exporters of cosmetics products fall under the following categories:

- (a) Registrant/marketing authorization holder of cosmetic products,
- (b) Cosmetic wholesalers appointed by the Registrant or Manufacturer of cosmetic product, or
- (c) Any other person authorized by the TFDA.

Exporters must obtain an export permit from TFDA, in addition to registering their premises with and obtaining valid licenses from TFDA (Guidelines for Importation and Exportation of Cosmetics Products, 2015; See also Figure 5 above).

The process for obtaining an export permit for cosmetics products appears to be quite straightforward. The application for an export permit is submitted to the **TFDA**, along with the appropriate fee as set forth in the **Fees and Charges Regulations** and assessed at TZS 50,000 (USD 23). The application form is prescribed in Annex VII of the Importation and Exportation Guidelines. Upon being satisfied by the information submitted in the application, the TFDA issues an Export Permit in the form provided under Annex VIII of the **Importation and Exportation Guidelines**. The permit is valid for three months from the date of issue, covers only one shipment, and cannot be transferred. The application will be rejected if it fails to meet any of the exportation requirements. The TFDA will give the applicant a rejection form stating the reason(s) for the rejection. According to the Guidelines for Importation and Exportation of Cosmetics Products, the export permit application is processed in two days.

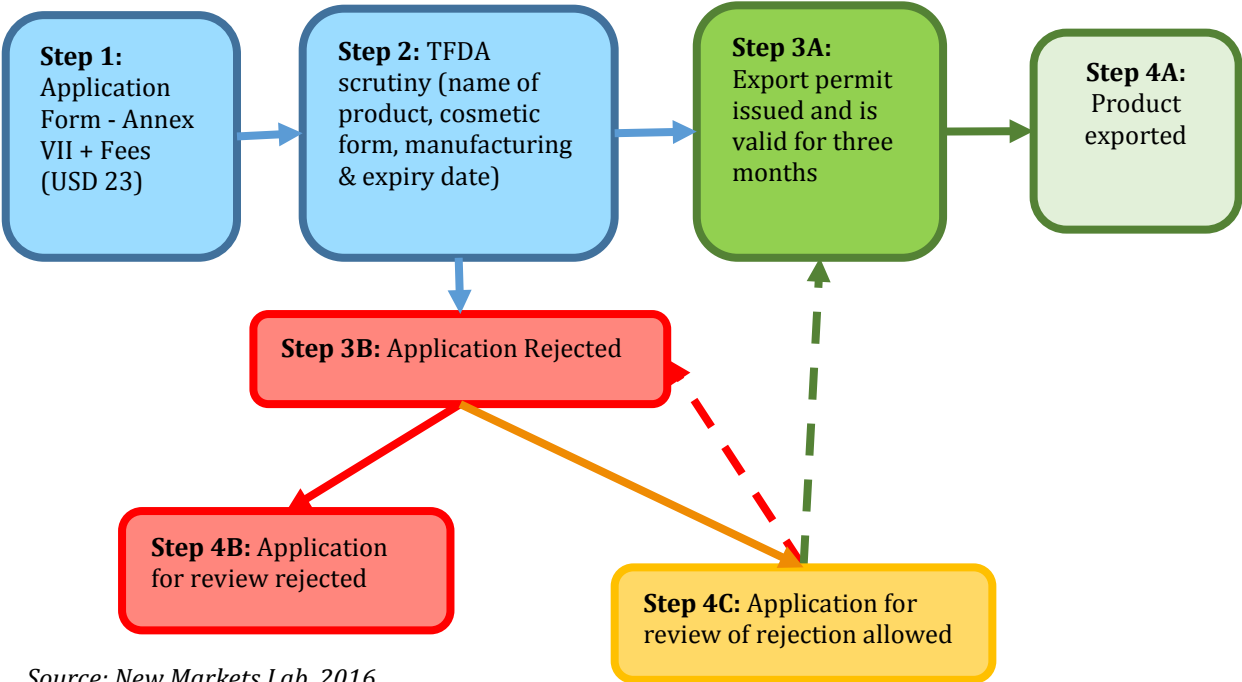
Before shipments can be examined and released for export in Tanzania, the exporter must work with a clearing and forwarding agent to submit the required documents online. Once completed, the export documents are uploaded into TANCIS for goods exiting the mainland and ASYCUDA++ for goods leaving Zanzibar. These required documents include the export permit issued by TFDA in the process described above. Additional required documentation

includes an invoice, packing list, TIN certificate of the exporter, and authorization letter. The exporter also may need to pay export taxes and duties. Once the goods have been cleared for export, the exporter notifies customs officials of its loading schedule. TRA oversees the transfer of the goods to the shipping container and approves the vessel schedule, loading report, and export manifest. Figure 10 below depicts the regulatory process for exporting cosmetics.

Although cosmetics stakeholders spoken with over the course of this project did not identify specific challenges with Tanzania’s export procedures, the World Bank Doing Business database shows that Tanzanian exporters experience higher costs (both in terms of expense and time) to comply with border and documentary export measures than their counterparts in sub-Saharan Africa (World Bank Doing Business Database, n.d.). Compliance with Tanzanian export measures costs traders an average of US \$1,160 versus US \$583 in sub-Saharan Africa (or US\$ 150 in OECD high income countries). In contrast, Tanzanian exporters spend approximately 96 hours to comply with border requirements compared with 103 hours in sub-Saharan Africa (or 12 hours in OECD high income countries) (World Bank Doing Business Database, n.d.).

In addition, it costs an average of US \$275 to comply with Tanzanian documentary requirements, versus US \$230 in sub-Saharan Africa (compared to US \$36 in OECD high income countries). It also takes approximately 96 hours for exporters in Tanzania to comply with documentary requirements compared to 93 hours in sub-Saharan Africa (or three hours in OECD high income countries) (World Bank Doing Business Database, n.d.).

Figure 10: Cosmetic Product Export Permit Process



Source: New Markets Lab, 2016

Key Takeaways: Regulatory Process for Importation of Cosmetics Products

- Although the exportation process on its own is relatively straightforward, it is closely tied to the regulatory process for registering manufacturing facilities (Figure 5), and delays or complexity in registering a manufacturing facility will spill over to exportation.
- In addition, due to the nature of the cosmetics sector, Tanzania's ability to increase exports is also closely tied to the ability to import needed inputs, so the relatively greater complexity surrounding imports shown in Figure 9 will also impact exports.

Streamlining export procedures and reducing documentary requirements can help lower the time and cost to export goods from Tanzania. Similarly, a focus on the implementation of laws and regulations could yield significant positive results by enhancing transparency and certainty for users of the system. In addition, a value-chain approach that benchmarks against good regulatory practices for cosmetics, from research and development to manufacturing to retail and cross-border trade, would help encourage increased exportation of cosmetics.

CHAPTER 4: RECOMMENDATIONS TO SUPPORT GROWTH OF COSMETICS INDUSTRY

A set of key findings emerged from the substantive analysis and stakeholder consultations that underpinned this study, which is a part of a larger process to foster a dialogue around issues in the enabling environment for business in Tanzania. Each of the recommendations below seeks to address a critical knowledge or implementation gap in the legal and regulatory system. While the recommendations include a discussion of regulatory options and good regulatory practices, further study on global best practices and their possible application in Tanzania and a more in-depth systems audit to identify overlapping and conflicting laws and regulations in the cosmetics sector would benefit both regulators and private sector stakeholders.

The Government of Tanzania clearly recognizes the important role that laws and regulations play in economic development and has been considering ways in which to improve its business enabling environment. The current legal and regulatory system for the cosmetics industry, an emerging growth sector that shares significant regulatory overlap with other key sectors (including medicines and agriculture), can be illustrative in identifying broader opportunities and challenges.

- The industry, like many sectors, experiences a disproportionately high concentration of regulatory oversight prior to market entry;
- Private sector stakeholders may lack knowledge of precise regulatory requirements or how measures will be implemented in practice; and
- Overlapping mandates exist among regulatory authorities, as the preceding chapter illustrated, sometimes with differing public policy goals such as increased manufacturing, environmental sustainability, and consumer health and safety, resulting in a system that can be complex for cosmetics companies to navigate.

Overall, regulatory objectives must be carefully balanced in order to avoid a situation in which the enabling environment discourages market development and creates barriers to entry for local and international companies alike. In such a case, it is often SMEs and women entrepreneurs who most heavily impacted, undercutting both market potential and broader economic development considerations.

(1) Benchmark Regulatory Options Along the Value Chain Against Good Regulatory Practices and International Standards

Laws and regulations form an intricate system of rules that govern processes all along the value chain and significantly impact the way industries and markets grow. A number of diverse regulatory options exist at multiple points along a value chain. Policymakers must carefully weigh the tradeoffs for each option and consider how to best design a legal and regulatory system in order to enhance economic growth; support increased investment and competitiveness of local firms; and achieve critical public policy objectives like

consumer and worker safety, job creation, and inclusive market development. Good regulatory practices from developed and developing countries around the world can provide guidance and important lessons. These good practices can then be refined and tailored into laws and regulations that respond to local conditions, including a country's current stage of growth and policy goals.

Good regulatory practices for cosmetics and the business enabling environment in general provide important insights into options that can facilitate growth along the entire cosmetics value chain, from research and development, to manufacturing of products, to distribution and sale. Spacing out regulatory functions along the value chain and allowing for more efficient use of resources can help build capacity for both private and public sector stakeholders. There are a number of ways in which Tanzania could shift some of the regulatory burden off of market entry and reallocate resources to reinforce good manufacturing practices and post-market surveillance.

A number of these options are described in the recommendations below, and there is no "one-size-fits-all" approach. The United States offers one example of a type of regulatory approach See Box 1. In the United States, the Food and Drug Administration (FDA)

regulates cosmetics, but some notable differences can be seen between the U.S. and Tanzanian systems. While individuals who manufacture and market cosmetic products are legally responsible to ensure their safety, the U.S. FDA does not mandate the registration of cosmetic products nor does it require preapproval of cosmetic products or their ingredients other than color additives (with an exception of coal tar hair dyes) before the products enter the market (FDA

Box 1: Key Features of U.S. Regulatory System for Cosmetics

U.S. FDA does not mandate registration of cosmetics products, encouraging firms instead to participate in the Voluntary Cosmetic Registration Program (VCRP). Differences between the U.S. FDA and Tanzania's system include:

- Product registration not required
- Notification by manufacturers
- Specific safety tests

However, U.S. FDA does require that:

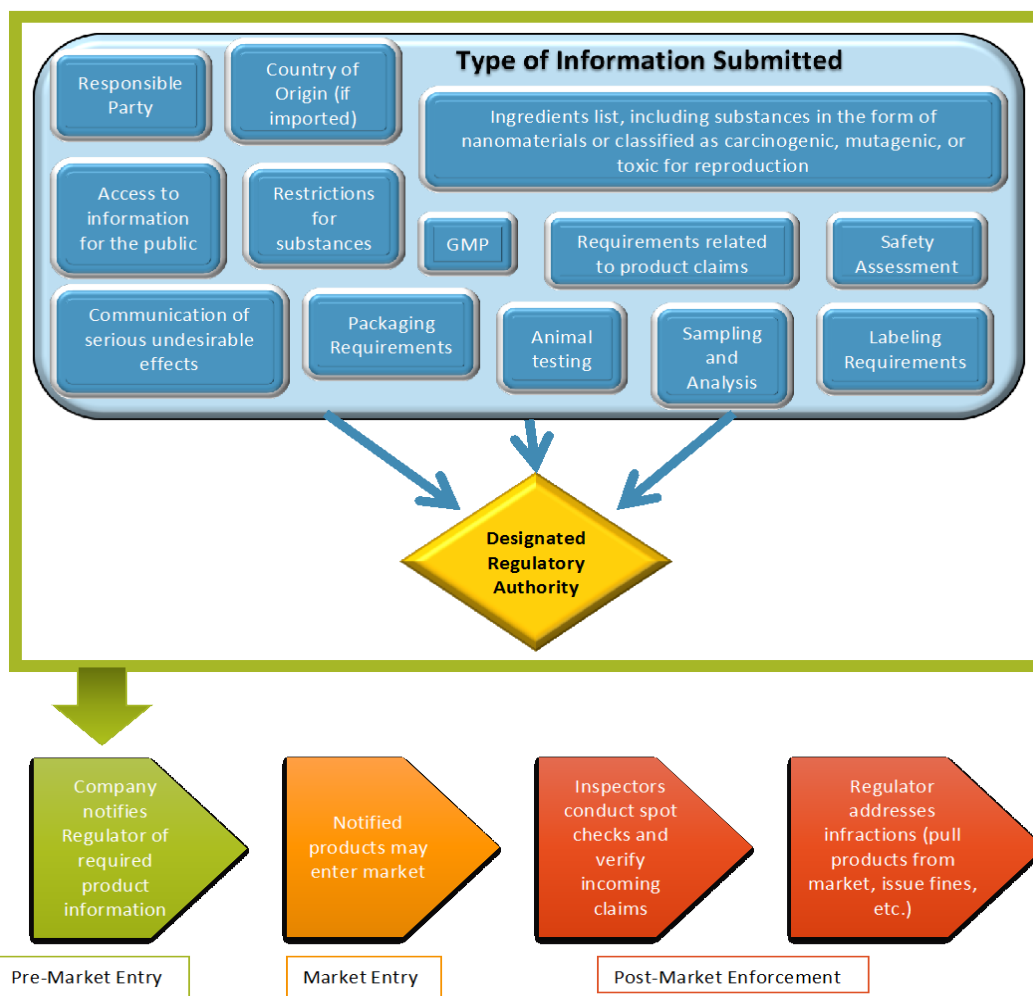
- Products for sale must be properly labeled
- Cosmetics products and ingredients must be considered safe under customary conditions of use or per product use instructions
- Cosmetic ingredients must not cause the product to be adulterated or misbranded
- Cosmetic ingredients may not appear on the prohibited or restricted ingredients list maintained by U.S. FDA
- Cosmetic ingredients containing color additives and coal tar hair dyes require approval before sale
- Cosmetic manufacturing facilities permit U.S. FDA to conduct inspections and collect samples to conduct safety assessments

website, n.d.). Except for color additives and prohibited or restricted ingredients on the list maintained by the U.S. FDA, a manufacturer is, in general, allowed to use any ingredient in a cosmetic product, if (1) the ingredient and the finished product are safe under labeled or customary conditions of use, (2) the product is properly labeled, and (3) the use of

ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that U.S. FDA enforces. The U.S. FDA also does not require specific tests of cosmetic products or their ingredients to demonstrate their safety nor does it mandate cosmetic companies to share their safety information with U.S. FDA. However, U.S. FDA can collect samples for examination and analysis as part of cosmetic manufacturing facility inspections, which are carried out to assure safety of cosmetic products and assess whether those products are adulterated or misbranded.

The U.S. system is only one approach to regulating cosmetics. Many countries have or are transitioning to a *notification system for cosmetics* as an alternative to product registration.

Figure 11: Overview of Notification System for Cosmetics



Source: New Markets Lab, 2017

A product notification system, illustrated in Figure 11 above, requires a company to submit to the relevant authority (TFDA in Tanzania’s case) key information relating to the product. This includes details about the responsible party; the country of origin in the case of importation; and the list of ingredients, including any substances in the form of

nanomaterials or anything classified as carcinogenic, mutagenic, or toxic for reproduction. This basic information often is supplemented by other data and records requirements. For example, the EU also requires information relating to GMP, safety assessment, sampling and analysis, restrictions on substances, disciplines on animal testing, packaging and labeling requirements, requirements related to product claims, access to information for the public, and communication of serious undesirable effects.

A notification system shifts some of the burden from regulators to the private sector and allows regulators to be more effective at different points within the market, such as enforcement post market entry. In fact, this shift is also occurring on a regional level, as seen in the TPP annex on cosmetics discussed in Chapter II above, which commits partner states to consider transitioning to a notification system by which companies increase their responsibility of ensuring cosmetics products and ingredients meet quality and safety standards. For example, in order to support more efficient use of resources and facilitate market growth, as well as achieve policy objectives, Tanzania might consider a standards-based regime, which could maintain a role for TFDA in the manufacturing process but replace product registration with a notification system and increase collaboration with other governments to facilitate trade (including through regional harmonization efforts). Importantly, TFDA's involvement in enforcing GMP would help ensure that products made in Tanzania are safe and help alleviate the need for product registration.

Alternatively, if product registration continues to be required, a change in the way it is conducted may help address some of the challenges associated with the process. That could include reducing the requirement for registration for nonmaterial changes, adding an altered product to an existing registration, or limiting the need for registration renewal.

In order to address these issues more fully and use resources more efficiently, streamline the legal and regulatory system, and significantly improve the business enabling environment, Tanzania, with support from international institutions, could conduct a full systems audit that identifies conflicting laws and regulations and overlapping regulatory mandates for cosmetics and related sectors (such as those for TFDA, GCLA, and TBS). For example, many countries have simplified the application of standards such that they are administered by a single regulatory authority. Tanzania's MIT has already commissioned a high-level independent committee advising the Permanent Secretary on business enabling environment reform more broadly. A systems audit could support this work and would be significant not only for the cosmetics industry but also for other important sectors, including food, pharmaceuticals, and medical devices.

In some countries, including emerging economies, *simple tracking systems* have been put in place that allow consumers and inspectors to more easily identify counterfeit products. These practices can not only support enhanced consumer protection, but they can be designed and implemented in a way that fosters growth of an industry and allows companies to more easily take advantage of market opportunities at the national, regional, and international levels.

Further, **trade facilitation reforms** have been found to improve the export performance of emerging markets, especially alongside reforms in infrastructure and the business enabling environment (Portugal-Perez & Wilson, 2012). In particular, transparency measures around customs processes and customs valuation determinations not only help companies understand the rules they must abide by but also help customs authorities combat improper invoicing that results in lost revenue for the government.

Although relatively few countries in sub-Saharan Africa have such a comprehensive system for cosmetics regulation, governments are noticing the growth potential that exists in the cosmetics industry and are beginning to design their own regulations. Within the EAC in particular, only Tanzania has a comprehensive system governing cosmetics. Rwanda, Uganda, and Burundi have started to consider developing their own regulations specific to cosmetics, and Kenya may soon look to enhance its own cosmetic regulations. As the newest EAC member, South Sudan is currently focused on measures to bring its legal regime into compliance with the EAC. As Tanzania examines ways to improve its system, it also has an immense opportunity to emerge as a leader within the region and on the continent.

Policy options include:

- Conduct a deeper regulatory systems audit that analyzes conflicting regulatory processes and overlapping mandates for cosmetics. This could include:
 - Ensuring laws and regulations are open and transparent.
 - Assessing Tanzania's alignment with international requirements, guidelines, and standards for cosmetics, including GMP.
- In the longer-term, transition to an ex post, standards-based system (including GMP) headed by a single regulatory authority with oversight over the streamlined system for cosmetics.

(2) Apply Global Good Regulatory Practices to Product Registration

Currently, Tanzania heavily regulates market entry in the cosmetics industry, but other regulatory approaches exist that could both allow for oversight of the sector and better support policy and regulatory objectives, including increased manufacturing, job creation, and health and safety. In particular, Tanzania requires registration of all cosmetics products before they enter the market (see Figure 6 in particular). However, many stakeholders report that the process is opaque, time consuming, and costly. In addition to submitting a new application when a product is modified (which can include even small changes such as different shades of lipstick), all product registrations must be renewed after three years in order for regulators to ensure that recent advances in research and information do not impact the product's safety.

For companies and investors, the current system acts to limit introduction of new products, ingredients, and innovations already considered safe and approved for use in other countries. Cosmetic and personal care products share some market characteristics with advanced technology items and fashion, where consumers demand access to the latest

products and innovations available in the global marketplace without delay. This market dynamic could be balanced with protection of health and safety through a process that allows for new products to enter the market if the underlying composition has already been tested for safety. Given TFDA's broader mandate and limited personnel, it is important for cosmetics regulations to be as streamlined and efficient as possible in order for TFDA to make the best use of its limited resources, focusing on new products only and effectively allocating institutional capacity to higher-risk sectors like food and drugs.

As noted above, alternate regulatory practices exist to product registration, which could both reduce the burden on industry and help regulators better achieve their public policy objectives. For example, while product registration places the burden primarily on regulators, a product notification system would require more even-handed division of resources and responsibility. Such an approach would shift the regulatory burden somewhat so that it is shared by the regulator and the entity responsible for the product's entry into the market, leaving the regulator to focus on critical enforcement functions, including cracking down on poor quality products and counterfeits in the market, and creating greater responsibility for market actors. It would also eliminate the need for upfront testing by permitting companies to self-regulate, with key checks for enforcement by regulators. Under such a system, limitations still can be placed on harmful or dangerous ingredients and substances without the need for product registration.

In addition to taking more responsibility for the product before it enters the market, companies also would play a role in enforcement and would be required to inform regulators of any non-compliance issues. In such a case, appropriate corrective measures would need to be taken, including possible withdrawal of the product from the market.

Under a notification system, regulators would still have the power to recall products deemed unsafe for consumers, and resources could be shifted towards that end. By requiring companies to share more responsibility, resources could be allocated differently so that regulators could begin to build greater capacity for post-market surveillance and enforcement activities. Lessons from post-market surveillance could be shared and applied to other sectors, particularly pharmaceuticals and food, which are also closely regulated by TFDA but which involve higher-risk products. A study on best regulatory practices on post-market enforcement, with a focus on the experience of developing countries, could enhance the development of an efficient and effective notification system in Tanzania.

A notification system is one way to balance regulatory interventions along multiple points in the value chain, as opposed to simply focusing on market entry (ex ante regulation), which currently does not adequately address concerns such as counterfeiting. Application of this good regulatory practice could enable the market to grow while allowing regulators to more efficiently allocate resources and better achieve public policy goals, and a notification system could be easily maintained at the regional level as well.

Policy options include:

- Transition from product registration system to notification system.

- As an initial step, conduct a review of countries that have experienced the transition to a notification system, such as Saudi Arabia, to learn from their experiences.
- In the short-term, reduce registration requirements for nonmaterial changes, adding an altered product to an existing registration, or limiting the need for registration renewal.

(3) Enhance Transparency in the Customs Valuation Process

Enhancing enforcement of customs valuation rules can positively impact both companies and customs officials charged with collecting accurate import duties. While Tanzania's rules on customs valuation are relatively clear, implementation is reported as inconsistent and often opaque. In practice, despite international practices, the invoice value is rarely accepted for cosmetics products, resulting in higher tax liability for importers. Although there are legitimate public policy concerns related to customs valuation, this challenge has ripple effects that impact not only enterprises, in particular SMEs, but also increase the price for consumers and ultimately negatively affect market growth.

A 2014 report by Global Financial Integrity (GFI) found that improper trade invoicing made up more than two thirds (80 percent) of the US \$542 billion annual figure for illicit financial outflows from developing countries during the years of 2002 to 2011 (Baker et al, 2014). This can occur as both under-invoicing, which allows the importer to reduce the amount of duties or VAT owed, or over-invoicing, which hides outflows of capital to decrease corporate taxes (Baker et al, 2014). Of the five countries studied (Ghana, Kenya, Mozambique, Tanzania, and Uganda), Tanzania had the largest annual average gross illicit flows of US \$1.87 billion. The GFI report authors found "[g]reater transparency is the key to designing new or improving policies to address these illicit transfers of capital out of the countries. Governments need to be able to see where, how, and at what value trade flows are moving across their country's borders, so that they can try to detect, deter, and prosecute any abuses of the laws governing these transactions." (Baker et al, 2014, p. viii).

To help increase transparency and address challenges with customs valuation, Tanzanian customs authorities could establish clearer, more detailed guidelines for customs valuation. The guidelines would be helpful for industry users of the system and would help enhance enforcement by customs officials in order to ensure that accurate import duties are collected. For example, such guidelines could provide clear examples of conditions under which customs authorities may reject an invoice price and set parameters to establish that the price had been settled in a manner consistent with certain factors, including:

- The normal pricing practices of the industry in question;
- The way in which the seller settles prices for sales to buyers in arms-length transactions; or
- Demonstrating that the price had not been influenced where the importer can show that the price is adequate to ensure recovery of all costs plus a profit which is

representative of the firm's overall profit realized over a representative period of time (for example, on an annual basis) in sales of goods of the same class or kind.

Guidelines could be developed in close consultation with the private sector to ensure that challenges with valuation are addressed. A public-private dialogue would help regulators better understand the challenges faced by the industry and would help industry participants better understand the valuation process and priorities of government. To support enhanced transparency, guidelines should be published and shared widely once completed.

Policy options include:

- Develop Customs Valuation Guidelines in close consultation with the private sector to ensure they address challenges face by the industry as well as take into account the critical government priority of ensuring appropriate valuation.
 - The Guidelines could also be useful in helping customs officials collect accurate import revenues.
- Publish the Customs Valuation Guidelines and update them as revisions occur, sharing widely with interested stakeholders.

(4) Streamline Importation Procedures for Cosmetics

Clearance of imports is a vital step in ensuring the safety of cosmetic products on the market, regardless of whether the imported goods are raw materials for domestic processing or final products that can increase demand in Tanzania. Yet, in order to continue to create and meet market demand for cosmetics and also attract investment, import procedures for cosmetics products should be simple and efficient. Regulations should aim to create the necessary balance between assuring safety of cosmetic products on the market and facilitating easy and effortless clearance procedures. At present, users of Tanzania's system report that it is complex, time-consuming, and costly, especially for small businesses and women entrepreneurs. Streamlining and increasing transparency of import procedures can have a positive impact on both economic development and increasing government revenue.

To help streamline the process for both companies and regulators, TFDA could consider adopting a PVoC program like the one applied by TBS (see Figure 8). As noted, transparent PVoC programs can also help improve customs valuation practices (Du Wulf & Sokol, eds., 2005). Currently, TFDA inspectors at the port of entry inspect consignments to ensure compliance with applicable standards and ensure the goods have a proper permit (see Steps 3-6 and Steps 18 – 19C in Figure 9). Although TFDA may not inspect every consignment that is imported, this inspection process has some overlap with the pre-arrival permitting, registration, and licensing by TFDA discussed in the previous chapter and can cause unnecessary delays to importers. By adopting a more formal PVoC process, TFDA could make better use of its resources and agents, which are spread thin across multiple industries including higher risk (and high priority) sectors such as food and pharmaceuticals. TFDA also could consider developing guidelines like those recommended

for customs valuation. The guidelines could describe the circumstances under which TFDA agents inspect consignments upon arrival, what they look for, and other details that could help companies better comply with import requirements. Like the proposed guidelines for customs valuation, guidelines for TFDA inspection of consignments should be developed with input from the private sector and shared widely when completed.

Policy options include:

- TFDA could consider adopting a PVoC program similar to that of TBS to help streamline the process for both regulators and companies.
- Develop guidelines, in close collaboration with the private sector, in order to increase transparency around the TFDA inspection process to help companies better comply with import requirements.

(5) Enhance Implementation of Exportation Procedures

The World Bank has documented that although Tanzanian exporters spend slightly less time complying with border measures than exporters in other countries in sub-Saharan Africa, they spend significantly more money doing so. In addition, compliance with Tanzanian documentary requirements costs Tanzanian exporters both more money and time than their counterparts in sub-Saharan Africa. While streamlining procedures and reducing documentation requirements can help reduce the time and cost that traders endure when exporting from Tanzania, even-handed and consistent application of export processes and requirements (including regional trade frameworks) is also critical. Enhancing transparency could help increase certainty and reduce the amount of time exporters spend navigating export processes, which would also save the exporter money and helps increase competitiveness.

Notably, streamlining export procedures alone cannot significantly increase exports of cosmetics products. A value chain approach, referenced in the first recommendation, that includes improved export processes would make a dramatic difference that would help address issues within the entire system to enable manufacturers, processors, and retailers to access regional and international markets and encourage investment in Tanzania.

Policy options include:

- Enhance implementation of export procedures, including regional trade and trade facilitation measures.
 - Implementation could be enhanced through entrepreneur case studies and test cases that document the experience of enterprises in navigating export procedures and share findings with policymakers. This could be done in collaboration with the institution discussed in the final recommendation below.
- Develop Exportation Guidelines, in close collaboration with the private sector, in order to increase transparency around export requirements and processes to help

companies better comply with export rules, increase transparency, and support increased knowledge and dialogue among the different regulators involved.

- Publish Exportation Guidelines, ensuring they are updated as revisions occur and are shared widely with interested parties.

(6) Lead Harmonization of Regional Regulatory Processes

Harmonized regional rules for cosmetics could increase the size of the cosmetics market and attract investors. Currently, Tanzania's cosmetics market lags behind its neighbors. For instance, the value of intra-EAC trade in cosmetics for Tanzania stood at US \$3 million for exports and US \$8.41 million for imports. However, a large amount of cosmetic imports to Tanzania, US \$6.89 million, came from Kenya (EAC, 2014), demonstrating a notable imbalance in trade in cosmetic products among Tanzania and its neighbors. The experience of regional cosmetics wholesalers and distributors also is instructive. One operator disclosed that in Kenya, more than 25,000 product lines are stocked for sale and distribution, compared to only 11,000 products in Tanzania.

Tanzania is one of the only countries in the EAC and SADC with a well-defined regulatory system for cosmetics and, therefore, could take a lead in regional harmonization (as it has done in other sectors) by taking steps to advance the adoption of a harmonized framework to regulate cosmetics. The harmonized system should be designed in a way that aligns with global good regulatory practices, for example, through a regional notification system, and international standards, including ISO good manufacturing practices.

Both the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme and the cosmetics annex to the chapter on Technical Barriers to Trade of the TPP Agreement provide good examples of harmonized regulatory frameworks that enable countries within a region to better take advantage of the growing demand for cosmetics and access larger populations with growing middle classes. These agreements, particularly TPP, were designed based on global good regulatory practices for the cosmetics industry. The ICCR's regulatory principles on cosmetics for sub-Saharan Africa also could serve as a helpful tool for Tanzania and other partner states as they consider development of a harmonized cosmetics scheme for the EAC, SADC, and eventually the TFTA.

Over the longer term, a harmonized framework would enhance Tanzania's competitiveness in the region. Tanzanian industry stands to benefit from domestic and regional demand for cosmetic products, given that its agricultural sector produces several key inputs used in cosmetics manufacturing. Since it has the largest market in the region, harmonization of regional practices also could unlock the significant hidden and unexplored potential of Tanzania's cosmetics market.

Policy options include:

- In the short term, conduct a study on multilateral and regional harmonization efforts for cosmetics regulation, including ASEAN Harmonized Regulatory Scheme

and the cosmetics annex to the chapter on Technical Barriers to Trade of the TPP Agreement

- Engage with private sector stakeholders in Tanzania’s cosmetics sector, perhaps through a workshop, to inform the regional harmonization process. This could perhaps be facilitated through the EABC or other industry associations as appropriate.

(7) Identify Institution to Facilitate Further Study and Stakeholder Dialogue

Given the growth potential in the cosmetics sector and interest in improving the business enabling environment, an institution could be identified (or perhaps created if necessary) that could facilitate further study and enable sector stakeholder collaboration and information exchange. Stakeholder input could be developed based on feedback from diverse stakeholders along the cosmetics value chain, including raw materials producers, cosmetics manufacturers, wholesalers and retailers, as well as consumer representatives. Existing industry associations, such as the Confederation of Tanzania Industries (CTI) or Tanzania Chamber of Commerce, Industry & Agriculture, could be potential institutions through which this work could be done.

During the field visits and consultations under this project, it was apparent that there is a gap in information exchange between the public and the private sectors. Bridging this gap would be mutually beneficial to regulators, private businesses, and consumers. Regulators would have an opportunity to share information with the private sector on the steps being undertaken to ensure that quality products are released to the market, and transparency in all health and safety decisions related to cosmetics also would increase consumer confidence without overburdening manufacturers, wholesalers, and retailers or stifling their ability to strongly compete with their counterparts in the region. The private sector, for its part, would have an opportunity to share the challenges and bottlenecks faced with respect to regulations and policies that prevent enterprises from realizing their full potential and succeeding in the rapidly changing and highly competitive cosmetics industry.

In addition to enhancing the enabling environment for cosmetics within Tanzania, an institutional partner also could support efforts aimed at regional harmonization in the EAC, SADC, and eventually TFTA, as well as share success stories and lessons learned through international fora like the ICCR in order to help inform efforts underway to harmonize international rules and standards for the industry. Other models for developing harmonized schemes on cosmetics, including the ASEAN system, could possibly provide useful lessons on how to engage diverse stakeholders in support of broader harmonization and an improved enabling environment.

Policy options include:

- Identify existing institution or industry association to facilitate further study and stakeholder dialogue, including around regional harmonization issues.

- Coordinate private sector input to inform the other policy options listed above, including assisting with development and dissemination of guidelines for trade processes, identifying implementation challenges associated with export requirements, and providing feedback where appropriate on regulatory processes.

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Annex I: Formation and Registration of a Company

- *Step 1: Conduct Name Search:* The company obtains clearance to use its proposed corporate name by submitting three names either by mail to the Registrar of Companies or at the counter of **BRELA**. Depending on the availability, the Company Registrar then approves one of the names proposed.³ Name search is free of charge and typically takes one day, depending on the backlog at the Companies Registry.
- *Step 2: Register the Company's Business Name:* The company registers the approved business name as required under the **Business Names (Registration) Act (Cap. 213)** by filling Form Number 1 with **BRELA** to disclose the nature, physical location, telephone number, and e-mail address of the business. The filing fees for the registration of the business name is TZS 15,000 (USD 6.85) and the process should conclude within one business day. The **Companies Act, 2002 (Cap 212)** also provides requirements regarding company names.
- *Step 3: Lodge Company Incorporation Documents:* A subscriber, secretary, or director named in the Articles of Association of the proposed company submits to the **Registrar of Companies** forms 14a (discloses the names of the first directors of the company, the secretary and the physical location of company's office) and 14b (a declaration that the company complies with all statutory requirements for the registration of a company) as well as the Memorandum and Articles of Association of the company. The filing fee is TZS 45,000 for each form. A stamp duty fee of TZS 6,200 also is payable on the original memorandum and articles of association plus TZS 5,000 for every additional copy. The company registration fee is based on the company's share capital.
- *Step 4: Obtain Company Certificate of Incorporation:* The company registration process usually takes four days. However, due to a backlog at the **Companies Registry**, the process may take longer than one week to conclude. A Certificate of Registration (Incorporation) demonstrates that an entity exists as a formal corporate entity recognized by law. Company incorporation process is governed by the **Companies Act, 2002 (Cap. 212)** and its implementing regulations.
- *Step 5: Taxpayer Registration:* This step is governed by the **Tax Administration Act, 2015** and implementing regulation and requires the cosmetics business to obtain a taxpayer identification number (TIN) from the **TRA** and requires the physical presence of one of the directors of the company to give their fingerprints (biometric data). At the TRA office, the tax officer may interview the director to record their business and personal background. The company also declares its estimated income or turnover for the provision of tax assessment. If the proposed cosmetics firm will have an annual revenue of over TZS 40 million, then it applies for a value-added tax

³ If the search reveals a similar name in the Companies Register, the proposed name will be rejected. The applicant has the option of submitting a fresh name.

(VAT) certificate. This process is free of charge and takes about four business days to conclude.

- *Step 6: Compliance with Social Security Requirements:* The business also must obtain a social security number at the **Social Security Regulation Authority (SSRA)**. This process is free of charge and takes seven days to conclude. It is governed by the **Social Security Regulatory Authority Act (Cap. 135), 2015 (SSRA Act)** and its implementing regulations and guidelines.
- *Step 7: Compliance with the Workmen's Compensation Insurance Requirements:* Companies must register for workmen's compensation insurance, which is regulated under the **Ministry of Labor and Employment** and governed by the **Workers Compensation Act (No. 20), 2008** and its implementing regulations. The insurance may be obtained through the **National Insurance Corporation (NIC)**. The cosmetics firm also may opt for a private insurance provider instead of the workers' compensation insurance. To register for workers' compensation insurance, a firm completes the Workmen's Compensation Tariff Proposal Form once it starts hiring employees and just before it becomes operational. This process is free of charge and takes one day to conclude.
- *Step 8: Business License:* Finally, a company must apply for a business license from the **Ministry of Industry and Trade (MIT)**. The process is governed by the **Business License Act (No. 25 of 1972)** and its implementing regulations. Together with the application, the firm must submit its certificate of incorporation; memorandum and articles of association; proof of a suitable company premises; and taxpayer identification number. The application fee for this process, which takes six business days to conclude, is TZS 1,000.

Compliance with the above process should take about 20 working days. However, the potential existence of a backlog in one of the offices could cause the process to take longer than it should.

Annex II: Process to Obtain EIA Certificate for Cosmetics Manufacturing

- *Step 1: Registration with NEMC*
- *Step 2: Complete Preliminary Environmental Assessment Form:* With the help of an environmental expert, applicant must fill out a 'Preliminary Environmental Assessment Registration Form' for the project. The expert must be registered by NEMC as required under Environmental (Registration of Environmental Experts) Regulations, 2005. The application fee is TZs 70,000 (USD 32).
- *Step 3: Submission of Application Form and Project Brief:* Applicant must prepare a project brief, which must comply with Environmental Impact Assessment and Audit Regulations, 2005. The applicant must submit to the NEMC three copies of a duly filled Application Form attached with 10 copies of the Project Brief for screening by NEMC. The NEMC should approve the screening report within 45 days from the date of submission of the brief (Environmental Impact Assessment and Audit Regulations, 2005, Section 10(1)).
- *Step 4: Submit Scoping Report and Terms of Reference (TOR):* Environmental expert/EIA consultant prepares and submits Scoping Report and TOR to the NEMC for review and approval to conduct the EIA. NEMC's approval should be given within 14 days. (Environmental Impact Assessment and Audit Regulations, 2005, Section 13(2)).
- *Step 5: Approval of Scoping Report and TOR by NEMC*
- *Step 6: Conduct EIA Study:* Applicant's consultant will conduct the EIA study in accordance with the TOR and in compliance with the EMA and the Environmental Impact Assessment and Audit Regulations, 2005. The timeframe required to conclude the EIA will depend upon the type and complexity of the individual project.
- *Step 7: Submit the EIA Report + Submission Form to TAC:* The EIA report and submission form (form no. 2) are presented to the **NEMC** for review by a Cross-sectoral Technical Advisory Committee (TAC), which may include TFDA. Prior to the review by TAC, NEMC and the applicant will facilitate consultation with all persons likely to be affected by the proposed project. This requires the applicant to:
 - Publicize the project and its anticipated benefits and effects using posters
 - Publish a notice for two successive weeks in a newspaper with national circulation
 - Advertise on national radio hold public hearings and ensure the minutes of the public meetings are recorded.

Oral and written comments and minutes of the meetings are attached as an annex to the EIS, once the EIS is complete. Section 87(1) of EMA requires TAC to conclude its review within 60 days following submission of the EIA report.

- *Step 9: TAC gives Recommendation:* The **TAC** gives its recommendations and comments on the EIS study for consideration by the applicant's consultant.
- *Step 10: Submit Final EIA Report for Scrutiny:* Upon compliance with the TAC's recommendations, the consultant will submit the final version of the EIA to the **NEMC** to scrutinize and forward recommendations to the **Minister of Environment** for final approval.
- *Step 11: Minister's Approval or Rejection of the EIA:* The **Minister of Environment** will either approve or reject the EIA within 30 days of receipt as per section 92 of EMA.
- *Step 12: Issuance of the EIA Certificate:* If approved, the signed EIA Certificate, together with the general and specific conditions to be followed, will be issued to the applicant.

Annex III: Import Permit for Cosmetics

The **TFDA** established an online web portal for handling import and export permit applications where an applicant applies for login credentials by filling the customer registration form available online. Section 1 of the Importation and Exportation Guidelines qualifies the following as importers of cosmetics products:

- (a) Registrant/marketing authorization holder of cosmetic product;
- (b) Cosmetic wholesalers appointed by the Registrant or Manufacturer of cosmetic product; and
- (c) Cosmetics manufacturers for importation of raw materials for manufacture of cosmetics.

Importers must register their premises and possess a valid license issued by TFDA.

All imported cosmetic products in Tanzania must be registered by the TFDA before arrival, enter through an official point, and have a shelf life of at least 24 months (the Importation and Exportation Guidelines). Prior to shipment, authorized importers submit a permit application to TFDA, along with an original pro-forma invoice from the marketing authorization holder of the product or authorized supplier. If the application meets the prescribed requirements, then the applicant pays an import fee as provided in the **Tanzania Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2015**. The import fee is one percent of the value of the imported cosmetic product (Free on Board (FOB)) and receives an import permit. Applications for importation of cosmetic products are processed within two working days.

Annex IV: Additional Detail on Importation Procedures

Pre-Shipment Verification of Conformity (PVoC) by TBS

TBS implements a product conformity assessment program for the control of certain categories of imported goods. Under the Pre-Shipment Verification of Conformity (PVoC) program, all regulated products to be imported to Tanzania must undergo verification and testing in the country of supply and a Certificate of Conformity (CoC) must be issued to demonstrate that the goods meet the requirements of the applicable national standards or approved equivalents and technical regulations. The CoC is mandatory for customs clearance. The guiding principle of the PVoC program is based on Article 5 of WTO Agreement on Technical Barriers to Trade (TBT Agreement), which requires that technical requirements (i.e. standards) applied to foreign products also must be applied to domestically manufactured products.

Three companies, SGS Tanzania Superintendence Co. Limited, Intertek International Limited, and Bureau Veritas/BIVAC implement the PVoC program in Tanzania. Every consignment of imported goods that contain regulated products must be accompanied by a CoC issued by the PVoC Country Offices (offices operated and managed by authorized PVoC Contractors) prior to shipment.

The verification process begins by the cosmetics exporter submitting to the TBS PVoC partner (Intertek, SGS or Bureau Veritas) the request for certification, pro-forma invoice, and conformity document (test reports, quality certificates, analysis reports, etc.). To obtain evidence that all requirements in the applicable standards or technical requirements are met, goods must undergo one or a combination of the verification processes, which include physical inspection, laboratory testing, factory audit and documentary verification.

There are three routes for certification under the PVoC: Routes A, B and C. Under Route A, products are tested and physically inspected for conformity with relevant standards and specifications. Route A is available for all products exported by traders or manufacturers and contains the following steps:

- a) Exporter submits Request for Certification (RFC);
- b) PVoC Contractor reviews RFC and documentation;
- c) Inspector inspects consignment;
- d) Consignment undergoes testing; and
- e) If compliant, PVoC contractor issues the Final Certification Document (Certification Decision/CoC).

Route B allows goods with “reasonable and consistent levels of quality” a fast track option through product registration by the PVoC contractor (Pre-Export Verification of Conformity to Standards, n.d.). TBS suggests this route for frequent exports of uniform products. Registered products must undergo continual compliance activities and may be

renewed after one year. In order to register a product, the exporter submits the application to the PVoC contractor for review, who accepts or denies it. If approved, the certification process involves the following steps:

- a) Exporter submits Request for Certification (RFC);
- b) Appointed inspector inspects the consignment;
- c) Consignment is subjected to random testing; and
- d) PVoC issues Certificate of conformity (CoC)/Non-Conformity Report (NCR).

Manufacturers who “can demonstrate existence of a quality management system in their production/ manufacturing process” may undertake Route C (Pre-Export Verification of Conformity to Standards, n.d.). Under Route C, production processes are subject to audits and manufactured products must be licensed, which may be renewed annually and must undergo continual compliance, by an authorized PVoC contractor. TBS suggests manufacturers with “high frequency/volumes of shipments” undertake Route C.

Product licensing involves the following steps:

- a) Exporter submits licensing application to PVoC contractor;
- b) PVoC contractor reviews the licensing application

Licensed products are subject to random consignment inspections and a license review. The PVoC contractor issues the CoC.

Pre-Arrival Declaration

Multiple authorities are involved in the pre-arrival declaration process. The customs control office of **TRA** plays an important role in customs clearance as per the CMA and the **TPA** has established a One Stop Centre (OSC) at the Dar es Salaam port. Document processing and cargo clearance procedures are streamlined under the OSC, which houses multiple government agencies with deputized representatives in order to simplify and enhance efficiency during the clearance process (Tanzania Ports Authority, 2015).

A pre-arrival declaration (PAD) facility allows importers/agents to start the clearance procedures before the goods arrive, which reduces clearance times and reveals to importers the amount of duties and taxes prior to the arrival of the goods (See “Pre-Arrival Declaration Procedure”, n.d.). PAD utilizes the Tanzania Customs Integrated System (TANCIS) in mainland Tanzania and the Automated System for Customs Data (ASYCUDA++) for imports through Zanzibar). These systems automatically reject incomplete or insufficient declarations through an Integrated Query System (IQS). Copies of required documentation are sent directly to the relevant authorities, e.g., TRA, TPA, and TFDA.

Customs Valuation

The customs valuation process involves the inquiry by customs officials into verifying the value of a good, which is critical for calculating the duty amount paid by the importer. For small and medium sized companies, the duty amount can be a significant factor in whether they can engage in international trade. Tanzania, as a Member of the WTO, grounds its customs valuation process in the principles contained in the ACV (Section 122 and the Fourth Schedule of the CMA). Tanzania's process involves a cursory screening and check on the declared value ("Import Procedures," n.d.).

After a customs authority receives an automatically generated e-mail notification from TANCIS during PAD, the official determines the customs valuation and classification and issues a Pre- Assessed PAD (P-PAD). The P-PAD for PADs submitted with complete set of final documents should be processed and issued within 48 hours. Appeals are allowed within 30 days of the decision for review by the commissioner. (Section 229 of EAC CMA). The commissioner's decision may be appealed to the Tax Tribunal (EAC Customs Valuation Manual, 2010).

Valuation must be determined according to one of the following six methods (Section 122 and the Fourth Schedule to the EACCMA):

- a) The Transaction Value Method; Para 2 and 9 of Part 1 of the Fourth Schedule to the EAC CMA, 2009 (Method 1), the Primary Method;
- b) The Transaction Value of Identical Goods Method; Paragraph 3 (Method 2);
- c) The Transaction Value of Similar Goods Method; Paragraph 4 (Method 3);
- d) The Deductive Value; Paragraph 6 (Method 4);
- e) The Computed Value; Paragraph 7 (Method 5); or
- f) The Fall-back Value; Paragraph 8 (Method 6).

These methods must be applied in sequence (Method 1- Method 6). Method 2 can only be considered if a value cannot be determined under the first method. Similarly, Methods 3 to 6 follow the same procedure. The only exception is that a customs officer has discretion on whether to reverse Methods 4 and 5 upon the request of the importer. Under the ACV, the value for customs purposes of the imported goods must be based on the actual value on which duty is assessed and should not be based on "arbitrary" or "fictitious" values.

After the customs valuation and classification process, **TRA** issues an Assessed PAD (A-PAD), which should be processed and issued within 24 hours after receipt of an A-PAD application. The A-PAD is uploaded into TISCAN to generate Tanzania Single Administrative Document (TANSAD) for electronic submission to TRA.

Customs Clearance

The documents to be attached to generate TANSAD include:

- e-bill of lading,

- e-commerce invoice,
- PAD,
- e-packing list,
- e-certificate of origin,
- A-PAD, and
- Import permit from TFDA.

The TANSAD is processed up to the point of payment before submission of the manifest. After accepted, an Acceptance Notice along with a Payment Notice is issued. The importer may submit an amendment to the notice if it disagrees with the payment notice, and receives an Amendment Acceptance Notice or an Amendment Rejection Notice from the customs authority.

Once the goods are cleared, the importer pays the required duties and taxes. There is a 25 percent duty for cosmetics and perfumes plus an excise duty of 10 percent. After the payment receipt is submitted to the cashier, payment is recorded in the TISCAN system and the customs officer enters the TANSAD registration number into TISCAN so the goods can be released.

TANSADs are directed into one of three channels:

- Green for direct release,
- Yellow for documentary check, and
- Red for scanning or physical verification.

Cosmetics are directed into the red channel to undergo joint inspections by the customs officer and **TFDA** inspector. First, the customs officer checks the documents and reconciles the information in A-PAD and TANSAD. Once the documents are approved, TFDA conducts a physical inspection.

On inspection, TFDA may approve, quarantine, or reject the consignment. The TFDA inspector may reject a consignment for not meeting importation requirements as provided under the Importation and Exportation Guidelines, and rejected goods may be re-exported or destroyed. Cosmetics rejected for quality reasons are destroyed at the owner's expenses. However, cosmetics rejected for being unregistered in Tanzania or not meeting labeling requirements may be re-exported to a third country on request. After payment is received and inspection completed, all agencies will circulate e-Release Orders as confirmation and an e-Gate Pass is issued under the OSC. Then the importer will be allowed to collect the cargo and exit the port.

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