

REGULATING COSMETICS IN EUROPE

ALL YOU
NEED TO KNOW



Cosmetics Europe
the personal care association

EU COSMETICS LEGISLATION: 1976 - TODAY

Adoption of the Cosmetics Directive 76/768/EEC

The nine Member States of the European Economic Community (EEC) harmonised their national cosmetic regulations to ensure **the highest level of consumer protection and to allow cosmetic products to freely circulate throughout the Community**. This regulatory approach chosen recognised cosmetics as **fast-moving consumer goods of inherent low risk**, entirely different from pharmaceutical products.

1976

1979

1980s/1990s

Establishment of the Scientific Committee on Cosmetology

The EEC created a panel of independent science experts to transparently assess the safety of cosmetic ingredients based on available scientific evidence.

Now called the **Scientific Committee on Consumer Safety**, the internationally recognised SCCS **supports the European Commission's evidence-based policy-making by providing risk assessment and scientific advice on matters linked to public health and consumer safety**.

Development of the positive and negative lists of ingredients

The EEC – with the support of the Scientific Committee – **developed positive and negative lists of substances** to provide companies with clear information on permitted/forbidden ingredients:

- **Annex II of banned substances**
- **Annex III of restricted substances**
- **Annex IV of allowed colorants**
- **Annex V of allowed preservatives**
- **Annex VI of allowed UV filters**

Regularly updated to reflect the latest scientific information, these lists provide transparent information on if and how substances can be legally used in cosmetics.

6th Amendment to the Cosmetics Directive 76/768/EEC

This amendment defined the six main principles of the European cosmetics legislation, which have since become the model and inspiration for many regions of the world:

1. **Risk-based legislation**
2. **A 'responsible person'**
3. **Comprehensive technical information file for each product**
4. **Mandatory safety assessment**
5. **Effective in-market controls**
6. **Ingredient labelling based on international INCI nomenclature**

1993

2003

The end of animal testing and a ban on CMRs

The 2003 Amendment to the Cosmetics Directive brought further major changes:

1. **A ban on animal testing for cosmetic products and ingredients** (that came into force in 2004 and 2009 respectively) **and a marketing ban**, which made it no longer legally possible in the EU **to market products that contained ingredients tested on animals after 2013**. The European Court of Justice further ruled in 2016 that **companies cannot put on the EU market ingredients and/or products using data on safety that comes from animal testing outside the EU**.
2. **A principle ban on the use of carcinogenic, mutagenic or toxic for reproduction (CMR) substances in cosmetics**, unless their safety can be unequivocally and scientifically demonstrated according to strict criteria.

From a directive to a regulation

In 2009 the Cosmetics Directive was amended to become an EU regulation meaning the text **became directly applicable law in all EU Member States**, rather than requiring inclusion into the various national legislations.

The new Cosmetic Products Regulation also replaced more than 20 different national product notification systems with **a more efficient single, electronic system (CPNP)**.

2009

2013 - 2016

New rules for cosmetic product claims

A new 2013 European Commission regulation No 655/2013 established **six Common Criteria to be used for the justification of cosmetic product claims**.

Three years later, following an extensive analysis of 38,995 cosmetics claims on packaging and in all forms of media across the EU, the European Commission issued a report concluding that **"the current regulatory framework is very comprehensive and ensures a high level of consumer protection"** from misleading claims.

Today, the EU Cosmetic Products Regulation is the most modern and successful cosmetics legislation in the world.

The European Cosmetic Products Regulation contains the best tools and mechanisms to fulfil its two objectives: ensuring the highest level of consumer safety and safeguarding the Single Market.

It is an inspiration for regulators world-wide.

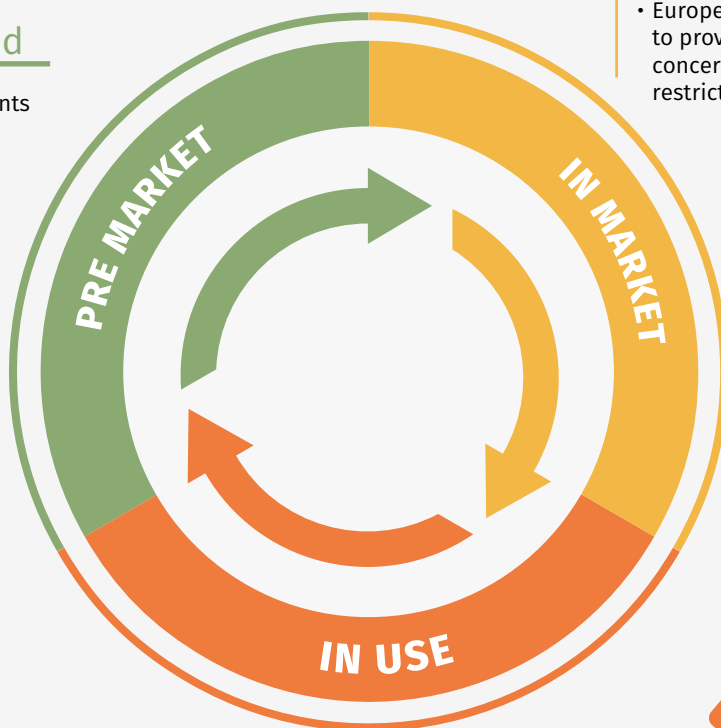


FOUR KEY PILLARS OF THE COSMETIC PRODUCTS REGULATION

01 SAFETY CYCLE

When manufactured

- Each product and its ingredients undergo mandatory safety assessment.
- International standards for manufacturing practices (GMP) are applied to ensure quality products.
- Each product is notified to the authorities via the Cosmetic Product Notification Portal (CPNP).



When on shelves

- Products, safety assessments, manufacturing sites, importers and retailers are inspected by market surveillance authorities.
- European Commission mandates SCCS to provide opinions on serious safety concerns, which may lead to ingredient restrictions or an outright ban.



When used

- Consumers may report cases of adverse reactions.
- Such reports have to be assessed and documented by companies (Cosmetovigilance).
- Cosmetics companies must report serious adverse effects to authorities.
- If appropriate, the European Commission triggers procedure leading to stricter requirements vis-à-vis cosmetic ingredients.



02 HAZARD & RISK

Hazard is based on the intrinsic properties of a situation, an object or an ingredient.

Risk is the probability, high or low, that living beings may be exposed to a hazardous situation, object or ingredient.

A LION IS INTRINSICALLY A HAZARDOUS ANIMAL.



THE SAME HAZARDOUS LION CLOSED IN A CAGE REPRESENTS A VERY LOW RISK TO HUMAN BEINGS.



Risk ≠ Hazard
Risk = Hazard x Exposure

“Everything is a poison, nothing is without poison; only the dose decides that something is not a poison”

Paracelsus (1493-1541)

03 COSMETICS: DEFINITION & APPLICATIONS

Cosmetic products are any substances or mixtures intended to be placed in contact with the external parts of the human body or with the teeth and the mucous membranes of the mouth.

Cosmetic products are applied for the purposes of:



CLEANING
e.g. shampoo, shower gel, soap



PERFUMING
e.g. eau de parfum, eau de toilette



CHANGING APPEARANCE
e.g. hair dyes, make-up



PROTECTING
e.g. sun protection, hand cream



KEEPING IN GOOD CONDITION
e.g. oral care, skin care, hair care



CORRECTING BODY ODOURS
e.g. deodorant, antiperspirant

04



COMPREHENSIVE INFORMATION TO CONSUMERS

The cosmetics sector is one of the few consumer product sectors that provides comprehensive mandatory information on the composition of its products on product labels. Furthermore, any claims made in relation to cosmetic products must comply with six legally binding Common Criteria:

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

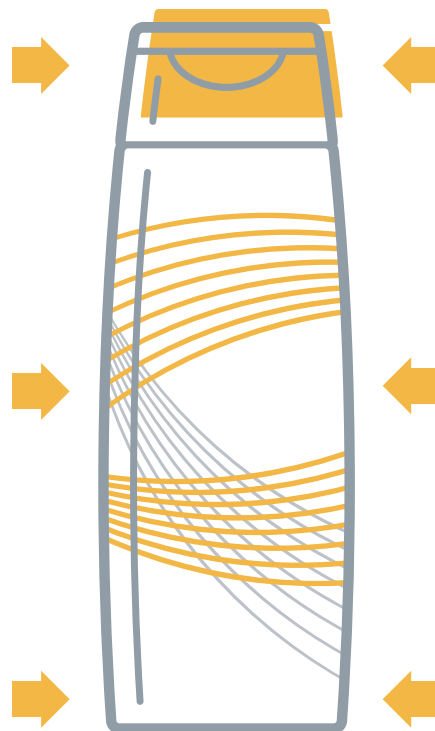
Regulating cosmetics across their life-cycle – an overview

Ingredient safety:

- The **Cosmetic Products Regulation and the REACH Regulation** (Registration, Evaluation and Authorisation of Chemicals) together address human health and environmental aspects of cosmetic ingredients.
- The **Classification, Labelling and Packaging Regulation (CLP)** classifies substances, including cosmetic ingredients, based on their intrinsic (hazard) properties.

Final product safety:

- The **Cosmetic Products Regulation** obliges products to be safe for use in normal and reasonably foreseeable conditions. This safety needs to be demonstrated - and available for authorities' inspection - through technical documentation and a safety assessment done by a qualified safety assessor. The EU's **General Product Safety Directive (GPSD)** allows authorities to exchange information on dangerous consumer products on the market and to alert each other and the general public via the RAPEX Website.



Packaging / Waste:

- The **Packaging & Packaging Waste Directive (PPWD)** aims, through harmonised rules, to prevent or reduce the impact of packaging and packaging waste on the environment. The **Waste Framework Directive (WFD)** protects the environment and human health by preventing or reducing the adverse impacts of waste generation and management.

Advertising and claims:

- In addition to the Common Criteria obligations in the Cosmetic Products Regulation, cosmetics must also comply with the **Unfair Commercial Practices Directive (UCPD)** and **Misleading and Comparative Advertising Directive (MCAD)**. Both laws ensure that commercial and advertising practices are fair and honest.

In-market surveillance:

- Under the **Cosmetic Products Regulation**, Member States are legally obliged to control products on the market for safety and legal compliance. Control practice is harmonised among Member States via the **Regulation on Enforcement and Compliance in the Single Market for Goods** which also facilitates cross-border collaboration between control authorities.

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