قرار مجلس الوزراء رقم (18) لسنة 2014
بشأن النظام الإماراتي للرقابة على مستحضرات التجميل و العناية الشخصية

مجلس الوزراء

- بعدالاطلاع على الدستور،
- وعلى القانون الاتحادي رقم (1) لسنة 1972، بشأن اختصاصات الوزارات وصلاحيات الوزراء والقوانين المعدلة له،
- وعلى القانون الاتحادي رقم (28) لسنة 2001، بشأن إنشاء هيئة الإمارات للمواصفات والمقاييس والقوانين المعدلة له،
- وعلى القانون الاتحادي رقم (24) لسنة 2006،في شأن حماية المستهلك، والقوانين المعدلة له،
- و على القانون الإتحادي رقم (31) لسنة 2006، في شأن النظام الوطني للقياس،
- وبناء على موافقة مجلس الوزراء،

قرر:

Article (1)
Definitions

The following definitions shall apply for the implementation of this scheme.

Country:	United Arab Emirates
Authority:	Emirates Authority for Standardization and Metrology (ESMA)
Council:	Board of the ESMA
Director General:	Director General (DG) of the ESMA
Concerned Authorities:	All those federal and/or local governmental authorities of the country who have been authorized to implement the requirements of this scheme.
Standard:	A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

UAE Scheme to Control the Cosmetics and Personal Care Products

Approved Standard:	A standard that is approved by ESMA and referred as United Arab Emirates standard and abbreviated as UAE.S.
Mandatory Standard (Technical Regulation):	A standard that is mandatory to implement by the decree of cabinet.
Conformity Certificate:	A certificate issued by ESMA to the given product ensuring that the product complies with the requirements of this scheme.
Mark:	Any illustration or symbol or stamp or engraving or picture appearing on the product that indicates that the given product complies with requirements of the standard issued by ESMA or any other international standards body in terms of quality.
Emirates Quality Mark:	A quality mark granted by ESMA indicating that the given product complies with the requirements stated in the approved standard.
Cosmetics and Personal Care Products:	Any substance or mixture intended for use on external parts of the human body (epidermis or hair system or nails or lips or external genital organs or with mucous membranes of the oral cavity) with a view mainly to cleaning them or perfuming them or changing their appearance or correcting body odors or protecting them or keeping them in good condition.
Supplier:	Any manufacturer or carrier or filler or assembler or processer or agent or storekeeper or distributer (main or secondary) of the cosmetic and personal care product(s) who may have impact on the safety aspects of the product, or any commercial or legal representative who may be responsible for importing products subjected to provisions of this scheme.
Consumer:	Any person obtaining a commodity or service, paid or unpaid, to satisfy his/her own needs or another person's needs.
Supply Chain:	Any stage that the product goes through after its production and till reaching the consumer such as import, supply, storage, delivery, trade (wholesale and retail) and any other relevant processes.
ECAS:	The system that verifies the fulfillment of the approved standards, either directly or indirectly like inspection, testing, examination, calibration or granting the products conformity certificates, and which is applied by the authority according to the general

regulation of Emirates Conformity Assessment Scheme (ECAS) that has been granted by Board Directors of the Authority by decision No. (8) For the year 2009.

Placing on the Market: A process that is intended to sell or lease or circulate or hold or present the product to the consumer whether for charge or free of charge.

Article (2)
Scope

The provisions of this scheme are applicable to all cosmetics and personal care products which are placed on the market or manufactured or imported or packaged or used within the country. The following are excluded from these provisions:

1. Medical products used to cure diseases.

2. Devices and tools accompanied with cosmetics.

Article (3)
Responsibilities of the Supplier

The supplier, at any stage of supply chain, shall comply with the following requirements:

a. Safety and quality requirements as per the below:

   1. Complying with requirements stated in the mandatory standard UAE.S GSO 1943 for safety requirements in cosmetic and personal care products.
   2. Product safety report, as per annex no. (3) in the scheme, issued by a competent assessor shall be made available to ESMA or concerned authority upon request.
   3. Complying with the good manufacturing practices as per the approved standard UAE.S GSO ISO 22716 or any quality management system accepted by ESMA.
   4. Product(s) shall comply with all requirements mentioned in this scheme except non-conformity/ies that arise after sale due to improper storage or transport.

b. Packaging and Labeling requirements as per the below:

1. The cosmetic product shall be packed in appropriate containers that are clean and do not interact with the cosmetic product or vice versa, and it shall be ensured that containers are properly closed and without any sharp edges.

2. The containers of perfume products shall comply with article 3 of approved standard UAE.S/GSO ISO 22715 (packaging and labeling).

3. In the case of glass containers they shall also meet the requirements of the approved standard UAE.S/GSO 2093.

c. The quantity of the products as per metrological requirements shall be expressed in the units of measurement (cubic meter or liter or kilogram) or their multiples, or their parts, and in accordance with the approved standard UAE.S GSO OIML R87.

d. Requirements for testing cosmetics and personal care products shall be as per the below:
    1. The products shall comply with the test methods stated in the approved standards or any other test methods standards that are approved by ESMA. In the absence of these, the product shall comply with the test methods carried out according to valid testing methods that are scientifically and internationally accepted.
    2. All tests shall be carried out in labs accepted by ESMA.

Article (4)
Labelling

Labeling of product(s) that are intended for placing on the market and using inside country shall comply with the following:

1. The labels of products that are intended for sale to the consumers shall comply with the requirements of the approved standard UAE.S GSO 1943 and the labeling shall be clear and legible.
2. In case of any product(s) containing any allergen, the presence of these allergens should be mentioned, as per the approved standard UAE.S GSO 1943, in the list of ingredients on labels.
3. Pictures and illustrations that are inconsistent with the prevailing social customs and values of the UAE shall not appear on the labels.
4. The information appearing on the label shall be valid and authentic and shall be based on scientific and laboratory evidence.

Article (5)
Conformity Assessment

a) The supplier shall observe the following in order to procure the conformity certificate:
    1. The product (s) shall comply with ESMA approved standards mentioned in annex (1) attached to this scheme.
    2. The product(s) that are manufactured or packed or imported by supplier shall comply with Model (B) of ECAS and its requirements, and ESMA shall issue the list of products that have to be registered according ECAS to fulfill the health and safety requirements.

b) Supplier shall provide all relevant technical documents and certificates and documented information in support of compliance of the product to the requirements of this scheme and in favor of annex (2) attached to this scheme.

c) Products that bear the Emirates Quality Mark or any other Mark approved by ESMA, shall comply with all the requirements of this scheme.

Article (6)
Control and Market Surveillance

1. ESMA and the concerned authorities have the right to withdraw the product sample(s) to carry out the required tests in order to check their compliance with the requirements stated in this scheme.

2. It is forbidden to sell or display the products falling under the provisions of this scheme unless they are registered according to Emirates Conformity Assessment Scheme (ECAS) or have the conformity certificate.

3. In case of non-conformities, if the source of non-conformity cannot be traced then the party with whom the non-complying product is found will be held responsible for the non-conformity unless it is proved otherwise within the stipulated time determined by ESMA or the concerned authority.

Article (7)
Violations and Penalties

a) In case of any violation(s) against any of the provisions of this scheme, ESMA or the concerned authority shall take appropriate action(s), depending on the circumstances, in order to eliminate the violation and its consequential results. Such actions include:

1. Instructing the responsible party to withdraw the product from the market with the aim of rectification or sending it back to the country of origin or destroying it within the period of time set by ESMA or the concerned authority.
2. The concerned authority shall take all necessary actions for withdrawal, retention or destruction of these products or any other necessary measures to withdraw the product from the market. ESMA or the concerned authority, depending on the circumstances, shall announce product withdrawal from the market and the violating entity shall bear all the emerging expenses.

b) Without prejudice to any more severe penalty stated in the legislations in force, the one who breached any of the provisions of this scheme, shall be penalized according to the Federal Law No. (28) of 2001 for Establishing the ESMA and its amendments.

c) ESMA has the right to take appropriate action(s) against products that do not comply with this scheme. Such actions include withdrawal or cancellation of the conformity certificate of the violated product(s) or removal of non-complying product(s) from the market.

Article (8)
Provisions for the Transition Period

1. The supplier shall register the cosmetics and personal care products with ECAS within 180 days from the date of publication of this scheme in the Official Gazette.

2. The non-complying products which are currently in circulation in the market are allowed to circulate for a period not more than one year from the date of publication of this scheme in the Official Gazette.

Article (9)
Final Provisions

1. The standards mentioned in annex (1) shall be considered as mandatory standards for the purpose of implementation of this scheme.

2. ESMA shall take appropriate measures to implement this scheme and authorize any of the concerned authorities to control the cosmetic products, to the provisions of scheme, under its supervision.

3. ESMA is responsible for receiving, studying any application form for registration and compliance of products under provisions of this scheme. It has the right to grant

authorization to concerned authorities for registering and ensuring the compliance of the products as per this scheme.

4. The concerned authority of each emirate is responsible for the commitment of the supplier to fulfill the provisions of this scheme, and to ensure that their products comply with the standards mentioned in this scheme. Their responsibilities include inspection, testing, and control of the process.

5. The Board of Directors have the right to approve any other standard(s) which are required to implement this scheme.

6. The Annexes attached to this scheme shall be considered as a part of this scheme, and the Board of Directors have the right to amend any of the Annexes, when required.

7. This scheme does not prevent the inspectors of the concerned authorities to conduct tests stated in other laws or regulations on the products falling under this scheme in order to ensure their compliance to other laws and regulations.

8. The supplier shall retain the safety report of the product, mentioned in article (3) of this scheme, for period of 10 years from the date on which the last batch of the cosmetic and personal care product was placed on the market or manufactured. The report shall be updated whenever the need arises, or whenever the product is altered.

9. All the stakeholders, related to this scheme, shall extend full cooperation and provide all the required information to the inspectors of the concerned authorities.

10. Any issue that cannot be resolved by the provisions of this scheme, the same shall be referred to the Director General in order to take the appropriate decision in the best interest of the public.

Article (10)
Cancellation

The requirements stated in any other scheme will be cancelled if such requirement(s) contradict with the one mentioned in this scheme.

Article (11)
Publication and Date of Implementation

This scheme is published in the Official Gazette and come in to force from the date of publication and all the concerned parties shall implement it.

Annex (1)
List of Approved Standards

#	Standard Number	Title of the 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 Product in Prepackages
4	UAE.S GSO 2093	Glass containers Used for Cosmetics

Annex (2)
Information and Technical Documents required for Emirates Conformity Assessment Scheme (ECAS) Registration

1. Product Category
2. Name of the product
3. Name and address of the supplier
4. Country of origin
5. Nanomaterial: identification and exposure conditions
6. Physical form of the product
7. Original Labeling
8. Clear Photograph of original packaging
9. Composition data
10. Frame formulation

Annex (3)
Product Safety Report

The cosmetic product safety report shall contain the following:

PART A- Cosmetic product safety information

1. **Quantitative and qualitative composition of the cosmetic product**: The qualitative and quantitative composition of the cosmetic product, including chemical identity of the substances (incl. chemical name, INCI, CAS, EINECS/ELINCS, where possible) and their intended function. In the case of perfume and aromatic compositions, description of the name and code number of the composition and the identity of the supplier.

2. **Physical/chemical characteristics and stability of the cosmetic product**: The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product. The stability of the cosmetics product under reasonably foreseeable storage conditions.

3. **Microbiological quality**: The microbiological specifications of the substance or mixture and the cosmetic product. Particular attention shall be paid to cosmetics used around the eyes, on mucous membranes in general, on damaged skin, on children under three years of age, on elderly people and persons showing compromised immune responses.

4. **Impurities, traces, information about the packaging material**
    a. The purity of the substances and mixtures.
    b. In the case of traces of prohibited substances, evidence for their technical unavoidability.
    c. The relevant characteristics of packaging material, in particular purity and stability.

5. **Normal and reasonably foreseeable use**: The normal and reasonably foreseeable use of the product. The reasoning shall be justified in particular in the light of warnings and other explanations in the product labeling.

6. **Exposure to the cosmetic product**: Data on the exposure to cosmetic product taking into consideration the findings under Section 5 in relation to:
    a. The site(s) of application.
    b. The surface area(s) of application
    c. The amount of product applied.
    d. The duration and frequency of use.
    e. The normal and reasonably foreseeable exposure route(s);
    f. The targeted (or exposed) population(s). Potential exposure of a specific population shall also be taken into account.

The calculation of the exposure shall also take into consideration the toxicological effects to be considered (e.g. exposure might need to be calculated per unit area of skin or per unit of body weight). The possibility of secondary exposure by routes other than those resulting from direct application should also be considered (e.g. non-intended inhalation of sprays, non-intended ingestion of lip products, etc.).
Particular consideration shall be given to any possible impacts on exposure due to particle sizes.

7. **Exposure to the substances:** Data on the exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under Section 6.

8. **Toxicological profile of the substances**: Shall contain the toxicological profile of substance contained in the cosmetic product for all relevant toxicological endpoints. A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation, and in the case of UV absorption photo-induced toxicity shall be made.

   All significant toxicological routes of absorption shall be considered as well as the systemic effects and margin of safety (M o S) based on a no observed adverse effects level (NOAEL) shall be calculated. The absence of these considerations shall be duly justified.

   Particular consideration shall be given to any possible impacts on the toxicological profile due to
   —Particle sizes, including nanomaterial,
   — Impurities of the substances and raw material used, and
   — Interaction of substances.

9. **Undesirable effects and serious undesirable effects**: All available data on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data.

10. **Information on the cosmetic product**: Other relevant information, e.g. existing studies from human volunteers or the duly confirmed and substantiated findings of risk assessments carried out in other relevant areas.

PART B – Cosmetic product safety assessment

1. **Assessment conclusion**
   A Statement on the safety of the cosmetic product.
2. **Labeled warnings and instructions of use**
   Statement on the need to label any particular warnings and instructions of use.

3. **Reasoning**
   Explanation of the scientific reasoning leading to the assessment conclusion set out under Section 1 and the statement set out under Section 2. This explanation shall be based on the descriptions set out under Part A. Where relevant, margins of safety shall be assessed and discussed.
   There shall be inter alia a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.
   Possible interactions of the substances contained in the cosmetic product shall be assessed.
   The consideration and non-consideration of the different toxicological profiles shall be duly justified.
   Impacts of the stability on the safety of the cosmetic product shall be duly considered.
4. **Credentials and approval of part B**
   Name and address.
   Proof of qualification of safety assessor.
   Date and signature of safety assessor

Note: Only Part B of the Cosmetic Product Safety Report could be made available to ESMA or the Concerned Authorities upon request