



CTPA Guide to Cosmetic Advertising Claims

Preface to the Second Edition

The first edition of the CTPA Guide to Advertising Claims was issued in October 2008 when the Cosmetics Directive was in force. Since then the Directive has been replaced by the Cosmetic Products Regulation (EC) No 1223/2009 that came fully in to force in July 2013. Amongst other changes, the Regulation introduced specific legislation covering claims made for cosmetic products, wherever they appear, in the form of 'Common Criteria' published as an additional Regulation. It is therefore necessary to update and re-issue guidance on cosmetic claims.

The basic elements of the first edition have been retained, namely: a discussion over product classification and the respective roles of the advertiser and regulators; a discussion on the classification of claims themselves so as to make it easier to assess the level of supporting information necessary; and a discussion on the conduct of studies themselves. However, additions to the second edition of the CTPA guide include references to:

- guidance on the 'Common Criteria' No 655/2013;
- the Charter and Guiding Principles on Responsible Advertising issued on behalf of the European cosmetics industry by Cosmetics Europe - the European personal care association (formerly Colipa);
- the Technical Document on Cosmetic Claims agreed by the European Sub-Working Group on Claims on 3 July 2017;
- the CAP/BCAP Advertising Guidance on the use of production techniques (e.g. 'airbrushing'); and
- additional guidance on study design and statistics.

Consequently, the objective of this second edition has moved on from that of the first and is now aimed at providing more detailed practical guidance for advertisers of cosmetic products rather than concentrating on a common understanding of the framework within which claims for cosmetic products are made.

Many claims are based upon the functionality of cosmetic products and therefore the discussions are largely around the scientific and technical elements of claims support information. However, because cosmetic products of all kinds contribute to positive feelings of well-being and self-esteem, claims relating to the emotional impact of cosmetics are also important. Such claims will also require evidence in their support and so this important element is now included in the guide.

Our thanks to the Advertising Standards Authority, Committee of Advertising Practice and Clearcast for their input to this guide.



Objective of the First Edition

The objective of the original guide was the creation of a common understanding in the form of written guidance by which cosmetic product claims could be evaluated in a fair and consistent manner, cognisant of developments in cosmetic science and recognising the dual needs of the consumer to be well-informed of product characteristics and to be protected from being misled.

The Cosmetic Toiletry and Perfumery Association (CTPA) Limited
Sackville House
40 Piccadilly
LONDON W1J 0DR
Tel: 020 7491 8891
E-mail: info@ctpa.org.uk
www.ctpa.org.uk
www.thefactsabout.co.uk

@TheCTPA

Table of Content

| | |
|--|-----------|
| Part 1 - Framework of Common Understanding | 5 |
| 1. Introduction and Background | 5 |
| 2. Regulatory Framework | 6 |
| 3. Terms and Definitions | 7 |
| 4. General Commentaries | 12 |
| 5. Substantiating Claims | 12 |
| Part 2- The Building Blocks of Claims Support | 13 |
| 1. Introduction, Purpose and Scope | 13 |
| 2. Supporting Information | 14 |
| 3. Nature of a Claim - Classes of Claims | 16 |
| Part 3 - Practical Guide to Good Study Design | 23 |
| 1. Introduction | 23 |
| 2. General Principles Applicable to All Studies | 24 |
| 3. Types of Experimental Studies | 24 |
| 4. Selection of Study or Studies | 24 |
| 5. Development of Study Protocol | 25 |
| 6. Specific Requirements for Different Types of Study/Evidence | 27 |
| 7. Conduct of Study | 30 |
| 8. Reporting of Study | 31 |
| 9. Presentation of Conclusions | 32 |
| 10. Other Sources of Information or Data | 32 |
| 11. Guidance on Statistical Principles | 33 |
| Annex I - Example Decision Trees for Claims | 35 |
| Annex II - Case Study Examples | 37 |
| Annex III - Links to External Guidance | 42 |

Part 1

Framework of Common Understanding

1. Introduction and Background

The cosmetics industry in the UK is represented by the Cosmetic, Toiletry and Perfumery Association (CTPA). As of 2017, the industry has annual retail sales in excess of £9,769.4m, employs over 20,000 people directly in manufacturing the products with more than ten times that number dependent on the industry for employment and has consistent year-on-year growth. The products of the cosmetics industry are used daily by virtually every single person in the UK, contributing significantly to the well-being of the individual through enhanced self-esteem and thereby contributing positively to society as a whole.

The cosmetics industry is also a major investor; there is heavy investment in product research and development and in market research to understand the wants and needs of the industry's customers.

The consumer demands innovative cosmetic products that are safe, effective and of high quality and the industry is committed to meeting those demands. Indeed, the cosmetics industry is among the most innovative of all industries, as demonstrated by the number of new products launched each year and the number of patents filed. Results of research in the discipline of cosmetic science are published in peer-reviewed scientific journals, demonstrating advancement of understanding and the acquisition of new knowledge.

In addition, the cosmetics industry is a major advertiser across all media, both broadcast and non-broadcast. The investment in advertising must inform the consumer of innovation and aid consumer choice through differentiating one product from the competition. Unless manufacturers have the opportunity to inform the customer of the product's attributes, the incentive for innovation is lost and the reason for investment in research and development goes too. But, advertising must be subject to rules designed to protect both the average consumer from being misled and the reputable manufacturer from the unreasonable activities of the unscrupulous. The CTPA and its members therefore are fully supportive of appropriate controls through a self-regulatory system in which all players - the consumer, the advertiser and the enforcing body alike - have confidence.

In the UK, as across the whole EU, that self-regulatory system has been augmented by additional legislation through Article 20 of the Cosmetic Products Regulation.

This guide consists of a number of sections:

- Objectives
- Introduction & Background
- Regulatory Framework
- Terms and Definitions
- General Commentary
- Claim Substantiation Guideline

In principle, the approach should be first to consider the product in question, then to consider the issue of claims and finally to look into the matter of claims support and substantiation. In effect, is the product a cosmetic, what is being claimed for it and are the claims substantiated?

This second edition of the CTPA Guide to Advertising Claims for Cosmetic Products has been revised in the light of changes to the regulatory framework across Europe following the replacement of the Cosmetics Directive 76/768/EEC with the Cosmetic Products Regulation (EC) No 1223/2009.

Cosmetics Europe, the European personal care association, has issued a Charter and Guiding Principles on responsible self-regulation in advertising. That document, in essence, is a commitment by the industry to comply with all of the relevant legal obligations and the relevant national codes of practice for advertising.

2. Regulatory Framework

Below is a list for reference purposes of legislation governing products that abut cosmetic products and which therefore gives rise to questions regarding borderline situations. Also listed are guidance documents with official status that refer to such borderline situations. This demonstrates the extensive regulatory framework within which cosmetic products operate and with which they must be aligned.

European Directives and Regulations

- The Cosmetic Products Regulation (EC) No 1223/2009 and Commission Regulation (EU) No 655/2013 on Common Criteria for Claims
The Cosmetic Products Regulation has introduced specific requirements regarding claims made for cosmetic products via any medium. Such claims must conform to the Common Criteria and claims must be legally compliant, truthful, supported by evidence, honest, fair and allow informed decision-making by consumers.
- The Medicinal Products Directive 2001/83/EC
- The EU Regulation on Medical Devices 2017/745
- The Biocidal Products Regulation 528/2012

European Commission Guidance Documents

Borderlines

- Guidance Document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83
- Manual of decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products
- Borderline between Directive 98/8/EC concerning the placing on the market of biocidal products and Directive 76/768/EEC concerning cosmetic products.
- Manual on borderline and classification in the community regulatory framework for medical devices.
- Guidance Document agreed between the Commission services and the competent authorities of Member States for the Biocidal Products Directive 98/8/EC and for the Cosmetic Products Directive 76/768/EEC
- Manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009

Claims

- Commission Recommendation of 7 June 2006 establishing guidelines on the use of claims referring to the absence of tests on animals pursuant to Council Directive 76/768/EEC
- Guidelines to Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products
- Technical Document on Cosmetic Claims agreed by the European Sub-Working Group on Claims (3 July 2017)

UK Regulations

- The Cosmetic Product Enforcement Regulations 2013 (2013 SI No 1478)
- The Consumer Protection from Unfair Trading Regulations 2008 (2008 SI No 1277)

UK Guidance Documents

- Supplying Cosmetic Products on the UK Market? A CTPA Guide to What You Need to Know
- The Medicines and Healthcare Products Regulatory Agency: A guide to what is a medicinal product. MHRA Guidance Note No.8 (2016)

Many of these documents are accessible via the CTPA website (www.ctpa.org.uk/legislation).

3. Terms and Definitions

A number of terms are used at various times. A common understanding of their meaning is necessary. Such understanding may easily avoid later difficulties of interpretation. The following list is not exhaustive.

Cosmetic Product

The EU Cosmetic Products Regulation ((EC) No. 1223/2009) harmonises the requirements for cosmetics in the European Community to achieve free trade whilst ensuring that the products are safe and consumers are not misled. The EU Cosmetic Products Regulation is directly applicable in all Member States and is given effect in the UK through the Cosmetic Products Enforcement Regulations 2013 SI 1478. What is and what is not a cosmetic product is defined in Article 2 of the Cosmetic Products Regulation:

Article 2 of (EC) No 1223/2009

A ‘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.

Article 2.2 states that “...a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product.”

Recital (7) to the Cosmetic Products Regulation provides an illustrative list of products which are considered to be cosmetic products for example, face masks, anti-wrinkle products.

In addition, the Medicinal Products Directive (2001/83/EC) refers to other cases where products that might fall within the definition of cosmetic products are, nevertheless, to be considered as medicinal products. These are products that produce, or are intended to produce, a restoration, correction or significant modification of physiological function by pharmacological immunological or metabolic action. The notion of intent might be important and lack of efficacy would not be an acceptable argument if intent was demonstrable.

The Cosmetic Products Regulation defines what a cosmetic is and prohibits, or places restrictions on, certain ingredients within a product. The definition envisages that a cosmetic product may have a secondary preventative (but not curative), purpose. When deciding whether or not a product on the borderline between cosmetics and medicines is a medicinal product, the Medicines and Healthcare products Regulatory Agency (MHRA) will apply the tests set out in Directive 2001/83/EC. If a product falls within the definition of a cosmetic and within the definition of a medicinal product it will be classified as a medicinal product (Delattre 1991, C369/88). The regulatory status of products in other Member States will also be taken into account.

Note that the definitions are silent on the matter of time of effect; cosmetics are not required to have an immediate effect on application; neither are cosmetics required to have a durable effect; nor are cosmetics required to have a fully reversible action. Time is not one of the elements that determine whether or not a product is a cosmetic product. However, there may be a time element involved in the claims made for a cosmetic product and it is to be expected that such a claim would be supported in the appropriate manner.

Cumulative Effect (Cumulative – formed by successive addition – source: Concise Oxford Dictionary)

Not all cosmetic products produce their optimal benefit following a single application; some require re-application to achieve optimal effect and are therefore maybe said to have cumulative effects. Furthermore, the benefits will not continue to increase beyond a desired optimum; even with continued re-application, a plateau of benefit will be reached (of course, not all cosmetics that are re-applied have cumulative benefits. For example, a lipstick may be re-applied in order to maintain the desired colour).

That cumulative effects are possible has long been accepted by many scientists working on skin, hair and oral tissues after the principle was demonstrated for skin moisturisation (see: A. Kligman, Regression method for assessing the efficacy of moisturisers, *Cosmetic and Toiletries* 93 (27), 27-35 (1978)) and the CTPA held a workshop during which that information was presented to the Advertising Standards Authority (ASA). CTPA is pleased to note that the ASA already accepts the principle of cumulative moisturisation of (and persistent effect on) dry skin, although noting that claims about the cumulative benefits of such products still require robust product-specific evidence.

Indeed, if the benefit claimed from a cosmetic product is only evident after repeated applications over a period of time, failure to advise the consumer of this might be considered misleading. Thus, if the maximum benefit is indeed a cumulative one, this should be indicated appropriately to avoid the impression that a single use of the product will achieve the desired maximum effect.

Permanent Effects (Permanent – lasting, is intended to last or function, indefinitely – source: Concise Oxford Dictionary)

Cosmetic products may have effects that are durable in that the benefits will endure long after product application has ceased (for example, hair colorants, tooth-whiteners). Such enduring effects may be termed permanent since they last indefinitely, or may be termed lasting or long-lasting depending on the product and the effect produced. In either case, where the duration of effect is part of a claim, it is expected that the duration of effect should be supported appropriately.

In the absence of explicit or implicit claims telling them otherwise, the average consumer would not expect a permanent effect from all cosmetic products but would, for example, expect a permanent colour change from a hair colorant product described as such.

Physiological Action

All cosmetic products will, to some extent, affect the physiology of the tissues to which they have been applied. In the case of products such as antiperspirants, this is how they exert their cosmetic efficacy: in the case of products such as foundations, a minor physiological effect is an inescapable consequence of their presence on the skin.

In 2001, the European Commission issued Guidance Document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83. In the document, clarification regarding physiological activity is provided by pointing out that the sentence as a whole must be read whereby a medicinal product is defined as:

“any substance... used or administered... with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological immunological or metabolic action...”.

The words ‘with a view to’ indicate there must be an intent to restore, correct or modify physiological functions through the mechanisms described, not just that such modification may occur as a consequence of the application of the product.

Specifying in the definition of a medicinal product the types of physiological action in this way confirms jurisprudence in this area, particularly as the terms are also defined in the guidance.

Pharmacological Action

This is defined in the guidance as: interaction between the molecules of a substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent.

Immunological Action

This is defined in the guidance as: action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction.

Metabolic Action

This is defined in the guidance as: action which involves an alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function. The fact that a product is metabolised by the human body does not necessarily mean that the substance contained in the product has a metabolic action upon the body.

This can be a complex matter and there is a need for all pertinent factors to be taken into account on a case-by-case basis when apparent borderline situations arise. For this reason, it is appropriate to involve the MHRA Borderlines Section for their expertise and not to attempt to provide absolute guidance here. Nevertheless, this is an area where some guidance is appropriate.

A medicinal product is defined as “any substance... used or administered... with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action”. Thus, if the restoration, correction or modification of the physiological function is not through one of these three actions (pharmacological, immunological or metabolic), the product is not a medicinal product regardless of the magnitude or significance of the effect produced. Cosmetic products may have physiological effects but that does not necessarily make them medicinal products; and the magnitude of any effect alone does not make the product a medicinal product.

Furthermore, if those physiological effects are as a consequence of the use of the cosmetic product rather than the intent of the use of the product, that alone does not make the product a medicine.

An antiperspirant is an example of a cosmetic product that has a significant physiological action: it stops perspiration in a way that is both measurable and is perceptible to the user, yet it remains a cosmetic product.

However, there is a recognition that any application of a substance to the body may have an effect on the physiology of the body and may indeed have an effect on the metabolism of the body too. For the Medicinal Products Directive to apply, **the effect must be more than insignificant**. This is explained, albeit rather confusingly, in paragraph 33 of the European Commission guidance:

33. Considering that every product that effects (sic) the actual functioning of the body has also an affect (sic) on its metabolism, it is clear that an insignificant modification of physiological functions does not suffice for the Medicinal Products Directive to apply: Rather, the modification has to be more than insignificant.

From this, it may be concluded that insignificant effects on metabolism that are inevitably part of physiological effects do not of themselves make a product a medicinal product. If a product is not a medicine and the product also complies with the definition of a cosmetic product then it is a cosmetic product (the Medicinal Products Directive takes precedence over the Cosmetic Products Directive - now Regulation, but the two are mutually exclusive and a product may be one or the other but cannot be both at the same time).

Enhanced scientific understanding has now enabled the mechanisms, whereby simple moisturisers improve the condition of dry skin, to be explained. It is a complex process involving altering the expression of various genes in the skin cells which, in turn, leads to changes in the metabolism of the keratinocytes as they mature to produce the stratum corneum. In spite of this, there is no call to reclassify all moisturisers as medicines.

Our scientific understanding of the action of cosmetic products such as moisturisers, anti-wrinkle and anti-ageing products is now such that a strict interpretation of the definition of a medicine could lead to unintended consequences regarding the classification of cosmetic products. The intent of a moisturiser is to protect the skin and keep it in good condition; in achieving this objective, there are changes to the skin's physiology. However, the primary intent of the product is not to change the physiology of the skin. In effect, the role of the cosmetic is to take essentially normal skin and make it better whereas the role of the medicine is to take the unhealthy and restore it to normal.

Classifying physiologically active cosmetic product as medicines would remove the stimulus for cosmetic scientists to continue to conduct research since cosmetics companies would be prevented from capitalising on their discoveries through advertising and enhanced sales. It is unlikely that the pharmaceutical industry would step in to make good the loss and the consequence would be reduced choice for the consumer and loss of innovative products for the future.

Common Criteria for Cosmetic Claims

The Technical Document on Cosmetic Claims was published by the European Sub-Working Group on Claims as a tool for the industry, with the scope to highlight best practice in claims.

The six Common Criteria for claims are:

1. Legal Compliance
2. Truthfulness
3. Evidential Support
4. Honesty
5. Fairness
6. Informed Decision-Making.

In 2016, the European Commission published a report regarding the use of claims on the basis of the Common Criteria. The research was carried out across 21 Member States. The main objective of this research was to check compliance of cosmetic claims with the Common Criteria to ensure that consumers are protected from misleading advertising. Approximately 90% of the analysed cosmetic claims were found compliant with the Common Criteria described in the Technical Document on Cosmetic Claims.

The Technical Document on Cosmetic Claims was updated in July 2017 to add references to 'free from' and 'hypoallergenic' claims. That document is not legally binding, although the new elements referring to 'free from' and 'hypoallergenic' claims should be applicable as of 1 July 2019.

‘Free from’ Claims

Annex III of the Technical Document on Cosmetic Claims applies the Common Criteria to ‘free from’ claims for cosmetic products specifically.

- ‘Free from’ claims should be legally compliant, which means that *“they should not be made concerning ingredients which are prohibited for use by Regulation (EC) 1223/2009 (e.g. ‘free from corticosteroids’ is not allowed as corticosteroids are banned by the EU Cosmetic Products Regulation)”*;
- ‘free from’ claims should be true, which means that they should not be made in reference to ingredients that are present or released in the formulation (e.g. ‘free from formaldehyde’ is *“not allowed if the product contains a formaldehyde-releasing ingredient”*);
- ‘free from’ claims *“should be demonstrated by adequate and verifiable evidence”*;
- ‘free from’ claims should be honest, which means that
 - o they should not be made in reference to *“ingredients which are typically not used in the particular kind of cosmetic product”* (e.g. ‘free from preservatives’ *“would be dishonest for fine fragrances that usually contain a high amount of alcohol and the use of preservative is not necessary”*);
 - o they *“should not be allowed when they imply guaranteed properties of the product based on the absence of ingredients (e.g. ‘free from allergenic/sensitizing substances’ is not allowed because a complete absence of the risk of an allergic reaction cannot be guaranteed)”*;
 - o they *“should not be allowed if the product contains ingredients with multiple functions and among these is the function that the product is claimed to be free from (e.g. ‘free from perfume’ should not be used when the product contains an ingredient which exerts a perfuming function, regardless of its other possible functions in the product)”*;
- ‘free from’ claims should be fair, which means that they *“should not be allowed when they imply a denigrating message because they are mainly based on a presumed negative perception of the safety of the ingredient (e.g. ‘free from parabens’ should not be accepted because it is denigrating ingredients that are approved for safe use by the Cosmetic Products Regulation)”*;
- ‘free from’ claims *“should be permitted when they allow an informed choice to a specific target group (e.g. ‘free from alcohol’ should be allowed in a mouthwash for family use, or ‘free from animal-derived ingredients’ should be allowed in products intended for vegans)”*.

‘Hypoallergenic’ Claims

Annex IV of the Technical Document on Cosmetic Claims focuses on ‘hypoallergenic’ claims, giving industry guidance on the meaning of the claim and how it should be substantiated. ‘Hypoallergenic’ claims should not give the impression of guaranteeing a complete absence of risk of an allergic reaction as no products can guarantee that; different individuals may react to different substances to different extents. ‘Hypoallergenic’ claims should be supported by verifying and confirming a very low allergenic potential of the product through scientifically robust and statistically reliable data. These data could be from a review of post-marketing surveillance data, and from a solid rationale for the selection of the ingredients of the formulation in order to minimise the allergenic potential of the finished product.

‘Not tested on animals’ Claims

‘Not tested on animals’ claims on cosmetic products need to be in compliance with Article 20 of the Cosmetic Products Regulation and with the Common Criteria for cosmetic claims. The Common Criteria, which are now part of European cosmetics law, prohibit claims that are no more than claiming compliance with legal requirements. Since the ban on animal testing applies equally to all cosmetic products on the EU market, it would appear that claims relating to avoidance of animal testing would not be permitted. That law covers claims in the form of text, illustrations, logos or pictorial forms and similar depictions. However, explicit statements relating to a company’s philosophy regarding animal testing ought to remain acceptable under the Common Criteria.

‘Natural’ and ‘Organic’ Claims

There is no specific guidance for ‘natural’ and ‘organic’ claims. Cosmetic natural and/or organic standards have been developed by different certification bodies. However, none of these standards or guidelines is specifically backed by law. They are all different, although the difference may be minor.

Between 2016 and 2017 the International Standards Organisation (ISO) published Guidance 16128 on definitions and assessment for 'natural' and 'organic' ingredients and products for cosmetics; ISO 16128 provides a technical approach to determine the 'natural' and 'organic' content of cosmetic products: it does not address product communication (claims and labelling), human safety, environmental safety or socio-economic considerations.

'Natural' or 'organic' cosmetic products must comply with the safety and product information requirements of the Cosmetic Products Regulation. In particular, 'natural' and 'organic' claims for cosmetic products have to comply with Article 20 of the Cosmetic Products Regulation and the Common Criteria for Cosmetic Claims.

Companies should set defined criteria for their understanding of 'natural' and 'organic' based on the above mentioned ISO Standard and adhere to these criteria. Companies should also be transparent to consumers about these criteria and should not imply that this type of product is safer than other cosmetics just because they are making 'natural' or 'organic' claims.

Average Consumer

Jurisprudence and the Consumer Protection from Unfair Trading Regulations 2008 refers to the average consumer as someone who is "*reasonably well-informed and reasonably observant and circumspect*". In other words, no one is expected to protect fools from the consequence of their folly. The relevance of this point arises when trying to ascertain what the average consumer might understand by a specific claim. The advertiser can expect the consumer to be reasonably well-informed, reasonably observant and circumspect and the advertiser can assume the consumer understands both the claim package as a whole, assuming the meaning is clear, and the context in which it is presented, including the medium through which the presentation is made.

In the context of televised advertisements, it must be remembered that many consumers are aware that advertisements are independently pre-vetted and therefore such consumers may presume claims are fundamentally true. This brings an added responsibility to the advertiser.

Relevance of Instructions for Product Use

There should be a logical relevance between any instructions for use of the product and any benefits claimed; this relevance link should also be carried through to the information provided in support of the claim, which should be consistent with the intended product usage.

Breakthrough Claims (breakthrough – a significant development or discovery – source: Collins Concise English Dictionary)

'Breakthrough' or 'new' claims are those that have either not been made previously or go beyond what is widely considered as established about a certain product, or type of product, by general scientific opinion, for which the ASA has not seen sufficient supporting evidence previously. For these reasons, such claims require a high level of robust supporting evidence.

For 'new' or 'breakthrough' claims, sound data, relevant to the claim made, should be collated to form a body of evidence. The 'totality' of this evidence is important; marketers should not ignore sound data that does not support the claim. There are generally recognised ways of collating existing data (where it is not immediately available) by conducting a systematic review of all available scientific evidence and evaluating it for its relevance (e.g. by using standardised data extraction procedures and electronic databases).

It is important to note, however, that even for claims which are not considered to be 'breakthrough' claims, marketers must still hold supporting evidence in relation to all objective claims.

For further guidance on the type and level of evidence likely to be required by the ASA, see CAP's Advertising Guidance on [Health, beauty and slimming claims substantiation](#).

4. General Commentary

Regarding claims, the cosmetics industry cannot define specific words or claims, particularly when taken in isolation, since that might prejudice the use of the same claim or words used in a different context. The cosmetics industry invests heavily in improving its understanding of the modes of action of its products and the benefits the consumer may experience. In doing so, new words and concepts arise describing the actions of existing as well as new products.

Therefore, this guide discusses and establishes some key guiding principles regarding types of claims for cosmetic products and the appropriate levels of support claims might need.

This guide applies only to cosmetic products as defined in law. There may be occasions when the status of a product as either a cosmetic or a medicinal product is not immediately clear. Resolution of such situations is properly and legally the province of the MHRA in consultation with the manufacturer or marketer of the product. Indeed, the MHRA has established a procedure involving its own Borderlines Section for just such circumstances. In addition, the ASA has a duty to consider complaints that, for example, advertisements contain unauthorised medicinal claims. Nothing written in this guide regarding the legal status of a product should be taken to imply that the ASA will not continue to exercise its duty regarding claims in this area. In doing so, the ASA will consult appropriately.

The key questions to be determined, it would seem, are usually: 'what has been claimed' and 'is that claim supportable' on the basis of all available information.

The cosmetics industry invests heavily in market research in order to understand the needs of the consumer and the effectiveness of advertising programmes. The results of such investigations are important in demonstrating the level of understanding of the average consumer and, where relevant, may be used as part of the body of evidence in support of a particular claim. The ASA Council has the duty to establish whether that market research was appropriately and fairly conducted, evaluated and presented.

5. Substantiating Claims

Further help on claims substantiation can be found in the following sections in this guidance:

- Building Blocks of Claims Support – a guide to help classify the type of claim being envisaged and therefore the likely body of evidence necessary for its substantiation.
- Practical Guide to Good Study Design – a guide to the framing of an hypothesis and the designing of an experiment to test it as that relates to advertising claims for a cosmetic product. It also covers data collection, statistical evaluation and results presentation.
- Annexes to this guidance – decision trees that demonstrate how to apply the information provided by 'Building Blocks of Claims Support' and 'Practical Guide to Good Study Design'. The annexes also include direct links to the guides from ASA, MHRA and Clearcast.
- Procedures – a guide to the procedures adopted by ASA and Clearcast to provide greater clarity to advertisers in their dealings with the regulators. ASA provides this on its website: <https://www.asa.org.uk/transparency/policies-and-procedures.html>. Clearcast provides information on its services and procedures at: www.clearcast.co.uk.
- Committee of Advertising Practice (CAP)
- Broadcast Committee of Advertising Practice (BCAP) – both CAP and BCAP offer guidance on the interpretation of the UK Code of Non-broadcast Advertising, Sales, Promotion and Direct Marketing (the CAP Code) and the UK Code of Broadcast Advertising (the BCAP Code). CAP and BCAP guidance is intended to help advertisers, agencies and media owners interpret the Codes but is not a substitute for those Codes.
- CAP/BCAP [Helpnote –Guidance on the use of pre and post-production techniques in ads for cosmetics](#) – this Advertising Guidance issued in April 2011 outlines the circumstances in which image manipulations and other production techniques ('airbrushing') might prove misleading and what advertisers may need to do to avoid the risk of being misleading.

Part 2

The Building Blocks of Claims Support

1. Introduction, Purpose and Scope

This guide deals with what a claim is, how a claim can be classified and the different types of evidence that might exist in supporting a claim. This document is designed to be used in close conjunction with the guideline on study design.

The European Cosmetic Products Regulation (EU) No. 1223/2009 does not define the term claim specifically but it does state in Article 20(1): In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.

Furthermore, Common Criteria have been established for cosmetic claims under Regulation (EU) No 655/2013 and these state: *“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”*.

Thus, in this context, a claim may be considered to exist in any one of a broad range of formats which, in essence, covers any marketing communication between the advertiser and the consumer with respect to the characteristics, functions or qualities of the cosmetic product.

In addition, Cosmetics Europe has issued a Charter and Guiding Principles for Responsible Advertising and Marketing Communications which sets out in broad terms the need for advertisers of cosmetic products to comply with both the letter and the spirit of both legislation and national self-regulation systems.

In order to fulfill these requirements, a marketer needs to consider the following series of questions:

1. What is the **nature of claim** (or consumer message) to be made?
2. How will the **supporting information** provide sufficient evidence to substantiate reasonable consumer expectation of that claim? In order to evaluate whether claims are appropriate companies should take into consideration:
 - o the benefits delivered by the product should be consistent **with reasonable consumer expectations created by the claims**; and
 - o the **general impression that the average consumer would gain in the context** of product presentation or advertising.
3. What are the requirements for the quality of tests within the supporting information?

This document offers a way to define the nature of a claim by separating claims into different classes. It then defines, in general terms, the type of supporting information that may be required for each claim class. Whilst all claims require some supporting information, the nature of this information will depend upon the strength of the claim. The third and final question, providing guidelines for how to define quality of tests from studies used to support claims, is covered in the third part of this guidance on good study design.

These guiding principles create a common understanding and reflect best practice for all current and future claims. These principles allow for the continued development of cosmetic claims with robust support by the industry and their consistent evaluation by those charged with ensuring compliance with both legislation and self-regulation. An additional benefit is that the guidance can help non-scientists and marketers understand the way each element of a claim must be substantiated.

The general context of a claim is important when adopting this approach to classification, support and testing. There are factors that may modify the sense of consumer perception of the claim or implied claim that is not overtly stated. In advertising, such factors are for example:

- multiple claims for a single product in one advertisement;
- the mix of speech, text, music and imagery.

2. Supporting Information

Claims should be supported by robust, relevant and clear evidence. Such evidence can be based on generally accepted data, published reports or experimental studies conducted *in vivo* (e.g. different types of studies conducted using human subjects), *ex vivo* (e.g. using swatches of hair) or *in vitro* (e.g. using cell cultures or glass plates on substrates). A set of evidence might consist of any one or a combination of several of these types of evidence as appropriate.

The supporting information is kept by the Responsible Person (as defined in the Cosmetic Products Regulation) as part of his obligations under the Cosmetic Products Regulation 1223/2009. The Responsible Person is required to ensure that each cosmetic product placed on the Community Market has a complete Product Information File (PIF). The PIF contains all of the mandatory information on the product, including proof of effect (where this is not self-evident). The Responsible Person is easily identifiable, as the name and address of the Responsible Person must be labelled on the cosmetics packaging. Guidance on this can be found in the CTPA publication 'Supplying Cosmetic Products on the UK Market? A CTPA Guide to what you need to know'.

Before embarking on the classification of claims, it is worth recognising that the supporting information will depend on the nature of the claim. Whilst it is impossible to preclude any difference of opinion, there are different levels of supporting evidence that might be appropriate for different classes of claims.

There are three levels of supporting evidence that might be required, based on the type or level of the claim:

1. evidence for claims widely accepted to be established;
2. evidence for claims with established rationale but requiring additional, often product-specific, evidence;
3. evidence for claims based upon a significant advance in science or technology.

This classification on type or level of claim is based upon the scientific, technical or consumer perception support available, not the claim itself. Repetition of a claim does not make it widely established. That only comes with the establishment of a comprehensive body of evidence across a wide spectrum of products. There will always be a need to provide evidence. This process is further explained in Table 1 on page 15.

Regardless of whether the claim is subjective, objective, established, based on an established rationale but requiring additional - perhaps product specific - evidence, or based on scientific or technological advances, all claims should be supported by sufficient, robust, relevant and clear evidence.

This classification process also allows industry to place one class of claim out of scope. Claims often referred to as hype, hyperbole, puffery or aspirational claims, for which there cannot possibly be any supporting evidence in terms of scientific, technical or consumer perception studies, need not be subjected to analysis for burden of proof since they are self-evidently not intended to be taken literally. However, claims for emotional benefits and enhancement of well-being or claims of a similar nature, although requiring appropriate supporting evidence, may not necessarily require the same standard of proof as claims of a more scientific or technical nature. Nevertheless, such claims are a very necessary part of the marketing of cosmetic products since they link to strong benefits which come from using cosmetics and which go beyond their pure functionality into the areas of promoting self-confidence, self-esteem, well-being and simple enjoyment.

TABLE 1 - LEVEL OF EVIDENCE FOR SUPPORTING CLAIMS

| | |
|---|--|
| <p>Claims Widely Accepted to be Established</p> | <p>Such a claim would be one whose rationale is consistent with the status of current knowledge commonly accepted within the scientific communities as applicable to cosmetic science and related disciplines.</p> |
| <p>Claims with Established Rationale but Requiring Product or Ingredient Specific Evidence</p> | <p>Such a claim would be one with an underlying rationale consistent with the status of current knowledge commonly accepted within the scientific communities. However, specific support or substantiation might be needed, e.g. because the claim is:</p> <ul style="list-style-type: none"> • highly dependent on formulation factor(s); • for a product type or format not normally associated with the established claim; • dependent on factors described in guidelines, industry recommendations or scientific reviews outlining the need for specific test(s); • an enhancement or quantification of an established claim (for example - intensity of benefit, duration of benefit, a percentage claim); • targeted to particular populations (for example hair or skin type, age, ethnic origin). |
| <p>Claims that are Based Upon a Significant Advance in Science or Technology</p> | <p>The claim will be based upon the advances in the science and technology behind it, not simply that the words used in the claim have not been used before. For example, where the claim is based upon:</p> <ul style="list-style-type: none"> • the action of an entirely new type of ingredient; • an entirely new consumer benefit; • an entirely new sensory property; • an entirely new means of qualifying or quantifying the product’s effects on the substrate; • a new insight into the biology of the body part to which the product is applied. |

3. Nature of a Claim - Classes of Claims

Any attempt to classify claims may lead to anomalies but the approach described here, based on the types of support that might be anticipated together with the potential to combine these factors, provides a means of ensuring any claim is supported by appropriate evidence.

Sensory Claims

Such claims refer to perceptions or sensorial attributes of the product during use: e.g. olfactory, tactile or visual effect(s).

Performance Claims

Such claims refer to the effect of using the product on the substrate: i.e. changing their appearance, protecting them, keeping them in good condition or correcting body odours; including both the intensity, mode of action, or duration of the effect, however measured.

Ingredient Claims

Such claims refer to the combination of ingredients or specific single ingredients that go to make up the product.

In the case of 'free from claims', more guidance has been provided in the Technical Document on Cosmetic Claims agreed by the Sub-Working Group on Claims on 3 July 2017 to provide an adequate and sufficient protection of consumers and professionals from misleading claims. Refer to page 8 of this guide.

Product Aesthetics Claims

Such claims refer to the appearance, fragrance, form (including pack) etc.

Combination claims

The above classes of claims can now be used as building blocks. By thinking in terms of combinations of each of these essential classes of claim, the individual claims that have been used to construct the final combination claim can be identified and the supporting information required for each block, and thus for the claim as a whole, becomes clearer.

Comparison claims

Comparison claims are permissible provided they are in compliance with the Misleading and Comparative Advertising Directive (2006/114/EC) and the Unfair Commercial Practices Directive (2005/29/EC). Any of the above claims can become a comparison claim where the claimed effect is compared to the same effect produced by another product, or group of products.

The classification is described below in the form of a flow-chart. The tables that follow then show how each of the basic classes differ in terms of the level of evidence required (as outlined in Table 1).

Even if they are not part of this classification, it is worth mentioning the differences between subjective and objective claims.

Subjective Claims

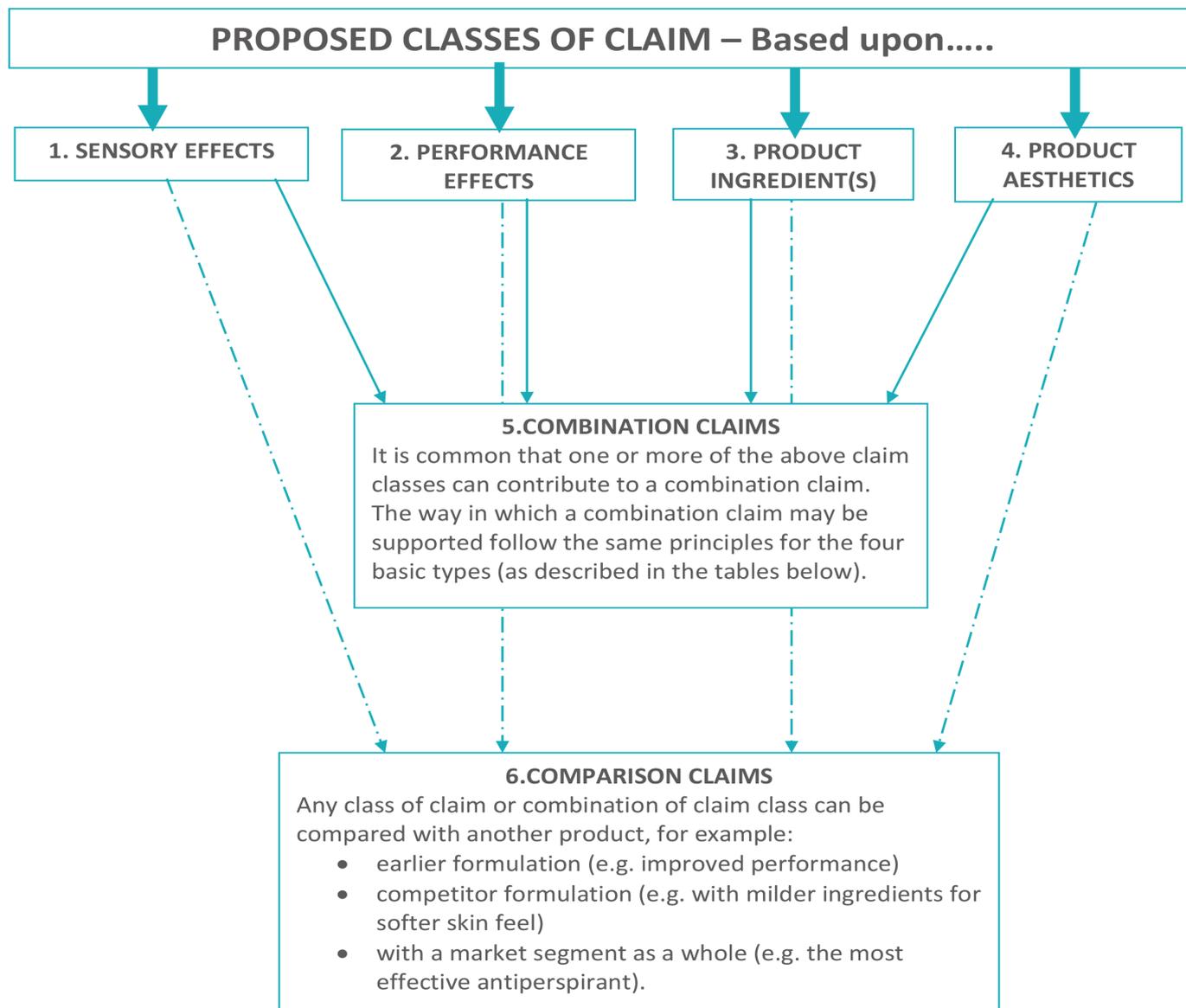
These are generally sensory, performance and aesthetic claims based on consumer perception, as they express the consumer's experience when using the product. Subjective claims should therefore be substantiated by home use tests or consumer use tests.

Objective Claims

These are generally performance claims that describe objective benefits, such as 'hair is 5X smoother'. Consumers could never measure that their hair is 5 times smoother, therefore this type of claims and benefits are best substantiated with an instrumental test or expert assessment.

Some claims involve both subjective and objective elements, such as 'skin feels firmer'. Such claims could be supported by instrumental measurements, expert assessment or self-assessment or a combination of such data sets.

Flow Chart indicating how the four basic classes of claims may be combined or used comparatively



Claims Based on Sensory Effects

| LEVEL OF EVIDENCE | | | |
|---|--|---|---|
| | Widely Accepted/Established | Established Rationale but Requiring Additional Evidence | Advances in Science and Technology |
| Possible Sources of Supporting Evidence | <p>The following might be drawn upon to show that the claim is widely accepted:</p> <ul style="list-style-type: none"> published reports ; publicly available information; product formulation details. <p>For any specific product, that support may be based upon any one, or an appropriate combination of, the following options:</p> <ul style="list-style-type: none"> published reports; publicly available information; data from studies on closely related, relevant products based on any combination of the following study types: <ul style="list-style-type: none"> market research sensory panel evaluation expert grader evaluation consumer evaluation product formulation details. | <p>The sensory claim described might be supported by any one, or an appropriate combination of, the following options:</p> <ul style="list-style-type: none"> published reports ; publicly available information; product formulation details; data on studies on the final product ; data from studies on closely related relevant products (relevance might need to be demonstrated); data on studies on the key ingredient(s). <p>These data might be based on any combination of the following study types:</p> <ul style="list-style-type: none"> market research sensory panel evaluation expert grader evaluation consumer evaluation. | <p>The sensory claim described might be supported by any one, or an appropriate combination of, the following options:</p> <ul style="list-style-type: none"> published reports; publicly available information; product formulation details; data on studies on the final product; data from studies on closely related relevant products (relevance might need to be demonstrated); data on studies on the key ingredient(s). <p>These data might be based on any combination of the following study types:</p> <ul style="list-style-type: none"> market research sensory panel evaluation expert grader evaluation consumer evaluation. |

Claims Based on Performance

| LEVEL OF EVIDENCE | | | |
|---|---|---|---|
| | Widely Accepted Established | Established Rationale but Requiring Additional Evidence | Advances in Science and Technology |
| Possible Sources of Supporting Evidence | <p>The following might be drawn upon to show that the claim is widely accepted:</p> <ul style="list-style-type: none"> • published reports ; • publicly available information; • product formulation details. <p>For any specific product, that support may be based upon any one, or an appropriate combination of, the following options:</p> <ul style="list-style-type: none"> • published reports; • publicly available information; • data from studies on closely related, relevant products based on any combination of the following study types: <ul style="list-style-type: none"> o market research o sensory panel evaluation o expert grader evaluation o consumer evaluation; • product formulation details. | <p>The performance claim described for the product or ingredient(s) should be supported by any one, or an appropriate combination of, the following options:</p> <ul style="list-style-type: none"> • published reports; • publicly available information; • data from scientific studies conducted on final product, relevant formulations or primary ingredient(s) (relevance might need to be demonstrated) based on experiments performed: <ul style="list-style-type: none"> o <i>in vivo</i> and/or o <i>in vitro</i> and/or o <i>ex vivo</i>. <p>Measures from the above experiments may be obtained from measures such as:</p> <ul style="list-style-type: none"> o instrumental evaluation o biochemical evaluation o expert grader evaluation. <p>• Data generated on the relevant product from any combination of the following product types:</p> <ul style="list-style-type: none"> o market research, o sensory panel evaluation, o expert grader evaluation o consumer evaluation. <p>• Product formulation details.</p> | <p>A description of the science including mode of action (product / ingredient) supported by an appropriate combination of data :</p> <ul style="list-style-type: none"> • published reports; • publicly available information; • data from scientific studies conducted on final product, relevant formulations or primary ingredient(s) (relevance might need to be demonstrated) based on experiments performed: <ul style="list-style-type: none"> o <i>in vivo</i> and/or o <i>in vitro</i> and/or o <i>ex vivo</i>. <p>Measures from the above experiments may be obtained from measures such as:</p> <ul style="list-style-type: none"> o instrumental evaluation o biochemical evaluation o expert grader evaluation. <p>• Data generated on final product and/or relevant formulations (relevance might need to be demonstrated) from any combination of the following study types:</p> <ul style="list-style-type: none"> o market research, o sensory panel evaluation o expert grader evaluation o consumer evaluation. <p>• Bioavailability studies.</p> <p>• Product formulation details.</p> |

Claims Based on Ingredients

| LEVEL OF EVIDENCE | |
|--|--|
| Widely Accepted Established | Established Rationale but Requiring Additional Evidence |
| <p>The following might be drawn upon to show that the claim is widely accepted:</p> <ul style="list-style-type: none"> • published reports; • publicly available information; • product formulation details. <p>For any specific product, that support may be based upon any one, or an appropriate combination of, the following options:</p> <ul style="list-style-type: none"> • published reports; • publicly available information; • data from studies on closely related, relevant products based on any combination of the following study types: <ul style="list-style-type: none"> o market research o sensory panel evaluation o expert grader evaluation o consumer evaluation; • product formulation details. | <p>The claimed properties of the ingredient(s) should be supported by any one, or an appropriate combination of, the following options:</p> <ul style="list-style-type: none"> • published reports; • publicly available information; • data on scientific studies conducted on product or relevant ingredient(s) (relevance being based upon the context of the final marketed product) based on experiments performed: <ul style="list-style-type: none"> o <i>in vivo</i> and/or o <i>in vitro</i> and/or o <i>ex vivo</i>. <p>Measures from the above experiments may be obtained from measures such as:</p> <ul style="list-style-type: none"> o instrumental evaluation o biochemical evaluation o expert grader evaluation. <ul style="list-style-type: none"> • Data generated on the relevant product from any combination of the following study types: <ul style="list-style-type: none"> o market research, o sensory panel evaluation o expert grader evaluation o consumer evaluation. • Product formulation details. |
| <p>Possible Sources of Supporting Evidence</p> | <p>Advances in Science and Technology</p> <p>No claims are anticipated to arise from mere presence of the ingredients alone since presence and properties will be covered in previous columns of this table.</p> <p>Other claims related to the ingredient will be performance or sensory in nature and therefore covered in tables 1 and 2 above.</p> <p>It is anticipated that many claims based on entirely new ingredients will be combined with a performance, sensory or aesthetic claim and thus be covered by combination claims.</p> |

Claims Based on Product Aesthetic

| LEVEL OF EVIDENCE | | | |
|---|--|---|--|
| | Widely Accepted Established | Established Rationale but Requiring Additional Evidence | Advances in Science or Technology |
| Possible Sources of Supporting Evidence | <p>The following might be drawn upon to show that the claim is widely accepted:</p> <ul style="list-style-type: none"> • published reports; • publicly available information; • product formulation details. <p>For any specific product, that support may be based upon any one, or an appropriate combination of, the following options:</p> <ul style="list-style-type: none"> • published reports; • publicly available information; • data from studies on closely related, relevant products based on any combination of the following study types: <ul style="list-style-type: none"> o market research o sensory panel evaluation o expert grader evaluation o consumer evaluation; • product formulation details. | <p>The inherent aesthetic characteristics claimed should be supported by any one, or an appropriate combination of, the following options:</p> <ul style="list-style-type: none"> • published reports; • publicly available information; • product formulation details; • pack details; • data from studies on the final marketed product; • data from previous studies on closely related products (relevance might need to be demonstrated). <p>Such data may be based on any combination of the following study types:</p> <ul style="list-style-type: none"> o market research o sensory panel evaluation o expert grader evaluation o consumer evaluation. | <p>The aesthetics of product/pack will not be different but they may impact on perception of performance or sensory properties (and this would be dealt with under combination claims).</p> <p>In practice, no new advance in aesthetics is anticipated at this time that could not be covered elsewhere in the tables of classes of claim.</p> |

Combination Claims

All of the above classes of claims can be, and typically are, combined with other claims. In such cases, the supporting evidence required for the combined claim will be a combination of the possible sources of support outlined in the tables above. When using a combination of claims, it is important to consider whether any additional claim might be implied by the final wording of the combination, or whether the average consumer might perceive that to be an additional implied claim.

Comparison Claims

Such claims would simply use the appropriate type of supporting evidence for each claim class used as the basis for comparison.

The ASA requires comparisons against identifiable competitors to be verifiable. As such, if the content of the advert alone doesn't make sufficiently clear how the comparative claim can be verified, the advert should include, for example, a signpost to where information on the basis of the claim can be obtained, so that both consumers and competitors are able to verify the comparison. For further information on this, see CAP's guidance on [verifiability](#).

Note from ASA/CAP Executive on its Assessment of Evidence

Claims that are based upon what the general scientific community would be likely to regard as a significant advance in science or technology require the highest level of supporting evidence. The ASA/CAP Executive accesses that community through its experts. Such evidence will be viewed in totality and advertisers should not ignore sound data that contradict the claim when compiling that body of evidence.

The total package should be presented in a way that explains the nature of the scientific or technological advance as well as how the product works (where applicable) in addition to providing sufficient evidence to demonstrate that the product does indeed work in the way claimed and so support the claim itself.

The 'Advances in Science and Technology' columns in the foregoing tables provide details on what might constitute sufficient evidence. In order to prevent consumers being misled and to maintain 'a level playing field', the ASA/CAP Executive is prepared to take interim action to stop such claims appearing pending investigation, where appropriate.

Non-broadcast advertisers are urged to seek CAP Copy Advice (<https://www.asa.org.uk/about-asa-and-cap/people/copy-advice-team.html>) before advertising such claims and may need to seek the view of their own subject expert.

Part 3

Practical Guide to Good Study Design

This guideline covers the following:

- General principles applicable to all studies
- Types of experimental study
- Selection of study or studies
- Development of study protocol
- Specific requirements for different types of study/evidence
- Conduct of study
- Reporting of study
- Presentation of conclusions
- Other sources of information or data
- Guidance on statistical principles

1. Introduction

Although many different sources of information may be collated to form a set of evidence to support a claim or claims, this guide is intended primarily to aid in the design and conduct of specific claim support studies and in their subsequent evaluation by an assessor. Best practice for claim substantiation evidence is also included in the guidelines to Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products, Annex II Best practice for claim substantiation evidence.

Not all claims will require the support of experimental studies; for example, some claims may be adequately supported by generally accepted data or by market research data. The guide, Building Blocks of Claim Support, provides guidance on levels of evidence likely to be required to support each class of claim and should be consulted prior to undertaking any particular study to ensure the work will be appropriate to support the claim being proposed.

Evidence in support of an advertised claim should be presented, when necessary, in a format in which the advertiser explains clearly the claim being made, how that claim is likely to be interpreted or understood by the target audience and how the information supplied supports the claim, both on specific details and in general impression. Clearcast has published its '[Claims Support Model](#)' which is intended to help advertisers format their approaches to Clearcast for the pre-clearance of broadcast advertisements, and this may be useful as a more general model on the organisation of claims support material regardless of whether that material is intended to be reviewed by a third party.

Advertisers are reminded that advertising content includes not only words but visual images and pictures. These images can be modified by post-production techniques to enhance the visual quality of the advertisement but advertisers should ensure any such enhancement does not make the advertisement misleading or make it likely to mislead. CAP/BCAP has issued Advertising Guidance called '[Use of Production Techniques in Cosmetic Advertising](#)'. Advertisers are urged to consult this document for guidance.

The use of testimonials or other endorsements, whether from celebrities, professional people or consumers, requires care. Testimonials do not constitute evidence by themselves in support of an objective claim as they are expressions of a personal opinion. However, testimonials may constitute claims if repeated by an advertiser and any such claims would require supporting evidence. Guidance on the use of testimonials is available [here](#).

2. General Principles Applicable to All Studies

Studies should be relevant to the claims being made and based upon reliable and scientifically valid methodologies, should be well-designed and executed and accurately reported. Processing of the data, interpreting the results and drawing conclusions must be fair and should not overstep the limits of the study's relevance; evidence should not be selected or presented so as to give a falsely positive or misleading view.

Studies involving human volunteers must respect sound ethical principles and be based on informed consent by the participants, consistent with the type of study under consideration. It is important that the person conducting the study has the appropriate training and experience in the field of the proposed study.

Experimental design is a complex subject which necessarily requires expert knowledge and awareness of statistical principles in both the design of the study and in the analysis of the data obtained. To ensure studies reach scientifically valid conclusions, an adequate understanding of statistics is necessary on the part of the person responsible for the study. Where this is not readily available, an appropriately knowledgeable person, such as a statistician, should be consulted.

3. Types of Experimental Studies

Depending on the intended use of the cosmetic product and the nature of the claims involved, several different experimental approaches may be used alone or in combination:

- sensorial studies, where the effect is assessed by sight, touch, smell, either by the study participants or by expert assessors;
- instrumental studies, where instruments measure specific parameters relevant to the product effect in question; such studies may involve *in vivo*^a, *in vitro*^b, or *ex vivo*^c systems.

a. In vivo: (L. in/from life) studies carried out in living organisms e.g. human volunteer studies.

b. In vitro: (L. in glass) studies carried out in artificial media, e.g. glassware such as test tubes or culture dishes, and involving substrates that may be biological, e.g. hair maintained artificially, cell cultures, reconstructed skin etc., or artificial, e.g. glass or quartz, plastic plates and various containers.

c. Ex vivo: (L. off the living) studies on biological substrates taken from the living organism without modification to the intrinsic properties, e.g. hair tresses, skin microflora samples, tape strippings of skin etc.

4. Selection of Study or Studies

4.1 Sensorial Studies

These studies are based on an appreciation of product performance made through the senses of study participants or experts and give information on perceived or observed parameters. The product may be used by a consumer and evaluated by them, used by a consumer and evaluated by an expert or simply evaluated by an expert, directly.

In-use tests by consumers

An in-use test evaluates the consumer's perception of product efficacy and cosmetic properties based on parameters they can observe or feel. The sensory assessment of cosmetic products may involve the consumer self-assessing based on an appropriate set of questions or according to a scoring system.

Consumer evaluation studies should, wherever possible, involve realistic in-use testing in a relevant consumer base so as to reflect the actual conditions of use. For example, they should involve the use of a realistic amount of the product relevant to the directions for use on the product to be marketed. With adequate data analysis techniques, this enables the evaluation of the product benefits by the end consumer to provide:

- a general assessment of the product efficacy resulting from the physical and sensory effects noted by the consumer; and
- depending on the method used, an objective or comparative test when performed in blind conditions on a sufficient number of volunteers and using appropriate statistical analysis; or even in non-blind/branded conditions provided the protocol followed is applicable to the claim or concept being tested.

Consumer evaluation tests can provide valuable data on the product benefits to the end user and for supporting the findings of instrumental/biochemical studies. However, for certain product performance and ingredient claims, consumer evaluation tests may not be acceptable as sole support, especially when the claim is based upon a significant advance in the science or technology (see Building Blocks of Claim Support for more specific guidance on how to support these types of claims).

Evaluation of effect by experts

Where the effect of a product on a volunteer is to be assessed, trained assessors who are experienced in the consistent application of a defined scoring system may be used. Such assessors may be drawn from a wide background including physicians, dentists, hairdressers, beauticians or other trained experts. Assessors should not be changed during the study unless this is unavoidable. The parameters are evaluated by clinical observation or scoring and may be compared with initial results (e.g. before and after) or with a reference product. The scoring system itself should be robust and reproducible.

The techniques for sensory evaluation, using a trained test panel or a panel of target consumers, strictly defined testing conditions as well as statistical analysis, are capable of providing reproducibility and sensitivity similar to objective instrumental studies.

The use of trained expert graders and a system of grading criteria enables a more consistent evaluation but results should also be discernible to consumers if that is what is implied by the claim.

Product aesthetics

The assessment of product aesthetic qualities rather than product efficacy or performance by a trained panel of assessors who will have experience in the consistent use of defined scoring systems is also possible.

4.2 Instrumental/Biochemical Studies - Using Human Volunteers

Studies following the application of a product on human volunteers and using instrumental or biochemical techniques measure given parameters with defined precision and can generate objective data which can be used to support quantitative performance and ingredient claims. Many published and standard techniques are available; new techniques are constantly being developed, modified and validated.

These tests are conducted on the target population, where possible, defined by specific inclusion and exclusion criteria. If another population must be used, their relevance to the intended population must be explained and, if necessary, supported with adequate evidence.

Depending on the aim of the study, it may be single-blinded (where the volunteer does not know the product in use or where the assessor does not know the product being assessed) or double-blinded (where neither the volunteer nor the assessor knows the identity of the product in question). Blinding removes one source of possible bias.

4.3 Instrumental/Biochemical Studies – Using *ex vivo*/*in vitro* Systems

Ex vivo systems include studies on hair tresses, skin biopsies and skin stripping for example. Such studies can be quantified and provide comparative data.

In vitro systems involve substrates that may be natural, such as cell cultures, reconstructed skin etc. or may be artificial such as glass and quartz plates. Studies using *in vitro* systems may be quantified and comparative and are used, for example, to demonstrate mechanisms of action of ingredients as well as performance characteristics of products.

5. Development of Study Protocol

Having decided upon the type of study to be conducted in order to support the intended claim(s), very careful consideration must be given to the design of a robust study protocol. A robust protocol will be key to the success of the study and should not be overlooked. It will provide the central reference document for controlling and monitoring the conduct of the study and to its subsequent interpretation and reporting. The protocol may be derived from existing standard test methods (e.g. validated 'in house' methods or standard operating procedures), or may need to be tailored more specifically to address the parameter being measured.

Protocols should be agreed prior to the commencement of the study by all those involved in its conduct and reporting. They may form the basis of contractual obligations between those parties involved.

5.1 General considerations regarding protocol development

Product formulation selection

In general, product-specific research should support product-specific claims, but research may be augmented where appropriate by ingredient-related studies to support the principle underlying the claim. Product-specific studies ensure the appropriate concentration of actives is used in studies. Normally, it is most appropriate to conduct claims studies on product that will be introduced in-market but a case can be made for relating results from one formulation to another when results are generated using comparable vehicles or delivery systems. If last-minute formulation changes mean that the test product is not identical to the marketed product, an explanation should be provided to show those changes would not materially affect product performance.

Controls and 'wash outs'

In general, because cosmetic products may be multifunctional, complex compositions containing a variety of ingredients, many of which may contribute to the performance effect claimed, ensuring an adequate control is not always a simple matter of, for example, comparing a test product against the same product minus a specific ingredient. Nevertheless, potential confounding factors must be controlled for. Where possible, that should be done by comparing the product with a placebo^d or with a 'standard' product with a generally accepted formula.

d. A placebo in this context is an inactive substance that looks the same, and is administered in the same way, as the product.

When a performance claim^e is for an effect that is said to be due to a specific ingredient in the product rather than the whole formulation and where that claim is not already well-known and accepted, a comparison with the product minus the specific ingredient will normally be required.

e. It is the current view of the ASA and Clearcast that, in these circumstances, a performance claim related to a specific ingredient should not be made unless such a control had been included.

Selection of a control has to be relevant to the effect being measured: before/after, treated/untreated, exposed/unexposed versus a benchmark or competitor, versus a company standard product already accepted for efficacy, etc. An adequate control should allow for variations in test conditions, e.g. environment, where these have an effect on results that makes the claim misleading. This is particularly important in the case of before/after studies to exclude the likelihood that another factor, such as changes in environmental conditions rather than the treatment, led to the results measured. For example, humidity affects the 'frizziness' of hair and it is important that humidity be consistent when assessments of hair 'frizz' are undertaken at different times.

Information on ingredients or combinations of ingredients can be used based on generally accepted data, data obtained 'in-house' or obtained from suppliers. This information should consider the concentration of the ingredient in the actual product if a specific action is claimed in relation to that ingredient in the product.

A pre-study 'wash-out' period may be appropriate to ensure no pre-treatment contamination and the rationale should be part of the study protocol. Whether a pre-treatment 'wash-out' is needed will ultimately depend on the claim. A standardised skin care regime using identical products for a period prior to the start of the study might be a suitable substitute for complete abstinence.

Post 'wash-out' or regression periods may be required to support 'long-lasting' or time-related claims.

Choice of volunteer group

Studies conducted on volunteers should respect ethical rules. Such studies should be carried out on a justifiable^f number of volunteers that are representative of the population at which the product is targeted. For example, evidence in support of a product that claims a cumulative moisturising effect on dry skin should include studies on subjects with dry skin.

f. Justifiable in this context means sufficient to ensure the results obtained are unlikely to be the result of chance alone but reflect the anticipated result in the target population. Common statistical parameters enable the necessary number of volunteers to be estimated and should be used to explain the selection of the group sizes.

Appropriate inclusion and exclusion criteria should be used to screen volunteers for obvious mismatches and for levels of key characteristics e.g. wrinkles and age spots. In comparative studies, good experimental design allocates subjects in such a way that groups are essentially similar at the start of a study in terms of the parameters being studied.

Studies can be performed on a relatively small number of subjects under certain specific conditions, on a relevant age group or on a certain skin type of subject where the benefit is targeted. The qualification of skin type is dependent on the parameter being tested or the claim to be substantiated.

Test site

The target site should be used where possible for experimental studies. Alternatively, where there are practical or ethical reasons for not using the correct target site, then a robust scientific explanation or rationale, if necessary backed up by empirical evidence, could be used to verify that an effect is achieved when used on the final target area.

Consumer benefit

Some objective measurements will demonstrate benefits that are of significance to the consumer and it is reasonable that this benefit should be explained in the study reports. However, the consumer may only experience a long-term benefit or the absence of a negative effect e.g. from the regular use of sunscreens. Where this is the case, the wording of the claim being made needs to be consistent with the study findings. The claim should not imply, for example, that the consumer will experience a visible, perceivable or in some other way meaningful benefit if that benefit is not demonstrated and supported by the evidence.

Consumer evaluation studies may be valuable as part of more objective testing, combining objective and subjective observations in the same study. Where practicable, such combined studies should be carried out. The benefit of carrying out consumer perception studies as part of more objective testing is that the test conditions will not vary. However, in many other cases, the protocols and treatment designs are not conducive to such combinations and it therefore may be appropriate to carry out separate studies but with conditions kept as closely comparable as possible relevant to the general expected use of the product and, if necessary, including a suitable control.

6. Specific Requirements for Different Types of Study/Evidence

Listed below are the various types of experimental study that may be considered for inclusion in support of a claim or advertisement.

This is an extensive list and should be used to stimulate thinking about how to conduct a particular study, what factors need to be considered and what information needs to be gathered and recorded. The actual choice of study type should be carried out as described in the second section 'Building Blocks of Claim Support'. That section indicates that not every claim requires the highest standard of evidence to support it; advertisers have considerable leeway in selecting studies to support their claims, but certain principles as expounded in that guideline need to be respected.

For example, claims relating to skin care products in which performance is claimed to be due to the presence of a particular ingredient; such claims, unless generally accepted already, are likely to require the highest standards of supporting evidence.

6.1 Instrumental/Biochemical Methods

Methodology

- Measurement principle
- Description of equipment used
- Summary of methodology
- Relationship between methodology and effect assessed should be justifiable
- Bibliographical reference, especially for novel methods to indicate information sources which confirm relevance
- Frequency and method of product application
- Frequency of measurement
- Measurement techniques
- Measurement site (to be justifiable if not the area of intended product use)
- Initial wash-out period
- Environmental conditions, as appropriate e.g. temperature, hygrometry, etc.

Volunteer subjects

- Inclusion/exclusion criteria
- Numbers to be justifiable (including, where appropriate, statistical analysis)

Type of test

- Choice of test adopted (single or comparative; subject used as own control or not; open, single- or double-blind)
- Randomisation (including, where appropriate, how confirmation of starting group equivalence in comparative studies will be determined)

Evaluation/efficacy criteria

- Definition of efficacy criteria adopted (i.e. what is being measured)

Withdrawals, interrupted tests

- Consideration of withdrawals and test interruptions, with justification

Presentation of results

- Method used to assess the observed effect
- Interpretation of results, taking into account the precision, power and reproducibility of the method used (e.g. the expected normal range for measured values, the expected magnitude of outcome and the variability of individual results)
- Consideration of extraneous factors, if justified

6.2 Expert Grader Evaluation

Methodology

- Observation journals
- Frequency of checks
- Criteria adopted for checks
- Where appropriate, an explanation or visualisation of the scale should be included along with reference to its robustness and reproducibility

Test conditions

- Directions of use of products
- Time of application
- Frequency of use
- Application areas
- Restrictions of use
- Prohibited/permitted concurrent product use

Volunteer subjects

- Inclusion/exclusion criteria
- Numbers to be justifiable (including, where appropriate, statistical analysis)

Type of test

- Choice of test adopted (single or comparative; subject used as own control or not; open, single- or double-blind)
- Randomisation (including, where appropriate, how confirmation of starting group equivalence in comparative studies will be determined)

Evaluation/efficacy criteria

- Definition of efficacy criteria adopted (i.e. what is being measured)
- If a consumer questionnaire is included, questions should be relevant for the benefits investigated and should match the claims made

Withdrawals, interrupted tests

- Consideration of withdrawals and test interruptions, with justification

Presentation of results

- Method used to assess the observed effect
- Interpretation of results, taking into account the precision, power and reproducibility of the method used (e.g. the expected normal range for measured values, the expected magnitude of outcome and the variability of individual results)
- Consideration of extraneous factors, if justified

6.3 Sensory evaluation

Methodology

- Criteria
- Questionnaire
- Design of presentation of products
- Product coding
- Number of products compared
- Derivation of vocabulary (scale descriptions)

Panel

- Inclusion/exclusion criteria (training of panellists; target consumers)
- Number of panellists (including, where appropriate, statistical analysis)

Type of test

- Choice of test adopted (discriminative or filing; ranking; monadic or comparative)
- Randomisation (including, where appropriate, how confirmation of starting group equivalence in comparative studies will be determined)

Test conditions

- Directions for product use
- Notation method (scale)
- Application site
- Presence of reference product or not

Evaluation/efficacy criteria

- Definition of efficacy criteria adopted (i.e. what is being measured)
- Questions should be relevant for the benefits investigated and should match the claims made
- Presentation of results
- Choice of presentation of results (e.g. spider profile, principal component analysis)
- List of criteria assessed

6.4 Studies Without Human Subjects

Model

- Type of model (biological or other)
- Nature, origin and method of obtaining model
- Principal characteristics of the model
- Specific characteristics justifying the model

Test conditions

- Quantity of product used, to mimic instructions for product use if possible

Methodology

- Measurement principle
- Description of equipment used
- Summary of methodology
- Relationship between methodology and effect assessed should be justifiable
- Bibliographical reference, especially for novel methods, to indicate information sources which confirm relevance
- Frequency and method of product application
- Frequency of measurement
- Measurement techniques
- Environmental conditions, as appropriate (e.g. temperature, humidity, etc.)

Evaluation/efficacy criteria

- Definition of efficacy criteria adopted (i.e. what is being measured)

Presentation of results

- Criteria recordings
- Interpretation of results, in particular with reference to the performance and limitations of the method used

6.5 Consumer Evaluation/Market Research

Methodology

- Method (interview, correspondence, telephone, internet)
- Format (evaluation form, questionnaire)
- Frequency of checks and duration of test

Subject group

- Inclusion/exclusion criteria
- Size of sample having responded

Type of test

- Choice of test adopted
- Randomisation

Test conditions (if product used)

- Directions for use of products
- Frequency of use
- Application areas
- Restrictions for use

Presentation of results

- Assessment method used (nominal, ordinal or visual analogical notation scale)
- Interpretation
- Consideration of extraneous factors, if justified

7. Conduct of Study

The study should be under the direct control of a single, named, person who is responsible for ensuring the study is carried out in strict compliance with the protocol. Any deviations from the protocol must be reported to this person without delay and must be recorded in the appropriate report book. The study controller need not be one of those actively involved in the performance of the study itself.

8. Reporting of Study

Identification

- Sponsor
- Organisation in charge of study
- Person responsible for the study (if appropriate, their qualifications and any necessary declarations of interest)
- If appropriate, other investigators or experts involved
- The location where study took place
- The products tested: batch or code numbers^g

g. The relationship between the product tested and the product being advertised needs to be stated, either in the study report or in the summary of the package of evidence. This should include an explanation of any differences and the likely consequences of those differences.

Objective of the test

- What factor is being assessed

Study schedule

- Period and duration; start and finish dates

Study protocol

- A summary of the protocol followed (which can refer to a published or well-accepted protocol); if necessary, the full protocol may be appended
- Documentation of any deviations from the protocol

Presentation of data

- Method of recording criteria
- Method of interpreting results

Statistical analysis of data

- Method employed
- Outcome of analysis
- Justification for the statistical methods used
- Statistics should support the apparent result and should generally concur with the statistical plan described in the protocol

Presentation of results

- Tables of analysed data including, where appropriate, mean values and estimates of variation (standard errors) for parametric data
- Probability or significance levels
- Graphical representations where appropriate

Discussion of the results and their interpretation

Appropriate rationales for data handling, statistical analysis and hypothesis testing should be adopted. Data processing and the interpretation of results should not overstep the limits of the study's relevance. Data recording and representation in chart or graphical form should be clearly explained (labelling of axes, spread of measurement for each product at each time point e.g. error bars). Analysis should not be designed to overstate the effect measured. Appropriate statistical analysis of the data should be performed.

Some methodologies will produce non-linear responses. These must be disclosed. The method chosen to express such results should not be capable of distorting the magnitude of the effect; if there is a potential for distortion, this should be clearly identified and explained.

The use of percentage changes in some parameters is an instance where the magnitude of effect can be distorted. Whilst percentage changes can be a simple and clearly understood way of presenting data, and a consumer-friendly way of expressing benefit, it is not always wise to use them in situations where distortion is possible.

The observation that some response curves with time are not smooth (saw-toothed) requires explanation. It is important that results are quoted 'like-for-like' and not distorted.

Conclusions

- Factual statements about the conclusions drawn on the basis of the study

Signature of persons responsible for testing on final report

- Copies that form part of a substantiation dossier can be submitted electronically so may not be signed. It must be clear that the report is final and not a draft

Summary of report including findings and conclusions

- This should be, at most, a single side of paper and, in effect, constitutes an 'executive summary'

9. Presentation of Conclusions

Conclusions must always be fair and should not overstep the limits of the study's relevance; evidence should not be presented so as to give a falsely positive or misleading view. The conclusions from one study or several studies may be put into context with other supporting information in support of a claim.

However, it is preferable to consider a separate concise explanatory summary document in which the support for an advertised claim is presented, when necessary, in a format in which the advertiser explains clearly the claim being made, how that claim is likely to be interpreted or understood by the target audience and how the total information supplied supports the claim, both on specific details and in general impression. Certainly, an overview of the data *in toto*^h would be appreciated by reviewers.

h. In toto in this context means as a whole. All relevant substantiation for a claim should be presented.

Clearcast has published its 'Claims Support Model' which is intended to help advertisers format their approaches to Clearcast for the pre-clearance of broadcast advertisements. This may be a useful as a more general model on the organisation of claims support material.

10. Other Sources of Information or Data

The different studies discussed above may be supplemented by evidence from other sources of information or data; in many cases, efficacy claims may be supported on this type of information alone. Guidance on this is available in the 'Building Blocks of Claim Support'.

Other sources of information or data fall into two main categories:

- generally accepted data; and
- consumer preference or market research studies.

Generally accepted data

Such data are likely to be related to ingredient claims and may be self-evident by virtue of the function of the product (e.g. that a shampoo cleans hair could be supported simply by data on the surfactant ingredients alone rather than studies on the shampoo itself) or by a clear, concise and reasoned account of the effect of an ingredient or combination of ingredients in relation to the claim made. In addition, a claim may be supported by information contained in authoritative reports, reputable guidelines or published or unpublished material that reflects general scientific opinion.

Consumer preference or market research studies

Market research surveys can be used to gauge reaction or understanding of a new concept, of an advertising campaign or of novel product packaging for example.

11. Guidance on Statistical Principles

Statistics is the science of using data to increase the probability of making correct decisions. Generally, inferences are made about populations based on data obtained by sampling that population. Statistical testing should be used to give confidence that the study outcome in the context of its biological, clinical or physical relevance is unlikely to be due to chance. In addition, knowledge of the magnitude and variance of the measured response can help to define the size of the experimental study sample to ensure the study has sufficient power.

In a guideline of this kind, it is not possible to provide a complete treatise on the selection of appropriate statistical methods for the analysis of data obtained in a wide variety of study types. Selection of relevant statistical tests must be based on a knowledge of the scale of measurement, the variability of the data and the normality of the observations or data. It is important to use a statistical method to analyse the data that is appropriate to the purpose of the analysis, to the data type and to the data independency: using an incorrect technique will mean the conclusions drawn are unlikely to be sound. If in doubt, refer to a suitable text or seek assistance from a suitably qualified person. The key steps are given in the sub-headings below.

Define objective

- Purpose of investigation
- Information required

Select sampling and measurement systems

Assess data properties

- Distribution (normal, other, etc.)
- Type of data (qualitative, quantitative)

Select appropriate statistical test

- Assumptions
- Requirements
- Power

Design experiment

- Replication
- Randomisation

Data collection and data management

Assess data

- Check assumptions
- Typical variability
- Discordant values
- Visual plots

Calculate statistical results

Interpret statistical results

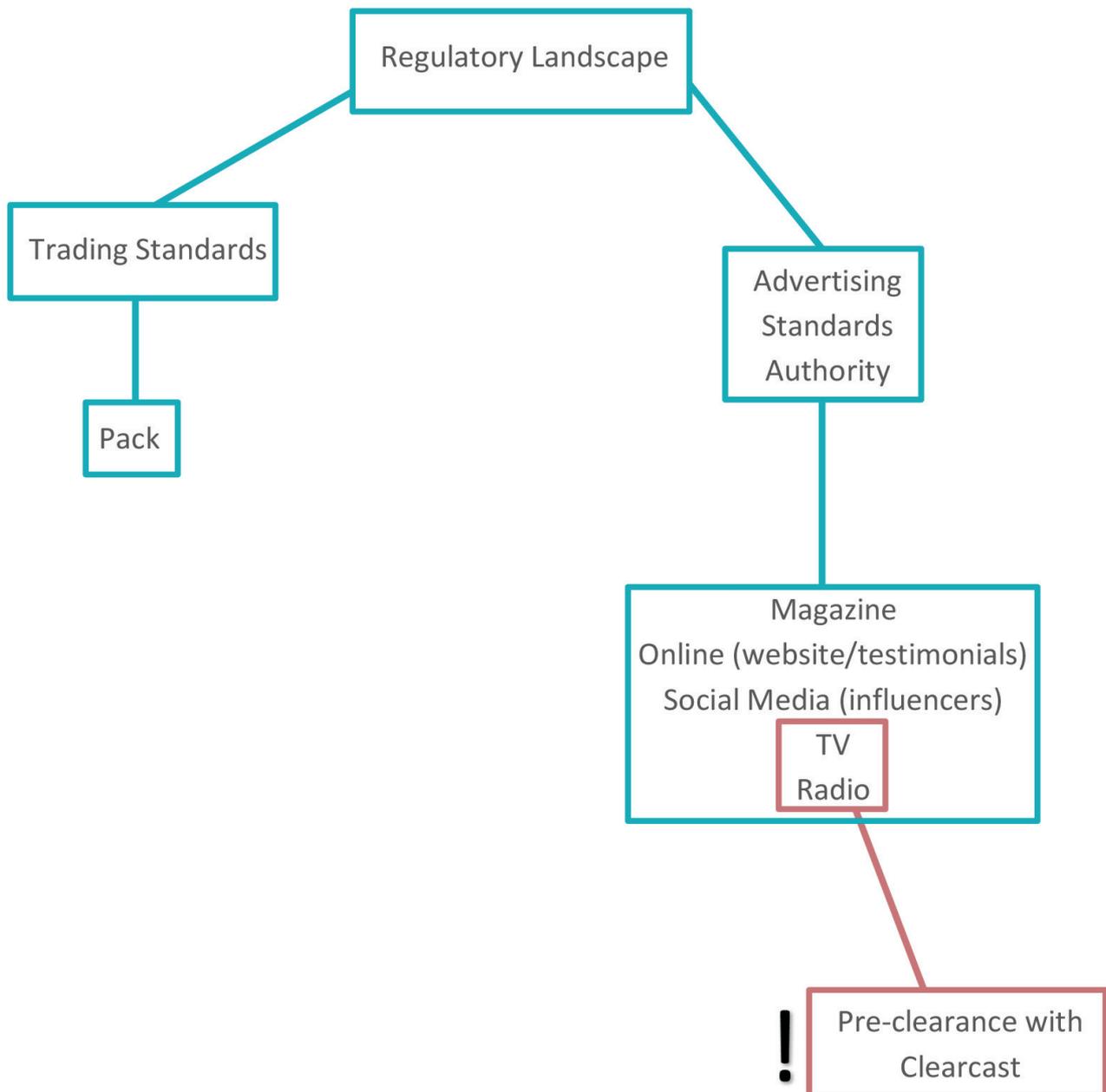
- Statistical significance
- Practical significance

Review

- Accept conclusions
- Objective achieved, or
- Modify objective, or
- More data required

Report conclusions

Annex I – Example Decision Trees for Claims



STEP 1

What is the product function/definition?

Cosmetic

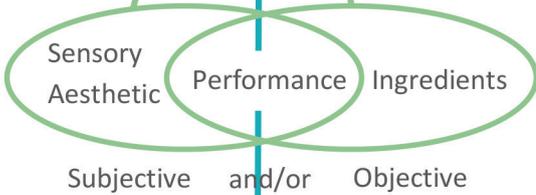
Borderline with medicine – refer to MHRA Guidance Note 8 - A Guide to What is a Medicinal Product

Borderline with biocide – refer to the Manual of Decisions for Implementation of Directive 98/8/EC concerning the placing on the market of biocidal products.

STEP 2

What are the claims?

! A claim is represented by text, but also images, names, symbols, trademarks



Borderline with General Product

STEP 3

How do I substantiate the claim in my advertising material?

Claims widely accepted to be established
Formulation rationale/literature

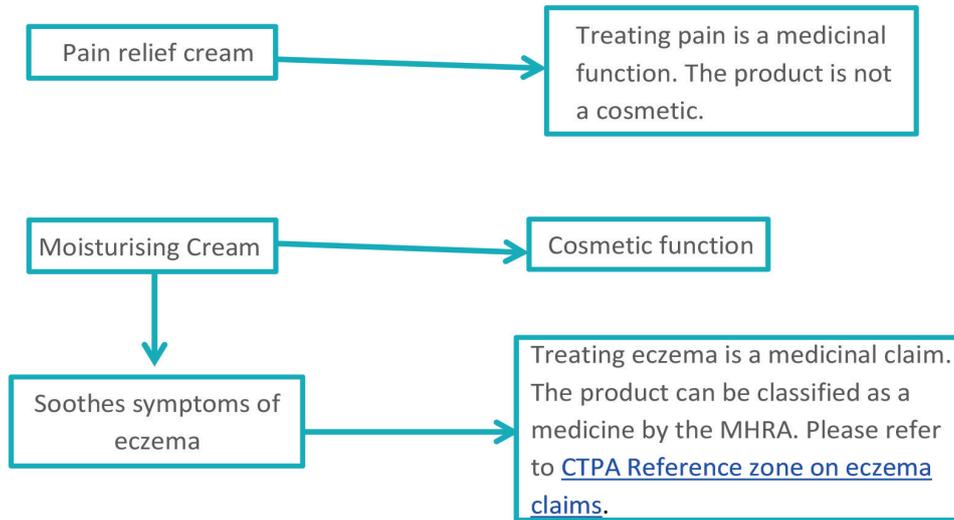
Claims with established rationale but requiring product or ingredient specific evidence
Claims based upon significant advance in science or technology

| | | |
|---------------|-------------------|-------------------|
| Consumer Test | Expert Evaluation | Instrumental Test |
|---------------|-------------------|-------------------|

Annex II- Case Study Examples

Borderline Case Studies

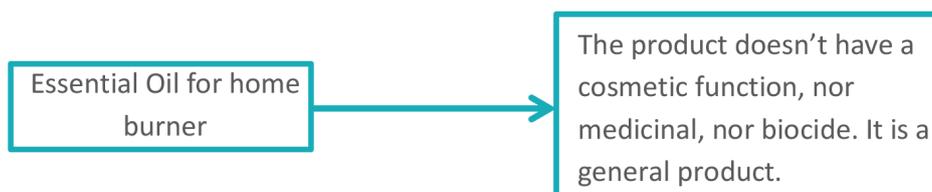
Borderline with medicines



Borderline with biocides



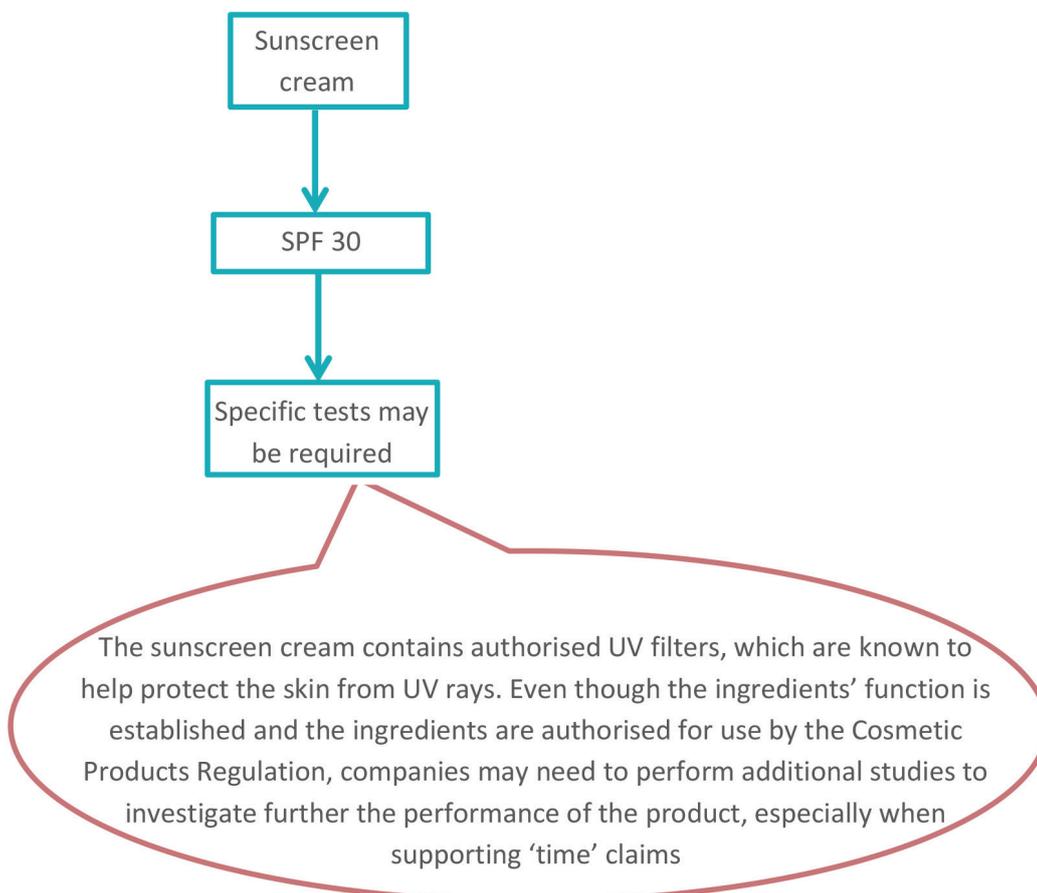
Borderline with general products



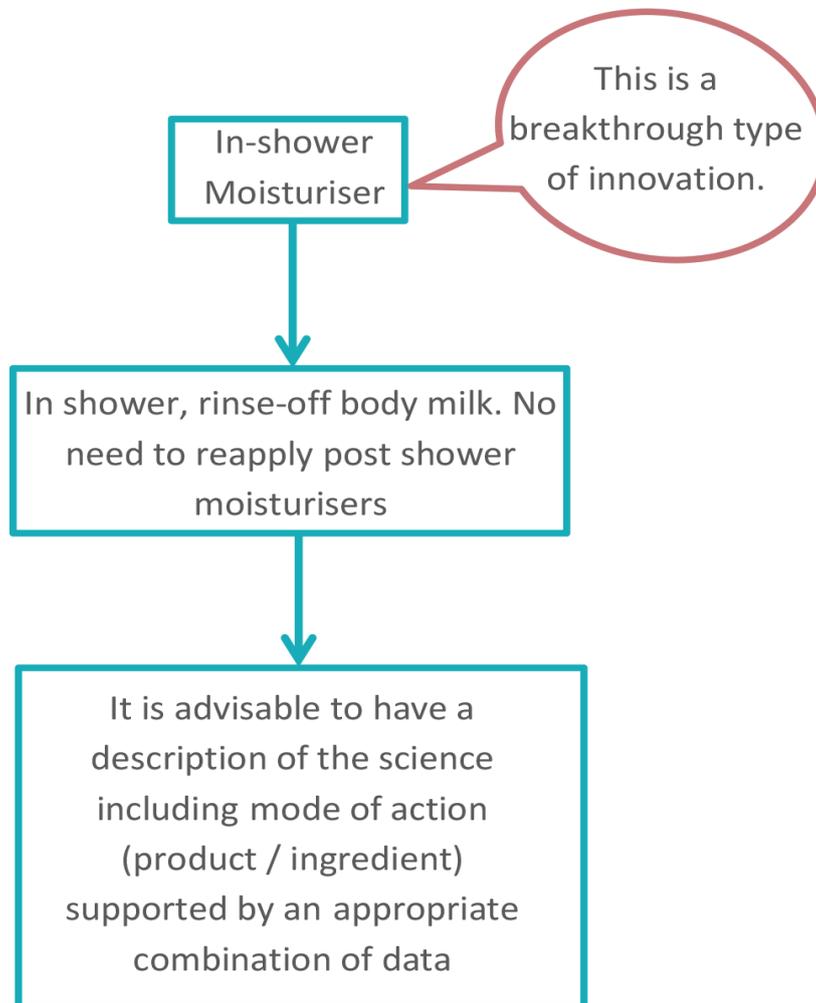
Claims Widely Accepted to be Established - Case Study



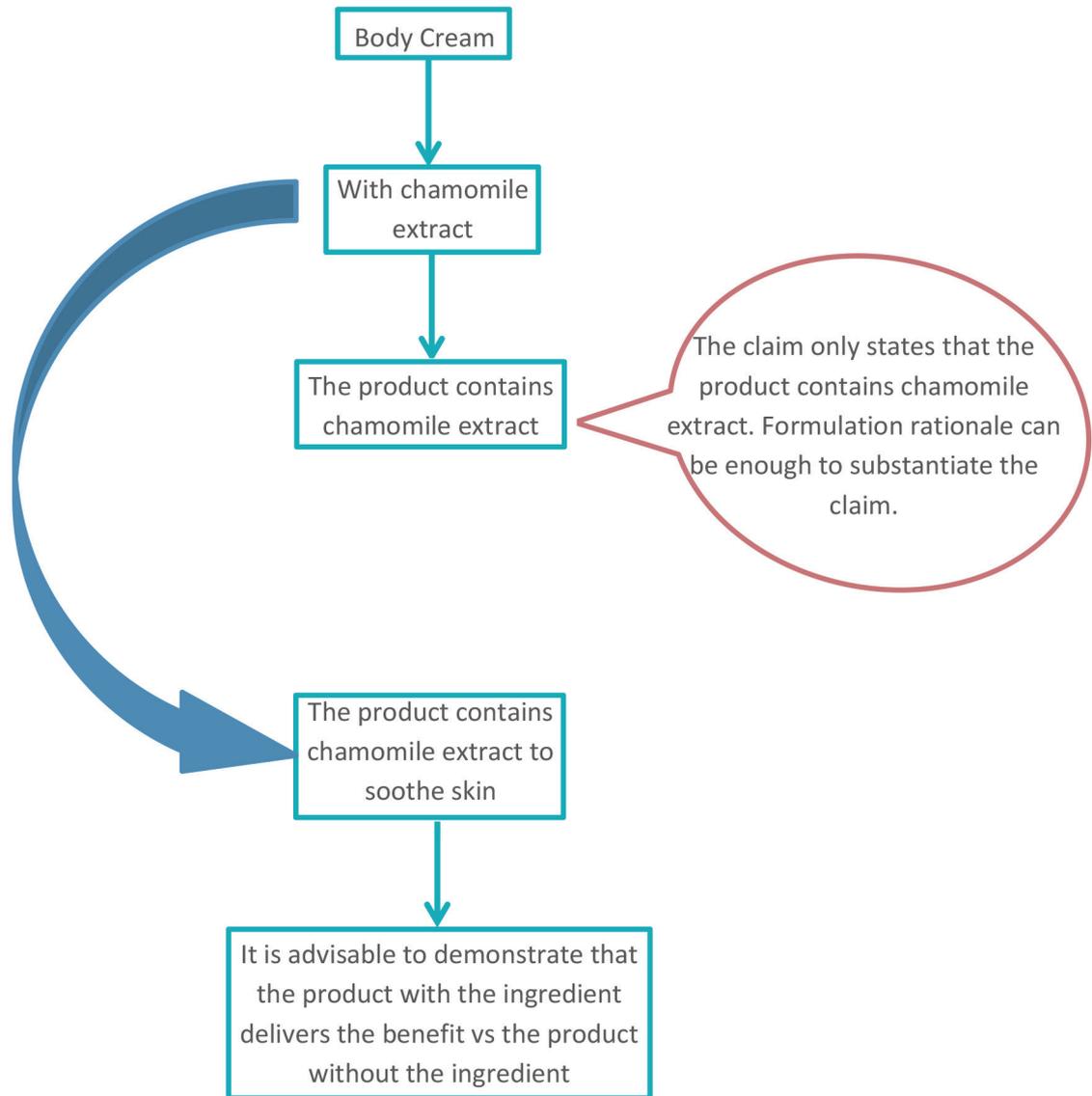
Claims With Established Rationale but Requiring Product or Ingredient Specific Evidence - Case Study



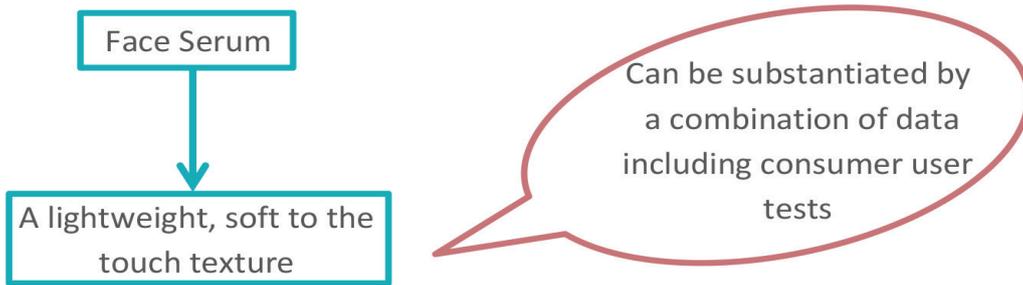
Claims that are Based Upon a Significant Advance in Science or Technology



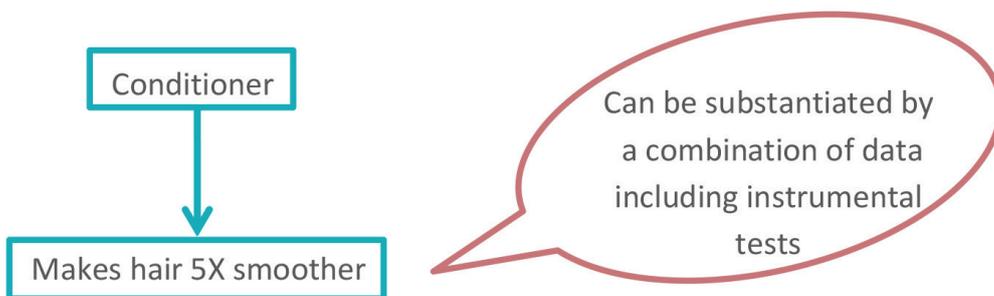
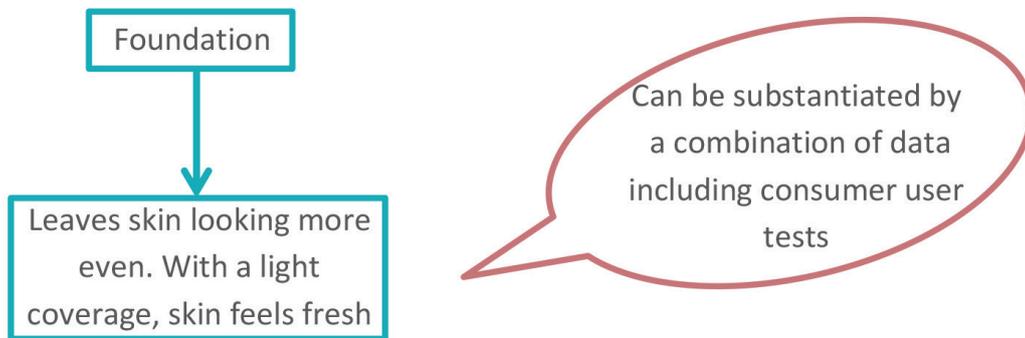
Ingredient Claims



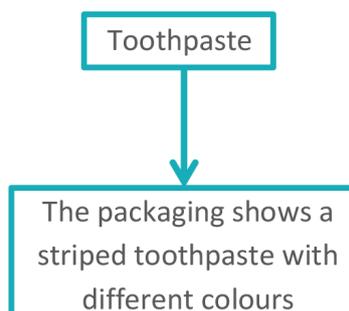
Sensory Claims



Performance Claims



Product Aesthetic Claims



Annex III - Links to External Guidance

- [European Commission Technical Document for Cosmetic Claims](#)
- [European Commission Guidance to Borderline Products](#)
- [MHRA Borderline Guidance Note 8](#)
- [CTPA Reference zone on eczema claims](#)
- [CAP Non-Broadcast Code](#)
- [BCAP Broadcast Code](#)
- [CAP/BCAP Advertising Guidance – Guidance on the use of pre and post-production techniques in ads for cosmetics advertising](#)
- [CAP eLearning - Social Media Advertising](#)
- [CAP Guidance on the use of Testimonials](#)
- [Clearcast Clearance Process](#)
- [Clearcast Claims Support Model](#)
- [Clearcast Notes of Guidance on the UK CAP Code](#)

The background is a solid teal color. In the lower-left quadrant, there are several overlapping, semi-transparent, light teal shapes that resemble stylized waves or organic forms. These shapes are layered, with some appearing in front of others, creating a sense of depth and movement.

The Cosmetic, Toiletry and Perfumery Association

Sackville House, 40 Piccadilly, London W1J 0DR | tel: +44 (0) 20 7491 8891
info@ctpa.org.uk | www.ctpa.org.uk | www.thefactsabout.co.uk