

Version July 2013

**Guidelines to Commission Regulation (EU) No 655/2013**  
**laying down common criteria for the justification of claims used**  
**in relation to cosmetic products**

The purpose of this document is to provide guidance for the application of Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products.

Based on Article 20 of Regulation (EC) No 1223/2009 on cosmetic products ('CPR'), Commission Regulation (EU) No 655/2013 established EU harmonised common criteria in order to assess whether or not the use of a claim is justified.

Article 20 of the CPR applies to products that fall within the definition of a cosmetic product under Article 2 of the CPR<sup>1</sup>. The common criteria only come into play when it has been assessed that the product in question is indeed a cosmetic product. It is for the national competent authorities and national courts to decide on a case-by-case basis which regulatory framework applies.

In order to ensure harmonisation across the single market as regards qualification of products, various guidance documents have been produced by the European Commission on the delimitation between cosmetic products and other product categories (e.g. between cosmetics and medicines<sup>2</sup>, between cosmetics and biocidal products<sup>3</sup>, and between cosmetics and other products<sup>4</sup>) in order to determine whether the product falls within the definition given in Article 2. In particular, the presentation of the product<sup>5</sup> (including all communication mediums) and the manufacturer's intended purpose must ensure that the cosmetic product falls within the definition laid down in Article 2 of the CPR.

The Commission adopted recommendations on the efficacy of sunscreen products and related claims<sup>6</sup> which were inspired by the same principles as those illustrated in Commission Regulation (EU) No 655/2013.

In accordance with Article 5 of the CPR, the responsible person must ensure compliance with Article 20 of the CPR and with the common criteria set out in Commission Regulation (EU) No 655/2013.

According to Article 6(1) of the CPR, distributors also have a duty to act with due care, in the context of their activities. Distributors should translate any claim provided by the responsible person in a way that keeps the essence of the claim, otherwise they become the responsible person under Article 4(6) of the CPR. For this purpose, close cooperation between the responsible person and distributor should be encouraged.

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<sup>1</sup> According to Article 2 of the CPR a cosmetic product is '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 or 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'.

<sup>2</sup> Guidance document on the demarcation between the Cosmetic Products Directive 76/768/EEC and the Medicinal Products Directive 2001/83/EC as agreed between the Commission services and the competent authorities of the Member States.

<sup>3</sup> Guidance document of the Commission services and the competent authorities of the Member States on the borderline between Directive 98/8/EC concerning the placing on the market of biocidal products and Directive 76/768/EEC concerning cosmetic products, Version 2002/2003, revision 1 of 24 May 2004.

<sup>4</sup> Manual on the scope of application of the Cosmetic Products Directive 76/768/EEC (Art. 1(1) of the Directive) Version 5.0, June 2009.

<sup>5</sup> See also Directive 87/357/EEC on products which, appearing to be other than they are, endanger the health or safety of consumers.

<sup>6</sup> Commission Recommendation 2006/647/EC of 22 September 2006.

Whilst ensuring that the same principles are respected throughout the EU, the common criteria are not aimed at defining and specifying the wording that can be used for cosmetic product claims. Nevertheless, the responsible person has a duty to ensure that the wording of the message communicated is in compliance with the common criteria and is consistent with the documentation in his possession for supporting the claim. If a company adapts a claim to the extent that the primary function of the notified product<sup>7</sup> is changed, it should be considered as a different product.

In accordance with Article 22 of the CPR, Member States' competent authorities shall monitor compliance with Commission Regulation (EU) No 655/2013 via in-market controls of the cosmetic products made available on the market, including the appropriateness and relevance of the supporting evidence for justifying the use of claims. A common approach at Union level will facilitate administrative cooperation between the competent authorities of the Member States and prevent distortions in the internal market.

In specific cases, where the common criteria may not provide an adequate and sufficiently detailed framework for the protection of consumers and professionals from misleading claims, additional common criteria for specific types of claims should be elaborated.

Annex I to this guidelines provides a detailed description of the common criteria established by Commission Regulation (EU) No 655/2013, including illustrative and non-exhaustive examples of claims.

Annex II to this guidelines provides for best practices specifically related to the type of evidential support used for the justification of cosmetic claims.

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<sup>7</sup> Notified according to Art. 13(1) of Regulation 1223/2009.

## ANNEX I

### Common criteria for claims used in relation to cosmetic products

According to Commission Regulation (EU) No 655/2013 claims on cosmetic products shall conform to the following common criteria:

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

These common criteria are of equal importance and are further elaborated in the table below.

Criterion	Description	Examples of claims (only illustrative and not exhaustive) and remarks
Legal compliance	<p>Claims that indicate that the product has been authorised or approved by a competent authority within the Union shall not be allowed since a cosmetic product is allowed on the Union market without any governmental approval. Equally, a CE-mark shall not be applied on cosmetic products as this would make the consumer think that they are under a regulatory regime different from the Cosmetic Product Regulation.</p> <p>The acceptability of a claim shall be based on the perception of the average end user of a cosmetic product, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors in the market in question.</p> <p>Claims which convey the idea that a product has a specific benefit when this benefit is mere compliance with minimum legal requirements shall not be allowed.</p>	<p>The claim <i>'this product complies with provisions of the EU cosmetics legislation'</i> is not allowed since all products placed on the EU market must comply.</p> <p>The claim <i>'skin care product does not contain hydroquinone'</i> is not allowed, as hydroquinone is banned by EU cosmetics legislation for this use.</p>
Truthfulness	<p>Neither the general presentation of the cosmetic product nor individual claims made for the product shall be based on false or irrelevant information.</p>	<p>The claim <i>'silicone-free'</i> shall not be made if the product contains silicone.</p>

	<p>If a product claims that it contains a specific ingredient, the ingredient shall be deliberately present.</p> <p>Ingredient claims referring to the properties of a specific ingredient shall not imply that the finished product has the same properties when it does not.</p> <p>Marketing communications shall not imply that expressions of opinions are verified claims unless the opinion reflects verifiable evidence.</p>	<p>The claim ‘48-hour hydration’ is not allowed if the set of evidence only supports a shorter period of hydration.</p> <p>Products explicitly or implicitly claiming that they contain honey must actually contain honey, and not only honey flavour, in order to be truthful.</p> <p>The claim ‘contains moisturising aloe vera’ or prominently picturing aloe vera shall not be made if the product itself has no moisturising effect.</p>
<p>Evidential support</p>	<p>Claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them<sup>8</sup>, including where appropriate expert assessments.</p> <p>The responsible person<sup>9</sup>:</p> <ul style="list-style-type: none"> <li>- Determines the appropriate and sufficient methodology to be used for claim substantiation. The appropriateness and relevance may be evaluated by the authorities as part of their market surveillance activities.</li> <li>- Determines the appropriate supporting evidence. Such evidence can be of different kinds and forms and must be justified where necessary in the product information file<sup>10</sup>.</li> </ul>	<p>Computers are now able to analyse and quantify skin coloration for even skin tone; this can also be done by trained observers using a grading scale.</p> <p>The presentation of results from <i>in vitro</i> or <i>in silico</i> studies should not suggest a result <i>in vivo</i>.</p>

<sup>8</sup> See Annex II

<sup>9</sup> See Articles 4 and 5 of Regulation (EC) No 1223/2009.

<sup>10</sup> See Article 11(2) of Regulation (EC) No 1223/2009, listing the information to be included in the product information file (11(2)(d): ‘where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product’).

<sup>11</sup> See Recommendation 2006/647/EC of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto, OJ L 265, 26.9.2006, p. 39.

<sup>12</sup> See Article 5 of Directive 2005/29/EC (‘(...) the common and legitimate advertising practice of making exaggerated statements or statements which are not meant to be taken literally is not considered as an unfair practice’).

	<ul style="list-style-type: none"> <li>- Must hold appropriate and adequate scientific evidence to substantiate the claim made whether explicit or implied, with appropriate support.</li> <li>- May consult an expert who will provide the appropriate support.</li> <li>- Must ensure that the evidential support is still applicable when the formulation of the product changes.</li> </ul> <p>Evidence for claim substantiation shall take into account state of the art practices (see Annex II on best practices).</p> <p>Where studies are being used as evidence, they shall be relevant to the product and to the benefit claimed, shall follow well-designed, well-conducted methodologies (valid, reliable and reproducible) and shall respect ethical considerations.</p> <p>The level of evidence or substantiation shall be consistent with the type of claim being made, in particular for claims where lack of efficacy may cause a safety problem, e.g. sun protection claims<sup>11</sup>.</p> <p>Statements of clear exaggeration<sup>12</sup> which are not to be taken literally by the average end user (hyperbole) or statements of an abstract nature shall not require substantiation.</p> <p>A claim extrapolating (explicitly or implicitly) ingredient properties to the finished product shall be supported by adequate and verifiable evidence, such as by demonstrating the presence of the ingredient at an effective concentration.</p> <p>Assessment of the acceptability of a claim shall 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 by the end users.</p>	<p>A claim <i>‘this perfume gives you wings’</i> is hyperbolic, as no one would take it literally and expect to grow wings.</p>
Honesty	<p>Presentations of a product’s performance shall not go beyond the available supporting evidence.</p>	<p>The claim <i>‘one million consumers prefer this product’</i> shall not be allowed if based only on the sale figure of one million units.</p> <p>Claims about efficacy shall not be based on electronically manipulated ‘before’/ ‘after’ images if the display is</p>

	<p>Claims shall not attribute to the product concerned specific (i.e. unique) characteristics if similar products possess the same characteristics.</p> <p>If the action of a product is linked to specific conditions such as use in association with other products, this shall be clearly stated.</p>	<p>misleading as to the performance of the product.</p> <p>Claims about improved properties of a new formulation shall reflect the actual improvement and shall not be overstated.</p> <p>Fine fragrances usually contain such a high amount of alcohol that the additional use of preservatives is not necessary. In this case, it would be dishonest to highlight in advertising the fact that a certain fine fragrance does not contain any preservatives.</p> <p>If the claimed performance of a shampoo is based on the combined use of that shampoo with a hair conditioner, this shall be specified.</p>
Fairness	<p>Claims for cosmetic products shall be objective and shall not denigrate the competitors, nor shall they denigrate ingredients legally used.</p> <p>Claims for cosmetic products shall not create confusion with the product of a competitor<sup>13</sup>.</p>	<p>A claim '<i>contrary to product X, this product does not contain ingredient Y which is known to be irritating</i>' shall not be made.</p> <p>'<i>Well tolerated as it does not contain mineral oils</i>' is an unfair statement towards other products which are equally well tolerated.</p> <p>'<i>Low in allergens because without preservatives</i>' is unfair because it assumes that all preservatives are allergenic.</p> <p>Comparing the effectiveness against wetness of an anti-</p>

<sup>13</sup> See Article 6 of Directive 2005/29/EC and Article 4 of Directive 2006/114/EC.

		perspirant with the effectiveness against wetness of a deodorant is not fair, as the two are different products with different functions.
Informed decision-making	<p>Claims shall be clear and understandable to the average end user.</p> <p>Claims are an integral part of products and shall contain information allowing the average end user to make an informed choice.</p> <p>Marketing communications shall take into account the capacity of the target audience (population of relevant Member States or segments of the population, e.g. consumers of different age and gender, or professionals) to comprehend the communication<sup>14</sup>. Marketing communications shall be clear, precise, relevant and understandable by the target audience.</p>	If the product is targeting professionals, it might be appropriate to use technical language.

## ANNEX II

### **Best practice for claim substantiation evidence**

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<sup>14</sup> See Article 5 of Directive 2005/29/EC: commercial practices which are likely to distort the behaviour of a clearly identifiable group of consumers in a way which a trader could reasonably be expected to foresee shall be assessed from the perspective of the average member of that group.

Different types of evidential support can be used to substantiate claims. It is usual to substantiate claims by using either experimental studies or consumer perception tests and/or published information or, indeed, a combination of these.

The aim of this annex is to define best practices specifically related to the type of support used.

### **Best practices applying to experimental studies**

Experimental studies include (but are not limited to) studies *in silico*, *in vitro*, *ex-vivo*, with instrumental or biochemical methods, studies conducted on volunteers, investigator evaluations, sensory evaluations, etc. Different types of experimental studies can be used to provide data on the performance of cosmetic products. It is useful to take into consideration existing relevant guidelines, e.g. guidelines relating to instrumental clinical techniques, other European or international guidelines or standards (e.g. CEN, ISO, etc.).

Such studies must comprise methods which are reliable and reproducible. The studies shall follow a well-designed and scientifically valid methodology according to best practices. The criteria used for evaluation of product performance shall be defined with accuracy and chosen in accordance with the aim of the test.

The experimental aspect of studies calls for reliance on knowledge and awareness of statistical principles in the design and analysis of the study, e.g. in terms of number of subjects, test samples, etc. This is necessary in order to ensure that the studies achieve scientifically and statistically valid conclusions.

A study protocol must be drawn up and validated in order to enable the study to be conducted and monitored appropriately, thereby ensuring its quality. Whatever the type of study, it is important that the person conducting the study:

- has the appropriate qualifications;
- has training and experience in the field of the proposed study; and
- has high ethical qualities standards and professional integrity.

Test facilities shall maintain a quality assurance system, including standardised operating procedures.

A monitoring system must be set up for each study in order to ensure that the protocol and the operating procedures are correctly followed.

Data processing and the interpretation of results must be fair and shall not overstep the limits of the test's significance. Data recording, transformations and representation in tabular or graphical form shall be transparent or clearly explained, if complex. It shall not be designed to overstate the effect(s) measured. Appropriate statistical analysis of the data shall be performed.

*Ex vivo/in vitro* tests must be conducted under standardised conditions and their protocols must refer to published and/or 'in house' validated methods. Clear descriptions of the methodology will be documented, as well as the statistical analysis of the data. These tests shall be conducted in a controlled environment. To be used as evidence, such tests shall be

predictive of an action or representative of an *in vivo* effect, but studies on humans must validate these predictive effects.

Studies conducted on volunteers must follow ethical principles<sup>15</sup> and products tested shall have been assessed as safe. Human studies shall be conducted on the target population where necessary, and be defined by strict inclusion/exclusion criteria.

Products may bear claims that relate to the nature of experimental studies. Consumer expectations regarding these claims may vary depending, in particular, upon the presentation of the claim and its specific context. However, in all circumstances, consumers will expect that such claims are made only when the effects tested are favourable.

The claim “tolerance tested” means that the product underwent tests under the supervision of a scientifically qualified professional intended to study its tolerance on a target group and that the results of those tests show that the product was well tolerated by this group.

The claim “tested under medical supervision” indicates that the product underwent tests conducted under the supervision of a medically qualified professional, such as a medical doctor or a dentist. Depending on the presentation of the claim, it may, for example, refer to a specific efficacy of the product or to skin tolerance.

The claim "dermatologically tested" implies that the product was tested on humans under the supervision of a dermatologist. Depending on the presentation of the claim, it may, refer to a specific efficacy or tolerance of the product. Consumer self-perceptions studies are not appropriate to support such claims.<sup>16</sup> The same logic would apply to a claim referring to any other medical discipline.

The claim “clinically tested” refers to expertise, process or conditions under which the tests were carried out. “Clinically tested” means that the product was tested on humans under the supervision of a medically qualified professional or another scientifically qualified professional according to a clinical protocol or in a clinical setting.

A report shall be prepared which includes clear identification of the product, enabling establishment of a link to the product available on the market. This report shall also include the study’s objective, test schedule and test protocol, presentation of results and their interpretation, statistics, and signature of the person in charge of the study.

### **Best practice applying to consumer perception tests**

Such tests evaluate consumers’ perception of product efficacy and cosmetic properties based on parameters that they can observe or feel.

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<sup>15, 24</sup> For instance, the principles as stated in the Declaration of Helsinki, adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, and its subsequent amendments, or national requirements.

<sup>16</sup> The use of the claim “dermatologically tested” for cosmetic products was assessed by the European Court of Justice in Case C-99/01. In its decision, the Court clarified that the average consumer’s expectation of such a claim is that the product underwent tests intended to study its effects on the skin and that the results of those tests were positive and showed that the product was well tolerated.

The experimental aspect of studies calls for reliance on knowledge and awareness of statistical principles in the design and analysis of the study, e.g. in terms of number of subjects, test samples, etc. This is necessary in order to ensure that the studies achieve scientifically valid conclusions.

A study protocol must be drawn up and validated in order to enable the study to be conducted and monitored appropriately, thereby ensuring its quality.

Studies conducted on consumers must follow ethical principles<sup>24</sup> and products tested shall have been assessed as safe. Human studies shall be conducted on a statistically representative sample of the target population, defined by strict inclusion/exclusion criteria including a clear definition of socio-demographic criteria.

A critical point for the validity of consumer tests is the wording of the questionnaire.

The questions and proposed answers shall be clear enough to be unequivocally understood by participants. The answers scale shall be well balanced (e.g. same number of positive and negative answers (a nominal, ordinal or visual analogical notation scale may be used)) and not capable of influencing the answer.

Special attention shall be paid to the wording of questions for which responses will be used to substantiate the claim: the claim must be directly substantiated by the results related to the relevant question without any questionable interpretation.

Data processing and the interpretation of results must be fair and shall not overstep the limits of the test's significance. Data recording, transformations and representation in tabular or graphical form shall be transparent or clearly explained if complex. It shall not be designed to overstate the effect(s) measured. Appropriate statistical analysis of the data shall be performed.

A report shall be prepared which includes clear identification of the product, enabling establishment of a link to the product available on the market. This report shall also include the study's objective, test schedule and test protocol, presentation of results and their interpretation, statistics, and signature of the person in charge of the study.

### **Best practice applying to the use of published information**

Published information may include scientific publications, scientific state-of-the-art and market data.

Reference to scientific publications on ingredients or combinations of ingredients to substantiate a claim is acceptable provided that they are relevant to the cosmetic product and the claim made. Particular weight can be given to articles that have been peer-reviewed before being published in the scientific literature where they are open to scrutiny by the scientific community at large.

Market data (e.g. a company's market share within a specific product category in a specific country) may be a legitimate source of information to substantiate claims. Such data shall be relevant to the claim made and representative of the market in question.

For example, the claim to be the best selling toothpaste in Europe may be supported by sales data from a reputable source such as a third party market research company.