

# Cosmetic product claim substantiation

- Cosmetics Europe's approach and its building blocks



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# 1. Introduction to Cosmetics Europe

As the voice for Europe's dynamic Cosmetics and Personal Care Industry since 1962, Cosmetics Europe represents cosmetics and personal care manufacturers, as well as cosmetics associations at national level, right across Europe.

[www.cosmeticseurope.eu](http://www.cosmeticseurope.eu)



## EUROPE IS A GLOBAL FLAGSHIP MARKET FOR COSMETIC PRODUCTS

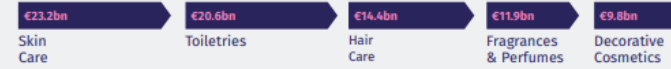


**> €36bn**  
trade in cosmetic  
products within  
Europe in 2021

**> €24bn**  
total export of  
cosmetic products from  
Europe in 2021

### SKIN CARE & TOILETRIES:

largest share of the European market (2021)



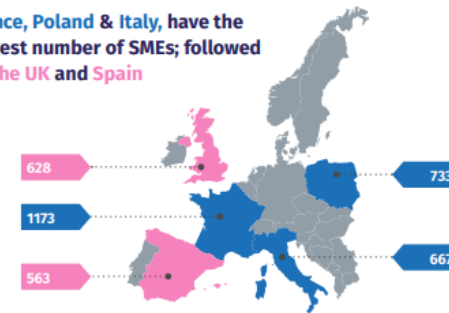
France & Germany: Europe's  
main exporters  
Over 50% of total global  
exports from Europe

Cosmetics Europe, Market Performance Report 2021.

**SMES & BIG COMPANIES ARE KEY  
DRIVERS OF INNOVATION & ECONOMIC  
GROWTH IN THE INDUSTRY**

**Close to 7,000 SMEs** THE NUMBER  
IS GROWING

France, Poland & Italy, have the  
largest number of SMEs; followed  
by the UK and Spain



Cosmetics Europe, Market Performance Report 2021.

**THE INDUSTRY SUPPORTS  
MILLIONS OF EUROPEAN JOBS UP  
& DOWN THE VALUE CHAIN**

Over  
**2 MILLION JOBS**  
across Europe



**255,111**  
people employed directly  
**1.71 million**  
people employed indirectly  
**>393,000**  
people employed through  
induced effects

Cosmetics Europe, Market Performance Report 2021.

ACTIVE CORPORATE MEMBERS (ACM)

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SUPPORTING CORPORATE MEMBERS

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# NATIONAL ASSOCIATIONS

## ACTIVE ASSOCIATION MEMBERS (AAM)

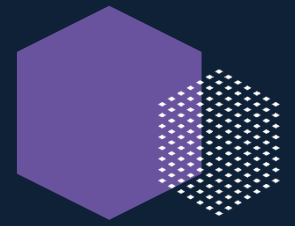
- |   |  |
|---|--|
| 1. Austria: FCIO  | 14. Italy: <b>Cosmetica Italia</b> –<br>Associazione Nazionale Imprese<br>Cosmetiche |
| 2. Belgium & Luxembourg: DETIC  | 15. Latvia: LAKIFA   |
| 3. Bulgaria: BNAEOPC  | 16. Lithuania: LIKOCHEMA   |
| 4. Croatia: Detergents and Cosmetics<br>Affiliation of the Croatian Chamber<br>of Economy | 17. The Netherland: NCV  |
| 5. Czech Republic: CSZV   | 18. Norway: KLF  |
| 6. Denmark: K&H   | 19. Poland: PACDI  |
| 7. Estonia: ECIA  | 20. Poland: Kosmetyczni.pl   |
| 8. Finland: Kosmetiikka- ja<br>hygieniateollisuus ry                                      | 21. Portugal: AIC  |
| 9. France: FEBEA  | 22. Romania: RUCODEM   |
| 10. Germany: IKW  | 23. Slovakia: SZZV   |
| 11. Greece: PSVAK   | 24. Slovenia: KPC  |
| 12. Hungary: KOZMOS   | 25. Spain: STANPA  |
| 13. Ireland: ICDA   | 26. Sweden: KoHF   |
|   | 27. Switzerland: SKW   |
|   | 28. United Kingdom: CTPA   |

## SUPPORTING ASSOCIATION MEMBERS

Russia: Association of Perfumery, Cosmetics and Household chemistry  
Manufacturers - APCoHM  
Russia: Perfumery and Cosmetics Association of Russia - PCAR  
Serbia: Association of Detergents and Cosmetics Producers and Importers of Serbia  
- KOZMODET  
South Africa: Cosmetic Toiletry & Fragrance Association of South Africa – CTFA  
Turkey: Turkish Cosmetics & Cleaning Products Industry Association – KTSD  
Ukraine: Association of perfumery and Cosmetics of Ukraine – APCU



## 2. Overview of the regulatory & self-regulatory background



UCPD currently under revision, will include additional requirements for environmental claims!



Further EU legislation is foreseen on the substantiation of 'green' claims

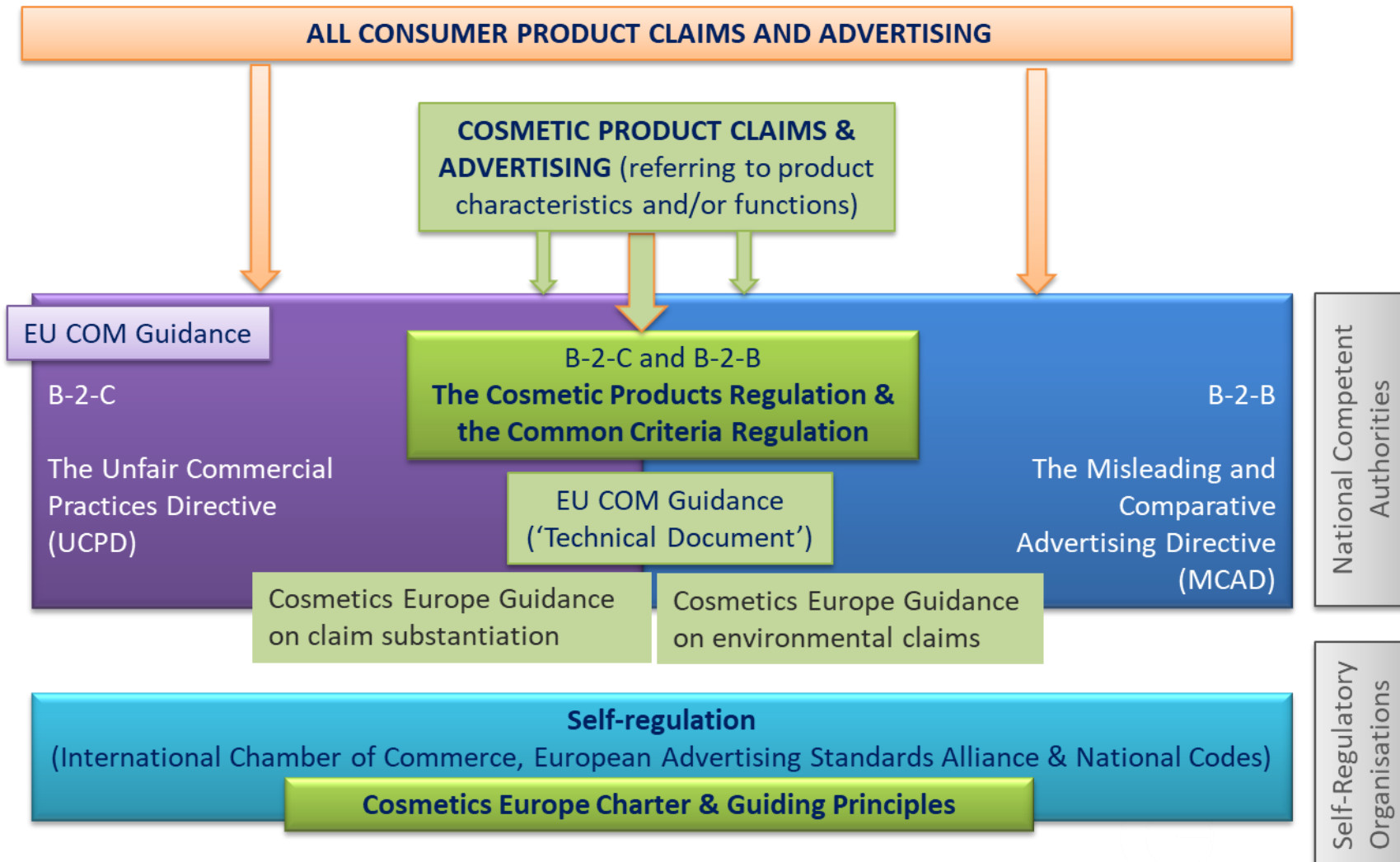
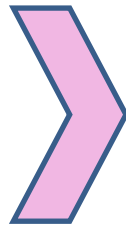


Illustration of the regulatory and self-regulatory landscape for cosmetic product claims and advertising

### 3. Cosmetic product claims: definition & scope

#### Definition:

- Generally accessible voluntary information – primarily for marketing purposes – on the **characteristics and functions of products**
- Can be, or consist of: **‘text, names, trademarks,**

#### **pictures and figurative or other signs’**

- May appear **on products** (e.g. on labels, packaging and inserts) or in advertising (**at the point of sale or across different media** )
- Can be (a combination of) **different types**, related to:

- Product performance (e.g. moisturising, wrinkle reduction, sun protection, etc.)
- Ingredients (e.g. content, properties, mode of action, patent, etc.)
- Sensory attributes (e.g. easily-absorbed, non-sticky, dry, etc.)
- Consumer perception ( e.g. product feel, product appeal, etc.)

- Comparison of same (e.g. ‘before’/ ‘after’ use) or of similar products
- Environmental characteristics (in relation to the formulation or its packaging)
- Lifestyle choices, personal values and beliefs (e.g. vegan, halal, natural, organic, etc.)
- Hyperbole / puffery (clear exaggerations not intended to be taken literally by the average consumer)

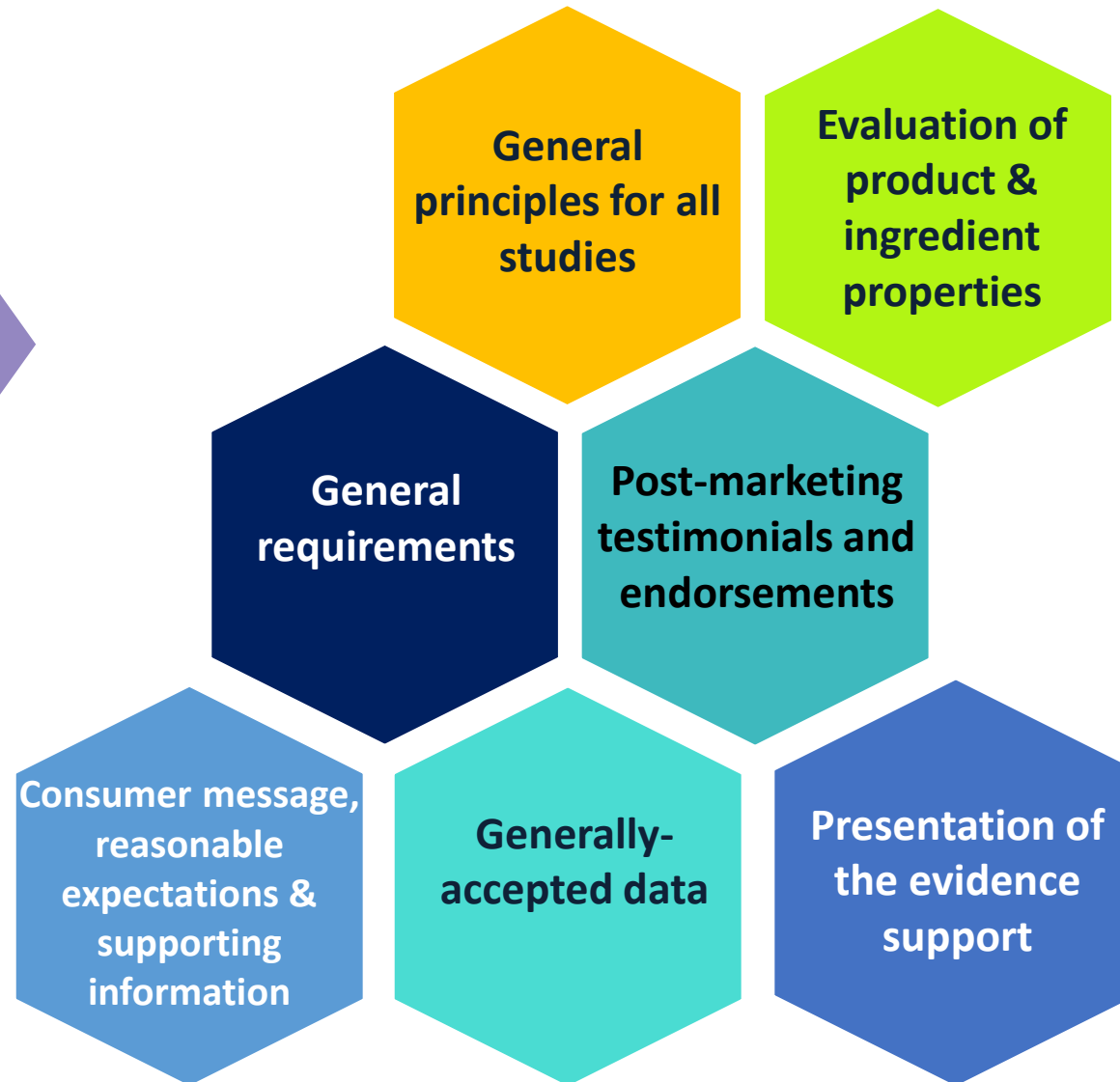




## 4. Evidence support



**THE BUILDING-BLOCKS:**





## 4.1 Evidence support: *general requirements*



- The Responsible Person must be able to **prove the validity** of the claim **using a 'body of evidence'**
- The evidence must be **reliable, relevant and robust**
- Studies should be **reliable and reproducible, use scientifically-based methods, taking account of the state-of-the art**
- Methods are constantly evolving and new ones are developed; therefore, there is **no list of approved tests** that have to be used for claim substantiation
- A **body of evidence** can consist of a single category of evidence or a combination of several categories
- The **principle of proportionality** should be applied to the extent of the evidence needed to substantiate a particular claim; special attention should be given to cases where a lack of efficacy would lead to a safety concern

### Sources of evidence:

- Published reports
- Publicly available information, including supplier documentation
- Product formulation details
- Market research studies
- Experimental studies of the final product
- Experimental studies of a closely related product
- Experimental studies on the key ingredients
- Opinions from credible experts

## 4.2 Evidence support: *consumer message, reasonable consumer expectations and supporting information*



- The supporting information must be **available when the product is placed on the market**
- Acceptability of the claim must be based on the **weight of evidence** of all studies, data and information available, depending on the nature of the claim and the prevailing general knowledge of end-users
- The Responsible Person should provide **clarity over the message** of the claim:
  - the end-user's level of understanding of the claim; in some cases it may be useful to conduct a preliminary market research study to explore ways to express a claim
  - the context of the message, as the context may alter the message itself
  - linguistic and cultural differences across different markets and the way the message may be perceived
  - the age bracket of the target population

## 4.3 Evidence support: *generally-accepted data*

- Generating **new data to support a claim is not always necessary**, especially if there are generally-accepted data available that can be referred to
- Often, generally-accepted data are **not sufficient on their own except for the simplest of claims**, but may be part of a body of evidence, e.g. in combination with a reduced quantity of experimental data
- Generally-accepted data used **must be relevant to the claim and to the product**, for example:
  - the substance should be present in the product at a level that can be related to the generally-accepted data
  - the method of application and the amount of exposure are the same or similar
  - the specification of the substance(s) is relevant to the cosmetic benefit claimed
- Where some aspects differ from the generally-accepted data, **additional rationale or data might be needed** to bridge the differences and show how the generally-accepted data can still be used as part of the body of evidence

### Examples of sources of generally-accepted data:

- Publications in peer-reviewed journals
- Reports by authoritative organisations
- Well-researched and referenced textbooks
- Reviews and conclusions of experts (with evidence of their expertise and relevant referencing)



## 4.4 Evidence support: *general principles for all studies*

### Claims can be:

- subjective (e.g. sensory, performance or aesthetic)
- objective (e.g. measurable, not quantifiable by a consumer)



### Studies should be:

- relevant, using methods that are reliable and reproducible
- well-designed and scientifically valid according to best practices
- based on a protocol agreed by all involved, followed through a study monitoring system

### When involving human volunteers:

- respect ethical rules
- conduct tests on a relevant test population, with strict inclusion & exclusion criteria
- determine size and detailed makeup of the study group according to relevant statistical parameters
- assess tested products for their safety

### Data processing & interpretation of results:

- Should be fair, not overstep the limits of tests' significance, not overstate the effect(s) measured
- Data recording, handling and representation should be transparent or clearly explained if complex
- Subject to appropriate statistical analysis

## 4.5 Evidence support: *evaluation of product & ingredient properties*

### Instrumental measurement of performance:

- Controlled objective clinical study with measurement by a validated and calibrated instrument
- Subjects provided with test products without branding or intended claims

### In-vitro tests:

- Simple biochemical assays without biological material, or
- Tests using living components of an organism (e.g. cells, hair follicles, skin explants, reconstructed skin), isolated from their usual biological surroundings
- Used for providing scientific proof for a specific biological efficacy, mechanism or mode of action of ingredients or formulas

- For the types of tests above, data can be classed as 'objective' with strong evidence of measurement validation or reproducibility if standardised and controlled conditions are applied



### Ex-vivo methods for performance assessment:

- Controlled objective clinical study on volunteers
- Samples are extracted by minimal invasive methods (e.g. cells, skin biopsies, etc.)
- The analysis of samples allows conclusions of actual effects of products/ingredients applied *in vivo*

## 4.5 Evidence support: *evaluation of product & ingredient properties*

### Controlled clinical testing:

- Performance perception by experts: assessment by a trained and calibrated expert in the parameters being affected to a validated scale; medical professional may be required e.g. for the claim 'ophthalmologically tested'
- Performance self-perception tests: assessment by the test subjects following pre-defined evaluation instructions on an intensity scale or by free evaluation without instructions as agreement to pre-defined statements



### In-use tests with self-evaluation by consumers:

- Products are tested without branding or intended claims, to avoid influencing the consumer's judgement and unconscious biasing of perception
- Data generated are 'subjective', giving a good understanding of the product's perceived performance and can be used to support claims of sensory or efficacy performance, likeability, etc.

### Sensory tests with self-evaluation by trained expert panels:

- Products are tested by a panel of experts based on agreed descriptors
- Data generated can be used as 'subjective' or, with strong evidence of reproducibility and agreement between the expert assessors, as 'objective'





## 4.6 Evidence support: *post-marketing testimonials and endorsements*

Testimonials, endorsements, consumer reviews and specialist recommendations may be used by the Responsible Person

They must avoid any misrepresentation or misinformation with regard to the nature of the product being advertised, its properties and the achievable results



They must be genuine, responsible and verifiable. The benefits communicated should also be adequately substantiated by other means



## 4.7 Evidence support: *presentation*

### Main principles:

- The data presented should be relevant to and support the specific claim
- Presentation of the data is not necessarily limited to material documentation; in some cases, the availability of an expert resource who can answer specific questions in more detail or even physical demonstrations of effect or methodology

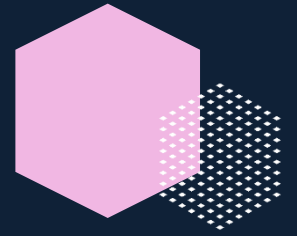
- Data must be **presented clearly and usefully** to avoid confusion or unfairly suggest lack of data or of appropriate quality



The **Responsible Person should determine how to present the data** that makes up the body of evidence.

In addition to the data and study reports in the Product Information File, it is advisable to include a synthesis of the claim's substantiation, presenting the evidence in a clear and logical way

## 5. Further information



- Aims to provide an **educational resource**, facilitate stakeholders' awareness and to support industry's compliance
- Provides an introductory overview of the **comprehensive European regulatory and self-regulatory landscape**
- Assembles the most important components of this framework in a user-friendly **index with links** to the main pieces of legislation, self-regulation, best practices and guidance



**THANK YOU FOR YOUR ATTENTION**

