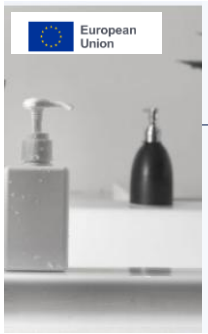


Cosmetic regulation in European Union

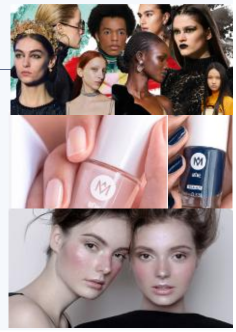
Pr MA Bolzinger

Summary

01

Definition

Cosmetic or “the art of dress and ornament”



Embellish: apply makeup – treat yourself!

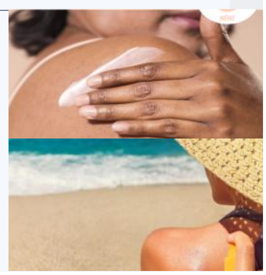
The general idea: To be trendy

Protection/take care

Using make-up to cover up a skin disease as rosacea and acne or prevent skin disorders.

https://www.ellequebec.com/beaute/shopping-beaute/toutes-les-tendances-beaute-de-lautomne-hiver-2023-2024
https://www.beaute-test.com/mag/article-comment-se-maquiller-quand-on-couperose.php
https://www.memecosmetics.fr/fr/23-tous-les-produits

But also....



Prevent

Repair – prevent the aging

Keep in good condition

Sun protection products, Hygiene products,...

https://www.memecosmetics.fr/fr/23-tous-les-produits
https://www.doctissimo.fr/beaute/diaporamas/creme-solaire-protection-solaire

Cosmetic product or not ?

Tattoos

Temporary tattoos, for which the inks used fall under the category of cosmetic products;
Permanent tattoos, performed by professionals who use inks subject to separate regulations.

Food supplements for beauty purposes

https://www.tatouagebelgique.org/post/need-to-know-pour-tatou%C3%A9s

Food supplements means foodstuffs the purpose of which is to supplement the normal diet, and which are concentrated sources of nutrients (vitamins and minerals) or other substances with a nutritional or physiological effect.

Food supplements are subject to all the general provisions of food law, as well as to the specific rules laid down by Directive 2002/46/EC

A product subject to regulation

Definition of European Regulation (EC) 1223/EEC

'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

It defines the scope of the regulation

- Clean
- Beautify
- Make more attractive
- Keep in good condition

Cosmetic product categories

https://www.lebeta.fr/le-secteur-cosmetique/chiffres-cles-du-marche-cosmetique

Cosmetic product

- Not ingested
- Not inhaled
- Not injected
- Not implanted

In Europe, the category "dermocosmetics" does not exist

Focus on tattoos

RÈGLEMENT (UE) 2020/2081 DE LA COMMISSION du 14 décembre 2020
modifiant l'annexe XVII du règlement (CE) n° 1907/2006 du Parlement européen et du Conseil concernant l'enregistrement, l'évaluation et l'autorisation des substances chimiques, ainsi que les restrictions applicables à ces substances (REACH), en ce qui concerne les substances contenues dans les encres de tatouage et les maquillages permanents

In the Union, the number of people who have a tattoo or permanent make-up is steadily increasing, particularly among young people. The procedures used for tattooing or permanent make-up (hereinafter collectively referred to as "tattooing"), whether involving the use of needles or other techniques such as eyebrow pigmentation with a blade (microblading), inevitably cause injury to the skin barrier.

As a result, the inks or other mixtures used for tattooing are absorbed into the body. The mixtures used for tattooing generally consist of colorants and auxiliary ingredients such as solvents, stabilizers, humectants, pH regulators, emollients, preservatives, and thickeners. These mixtures are injected into the human skin, inside the eyeball, or into the mucous membranes.

Most of the colorants remain close to the site where the mixture has been administered, so that the tattoo or permanent make-up remains visible. However, the soluble ingredients of the mixture spread throughout the body within a few hours or days. Consequently, the skin and other organs are exposed to the effects of these soluble substances over an extended period. Some of these substances have hazardous properties that pose a potential risk to human health.

In addition, the metabolism of colorants in the skin, as well as their degradation following exposure to sunlight or laser irradiation, may also lead to the release of hazardous chemicals from the area of the body where the tattoo or permanent make-up is located.

In France, cosmetics are "classified" under the Public Health Code

Cosmetic products are classified as health products and listed in articles L5131-1 – L5131-8 of the Public Health Code

The legislator has not defined what is a health product. He has drawn up a list of products under Article L. 5311-1 of the Public Health Code. Most of these products are regulated, with their status generally established by a European Union directive or regulation.

Article 205 of the 2023 Finance Act stipulates that, with effect from 1 January 2024, responsibility for cosmetics and tattoo products will transfer from the ANSM to the ANSES and the DGCCRF (directory general for competition policy, consumer affairs and fraud control)

From 1 January 2024, the DGCCRF will be solely responsible for monitoring cosmetic products and establishments. Previously, this task was carried out jointly with the French National Agency for Medicines and Health Products Safety (ANSM).

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has taken over the cosmetovigilance and risk assessment tasks that were previously carried out by the ANSM.

.

DGCCRF

02

The cosmetic market

Global market 2023

At net manufacturers prices

270 Billion euros
+8% growth
+13 % for cosmetics

France is the leader

France remains the world's biggest exporter of cosmetics (22.5 billion euros) (+6.8%)

Cosmetic is the the second-largest exporting industry in France, just behind aeronautics.

France sets new record for cosmetic exports, fueled by strong perfume sales

Premium Beauty News (Photo: Dan Dalton / Stock.it)

9 February 2025

SHARE

French cosmetic exports broke a new record in 2024, reaching a value of 22.5 billion euros, an annual increase of +6.8%. While France, which exports more than 60% of its cosmetics production, remains a global leader in this sector, the country is facing increasingly intense competition.

03

Brands and drivers of the market

Groups and brands

Some groups own portfolios of brands.
All of these brands use the concept of market segmentation: Market segmentation helps identify the population most likely to buy in both the short and long term.

The segment offers a selection of products designed to address a specific issue or cater to a particular consumer group, working together to achieve this goal.

Who owns the brands ?

L'OréaL Group (1er)

LVMH Group (9ème)

Who owns the brands ?

Yves Rocher Group (24ème)

Clarins Group (27ème)

Pierre Fabre Group (31ème)

Nuxe Group (82ème)

L'Occitane Group (30ème)

Cartier (79ème)

Caudalie (90ème)

ALES Group (70ème)

Laboratoires Expanscience (89ème)

04

Cosmetic product legislation

The Morhange Talc Affair : 1972

The Mohrange talcum powder scandal broke out in 1972.

36 infants died from hexachlorophene (HCP) poisoning.

An error occurred during the preparation of the talc. A drum containing 38 kg of HCP was used unwittingly during the manufacturing process, resulting in a concentration of 6.3% in the final product instead of the permitted maximum of 0.5%.

The barrel used did not bear any hazard labeling

The batches were not traceable.
- no batch number.
- no date of manufacture

⇨ Importance of legal regulation

https://www.sudouest.fr/santefr-y-a-50-ans-la-scandaleuse-affaire-du-talc-morhange-11986356.php

From the Veil Act to the Cosmetic Regulation (EC) 1223/2009.

- It will be the starting point for regulatory developments at national and European level.
- The European Community drew inspiration from this law to draft Directive 76/768/EEC of 1976.
- The directive was changed many times:

Changes to the directive: 6th amendment in 1993 (Council Directive No. 93/35/EEC of 14 June 1993 (OJEC L151 of 23 June 1993)):
- Manufacturer's declaration requirement,
- Introduction of a product file and list of ingredients on packaging, conditions of use and warnings, and the manufacturer's address.
- **7th amendment 1998: Council Directive No. 2003/15/EEC of 27 February 2003 (OJEC L66/26 of 11 March 2003):**
- End of animal testing and ingredients if alternative methods validated by (ECVAM) (2004) exist.
- Establishment of a list of 26 allergenic fragrance substances

⇨ The draft regulation was adopted on 24 March 2009 for implementation in three years, i.e. in July 2013. Cosmetics Regulation (EC) No 1223/2009 published on 22 December 2009 and applicable in 2013, except for specific points.

Cosmetic products are regulated in EU

• A directive
Following its adoption, Member States have a period of time to transpose it into their domestic law: they decide on the form and means to achieve this.

•A regulation
The regulation is applied in its entirety as soon as it is published in the OJEU
The results to be achieved and the means to achieve them are imposed.

Its advantages:
- Immediate application
- Reduction of the regulatory burden
- Elimination of possible discrepancies between Member States

Cosmetic products are regulated at European level.

DG SANTE : Its mission is to contribute to improving the health, safety and confidence of European citizens.

It is supported by the SCCS or Scientific Committee on Consumer Safety: Advice on scientific issues

It is responsible for scientific and technical issues concerning consumer health in the field of non-food products intended for consumers, and in particular issues relating to the substances used in the preparation of these products, their composition, their use and their packaging.

EXPERT OPINION

Safety of aluminium in cosmetic products - Submission IV

Preliminary Opinion open for comments - **Deadline for comments: 16 February 2024**

https://health.ec.europa.eu/publications/sccs-notes-guidance-testing-cosmetic-ingredients-and-their-safety-evaluation-12th-revision_en

What legislation applies to cosmetics?

Regulation (CE)1223/2009

REACH Regulation (CE)1907/2006

CLP Regulation (CE) n°1272/2008

Regulation (CE) N°655/2013

Evaluation REACH Registration Authorisation Chemical substances

REACH establishes procedures for collecting and assessing information on the properties and hazards of substances.

Classification, labelling and packaging of substances and mixtures

This Regulation shall apply to claims in the form of texts, names, trademarks, pictures and figurative or other signs of cosmetic products.

Founded in Geneva in 1973, IFRA is the International Fragrance Association, the official international representative body for the fragrance industry. Its main purpose is to ensure the safety of fragrance raw materials for health and the environment through a dedicated scientific programme.

The European regulation: 40 articles in 10 chapters and 10 annexes

Regulation (CE)1223/2009

I	SCOPE DEFINITION
II	SAFETY, RESPONSIBILITY, FREE MOVEMENT
III	SAFETY ASSESSMENT, PRODUCT INFORMATION FILE, NOTIFICATION
IV	RESTRICTIONS FOR CERTAIN SUBSTANCES
V	ANIMAL TESTING
VI	CONSUMER INFORMATION
VII	MARKET SURVEY
VIII	NON-COMPLIANCE, SAFEGUARD CLAUSE
IX	ADMINISTRATIVE COOPERATION
X	IMPLEMENTING MEASURES, FINAL PROVISIONS

The European regulation: 40 articles in 10 chapters and 10 annexes

Consumer safety must be ensured.

Before placing on the market:

1. The person responsible for placing the product on the market has obligations set out in the regulation.
2. Rules are imposed for the design and manufacture of CPs.
3. Human health safety assessment is mandatory.
4. The cosmetic product is subject to a product information file (different from that for medicinal products)
5. Labelling rules must be complied with.

After placing on the market:

1. Cosmetovigilance
2. Advertising
3. Information for the public and authorities
4. Role of distributors and authorities

The European regulation: 40 articles in 10 chapters and 10 annexes

Major Changes:

Notion of Responsible Person : Any product placed on the EU market must be represented by a RP established in the EU.

Nanomaterials: Must be notified, assessed and appear on the labelling [nano].

CMR substances: Their presence is prohibited except in exceptional cases (mandatory since 1 December 2010).

Notification: Each product must be notified on the CPNP portal before being placed on the market. The CPNP then makes some of this information available to the competent authorities and poison control centres.

Cosmetovigilance: Serious adverse effects must be reported to the competent authorities of the Member State where the effect was observed.

Packaging material: Its composition must be known and assessed to ensure safety in the event of transfer between container and contents.

Good Manufacturing Practices for Cosmetics: This European Standard EN ISO 22716 provides guidelines for the production, control, storage and shipment of cosmetic products.

Chapter 1 Scope, Definitions

- b) 'substance' means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- c) 'mixture' means a mixture or solution composed of two or more substances;.....
- k) 'nanomaterial' means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm;

.....

- q) 'withdrawal' means any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain;
- r) 'recall' means any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user;

Chapitre 2: Safety, responsibility, free movement

- Major amendments: Chapter II: The responsible person

Product safety is enhanced

"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":

- Presentation,
- Labelling ,
- instructions for use and disposal;,

any other indication or information provided by the responsible person defined in Article 4. .

Responsible person

The manufacture of cosmetic products shall comply with good manufacturing practice (article 8)

30

Responsible person

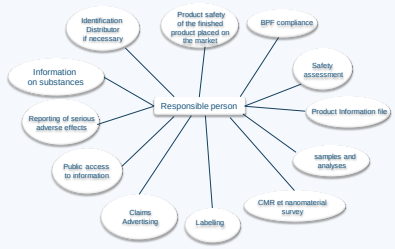
"Only cosmetic products for which a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market"

No qualifications are required.

- The manufacturer may designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.
- For an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market. .
- The distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.

31

Obligations of responsible persons

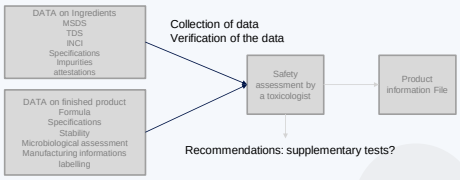


Chapitre III – Safety assessment, product information file, notification

It is structured around the safety assessment report (Annex I of the Regulation).

→ This applies to all cosmetic products placed on the market, including soaps, free samples and promotional products.

The report contains key information about the product and must be kept for 10 years after the production date of the last batch.



Chapitre III – Safety assessment, product information file, notification

The first Annex contains key information about the product and is kept for 10 years after the date of the last batch produced.

A. Cosmetic product safety information	B. Evaluation of cosmetic product safety
Qualitative and quantitative formula of the product	Conclusion of the evaluation
Physical and chemical characteristics and product stability	Warnings and instructions for use on the label
Impurities, traces Information on packaging material	Reasoning
Normal and reasonably foreseeable use	Evaluator references* and final approval*Pharmacist, toxicologist
Exposure to cosmetic products	
Exposure to substances	
Adverse events	

...onclusion of the assessment. It is based on the descriptions in Part A. It includes a specific assessment of CPs intended for children under 3 years of age and intimate hygiene products. Any interactions between the substances contained in the CP must be assessed.

34

SAFETY ASSESSMENT, PRODUCT INFORMATION FILE, NOTIFICATION : PIF and CPNP

Description of the cosmetic product
- Trade name
- Capacity Brand
- Its primary function,
- its category

Electronic notification on the CPNP portal (Cosmetic Products Notification Portal)

Administrative data
- Contact details of the responsible person
- Declaration of the establishment manufacturing and packaging the CP

ANNEX I

Description of the manufacturing method
(manufacturing diagram, packaging processes, relevant controls during manufacturing)

Compliance to BPF

Methods for identifying manufacturing batches

Claims and efficacy

Data relating to animal testing

Category of CP and full trade name - Name and address of the person responsible where the product information file is available - he Member State in which the CP is placed on the market and the contact details of a natural person to be contacted if necessary - The presence of substances in micronised particle form (Article 16) - The presence of CMR substances - Exact composition of the product (framework formulas) with details on substances of concern (ethanol, substances in Annex 6 of the CLP), -photos of the product

Each product must be notified on the CPNP portal. The portal makes the information available to the competent authorities and poison control centres.

Glossary of common ingredient names

The INCI list

- The ingredients are to be expressed using the **common ingredient name** set out in a glossary compiled and updated by the Commission pursuant to Article 33 of that Regulation
- New Glossary of ingredients came into effect on 9 May 2020
- Establishes the INCI names of ingredients that brands can use on packaging.
- Ingredients listed in descending order according to their percentage in the formula
  - **Ingredients > 1%: in descending order of quantity**
  - **Ingredients < 1%: may be listed in any order**

36

Chapter IV: RESTRICTIONS FOR CERTAIN SUBSTANCES

1 Annexe II List of substances prohibited in cosmetic products
2 Annexe III List of substances which cosmetic products must not contain except subject to the restrictions laid down
3 Annexe IV List of colorants allowed in cosmetic products
4 Annexe V List of preservatives allowed in cosmetic products
5 Annexe VI List if UV filters allowed in cosmetic products
6 Annexe VII symbols used on packaging/container
7 Annexe VIII List of validated alternative methods to animal testing

Article 15 CMR substances
Article 16 : déclaration of nanomaterials

Annexe IX (directives abrogated) et X (ccorrelation table between directive/ regulation)

37

What is marketing and what is mandatory?

Range launched in 2020: 'powerful, sensory and committed'
Labels :
- Organic, vegan, recyclable

Ingredients :
- Description of key active ingredients : Chia seeds
- 99% natural origin
- 78% of the total ingredients are from organic farming.

Pack : 30% recycled glass, box made from recycled fibres

38

Chapter VI – Consumer information

Indicates that the instructions and listof ingredients are provided on a label or attached card

If your product has a lifespan of more than 30 months, you're likely to find a PAO symbol. It is the 'period after opening' for which your product will stay safe to use and still perform as you'd expect. This could be 6M, 12M (12 months) or 24M (24 months) or even longer.

Hourglass symbol: if the minimal lifespan is lower than 30 months :

- DDM date of minimum durability ou expiration date or deadline for optimal use MM/AAAA
- Utiliser de préférence avant MM/AAAA
- Hourglass+ date

39

Can you decrypt this product?

DON'T CONFUSE VEGAN WITH ORGANIC!

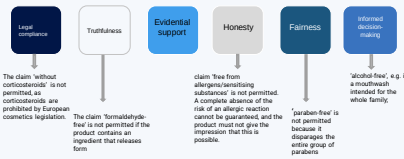
VEGAN COSMETICS

Vegan cosmetics define products that are free of ingredients of animal origin and as such are not tested on animals. These are the basic criteria to qualify a product as "vegan" to which additional criteria/requirements can be added as there is no official certification. The vegan or cruelty free labels therefore only focus on animal welfare and not necessarily on organic.

There is no "common" standard or label for vegan. Each private label and each marketer can impose its own criteria according to very different specifications and conditions.

Chapter VI – CONSUMER INFORMATION – Regulation 655/2013

- In 2013, the commission Regulation laid down 6 common criteria for the justification of claims used in relation to cosmetic products



Chapter VI – CONSUMER INFORMATION – Regulation 655/2013

Claims may not:

- Suggest that a product provides a particular benefit if it complies with the minimum requirements of the legislation.
- Mention the presence of an ingredient that is not present.
- Transpose the properties of an ingredient without supporting evidence.
- Be exaggerated.
- Go beyond the effects demonstrated by supporting evidence.
- Denigrate the competition
- Denigrate ingredients used legally

Chapter VI – CONSUMER INFORMATION – Regulation 655/2013

The ARPP is the French Advertising Regulatory Authority – It emitted new recommendation in 2019.

1. A product is classified as natural if it contains at least 95% natural ingredients.
2. Presentation of tests: take the average result: slims by 2 cm (OK)// slims by up to 4 cm (not OK).
3. Precise definition of the sensitive skin claim:
   - The volunteers included in the tests reported having sensitive skin.
   - The volunteers did not experience an increase in their symptoms during the test.

4. Clarification of the nature of the tests
   Objective tests: instrumental tests and sensory tests
   Satisfaction tests based on consumer surveys
5. Claim 'not tested on animals' is prohibited. The DGCCRF (French Directorate General for Competition, Consumer Affairs and Fraud Control) reminds us that the use of the 'cruelty free' and 'leaping bunny' logos and their derivatives, even without the phrase, is prohibited.

6. Hypoallergenic claim: addition of very restrictive criteria on ingredients that make this claim impossible.
7. Three claims "XX free" are still permitted: alcohol-free (mouthwashes for the family), acetone-free (due to unpleasant odour), and animal derivative-free (vegan).

How should we position ourselves in relation to the excesses of the discourse?/!\

Law 1er July 2019

- Claims "free" : misused
- Claims "hypoallergenic" authorized under conditions

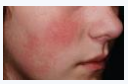
Unfair
Ban on packs
Refocusing on the product

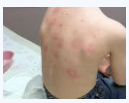
Sources : Site internet de la FEBEA

Chapter VII - Market surveillance - Article 23 Communication of serious undesirable effects

In the event of serious undesirable effects, the responsible person and distributors shall without delay notify the following to the competent authority of the Member State where the serious undesirable effect occurred:

The Cosmetics Regulation defines:
- undesirable effects as "adverse reactions for human health attributable to the normal or reasonably foreseeable use of a cosmetic product".
- Serious undesirable effects are defined as "undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death"



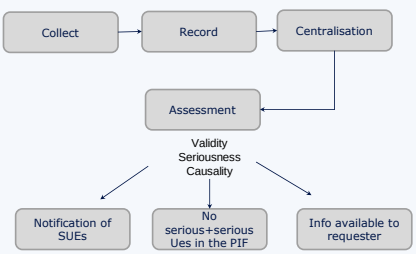


Relatedness with the use of the product

Not confirmed → Undesirable event

Confirmed → Undesirable effect

Chapter VII - Market surveillance - Article 23 practical aspects of pharmacovigilance



Collect

- All UEs that a member of the Company has become aware of by
  - Phone call
  - E-mail
  - Letter
  - Others
- Only spontaneous reports (excludes solicited reports)
- Reporter may be
  - Consumer
  - Healthcare professional
  - Distributor
  - Competent Authorities
  - Others
- Objective
  - Collect maximum of information at initial contact
  - Let, first, the reporter to speak
  - Follow-up with reporter or healthcare provider if needed

Record

- Nothing officially required but
  - System reliable and searchable is needed
    - If many cases: database recommended
    - If very few cases: paper file may be enough
  - Coding of the UEs with a medical dictionary
    - MedDRA or other
  - Use a company specific numbering system
  - Include the very first date of awareness of the UE by an employee of the Company
  - Consider data privacy protection rules

Centralisation

- To ensure a centralised and harmonised assessment of all European reports by a qualified evaluator
- To facilitate the compilation of all cases on a specific product for inclusion in the Product information File
- To facilitate the search for safety signals based on all UEs occurred on the product whatever the country.

Assessment

- Is the case valid ?
- Is the case serious ?
- Is the case related to the use of the product ?

Chronology		Symptomatology: Evocative –	Evocative ?	Evocative +	Non evocative –	Non evocative ?	Non evocative +
		Rechall. / Invest.			Rechall. / Invest.		
Delay between exposure and reaction onset	Compatible	VL	L	NCA	L	NCA	UL
	Not clearly Compatible	L	NCA	UL	NCA	UL	UL
	Incompatible	Excl	Excl	Excl	Excl	Excl	Excl

Development of a method to establish the causality assessment

- If chronology incompatible
- If other cause identified

} Causality excluded

- In all other cases: use a decision tree or a decision table

Chapter VII - Market surveillance - Article 23 assessment : case validity

→ 4 criteria in Europe

Identifiable Reporter

Identifiable Consumer

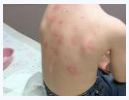
Identifiable Product

Well defined reaction

Chapter VII - Market surveillance - Article 23 Communication of serious undesirable effects

Notification : To the National Competent Authority of the member state where it occurred (only EU) :

- In 20 calendar days
- With a specific form (EU Commission website)
- By the Responsible Person / by the Distributor
- All SUEs with causality 'very likely', 'likely', not clearly attributable ' or 'Unlikely' ans



52

International cosmetic regulations

- Europe is not the world