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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on product claims made based on common criteria in the field of cosmetics

1. INTRODUCTION

The European cosmetics industry is a dynamic and competitive sector. Each year, about 25 % of cosmetic products on the European market are new. Europe is the global leader in cosmetics, with a EUR 77 billion total retail market size. It exports one-third of all cosmetic products sold worldwide.

Cosmetics encompass a very wide spectrum of products in a variety of product categories, ranging from shampoos, fragrances and hair colours to sunscreens, toothpaste and deodorants. Considering the high number of cosmetic products available on the EU market (more than 1 million different products), it is very important to provide consumers with specific, understandable and reliable information, substantiated using generally accepted methods, to enable them to make informed choices and compare products to find the ones that best suit their needs.

Product claims and advertising are essential tools for informing consumers about characteristics and qualities and help them choose the products that best suit their needs and expectations. Today, virtually every cosmetic product placed on the EU market bears a type of communication which falls into the scope of product claims.

Product claims are also marketing tools used by the cosmetic companies to distinguish their products from the competitors, thus they might contribute to the functioning of the internal market and to stimulating innovation and competition among companies.

For cosmetic product claims to meet their purposes adequately, it is important to have an efficient framework in place which ensures that they are fair and do not mislead consumers, taking into account the context and the marketing tools (irrespective of whether it is printed material, a TV advertisement or using any kind of new media such as internet or smart phones) in which such claims are shown.

To achieve this, competent authorities in charge of market surveillance must be able to easily verify all claims based on harmonised common criteria at EU level. The Commission adopted common criteria by Regulation (EU) 655/2013 (the Claims Regulation)[1], for the justification of claims made in relation to cosmetic products. In addition, Regulation (EC) No 1223/2009 (the Cosmetics Regulation)[2] requires the Commission to submit by 11 July 2016 to the European Parliament and the Council a report regarding the use of claims on the basis of the common criteria adopted.

The main objective of this report is to assess the legal compliance of cosmetics-related claims with the common criteria adopted and to specify the corrective measures that the Commission and Member States intend to take in cases of non-compliance.

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1 Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products, OJEU L 190/31 of 11.7.2013.

2 Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products, OJEU L 342/59 of 22.12.2009.

2. EU LEGISLATION APPLICABLE TO CLAIMS MADE IN RELATION TO COSMETIC PRODUCTS

2.1. Article 20 of the Cosmetics Regulation

Claims made in relation to cosmetic products (cosmetic claims) are voluntary marketing messages used by economic operators in the labelling, marketing or advertising of their products. According to Article 20 of the Cosmetics Regulation, cosmetic claims are text, names, trademarks, pictures and figurative or other signs that explicitly or implicitly convey product characteristics or functions in the labelling, making available on the market and advertising of cosmetic products. They do not include mandatory information required for cosmetic products, e.g. by Article 19 of the Cosmetics Regulation on product labelling.

Article 20 requires claims not be used to imply that cosmetic products (as defined under Article 2(1)(a) of the Cosmetics Regulation) have characteristics and functions which they do not have.

However, Article 20 does not cover all claims made in relation to the marketing of cosmetic products. For instance, claims which are not related to the product's characteristics and functions and which do not fall under the Cosmetics Regulation (e.g. claims related to packaging or to pricing) are covered by other EU legislation, such as Directive 2005/29/EC on business-to-consumer unfair commercial practices (UCPD)[3] and Directive 2006/114/EC on misleading and comparative advertising (MCAD) [4].

Accordingly, for the purposes of this report, the term 'cosmetic claims' only refers to those claims falling under the scope of Article 20 of the Cosmetics Regulation.

The adoption of common criteria for cosmetic claims was the most important step of the implementation of Article 20 of the Cosmetics Regulation[5]. They were published in the Claims Regulation on 11 July 2013 and entered into force immediately[6].

2.2. The common criteria for the justification of cosmetic claims

The main objective of the common criteria is to guarantee a high level of protection for consumers, in particular from misleading cosmetic claims. The common criteria provide an EU-level framework for companies, give Member States' competent authorities a much stronger legal basis for in-market control decisions, and should therefore be the reference for

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3 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, OJEU L 149/22 of 11.6.2005.

4 Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising, OJEU L 376/21 of 27.12.2006.

5 The common criteria were developed by the sub-working group on claims set up under the Working Group on Cosmetic Products with the aim of implementing Article 20 of the Cosmetics Regulation. The sub-working group is chaired by the Commission and consists of representatives of Member States, the cosmetics industry, including small- and medium-sized enterprises (SMEs), and European Consumer Organisation BEUC.

6 In order to ensure the harmonised application of the common criteria, the Commission and the sub-working group on claims also developed legally non-binding guidelines, which are available on the Commission's website (http://ec.europa.eu/growth/sectors/cosmetics/legislation/index_en.htm). Annex I to the guidelines provides a detailed description of the common criteria set out by the Claims Regulation, including illustrative and non-exhaustive examples of claims. Annex II includes best practices specifically related to the type of evidential support used for the justification of cosmetic claims.

any further analysis. Competent authorities can verify cosmetic claims much more easily when they use the common criteria.

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

The six common criteria are legal compliance, truthfulness, evidential support, honesty, fairness and informed-decision making.

2.3. Horizontal EU legislation applicable to cosmetic claims

2.3.1. Relationship between the Cosmetics Regulation and the UCPD

The Cosmetics Regulation and Directive 2005/29/EC on business-to-consumer unfair commercial practices have a similar objective, to protect consumers from misleading claims, and the latter may apply in a complementary manner to cosmetic claims, to the extent these qualify as a commercial practice within the meaning of the UCPD.

The provisions of the Cosmetics Regulation prevail as *lex specialis* over the UCPD where the specific aspects of unfair commercial practices are regulated by the former. That principle is clearly established in the UCPD, which provides in its Article 3.4 that in the case of conflict with *'other Community rules regulating specific aspects of unfair commercial practices'* the latter shall prevail and apply to those specific aspects. That principle is further clarified in recital 10 of the UCPD which states that the *'Directive accordingly applies only in so far as there are no specific Community law provisions regulating specific aspects of unfair commercial practices, such as information requirements and rules on the way the information is presented to the consumer'*[7].

With the adoption of the common criteria and their accompanying guidelines, the Cosmetics Regulation is a more precise, detailed and sector-specific framework under which cosmetic claims within the scope of Article 20 are to be primarily assessed.

2.3.2. Relationship between the Cosmetics Regulation and the MCAD

The purpose of Directive 2006/114/EC on misleading and comparative advertising is to protect traders from misleading advertising and to set out the conditions under which comparative advertising is permitted. While the MCAD may in specific cases cover similar practices to those addressed under the UCPD, the assessment of such practices under the MCAD focuses on their impact on competitors.

Article 20 of the Cosmetics Regulation, for its part, does not distinguish between the protection of consumers and that of competitors.

Although recital 51 of the Cosmetics Regulation emphasises the need to protect consumers from misleading claims, the scope of Article 20 is not limited to the protection of consumers. 'Fairness' has been included in the common criteria as a key principle aimed at protecting competitors' interests and fair trading.

[7] See also Section 3.3.3 on the implementation/application of Directive 2005/29/EC on unfair commercial practices, SEC(2009) 1666 final, p.54.

However, while encompassing similar objectives, the scope of the MCAD is broader than that of Article 20 of the Cosmetics Regulation and is not limited to products' function and characteristics. The MCAD may address any advertising used to promote the supply of products.

2.4. Self-regulation for cosmetic claims

Self-regulation has been a long-standing practice in the field of advertising, with the three main parties in the advertising industry (advertisers, agencies and media) working together and committing to specific rules and codes of practice and conduct. These codes are entrusted to advertising Self-Regulatory Organisations (SROs), who are responsible for their establishment, review, application and enforcement.

The Commission's Better Regulation Package[8] refers to self-regulatory tools as being important and complementary to regulatory tools. It endorses, as a benchmark, the principles of good practice of self-regulation and co-regulation established by the European Commission Community of Practice for Self- and Co-Regulation[9]. Self-regulation is also enshrined in legislation, e.g. Article 2(f) of the UCPD.

Self-regulatory systems help industry provide an additional level of consumer protection by building consumer trust in brands through the promotion of responsible advertising.

In 2012, the European cosmetic products association Cosmetics Europe developed a Charter and Guiding Principles on Responsible Advertising and Marketing Communications (C&GPs)[10] regarding advertising of cosmetic products in the EU. The C&GPs are being gradually implemented in national advertising codes, to the extent relevant.

In line with the commitments undertaken in the C&GPs, a first monitoring exercise was carried out in 2015 by the European Advertising Standards Alliance (EASA) across six European countries: France, Hungary, Italy, Poland, Sweden and UK. A total of 1 861 advertisements (including 577 television and 1 284 print advertisements) of cosmetic products, broadcast/published in September 2014, March 2015 and June 2015, were analysed by SROs. The EASA report[11] indicates a level of compliance with all relevant advertising codes and laws of 91 %, as well as with the common criteria of 91 %; it thus shows the cosmetics industry's commitment to responsible advertising.

Whilst self-regulation does not replace regulation, the C&GPs apply beyond the national and European legal and regulatory framework. They complement the list of common criteria with additional provisions which address societal concerns.

3. MEMBER STATES' MARKET SURVEILLANCE ACTION ON COSMETIC CLAIMS

3.1. Introduction

Article 22 of the Cosmetics Regulation states that Member States must monitor compliance with the Regulation via in-market controls of the cosmetic products made available on the EU

[8] The European Commission's Better Regulation Package, 13.04.2016: http://ec.europa.eu/smart-regulation/index_en.htm.

[9] https://ec.europa.eu/digital-agenda/best-practice-principles-better-self-and-co-regulation.

[10] https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=87.

[11] Cosmetics Europe and the European Advertising Standards Alliance: Cosmetics Advertising Audit, 2015.

market. In July 2014, the Commission sent a letter to all Member States inviting them to carry out market surveillance controls on cosmetic claims. It requested Member States to communicate the results of their controls by 31 December 2015.

In order to obtain the right input for its report, the Commission requested that Member States' market surveillance authorities take the following principles into account:

1. Purpose

The market surveillance action should be conducted in the context of Article 20 of the Cosmetics Regulation, namely focusing on the use of claims on the basis of the common criteria. The action should apply to cosmetic products after clarifying any borderline issues with medical devices or medicinal products.

Due to the wide scope of Article 20, priority will be given in the Commission report to cosmetics claims where their non-compliance with the common criteria could have a possible negative impact on the consumer's health.

Competent authorities of each Member State must have integrated the common criteria and the accompanying guidance in their control practices and must use them as a tool to check whether claims could potentially mislead the consumer.

2. Scope

The claims verified should cover all forms (text, signs, symbols, etc.) and vehicles (on-pack labels, television advertising, print advertising, etc.) for communicating claims. They should not be limited to on-pack text claims.

3. Time-frame

The time-span during which in-market controls linked to market surveillance action should be carried out should be one calendar year (to allow coverage of seasonal products).

4. Methodology

Competent authorities should report to the Commission the total number of controls, as well as the number of non-compliant claims.

In case of on-pack claims not complying with the common criteria, it should be checked whether the common criteria were applicable at the time when the product was placed on the market i.e. whether the product was placed on the market before or after 11 July 2013.

In cases of suspected non-compliance, the responsible person should be contacted for an explanation and relevant reporting should be provided.

Contributions were received from 21 Member States, showing that national public health authorities used the common criteria and related guidelines to assess the compliance of cosmetic claims. Since the implementation of the Cosmetics Regulation, the common criteria are regularly used for market surveillance, including when the responsible person or

distributor places a product on the market. Some Member States also used additional EU guidance documents[12].

In addition to the EU guidelines on cosmetic claims, some Member States introduced additional national guidelines with more detailed instructions and interpretations to take into account specific social, cultural and linguistic context, within the framework established at EU level.

The necessity to take account of the national context is particularly relevant for assessing the average consumer's understanding of the messages communicated through certain product claims. Moreover, ethical criteria such as taste and decency are not included in the EU legal framework and are exclusively addressed under the laws of the Member States, and their assessment depends on each Member State's specific linguistic, social and cultural context[13].

Some countries focused more on certain common criteria, such as 'legal compliance', 'truthfulness', 'evidential support' and 'honesty'. Others analysed in depth only the 'legal compliance', 'fairness' and 'informed decision making' criteria. Due to difficulties in certain cases with accessing the product information files from responsible persons that were not in the same country, some criteria, such as 'truthfulness', 'evidential support' and 'honesty', were only partially verified.

The emphasis of inspection in all Member States was on health claims as it was advised by the Commission to focus on claims that might pose a health risk to the consumer in case they are non-compliant and misleading and thus have a negative impact on consumer's health.

3.2. Methodology used by the Member States authorities

Market surveillance bodies of the Member States focused primarily on assessing products available on their national markets.

Checks were carried out either as part of regular market surveillance or as specific on-site checks in preparation of the drafting of this report. Most Member States visited the distributors, responsible persons, manufacturing sites, retail locations, e-shops and wholesale units involved. Several Member States examined importers' and exporters' sites as well.

Member States examined claims found on various media (television, radio, general and specialised press, online), packaging, promotional leaflets, brochures, magazines and websites (websites of certain brands, health websites). Selected social media targeting different groups of consumers were also taken into account. Member States also sampled products sold in pharmacies and parapharmacies.

Most samples used for the analysis represented products containing the following categories of claims:

- claims characterising ingredients (e.g. 'anti-ageing');
- claims related to the product's efficacy (e.g. a skin cream with a sun protection factor);

[12] Such as the Manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Article 2(1)(a)), version 1.0 (November 2013) or the Guidance document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83: http://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products/index_en.htm.

[13] See Recital 7 of the UCPD, as well as section 1.6 of the Commission Guidance on the implementation/application of UCPD, SEC(2009) 1666 final, p. 12.

- claims highlighting the absence of substances (e.g. 'free from perfume');
- claims addressing skin compatibility of the product (e.g. 'hypoallergenic', 'for sensitive or atopic skin');
- claims addressing health or additional benefits other than the cosmetic purpose (e.g. sunscreens or intimate hygiene products).

Member States reviewed the product information files, safety evaluation documents, and the claims on the products themselves, such as text, images, symbols, brand names and denominations. Samples were also analysed scientifically to examine the presence of an ingredient that was claimed to be present or absent.

Some Member States also monitored the notifications of serious undesirable effects under Article 23 of the Cosmetics Regulation, and the Rapid Alert System (RAPEX)[14].

3.3. Results of market surveillance carried out by Member States

According to the contributions from 21 Member States, 38995 cosmetic claims were analysed in total in 2014 and 2015. There were 3730 non-compliant claims out of 38995 (10 %). The percentage of compliance and non-compliance varies significantly according to the type of product distribution. In some Member States, up to 70 % of non-compliant claims were found online, only 17 % were found on the actual product, and 13 % were found in brochures.

3.3.1. Product performance

16 out of the 21 Member States that replied stated that they found cases where 'evidential support' and 'honesty' criteria were breached in products claiming a function that could not be supported with sufficient evidence, with the available studies lacking reproducibility and scientific strength. This was also the case for claims highlighting the function of one of the substances to be the function of the final product. Due to the low concentration of the substance in the product, its effectiveness could not been achieved and evidential support for the function claimed by the manufacturer was considered insufficient. For example, such products claimed to have a sun protection effect or not to contain any allergens. These claims were considered to be dishonest.

3.3.2. Medicinal properties, claims of treatment ability and therapeutic effects

10 Member States found claims stating a cosmetic product's medicinal effect, breaching a number of criteria such as, 'informed-decision making', 'honesty', 'evidential support' and 'legal compliance'. They highlighted increased difficulties to distinguish and classify borderline products, i.e. whether a product is a cosmetic or a medicine or a medical device.

The common criteria must only be used once the product has been determined to be a cosmetic product under Article 2 of the Cosmetics Regulation[15]. Otherwise, there is a risk that, for example, products are wrongly concluded to be non-compliant cosmetics, when in

[14] The Rapid Alert System (RAPEX) makes it possible for 31 European countries and the Commission to quickly exchange information about dangerous non-food products posing a risk to consumer health and safety: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm.

[15] 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 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.

fact they are medical devices or medicine. Consequently, market surveillance checks should only be carried out for cosmetic products, after any borderline issues with medical devices or medicinal products have been resolved.

Most Member States identified claims with a medicinal effect as being the most dangerously misleading claims for consumers. Believing that a cosmetic product has therapeutic effects and medicinal properties could lead consumers to delay seeing their doctor and follow their own treatment. Such misleading claims included therapeutic effects on skin, blood circulation, deeper tissue, muscles, joints, veins or adipose tissue, anti-inflammatory function, and healing properties. Products claimed to have medicinal functions or curative or biocidal effects, although the responsible person could not give evidence to support this.

3.3.3. Free from authorised ingredients

10 Member States raised the issue of the 'fairness' criterion being breached in the claims checked because of the denigration of authorised ingredients. Such claims include for instance 'free from parabens' or 'free from aluminium'.

20 % of the monitored cosmetic products had a 'free from' claim and many of them were 'parabens free'. This claim is attractive for marketing purposes because of the media attention. However, Member States considered that it is against the 'fairness' criterion because it denigrates legally authorised ingredients.

On the other hand, many Member States stated that claims addressing the absence of ingredients such as alcohol, essential oils or soap were considered to be compliant as it is essential for the consumer to be able to choose to avoid these ingredients for specific reasons such as religion or allergies.

3.3.4. Free from banned ingredients

Some Member States notified that cases of claims highlighting the absence of prohibited ingredients and claims mentioning the respect of EU quality standards and 'good manufacturing practices' were considered non-compliant, breaching the 'legal compliance' criterion. Such claims can create confusion for consumers and increase competition with other manufacturers who also comply with the Cosmetics Regulation but do not make this clear.

3.3.5. Hypoallergenic claims

7 Member States reported cases of 'hypoallergenic' claims without supporting documents or evidence. Some national authorities notified claims made about hair dyes, according to which the dyes contained ingredients that guaranteed or offered protection from skin problems (or reduced the risk of allergy) during the colouring process. These products nonetheless contained resorcinol and para-phenylenediamine, which are well known allergens. Claims that attempt to underestimate the risks of allergic reactions associated with the use of hair dyes pose a risk to human health and may prevent consumers from making an informed choice to use the product.

3.3.6. Claims on the presence/absence of ingredients although they were not found/found in the product

5 Member States reported cases of absence of ingredients mentioned in a product claim, which breaches the 'truthfulness' criterion.

3.3.7. 'Not tested on animals' and the rabbit logo

4 Member States found cases of non-compliance with the 'evidential support' criterion when, although products were claiming to be 'not tested on animals' through the presence of the rabbit logo or text, the responsible person did not have evidence of this for all the cosmetic components. Since 2013, the Cosmetics Regulation prohibits using cosmetics or substances tested on animals as part of the final cosmetic product.

3.4. Corrective action in cases of non-compliance

According to the contributions received from Member States, a wide variety of corrective actions were carried out in reaction to non-compliance of claims with the common criteria. The most frequently reported corrective actions were:

- Written advice to the responsible person, importer or manufacturer, ordering and prohibiting sales until the product complies with the requirements. This measure was also taken for e-shops selling non-compliant cosmetic products.
- Request to the responsible person to modify the claim in the advertisement not only on the product but also in the media and on the internet.
- Order for the responsible person to retroactively carry out skin-compatibility tests for a specific target group.
- Instruction to the responsible person to conduct new studies to get enough evidence to retroactively support the claims.
- Financial sanctions imposed in some Member States.
- For erroneous translations, request to correct the labelling.
- Reminder of the law or injunction to responsible persons.
- Ensuring that the labelling is corrected through repeated market surveillance actions or the reception of relevant documentary evidence before accepting the products back on the market.

4. CONCLUSIONS

The existing European regulatory framework for claims and advertising of cosmetic products is very comprehensive and ensures a high level of consumer protection. At the same time, it enables the European cosmetics industry to be competitive within the EU and in the world.

Based on Member States' contributions to this report, 90 % of analysed cosmetic claims were found compliant with the common criteria set out in Regulation (EU) 655/2013.

It should be noted that the common criteria should only be applied to products which fall under the definition of a cosmetics product under the Cosmetics Regulation, and for which any borderlines issues with medical devices or medicinal products have been resolved. It is for Member States to decide on a case-by-case basis whether a product is a cosmetic or not.

Most non-compliant claims were found to be misleading as regards the function and performance of the cosmetic product. Furthermore, as also mentioned in the difficulties faced by the national authorities whilst controlling claims on cosmetic products, it was not clear how to regulate the 'hypoallergenic' claim and the 'free-from (an authorised ingredient)'

claim. Such a claim is considered to be denigrating as it is giving a negative impression to the consumer about an authorised and scientifically proven safe ingredient.

All Member States that contributed to this report concurred that there is a need to clarify the ‘free from’ and ‘hypoallergenic’ claims. This could be done through the existing sub-working group on claims and ad hoc technical documents on the two issues.