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Building competitiveness for export of cassava, fruits and cosmetics value chains in Ghana

**ANALYSIS OF THE
REGULATORY FRAMEWORKS
FOR ACCESSING GLOBAL
MARKETS FOR GHANA'S COSMETIC
AND PERSONAL CARE INDUSTRY**

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Table of Contents

1. Background and Project Scope	1
1.1 Priorities of the Ghanaian Government.....	1
1.2 Ghanaian Target Groups	1
2. Ghanaian Regulatory Situation Analysis	3
2.1 Regulation Driving Cosmetics within the Country	3
2.2 Cosmetic Product Definition	4
2.3 Ingredients Regulation	4
2.4 Safety.....	4
2.5 Consumer Information	5
2.5.1 Labelling	5
2.5.2 General Requirements	5
2.5.3 Claims	6
2.5.4 Deception of consumers	6
2.6 Good Manufacturing Practice	7
2.7 Market Access – Registration.....	8
2.8 Exporting Cosmetic Products	8
2.8.1 General consideration for exporting.....	9
2.9 Competent Authorities.....	10
3. Target markets and regulations requirements for imported products	13
3.1 European Union (EU) + United Kingdom (UK).....	14
3.1.1 a) Regulation driven cosmetics in the EU.....	14
3.1.1 b) The regulatory frame for cosmetics in Europe	14
3.1.1 c) Cosmetics legislation at EU level	14
3.1.2 Cosmetic Product Definition	15
3.1.3 Ingredients Regulation - Nomenclature (INCI).....	15
3.1.4 Safety of Cosmetics	18
3.1.5 The Cosmetic Product Safety Report	19
3.1.6 Good Manufacturing Practices.....	21
3.1.7 Consumer Information	21
3.1.7 a) Labelling	21
3.1.7 b) Claims	22
3.1.8 Market Access Registration.....	23
3.1.9 Competent EU Authorities and Specific National Requirements.....	24
3.1.10 Other European Legislation Applicable to Cosmetics	25
3.1.10. b) United Kingdom	26

3.2 United States of America	29
3.2.1 Regulations driving cosmetics in the USA	29
3.2.2 Cosmetic Product Definition	30
3.2.3 Ingredients Regulation	33
3.2.4 Safety of Cosmetics	34
3.2.5 Good Manufacturing Practices.....	35
3.2.6 Consumer Information	36
3.2.6 a) Labelling	36
3.2.6 b) Claims	39
3.2.7 Market Access - Registration.....	40
3.2.8 Competent Authorities.....	41
3.2.8 a) Standards applying cosmetics	42
3.2.8 b) FDA General Information	42
3.3 Middle East - United Arab Emirates UAE	44
3.3.1 Regulations driving cosmetics in the United Arabian Emirates	44
3.3.2 UAE Scheme for Cosmetics and Personal Care Products	44
3.3.3 Cosmetic Product Definition	45
3.3.4 Ingredients Regulation	46
3.3.5 Consumer Information	46
3.3.5 a) Labelling	46
3.3.5 b) Claims	48
3.3.6 Cosmetics Safety	48
Packaging and Wrapping Requirements	49
Metrology requirements	50
3.3.7 Good Manufacturing Practices.....	50
3.3.8 Market Access - Registration.....	50
SFDA eCosma Notification System for Cosmetic Products	51
3.3.9 Other Regulations Applying Cosmetics	51
3.3.10 Standards Applying Cosmetics	52
Applicable technical standards	53
3.3.9 Halal Certificate	55
Halal National Mark Scheme	55
4. Specific Analysis on Natural and Organic Cosmetic Products	56
4.1 Safety on natural and organic cosmetic products.....	56
4.2 Regulation on Natural and Organic Cosmetic Products	56
4.3 Natural and Organic claim support for cosmetics.....	57

How does COSMOS certification work	58
NATRUE	59
4.4 ISO 16.128 Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1&2	60
4.5 Natural and Organic Cosmetic Ingredients and Products in Ghana.....	61
5. Comparison among regulatory situation in Ghana and the Target markets.	62
Cosmetic Definition	62
6. Needed adaptations of standards, safety evaluation and other quality pre-requirements for Ghanaian companies producing cosmetics and personal care products to be exported to the target markets.....	63
Main aspects to be taken into consideration.....	63
Safety evaluation for finish cosmetic products.....	65
Emphasis for natural and organic cosmetic ingredients and products.....	66
Steps to Look for a Successful Export.....	67

List of tables

Table 1 summary of market regulations/Requirement for imported/exported products (Ghana)	12
Table 2: Summary of market regulations/Requirement for imported products (EU +UK)	28
Table 3: Summary of market regulations/Requirement for imported products (USA) .	43
Table 4: Summary of market regulations/Requirement for imported products (Middle East)	54
Table 5:Comparative Country Analysis of Regulations for Cosmetics Matrix	73

List of figures

Figure 1	7
Figure 2	10

1. Background and Project Scope

The United Nations Industrial Development Organization (UNIDO) is the specialized agency of the United Nations that promotes industrial development for poverty reduction, inclusive globalization, and environmental sustainability.

UNIDO is the agency responsible for the implementation of the European Union-funded West Africa Competitiveness Programme (WACOMP), Ghana Component, Building Competitiveness for Exports project in close collaboration with the Ministry of Industry and Trade in Ghana as the Government Coordinating Agency in Ghana. The overall objective of the WACOMP, Ghana Project is to strengthen the export competitiveness of the Ghanaian economy through enhanced value-added, low carbon, sustainable production and processing and increased access to regional and international markets. The expert, in close cooperation with the Associate Industrial Development Officer and the Project Manager, has undertaken the needed research and information collection regarding standards, safety evaluation and other quality pre-requirements for Ghanaian companies producing cosmetics and personal care products.

This will aim to provide Ghanaian companies with the capabilities, tools and information for improving the performance and growth of the cosmetics and personal care products.

Improving the quality of their products and its integration into regional and global value chains, this sector will be in line with the priorities of the Ghanaian Government and will have a high potential for industrialization and job creation. Meanwhile, its capacity to succeed exporting goods to third countries will be improved.

1.1 Priorities of the Ghanaian Government

The Ghanaian government settled on a plan called “One District One Factory”, aiming to equip and empower communities to utilize their local resources in manufacturing products that are in high demand both locally and internationally. This will allow the country to reap the well-known rewards of industrialization, such as gains in efficiency in every facet of life in the society, increase in agricultural and manufacturing output, a reduction in the reliance on imports and promote the local workforce.

1.2 Ghanaian Target Groups

Several high growth businesses were identified in the strategic sectors of the economy. These include:

- *Input/Raw material producer groups*
- *Agro-processing and business*
- *Textiles and Clothing*
- *ICT*
- *Pharmaceutical and cosmetics*
- *Waste management*
- *Distribution and trading*
- *Tourism, Arts and Crafts*

The target group is segmented to cover:

- 1. Existing businesses that are ready to move to the districts and expand their operations.*
- 2. New businesses that seek to operate within the districts and have the capability of sourcing for raw materials and employing 5-25 people from the district through their operations.*
- 3. Businesses that have the capability of enhancing the operations of input providers and suppliers towards the demand of factories in the districts*
- 4. Businesses whose operations focus on distribution and market access for goods produced in the districts.*
- 5. District-level businesses which have the potential to grow but need all or any of the below:*
 - a) Technical support*
 - b) Long term investment*
 - c) Standardization to meet competition*
 - d) Brand improvement*
 - e) Market access*

Being the cosmetic sector identified as strategic, the expert focused on providing guidance and reference materials regarding regulatory, standardization and technical areas of the cosmetic sector to strengthen point a) and c) in such a way that local producers could get not only expand their operations but also expand access to export cosmetics to third countries/regions.

The project will undertake the needed research and information collection regarding standards, safety evaluation and other quality pre-requirements for Ghanaian companies producing cosmetics and personal care products to be exported to the three regions under the project scope:

- i. EU
- ii. USA
- iii. Some guidelines on the standards and regulations to be considered for exporting to the Middle East will also be provided.
- iv. A point analyzing the situation of natural ingredients and cosmetic products has been added.

2. Ghanaian Regulatory Situation Analysis

Ghana is a country located in the Gulf of Guinea, on the west coast of Africa, linking: West with Ivory Coast, east with Togo and north with Burkina Faso. Capital: Accra. Organized into 10 regions and subdivided into 138 districts.

2.1 Regulation Driving Cosmetics within the Country

The regulatory competent authority is the Food and Drugs Authority (FDA), which aims to dictate and enforce the regulations for the sale of food, beverages, cosmetics, medicines, medical devices and household chemicals.

The sector is regulated according to *Part 7 of the Public Health Act, 2012, Law 851*

By Ghana's Public Act 185, producers of cosmetics must be registered with the FDA to gain market sale license.

WACOMP¹ has issued a short guide² on cosmetics labelling, certification and registration procedures requirements for locally manufactured cosmetics.

The legislation is according to Part 7 of the Public Health Act, 2012, Act 851, which among other things includes the following aspects:

A person commits an offence if that person sells a drug, herbal medicinal product, cosmetic, medical device or household chemical substance which:

(a) has in or on it a substance that may cause injury to the health of the user when the article is used

(i) according to the directions on the label accompanying the article; or

(ii) for a purpose and by a method of use that is customary or usual.

(b) consists in whole or in part of a filthy, rotten, decomposed or diseased substance or of a foreign matter likely to cause injury.

(c) is adulterated; or

(d) is prepared, preserved, packed or stored under insanitary conditions. The Minister may, by executive instrument, prohibit the import, manufacture, export, advertising or sale of medicine, cosmetic, medical device or domestic chemical substance as specified in the instrument.

An application for registration of a medication, cosmetic, medical device, or household chemical must be submitted to the FDA in an established manner and the corresponding fees must be paid.

¹ WACOMP is a partnership initiative between the Economic Community of West African States (ECOWAS) and the European Union (EU).

² "How to comply with GSA and FDA requirements and procedures"

No person may manufacture, prepare, import, export, distribute, sell, supply, or display for sale a medication, cosmetic, medical device, or household chemical unless the item has been registered by the FDA.

2.2 Cosmetic Product Definition

Definitions: “*cosmetic*” refers to a substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes.

NOTE: The cosmetic definition is wide enough to have problems fitting to other countries/regions definitions.

For example: as headed by the standard GS 1090: 2017 - Cosmetics – Specification for Mosquito Repellent:

This standard prescribes the requirements, methods of sampling and test for products intended for use on the body as a mosquito repellent.

Insect repellents are not cosmetics in the European regulation, but they are included in the plant protection regulation.

2.3 Ingredients Regulation³

Ghana standard GS 227-2:2017. This Ghana standard, on table 1, lists substances, which shall not form part of the composition of cosmetic products. On the last revision (2017) there were 418 prohibited substances.

Ghana standard GS 227-3:2017 - This Ghana standard contains restrictions and conditions of Chemical substances, coloring agents, preservatives and UV filters as specified in Annexes A, B, C and D respectively shall apply to Cosmetic products⁴.

2.4 Safety

The finish product is submitted to pre-market approval.

Finish product safety relies on the standard compliance for raw materials, manufacturing site and finish product.

As deducted from Part 7 of the Public Health Act, 2012, Act 851, where infringements are mentioned, a product needs to be safe not committing the following offences:

³ Ghana standard GS 227-2:2017– LIST OF SUBSTANCES NOT PERMITTED IN COSMETIC PRODUCTS Ghana standard GS 227-3:2017 - LIST OF SUBSTANCES RESTRICTED IN COSMETIC PRODUCTS

⁴ The structure of the standard is very similar to the Annexes of the European Regulation 1223/2009

A person commits an offence if that person sells a drug, herbal medicinal product, cosmetic, medical device or household chemical substance which

(a) has in or on it a substance that may cause injury to the health of the user when the article is used:

(i) according to the directions on the label accompanying the article; or

(ii) for a purpose and by a method of use that is customary or usual.

(b) consists in whole or in part of a filthy, rotten, decomposed or diseased substance or of a foreign matter likely to cause injury.

(c) is adulterated; or

(d) is prepared, preserved, packed or stored under insanitary conditions. The Minister may, by executive instrument, prohibit the import, manufacture, export, advertising or sale of medicine, cosmetic, medical device or domestic chemical substance as specified in the instrument.

2.5 Consumer Information

2.5.1 Labelling⁵

Package Labelling' includes the label on the immediate container plus all other printed matter, such as an outer wrapper, carton or leaflet associated with the package.

Labelling requirements to be met are in *Section 148 of the Public Health Act of 2012, Law 85*. In pursuance of Section 148 of the Public Health Act 2012, (Act 851), Guidelines are published to ensure the proper labelling of all cosmetics and household chemical substances. Document FDA/MCH/CHC/GL-LCH/2013/03.

Standard GS ISO 22715: 2013 - Cosmetics - Packaging and Labelling: The standard specifies requirements for packaging and labelling of all cosmetic products as defined according to national regulations or practices intended for sale or free distribution

2.5.2 General Requirements

1.1. Labelling shall be informative and accurate,

1.2. Product labels shall be printed. The print shall be in a clear font and legible. The print shall be indelible and not fade when exposed to sunlight,

1.3. The information on a label shall include, but not be limited to, the following:

(a) The name of the product, and the generic or INN/INCI,

(b) A list of the active ingredients using INN/INCI or IUPAC system, where applicable, showing the amount of each present in a dosage unit,

⁵ FDA GUIDELINES FOR LABELLING OF COSMETICS AND HOUSEHOLD CHEMICAL SUBSTANCES.

- (c) The net content of the container,
- (d) The batch number,
- (e) Date of manufacture and best before/expiry date,
- (f) Directions for use, and any warnings or precautions that may be necessary.
- (g) Any special storage conditions or handling precautions that may be necessary.
- (h) Indications, frequency, route and conditions of use where applicable,
- (i) The names of any excipients known to be a safety concern,
- (j) Name, postal address and premises address of the manufacturer and Distributor,
- (k) Country of origin.

2.5.3 Claims

Advertising needs a preapproval application. An application for the advertisement of a product shall be made in writing by submitting a completed application form with a cover letter addressed to the Food and Drugs Authority CEO.

All approved advertisement shall include the phrase “This advertisement has been vetted and approved by the FDA”.

In pursuance of Sections 59, 113, 114 and 118 of the Public Health Act, 2012, Act 851, these Guidelines are hereby promulgated for information, guidance and strict compliance by all concerned on the procedure and requirements for submission of application for the advertisement of drugs (orthodox, herbal and homoeopathic medicines), medical devices, cosmetics and household chemical substances.

A Guideline on advertising has been published with application Guidance⁶:

- No person or media shall advertise any product unless the product is registered with the Authority.
- No person or media shall advertise any registered product that has undergone some variation that has not been approved by the Authority.
- No person or media shall advertise any product in the print, electronic media including internet or by any means unless such advertisement has been approved by the Authority.

2.5.4 Deception of consumers

A person commits an offence if that person labels, packages, sells or advertises a drug, an herbal medicinal product, cosmetic, medical device or household chemical substance:

- (a) in contravention of Regulations or Guidelines made under this Part, or

⁶ Guidelines for Advertisement of Drugs, Medical Devices, Cosmetics and Household Chemicals

(b) in a manner, that is false, misleading or deceptive or misbranded as regards its character, constitution, value, potency, quality, composition, merits or safety.

Specific Requirements for Cosmetics

Claims on cosmetics shall not imply actions that are normally considered therapeutic. All approved advertisement for skin toning/ skin lightening shall include the phrase “Does not contain hydroquinone”.

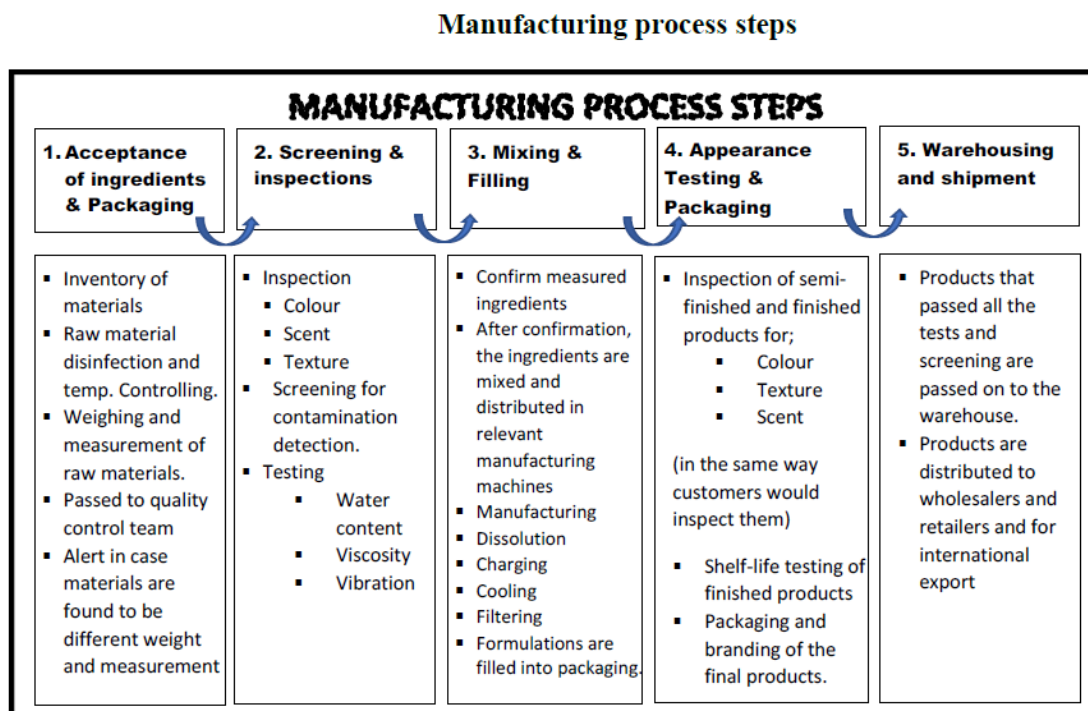
2.6 Good Manufacturing Practice

The Ghana Standards Authority has adopted the ISO 22.716 standard on GMP’s.

Standard GS ISO 22716: 2017 - Cosmetics -- Good Manufacturing Practices (GMP) -- Guidelines on Good Manufacturing Practices (ISO 22716:2007, IDT) gives guidelines for the production, control, storage and shipment of cosmetic products.

The cosmetics manufacturing process and value chain⁷

Figure 1



Control of manufacturing⁸

⁷ September 2019 value chains in Ghana - Competitiveness Programme (WACOMP) A Value-Chain Analysis of the Cosmetics and Personal Care Products Sector in Ghana

⁸ Act 851, Public Health act 2012 -112 (115)

A person shall not manufacture a drug, herbal medicinal product, cosmetic, medical device or household chemical substance for sale unless:

- (a) the manufacturing operation is carried on, or is supervised by a pharmacist or a qualified person approved by the Authority as having specialist knowledge in the article to be manufactured, and
- (b) the conditions under which the manufacture is to be carried on areas specified in the Guidelines of the Authority to ensure that the article will be of good quality and safe to use.

An application for approval shall be made to the Authority and may be granted by the Authority subject to the conditions determined by the Authority.

2.7 Market Access – Registration

Products must be registered before being commercialized. FDA registration procedures for locally manufactured cosmetics and household chemical substances must be followed.

GSA has a Product Certification Procedure that involves the issuance of a certificate or mark (or both) to demonstrate that a specific product meets a defined set of requirements for that product. Specified requirements for products are generally contained in Standards or other normative documents.

The FDA through the registration process gathers adequate information for evaluation and assessment on the quality and safety of cosmetics and household chemical substances⁹.

An application for the registration of a cosmetic or household chemical substance either locally manufactured or imported, shall be made in writing.

2.8 Exporting Cosmetic Products

FDA Guidelines for processing of export permit and clearance of cosmetics, medical devices and household Chemical substances.

In exercise of the powers conferred on the Food and Drugs Authority (FDA) by Part 7, section 118 of the Public Health Act 851, 2012, these guidelines apply to all cosmetics, household chemicals, medical devices that are to be exported from Ghana and are for adherence by all exporters of these products.

These guidelines outline the processes and procedures involved in the application for and issuance of electronic permits as well as the inspection and release of consignments for the exportation out of the country.

⁹ GUIDELINES FOR THE REGISTRATION OF COSMETICS AND HOUSEHOLD CHEMICAL SUBSTANCES

All cosmetics, household chemicals, medical devices to be exported shall comply with existing Ghana Standards.

2.8.1 General consideration for exporting

Only businesses duly registered by the Registrar-General's Department shall be permitted to export cosmetics, household chemicals, medical devices.

The cosmetics, household chemicals, medical devices to be exported must be registered with the Food and Drugs Authority in accordance with Part 7, section 118 & 124 of the Public Health Act, Act 851 of 2012.

A person shall not be permitted to export cosmetics, household chemicals, medical devices unless issued with an export permit by the Food and Drugs Authority in accordance with these guidelines for each consignment of cosmetics, household chemicals, medical devices.

Supporting SMEs, the Ghana National Chamber of Commerce & Industry (GNCCI) is an association of business operators, firms, and industries with interests spanning every sector of private enterprise in Ghana. As an advocacy organization, the GNCC was established with the prime objective of promoting and protecting commercial and industrial interests in the country

Standards¹⁰

The Ghana Standards Authority (GSA) is the National Statutory body responsible for the National Quality Infrastructure embracing Standardization, Metrology, and Conformity Assessment.

GSA as the National Standard body relies on ISO standards to help develop better standards for regulation.

Standards¹¹ *Where a standard is prescribed for a drug, herbal medicinal product, cosmetic, medical device or household chemical substance, a person who manufactures, labels, packages, sells or advertises any other substance in a manner that it is likely to be mistaken for that drug, product, cosmetic, medical device or household chemical substance commits an offence unless the substance is the drug, herbal medicinal product, cosmetic, medical device or household chemical substance in question and complies with the prescribed standard.*

The Ghana National Standard on Cosmetic Products, GS 227-2:2017 was prepared by the Technical Committee on Cosmetics by GSA in collaboration with the FDA.

¹⁰ Catalogue of Ghana standards - 2018

¹¹ Act 851, Public Health act 2012 -112

There is an important list of standards to be applied to cosmetic products in general and for different products categories and raw materials¹².

Figure 2

Table 1: Standards for the cosmetics and personal care products industry	
Raw materials	Finished products
<ol style="list-style-type: none"> 1. GS 953:2018 67.200.10 – Shea nuts 2. GS 956:2008 – Code of practice for shea kernel and butter 3. GS 238: 2006 / 1:2014 67.200.10 – Shea butter (unrefined) 4. GS 238:2014 – Unrefined shea butter 5. GS 289:2007 71.100.40 – Soaps and detergents (specifications for anago soap) 6. GS 998:2019 – Medicinal plants (specifications for moringa leaf products) 7. GS 738:2017 – Specification for cocoa butter 	<ol style="list-style-type: none"> 1. GS 258.2017 – Skin creams 2. GS 285.2018 – Conditioners 3. GS 284.2018 – Hair relaxing cream 4. GS 281.2018 – Hair pomade 5. GS 228.2018 – Setting lotion 6. GS 225.2018 – Detergent hair shampoo
Manufacturing	Packaging and labelling
<ol style="list-style-type: none"> 1. GS ISO 22716:2017 71.100.70 – GMP (Guidelines on Good Manufacturing Practices – Cosmetics) 	<ol style="list-style-type: none"> 1. GS ISO 22716:2017 71.100.70 – GMP (Guidelines on Good Manufacturing Practices – Cosmetics) 2. GS ISO 22715:2013 71.100.70 – Cosmetics packaging and labelling
Product control, storage and shipment	Other codes and standards
<ol style="list-style-type: none"> 1. GS ISO 22716:2007 – GMP (Guidelines on Good Manufacturing Practices – Cosmetics) 2. EU Market - Regulation (EC) No 1223/2009 3. US Market – FD&C Act and FPLA 	<ol style="list-style-type: none"> 1. Code of practice for extraction of local essential oils 2. Standard for black soap shower gel 3. Ghanaian standard for hair and body oils

2.9 Competent Authorities

GSA: The Ghana Standards Authority and Food and Drugs Authority (FDA) are the institutions responsible for ensuring producers’ quality compliancy through metrology, standardization, and conformity assessments (i.e. Testing, Inspection and Certification). It is a Government of Ghana agency responsible for the maintenance of acceptable standards for product and services and sound management practices in industries and public institutions. GSA aims to dictate and enforce the rules for the sale of food, beverages, cosmetics, medicines, medical devices and household chemicals.

GSA develops standards and certifies systems used in industries. It also certifies products and runs test training for industries to promote compliance with the set of standards of the board. Also performs physical analysis of products before they can be sold.

FDA: The FDA is the National Regulatory Body responsible for the regulation of food, drugs, food supplements, herbal and homoeopathic medicines, veterinary medicines,

¹² September 2019 value chains in Ghana - Competitiveness Programme (WACOMP) A Value-Chain Analysis of the Cosmetics and Personal Care Products Sector in Ghana

cosmetics, medical devices, household chemical substances, tobacco and tobacco products, and the conduct of clinical trials protocols.

The department processes and grants market authorization for cosmetics and household chemical substances intended for export and/or sale on the Ghanaian market. The Medical Devices Cosmetics and Household Chemical Substances Division (MDCHCD) mandate derives from Part 7 of the Public Health Act 2012, Act 851. The scope is the protection of public health by ensuring the availability of safe, effective and quality medical devices, cosmetics, and household chemical substances on the Ghanaian market.

The regional offices of FDA and GSA only collect test samples, which they forward to their main laboratories in Accra, where testing is conducted. Intertek, SGS and Ecocert are private certification bodies that also provide laboratory testing services mainly for export products. While Intertek and SGS are inspections, verification, testing and certification companies for any type of products.

Table 1 summary of market regulations/Requirement for imported/exported products (Ghana)

COUNTRY	COSMETIC DEFINITION	INGREDIENTS/COMPOSITION	GMPs	LABELLING	CLAIMS	SAFETY	ACCESS TO THE MARKET
GHANA	“cosmetic” refers to a substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes.	Ghana standard GS 227-2:2017. This Ghana standard, on table 1, lists substances, which shall not form part of the composition of cosmetic products. On the last revision (2017) there were 418 prohibited substances + Narcotic drugs. Ghana standard GS 227-3:2017. This Ghana standard contains restrictions and conditions of Chemical substances, coloring agents, preservatives and UV filters as specified in Annexes A, B, C and D respectively shall apply to Cosmetic products	Manufacturing sites need a pre-approval	The information on a label shall include, but not be limited to, the following: (a) The name of the product, and the generic or INN/INCI (b) A list of the active ingredients using INN/INCI or IUPAC system, where applicable, showing the amount of each present in a dosage unit. (c) The net content of the container (d) The batch number (e) Date of manufacture and best before/expiry date (f) Directions for use, and any warnings or precautions that may be necessary (g) Any special storage conditions or handling precautions that may be necessary (h) Indications, frequency, route and conditions of use where applicable (i) The names of any excipients known to be a safety concern (j) Name, postal address and premises address of the manufacturer and Distributor (k) Country of origin	Claims on cosmetics shall not imply actions that are normally considered therapeutic. Advertising needs a preapproval application. FDA guidelines for the advertisement of drugs, medical devices, cosmetics and household chemicals	Products must be safe. Documentation not clearly defined	Pre-registration needed. FDA processes and grants market authorization for cosmetics and household chemical substances intended for export and/or sale on the Ghanaian market.

3. Target markets and regulations requirements for imported products

I. EUROPEAN UNION (UE) + UNITED KINGDOM (UK)¹³

- Regulation driven cosmetics within the region
- Cosmetic product definition
- Ingredients regulation and nomenclature (INCI).
- Safety of cosmetics – Product information file (PIF)
- GMP's (good manufacturing practices)
- Consumer information:
 1. Labelling
 2. Claims
- Registration
- Competent Authorities
- Standards applying cosmetics

II. USA

- Regulation driven cosmetics within the country
- Cosmetic product definition:
- Ingredients regulation:
- Safety of cosmetics:
- GMP's (good manufacturing practices)
- Consumer information:
 1. Labelling
 2. Claims
- Registration
- Competent Authorities
- Standards applying cosmetics

III. MIDDLE EAST (EMIRATES)

- Regulation driven cosmetics within the country
- Cosmetic product definition
- Ingredients regulation
- Safety of cosmetics - Product information file (PIF).
- GMP's (good manufacturing practices)
- Consumer information:
 1. Labelling
 2. Claims
- Registration
- Competent Authorities Standards applying

¹³ Due to the recent United Kingdom's decision to leave the European Union (EU), the cosmetic regulation within this country will be particularly addressed.

3.1 European Union (EU) + United Kingdom (UK)

The European Union (EU) is political and economic, consisting of 27 Member States that are subject to the obligations and the privileges of the membership. Every Member State is part of the founding treaties of the Union and is subjected to binding laws within the common legislative and judicial institutions.

3.1.1 a) Regulation driven cosmetics in the EU¹⁴

Any cosmetic product, either manufactured in EU or imported into the UE, needs to comply with the same European legislation.

Regardless of the manufacturing processes or the channels of distribution, cosmetic products placed on the EU market must be safe. The manufacturer is responsible for the safety of their products and must ensure that they undergo an expert scientific safety assessment before they are sold.

3.1.1 b) The regulatory frame for cosmetics in Europe

- Regulation (EC) No 1223/2009 of the European Parliament and of The Council of 30 November 2009 on cosmetic products¹⁵ and its amendments.
- Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic productsⁱ
- Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used concerning cosmetic productsⁱⁱ + Technical document on cosmetic claims.
- Commission Decision 96/335/EC of 8 May 1996 establishing an inventory and a common nomenclature of ingredients employed in cosmetic products

3.1.1 c) Cosmetics legislation at EU level

- Only cosmetic products with a designated Responsible Person (RP) can be placed on the market. The RP is the one that must ensure all the relevant obligations set out in the EU Cosmetics Regulation are met. No “distributors” specific role when importing products into the EU.
- Each cosmetic product must have its Product Information File (PIF) containing information about the product. This is a legal requirement and the files are open to inspection by the enforcement authority where the PIF is located (Trading Standards Officers in the UK). The Responsible Person (RP) is the one that should guarantee that the product is safe and makes the PIF accessible to the enforcement authority.

¹⁴ Updated regulations within the EU can be found at the website of the DG Internal Market, Industry, Entrepreneurship and SMEs, sector cosmetics https://ec.europa.eu/growth/sectors/cosmetics_en

¹⁵ Replacing since 11 July 2013 the Directive 76/768/EC

- Requires that all products to be marketed in the EU must be notified to the Cosmetic Products Notification Portal (CPNP) before being placed on the market.
- Requires that some cosmetic products are given special attention from regulators due to their scientific complexity or higher potential risk to consumer health
- Ensures that there is a ban on animal testing for cosmetic purposes
- Makes EU countries responsible for market surveillance at the national level

3.1.2 Cosmetic Product Definition

The assessment of whether a product is a cosmetic product has to be made based on a case-by-case assessment, taking into account all characteristics of the product.

The delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use.

The European Regulation 1223/2009 defines cosmetics products as:

“Cosmetic product” means *any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.*

Sometimes it may be unclear whether a particular product is a cosmetic product under cosmetics legislation or whether it falls under other sectorial legislation. In the case of these 'borderline products', the decision on a product's classification must be taken on a case-by-case basis.

Various guidance documents have been produced by the European Commission on the delimitation between cosmetic products and other product categories (e.g. between cosmetics and medicines, between cosmetics and biocidal products, and between cosmetics and other products) is a tool for guidance to determine whether the product falls within the definition given.

3.1.3 Ingredients Regulation - Nomenclature (INCI)

The European Commission regulates cosmetic ingredients of concern, through the advice of the Scientific Committee on Consumer Safety (SCCS) that provides “Opinions” on health and safety risks. The Opinion is not legally binding until it is published via Regulation into the Official Journal of the European Union, but it could be used as ingredients safety support.

SCCS Opinions can be consulted at the SCCS website¹⁶

¹⁶ https://ec.europa.eu/health/scientific_committees/consumer_safety_es

The regulated ingredients can be found on the Regulation 1223/2009 Annexes, periodically amended to introduce new ingredients regulations¹⁷:

Annex II: list of substances prohibited in cosmetic products

Annex III: list of substances which cosmetic products must not contain except subject to the restrictions laid down

Annex IV: list of colorants allowed in cosmetic products

Annex V: list of preservatives allowed in cosmetic products

Annex VI: list of UV filters allowed in cosmetic products

Ingredients nomenclature

European Ingredients Glossary:

Out of the regulated substances, there is a Glossary¹⁸ establishing a common nomenclature of ingredients employed in cosmetic products.

This glossary should not be intended to constitute a limitation list of substances used in cosmetic products.

The glossary takes account of internationally recognized nomenclatures including the International Nomenclature of Cosmetic Ingredients (INCI).

The glossary **does not** constitute a list of ingredients authorized for use in cosmetic products. The assignment of an INCI name to an ingredient also does not imply that the ingredient is safe, or that its use in a cosmetic product complies with the laws and regulations of the United States or other global regions. The safety and fitness of use for an ingredient, along with regulatory considerations, is carefully evaluated by the manufacturer as part of the development process before the product is marketed.

This Inventory can now be found into the European Commission database for information on cosmetic substances and ingredients “*COSING*”, a special database with information on cosmetic substances and ingredients, that enables easy access to data on these substances, including legal requirements and restrictions.

The INCI nomenclature

The designation of an INCI name for a cosmetic ingredient is an essential part of ingredient identification. INCI names are systematic names internationally recognized to identify cosmetic ingredients.

INCI is an acronym that stands for *International Nomenclature of Cosmetic Ingredients*. It was developed by the CTFA (current PCPC¹⁹).

¹⁷ Updated Regulations modifying Annexes, can be find on DG GROWTH website https://ec.europa.eu/growth/index_en (cosmetic sector)

¹⁸ Commission Decision 96/335/EC of 8 May 1996

¹⁹ Personal Care Products Council

INCI was created to achieve transparency and to ensure uniformity throughout the labelling names used for the ingredients in cosmetic products.

This helps the consumer identify the same ingredient across different countries and regions. Transparency is provided to consumers as ingredients are identified by a single labelling name regardless of the national origin of the product.

INCI names are developed by the International Nomenclature Committee (INC) and published by the PCPC in the International Cosmetic Ingredient Dictionary and Handbook.

PCPC manage the assignments of INCI names, at request of the ingredient's producers.

INCI names are widely used for listing ingredients on cosmetic product labels.

With few exceptions, the INCI labelling names in all countries are the same. While in Europe the use of the ingredients database that includes the INCI name and other identifiers (CAS, EINECS/ELINCS, EC) is free for users, in the USA you need to pay a fee.

There are some differences in the INCI ingredients nomenclature among both INCI lists (EU and USA), but those are limited to a short number of ingredient categories:

- *Common names:* Names based on the European Pharmacopeia are used in the EU. Admitted examples are AQUA (WATER), for the United States) or MARIS SAL (SEA SALT).
- *Colorants:* In the EU they are generally designated by the Color index (CI). In the United States, the abbreviations FD&C (Food, drug and cosmetics), D&C and Number are used, together with the name of the colorant.
- *Ethanol:* While in EU the INCI to be used is Alcohol or Alcohol Denat, for US the INCI names changes for the different denaturants used: Alcohol SD
- *Botanical names:* In the EU they are designated with the Latin name (genus and species), while in the United States the common name of the plant, the part used, and the type of preparation are also included.

FDA does not object to their use in parentheses following the common or usual name in English (or Spanish, in Puerto Rico). Here are some examples²⁰:

Water (Aqua)

Fragrance (Perfume)

Honey (Mel)

Sweet Almond (Prunus Amygdalus Dulcis) Oil

FD&C Yellow No. 5 (CI 19140)

²⁰ FDA Response to CTFA Requests Regarding Harmonization of Ingredient Names (Color Additives, Denatured Alcohol, and Plant Extracts)

An ingredient with INCI name **is not** *per se* safe for its use in cosmetics. Only ingredients evaluated by the European SCCS or the Cosmetic Ingredient Review (CIR) or another recognized scientific body and found safe for its intended use can be used in cosmetics.

Just because an ingredient has an INCI name does not mean that the ingredient has been approved for cosmetics. The assignment of an INCI name to an ingredient also does not imply that the ingredient is safe, or that its use in a cosmetic product complies with the laws and regulations of EU, USA or other global regions. The safety and fitness of use for an ingredient, along with regulatory considerations, is carefully evaluated by the manufacturer as part of the development process before the product is marketed.

3.1.4 Safety of Cosmetics

The responsibilities: The Responsible person

In order to establish clear responsibilities, each cosmetic product should be linked to a responsible person established within the European Union.

Only cosmetic products for which a legal or natural person is designated within the EU as ‘responsible person’ shall be placed on the market.

Responsible persons shall ensure compliance with the Regulation. A ‘Responsible Person’ guarantees compliance with all safety and labelling requirements.

For an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market.

A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

- (a) presentation including conformity with Directive 87/357/EEC²¹.
- (b) labelling.
- (c) instructions for use and disposal.
- (d) any other indication or information provided by the responsible person defined in Article 4.

With safety being key into the Regulation, each responsible person needs to have a full Product Information File readily available to public authorities, therefore placing greater

²¹ Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers

responsibility on the manufacturer in regard to the ingredients and make-up of each cosmetics product.

The Product information file (PIF)

Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health.

When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it.

There is no pre-approval of the PIF by the competent authorities. Under the responsibility of the Responsible person, it should be made readily accessible, at one single address within the Community, at request to the competent authority of the Member State where the file is located.

The PIF should include all the necessary particulars relating to identity, quality, safety for human health and the effects claimed for the cosmetic product. In particular, this product information should include a cosmetic product safety report documenting that a safety assessment has been conducted.

The product information file shall contain the following information and data which shall be updated as necessary:

- (a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product.
- (b) The cosmetic product safety report.
- (c) a description of the method of manufacturing and a statement on compliance with good manufacturing practices.
- (d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product.
- (e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

3.1.5 The Cosmetic Product Safety Report

To demonstrate that a cosmetic product is safe, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment based on the relevant information and in accordance with Annex I. This safety assessment is called “cosmetic product safety report” that forms part of the PIF requirements.

The cosmetic product safety report has two parts that shall, as a minimum, contain the following:

PART A

1. Quantitative and qualitative composition of the cosmetic product
3. Microbiological quality
4. Impurities, traces, information about the packaging material
5. Normal and reasonably foreseeable use
6. Exposure to the cosmetic product taking into consideration:
 - The site(s) of application.
 - The surface area(s) of application.
 - The amount of product applied.
 - The duration and frequency of use.
 - The normal and reasonably foreseeable exposure route(s).
 - The targeted (or exposed) population(s). Potential exposure to a specific population shall also be taken into account.
7. Exposure to the substances
8. Toxicological profile of the substances
9. Undesirable effects and serious undesirable effects
10. Information on the cosmetic product

PART B

- 1 Assessment conclusion
2. Labelled warnings and instructions of use
3. Reasoning
4. Assessor's credentials and approval of part B

The safety assessment shall be carried out by a person in possession of a diploma or other evidence of formal qualifications.

PIF Format: The PIF does not have a particular format. PIF requirements are not a checklist, the evaluation must be done in a case by case situation.

Whenever any particular point or aspect detailed onto the Regulation does not need to be included in the report, the safety assessor will justify, with scientific reasoning, the absence of this particular data.

3.1.6 Good Manufacturing Practices

The manufacture of cosmetic products shall comply with good manufacturing practices to ensure their safety.

Compliance with good manufacturing practices shall be presumed where the manufacture is following the relevant harmonized²² standards, the references of which have been published in the Official Journal of the European Union²³.

The harmonized standard for GMPs is the *ISO 22716 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices*²⁴.

The importance of ISO 22716 for those organizations that need to comply with GMP has been stressed by EU publication 2011/C 123/04 from April 2011.

There is an ISO Technical Report: *ISO/TR 24475:2010 Cosmetics — Good Manufacturing Practices — General training document*, that serves as guidelines to support the application of the ISO standard 22716.

For imported cosmetics, the competent national authorities of each Member State will regulate the establishment of economic operators in the area of cosmetic products. So, each Member State will regulate the conditions for importers of cosmetic products within their countries.

There is no need for facilities certification on ISO 22716. A self-declaration of compliance is enough.

3.1.7 Consumer Information

3.1.7 a) Labelling

Article 19 of Regulation 1223/2009 states that cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible, and visible lettering:

- the name or registered name and the address of the responsible person.
- The nominal content at the time of packaging, given by weight or by volume,

²² Harmonized for the EU Regulation means a standard adopted by one of the European standardization bodies on the basis of a request made by the Commission. Manufacturers, other economic operators, or conformity assessment bodies can use harmonized standards to demonstrate that products, services, or processes comply with relevant EU legislation.

²³ Standard developed by ISO TC217 - Cosmetics

²⁴ ISO 22716:2007 gives guidelines for the production, control, storage and shipment of cosmetic products. These guidelines cover the quality aspects of the product, but as a whole do not cover safety aspects for the personnel engaged in the plant, nor do they cover aspects of protection of the environment.

- the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function and, in particular, will remain safe ‘*date of minimum durability*’
- Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period after opening for which the product is safe and can be used without any harm to the consumer (PAO). This information shall be indicated, except where the concept of durability after opening is not relevant, by the symbol of the open jar.
- particular precautions to be observed for safe use.
- the batch number of manufacture or the reference for identifying the cosmetic product.
- the function of the cosmetic product unless it is clear from its presentation.
- a list of ingredients. The list shall be preceded by the term ‘INGREDIENTS’.

There are no specific requirements on the minimum letter height (except on net weight declaration²⁵), for the label size or for the positioning of the different letterings.

Cosmetics Europe²⁶ issued a document: “*Guidelines on cosmetic product labelling*”. These guidelines are intended to provide information and guidance on the labelling requirements of the Regulation. It consist of three main parts: a quick guide for cosmetic product labelling in the EU-; specific guidance on the individual requirements and references to labelling requirements coming from other horizontal regulations that will apply to cosmetic products.

Language: The language of the compulsory label declarations is determined by the competent authorities of the country where the product is sold.

3.1.7 b) Claims

Product claims of cosmetic products serve mainly to inform end-users about the characteristics and qualities of the products.

In the EU, the labelling, making available on the market and advertising of cosmetic products, text, names, trademarks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.

At Union level, common criteria have been laid down to justify the use of a claim made concerning cosmetic products. The main objective of laying down common criteria is to guarantee a high level of protection for end-users, in particular from misleading claims concerning cosmetic products.

The six criteria are:

²⁵ Council Directive 80/232/EEC of 15 January 1980 on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products

²⁶ Cosmetics Europe is the European trade association for the cosmetics and personal care industry.
<https://cosmeticseurope.eu/>

1. Legal compliance
2. Truthfulness
3. Evidential support
4. Honesty
5. Fairness
6. Informed decision-making

To guide the application of Commission Regulation 655/2013, a Technical Document has been issued²⁷ (not legally binding).

For the particular case of sunscreen products, the Commission adopted recommendations on the efficacy of sunscreen products and related claims²⁸ which were inspired by the same principles as those illustrated in Commission Regulation (EU) No 655/2013.

3.1.8 Market Access Registration

No pre-registration is required to market cosmetics into the EU.

Only a notification to the Cosmetic Products Notification Portal (CPNP) is necessary before placing the cosmetic product on the market.

The Notification is free of charge.

The (CPNP) is free of charge online notification system. When a product has been notified in the CPNP, there is no need for any further notification at national level within the EU.

The responsible person shall submit, by electronic means, the following information to the Commission:

- (a) the category of cosmetic product and its name or names, enabling its specific identification.
- (b) the name and address of the responsible person where the product information file is made readily accessible.
- (c) the country of origin in the case of import.
- (d) the Member State in which the cosmetic product is to be placed on the market.
- (e) the contact details of a physical person to contact in the case of necessity.
- (f) the presence of substances in the form of nanomaterials

²⁷ Technical document on cosmetic claims - Agreed by the Sub-Working Group on Claims

²⁸ COMMISSION RECOMMENDATION of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto.

(g) the name and the Chemicals Abstract Service (CAS) or EC number of substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR), of category 1A or 1B.

(h) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

(i) When the cosmetic product is placed on the market, the responsible person shall notify the Commission the original labelling, and, where reasonably legible, a photograph of the corresponding packaging.

The information may be used by competent authorities only for market surveillance, market analysis, evaluation, and consumer information (if need be).

The information may be used also by poison centers or similar bodies, established by the Member States for medical treatment.

3.1.9 Competent EU Authorities and Specific National Requirements

The frame cosmetics regulations are issued at the European level by the European regulatory bodies: EU Parliament, Commission, DG GROWTH²⁹.

Afterwards, the European authorities give to the Member States the following responsibilities and mandates:

- To designate their national competent authorities. Each Member State decides the competences of the national authorities within their countries. A list of
- To monitor compliance with the principles of good manufacturing practices.
- Monitor compliance with the Regulation via in-market controls of the cosmetic products made available on the market.
- To lay down the provisions on penalties applicable for infringement of the provisions of the Regulation and take all measures necessary to ensure that they are implemented.
- To determine the language of the information in which the product is made available to the end-user (Partially).

Then, when exporting cosmetic products to a particular UE country, the exporting company should review the regulation for this country on the above.

²⁹ https://ec.europa.eu/growth/index_en DG Internal Market, Industry, Entrepreneurship and SMEs – Sector cosmetics

3.1.10 Other European Legislation Applicable to Cosmetics

Apart from the main regulatory framework for finished cosmetic products, additional requirements covered by other EU legislation might apply. Some of them are listed below.

The main ones (non-exhaustive list) are:

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

REACH requires that any substance, isolated or as a part of a product, must be registered in Europe before being commercialized.

What this means in practice is that raw materials contain in cosmetics products imported into the UE, must have in Europe a previous registration.

Registration is not required for substances:

- Substances imported in less than 1 ton/year,
- Substances that present a minimal risk because of their basic properties (e.g. water, nitrogen) listed in Annex IV of REACH
- Substances occurring in nature (e.g. minerals, ores and ore concentrates that are not chemically modified) where registration is deemed inappropriate or unnecessary, listed in Annex V of REACH³⁰

These are especially important points to be checked before starting exporting procedures.

- Regulation ((EC) No 1272/2008) Classification, Labelling and Packaging (CLP). Based on the United Nations' Globally Harmonized System (GHS)

Cosmetics as a finished product are exempted from the application of CLP (Art. 2c). If the cosmetic product is not a finished product (e.g. bulk) CLP applies.

- Packaging and Packaging Waste. The Producer Responsibility Obligations (Packaging Waste) Regulations 2007.
- Aerosol Legislation Dispensers Regulations 2009.
- The current EU 'Ozone Regulation' (Regulation (EC) 1005/2009) The Ozone Regulation prohibits their use in most cases (certain uses are still permitted in the EU)
- DIRECTIVE (EU) 2019/904 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 on the reduction of the impact of certain plastic products on the environment.

³⁰ This point will be relevant whenever exporting natural ingredients to the EU.

3.1.10. b) United Kingdom

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a ‘third’ country. The Withdrawal Agreement provides for a transition period ending on 31 December 2020. Until that date, EU law in its entirety applies to and in the United Kingdom.

As of the end of the transition period, the UK will have its own cosmetics regulation meaning that products sold on the UK market will have to comply with this new regulation. This new regulation is not yet published, but we are expecting it to maintain the same standards as the EU cosmetics regulation.

During the transition period, the EU and the UK will negotiate an agreement on a new partnership, providing notably for a free trade area. However, it is not certain whether such an agreement will be concluded and will enter into force at the end of the transition period.

The EU published a specific Technical Notice³¹ on cosmetics to inform companies on how to prepare for a 'no deal' Brexit. The technical notice clearly states that UK companies who want to continue selling cosmetic products in the EU will need to comply with the EU Cosmetics Regulation after Brexit.

To address the consequences for companies exporting products to the UK should:

- ensure establishment in the UK, and Responsible Person reflect this in the corresponding labelling.
- ensure compliance of the safety assessment and with the qualifications of safety assessor.
- take the necessary steps to update products into the UK Cosmetic Product Notification Portal (CPNP).

The UK Cosmetics Regulation Statutory Instrument³² (SI), which is part of the Product Safety & Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, was finally debated in the House of Commons on 12 March and passed in Parliament on 20 March. The SI will, therefore, come into force on exit day in the event of a 'no deal' Brexit.

The UK Government has also published a guidance document outlining the changes regarding product safety across the different sectors included in the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019. The guidance will also apply from Exit day in the event of a 'no deal' Brexit.

On 2 July, ³³the UK Government Department Office for Product Safety and Standards (OPSS) announced the entry into force of the same SI from 1 January 2021; we, therefore,

³¹ NOTICE TO STAKEHOLDERS WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF COSMETIC PRODUCTS

³² legislation.gov.uk.

³³ As Brexit situation is evolving, I decide to “freeze” the status at the time of issuing the document. As the negotiations for the UK/EU Free Trade Agreement (FTA) are still ongoing, to date, there are a lot of uncertainties. Therefore, it is impossible to say at this stage what this will

have confirmed that the UK legislation that was published for a ‘no deal’ Brexit is not expected to change in the current context.

However, a series of Statutory Instruments (SIs) has been published to implement technical modifications and make the Product Safety and Metrology SI suitable to the context where the UK left the EU with a Withdrawal Agreement.

be, and it will only be known with very short notice. So, the regulatory situation needs to be further tracked.

Table 2: Summary of market regulations/Requirement for imported products (EU +UK)

COUNTRY	COSMETIC DEFINITION	INGREDIENTS/COMPOSITION	GMPs	LABELLING	CLAIMS	SAFETY	ACCESS TO THE MARKET
EU	Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors	Cosmetic products shall not contain: Prohibited substances that are listed in Annex II Restricted substances listed in Annex III Any colorants than those listed in Annex IV Preservatives other than those listed in Annex V UV-filters other than listed in Annex VI	Compliance with good manufacturing practices shall be presumed where the manufacture is in accordance with the relevant harmonized standards, the references of which have been published in the Official Journal of the European Union. The harmonized standard for GMPs is the ISO 22716 Cosmetics — Good Manufacturing Practices	Cosmetic products may only be made available on the market if their container and packaging meet the Art. 19 guidelines for providing information to the consumer. The law of the Member States where the cosmetic product is made available to consumers will determine the language that the required labelling information will need to be provided in.	Regulated by "Common Criteria" 1. Legal compliance. 2 Truthfulness 3. Evidential support 4. Honesty 5. Fairness 6. Informed decision-making	Detailed Product Information File available to the competent authorities at the address of the RP	No pre-registration is required to market cosmetics into the EU. Only a notification to the Cosmetic Products Notification Portal (CPNP) is necessary before placing the cosmetic product on the market. The RP will be located in the EU.

3.2 United States of America

The United States of America (USA), is a country mostly located in central North America, between Canada and Mexico. It consists of 50 states, a federal district, five major self-governing territories, and various possessions.

3.2.1 Regulations driving cosmetics in the USA

While in Europe the regulatory frame is homogeneous, and in some way simple and detailed, in the USA there are more “*degrees of freedom*” that in one way gives more possibilities, but, in the other side, for companies introducing cosmetics in the USA it becomes sometimes difficult to be compliant. The regulation has some imprecision, which will produce a certain degree of legal uncertainty.

Nevertheless, the FDA provides a lot of information/clarification for different issues regarding the cosmetic regulations via “Guidance Documents” that represent FDA’s current thinking on a topic.

Guidance do not create or confer any rights for or on any person and do not operate to bind FDA or the public. Manufacturers can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. Those can be found at the FDA cosmetics website³⁴.

For importers, the FDA often receives questions from cosmetics firms about requirements for importing cosmetics into the United States. A commonly asked questions and FDA responses document can be found also at the FDA cosmetics website³⁵.

The United States, federal laws are enacted by Congress. To make the laws work on a day-to-day level, Congress authorizes certain government agencies, such as the FDA, to create regulations.

U.S. regulations are not centralized. Those are divided among the federal government, state, and the local authorities. Due to such complexity, a product or service may be forced to comply with the various standards of these three levels, to have access to the commercial traffic of the country.

FDA issues regulations to implement its statutory authority. The regulations can create binding obligations and have the force of law.

The two most important laws on cosmetics marketed in the United States are:

Federal Food, Drug, and Cosmetic Act (FD&C Act)

Fair Packaging and Labelling Act (FPLA).

FDA regulates cosmetics under the authority of these laws.

³⁴ <https://www.fda.gov/cosmetics>

³⁵ <https://www.fda.gov/cosmetics/cosmetics-international-activities/cosmetics-importers#english>

The frame regulation is the FEDERAL FOOD, DRUG, AND COSMETIC ACT (FD&C ACT) [Title 21 Chapter 9 of the United States Code]. The United States Code is a consolidation and codification by subject matter of the general and permanent laws of the United States.

Regulations related to cosmetics are in Title 21 of the Code of Federal Regulations (21 CFR). Updated regulations can be found at the Electronic Code of Federal regulations website³⁶

The Electronic Code of Federal Regulations (e-CFR) is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation. The Electronic Code of Federal Regulations is updated daily.

This dataset is intended for public access and use. Updated Title 21 Food and Drugs can be found there.

Citations to the Code of Federal Regulations in the Federal Register are cited with the title number, the abbreviation CFR, the word “part” or the symbol “§” for section, and the number of the part or section, as in 21 CFR Part 701 Subpart C - (Sections 701.20 through 701.30)- Labelling of Specific Ingredients.

3.2.2 Cosmetic Product Definition

While in Europe there is one definition for cosmetics, what a clear differentiation with medical devices or drugs, in the FDA definition we find differences. Products being cosmetics under the definition of the UE Regulation can be Drugs under the FDA regulation.

“Cosmetic product” The FD&C Act defines cosmetics by their intended use, as *“articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles”* (FD&C Act, sec. 201(i)).

If we break this down, we can see that a heavy emphasis is made to incorporate into the definition of a cosmetic the different application methods and to make sure that all are covered within. This comes as a contrast to the European Regulation in which the stress was made to define a cosmetic through the area of application rather than methods. Secondly and probably most importantly are the functions which define a cosmetic. In the US regulation, the definition does not include two key terms: “protecting” and “correcting”. While it might not look like a truly relevant omission, it is the source of great concern for those in the industry willing to import or manufacture inside the US.

The implications that these two words have are bigger than one might expect. The absence of the first of these terms, protecting, directly affects products such as sunscreen

³⁶<https://www.ecfr.gov/>

preparations, which have a function of protecting the skin against UVA and UVB radiation.

In the case of the second term, correcting, it can relate to antiperspirants, for which the function would be to correct excessive sweating. In both these cases, the products mentioned would not be considered as a cosmetic product. Better said, they would be doubly classified as a cosmetic and an over the counter (OTC) drug at the same time and as such would have to be compliant to both the cosmetic and OTC drug regulations. Other products such as anti-dandruff shampoos also have this double classification because of its dual function, both as a tool to clean hair and to treat dandruff conditions (treating being an element of the definition of a drug).

“Introduced into” is another issue that does not fit into the European cosmetic definition.

Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product. Cosmetics products are not the same as drug products, and they are regulated differently by the FDA. The definition does not include soaps. Some examples of cosmetic products:

Tattoos and permanent makeup³⁷

Face and body cleansers, moisturizers and other skin lotions and creams

Deodorants and makeup

Baby lotions and oils

Haircare products, dyes, conditioners, straighteners/relaxers, perms

Hair removal creams

Nail polishes

Shaving products

Perfumes and colognes

Face paints and temporary tattoos

These products and their ingredients are not subject to FDA premarket approval, except color additives (other than coal tar hair dyes).

The law does not require cosmetic products and ingredients, other than color additives, to have FDA approval before they go on the market, but some laws and regulations apply to cosmetics on the market in interstate commerce.

³⁷ Inks used in intradermal tattoos, including permanent makeup, fall within the definition of cosmetics under the Federal Food, Drug, and Cosmetic Act. The actual practice of tattooing, including tattoo parlor practices and safety, is generally regulated by local jurisdictions.

Soaps³⁸

Whether a product is a “soap” in the traditional sense or is a synthetic detergent, helps determine how the product is regulated.

To meet the definition of soap³⁹ in FDA’s regulations, a product has to meet three conditions:

- What it’s made of: To be regulated as “soap,” the product must be composed mainly of the “alkali salts of fatty acids,” that is, the material you get when you combine fats or oils with an alkali, such as lye.
- What ingredients cause its cleaning action: To be regulated as “soap,” those “alkali salts of fatty acids” must be the only material that results in the product’s cleaning action. If the product contains synthetic detergents, it’s a cosmetic, not a soap. You still can use the word “soap” on the label.
- How it's intended to be used: To be regulated as soap, it must be labelled and marketed only for use as soap. If it is intended for purposes such as moisturizing the skin, making the user smell nice, or deodorizing the user’s body, it’s a cosmetic. Or, if the product is intended to treat or prevent diseases, such as by killing germs, or treating skin conditions, such as acne or eczema, it is a drug. You still can use the word “soap” on the label.

Drugs

The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)]. Products intended for therapeutic use, such as treating or preventing disease, or to affect the structure or function of the body, it’s a drug⁴⁰ or in some cases a medical device⁴¹, even if it affects the appearance. Some examples are treatments for dandruff or acne, sunscreen products, antiperspirants, and diaper ointments. For this type of products, it is necessary to review the corresponding monograph.

Generally, drugs must receive premarket approval by the FDA or, if they are nonprescription drugs, conform to special regulations, called "monographs," for their category.

The FD&C Act prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce.

“Adulteration” refers to violations involving product composition whether they result from ingredients, contaminants, processing, packaging, or shipping and handling. Section 601 of the FD&C Act [21 U.S.C. 361] describes what causes a cosmetic to be considered adulterated.

³⁸ As “black soap” is a relevant product for Ghana, this definition must be carefully taken into consideration.

³⁹ Soaps regulation can be found at 21 CFR 701.20

⁴⁰ (FD&C Act, 201(g)),

⁴¹ (FD&C Act, 201(h))

“Misbranding” refers to violations involving improperly labelled or deceptively packaged products. Section 602 of the FD&C Act [21 U.S.C. 362] describes what causes a cosmetic to be considered misbranded.

Some products meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Among other cosmetic/drug combinations are tubes of toothpaste that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs.

Over the Counter Drugs (OTC) ⁴² - OTC Drugs are drugs that are safe and appropriate for use without a prescription. Legal marketing of OTCs requires for the products meeting the provisions of a regulation called ‘OTC drug monograph’. A monograph includes requirements on ingredients.

Monograph Regulated OTC Health & Beauty Products:

Acne

Anticaries

Astringent

Dandruff

Dental Care

Skin Bleaching

Skin Protectant

Sunscreens

OTC products that do not fit under an existing monograph must be approved under an application like for prescription products.

3.2.3 Ingredients Regulation

The Cosmetic Ingredient Review was established in 1976 by the industry trade association (then the CTFA, now the Personal Care Products Council), with the support of the U.S. Food and Drug Administration and the Consumer Federation of America.

⁴² On March 27, 2020, the President signed into law HR 748 the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The CARES Act includes an important legislative initiative that reforms and modernizes the way OTC monograph drugs are regulated in the United States.

The CARES Act amends the FD&C Act to Modernize the OTC drug review and OTC monograph drug development process. Provides FDA with the authority to collect user fees dedicated to OTC monograph drug activities.

Although funded by the Council, CIR and the review process are independent of the Council and the cosmetics industry.

The Cosmetic Ingredient Review (CIR) studies individual chemical compounds as they are used in cosmetic products. CIR relies heavily on the International Nomenclature of Cosmetic Ingredients (INCI) when identifying the ingredients to be assessed.

Cosmetic manufacturers have a legal responsibility for the safety and labelling of their products.

Under U.S. law, cosmetic products and ingredients, other than color additives, do not need FDA approval before they go on the market. Color additives are permitted in cosmetics only if the FDA has approved them for the intended use. Also, some may be used only if they are from batches that the FDA has tested and certified.

It's against the law for a cosmetic to contain any ingredient that makes the product harmful when consumers use it according to directions on the label, or in the customary or expected way. This is true whether or not there is a regulation that specifically prohibits or restricts the use of the ingredient in cosmetics.

Although it's against the law to use any ingredient that makes a cosmetic harmful when used as intended, the FDA has regulations that specifically prohibit or restrict the use of the specific ingredients in cosmetics⁴³.

A list of specific ingredients which are prohibited from being included into a cosmetic product has been issued by the FDA and is included in the Federal Regulations, but it is a small list, with only 12 items, in comparison to the ones established by the European Commission. Once again, the responsibility that the ingredients included are safe and that the labelling gives the appropriate indications lies solely on the person who has made the cosmetic available in the market, be it manufactured or imported.

3.2.4 Safety of Cosmetics

Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA.

The safety of a cosmetic can be considered adequately justified if experts qualified by scientific training and experience can reasonably conclude from the available toxicological data, tests, chemical composition, and other relevant information that the product is safe to consumers under normal or reasonably foreseeable conditions of use.

FDA has stated that *"the safety of a product can be adequately substantiated through"*⁴⁴:

⁴³ For specific restrictions, 21 CFR Part 700 must be checked

⁴⁴ Federal Register, March 3, 1975, page 8916

(a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and

(b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information."

Cosmetic Safety Enhancement Act of 2020

The bill would, among other provisions:

- ✓ Require cosmetics companies to substantiate the safety of their products
- ✓ Notify the FDA of any adverse health events
- ✓ Give the FDA the power to conduct its safety reviews
- ✓ Mandate that manufacturers provide more transparency about ingredients on their labels

Failure to adequately substantiate the safety of a cosmetic product or its ingredients prior to marketing causes the product to be misbranded unless the following appears on the principal panel of the label..... *“Warning-The safety of this product has not been determined”*

Using available safety data⁴⁵

Safety data are already available on individual ingredients and on products whose formulations are similar can be used. Here are some examples:

Cosmetic ingredient suppliers often have safety data on their products.

Safety data may be published in scientific journals (sources include PubMed,⁴⁶ and TOXNET⁴⁷).

The Cosmetic Ingredient Review⁴⁸ (CIR) website has information on the safety of cosmetic ingredients that they have reviewed. FDA takes CIR reviews into consideration when we evaluate cosmetic ingredient safety.

3.2.5 Good Manufacturing Practices

Good manufacturing practice (GMP) is an important factor in helping to assure that your cosmetic products are neither adulterated nor misbranded.

While FDA has provided guidelines for cosmetic GMP (see "Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist" and "Guidance for Industry Cosmetic

⁴⁵ European Regulation accepts the same scientific sources for ingredients safety evaluation within the PIF.

⁴⁶ <http://www.ncbi.nlm.nih.gov/pubmed>

⁴⁷ <http://toxnet.nlm.nih.gov/>

⁴⁸ (CIR is an industry-funded panel of scientific and medical experts who review the safety of cosmetic ingredients

Good Manufacturing Practices”), there are no regulations set for specific GMP requirements for cosmetics⁴⁹.

In contrast, the law requires strict adherence to GMP requirements for drugs, and regulations are specifying minimum current GMP requirements for drugs.⁵⁰ Failure to follow GMP requirements causes a drug to be adulterated⁵¹.

Although not mandatory, the FDA recommends compliance with GMP’s to ensure that the cosmetic product has not been adulterated.

Nevertheless, the International Cooperation on Cosmetic Regulation (ICCR)⁵² agreed to implement ISO 22716, wherever possible. So, the application of ISO 22.716 is widely recognized as being compliant with GMPs for cosmetics.

3.2.6 Consumer Information

3.2.6 a) Labelling

Cosmetics marketed in the United States must comply with the labelling standards published by the FDA, regulated by the Federal Food, Drug, and Cosmetic (FD&C) Act (21 USC section 301) and the Fair Packaging and Labelling (FP&L) Act (15 USC section 1451).

The FDA does not approve of cosmetic labelling. However, it does provide guidance documents for labelling, which cosmetics manufacturers and private labellers must make sure to comply with.

Cosmetic labelling has two parts:

- Main display panel
- Information panel

The Main Display Panel (PDP) is the part of the label that is likely to be displayed or examined under the usual display conditions for sale.

Labelling requirements are very detailed in terms of description, different panels descriptions, location within the inner and outer packs, sizes, minimum letter height, etc.

Cosmetics marketed in the United States must comply with FDA-published labelling standards, regulated by:

⁴⁹ In addition, as part of an international harmonization effort with the International Cooperation on Cosmetic Regulations (ICCR), FDA agreed to consider the current International Organization for Standardization (ISO) standard for cosmetic GMPs (ISO 22716:2007) when revising this guidance.

⁵⁰ [Title 21 of the Code of Federal Regulations (CFR), parts 210 and 211].

⁵¹ [FD&C Act, sec. 501(a)(2)(B)]

⁵² <https://www.iccr-cosmetics.org/> ICCR) is a voluntary international group of cosmetics regulatory authorities from Brazil, Canada, the European Union, Japan and the United States. This group of regulatory authorities meet on an annual basis to discuss common issues on cosmetics safety and regulation, as well as enter into a constructive dialogue with relevant cosmetics industry trade associations.

Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. section 301

Fair Packaging and Labelling Act (FPLA), 15 U.S.C. section 1451

The Food and Drug Administration issued a “*Cosmetic Labelling Guide*” that provides step-by-step help with cosmetic labelling, with examples and answers to questions manufacturers often ask about labelling requirements under U.S. laws and related regulations.

FDA issued a code: CFR - Code of Federal Regulations Title 21 - FOOD AND DRUGS - CHAPTER I -FDA Department of Health and Human Services - Subchapter G—Cosmetics. Part 700 TO 740 Cosmetic Labelling

The FD&C Act defines in sec. 201(m) "labelling" to mean "all labels and other written, printed or graphic matter on or accompanying such article."

This includes labels, inserts, risers, display packs, leaflets, promotional literature or any other written or printed information distributed with a product.

The term "label" is defined in the FD&C Act and the FP&L Act. The definitions differ in that under the FD&C Act definition a label is "*a display of written, printed or graphic matter upon the immediate container,*" and under the FP&L Act definition "*written, printed or graphic matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.*"

The FD&C Act requires in sec 201(k) that any information required to appear on the label of the immediate container shall also appear on the outside container of the retail package or is legible through the outside container.

Principal Display Panel

The part of a label that the consumer sees or examines when displayed for retail sale

A label may consist of more than one panel. It may consist of a front panel, side panels and a back panel. Back and side panels are generally called information panels.

The "principal display panel" is that part of a panel that is most likely to be shown or examined under customary conditions of display for retail sale. Usually, it is the front panel of the label of the outer package.

Placement and Size of Principal Display Panel (PDP)

PDP be large enough to accommodate all required label information with clarity and conspicuousness.

If a package bears more than one PDP, the information required to be placed on the PDP must be duplicated on all PDPs.

To assuring uniform type size for declaring a product's net quantity of contents, the size of the surface area bearing the PDP, and not the size of the PDP itself, is the determining factor. The area of the PDP is for a:

Rectangular package: One entire side.

Cylindrical package: 40% of height x circumference.

Any other shape of container: 40% of the total container surface, excluding top, bottom, neck, shoulder, flanges.

The PDP of a "boudoir-type" or decorative cosmetic container, e.g., cartridge, pillbox, compact or special variety, and those containing 1/4 oz or less may be a tear-away tag or tape affixed to the container⁵³. It may also be the display panel of a card to which the immediate container is affixed⁵⁴.

There are no U.S. laws or regulations that require cosmetics to have specific shelf lives or have expiration dates on their labels. However, manufacturers are responsible for making sure their products are safe. FDA considers determining a product's shelf life to be part of the manufacturer's responsibility.

Language

All label or labelling statements required by law or regulation must be in the English language. Products distributed solely in Puerto Rico or a Territory where the predominant language is one other than English may state the required label information in the predominant language in place of English.

Foreign Language Statements: If the label contains any foreign language representation, all statements required by regulation must also appear on the label in the foreign language. If labelling bears foreign language representations, the required statements must appear on the label or other labelling as required in English.

Type Size

Ingredients: 1/16", 1/32" (Labelling surface, less than 12 sq. in.)

Net Contents:

- 1/16" (PDP less than 5 sq. in.)
- 1/8" (PDP 5-25 sq. in.)
- 3/16" (PDP 25-100 sq. in.)

Warning: 1/16"

All Others: Reasonably related to panel size

⁵³ [21 CFR 701.13(e)(1)]

⁵⁴ [21 CFR 701.13(e)(2)]

Ingredients labelling

The label on each package of a cosmetic shall bear a declaration of the name of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor. Where one or more ingredients is accepted by the Food and Drug Administration as exempt from public disclosure, in lieu of label declaration of identity the phrase "and other ingredients" may be used at the end of the ingredient declaration.

There is an exemption from ingredient labelling that may apply to imported cosmetics without labelling, and label them in the United States before marketing them.

Bulk cosmetics do not have to comply with the cosmetic labelling regulations if the person introducing the shipment is the operator of the establishment where the shipment is going to be repackaged and labelled, or, in a case where someone else is going to introduce the shipment into the United States if a written agreement signed by the establishment operator is available for customs officials at the time the shipment is offered for import.

The labelling exemption will be void, however, if the product is moved from the establishment without the required labelling⁵⁵.

3.2.6 b) Claims

The legal definition of a cosmetic crosses over into the drug category when the intended use is associated with cleansing, beautification, promotion of attractiveness, disease prevention or other issues that affect the structure or function of the human body.

A cosmetic also is classified as a drug when the intended use is associated with exerting physical or psychological effects.

As explained on the Point "Cosmetic definition" the FD&C Act prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce.

"Adulteration" refers to violations involving product composition whether they result from ingredients, contaminants, processing, packaging, or shipping and handling. Section 601 of the FD&C Act [21 U.S.C. 361] describes what causes a cosmetic to be considered adulterated.

FDA may conclude that a product is misbranded if the following violations occur:

- ✓ false or misleading labelling
- ✓ label omits name and address of the manufacturer, packer or distributor
- ✓ net quantity of contents is not listed
- ✓ the labelling fails to be conspicuous for consumers to read
- ✓ misleading container or fill

The intended use of the product must also be specifically stated, along with the

⁵⁵ For complete information, see the regulation at 21 CFR 701.9.

consequences that result from unintended usage. The legal definition of the term "intended" specifically corresponds with package labelling. Courts usually depend on consumer perceptions of label meanings and not so much on the company's interpretation.

In other words, the intended use must be stated clearly.

3.2.7 Market Access - Registration

The first step for a company doing business in the United States is to know whether their product is subject to any U.S. regulation. If the product is regulated, the company needs to determine which technical regulations applicable to its products. This includes U.S. federal regulations, as well as relevant state and local level regulations. If a product fails to meet a market access requirement, it could be denied access to the U.S., or the manufacturer could be fined, imprisoned, or face other penalties imposed by the government.

Using the online U.S. Code of Federal Regulations (CFR), companies can search all current federal-level regulations (including technical regulations) by keyword, subject, or regulatory agency.

Under the FD&C Act, cosmetic products and ingredients, except for color additives, do not require FDA approval before they go on the market.

Drugs, however, must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over the Counter (OTC) Drug Review.

These monographs specify conditions whereby OTC drug ingredients are generally recognized as safe and effective, and not misbranded. Certain OTC drugs may remain on the market without an NDA approval until a monograph for its class of drugs is finalized as a regulation.

However, once FDA has made a final determination on the status of an OTC drug category, such products must either be the subject of an approved NDA⁵⁶, or comply with the appropriate monograph for an OTC drug. A note on the term "new drug": Despite the word "new," a "new drug" may have been in use for many years. If a product is intended for use as a drug, it must comply with the requirements outlined above.

While federal regulations must be followed to do business within the U.S., it is important to remember that each of the 50 U.S. states and the District of Columbia have their unique regulations as well. This means that a business wishing to operate within the U.S. must also consider which additional requirements may be necessary for the state where their business will operate.

⁵⁶ [FD&C Act, sec. 505(a) and (b)]

Voluntary Cosmetic Registration Program⁵⁷

FDA's Voluntary Cosmetic Registration Program (VCRP) is a reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States.

VCRP regulations can be found in 21 CFR, parts 710 and 720.

The VCRP applies only to cosmetic products being sold to consumers in the United States. It does not apply to cosmetic products for professional use only, such as products used in beauty salons, spas, or skincare clinics. It also does not apply to products that are not for sales, such as hotel samples or gifts.

The VCRP is defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), section 201(i). Drugs are subject to different FDA registration and marketing requirements (FD&C Act, sec. 510; 21 CFR 207). Depending on the claims made, some cosmetic products may also be drugs. If a cosmetic product is also a drug, it must comply with the requirements for both cosmetics and drugs.

The VCRP is not a cosmetic approval program or a promotional tool. Cosmetics are not subject to FDA premarket approval. It is the firm's responsibility to ensure that its cosmetic products and ingredients are safe and properly labelled, in full compliance with the law.

The VCRP is not part of a prior notice system for imported cosmetics. Firms importing products considered to be solely cosmetics in the United States are not required to register with FDA.

Red List

As a result of an Import Alert, FDA will automatically detain your products at the border, resulting in FDA Detention Without Physical Examination (DWPE). The company and product will then appear on the Import Alert's "Red List."

3.2.8 Competent Authorities

Regulations in the US are not centralized but are distributed among the Federal government state and local authorities. Due to such complexity, a product or service may be forced to comply with the various standards of these three levels, to have free access to the country's commercial traffic.

⁵⁷ <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program>

3.2.8 a) Standards applying cosmetics

Being ISO standards internationally recognized, the USA competent authorities for cosmetics accept and uses ISO standards as a method of compliance.

The American National Standards Institute⁵⁸ (ANSI) provides answers to the critical standards, conformance, market access, and trade-related questions that companies require to succeed in the U.S. and internationally.

ANSI is a member of the ISO TC217 Cosmetics.

www.StandardsPortal.org provides answers to the critical standards, conformance, market access, and trade-related questions that companies require to succeed in the U.S. and internationally.

3.2.8 b) FDA General Information

FDA has published general regulatory information and support guides for the sector concerned on its Internet portal.

<http://www.fda.gov/Cosmetics/ResourcesForYou/Industry/ucm2005224.htm>

Guides on labelling standards are of special interest to the manufacturer/ importer:

<http://www.fda.gov/Cosmetics/CosmeticLabellingLabelClaims/CosmeticLabellingManual/default.htm>

It is also relevant to always check the authorized or restrictive use of ingredients and colorants. Ingredients authorized in other regions not necessarily will be approved in the USA:

<http://www.fda.gov/Cosmetics/ProductsIngredients/default.htm> (Ingredients)

<http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/default.htm> (Colorants)

<http://www.fda.gov/Cosmetics/Labelling/IngredientNames/ucm109084.htm> (Allowed Colorants)

⁵⁸ www.standardsportal.org

Table 3: Summary of market regulations/Requirement for imported products (USA)

COUNTRY	COSMETIC DEFINITION	INGREDIENTS/ COMPOSITION	GMPs	LABELLING	CLAIMS	SAFETY	ACCESS TO THE MARKET
USA	<p>"Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles" (Except soaps). The raw materials used as ingredients of cosmetic products are by law also cosmetics</p> <p>SOAPS: What it's made of What ingredients cause its cleaning action How it's intended to be used.</p> <p>OTC: A cosmetic is also a drug when it is intended to cleanse, beautify or promote attractiveness as well as treat or prevent disease or otherwise affect the structure or any function of the human body. A cosmetic is legally also a drug if it is intended to exert a physical as well as a physiological effect. The categories of "drug" and "cosmetic" are not mutually exclusive.</p>	<p>Cosmetic manufacturers have a legal responsibility for the safety and labelling of their products.</p> <p>Under U.S. law, cosmetic products and ingredients, other than color additives, do not need FDA approval before they go on the market. Color additives are permitted in cosmetics only if the FDA has approved them for the intended use. Prohibition of 12 ingredients. The rest are to be used only when considered safe.</p>	<p>ISO 22.716 cosmetics GMP recognized for compliance. The FDA may still inspect manufacturing facilities to make sure that proper controls and practices are in compliance with applicable laws.</p>	<p>The FDA does not pre-approve cosmetic labelling. However, it does provide guidance documents for labelling, which cosmetics manufacturers and private labellers must make sure to comply with.</p> <p>Cosmetic label has two parts: Main display panel and information panel. Declaration within each panel is described.</p>	<p>FD&C Act prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce. "Adulteration" refers to violations involving product composition whether they result from ingredients, contaminants, processing, packaging, or shipping and handling.</p> <p>A product is misbranded if the following violations occur.</p> <ul style="list-style-type: none"> -false or misleading labelling - label omits name and address of the manufacturer, packer or distributor - net quantity of contents is not listed -the labelling fails to be conspicuous for consumers to read - misleading container or fill 	<p>The safety of a cosmetic can be considered adequately justified if experts qualified by scientific training and experience can reasonably conclude from the available toxicological data, tests, chemical composition, and other relevant information that the product is safe to consumers under normal or reasonably foreseeable conditions of use.</p>	<p>Imported cosmetics must comply with the same laws and regulations that apply to those produced domestically</p> <p>Under the FD&C Act, cosmetic products and ingredients, with the exception of color additives, do not require FDA approval before they go on the market. The cosmetic product can be voluntarily registered with the FDA. Imported products are examined upon entry but not all cosmetics are inspected or sampled upon entry into this country. In order to focus inspection efforts most efficiently, FDA issues Import Alerts to advise inspectors of trends in violations. However, examination of imported cosmetics is not limited to the types of products specified in Import Alerts. The FDA might periodically purchase cosmetic products to analyze them for potential hazards or other issues. If problems arise associated with ingredients, the agency may issue consumer alerts through mass media press releases.</p>

3.3 Middle East - United Arab Emirates UAE

The United Arab Emirates is a federation of seven states at the northeast end of the Arabian Peninsula on the Persian Gulf: Abu Dhabi (which serves as the capital), Ajman, Dubai, Fujairah, Ras Al Khaimah, Sharjah and Umm Al Quwain.

3.3.1 Regulations driving cosmetics in the United Arab Emirates

As in many other countries, cosmetics and personal care products must be registered with the competent authority to be imported and subsequently marketed. Due to the country's idiosyncrasies, there are two entities in the UAE that claim the authority for the registration of such products: The Municipality of the emirate of Dubai and the Emirates Authority for Standardization and Metrology (ESMA, federal entity).

The Cosmetics Law applies to all types of cosmetics and personal care products offered, manufactured, imported, supplied, packed, or used within the UAE.

To be offered for sale and used in the UAE, imported and locally manufactured cosmetics and perfumery products must comply with health and safety requirements that are primarily set out by the following legislation:

- Cabinet Decision No. 18 of 2014 on the UAE Regulations for the Control of Cosmetics and Personal Care Products, the Cosmetics Act.
- Cabinet Decision No. 5 of 2014 on the UAE Regulations for The Supervision of Fragrances (the "Fragrances Law").

The Gulf Cooperation Council cosmetics legislation closely follows the EU Cosmetics Regulation 1223/2009. However, it has some of its criteria when it comes to processes, ingredients, labelling and claims.

3.3.2 UAE Scheme for Cosmetics and Personal Care Products

Approved by UAE Cabinet Resolution No.18 for the year 2014, in which all cosmetics & personal cares will be subjected to the procedures for obtaining a certificate of conformity under type approval from ESMA.

Scope: This technical regulation applies to all cosmetics & personnel care products which are placed on the market or manufactured or imported or supplied or packaged or used within the country.

Medicinal products, medical and cosmetics devices are not covered under this system.

UAE Scheme for Perfumes

Approved by UAE Cabinet Resolution No.5, issued on 19/01/2014 in which all perfumes will be subjected to the procedures for obtaining a certificate of conformity under type approval from ESMA.

Scope: This technical regulation applies to all perfume products which are placed on the market or manufactured or imported or supplied or packaged or used within the country.

Applicable Standards

#	Standard	Title of Standard
1	UAE .S GSO 1943	Cosmetic Products – Cosmetic Products Safety Requirements
2	UAE .S GSO ISO 22715	Cosmetics – Packaging and Labeling
3	UAE .S GSO OIML R 87	Quantity of Products in Prepackages
4	UAE .S GSO 2093	Glass Containers used for cosmetics

3.3.3 Cosmetic Product Definition

The Cosmetics Law defines cosmetics and personal care products as:

"any substance or mixture made for the use and contact of the external organs and parts of the body (such as the skin, hair, nails, lips, teeth, genitals or the mucosa of the oral cavity) for cleaning or perfuming them, changing their appearance, or enhancing their smell, or protecting or keeping them in the best shape."

This excludes:

- medical products used in the treatment of diseases; and
- devices and tools accompanying cosmetics.

The Fragrances Law applies to all types of perfume products offered, manufactured, imported, exported, packed, or used within the UAE.

The Fragrances Law defines perfume products as:

"any cosmetics and personal care products with a nice scent, composed of essential oils, fixatives, alcohol solution, water, permissible colorants, anti-oxidants and solvents."

The cosmetic product definition, which is also given in the GSO standard, is completely in line with the one in the European regulation.

Cosmetics products medicinal, curative, or recommended by dermatologists could be classified as pharmaceuticals and should be registered with the Ministry of Health.

Therefore, it is important to avoid in the labelling and packaging of cosmetics terms like "treatment" or "healthy" since it may cause the product to end up being classified as medicinal.

3.3.4 Ingredients Regulation

The legislation is organized in the same way as the EU Regulation when it comes to restricted and prohibited substances. Annex II lists the prohibited substances, Annex III lists the restricted substances and Annexes IV to VI list the allowed colorants, preservatives and UV filters, the list of such ingredients is also remarkably similar to the Annexes of the EU Regulation.

Products should fulfil certain requirements, some of which are: they should be completely free from pork and its derivatives, they should be safe for human health under normal and reasonably foreseeable conditions of use, they should be stable and their properties impacting safety, efficacy and quality should not change during their shelf life, they should be free from any filthy or decomposed substances.

Annex 2 to of GSO 1943 describes a List of Substances Prohibited in Cosmetic Products.

3.3.5 Consumer Information

Labelling and claims also follow the same schemes as the European Cosmetic Regulation

3.3.5 a) Labelling

In terms of labelling requirements, it is important to note that the graphics, images and phrases on the labels should be consistent with Islamic traditions and social values, that certain parts of the label have to be translated into Arabic and that claims have to be truthful (the legislation on claims follows the EU common claims criteria).

Labelling Requirements. Labelling requirements for UAE are remarkably similar to the ones in Europe.

Cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible, and visible lettering:

Cosmetic products intended for sale to consumers in the UAE must comply with the requirements stipulated by the UAE Standard UAE.S GSO 1943: (Detailed on Point 5)

5.1 The name of the product and the name of the trademark.

5.2 The name and address of the manufacturer or distributor.

The name and the address must be sufficient to identify the undertaking.

5.3 Country of origin of the product.

5.4 Nominal content of the product. Products must comply with Standard UAE.S GSO OIML R87.

5.5 The period, from the date of manufacturing, the cosmetic product shall fulfil its initial requirements and complies with article 4.2 provided it is stored at the stated conditions. This can be expressed by any one of the following options depending on the situation: “date of minimum durability” or the period after opening, indicated by the symbol, shown in Fig2 of Annex 7.

The declaration of the period after opening is not relevant in the following cases:

- a) Products presented in containers where there is no need for physical opening and there is no possibility of contact between the product in the container with the external environment
- b) Single-application products.
- c) Products with low microbiological contamination. (In this case, ISO 29621: Guidelines for the Risk Assessment of Microbiologically Low-Risk Finished Products applies)

5.6 Conditions of use, Warning Statements and precautionary information shall clearly express on the label

5.7 Batch Number or Lot Code. A code which enables the manufacturer or supplier to identify the batch in which the product was manufactured.

5.8 Product Function. The function of the cosmetic product should be clearly printed on the container and the packaging unless it can be spontaneously and obviously deduced from a combination of:

The product presentation (shape, size and volume) e.g. lipstick

Its name (e.g. cream) or trademarks

Its function claims

Pictures, logos and figurative or other signs (e.g. the picture of an eye on an eyeshadow)

5.9 List of Ingredients shall be printed on either both primary container and packaging or only packaging of the product or tag, cards...etc. as in the article. The list shall be preceded by the term ‘INGREDIENTS’.

5.10 The information required by (Article 5.1 to 5.8) must appear on the label of both the container and the packaging of each cosmetic product.

5.11 The requirements in the article (5.1 to 5.5) shall be in Arabic and/or English Languages. However, the following requirements must be present in both Arabic and English Languages on the products:

- Name of the product
- Product function and/or use instructions
- Warnings instructions and precautionary information
- Necessary storage instructions for safe use

For product labelling regarding composition, there is a specific standard that deals with the particularities of cosmetics products containing alcohol within an Islamic environment . This standard is the SASO 585, which can be summed up as the inclusion of two indications that must appear clearly on the label.

An indication of the alcohol concentration in the finished product must be given.

Secondly, precautionary statements must be included such as “not suitable for drinking” or “external use only” and these must appear in Arabic to reach the end consumer.

3.3.5 b) Claims

Claims on cosmetic and personal care products shall fall under the scope in article 1 and cosmetic definition in article 3.1.

Claims on cosmetic products shall conform to the following common criteria:

- Legal compliance
- Truthfulness
- Evidential support
- Honesty
- Fairness
- Informed decision-making

3.3.6 Cosmetics Safety

Responsibilities:

A Responsible Person based in the United Arab Emirates needs to be appointed. This can be the manufacturer’s representative or the importer.

At any stage of the supply chain, products must comply with the general safety requirements of GSO Standard 1943/2016 established by the Gulf Standardization Organization (GSO).

The Regulation for Cosmetics and Personal Care, Cabinet Decision 18\ 2014, details the content of the cosmetic Health and Safety report related to the product. This report shall contain information regarding:

- o Quantitative and qualitative composition of the product
- o Physical/chemical characteristics and stability of the product
- o Microbiological specifications

- o Impurities, traces, and information about the packaging material
- o Normal and foreseeable use of the product
- o Exposure to the product (taking into its toxicological effects)
- o Toxicological profile of the substances contained in the product
- o Undesirable effects
- o A statement on the safety of the product
- o Statement on the need to label any particular warnings and instructions of use
- o Electronic Declaration of conformity of the products

The Standard “*UAE.S/GSO 1943 – Cosmetic products – Cosmetic Products safety requirements*”, is concerned with the cosmetic products safety requirements which cosmetic products shall be fulfilled.

It specifies the substances which may not form part of the composition of cosmetic products as well as those subject to restrictions.

This gulf standard is concerned with the general safety requirements and parameters as well as labelling and packaging requirements (Points 5 and 8 of the standard) that should be fulfilled by all cosmetics and personal care products. An illustrative list of these products is given in Annex 1 of the standard.

The general safety and safety requirements under this standard are as follows:

Cosmetic and personal care products shall fulfil the following requirements (Point 4 of the standard):

- 4.1 The products shall be completely free from pork and all its derivatives.
- 4.2 They shall be safe for human health when used under normal or reasonably foreseeable conditions of use.
- 4.3 They shall be homogenous, stable and their properties shall not change during its shelf life when stored and used as per the instructions.
- 4.4 It should be free from any filthy or decomposed substance.
- 4.5 It should not contain graphics or images or phrases that are inconsistent with Islamic traditions and prevailing social values in GCC countries.
- 4.6 Cosmetic and personal care products shall not contain any of the following.

The GSO 12/ DS 1943 /2015 standard lists within the Annexes: Prohibited substances; Restricted substances; Coloring agents; Preservatives; UV-filters

Packaging and Wrapping Requirements

8.1 The packaging of cosmetics and personal care products shall be designed so that, under conditions specified by the manufacturer for storage, transport and handling, it protects against damage and deterioration and it does not adversely affect the product⁵⁹.

Products shall be packed in appropriate and clean containers that do not interact with the cosmetic product and vice versa, and it shall be ensured that the containers are free of sharp edges and are properly closed.

Containers used for products shall comply with the requirements set forth in Standard UAE S. GSO ISO 22175 relating to packaging and labelling and Standard UAE.S GSO 2093 relating to glass containers (in case of glass containers) used for cosmetics.

Metrology requirements

Products shall meet the requirements of Standard UAE.S GSO OIML R87 relating to the quantity of a product in containers.

3.3.7 Good Manufacturing Practices

The manufacture of cosmetic products shall comply with good manufacturing practice with a view to ensuring the objectives of Article 4.2. Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonized standards such as GSO ISO 22716.

3.3.8 Market Access - Registration

Despite having the same basic legislation across all the GCC member countries, each country requires a separate product notification (Bahrain does not require any notification) and the customs clearance process requirements may differ from country to country.

All Cosmetics, Perfumery and Personal Care Products placed in the UAE market should be in conformity with the ECAS requirements.

- ECAS Certificates of Conformity (CoC) issued by ESMA approved Notified Bodies are mandatory for its Customs clearance and for placing the products in the UAE marketplace.
- The Certificate confirms that the products comply with the relevant UAE technical regulations
- The Certificate is valid for one year and needs to be renewed on an annual basis

⁵⁹ This point is related to the stability and compatibility packaging/formula

- For importers, any shipments of regulated products arriving without the ECAS Certificate of Conformity will be rejected causing severe delays in goods clearance, penalties or even shipments being returned and products withdrawn from the market.
- All certified products shall bear the ECAS Mark of conformity.

SFDA eCosma Notification System for Cosmetic Products

Since 2015, Cosmetic product listing has gradually become compulsory, depending on product category.

In the UAE, the Emirates Standardization and Meteorological Authority (ESMA) is the body established and mandated by the Federal Law No 28 of 2001 to regulate and supervise the personal care sector in the country.

ESMA has implemented a product certification scheme, the Emirates Conformity Assessment Scheme (ECAS) for all imported and locally manufactured cosmetic and perfumery products.

The purpose of the ECAS is to ensure that such products comply with the applicable technical standards before they are imported into the UAE, at the port of entry, or put on the UAE market (for locally manufactured products).

If the products are deemed to comply with the ECAS requirements, ESMA issues an ECAS Certificate of Conformity. Ports and custom departments would only allow imported products with an ECAS Certificate of Conformity to enter the country and be distributed onwards.

It must be noted that only an entity incorporated in the UAE may register such products with ESMA and Municipalities. As such, this means that international companies seeking to market their products in the UAE must either establish a local presence or appoint a local distributor to import, register and distribute the products on their behalf.

3.3.9 Other Regulations Applying Cosmetics

Metal aerosol dispensers used for packing cosmetics and personal care products shall comply with the requirements in the standard in the article 2.12. of GSO

Registration with the Municipality

In addition to the foregoing, cosmetics and personal care products must be registered with the Dubai Municipality or the Municipality of the relevant Emirate in which the products are intended to be sold.

It is important to note that, again, only a company incorporated in the UAE may proceed with such registration process. It may, therefore, be the local importer, manufacturer or distributor of the product.

To the extent that only an entity incorporated in the UAE may register the products with ESMA and the Municipalities, this means that international companies seeking to market its products in the UAE must choose one of the following approaches:

Establishing a local presence by incorporating a UAE entity

Appointing a local distributor

An international company may choose to appoint an already existing local company to import and distribute its products in the UAE.

The most suited approach will depend upon the circumstances.

Emirates Quality Mark (EQM)

To increase UAE consumer confidence in their products which are placed on the market, exporters/importers trading Cosmetics, Perfumery and Personal Care products with the UAE can apply for an EQM License, this involves a comprehensive ESMA evaluation of the product and the quality system used by the manufacturer in production through auditing, testing and inspection.

Saudi Arabia

As one of the most influential members of the Gulf Cooperation Council (GCC), and as a representative country of the Middle Eastern community to which it belongs, Saudi Arabia is important to bring it into the comparison. It is relevant to make a review as a window into the regulations on cosmetics in the Middle East.

The Saudi health authorities, the Saudi Food and Drug Administration (SFDA) gives prevalence to SASO 1953 Standards but sanctions GSO 1943/2009. As in most of the Middle Eastern countries, Saudi Arabia includes European cosmetic regulation as reference material.

From 2015, a notification scheme has been launched from the SFDA into which all products and manufacturers/distributor must be included. This notification also constitutes a marketing authorization, as the SFDA verifies the data submitted and issues a response that fits into the accept/reject kind. Foreign cosmetic products being imported into Saudi Arabia and the corresponding foreign manufacturers also have to be notified through the same system.

3.3.10 Standards Applying Cosmetics

ESMA is the sole Authority in UAE for Quality, Metrology and Standards.

ESMA Strategic Objectives:

- Ensuring product conformity to ESMA mandatory schemes in the field of safety and health protection.
- The development of test and measurement references within the UAE in accordance with international standards
- Ensuring delivery of administrative services in accordance with the standards of quality, efficiency and transparency

ESMA is holding the Secretariat of several GSO standard developing committees
GCC Standardization Organization (GSO) is a regional Organization which consists of the National Standards Bodies of GCC member States. One of GSO main functions is to

issue Gulf Standards /Technical regulations through specialized technical committees (TCs).

The Cosmetics Law and the Fragrances Law (the "Regulations") set out the technical adopted standards to be fulfilled in relation to safety, packaging, wrapping, labelling and metrology for all cosmetics and perfumery products to be offered for sale and used in the UAE.

Applicable technical standards

Most of the standards are adopted by GSO from the ISO TC217 Cosmetics:

GSO ISO 22716 “Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices” .

GSO ISO 18416 “Microbiology - Detection of *Candida albicans*” .

GSO ISO 18415 “Detection of Specified and Non- Specified Microorganisms”

GSO ISO 10130 “Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC, post-column photolysis and derivatization”

GSO ISO 16212 “Enumeration of yeast and moulds”

GSO ISO 21149 “Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria”

GSO ISO 21150 “Detection of *Escherichia coli*”

GSO ISO 22717 “Detection of *Pseudomonas aeruginosa*”

GSO ISO 22718 “Detection of *Staphylococcus aureus*”

GSO 917 “Metal Aerosol Dispensers”

GSO 918 “Methods of testing Metal Aerosol Dispensers”

GSO ASTM 640 06 “Standard Test Method for Preservatives in Water-containing Cosmetics”

GSO ISO 17516 “Microbiology--Microbiological limits”

GSO ISO 24443, “Determination of sunscreen UVA photoprotection in vitro”

ISO 17280:2015 Surface active agents “Determination of 1,4-dioxan residues in surfactants obtained from epoxyethane by gas chromatography”

ISO 21148:General Instructions for microbiological examination

ISO 29621: Guidelines for the Risk Assessment of Microbiologically Low-risk Finished Products

ISO 11930: Evaluation of the antimicrobial protection of a cosmetic product

ISO 24442: cosmetics-Sun protection test methods -In vivo determination of sunscreen UVA protection

ISO 24444: Cosmetics -Sun protection test methods -In vivo determination of the sun protection factor (SPF)

Table 4: Summary of market regulations/Requirement for imported products (Middle East)

COUNTRY	COSMETIC DEFINITION	INGREDIENTS/COMP OSITION	GMPs	LABELLING	CLAIMS	SAFETY	ACCESS TO THE MARKET
EMIRATES	Cosmetic: Any substance or mixture made for the use and contact of the external organs and parts of the body (such as the skin, hair, nails, lips, teeth, genitals or the mucosa of the oral cavity) for the purpose of cleaning or perfuming them, changing their appearance, or enhancing their smell, or protecting or keeping them in the best shape.". PERFUMES: "any cosmetics and personal care products with a nice scent, composed of essential oils, fixatives, alcohol solution, water, permissible colorants, anti-oxidants and solvents."	Adapted version of the European Regulation. Total prohibition of pork derivatives. Special conditions for inclusion of alcohol. Annex II lists the prohibited substances, Annex III lists the restricted substances and Annexes IV to VI list the allowed colorants, preservatives and UV filters, the list of such ingredients is also remarkably similar to that of the EU.	Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonized standards such as GSO ISO 22716 Cosmetics GMP's	Emirati Standard No. UAE.S GSO 1943 has stipulated general requirements that must be satisfied by labels of products. Labelling requirements for UAE are similar to the ones in Europe.	Claims on cosmetic products shall conform to the following common criteria: Legal compliance Truthfulness Evidential support Honesty Fairness Informed decision-making	Imported products must comply with the general safety requirements of Standard GSO 1943/2016 set by the Gulf Standardization Organization (GSO)	Pre-registration. ESMA conducts market surveillance and periodic review to ensure product compliance with current technical regulations.

3.3.9 Halal Certificate

UAE recent regulations made it obligatory for companies manufacturing Personal Care and/or Cosmetic products to comply with Halal Standards and obtain Halal Certificate to be allowed to enter the local market.

ESMA announced in 2015 its intention to make it a mandatory requirement in the future. However, various companies in the sector have decided to obtain certification Halal as a marketing measure towards its Muslim consumers. Certification can be obtained in the countries of origin through accredited certifiers for the UAE market.

ESMA, in 2016 it launched its halal label based on Resolution N°10 (2014) concerns cosmetic and personal care products (in addition to food) with categories identified in a range of letters A-N within the UAE.S. 2055-2: 2016 regulation published on March 2016.

Halal National Mark Scheme

- 1) UAE Cabinet Resolution No.(10) / 2014 “UAE Regulation for Control on Halal Products” covers the provisions of this Regulations apply to all Halal Products including production systems and services associated with these products.
- 2) ESMA board has approved “National Halal Mark & Licensing Requirements” under ESMA Board Resolution No. (36)/2014.
- 3) ESMA has approved “Slaughterhouses (Abattoirs) Registration procedures” Board Resolution No. (37)/2014

4. Specific Analysis on Natural and Organic Cosmetic Products

Ghana produces locally natural raw materials⁶⁰ (shea butter, cocoa butter, coconut oil and black soap) used in finished cosmetics and personal care products. Shea butter and black soap are by far the most common ingredients in most cosmetics and personal care products manufactured in Ghana, followed by cocoa butter, coconut oil and other.

Having this in mind, and also that the market for natural ingredients and cosmetics is an increasing trend, it seems to be a possible competitive advantage for Ghanaian companies to have any type of certification both natural ingredients and cosmetic products.

4.1 Safety on natural and organic cosmetic products

An ingredient's source does not determine its safety. For example, many plants, contain substances that may be toxic or allergenic. All cosmetic products and ingredients are subject to the same safety requirement: They must be safe for consumers under labelled or customary conditions of use whatever the region.

Companies and individuals who market cosmetics have a legal responsibility to ensure that their products and ingredients are safe for the intended use.

4.2 Regulation on Natural and Organic Cosmetic Products

While in the plant and livestock sector in most countries, the regulation is clear how such claims should be substantiated, with respect to cosmetic, in most markets, there is no regulated definition of “natural” or “organic”, and no health authorities have issued formal positions for finish products.

Europe

As mentioned in the European cosmetic regulatory frame, it exists a Regulation for claims (Common criteria). Also, there is a “Technical Report” aiming to serve as guidance for a specific type of claims.

Regarding “natural and organic” cosmetics, the European Commission stated, at the time of drafting the document: “...*The group agreed that its first objective was to develop common general criteria for all types of claims used with respect to cosmetic products, including natural and organic claims ...it was noted that an ISO standard for natural and organic cosmetics is currently being developed. In order to avoid duplication of the work at the EU and ISO level, the group will take into account the progress of the future ISO standard*”

⁶⁰ value-chain analysis of the cosmetics and personal care products sector in Ghana

USA

The laws and regulations that FDA enforces do not have definitions for “natural” or “organic” Cosmetics. The same legal requirements apply to your product no matter whether the ingredients are plant, animal, mineral, or synthetic.

It’s important not to assume that using only ingredients from plants will make your products safe. Remember that all cosmetics are required to be safe, regardless of the sources of their ingredients. An ingredient’s source does not determine its safety.

FDA regulates cosmetics under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labelling Act External Link Disclaimer (FPLA). The term “organic” is not defined in either of these laws or the regulations that the FDA enforces under their authority.

The Agricultural Marketing Service of the U.S. Department of Agriculture (USDA) oversees the National Organic Program (NOP). The NOP regulations include a definition of “organic” and provide for certification that agricultural ingredients have been produced under conditions that would meet the definition. They also include labelling standards based on the percentage of organic ingredients in a product.

If a cosmetic, body care product or personal care product contains or is made up of agricultural ingredients, and can meet the USDA/NOP organic production, handling, processing and labelling standards, it may be eligible to be certified under the NOP regulations.

Cosmetics, body care products, and personal care products may be certified to other private standards and be marketed to those private standards in the United States. These standards might include foreign organic standards, eco-labels, earth-friendly, etc. USDA’s NOP does not regulate these labels at this time.

However, these organizations are in no way affiliated with FDA.

4.3 Natural and Organic claim support for cosmetics

There are two possibilities for companies aiming to declare the claim “natural” or “organic” for their products or ingredients:

1. PRIVATE LABELS
2. ISO 16.128 *Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1&2*

1. PRIVATE LABELS.

For cosmetics, several private organizations developed certifications to support natural and organic claims, mostly using the plant and livestock sector as a mirror. While there are similarities in private certifiers’ approaches, there are critical technical differences in how ingredients are defined, how content is calculated, and which ingredients are prohibited.

Those organizations certify using their standard and permit the use of their logo on the product label. The certification, cost-wise, is an economic burden for companies that need to maintain a fee payment over sales to keep the logo.

At the international level, now, there is currently a plethora of divergent, often conflicting and competing ‘standards’ and ‘certification schemes’ for cosmetics, depending on the region.

In Europe, there are several private organizations with their own standards: NATRUE – France; BDIH – Germany; COSMEBIO – France; ECOCERT – France; ICEA - Italy and the SOIL ASSOCIATION - UK

Five out of the six private organizations (BDIH - Germany, COSMEBIO - France, ECOCERT - France, ICEA - Italy and the SOIL ASSOCIATION - UK) create a common standard: COSMOS standard.

COSMOS stands for "*COSMetic Organic and Natural Standard*". The standard document defines the COSMOS requirements and definitions for organic and/or natural cosmetics that those five organizations defined.

The COSMOS-Standard is owned and managed by the COSMOS-standard AISBL⁶¹; a not-for-profit, international association registered in Belgium.

How does COSMOS certification work⁶²⁶³

Manufacturers or brand owners should choose an authorized Certification Body out of the 10 authorized by COSMOS.

Certification Bodies (or Certifiers) will assess a company against the standard’s requirements, issue a certificate of conformity and continually monitor adherence to the standard. Each Certifier is assessed by an Accreditation Body against requirements detailed into the COSMOS Control Manual.

For organic or natural certification, the Certification Body shall evaluate clients against all certification requirements specified in the Scheme Documents. An on-site audit includes a review of documents, personnel interviews and a supply chain review. The audit shall happen annually according to the certification process.

Audit by the on-site visit is carried out to verify information and compliance with certification requirements applicable to the client. It shall follow a set protocol.

The certification body shall implement its checklist.

For the use of the logo and labelling claims the standard has the “*COSMOS Labelling Guide*”. Certification Body’s logo is displayed in conjunction with the COSMOS signature.

⁶¹ <https://www.cosmos-standard.org/>

⁶² Based on the information provided by the COSMOS-standard website official documents.

⁶³ As the private label have very similar processes, we take COSMOS s an example of procedures.

There are some particular conditionings on the ingredients and packaging materials (e.g.: Nanomaterials, GMOs and Irradiation are forbidden. Specific criteria on palm oil, palm kernel oil and derivatives. Primary, secondary packaging and fabric components must be validated and compliant)

All finished products that are COSMOS certified incur license fees for the right to use the COSMOS ORGANIC and NATURAL signatures on the label.

COSMOS certifies two signatures for finish cosmetic products:

COSMOS Organic

The COSMOS ORGANIC signature is available for products that comply with the COSMOS-standard in all respects and contain the required percentages of organic ingredients as specified in the COSMOS-standard.

COSMOS Natural

The COSMOS NATURAL signature is available for products that comply with the COSMOS-standard in all respects but do not meet the required minimum organic percentages as specified in the COSMOS-standard.

The signature and logo assignment requires thresholds defined for natural and organic ingredients content. The standard includes rules for cosmetic products under organic or natural certification.

Also, ingredients can be certified by COSMOS. In this case, the signatures are:

COSMOS Certified

The COSMOS CERTIFIED signature is available for physically processed and chemically processed agro-ingredients with organic content that meet the COSMOS-standard.

COSMOS Approved

The COSMOS APPROVED signature is available for non-organic raw materials that are approved for use in cosmetics products certified to the COSMOS-standard.

NATRUE⁶⁴ has not joined the COSMOS-standard AISBL and certifies with their standard. They also have specifically approved certifiers and specifically require minimum levels of natural substances and substances of organic grade, and the maximum levels for derived natural raw materials in the three categories “natural cosmetics”, “natural cosmetics with an organic portion” and “organic cosmetics” and criteria for packaging and certain carrier materials.

NATRUE has three certification levels⁶⁵:

- NATRUE Natural

<https://www.natrue.org/>

⁶⁵ Based on the information provided by the NATRUE website official documents.

- NATRUE Natural with organic portion
- NATRUE Organic

They also certify ingredients.

4.4 ISO 16.128 Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1&2

The “naturalness” and “organicness” definitions for food and cosmetics are not directly comparable.

So, using the plant and livestock sector as a mirror seems not to be the best way. Cosmetics are usually complex compositions of natural/organic and synthetic ingredients.

Hence, cosmetics deserve specific standards.

Aiming harmonization, the International Organization for Standardization (ISO) through the ISO Technical Committee 217- Cosmetics, has developed and published several International Standard for natural and ingredients cosmetics and products:

ISO 16128-1:2016 - Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1: Definitions for ingredients.

ISO 16128-2:2017 - Cosmetics — Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients — Part 2: Criteria for ingredients and products.

How does ISO 16.128 work

ISO 16.128 is a technical characterization and calculation tool.

With Part 1 (definitions), ingredients are defined and characterized; with Part 2 (calculations) in conjunction with Part 1, natural, natural origin, organic and organic origin contents of the finish cosmetic products are calculated.

Third-party certification is not needed as using the standard and based on the ingredient’s characterization, the manufacturer can determine the % of naturalness or organicness of the product and so declare it on the label.

ISO 16.128 standards are:

- Internationally recognized
- specific to the cosmetics sector
- apply scientific judgment and offer principles towards a consistent & logical framework for natural and organic cosmetic ingredients and products
- Clearly defined and verifiable criteria
- Considers existing regulations and common practices.
- Voluntary – not linked to any certification/approval system.
- Allows existing labels to persist and compete fairly

There are not thresholds within the standard. Just the % of content should be declared on the label.

ISO TC 217 – Cosmetics has also developed several Technical Reports (TR's) as supplemental information for ISO 16128.

ISO/TR 23199:2019 - Cosmetics — Calculation of organic indexes of hydrolates — Supplemental information for ISO 16128-2.

ISO/TR 22582:2019 - Cosmetics — Methods of extract evaporation and calculation of organic indexes — Supplemental information to use with ISO 16128-2.

4.5 Natural and Organic Cosmetic Ingredients and Products in Ghana

Ghana is extraordinarily rich in ingredients for natural cosmetics and personal care products and has a comparative advantage in shea butter, coconut oil and essential oils. These products that have a high global demand have strong export potential but are lacking quality, institutional capacities and marketing strategies⁶⁶.

The biodiversity can be a strength for local Small and medium scale enterprises whenever they improve the compliance capacities and their competitiveness. This will allow Ghana to compete with natural ingredients-based cosmetic products⁶⁷.

“Lack of awareness of standards among shea butter and black soap producers, in particular with regard to processing, certification and marketing.⁶⁸”

If Ghanaian, either natural ingredients or finished products suppliers, want to have access to foreign markets, they not only make sure that they comply with regulations but also that provide a high-quality level of products.

Cosmetics non-animal testing is a global movement. Manufacturers should be prepared to provide data supporting no animal-testing claims. They should also make sure to inform manufacturers of any animal tests relating to development or safety evaluation having been performed. Suppliers of cosmetics ingredients from developing countries need to provide buyers with information on the properties and attributes of their ingredients.

⁶⁶ WACOMP Guide on how to comply with GSA and FDA procedures

⁶⁷ Annex VI: SWOT analysis of the cosmetics industry in Ghana

⁶⁸ Annex VI: SWOT analysis of the cosmetics industry in Ghana

5. Comparison among regulatory situation in Ghana and the Target markets.

- Definitions
- Ingredients regulations
- Consumer information:
 - i. Labelling
 - ii. Claims
- GMP's
- Cosmetics Safety evaluation
- Standards

Cosmetic Definition

REGION/COUNTRY	DEFINITION
GHANA	Substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes.
EUROPE	Substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.
USA	<u>Cosmetics</u> : A product, except soap, intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. The raw materials used as ingredients of cosmetic products are by law also cosmetics
	<u>OTC</u> : A cosmetic is also a drug when it is intended to cleanse, beautify or promote attractiveness as well as treat or prevent disease or otherwise affect the structure or any function of the human body. A cosmetic is legally also a drug if it is intended to exert a physical as well as a physiological effect. The categories of "drug" and "cosmetic" are not mutually exclusive.
	<u>Soap</u> : product in which the non-volatile portion consists principally of an alkali salt of fatty acids, i.e., the traditional composition of soap; the product is labelled as soap; and the label statements refer only to cleansing. If cosmetic claims, e.g., moisturizing, deodorizing, skin softening etc., are made on a label, the product is cosmetic. Synthetic detergent bars are also considered cosmetics, although they may be labelled as "soap."

EMIRATES	<u>Cosmetic</u> : Any substance or mixture made for the use and contact of the external organs and parts of the body (such as the skin, hair, nails, lips, teeth, genitals or the mucosa of the oral cavity) for the purpose of cleaning or perfuming them, changing their appearance, or enhancing their smell, or protecting or keeping them in the best shape."
	<u>Perfume</u> : any cosmetics and personal care products with a nice scent, composed of essential oils, fixatives, alcohol solution, water, permissible colorants, antioxidants and solvents.

6. Needed adaptations of standards, safety evaluation and other quality pre-requirements for Ghanaian companies producing cosmetics and personal care products to be exported to the target markets

Not having and direct first-hand knowledge, but based on the information content of the document "*Value-chain analysis of the cosmetics and personal care products sector in Ghana*"⁶⁹, and from the personal point of view of this consultant, the main weakness for Ghanaian companies, not only those aiming to export cosmetic products to a third country/region but also for those who market products into the country, is a lack of training and practice on the knowledge and application on those aspects that directly influence the quality and safety of the cosmetic product.

Also, a deeper knowledge on cosmetic regulations of the export destination country is relevant

Main aspects to be taken into consideration

→ Cosmetic definition.

As stated on Point 2 of the document, the definition of "cosmetics" for Ghanaian products) is wide enough to have problems fitting to other countries/regions definitions:

substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes – Only function

The cosmetic definition of the destination country needs to be carefully checked before starting to think in export to that particular country.

For Europe and UAE there are two requirements:

Body part:

⁶⁹ WACOMP – Building competitiveness for export of cassava, fruits and cosmetics value chains in Ghana.

- ✓ *to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity*

and function:

- ✓ *with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.*

For the US: Soap is out of this particular definition.

A product, except soap, intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. The raw materials used as ingredients of cosmetic products are by law also cosmetics

- As soap (black soap) seems to be important for the small Ghanaian producers, it will deserve a careful analysis of manufacturing and composition to check the viability of exportation. The document “value-chain analysis of the cosmetics and personal care products sector in Ghana” states: *Black soap manufacturers do not supply products of consistent quality No standard for black soap No code of practice for black soap production*

Claims are truly relevant as the sense and definition of the product can be moved to be an OTC:

OTC: *A cosmetic is also a drug when it is intended to cleanse, beautify or promote attractiveness as well as treat or prevent disease or otherwise affect the structure or any function of the human body. A cosmetic is legally also a drug if it is intended to exert a physical as well as a physiological effect. The categories of "drug" and "cosmetic" are not mutually exclusive.*

→ **Good Manufacturing Practices.**

Adequate conditions and operators training are of paramount importance for the appropriate functioning of the manufacturing facilities and the production of a high-quality cosmetic product.

Manufacturing processes are particularly important results-wise, both for quality and safety of the final products.

Putting in place the appropriate standard operating procedures, defining responsibilities and training of the personnel on the correct use of procedures, will make a big difference in the product quality.

Depending on the level of the producers and the facilities, operating procedures can be different, but training is always needed.

The learning and proper application of the ISO standard 22.716 on GMP's is a "*sine qua non*" condition.

ISO 22.716 on GMP's is internationally recognized and a declaration on compliance and/or certification by third parties are normally required.

Whenever exporting products to the US that fall into the OTC – DRUG categories (antiperspirants, antidandruff shampoo, etc.) the requirements are still higher.

As an example of the relevance and focus of the training and responsibilities on ISO 26.716, here is the first part of the Index:

1. Scope
2. Terms and Definitions
3. Personnel
 - 3.1 Principle
 - 3.2 Organization
 - 3.2.1 Organization Chart
 - 3.2.2 Number of people
 - 3.3 Key responsibilities
 - 3.3.1 Management responsibilities
 - 3.3.2 Responsibilities of personnel
 - 3.4 Training
 - 3.4.1 Training and skills
 - 3.4.2 Training and Good Manufacturing Practices
 - 3.4.3 Newly recruited personnel
 - 3.4.4 Personnel training evaluations
 - 3.5 Personnel hygiene and health
 - 3.5.1 Personal hygiene
 - 3.5.2 Personal health
- 3.6 Visitors and untrained personnel

Safety evaluation for finish cosmetic products

Being safety of the consumer the milestone for cosmetics worldwide is particularly relevant to guaranty it. Cosmetic products must be safely taken into account all the steps and processes: from raw materials and packaging to the placing on the market, going through correct manufacturing and quality control.

For the three target countries analyzed, in some way or other, the manufacturer or the responsible person needs to properly document the safety of the product in a scientific manner.

Unless misunderstanding, there is not within the Ghanaian regulation for cosmetics a detailed and specified requirement or description of the documentation and procedures

needed for proper safety evaluation of the cosmetic products. Indeed, the cosmetic product must be safe and the manufacturer is responsible.

The European Product information file and the subsequent Safety evaluation report could serve as a model for organizing all the required documentation that guarantees that the cosmetic product is safe for its intended use.

It is necessary to make sure that all safety requirements are implemented and that qualified personnel are located for this task. Training will perhaps be needed on this point,

In the first step of the exporting operations, the safety evaluation reports and PIF's can be subcontracted but it is important to take adequate measures to have locally the required expertise.

Emphasis for natural and organic cosmetic ingredients and products⁷⁰

- If exporting of natural ingredients is to be taken into consideration, an additional assessment will be needed to evaluate the requirements that the destination countries have for this type of ingredients.

For instance, in Europe, the need for a registration based on Regulation Nr.1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) should be explored. Natural ingredients could be exempted but it will be necessary to document the conditions.

Also, the requirements for cosmetic ingredients of the European SCCS or the CIR need to be reviewed and the compliance of the Ghanaian raw materials checked against them.

The safety, qualification and quality of the ingredients referred above is also crucial when exporting (or marketing in Ghana) finish cosmetic products containing those ingredients.

→ Standards

Standards are tools to hone the products and services, open up to new customers and markets, grow the business faster, and increase profits.

Ghanaian regulation seems to be supported by an important set of standards. Nevertheless, it seems that GSA has limited resources and does not have the capacity to conduct all product quality tests that are mandatory for the export market⁷¹. (and this is a critical point when cosmetics were identified as a high growth business in the strategic sectors of the economy.

Due to the lack of resources for conducting tests, perhaps the pre-approval for export should be reviewed. Emphasis could be made on fund and finance local analysis facilities inside or outside the manufacturing companies, giving them training and responsibilities for the products they produce.

⁷⁰ In order to no repeat constantly "natural an organic", we will understand that both concepts are included when speaking of "natural"

⁷¹ Document "A value-chain analysis of the cosmetics and personal care products sector in Ghana"

Steps to Look for a Successful Export

For a Ghanaian company aiming to export cosmetic products to a third country/region, there are several questions that need to be considered:

1. Is my product a cosmetic?

As we have seen along with the Paper, the definition of cosmetic differs from country to country. So, analyzing the definition is of paramount importance. If the answer is:

YES: check regulation in the destination country/region. Allow time for regulatory compliance.

NO:

- Does it fit into any of other categories in the destination country/region?
Check regulation in the destination country/region
 - Can I reformulate the product to be compliant with the definition?
2. Will I need to appoint a responsible person/legal representative within the country? Will I need a representative to act on my behalf?
 3. Do I need a pre-registration or only a pre-notification?

This is an important budget-wise. If pre-market is required, the cost of testing will be probably higher and timing for putting the product into the destination country market longer.

4. Are any of the ingredients in my formula?
 - a. CMRs? ; Nanomaterials? ; Prohibited/limited in the destination country/region?.

Colorants, preservatives, UV filters? If such, the product perhaps needs a reformulation.

5. Do I need to comply with GMP's? - ISO 22.716 or another standard? Do I need a third-party certification? Is my GSA certification valid in the destination country?
6. Can I formulate the product to export to more than one market?

7. Documentation and Sources Consulted.

GHANA

- A Value-Chain Analysis of the Cosmetics and Personal Care Products Sector in Ghana
- GHANA standards authority product certification scheme
- Catalogue of Ghana Standards 2018
- Guidelines for labelling of cosmetics and household chemical substances
- Ghana Standard GS 227-2: 2017 and GS 227-3: 2017
- How to comply with GSA and FDA requirements and procedures.
- FDA Guidelines for the registration of cosmetics and household chemical substances
- FDA guidelines for the advertisement of drugs, medical devices, cosmetics and household chemicals
- FDA guidelines for processing of export permit and clearance of cosmetics, medical devices and household chemical substances
- Public Health Act, 2012 – 851
- District industrialization for jobs & wealth creation

EUROPE

- Regulation (EC) No 1223/2009 of the European Parliament and of The Council of 30 November 2009 on cosmetic products
- Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic products
- Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products.
- Commission Decision 96/335/EC of 8 May 1996 establishing an inventory and a common nomenclature of ingredients employed in cosmetic products + Technical document on cosmetic claims.
- Cosmetics Europe (COLIPA) guidelines on cosmetic product labelling, 2011
- Organic Cosmetics Fact sheet USDA
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Regulation ((EC) No 1272/2008) Classification, Labelling and Packaging
- Packaging and Packaging Waste. The Producer Responsibility
- BREXIT: European Commission: Notice to stakeholders - withdrawal of the United Kingdom and EU rules in the field of cosmetic products

USA

- FDA Cosmetic Labelling Guide
- The Electronic Code of Federal Regulations (e-CFR)
- CFR - Code of Federal Regulations Title 21
- Guidance for Industry - Cosmetic Good Manufacturing Practices
- INCI FAQs – PCPC
- Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. section 301
- Fair Packaging and Labelling Act (FPLA), 15 U.S.C. section 1451
- Cosmetics & U.S. Law - <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/cosmetics-us-law>
- FDA Cosmetics Guidance & Regulation <https://www.fda.gov/cosmetics/cosmetics-guidance-regulation>

EMIRATES

- Cabinet Decision No. 18 of 2014 on the UAE Regulations for the Control of Cosmetics and Personal Care Products, the Cosmetics Act.
- Cabinet Decision No. 5 of 2014 on the UAE Regulations for The Supervision of Fragrances (the "Fragrances Law").
- GCC Cosmetic Products Safety Requirements of Cosmetics and Personal Care Products
- ESMA UAE Scheme for Cosmetics and Personal Care
- Technical Guidelines for Cosmetics Personal Care & Perfumes Lab Tests
- UAE Imports & Exports Guide – Ministry of economy.
- EMIRATES conformity assessment scheme (ECAS): overview of compliance
- ECAS safety assessment
- User Manual of electronic / smart services for Emirates Authority for Standardization and Metrology

NATURAL AND ORGANIC

- ISO 16128-1:2016 - Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1: Definitions for ingredients.
- ISO 16128-2:2017 - Cosmetics — Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients — Part 2: Criteria for ingredients and products.
- ISO/TR 23199:2019 - Cosmetics — Calculation of organic indexes of hydrolates — Supplemental information for ISO 16128-2.
- ISO/TR 22582:2019 - Cosmetics — Methods of extract evaporation and calculation of organic indexes — Supplemental information to use with ISO 16128-2.
- COSMOS-standard Cosmetics Organic and Natural Standard
- NATRUE Label: requirements to be met by natural and organic cosmetics

INTERNATIONAL STANDARDS BY ISO/TC 217 - Cosmetics

ISO 29621:2017 - Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products.

ISO/TR 26369:2009 - Cosmetics — Sun protection test methods — Review and evaluation of methods to assess the photoprotection of sun protection products.

ISO/TR 24475:2010 Cosmetics — Good Manufacturing Practices — General training document

ISO 24444:2019 Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)

ISO 24443:2012 - Determination of sunscreen UVA photoprotection in vitro

ISO 24442:2011 - Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection.

ISO 22718:2015 - Cosmetics — Microbiology — Detection of *Staphylococcus aureus*.

ISO 22717:2015 - Cosmetics — Microbiology — Detection of *Pseudomonas aeruginosa*.

ISO 22716:2007 - Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

ISO 22715:2006 - Cosmetics — Packaging and labelling

ISO 16128-1:2016 - Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1: Definitions for ingredients.

ISO 16128-2:2017 - Cosmetics — Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients — Part 2: Criteria for ingredients and products.

ISO/TR 23199:2019 - Cosmetics — Calculation of organic indexes of hydrolates — Supplemental information for ISO 16128-2.

ISO/TR 22582:2019 - Cosmetics — Methods of extract evaporation and calculation of organic indexes — Supplemental information to use with ISO 16128-2.

ISO/TS 22176:2020 - Cosmetics — Analytical methods — Development of a global approach for validation of quantitative analytical methods.

ISO 21150:2015 - Cosmetics — Microbiology — Detection of *Escherichia coli*.

ISO 21149:2017 - Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria.

ISO 21148:2017 - Cosmetics — Microbiology — General instructions for microbiological examination.

ISO/TR 19838:2016 - Microbiology — Cosmetics — Guidelines for the application of ISO standards on Cosmetic Microbiology.

ISO/TR 18818:2017 - Cosmetics — Analytical method — Detection and quantitative determination of Diethanolamine (DEA) by GC/MS.

ISO/TR 18811:2018 - Cosmetics — Guidelines on the stability testing of cosmetic products.

ISO 18416:2015 - Cosmetics — Microbiology — Detection of *Candida albicans*.

ISO 18415:2017 - Cosmetics — Microbiology — Detection of specified and non-specified microorganisms.

ISO 17516:2014 - Cosmetics — Microbiology — Microbiological limits.

ISO/TR 17276:2014 - Cosmetics — Analytical approach for screening and quantification methods for heavy metals in cosmetics.

ISO 16217:2020 - Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance.

ISO 16212:2017 - Cosmetics — Microbiology — Enumeration of yeast and mould.

ISO 15819:2014 - Cosmetics — Analytical methods — Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS.

ISO/TR 14735:2013 Cosmetics — Analytical methods — Nitrosamines: Technical guidance document for minimizing and determining N-nitrosamines in cosmetics.

ISO 12787:2011- Cosmetics — Analytical methods — Validation criteria for analytical results using chromatographic techniques.

ISO 11930:2019 - Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product.

ISO 10130:2009 - Cosmetics — Analytical methods — Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC, post-column photolysis and derivatization.

Table 5: Comparative Country Analysis of Regulations for Cosmetics Matrix

REGION/ COUNTRY	COSMETIC DEFINITION	INGREDIENTS/COMP OSITION	GMPs	LABELLING	CLAIMS	SAFETY	ACCESS TO THE MARKET
GHANA	“Cosmetic” refers to a substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes.	Ghana standard GS 227-2:2017. This Ghana standard, on table 1, lists substances, which shall not form part of the composition of cosmetic products. On the last revision (2017) there were 418 prohibited substances.+ Narcotic Drugs Ghana standard GS 227-3:2017 - . This Ghana standard contains restrictions and conditions of Chemical substances, coloring agents, preservatives and UV filters as specified in Annexes A, B, C and D respectively shall apply to Cosmetic products	Manufacturing sites need a pre-approval. The Ghana Standards Authority has adopted the ISO 22.716 standard on GMP’s.	The information on a label shall include, but not be limited to, the following: (a) The name of the product, and the generic or INN/INCI (b) A list of the active ingredients using INN/INCI or IUPAC system, where applicable, showing the amount of each present in a dosage unit. (c) The net content of the container (d) The batch number (e) Date of manufacture and best before/expiry date (f) Directions for use, and any warnings or precautions that may be necessary (g) Any special storage conditions or handling precautions that may be necessary (h) Indications, frequency, route and conditions of use where applicable (i) The names of any excipients known to be a safety concern (j) Name, postal address and premises address of the manufacturer and Distributor (k) Country of origin	Claims on cosmetics shall not imply actions that are normally considered therapeutic. Advertising needs a preapproval application. FDA guidelines for the advertisement of drugs, medical devices, cosmetics and household chemicals	Products must be safe. Documentation needed is not clearly defined. The finish product is submitted to pre-market approval.	Pre-registration needed. FDA processes and grants market authorization for cosmetics and household chemical substances intended for export and/or sale on the Ghanaian market.

REGION/ COUNTRY	COSMETIC DEFINITION	INGREDIENTS/COMP OSITION	GMPs	LABELLING	CLAIMS	SAFETY	ACCESS TO THE MARKET
EUROPE	Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors	Ingredients are regulated under the Annexes of Regulation 1223/2009 Annexes, periodically amended: Annex II lists the prohibited substances, Annex III lists the restricted substances and Annexes IV to VI list the allowed colorants, preservatives and UV filters	Compliance with good manufacturing practices shall be presumed where the manufacture is in accordance with the relevant harmonized standards, the references of which have been published in the Official Journal of the European Union. The harmonized standard for GMPs is the ISO 22716 Cosmetics — Good Manufacturing Practices	Cosmetic products shall bear on packaging the following information: — the name or registered name and the address of the responsible person. — The nominal content at the time of packaging, — the date until which the cosmetic product, will continue to fulfil its initial function and will remain safe ‘date of minimum durability’ — If date of minimum durability is more than 30 months, there shall be an indication of the period after opening for which the product is safe (PAO) except where the concept of durability after opening is not relevant, by the symbol of the open jar. — particular precautions to be observed for safe use. —the batch number of manufacture. — the function of the cosmetic product unless it is clear from its presentation. —a list of ingredients. preceded by the term ‘INGREDIENTS’. The language will be determine by the Member States where the cosmetic product is made available to consumers	Labelling and advertising of cosmetic products, text, names, trademarks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have Regulated by "Common Criteria" 1. Legal compliance. 2 Truthfulness 3. Evidential support 4. Honesty 5. Fairness 6. Informed decision-making	Detailed Product Information File (PIF) available to the competent authorities at the address of the RP. The PIF shall contain a Cosmetic Product Safety Report (Annex I Regulation 1223/2009)	No pre-registration is required to market cosmetics into the EU. Only a notification to the Cosmetic Products Notification Portal (CPNP) is necessary before placing the cosmetic product on the market. The RP will be located in the EU.

REGION/ COUNTRY	COSMETIC DEFINITION	INGREDIENTS/COMP OSITION	GMPs	LABELLING	CLAIMS	SAFETY	ACCESS TO THE MARKET
USA	<p>"Articles, except soaps, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles" (Except soaps). The raw materials used as ingredients of cosmetic products are by law also cosmetics</p> <p>SOAPS: What it's made of What ingredients cause its cleaning action How it's intended to be used.</p> <p>OTC: A cosmetic is also a drug when it is intended to cleanse, beautify or promote attractiveness as well as treat or prevent disease or otherwise affect</p>	<p>Cosmetic manufacturers have a legal responsibility for the safety and labelling of their products. Under U.S. law, cosmetic products and ingredients, other than color additives, do not need FDA approval before they go on the market. Color additives are permitted in cosmetics only if the FDA has approved them for the intended use. Prohibition of 12 ingredients. The rest are to be used only when considered safe.</p>	<p>ISO 22.716 cosmetics GMP recognized for compliance. The FDA may still inspect manufacturing facilities to make sure that proper controls and practices are in compliance with applicable laws.</p>	<p>The FDA does not approve cosmetic labelling. However, it does provide guidance documents for labelling, which cosmetics manufacturers and private labellers must make sure to comply with.</p> <p>Cosmetic label has two parts: Main display panel Information panel. Declaration within each panel is described.</p>	<p>FD&C Act prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce: "Adulteration" refers to violations involving product composition whether they result from ingredients, contaminants, processing, packaging, shipping or handling. A product is misbranded if the following violations occur.</p> <p>a. false or misleading labelling b. label omits name and address of the manufacturer, packer or distributor- net quantity of contents is not listed</p>	<p>The safety of a cosmetic can be considered adequately justified if experts qualified by scientific training and experience can reasonably conclude from the available toxicological data, tests, chemical composition, and other relevant information that the product is safe to consumers under normal or reasonably foreseeable conditions of use.</p>	<p>Imported cosmetics must comply with the same laws and regulations that apply to those produced domestically Under the FD&C Act, cosmetic products and ingredients, with the exception of color additives, do not require FDA approval before they go on the market. The cosmetic product can be voluntarily registered with the FDA. Imported products are examined upon entry but not all cosmetics are inspected or sampled upon entry into this country. In order to focus</p>

	<p>the structure or any function of the human body. A cosmetic is legally also a drug if it is intended to exert a physical as well as a physiological effect. The categories of "drug" and "cosmetic" are not mutually exclusive</p>				<p>d. the labelling fails to be conspicuous for consumers to read e. misleading container or fill</p>	<p>inspection efforts most efficiently, FDA issues Import Alerts to advise inspectors of trends in violations. However, examination of imported cosmetics is not limited to the types of products specified in Import Alerts. The FDA might periodically purchase cosmetic products to analyze them for potential hazards or other issues. If problems arise associated with ingredients, the agency may issue consumer alerts through mass media press releases. Imported cosmetics must comply with the</p>
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REGION/ COUNTRY	COSMETIC DEFINITION	INGREDIENTS/COMP OSITION	GMPs	LABELLING	CLAIMS	SAFETY	ACCESS TO THE MARKET
							same laws and regulations that apply to those produced domestically.
EMIRATES	Cosmetic: Any substance or mixture made for the use and contact of the external organs and parts of the body (such as the skin, hair, nails, lips, teeth, genitals or the mucosa of oral cavity) for the purpose of cleaning or perfuming them, changing their appearance, or enhancing their smell, or protecting or keeping them in the best shape.". PERFUMES: "any cosmetics and personal care products with a nice scent, composed of essential oils, fixatives, alcohol solution, water, permissible colorants, anti-oxidants and solvents."	Adapted version of the European Regulation. Total prohibition of pork derivatives. Special conditions for inclusion of alcohol. Annex II lists the prohibited substances, Annex III lists the restricted substances and Annexes IV to VI list the allowed colorants, preservatives and UV filters, the list of such ingredients is also remarkably similar to that of the EU.	Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonized standards such as GSO ISO 22716. Cosmetics GMP's	Emirati Standard No. UAE.S GSO 1943 has stipulated general requirements that must be satisfied by labels of products. Labelling requirements for UAE are remarkably similar to the ones in Europe.	Claims on cosmetic products shall conform to the following common criteria: Legal compliance Truthfulness Evidential support Honesty Fairness Informed decision-making	Imported products must comply with the general safety requirements of Standard GSO 1943/2016 set by the Gulf Standardization Organization (GSO)	Pre-registration. ESMA conducts market surveillance and periodic review to ensure product compliance with current technical regulations.

ⁱ Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

ⁱⁱ Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products.



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