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Cosmetics Regulatory requirements in Russia and in Turkey, Middle East

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Vermeer Project for Safety evaluation – Milan, 5th of December 2018

Russian Federation

- Reference law: Technical Regulation (TR) on the safety of cosmetic products for Customs Union (TR CU 009/2011)
- Ingredients: according to EU Regulation 1223/2009. Annexes are not automatically updated however the safety evaluation of an ingredient can follow the same concept, including in vitro evaluation
- When a product is in compliance with Technical Regulation the following mark of conformity can be showed on the label:

EAC

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How to obtain mark of conformity?

- A local legal entity/distributor is required
- Only a third party laboratory/notified body can release the mark of conformity
- Depending on the product there are two different certification to require:

Russian Federation

1) State Registration of Customs Union is required for:

- artificial tanning (self-tanning) products;
- skin whitening;
- Tattooing;
- personal (intimate) hygiene;
- protection products against harmful manufacturing factors;
- cosmetics for children;
- hair dyes and hair bleaching products;
- hair waving and straighteners;
- products containing nanomaterials;
- depilatory products;
- peelings;
- products for dental and oral hygiene containing fluorine (> 0.15%; for liquid oral hygiene products –0.05%-expressed as molar weight of fluorine);
- tooth whiteners containing hydrogen peroxide and other ingredients producing hydrogen peroxide, including carbamide peroxide and zinc peroxide in the concentration of hydrogen peroxide 0.1–6.0%

2) Declaration of Conformity of Custom is required for all of other cosmetic products.

Russian Federation

The validity of EAC mark is limited to a maximum of 5 years when:

- there are no variations on the product formulation to impact the safety of product itself
- there are no variations in the contract in force between manufacturer and local distributor

Turkey

- Reference law: Cosmetic Regulation 2015-29417
- Ingredients: according to EU Regulation 1223/2009. Annexes are not automatically updated however the safety evaluation of an ingredient can follow the same concept, including in vitro evaluation
- The definition of a cosmetic product correspond with the definition of EU Regulation 1223/2009. However following products are classified as OTC (Over The Counter):

Oral hygiene products anticavity (for example with fluorine > 0,15% or clorexidina digluconate > 0,2% ecc.);

Oral hygiene withening products (for example with hydrogen peroxide > 0,1%);

Sun products with insect-repellent substances

Ear and nose/nostrils hygyene products

Eyelashes hygiene products

Hair growth products

Skin withening products with hydroquinone an derivatives > 2%

Skin peeling with AHA >10% and pH= 3,5

Turkey

- As in Europe a product information file (PIF) must be available at the address indicated on the label (Turkish Responsible Person)
- Turkish Responsible Person has to notify every SKU on the UTS web portal. Frame formulations are not accepted. The Cosmetic Product Safety Report (as defined in EU Regulation 1223/2009) has to be uploaded as well.
- A specific notification is required for products containing nanomaterials

- The Gulf Cooperation Council (GCC) is a regional intergovernmental political and economic union that include United Arab Emirates, Saudi Arabia, Kuwait, Bahrain, Qatar and Oman.
- Reference law: GSO-1943-2016 – Safety Requirements of cosmetics and personal care products
- Ingredients: according to EU Regulation 1223/2009. Annexes are not automatically updated however the safety evaluation of an ingredient can follow the same concept, including in vitro evaluation

- United Arab Emirates are: Abu Dhabi, Ajman, Dubai, Fujaira, Ras-al-Khaimah, Sharjah ed Umm al-Qaiwain.
- The certificate of conformity to the cosmetic standard (CoC) is released in UAE by ESMA according to the on-line procedure ECAS (Emirates Conformity Assessment Scheme)
- For local distributor located in Dubai it is mandatory to register the cosmetic products also to Dubai Municipality
- Mandatory information is the free sale certificate released in Italy by Ministry of Health and the ISO 22716 certification for cosmetic good manufacturing practice (GMP)

Saudi Arabia

- The certificate of conformity to the cosmetic standard (CoC) can be released by a recognised notified body
- Saudi distributors must notify the products on eCosma portal.

Kuwait

- The conformity to the cosmetic standard GSO-1943-2016 is verified by the local Ministry of Health at the end of registration process
- All of documents required for the registration must be in English (or with an English translation) and must be notarized by Kuwait local Ambassy

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Bahrain

- The product must obtain a Registration Certificate released by Ministry of Health according to the GSO-1943-2016
- The registration must be compulsory applied by the local distributor
- Mandatory information is the free sale certificate released in Italy by Ministry of Health

Quatar

- The conformity to the cosmetic standard GSO-1943-2016 is verified by the local Ministry of Health at the end of registration process
- The registration must be compulsory applied by the local distributor
- All of documents required for the registration must be notarized by Quatar local Ambassy

Oman

- The conformity to the cosmetic standard GSO-1943-2016 is verified by the local Ministry of Health at the end of registration process
- The registration must be compulsory applied by the local distributor
- Local distributors must notify the products on BAYAN Electronic Single Window system (BAYAN system)

Iran

- Reference law: D/1/125930, 08/01/06 (18/10/1384), last update 2009 Executive Guidelines inspection of documentation and scientific records for processed cosmetics and hygiene products and the issue of health permits for imports

- Ingredients: according to EU Regulation 1223/2009. Annexes are not automatically updated however the safety evaluation of an ingredient can follow the same concept, including in vitro evaluation

- Local authority for the verification and the registration of cosmetic products is the Food and Drug Administration (FDA) within the Iranian Ministry of Health and Medical Education.

Iran

Import Procedure

- Step 1: evaluation of Good Manufacturing Practice (GMP) → Plant Master File
- Step 2: evaluation of documents on final product and its ingredients → Product Master File
- Step 3: Iranian distributor apply for the import licence
- Step 4: Customs testing (3 to 12 samples are analysed)
- Step 5: If testing results are in compliance with iranian requirements FDA will release the "hygiene certificate for importation"
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Iran

- At the present time the Iranian FDA has stopped registration procedures for many products including creams (in general), shampoo, hair conditioner, shower gels, mouthwashes, toothpastes. This stop refers both to new products and renewals

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Thanks for your attention!