

COMMISSION REGULATION (EU) No 655/2013

of 10 July 2013

laying down common criteria for the justification of claims used in relation to cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products⁽¹⁾, and in particular the second subparagraph of Article 20(2) thereof,

Whereas:

- (1) End users as defined in Article 2(1)(f) of Regulation (EC) No 1223/2009 are faced with a wide diversity of claims relating to the function, content and effects of a cosmetic product. As cosmetic products play such a big part in end users' lives, it is important to ensure that the information conveyed to them through such claims is useful, understandable and reliable, and that it enables them to take informed decisions and to choose the products that best suit their needs and expectations.
- (2) Product claims of cosmetic products serve mainly to inform end users about the characteristics and qualities of the products. Those claims are essential ways of differentiating between products. They also contribute to stimulating innovation and fostering competition.
- (3) Common criteria should be laid down at Union level in order to justify the use of a claim made in relation to cosmetic products. The main objective of laying down common criteria is to guarantee a high level of protection for end users, in particular from misleading claims in relation to cosmetic products. A common approach at Union level should also ensure better convergence of actions taken by the Member States' competent authorities, and prevent distortions in the internal market. Such an approach should also enhance cooperation between national authorities responsible for the enforcement of consumer protection as laid down in Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (the Regulation on consumer protection cooperation)⁽²⁾.

(4) Article 20 of Regulation (EC) No 1223/2009 applies to products that fall under the definition of a cosmetic product in Article 2 of this Regulation. The common criteria only apply 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.

(5) The common criteria should apply without prejudice to Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive')⁽³⁾, to Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising⁽⁴⁾, and to other applicable Union legislation.

(6) A flexible approach should be taken towards communicating the messages to end users so as to take into account the social, linguistic and cultural diversity of the Union and to preserve the innovation and the competitiveness of European industry. Such an approach is consistent with the principles enunciated by the Court of Justice, which has pointed out on several occasions that, in order to determine whether a claim is capable of misleading the consumer, it is necessary to consider the latter's expectations, taking account of the specific context and circumstances in which the claim is made, including social, cultural and linguistic factors⁽⁵⁾.

(7) Whilst ensuring that the same principles are respected throughout the Union, the common criteria should not aim at defining and specifying the wording that can be used for cosmetic product claims.

(8) In order to ensure that the common criteria for cosmetic claims apply from the same date as Regulation (EC) No 1223/2009, this Regulation should apply from 11 July 2013.

⁽³⁾ OJ L 149, 11.6.2005, p. 22.

⁽⁴⁾ OJ L 376, 27.12.2006, p. 21.

⁽⁵⁾ See e.g. Case C-220/98, Estée Lauder Cosmetics vs. Lancaster [2000] ECR I-00117, paragraph 29.

⁽¹⁾ OJ L 342, 22.12.2009, p. 59.

⁽²⁾ OJ L 364, 9.12.2004, p. 1.

- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation shall apply to claims in the form of texts, names, trademarks, pictures and figurative or other signs that convey explicitly or implicitly product characteristics or functions in the labelling, the making available on the market and advertising of cosmetic products. It shall apply to any claim, irrespective of the medium or type of marketing tool used, the product functions claimed, and the target audience.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 July 2013.

Article 2

The responsible person referred to in Article 4 of Regulation (EC) No 1223/2009 shall ensure that the wording of the claim in relation to cosmetic products is in compliance with the common criteria set out in the Annex and is consistent with the documentation proving the effect claimed for the cosmetic product in the product information file referred to in Article 11 of Regulation (EC) No 1223/2009.

Article 3

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 11 July 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

COMMON CRITERIA**1. Legal compliance**

- (1) Claims that indicate that the product has been authorised or approved by a competent authority within the Union shall not be allowed.
- (2) 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.
- (3) 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.

2. Truthfulness

- (1) If it is claimed on the product that it contains a specific ingredient, the ingredient shall be deliberately present.
- (2) 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.
- (3) Marketing communications shall not imply that expressions of opinions are verified claims unless the opinion reflects verifiable evidence.

3. Evidential support

- (1) 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, including where appropriate expert assessments.
- (2) Evidence for claim substantiation shall take into account state of the art practices.
- (3) 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.
- (4) 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.
- (5) Statements of clear exaggeration which are not to be taken literally by the average end user (hyperbole) or statements of an abstract nature shall not require substantiation.
- (6) 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.
- (7) 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 the end users.

4. Honesty

- (1) Presentations of a product's performance shall not go beyond the available supporting evidence.
- (2) Claims shall not attribute to the product concerned specific (i.e. unique) characteristics if similar products possess the same characteristics.
- (3) If the action of a product is linked to specific conditions, such as use in association with other products, this shall be clearly stated.

5. Fairness

- (1) Claims for cosmetic products shall be objective and shall not denigrate the competitors, nor shall they denigrate ingredients legally used.
- (2) Claims for cosmetic products shall not create confusion with the product of a competitor.

6. Informed decision-making

- (1) Claims shall be clear and understandable to the average end user.
 - (2) Claims are an integral part of products and shall contain information allowing the average end user to make an informed choice.
 - (3) Marketing communications shall take into account the capacity of the target audience (population of relevant Member States or segments of the population, e.g. end users of different age and gender) to comprehend the communication. Marketing communications shall be clear, precise, relevant and understandable by the target audience.
-