

GUIDELINES FOR A CLIENT WHO WISH TO APPLY FOR REGISTRATION OF COSMETICS

NOVEMBER, 2022

ABBREVIATIONS AND ACRONYMS

FIFO First in First Out

FSC Free Sales Certificate

GMP Good Manufacturing Practice

ICID International Cosmetic Ingredient Dictionary

INCI International Nomenclature of Cosmetic Ingredient

TBS Tanzania Bureau of Standards

UV Ultra Violet

OAS Online Application System

TIN Tax Identification Number

TZS Tanzania Standards

DQM Director of Quality Management

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Director of Quality Management (DQM)

FOREWORD

TBS is mandated among other things to protect consumers against health hazards associated with cosmetics. One of the means for achieving this goal is subjecting imported cosmetics to evaluation to ascertain them compliance with set standards of quality and safety prior to authorizing their sale in Tanzania. A cosmetic that passes the evaluation is registered and registration certificate is issued as evidence that it may be allowed for sale in Tanzania.

These guidelines for product registration have been developed to describe the scope and provide minimum requirements for registration of imported cosmetics in Tanzania mainland. The guidelines explain Bureau's responsibilities and application procedures for obtaining product registration certificate.

The guidelines are divided in four chapters. Chapter one contains introduction whereas chapter two deals with general requirements for preparation and submission of applications for registration of cosmetics. It also details requirements for payment of fees. Chapter three contains categories of cosmetics and Chapter four deals with application steps for cosmetics registration, application for alteration of registered cosmetics and application for renewal of registration.

It is our hope that applicants will find the document easier to follow and be encouraged to apply for registration of their products, so as to comply with provisions of the Standard Act, CAP. 130 and relevant regulations.

It is expected that evaluation for safety of cosmetics will not only be thorough but also faster so effectively protecting consumers and at the same time promoting business and national economy as a whole.

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DEFINITION OF TERMS

	are defined specifically for the purpose of these guidelines:- Means the standard Act, CAP. 130;		
"Act"	means a person or company who may submit, to the		
"Applicant"	Bureau, application for registration of cosmetics		
"Advertisement"	means and includes every form of presentation, whether in means publication, or by the display of any notice or by means of any catalogue, price list, letter, whether circula or addressed to a particular person or by the exhibition of a photograph or acinematograph film, or by way of sound recording, sound broadcasting, or television or any means of communication;		
"Brand name"	means a trade name of the cosmetics;		
"Bureau "	means the Tanzania Bureau of Standards established by section 3 of the Acts;		
"Botanical"	means an ingredient that is directly derived from plant and that has not been chemically modified before it is used in the preparation of a cosmetic		
"Claim"	means any message or representation including pictorial graphics, symbolic or any form of representation which states, suggests or implies that a cosmetic has particular characteristics relating to its origin, function, nature composition or any other characteristics;		
"Colorants"	means substances which are exclusively or mainlineended to colour the cosmetics, the body as a whole of certain parts thereof, by absorption or reflection of visible light;		
"Cosmetic"	means any article intended to be used by means of rubbing, pouring, steaming, sprinkling, spraying on of otherwise applied to the human body or any part thereofor cleansing, beautifying, promoting attractiveness of altering the appearance and includes any article intended for use as component of a cosmetic, but excludes article intended for use in the diagnosis, treatment or prevention of diseases and those intended to affect the structure of any function of the body;		
"Fragrance"	means a substance used as an ingredient of cosmeti solely to impart odour to the product;		
"Free Sales Certificate"	means a document that indicates that the product is freel sold in the country of origin		
"Ingredient of a cosmetic"	means any substance which is a component of a cosmeti and includes coloring agents, botanicals, fragrance an flavour;		
"INCI name"	means a name used for listing an ingredient on a cosmetic product label;		

"Label"	means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed on or attached to a container;
"Labeling"	means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets.
"Label of a cosmetic"	means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any cosmetic;
"Leaflet of a cosmetic"	means and includes any written information related to a cosmetic;
"Manufacture of cosmetics"	means and includes all operations involved in the production, processing, compounding, formulating, filling, refining, transforming, packing, packaging, repackaging and labeling of the cosmetics;
"Manufacturer"	means a person or a firm that is engaged in the manufacture of cosmetics;
"National Standard"	means a Tanzania Standard prescribed by the Tanzania Bureau of Standards (TBS);
"Package"	means any box, packet or any other article in which one or more containers of cosmetics are to be enclosed in one or more other boxes, packets or article in question, the collective number thereof;
"Premises"	includes land, buildings, structures, basements and vessels and-(a) in relation to any building, includes a part of a building and any cartilage, forecourt, yard or place of storage used in connection with building or part of that building; and b) in relation to "vessel", means ship, boat, aircraft, and includes a carriage or receptacle of any kind, whether open or closed;
"Preservative"	means a substance which is added to a cosmetic for the primary purpose of inhibiting the development of microorganisms in that product;
"Prohibited Cosmetics"	means any cosmetic that contains prohibited ingredients;
"Prohibited ingredient"	means a substance which is forbidden to be a component of a cosmetic;
"Product Variant (s)"	For the purpose of this guideline product variants shall mean, items in a range of cosmetics, which are produced by the same manufacturer, similar in composition with the same brand and common name and are intended for the same use but differ in colours, fragrances, flavours or package material.
"Promotion"	means and includes advertising and any other activity undertaken to increase the supply, sale or consumption of a product or commodity.

"Registration of product"	means an official authorisation by the Bureau for the purpose of launching or release to the market after evaluation for safety and quality.
"Registrant (market authorization)"	means the holder of the authorization for the cosmetics, any person who may either be the trademark owner or person authorized by him, who has rights to sale the cosmetics and is responsible for placing the cosmetics on the Tanzania market;
"Sunscreen"	means cosmetics that protects the skin from the harmful radiation of the sun.

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Tanzania Bureau of Standards is a Parastatal Organization under the Ministry responsible for Industry and Trade. Specifically, the Bureau is mandated to prepare standards, promote standardization and undertake measures for quality control of products of all description in industry and commerce. The Bureau is further mandated by the Finance Act No. 8 of 2019 to regulate the safety and quality of cosmetics.

The mandates regarding cosmetics safety are vested under section 21(T-Y) of the Finance Act No. 8 of 2019. The mandates are further clarified under regulations 7-10 of the Standards (Imports Registration and Batch Certification) Regulations, 2021 and regulations 13-19 of the Standards (Registration of Premises and Certification of Products) Regulations, 2021.

All cosmetics to be imported, supplied, distributed, promoted or sold in Tanzania market should prior be registered by the Bureau. The guidelines aim to assist applicants to apply and register their cosmetics intended to be imported into Tanzania. It describes steps for submission of documentation for registration of new cosmetics, variation to registered cosmetics and renewal of registration.

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CHAPTER TWO

2.0 GENERAL REQUIREMENTS

2.1 Language

All applications for cosmetics registration and their supporting documents shall be in English/Kiswahili or both.

2.2 Cosmetics registration requirements

- 2.2.1 The cosmetics intended to be imported into Tanzania shall not contain poisonous or harmful substance that might injure users under normal conditions or be counterfeit cosmetics.
- 2.2.2 Application for cosmetics registration shall be made to the Bureau vide TBS online application system and shall be accompanied by the following documents; cosmetics label/label artwork, business license, certificate of analysis, material safety data sheet, product information leaflet where applicable, statement of authorization from the manufacturer (if any); and any other requirement as the Bureau may determine.
- 2.2.3 The importer of cosmetics shall have a registered cosmetic premises in accordance to the requirements prescribed in the Standards (Registration of Premises and Certification of Products) Regulations, 2021.
- 2.2.4 Application for registration of cosmetics shall be made on each product except for variant cosmetics.
- 2.2.5 Application for registration of cosmetics submitted as kit shall be treated as single application. However, each item in the kit shall be evaluated and tested separately.
- 2.2.6 Registration shall not apply to donated cosmetics, occasional cosmetics and any category of cosmetics as the Bureau may determine.

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2.2.7 During application, each cosmetics ingredient shall be declared by its specific name as provided by International Nomenclature of Cosmetic Ingredient name (INCI).

2.3 Marking and labelling requirements for cosmetics

- 2.3.1 Cosmetics shall not be sold unless it's marking and labelling complies with standard TZS 774/EAS 346 for general requirements of cosmetics and any other specific requirement of a relevant cosmetic standard recognised by the Bureau.
- 2.3.2 Cosmetics container or package shall be labelled or marked in such a way that it neither falsely describing the cosmetics nor it is likely to be misleading as to the nature, quality or uses of the product.

2.4 Payment for cosmetics registration

The applicant shall pay registration fees as prescribed in the Standards (Fees and Charges) Regulations, 2021 before evaluation process is carried out and the fees is non-refundable.

2.5 Who should apply

2.5.1 For domestic manufactured products;

Domestic manufacturer or local firm to whose order and specifications of the product is manufactured or any other person authorized by the manufacturer or owner of the product. Registration of cosmetics and its respective manufacturing premises shall be integral part of the product certification process and the granted licence to use the TBS standards mark shall deem the cosmetic product and its respective manufacturing premises to be registered and certified by the Bureau. A person shall not manufacture, sell or supply any cosmetic product unless, they are registered and certified by the Bureau.

2.5.2 For imported products;

Dealers of cosmetics or overseas cosmetics manufacturers or local firms to whose order and specifications of the cosmetic product is manufactured or any other person authorized by the manufacturer or owner of the product. A person shall not carry on

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the business of importation of cosmetics unless is registered by the Bureau.

2.6 Applicant

Applicant shall be a person who is a resident in Tanzania. If the applicant is not resident in Tanzania, then he shall appoint **a local** authorized **person** who must be residing in Tanzania or a company incorporated in Tanzania. Proof of official appointment shall be submitted to the Bureau.

2.7 Responsibility of Applicant

Applicant shall be responsible for facilitating communication with the Bureau and when the cosmetic product is registered, he shall undertake all responsibilities regarding the safety, quality, performance or efficacy of product on the Tanzanian market as a Registrant.

2.8 Type of cosmetics applications

There are three (3) types of applications as follow: -

2.8.1 New application

- 2.8.1.1 This is an application for registration of a cosmetic product that is intended to be placed on the Tanzanian market for the first time. New application may only be made by the applicant vide TBS online application system.
- 2.8.2.1 A separate application is required for each cosmetic product with exception of variant products which having similar composition/common base formulation but with different colour, flavor, fragrance, shade. However, declaration of the available pack sizes and shapes shall be stated.
- 2.8.3.1 Request for registration of cosmetic product shall be submitted

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in one application including variant(s) which shall be charged half of the prescribed fee.

- 2.8.4.1 Products with the same cosmetic product formulation, cosmetic product name, and the same manufacturer name but sourced from different manufacturing sites shall be treated as different products hence registered separately.
- 2.8.5.1 A kit shall be submitted as one application. Categorization of such kit shall base on the components therein. One component will be regarded as main and charged with registration fee and each other component shall be charged the testing fees separately as prescribed in the Standards (Fees and Charges) Regulations, 2021.

2.8.2 Variation

- 2.8.2.1 If for any reason the applicant changes any matter related to a registered cosmetic product including but not limited to change of packaging, labeling or any other change, shall before selling the changed cosmetic product, notify and obtain approval of the Bureau regarding the change. The notice to the Bureau shall be accompanied with the reason(s) for such change.
- 2.8.2.2 The Bureau will evaluate reasons provided in the notice and if satisfied with such reasons it will approve the changes by issuing approval notice and if it is not satisfied the registrant will be notified by stating the reasons thereof.
- 2.8.2.3 Changes involving product(s) composition and manufacturing sites shall be treated as new application.

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2.9 Marketing and advertising of cosmetics

Advertising and marketing of cosmetics to the public shall be conducted in a manner that promotes safe use of cosmetics and does not mislead or deceive consumers. All cosmetics promotions shall be approved by the Bureau as per respective marketing and advertising requirements as prescribed in the "TBS Guidelines for Control of Food and Cosmetics Promotional Materials".

2.10 Reporting of adverse reactions

Marketing and advertising authorization permit holder shall report to the Bureau of any adverse event or high incidences of adverse event occurred, regardless of the source of the report (consumer, health care professionals etc.

2.11 Record keeping

The company or person responsible for placing cosmetic product in the market shall keep records of the primary distribution of their products for the purpose of traceability.

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CHAPTER THREE

3.0 CATEGORIES OF COSMETICS

3.1 Classification of cosmetics

For the purpose of these guide cosmetics are classified into two (2) categories namely special cosmetics and normal cosmetics.

3.2 Special and normal categories of cosmetics

3.2.1 Special cosmetics

These are functional cosmetics which offer additional benefit over normal cosmetics. They contain bioactive ingredients that although are not drugs have visible and measurable short and long term effects on the body. Manufacture of special cosmetics shall observe Good Manufacturing Practice (GMP) and manufacturing plants may be subjected to GMP inspection prior to grant of registration. They include but not limited to: -

- i. Sunscreens or sun blocks, sunbathing products,
- ii. Products for tanning without sun,
- iii. Skin lightening/brightening,
- iv. Anti perspirants,
- v. Anti-cavity toothpastes,
- vi. Sensitivity toothpastes,
- vii. Anti-dandruff,
- viii. Cosmetics for hair growth, hair removal (Depilatories), hair relaxer, hairweaving, hair straightening, hair fixing, hair tints and bleaches, hair setting products, hair colorant (hair dyes),
 - ix. Hair artificial waxes and prepared waxes
 - Cosmetics containing components derived from living organisms, microorganisms or produced through biotechnology process,
 - xi. Baby care products including cleaning baby wipes,
- xii. Cosmetics which have potential to be absorbed through the mucous membrane such as products for application in the area around the eyes (except eyebrow products), lips and oral cavity.

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3.2.2 Normal cosmetics

These are cosmetics which do not fall under special cosmetics. They normally contain only cosmetics ingredients which are used in products to provide them with appropriate aesthetics, texture, pH, color and smell. They include but not limited to: -

- i. Creams, emulsions, lotions, gels (hands, face, feet, etc.)
- ii. Oils for the skin (hands, face, feet, etc.)
- iii. Face masks (with the exception of chemical peeling products)
- iv. Tinted bases (liquids, pastes, powders)
- v. Make up powders, after bath powders, hygienic powders,
- vi. Petroleum jelly for cosmetics industry
- vii. Essential oils for cosmetics industry
- viii. Cosmetic pencils including eye-brow pencil, eye-liner pencil, bindi pencil; and lip-liner pencil
- ix. Lip make-up, eye make-up and manicure or pedicure preparations
- x. Skin powders for body and face including talcum powders, toilet powders, deodorant powders and dusting powders
- xi. Butter for cosmetic use
- xii. Hair oils, hair wax gel
- xiii. Glycerine for cosmetics industry
- xiv. Nail polishes and removers,
- xv. Hair shampoo synthetic detergent-based, hair shampoo soap-based,
- xvi. Body sprays, deodorants, perfumes, toilet waters and eau-de-cologne
- xvii. Toilets soaps, bathing soap,
- xviii. Herbal cosmetics,
- xix. Cleansing products (lotions, powders, shampoos)
- xx. Hair conditioning products (lotion, creams, oils)
- xxi. Hair dressing products (lotions, lacquers, brilliantines)
- xxii. Shaving products (creams, foams, lotions)
- xxiii. Products for making up and removing make up from the face and the eyes

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xxiv. Products for nail care and make up

xxv. Preparations for oral or dental hygiene, including denture fixative Pastes and powders; in individual retail packages

xxvi. Bath preparations based on foam baths, cream baths, body wash, Cream wash, cream shower, bath shower, shower shampoo and shower gels

xxvii. Bath preparations based on bath oils and soap-based bath.

xxviii. Scrubs for face and body

xxix. Hand wash

3.3 Prohibited ingredients in cosmetics

- 3.3.1 A cosmetics intended to be placed on the Tanzanian market shall not contain substances from the prohibited list and/ or substances that exceeds the level permitted as listed in the relevant standard TZS 638/EAS 377 or any substance determined by the Bureau as not safe.
- 3.3.2 A person shall not manufacture or sell any cosmetics under unsanitary conditions or pack cosmetics in a container which may alter its safety and quality and shall not, by himself or any other person acting on his behalf, manufacture, supply or sell any cosmetics that contain prohibited ingredient as shall be declared by the Bureau from time to time and published on the following link https://www.tbs.go.tz/.

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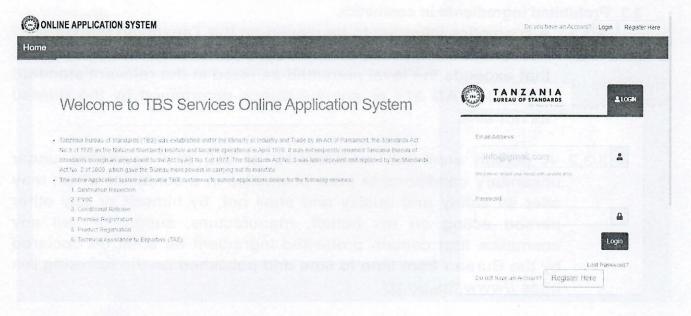
CHAPTER FOUR

4.0 APPLICATION STEPS FOR COSMETICS REGISTRATION

4.1 Creation of applicant account

4.1.1 All applications shall be submitted through the TBS online application system portal link https://oas.tbs.go.tz.

Figure 1: TBS online portal home page



4.1.2 Click register here to create account and select on normal company for product registration, select normal business and fill the following information TIN (Tax Identification Number), Company name, mobile number, Address, email/user login email and upload copies of TIN Certificate & Business Licence as seen in figure 2.

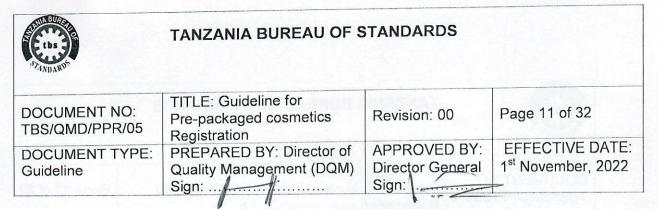
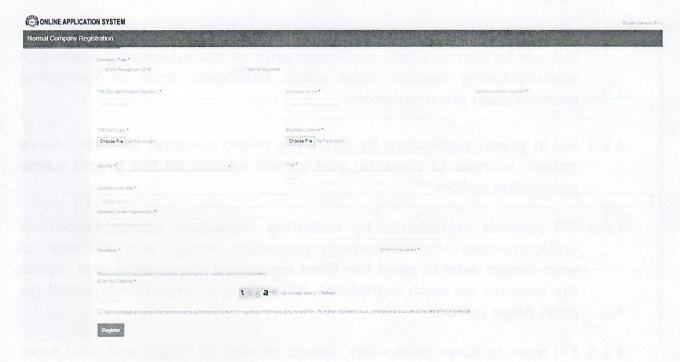


Figure 2: Registration option



4.1.3 Enter password then confirm your password and click on register option to finalize online company registration using verification code sent to your phone/mail as seen in figure 3.

Figure 3: Normal company registration form



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4.2 Submission of cosmetics registration application

Documents and information to be submitted shall depend on category of cosmetics and type of application as described below: -

- 4.2.1 Submission of application for new and renewal registration of cosmetics shall be made through the TBS online application system portal by login using company email/user login email and password.
- 4.2.2 After log in, click register option, select register product and fill in product particulars by declaring product common name and select product type as cosmetic and upload the following required documents; product Label/label artwork, certificate of analysis, material safety data sheet and other supporting documents as seen in figure 4.
- 4.2.3 For special cosmetics applications the following documents such as but not limited to GMP certificate and/ or manufacturing license of manufacturing facility, Free sales certificate and/ or marketing authorization are mandatory.
- 4.2.4 Fill in brand particulars by declaring brand name(s) and click save option. In case of variants, add variant names on the brand name particulars option.
- 4.2.5 Fill product ingredients by declaring Ingredient name, proportion unit/composition/concentration, proportion value and purpose of use. Select add to save the filled ingredient information and repeat the process for each ingredient. After filling all ingredients select go next page option.
- 4.2.6 Fill manufacturer particulars, select country of origin and click **save** option to complete your application and confirm that all the information filled and all the accompanying documents are true and correct by ticking the **box**, then **submit** your application.



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Figure 4: Product particulars registration form

board		
Register Product		
D Product 1 Ingredient	5 Variboure	⁴ Complex
Product Common name *	Product type *	
		•
	Product particular	375
Type of packaging container eighbox, bottle *	Retal parkaging units) *	Shelf ife (norths) 1
Shelf life after opening of container (months) *	instruction for user *	Recommended storage condition *
		Marine Company of Phonography (1997)
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4.3 Processing of the application

- 4.3.1 Upon receiving the application, the Bureau reviews application for cosmetics registration and notifies the applicant in case the application is incomplete or does not require registration vide TBS online application system.
- 4.3.2 The Bureau generates and issue debit advice vides TBS online application system as per the fees prescribed in the Standards (Fees and Charges) Regulations, 2021. In case of application for variant cosmetics, one main cosmetic will be charged full and the remaining variants will be charged half of prescribed fees.
- 4.3.3 For cosmetics presented in form of kit or set shall be treated as single application. However, in the kit one item will be charged full registration fees as prescribed in the Standards (Fees and Charges) Regulations, 2021 and the remaining items will be charged only testing fees for parameters as prescribed in a relevant standard.
- 4.3.4 The applicant shall submit samples after effecting payment as per annex I.
- 4.3.5 The sample for cosmetics registration shall be of the same batch.
- 4.3.6 The Bureau review and receives cosmetics samples at TBS headquarters or Zone offices for evaluation. Physical evaluation of the submitted samples is conducted based on regulations, guidelines and relevant standards such as TZS 638/EAS 377 & TZS 774/EAS 346 for evaluating labelling information and ingredients prohibited to be used in cosmetics.
- 4.3.7 The Bureau conducts cosmetics tests for compliance to the set of safety and quality requirements depending on the available relevant standards for the cosmetics.
- 4.3.8 The Bureau reserves the right to inquire applicant to submit additional cosmetics samples, documents, information or clarification during

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evaluation process.

- 4.3.9 The Bureau shall hold the processing of the application pending for the compliance of the requirements. If applicant fails to submit or cause to be submitted the additional requirements within the period of four months without reasonable cause, the application shall be rendered invalid.
- 4.3.10 The applicant whose application has been invalidated may submit another application which shall be considered as a new application.
- 4.3.11 The applicant may view the evaluation report findings as **notifications** vide TBS online application system for rectification of the shortcomings and respond to the Bureau. If queries response is incomplete, un-attended by the applicant for a period of more than four (4) months, the Bureau rejects the application.
- 4.3.12 The Bureau issue registration certificate if the cosmetics comply with registration requirements. The cosmetics registration certificate is valid for the period of five years and can be renewed subject to continued compliance to registration conditions.

4.4 Termination, suspension/revocation of registration certificate

The Bureau may terminate, suspend or revoke registration of cosmetics due to the following reasons:

- i. New requirements of the law, regulations or relevant standard(s);
- ii. Upon receipt of a notice from the registrant/applicant informing on his/her intention to withdraw from dealing with the cosmetic product;
- iii. Whenever there is new scientific development which justifies that the cosmetic product or ingredient(s) used have significant health effect to consumers; and
- iv. Discovery of the fact that the registrant/applicant provided false information related to the cosmetic product that has bearing on the safety or quality of the product.

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4.5 Notification of Change (Alteration) of Registered Cosmetics

- i. The Bureau receives from applicant; notification of change or Alteration of registered cosmetics product vide TBS online application system.
- ii. The Bureau reviews the notified change and the given reasons for the change to ascertain compliance to the requirements for cosmetic product registration based on available law, regulations, standards and guidelines.
- iii. Approval of change is done by the Bureau as per the available law, regulations and procedures.

4.6 Renewal of cosmetics registration

- i. Applications for renewal of cosmetics registration is done as Per clauses 4.2 and 4.3
- ii. Application for renewal of cosmetic product registration shall be made at least 60 days before the expiration of registration validity.
- iii. Application for renewal shall be made by the registrant who shall be responsible for the safety and quality of the cosmetics.

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ANNEXES

ANNEX I:SAMPLE SIZE REQUIREMENTS FOR COSMETICS REGISTRATION

COSMETICS CATEGORY	SKIN CARE PRODUCTS- Included (lotions, creams, gels), eye (continuous, make up spray, cleans care (lotions, creams, scrubs, gremovals, butter, petroleum jelly	creams, lotions ser, face mas lels and balms	s and gels), sunscreen, k, scrub, exfoliator, foot
SN	PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT
1.	Less than 25g or 25ml	15 units	Samples shall be of the
2.	26g – 50g or 26ml –50 ml	11 units	same type, form, colour, size, brand,
3.	51g – 100g or 50ml 99 ml	9 units	ingredients and
4.	101g – 250g or 100ml- 250 ml	5 units	lot/batch number and manufacturer
5.	251g – 999g or 251ml – 999ml	4 units	ANKAGE COMMON ANA
6.	More than 1kg or 1L	3 units	
COSMETICS CATEGORY	DECORATIVE COSMETICS - concealer, makeup powder, primer, lipstick, lip balm, nail p	rimer, contour	, blush, highlighter, eye
	body and face	Johan and Ten	novals, skin powders for
SN	body and face PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT
SN 1.		NO.OF SAMPLES	ADDITIONAL REQUIREMENT Samples shall be of the
	PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT Samples shall be of the same type, form,
1.	PACKAGING SIZE Less than 10g or 10ml	NO.OF SAMPLES REQUIRED 10 units	ADDITIONAL REQUIREMENT Samples shall be of the same type, form, colour, size, brand, ingredients and
1. 2.	PACKAGING SIZE Less than 10g or 10ml 11g – 25g or 11ml –25 ml	NO.OF SAMPLES REQUIRED 10 units 8 units	ADDITIONAL REQUIREMENT Samples shall be of the same type, form, colour, size, brand,
1. 2. 3.	PACKAGING SIZE Less than 10g or 10ml 11g – 25g or 11ml –25 ml 26g – 50g or 26ml –50 ml	NO.OF SAMPLES REQUIRED 10 units 8 units 6 units	ADDITIONAL REQUIREMENT Samples shall be of the same type, form, colour, size, brand, ingredients and lot/batch number and



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COSMETICS	HAIR CARE - Including but relaxer, hair oil, hair dressing p hair dye, hair tints & bleaches, shampoo, dye, conditioner, lotic	roducts (lotions hair food, styl	s, lacquers, brilliantines), ing gel, beard care (oils,
SN	PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT
1.	Less than 25g or 25ml	12 units	Samples shall be of
2.	26g - 50g or 26ml -50 ml	9 units	the same type, form,
3.	51g - 100g or 50ml -99 ml	8 units	colour, size, brand,
4.	101g – 250g or 100ml- 250 ml	5units	ingredients and
5.	251g-999kg or 251ml - 999L	4 units	lot/batch number and
6.	More than 1kg or 1L	3 units	manufacturer
COSMETICS CATEGORY	SAIN CARE OILS- INCHOING OUL NOUTHINGO TO TACE OILS ESSENTALOILS		
SN	PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT
1.	Less than 25g or 25ml	10 units	Samples shall be of the
2.	26g - 50g or 26ml -50 ml	9 units	same type, form, color,
3.	51g - 100g or 50ml -99 ml	6 units	size, brand, ingredients
4.	101g – 250g or 100ml- 250 ml	5 units	and lot/batch number
5.	251g-999kg or 251ml - 999L	4 units	and
6.	More than 1kg or 1L	3 units	manufacture
SN	PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT
1.	Less than 25g or 25ml	12 units	Samples shall be of the
2.	26g - 50g or 26ml -50 ml	9 units	same type, form,
3.	51g – 100g or 50ml –99 ml	6 units	colour, size, brand,
4.	101g – 250g or 100ml- 250 ml	5 units	ingredients and
5.	251g-999kg or 251ml - 999L	4 units	lot/batch number and
6.	More than 1kg or 1L	3 units	manufacturer



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COSMETICS CATEGORY	PREPARATIONS FOR ORAL not limited to denture fixative packages, teeth gel, mouth was	pastes and pov	wders in individual retail	
SN	PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT	
1.	Less than 25g or 25ml	12 units	Samples shall be of the	
2.	26g - 50g or 26ml -50 ml	9 units	same type, form,	
3.	51g – 100g or 50ml –99 ml	6 units	colour, size, brand,	
4.	101g – 250g or 100ml- 250 ml	5 units	ingredients and	
5.	251g-999kg or 251ml - 999L	4 units	lot/batch number and	
6.	More than 1kg or 1L	3 units	manufacturer	
COSMETICS	ODORIFEROUS SUBSTANCES-Including but not limited to perfume, body mist, body spray, deodorants, toilet waters and eau de cologne, anti-perspirants, cosmetic aerosols			
SN	PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT	
1.	Less than 25g or 25ml	10 units	Samples shall be of	
2.	26g - 50g or 26ml -50 ml	9 units	the same type, form,	
3.	51g - 150g or 51ml -150 ml	6 units	colour, size, brand,	
4.	151g - 250g or 151ml- 250 ml	5 units	ingredients and	
5.	251g-999kg or 251ml - 999L	4 units	lot/batch number and	
6.	More than 1kg or 1L	3 units	manufacturer	
COSMETICS	HAIR REMOVING PRODUCTS- Including but not limited to hot and			
CATEGORY	cold hair wax, shaving products (creams, foams, lotions)			
SN	PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT	
1.	Less than 25g or 25ml	12units	Samples shall be of	
2.	26g – 50g or 26ml –50 ml	9 units	the same type, form,	
3.	51g – 150g or 51ml –150 ml	6 units	colour, size, brand,	
4.	151g – 250g or 151ml- 250 ml	5 units	ingredients and	
5.	251g-999kg or 251ml - 999L	4 units	lot/batch number and	
6.	More than 1kg or 1L	3 units	manufacturer	



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COSMETICS CATEGORY	COSMETIC PENCILS- Including but not Limited to mascara, lip and eye liners pencils, eye brow Pencils, Bindi Pencil			
SN	PACKAGING SIZE	NO.OF SAMPLES REQUIRED	ADDITIONAL REQUIREMENT	
1.	Less than 10g or 10ml	11units	Samples shall be of	
2.	11g – 25g or 11ml –25 ml	9 units	the same type, form,	
3.	26g - 50g or 26ml -50 ml	8 units	colour, size, brand,	
4.	51g – 100g or 51ml –100 ml	7 units	ingredients and lot/batch number and manufacturer	

ANNEX II: TERMINOLOGIES USED IN COSMETICS

Aerosol: A product that is packed under pressure and contains various ingredients that are released upon activation of an appropriate valve system example some hair sprays, body sprays, perfumes.

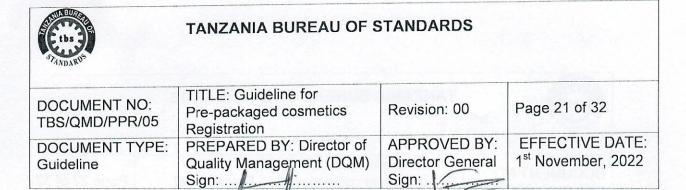
Capsule: A solid dosage form consisting of a shell and a powder or liquid filling example bath oil capsules.

Cream: A semisolid emulsion with medium viscosity. It is more viscous than a lotion, but less viscous than an ointment.

Emulsion: Usually a white, opaque system that consists of at least two immiscible liquids, one of which is dispersed as droplets (internal phase) in the other (external phase). The system is generally stabilized with emulsifiers.

Gel: A clear semisolid dosage form that contains a gelling agent, which provides stiffness to the product.

Granules: bath pellets, crystals, pearls, etc.



Kit: If the product consists of two or more components of different forms which are mixed before use, then insert "Kit" and write in brackets the forms of the various components.

Liquid Suspension: Solids in liquid.

Loose powder: A solid dosage form containing a freely flowing mixture of different drysolid ingredients, e.g. dusting powder, talcum.

Lotion: A low-viscosity liquid emulsion.

Ointment: A highly viscous, usually greasy, semisolid dosage form. It is more viscous than a cream.

Paste: A very thick semisolid dosage form containing a high amount of solids finely dispersed in the vehicle, e.g. dentifrice.

Pressed powder: A solid dosage form that contains a freely flowing mixture of different dry solid ingredients in a compressed form, e.g. blush, eye makeup.

Pressed Cake: A solid dosage form that consists of primarily dry solid particles mixed and/or pressed together, or waxy ingredients molded into a specific shape, e.g. soap, bath bar.

Solution: A clear, homogeneous liquid dosage form that contains one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.

Stick: A solid dosage form that is made of waxes and a smaller amount of oils and is prepared in a relatively long cylindrical form, e.g. lipsticks, eyebrow pencil.

Other (Please specify) - Product which does not fall into one of the general

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categories above. Please provide the rationale as to why the form is unique.

Ant wrinkle Preparation: Product applied as a makeup or moisturizer generally to the face to mask or reduce the appearance of fine lines or wrinkles. (See also, Eye Lotion and Eye Makeup).

Baby Product: Product labeled for use on infants 2 years old or less.

Barrier Cream: Product which protects the hands from dirt, grease, solvents, etc.

Bath Preparation: Product added to the bath water, it includes bath oils, tablets, salts, bubble baths, etc.

Body Makeup: Product applied as makeup to the body excluding the hair, eyes or face. Includes leg and body paints. (See also, Eye Makeup and Face makeup.)

Dentifrice: Product which cleans and/or polishes the teeth.

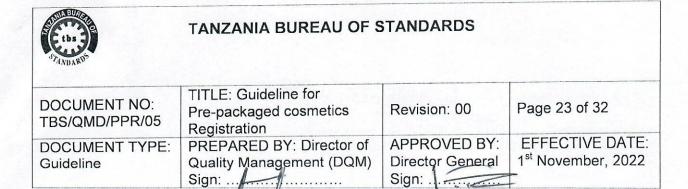
Deodorant: Product which modifies, reduces, or prevents the development of body odors, excludes genital deodorants and products which claim to reduce perspiration.

Douche: Product used for personal feminine hygiene. (See also, Genital Deodorant.)

Eye Lotion: Non-makeup product specifically indicated for use in the area of the eye, it includes lotions and moisturizers.

Eye Makeup: Product specifically indicated for use in the area of the eye, it includes eyebrow pencils, eyeliners, eye shadows, eye makeup removers, mascara, etc.

Face Makeup: Product for use in the area of the face, it includes blushes, face powders, foundations, rouges, makeup fixatives, etc. (See also, Anti-



wrinkle Preparation, Eye Lotion, Eye Makeup, Lipstick and Skin Moisturizer.)

Hair Bleach: Product which bleaches the hair excluding hair lighteners with colours.

Hair Conditioner: Non-shampoo product which increases the suppleness or body of the hair, facilitates combing, adds gloss or texture to the hair, etc. (See also, Hair Shampoo.)

Hair Dye: Product which changes the colour of the hair.

Hair Grooming: Product which improves the appearance or is used to shape/style the hair. Includes mousses, gels, pomades, sprays etc. (See also, Hair Straightener and Hair Waving Preparation).

Hair Removal: Depilatory/epilators product which facilitates the removal of hair by chemical or mechanical means. Includes wax treatments. (See also, Shaving Preparation.)

Hair Shampoo: Product which cleanses the hair. Product is washed off after use.

Hair Straightener: Product which contain agents which chemically soften the hair to facilitate straightening of the hair.

Nail lacquer (Nail polish): Products which changes the colour of the nail.

Nail polish remover: Products which removes the colour from the nail.