

Guidelines for cosmetic product claim substantiation

Revising and expanding the Colipa Guidelines on Efficacy (2001/rev. 2008)

22 May 2019

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1. INTRODUCTION

1.1 Regulatory and self-regulatory background

Cosmetic product claims are essential tools for differentiating between products, stimulating innovation and fostering competition. To fulfil this role, claims must be able to evolve with national markets, scientific progress and the diversity of consumers, as well as with changes in societal demands, trends and fashions.

Cosmetic product claims are subject to a framework of regulation and self-regulation that is comprehensive and ensures a high level of consumer protection¹ from misleading claims. This framework combines horizontal (i.e. applying to all advertising and commercial practices) and cosmetic-specific legislation with self-regulation. This is illustrated in the figure below:

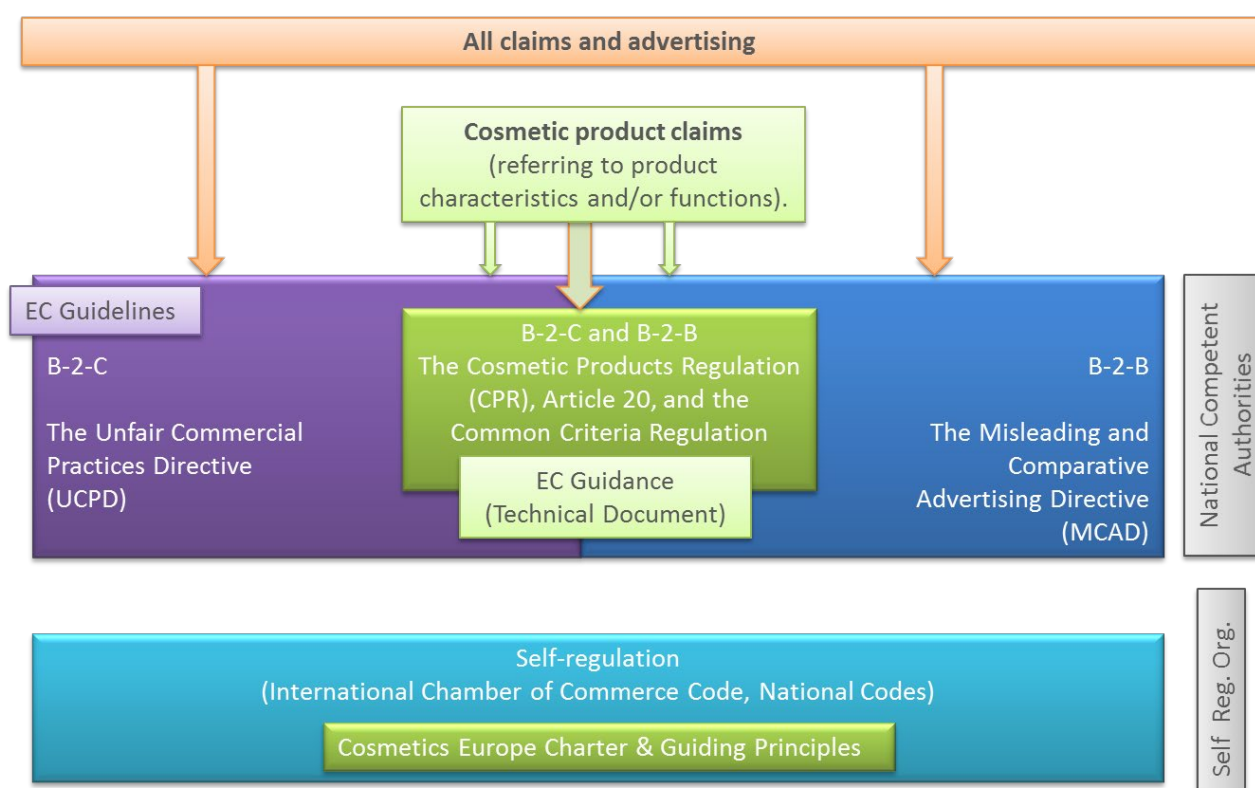


Illustration of the regulatory and self-regulatory landscape for cosmetic product claims and advertising

It is acknowledged that claims must be assessed case-by-case and that 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 European 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

¹ As confirmed by the European Commission in its Report on product claims made based on common criteria in the field of cosmetics, COM (2016) 580 final, 19.09.2016

latter's expectations, taking account of the specific context and circumstances in which the claim is made, including social, cultural and linguistic factors².

In all Member States, cosmetic product claims are controlled by appointed control authorities; in addition, in many Member States cosmetic product claims used in advertising are controlled by self-regulatory bodies. In some Member States, control of claims is largely achieved through court action³.

Not all claims made in relation to the marketing of cosmetic products are covered by Article 20 of the Cosmetic Products Regulation⁴ (CPR). For example, claims that are not related to the product's characteristics and functions (e.g. claims related to packaging or to pricing) are covered by other regulatory frameworks. These include, in particular, the Unfair Commercial Practices Directive (UCPD), and the Misleading and Comparative Advertising Directive (MCAD).

Accordingly, for the purposes of this document, the term "cosmetic product claims" only refers to those claims falling under the scope of Article 20 of the CPR.

1.1.1 Regulatory requirements

Article 20 of the CPR requires claims not to be used to imply that cosmetic products (as defined under Article 2.1.a of the CPR) have characteristics and functions which they do not have.

To ensure that cosmetic product claims are not misleading, the benefits provided by the product must correspond to the reasonable expectation(s) of consumers, as created by the claims. The assessment of claims' acceptability must 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 on the market in question.

Where justified by the nature or the effect of the cosmetic product, in accordance with Article 11.2.d of the CPR, the proof of the effect claimed must be documented in the Product Information File (PIF). In other words, the effect claimed must be substantiated and the evidence must be recorded and referenced in the PIF. Responsible Persons are responsible for the evidence provided for the claims they make; these claims must be consistent with the nature and the scope of such evidence. Guiding principles regarding the level of detail are provided in section 3.7 Presentation of the Evidence Support.

Cosmetic product claims must comply with the legally-binding Common Criteria Regulation⁵ which lays down six criteria that must be met for the justification of claims used in relation to cosmetic products:

- legal compliance;

² See e.g. Case C-220/98, Estée Lauder Cosmetics vs. Lancaster [2000], ECR I-00117, paragraph 29.

³ For example, the specific enforcement system against unfair commercial practices in Germany is explained under <https://www.wettbewerbszentrale.de/media/getlivedoc.aspx?id=33612>

⁴ 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

⁵ 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 11.07.2013

- truthfulness;
- evidential support;
- honesty;
- fairness;
- informed decision-making.

Cosmetic product claims' compliance with the relevant horizontal legislation (mainly the Unfair Commercial Practices Directive⁶ and the Misleading and Comparative Advertising Directive⁷) is also required.

Official technical documents and guidance notes are useful to help the interpretation of the legal requirements. The Cosmetics Unit of the European Commission's Directorate General 'Internal Market, Industry, Entrepreneurship and SMEs' (DG GROW) has issued a Technical Document on Cosmetic Product Claims⁸ which provides non-binding guidance for the case-by-case application of the Common Criteria. In a Communication to its membership, issued on 5 October 2017, Cosmetics Europe strongly advised its members to follow the guidance therein since it is a reference for national competent and control authorities and may be used in their market surveillance activities.

1.1.2 Self-regulation

Self-regulatory systems (e.g. the codes of the International Chamber of Commerce and national codes) help industry provide an additional level of consumer protection by building consumer trust in brands through the promotion of responsible advertising.

In 2012, Cosmetics Europe developed its Charter and Guiding Principles on Responsible Advertising and Marketing Communications (C&GP), demonstrating a voluntary and proactive commitment to the responsible advertising of cosmetic products in the EU. The C&GP has been adopted by all national association members of Cosmetics Europe and is being gradually implemented in the national advertising codes, to the extent relevant.

1.2 Aim of this document

The objective of this document is to provide guidance for cosmetics companies regarding the substantiation of their product claims. The document addresses claim substantiation from a European perspective but more specific requirements, guidelines or case law may exist at national level in the EU Member States and, where this is the case, these should take precedence over this guidance. See **Annex 3** for a non-exhaustive list of relevant national documents.

⁶ 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, 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, OJEU L149/22 of 11.6.2005

⁷ Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising, OJEU L376/21 of 27.12.2006

⁸ <https://ec.europa.eu/docsroom/documents/24847>

2. COSMETIC PRODUCT CLAIMS

2.1 The cosmetic product

Cosmetic products are defined under Article 2.1.a of the CPR: “cosmetic product means 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”.

Cosmetic products cover a wide variety of categories ranging, for example, from personal hygiene, fragrances, and colour cosmetics to sunscreens, skin-, oral- and hair-care, anti-perspirants and deodorants.

Any assessment of a cosmetic product claim can only be made once it has been clearly established that the product is a cosmetic product.

Where a product’s regulatory status is not clear, national authorities and courts assess products on a case-by-case basis to decide which regulatory framework applies. For such decisions, the following elements need to be considered:

- main and, where applicable, secondary function (which may be other than cosmetic);
- intended site of application on the human body;
- claims, labelling, logo(s)/symbol(s) and general presentation;
- qualitative composition;
- product name, brand.

If a product happens to fall simultaneously under two or more regulatory frameworks, generally the most restrictive one applies⁹. Close co-ordination among various competent authorities is important to ensure that coherent decisions are taken.

2.2 Claims: definition and scope

Cosmetic product claims are generally accessible information – primarily for marketing purposes – on the content, type, effect, properties or efficacy of the products. As defined under Article 20 of the CPR, they can be or consist of “text, names, trademarks, pictures and figurative or other signs”, which may appear on products (e.g. on the packaging, labels and inserts) or in advertising (e.g. at the sales outlets or across different media).

Claims may be (a combination) of different types:

A. Performance claims (i.e. a claim relating to product efficacy such as moisturising, wrinkle reduction, sun protection, etc.):

⁹ see e.g. the “Guidance document on the demarcation between the cosmetic products Directive and the medicinal products Directive”: <http://ec.europa.eu/DocsRoom/documents/13032/attachments/1/translations>

- The nature of the test (efficacy (objective) study, consumers perception (consumers test), *in vitro/ ex-vivo* test), should be specifically included in the claim substantiation;
- The relevance of tests should be explained in the claim substantiation;
- The results, obtained across the entire tested population (the total number of subjects), or a described subset of that population, must be clearly indicated and statistically valid.

B. Ingredient-related claims (i.e. claims relating to ingredients such as content, properties, mode of action, patent, etc.):

- If a product claims that it contains a specific ingredient, the ingredient should be deliberately present;
- Ingredient claims referring to the properties of a specific ingredient should not imply that the finished product has the same properties when it does not. A good example for the significance of the consumer expectation in individual cases is the **“contains X” claim** when ingredient X has a well-known (implicit) benefit. In such circumstances, the finished product should have the benefit that the consumer expects; the benefit may come from the functional amount of ingredient X or from the product as a whole. However, not every ‘contains x’ claim gives rise to such expectations; in cases of doubt, it should be assessed as to whether the claimed ingredient is known by consumers in the respective market for a particular activity that the product should then be able to deliver.
- A claim extrapolating (explicitly or implicitly) ingredient properties to the finished product should be supported by adequate and verifiable evidence, such as by demonstrating the presence of the ingredient at an effective concentration.
- All ingredient properties claimed have to be supported by a technical rationale that can include studies or generally accepted data; the relevance of these data to the finished product must be justified (e.g. concentration, delivery system, type of formulation, etc.).
- The claimed absence of an ingredient should be demonstrated by adequate and verifiable evidence; this evidence can consist of documented information and does not necessarily include analytical proof of the absence of the ingredient.

C. Sensory claims

- Sensory claims may be based on a trained expert’s evaluation of the relative level of a sensory attribute (e.g. sticky, greasy, easily absorbed product) on a relevant scale, without any judgement of the appeal of that attribute.

D. Consumers perception claims

- Consumer perception is based on a target user-population sample evaluating its own personal perception of a sensorial or performance attribute and may include evaluation of product appeal.

E. Comparative claims

- Comparison of similar products: claims of this type are also subject to the Misleading and Comparative Advertising Directive which defines comparative advertising as ‘any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor’; moreover, ‘fairness’ is included in the Common Criteria as a key principle aimed at protecting competitors’ interests and fair trading.
- Comparison before/after the use of the product: visual representations should proportionately and coherently reflect the performance of the product and be representative of the tested

sample. If making a claim related to a competitor product, the test should be carried out against a relevant competitor product¹⁰; the competitor batch code should be included in the PIF. If the claim is related to the market as a whole, a representative sample of relevant products should be used.

F. Environmental claims:

- Environmental claims related to the functions or characteristics of cosmetic products must be justified in the same way as any other cosmetic product claims, under Article 20 of the CPR;
- Guidance related to environmental claims has been provided by the European Commission in the context of the Unfair Commercial Practices Directive and its application to environmental claims¹¹.

G. Claims related to life-style choices, personal values & beliefs, (e.g. vegan, halal, natural or organic, etc.):

- Such claims are also covered by the six Common Criteria. Such claims can provide an opportunity for a consumer to make an informed choice, yet they should not imply any additional benefit for the consumer other than the factual ones (e.g. it should not be claimed that products are safer because they contain natural ingredients).
- While there is no specific European regulatory reference for claims of this type, international standards should be consulted where they exist.
- Certification according to private standards and compliance with other sectorial regulations can strengthen the substantiation of such claims.

H. Hyperbolic/ Puffery claims

- Statements of clear exaggeration which are not intended to be taken literally by the average consumer do not require substantiation. These are 'claims' that the product would never be expected to deliver. - The Technical Document mentions the example of the claim '*this perfume gives you wings*'. This claim is hyperbolic, as no one would take it literally and expect to grow wings.
- Equally, claims that can clearly be related to other claims that are inherent or have evidence, can be labelled as 'puffery' not requiring specific supporting evidence, e.g. a Body Butter, already proven or known to leave skin soft and smooth, can claim 'allows jeans to slide on' without that claim needing specific evidence.

3. EVIDENCE SUPPORT: THE BUILDING BLOCKS

3.1 General requirements

Claims must be supported by reliable, relevant, and robust evidence. This evidence can be based on generally recognised data, internal or external experimental studies (instrumental/biochemical methods, assessments by investigators, sensory assessments, *in vitro* and *ex vivo* studies) and assessments by consumers.

¹⁰ For example, comparing the effectiveness against wetness of an antiperspirant with the effectiveness against wetness of a deodorant is not fair, as the two are different products with different functions.

¹¹ Commission SWD(2016) 163/2, 'Guidance on the implementation/application of Directive 2005/29/EC on unfair commercial practices, 25.05.2016, chapter 5.1, pages 100 – 115.

A body of evidence can consist of a single category of evidence or a combination evidence from several categories. The manufacturer must decide which methodology is applied for the substantiation of the claimed effect and whether the chosen methodology is appropriate and sufficient. In this connection, there is no difference between subjective, objective, established or new advertising claims: all must be supported by relevant, reliable and robust evidence. In accordance with the European Commission's Technical Document on Cosmetic Claims, the studies should be reliable and reproducible and should utilise scientifically reliable methods, which naturally take into account the current state of the art. Such methods are continuously evolving and new methods are developed; therefore, there is no list of approved tests that have to be used for claim substantiation. The probative force of the evidence must be in conformity with the kind of advertising claim made.

The Responsible Person must be able to prove the validity of product claims. The principle of proportionality should be applied to the extent of the supporting evidence needed to support any particular claim. However, special attention should be paid to the substantiation of claims in cases where a lack of efficacy would lead to a safety concern or even a risk of harm.

When preparing proof of efficacy, the following aspects must be taken into account:

- Tests may be performed on raw materials by many actors whether directly involved in the manufacture of the cosmetic product or not. The results of such tests may indicate the benefits the ingredient concerned might have in a finished cosmetic product. Indeed, the raw material may be promoted by the supplier on the basis of such data and the potential benefits the ingredient might bring to a cosmetic product. However, the tests carried out on the raw material cannot automatically be used as evidence to support a benefit in the cosmetic. Unless a clear link and rational comparison can be made between the test data on the raw material and the way that material is to be used in the cosmetic product, it would be insufficient to rely upon the raw material test data alone to substantiate a claimed benefit in the cosmetic product.
- Information on ingredients or combinations of ingredients from generally recognised data or data from internal documents or data compiled by suppliers must be reviewed and used in an appropriate manner.
- The expectations and perceptions of the claimed product benefit by the consumer are, as a rule, dependent on many factors as already explained.
 - Application tests by consumers and sensory assessment methods can be sufficient support in their own right and may also be used as part of a body of evidence of the product perception intended and claimed. The same rules apply to performance self-perception tests as for consumer tests: data should be gathered from subjects representing the key target consumers and in a sufficient number of subjects to enable the appropriate statistical analysis to be performed.
 - A product benefit which is not simply or immediately perceived or cannot be quantified by the consumer (e.g. radical scavengers) can be measured through

instrumental or biochemical methods. An application test by consumers is not appropriate in this case.

- If different methods can be used, the selection of the corresponding approach must be made dependent on the appropriateness of the method with respect to the intended claim.
- The presentation of the various types of tests described in section 3.5 below is not restrictive and does not exclude tests which may correspond to other experimental approaches, which must nevertheless satisfy the general principles applicable to all scientific procedures.
- Combinations of different methods may be necessary depending on the claimed effect. If external test institutes are awarded a contract, a close co-ordination may be necessary in order to ensure that the intended claims are actually in conformity with the proof.
- Where pictures or images are to be used as claims, the Responsible Person should consider the evidence supporting the message conveyed by the picture or image, based on the expected consumer understanding. The use of post-production techniques, including digital manipulation ('photo-shopping'), should not alter the pictures or images to the extent that they mislead regarding the achievable performance or other attribute of the product.

3.2 Consumer message, reasonable consumer expectations and supporting information

Regarding the consumer message, the Responsible Person should provide clarity over what the claim is intended to convey. The Responsible Person should also be aware of:

- the consumer's level of understanding of the claim (e.g. known, assumed, unknown); this should be assessed first; in very complex or technical situations it might be useful to conduct a preliminary market research study to explore articulations of a claim. Such a study might aid clarity of message and demonstrate understanding across the target market sectors. However, such studies are not to be considered necessary in all cases;
- the context of the message, as context may alter the message itself;
- linguistic and cultural differences across different markets and the way a message may be perceived (this may be related to the demographics of the market segment, such as age, and not just national character).

When considering what would constitute reasonable consumer expectations, the Responsible Person should assess whether the claim over-promises as well as whether the expectations of the consumer are excessive or unreasonable.

The supporting information should be available when the product bearing that claim is placed on the market. Assessment of the acceptability of a 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.

Sources of evidence (a combination of which will often be necessary):

- 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

3.3 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. However, the relevance of those data to the product and the claim being made for the product must be shown if those data are to be used as evidential support. 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 in combination with a reduced quantity of experimental data to support a claim adequately.

Three key considerations are needed with this kind of support. One is the source, and therefore the provenance, of the support; secondly, the relevance of that support to the product and claim; and third, the rigour of the data.

3.3.1 Sources of Generally Accepted Data

Generally accepted data may take several forms, including but not limited to:

- publications in peer reviewed journals
- reports produced by authoritative organisations, such as a competent authority or relevant professional organizations
- well-researched and referenced textbooks
- reviews and conclusions of experts (with evidence of their expertise, and relevant referencing).

One source of the readily available data can be ingredient suppliers. Such data may be of use and sometimes may reflect state-of-the-art research that could be used, if the relevance to the specific cosmetic product making the claim can be shown. Generally, though, these documents should be treated with caution since marketing communications from ingredients suppliers would not be considered independent, authoritative evidential support when taken in isolation. Testing organised by some ingredient suppliers can be independent and therefore can reflect a high degree of scientific rigour. That said, references in such documents may provide links to more useful published data of the type noted in the previous section.

Other sources, believed anecdotal consumer understanding of a claim and information found on websites are unlikely to be sufficient as support on their own, but if properly referenced may point to published data and those primary sources may provide the support needed. Commercial websites or those where individuals can freely add or change data should be treated with caution.

3.3.2 Relevance of Generally Accepted Data

Just because generally accepted data are available and come from a reputable source does not mean that they will be relevant for any specific claim or product. The presence of an ingredient that has been shown, for example in literature, to have a cosmetic benefit does not mean that a product containing that ingredient also has that cosmetic benefit or has the benefit to the same level of effectiveness as in the published source. Instead, the generally accepted data need to be considered in the context of the product and claim concerned, including but not limited to whether:

- the substance is present at a level that can be related to the generally accepted data as indicated in the source;
- the method of application, including any carrier formulation, instructions for application and amount of exposure is the same or similar;
- the specification of the substance(s) is relevant to the cosmetic benefit being claimed and if so how does the supply in the product being supported differ or not from the source of generally accepted data?

Generally accepted data may still be useful as support even when some aspects of the above differ. In such cases, additional rationale or data might be needed to bridge the differences and show how these generally accepted data could still be applied as part of a body of evidence.

Example of the use of generally accepted data: A Responsible Person has a cosmetic product, a lotion, containing substance X. There is published scientific data in a peer reviewed journal that substance X, at a level of 2% in a similar lotion form has a significant moisturising benefit. The supply of substance X used by the RP is of a similar grade and at 2%. The generally accepted data from the publication would be adequate to support the claim that the lotion ‘moisturises’. However, should the RP wish to claim beyond this, for example putting a numeric value on the moisturising benefit based on the data from the similar lotion, additional support would be needed (for example including instrumental measurements of skin moisturisation before and after product application).

3.3.3. Usefulness of Generally Accepted Data

Extrapolating from generally accepted data, including use of techniques such as meta-analysis, can be problematic owing to differences between methodologies used in published studies or because of a lack of information on the methodologies used, as well as uncertainties over the specification of the materials used and level of Good Laboratory Practice observed. Establishing these elements may be difficult when reviewing older data sources. Generally accepted data are normally used for non-quantitative, simple claims that revolve around the statement of a straightforward cosmetic effect. However, such data can form a useful part of a body of evidence in support of a claim and may reduce the quantity of new data that need to be generated.

3.4 General principles for all studies

Studies should be relevant and use methods which are reliable and reproducible. The studies should be well-designed and scientifically valid according to best practices¹². The criteria used for evaluation of product performance should be clearly defined and chosen according to the aim of the test.

¹² See the Technical Document on Cosmetic Claims, Annex II ‘Best practice for claim substantiation evidence’, as agreed by the European Commission’s Sub-Working Group on Claims, 3 July 2017.

Depending on the aim of the study, tests can be open, single- or double-blind.

Tests should be conducted under standardized procedures and their protocols should refer to published or 'in house' validated methods. Clear descriptions of the methodology will be documented along with the statistical analysis of the data.

Depending on the nature of the claim, it is important to understand whether the claim is subjective or objective. A subjective claim can be a sensory, performance or aesthetic claim based on consumer perception, as it expresses the consumer experience when using a product. An objective claim is generally a performance claim that describes an objective benefit that a consumer may not be able to quantify, for example 'hair is 5X smoother'.

Studies conducted on human volunteers should respect ethical rules and products tested should have previously undergone a safety assessment. Human efficacy studies should be conducted on a relevant test population¹³, defined by strict inclusion and exclusion criteria. The size and detailed make-up of that study group should be determined according to relevant statistical parameters.

A study protocol should be drawn up and agreed by the parties involved. This is essential to enable the study sponsor to monitor the study and the investigator to carry out the test in order to ensure its quality.

Test laboratories should have standardized operating procedures. The equipment used should be the subject of documented maintenance adapted to its use. Whatever the type of study, it is important that the person conducting the study:

- has the appropriate qualifications;
- has the training and experience in the field of the proposed study; and
- is respected for ethical quality and professional integrity.

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

Data processing and the interpretation of results should be fair and should not overstep the limits of the test's significance. Data recording, transformations and representation in tabular or graphical form should be transparent or clearly explained if complex. It should not be designed to overstate the effect(s) measured. Appropriate statistical analysis of the data should be performed; for further details see **Annex 1 Statistical Guidance**.

3.5 Evaluation of product & ingredient properties

Testing needs to provide a high level of confidence that the product delivers the benefits that are expected based on the ingredients claimed, the advertised claims and the general presentation of the product. There are many test methodologies, each with its strengths and limitations on usefulness and which may provide evidence supporting various claims.

¹³ For example, if an anti-ageing cream is subject to a consumer use test, the panel should involve people of the targeted age; if a hair care product for damaged hair is subject to an instrumental test on hair tresses, the tresses should be of damaged hair.

3.5.1 Performance measurement by instrumental methods

Products are tested in a controlled objective clinical study, with measurement, rather than assessment, by a validated and calibrated instrument for the parameters being affected. The subjects in the clinical test are provided with products with no branding or intended claims. The data generated from this type of test can be classed as 'objective' with strong evidence of measurement validation. The data can be used to support claims of product performance.

3.5.2 Performance assessment by ex-vivo methods

Products are tested in a controlled objective clinical study on volunteers and samples are extracted by minimal invasive methods (e.g. cells, suction blister samples, skin biopsies, D-Squames, skin lavage etc.). The analysis of these samples (e.g. by biochemical, molecular biological, biophysical etc. methods) allows conclusions to be drawn on the actual effect of a product or ingredient topically applied *in vivo*. The data generated from this type of tests can be classified as 'objective' with strong evidence of reproducibility if standardized and controlled conditions are applied. The data can be used to support claims of product performance.

3.5.3 Evaluation of Sensory or Performance by Perception Tests

Perception tests provide data that are either:

- subjective in nature and affected by individual differences in previous experience with use of similar products, varying expectations of product performance, and differences in behaviour and use of the product, as part of a normal day's routine.

or

- objective in nature through training to high consistency and validation with others

Illustrative (non-exhaustive) list of examples:

3.5.3.1 In-use Test with self-evaluation by consumers

Products are usually tested with no branding or intended claims supplied, to avoid influence on a consumer's judgement and an unconscious biasing of perceptions and subsequent ratings or responses. The data generated are 'subjective' giving a good understanding of a product's perceived performance when used by the consumer as part of their normal regime at home. and can typically be used to support claims of sensory performance (skin feel etc.) efficacy performance (skin appearance, etc.), likeability, and general perception vs previous experience or other products. If true preference is desired, then one or more comparative products should be placed in the study and possibly used alongside other normally used products in the consumer's regime.

3.5.3.2 Sensory tests with self-evaluations by trained expert panels

Products are tested by a panel of experts, who have agreed amongst themselves on a common language set of descriptors to assess the product's

sensory benefits. The data generated from this type of test can be classed as 'subjective' or, with strong evidence of reproducibility and agreement between the expert assessors, as 'objective'. Such data may be used to support claims related to a product's perceived sensory performance.

3.5.3.3 Controlled clinical testing

Performance Perception-by-others Tests

Products are tested in a controlled objective clinical study, with assessment by a trained and calibrated expert in the parameters being affected to a validated scale. The data generated from this type of test can be classed as 'objective' with strong evidence of reproducibility and agreement between expert assessors, if more than one is used in the test. The data can be used to support claims of product performance. An expert with additional medical qualification may be required by the specifics of the claim, e.g. ophthalmologist approved.

Performance Self-perception Tests

Products are tested in a controlled objective clinical study, with assessment by the test persons in the parameters being affected following pre-defined evaluation instructions on an intensity scale or by free evaluation without instructions as agreement to pre-defined statements. The subjects in the clinical test are provided with products with usually no branding or intended claims. The data generated from this type of test can be classified as 'subjective' and can be used to support claims of product performance.

3.5.4 In Vitro tests:

These studies include

- simple biochemical assays without biological material as well as
- tests conducted using living components of an organism (e.g. cells, hair follicles, skin explants, reconstructed skin, etc.) that have been isolated from their usual biological surroundings.

These assays are typically conducted in laboratory ware (e.g. test tubes, flasks, petri dishes, microtiter plates, etc.) in order to perform all kinds of treatments and analysis under controlled test conditions to provide the scientific proof for a specific biological efficacy, mechanism or mode of action of ingredients or formulas. The data generated from this type of test can be classified as 'objective' with strong evidence of reproducibility if standardized and controlled conditions are applied. Protocols should refer to published or 'in house' validated methods.

3.6 Post-marketing testimonials and endorsements

Testimonials, endorsements, consumer reviews and specialist recommendations may be used by the Responsible Person. They must be genuine, responsible and verifiable. The benefits communicated should be adequately substantiated by other means. They shall avoid any misrepresentation or misinformation with regard to the nature of the product being advertised, its properties and the achievable results.

3.7 Presentation of the evidence support

The presentation of data can be as important as the quality of the data available. If data are not presented clearly and usefully, then they may cause confusion or suggest, perhaps unfairly, that data do not exist or are not of the appropriate quality.

The Responsible Person should determine how to present the data that makes up the body of supporting evidence and there is not a set format, nor is there a need for one. Yet, in addition to the data and study reports that need to be made available in the Product Information File, a synthesis of the claims' substantiation is advisable. This should present the main elements of the evidence linked to the claims made in a clear and logical way. To that end, a table listing all the claims (including trade name, pictures, logo, etc if relevant) used on the communication could be prepared, each one being related to the available support (top level summary and references, date) and relevant argumentation.

However, certain principles might be considered in relation to presentation.

- The data presented should be relevant to the specific claim being supported. Data that underscore the claim but are not directly relevant can and should be referenced but while presenting lots of data sources may on the surface look convincing, this is unhelpful if it creates confusion.
- Presentation of data is not necessarily limited to physical documentation. In a case where there is likely to be a discussion on a claim, the Responsible Person might consider ensuring the availability of an expert resource who can answer specific questions in more detail, or even physical demonstrations of effect or methodology.

4. INFORMATION WHICH SHOULD APPEAR ON ALL TEST PROTOCOLS

4.1 General introduction:

Studies should be:

- Reliable: consistently good in quality or performance
- Reproducible: able to be reproduced by someone skilled in the art

This should be reflected in the test protocol of the claims studies to be performed.

Remark:

The indications below are given as examples; they might not all be relevant depending on the test under consideration and they are not exhaustive; they illustrate the need to include in the test protocols all useful information that can assure the reliability and reproducibility of the study.

4.2 Study protocol

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

The following information should appear on the study protocol:

- Study objective
- Product information:
 - Type of product (e.g. skin cream)
 - Products to be tested and reference product (if used) including unique product identifier.
 - The product(s) to be tested should be correctly identifiable and retraceable. They should indicate a batch number, which links it to a date of manufacture and a specific formulation. The products storage conditions should be in line with data on product stability. A use-by date may possibly be mentioned in the protocol for the requirements of the test.
 - The product(s) can be prepared extemporaneously (in the case of mixtures or the making up of solutions) and their use should be consistent with the test objective. The preparation should be adapted to the tests, and not bias them in any way.
 - After the test, a sample of the product tested, and the reference product should be retained for suitable amount of time under suitable conditions by the investigator and/or the sponsor.
 - Quantity of product applied if applicable
- Test procedure:
 - Timetable
 - Study location
- Methodology used and relevant parameters:
 - Relevance of the methodology used in relation to the study objective
 - Key test parameters
 - Equipment used: Description, specification and identification of equipment.
 - Experimental design including number of samples/subjects, number of tests, randomization of the test.
 - Evaluation parameters and measurements
- Some specifics for ex vivo/in vitro tests:
 - Reagents used and usage conditions.
 - Bibliographical reference of instrumental methodology used. In the case of novel methods, indication of information sources which confirm their relevance;
 - Where appropriate, environmental conditions, e.g. temperature, hygrometry
- Some specifics for evaluation on or with human volunteers:
 - The safety of using the product under the protocol conditions must be established.
 - Volunteers:
 - Inclusion and exclusion criteria: demographic criteria, criteria linked to the study.
 - Number: justification of the number of subjects based on statistical and/or methodological expertise (background data). It is possible to include more subjects to allow for subject dropouts.
 - Training (time period, validation, etc.) and number of trained panelists for sensory evaluation.
- Evaluation parameters: definition of efficacy parameters adopted

- Product application methods
- Chronology of examinations, measurements
- Data management – Data processing – Analysis of results:
 - The methods of collecting data (questionnaire, observation notebooks, laboratory books, diaries, electronic means) are indicated. Details should be given regarding the management of electronic data (single or double capture of data input; control to assure the coherence of data, etc.).
 - Calculations carried out and the statistical analysis used to meet the defined test objective should be specified. Statistical methods (statistical tests chosen, alpha risk and software used) should be indicated. The data obtained on the reference product(s) should help to validate the study and/or provide a comparison with the product studied.

5. INFORMATION WHICH SHOULD APPEAR ON ALL TEST REPORTS

Remark:

The indications below are given as examples; they might not all be relevant depending on the test under consideration and they are not exhaustive; they illustrate the need to include in the test reports all useful information that can assure the reliability and reproducibility of the study.

The results of a test should be reported in a document which can be referred to in the claims dossier.

When pertinent, the following information should appear in test reports:

5.1 General information

Identification

- The sponsor of the study.
- The organisation in charge of the assessment and the address of the laboratories where the tests actually take place.
- The person responsible for testing (if applicable, the identification and qualifications of the investigator).
- If appropriate, other investigators involved.
- The product(s) tested: type of product, formula number, unique product identifier, formulation sheets,
- Issue date of the report.

Study objective

Test schedule

- Start- and finishing date

Methodology

- Summary of protocol (if necessary, the detailed protocol will be appended to the report).
- Documentation of any deviation from the protocol.

Statistics

- Definition of method employed, outcome and justification

Results

- Presentation of results.
- Methods for analyzing and interpreting results.
- Individual data can be given in appendix.

Discussion

Conclusion

Summary of the report

Signatures of the person(s) responsible for testing.

5.2 Specific information

Evaluation on human volunteers

Panel:

- Justification of panel choice with regard to specific effects' assessment; and demographic criteria.
- Size of sample analyzed and consideration of dropouts with justification (as far as possible).

Use tests by consumers

Panel:

- Socio-demographic criteria

Presentation of results:

- Wording of questions for which responses confirm effects relevant to the claim; assessment method used (nominal, ordinal or visual analogical notation scale); and if justified,
- Consideration of extraneous factors.

Sensory evaluation tests by trained expert panels

Presentation of results:

- Choice of presentation of results (e.g. spider profile, principal component analysis, etc.);
- Analysis of the inter-variability of the panel; and
- List of criteria assessed.

Evaluation by a professional expert and Instrumental tests

Presentation of results:

- For quantitative data: appropriate estimators of location and dispersion;
- For qualitative data: absolute or relative frequency (percentages);
- Method used to assess the observed effect;

- Interpretation of results, taking into account the expected normal range for measured values, the expected magnitude of outcome, the variability of individual reactions; and, if justified, consideration of extraneous factors.
- If several experts are used, analysis of the inter-variability (see section 3.5.3.3 “strong evidence of reproducibility and agreement between expert assessors, if more than one is used in the test”)

Ex vivo / in vitro tests

Presentation of results:

- Results recording;
- Interpretation of results, with reference to the performance and limitations of the method used.

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