

### COSMETIC PRODUCTS DEFINITION



EC REGULATION 1223/2009  
(ART. 2)



#### ZONE OF APPLICATION

**Superficial** zones of the body: epidermis, hair, system, nails, lips and external genital organs

**Teeth and oral mucosa**



#### FUNCTIONS

**Cleaning**

**Perfuming**

**Altering** the appearance

**Protecting**

**Maintaining** in good condition

**Correct body odors**



FEDERAL FOOD DRUG AND COSMETIC ACT  
(FD&C ACT)



#### ZONE OF APPLICATION

**No specific zones defined**

**Type of application specified:** rubbed, poured, sprinkled, sprayed, or introduced into or otherwise applied to the human body



#### FUNCTIONS

**Cleansing**

**Beautifying**

**Altering** the appearance

**Promoting** attractiveness

### REGULATORY FRAMEWORK



EC REGULATION 1223/2009

**Annex I:** Structure of cosmetic product safety report

**Annex II:** List of substances prohibited in cosmetic products

**Annex III:** List of substances with restrictions

**Annex IV** and **Annex V:** List of colorants and preservatives allowed in cosmetics

EU portal for cosmetic product:  
CPNP notification mandatory  
before product marketing



21 CFR PART 700  
21 CFR PART 701

**FDA list and 21 CFR Part 700:** Prohibited and Restricted Ingredients

**21 CFR Part 701:** Labeling Requirements

**FDA GMP Checklist:** Manufacturing Guidelines

**Cosmetics are not “True soap”:** separated product category (21 CFR 701.20) regulated under the Consumer Product Safety Commission (CPSC)

No specific authorization procedure  
before product marketing  
Voluntary registration process  
available

### CLASSIFICATION OF COSMETIC: VIGILANCE POINTS

#### BIOCIDE

i.e.: hand hydroalcoholic gel

#### MEDICAL DEVICES

i.e.: healing gel (mechanical action)

#### COSMETICS

#### DRUG

i.e.: antibiotic cream

#### FOOD

i.e.: nutricosmetics

**Massage product:** MAIN COSMETIC CLAIM mandatory (nourishing, moisturizing, perfuming...) because muscle and joint are not considered as superficial application zones

**Nasal spray:** outside application zone of cosmetic products

**Gel/spray for heavy legs and mouthwash:** MAIN COSMETIC CLAIM mandatory (refreshing, moisturizing, protecting, calming) before secondary claims (antimicrobial, heavy legs...)

**Products for acne or atopic skins:** classification possible in cosmetics if primary action is a cosmetic action such as cleaning, protecting, pores tightening

**Therapeutical claims for disease prevention and infection treatment** are outside the scope of cosmetic products (gingivitis, conjunctivitis, atopic dermatitis)

**SPF sunscreen:** drug action – outside cosmetic product scope; must be compliant with drug status

**SPF sunscreen with moisturizing claim, anti-perspirant deodorant, anti-dandruff shampoo:** have both drug and cosmetic actions; must be compliant with both status

**Acne control / Joint & muscle pain gel:** drug action – outside cosmetic product scope; must be compliant with drug status

**Gel/spray for heavy legs / Massage product:** must use cosmetic compliant claim (moisturizing, cleansing, perfuming) to avoid being considered a drug

**Claims for the appearance are in scope for cosmetics but claims to modify or alter skin structure are drug claims** (physiological action)

**Therapeutical claims and Structure Function (SF) claims** are outside the scope of cosmetic products



### COSMETIC CLAIMS



EC REGULATION 655/2013  
EC REGULATION 1223/2009 – ARTICLE 20  
ARPP REGULATION FOR ADVERTISEMENT

#### No therapeutical claims

**Cosmetics must be truthful and not misleading**

**6 common criteria:** compliant to regulation, veracity, evidence driven, sincerity, equity, informed choice

**>> Justification of cosmetic claims mandatory by scientific evidence**

**Tolerated claims (with justification) because they are informative**

- Free from colorant, preservative, alcohol, silicon, mineral oil, acetone
- Vegan or free from ingredient with animal origin

#### Natural/organic claims

- Norme ISO 16128: calculation % of ingredients from natural and organic origin
- 95% of ingredients from natural origin: the final product can be considered as natural / from natural origin

#### Forbidden Free from claims

- Free from "a forbidden substance"
- Free from allergens
- Free from "an authorized ingredient with a bad image for consumers": free from parabens, phtalates



#### No Structure Function claim

#### No therapeutical claims

**Cosmetic claims must be truthful and not misleading**

**>> Cosmetic claims should be supported by appropriate scientific evidence**

#### Tolerated claims (with justification)

- Generally "Free from" claims are permitted if truthful and not misleading
- Environmental friendly claims: FTC guideline
- Cruelty free/Vegan: generally permitted (FDA guideline and certification bodies exist)

#### Organic claims - 4 categories (USDA):

- 100% organic
- Organic (=95% organic ingredients)
- Made with organic (=70% organic ingredients)
- Or if less than 70% in total, individual ingredient as organic stated in the ingredient list but cannot state "organic" anywhere on the PDP (front panel) or make any organic claims

**Risky claims in the USA:** lack of regulatory definition from FDA leaves these open to risk of being considered false or misleading; very difficult to justify:

- Hypoallergenic
- Natural

### JUSTIFICATION OF COSMETIC CLAIMS

#### TIERED APPROACH



#### SAFETY AND REGULATORY ASPECTS DURING FORMULATION:



- **Formulation** with ingredients with complementary mechanism of action
- **Scientific literature review for actives dose, administration route**
- **Experts opinion review**
- **Regulatory review of the formula**
- **Regulatory tests**
- Galenic test

#### EFFICACY TEST:



- **In vitro test/ex vivo test** (skin explant): mechanism of action
- **Usage test/Clinical study:**
  - Clear objective of the study
  - Study population representative of consumer target
  - Objective parameters assessed by clinicians and equipment (corneometry, profilometry)
  - Auto-evaluation of consumers: perceived efficacy and acceptability (subjective parameters)
  - Gold standard method: randomization, controlled study

#### CONSUMER TEST FOR COMMERCIALIZED PRODUCT:



- Product satisfaction in real conditions of use
- Importance of the quality of the questionnaire
- Number of volunteers to be assessed for robust statistical analysis



- **PIF Dossier writing:** Product Information File on Safety and Efficacy
- **CPNP notification**
- **Cosmetovigilance**



- **Voluntary Cosmetic Registration Program** with the FDA

### DISCOVER RNI EXPERTISE FOR COSMETICS IN EU AND THE US:

- **Regulatory analysis of formulas and labels**
- **Toxicological profile of substances (RNI expert toxicologist)**
- **Writing or review of PIF dossier**
- **Coordination of regulatory tests and studies for efficacy data**
- **Justification of cosmetic claims**
- **Notification on CPNP portail (EU)**

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