Supplying Cosmetic Products on the UK Market?

A CTPA Guide to What You Need to Know

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The Cosmetic, Toiletry and Perfumery Association

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The Cosmetic Toiletry and Perfumery Association (CTPA) is the trade association for the UK cosmetic and personal care industry.

The Association's role is to advise manufacturers, distributors and suppliers about the strict legal framework for cosmetics, to represent industry views to UK government, and external stakeholders and help promote information to the media on issues relating to the safety of cosmetic products. The CTPA acts as the voice of the UK industry and provides the most up-to-date interpretation of, and guidance on, regulatory matters affecting cosmetic products in Europe.

Why join the CTPA?

CTPA membership gives companies access to experienced regulatory, scientific and technical staff to help them market safe, effective products that provide a wide range of consumer choice both in the UK and overseas. Membership provides companies with peace of mind with easy access to:

- up-to-date legislative references;
- guidance on compliance;
- confidential one-to-one advice;
- advice on best practice;
- advance knowledge of upcoming changes;
- global updates on key issues;
- media and consumer information; and
- 24/7 online resources accessible worldwide.

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10 Key Principles

All cosmetic products placed on the Community Market intended for sale or to be given away for free in the course of a commercial activity must comply with the Regulation EC 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (hereafter 'the Regulation').

1. Definition

A cosmetic product is defined under Article 2 of the Regulation as "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".

2. Responsible Person and Safety

The Responsible Person is responsible for ensuring that each cosmetic product placed on the Community Market is safe and complies with the Regulation.

3. Ingredients

Any "ingredient" or "substance" may be used in a cosmetic product providing that the final product is safe and that any restrictions or prohibitions in the Regulation are followed.

4. Good Manufacturing Practices

Cosmetic products placed on the Community Market must be manufactured according to Good Manufacturing Practices.

5. Documentation

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 the Cosmetic Product Safety Report (CPSR). The CPSR is a safety assessment that must be performed by a duly qualified professional prior to the product being placed on the market.

6. Labelling

Cosmetic products shall be made available on the market only where the container and packaging of the products bear the information listed in Article 19 of the Regulation in indelible, easily legible and visible lettering.

7. Claims

The labelling, making available on the market and advertising of cosmetic products shall not imply that these products have characteristics or functions which they do not have.

8. Notification

Each cosmetic product must be notified to the European Commission using the Cosmetic Product Notification Portal (CPNP) prior to placing the product on the market.

9. Serious Undesirable Effects

Any adverse reactions meeting the definition of a Serious Undesirable Effect must be reported to the Competent Authority by the Responsible Person and/or Distributor, without delay.

10. Market Surveillance

Member States' Competent Authorities monitor compliance with the Regulation via in-market controls. The Responsible Person should make the PIF readily accessible to the Competent Authority of the Member State in which the file is kept.

1. The Rules and Regulations

In the European Union (EU), the manufacture of cosmetics is governed by the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (hereafter "the Regulation"). The Regulation and its amendments are directly applicable in all EU and European Economic Area (EEA) countries (hereafter "the Community Market"). The Regulation has been fully in force since 11 July 2013 and is directly applicable in the UK; in addition, the Cosmetic Products Enforcement Regulations 2013 establish the enforcement powers in the UK and set the penalties that apply.

Key Reference Documents

The Regulation (EC) 1223/2009:

http://www.ctpa.org.uk/content.aspx?pageid=303#recast

The Cosmetic Products Enforcement Regulations 2013 - SI 2013 No. 1478:

http://www.legislation.gov.uk/uksi/2013/1478/made

BIS - A guide to the Cosmetic Products (Safety) Regulations 2008 (under review):

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/39334/10-761-guide-to-cpsr.pdf

The main purpose of the Regulation is to ensure human safety. The Regulation applies to all cosmetic products placed on the Community Market intended for sale and products given away for free in the course of a commercial enterprise.

The Regulation applies to everyone placing finished cosmetic products on the market; whether they are a small business or a multinational company. Ignorance of the law is no excuse and no defence and the penalties for non-compliance can be severe; heavy fines and even periods of imprisonment are options open to the Courts.

1.1 Enforcement in the UK

The Regulation is enforced by local Trading Standards Officers (TSOs). Companies operating in more than one area of the UK should contact their local TSO and consider entering in to a Primary Authority Partnership (PAP), which can provide assured advice that others must take notice of.

The Primary Authority for a business will usually be the Trading Standards Service in whose local authority area the decision-making centre of the enterprise is based.

To find your local Trading Standard office please visit: http://www.tradingstandards.uk/advice/index.cfm and for more information on PAPs go to https://primaryauthorityregister.info/par/index.php/home

2. Definition of a Cosmetic Product

According to the Regulation a "cosmetic product" shall mean 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.

There are three preliminary questions which should be addressed when deciding whether a product could legally be classified as a cosmetic.

- Is the product a substance or a mixture?
- Is the product intended to be applied on the external part of the body?
- Is the purpose of the product wholly or mainly cosmetic? i.e. is it intended to:
  - Clean?
  - Perfume?
  - Change appearance?
  - Correct body odour?
  - Protect?
  - Keep in good condition?

If the main purpose of the product is not to perform one of these functions it is unlikely to be a cosmetic product. Depending on its intended function and its claims, a product can fall under other sectorial legislations such as medicines, medical devices, biocidal products and general products. Account will be taken of the main purpose of the product, the claims made for it, the composition of the product and the purpose for which it is likely to be used by the consumer, including its presentation to the consumer.

European Commission manual for Member States' Competent Authorities on the scope of application of the Regulation:

http://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products/docs/manual_borderlines_ol_en.pdf

MHRA (Medicines and Healthcare producs Regulatory Agency) guidance note 8:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/398998/A_guide_to_what_is_a_medicinal_product.pdf

Health and Safety Executive website:

http://www.hse.gov.uk/biocides/

3. Obligations

3.1 Responsible Person (RP)

Each cosmetic product placed on the Community Market should be labelled with the name and address of the 'Responsible Person' (RP). The RP is responsible for ensuring that each cosmetic product placed on the Community Market complies with all the requirements of the Regulation. The RP may be an individual (a natural person) or a company (a legal person) located within the Community and should have access to the Product Information File (PIF). For further information see section 4.4.

The RP may be:

- the manufacturer or a brand owner marketing a cosmetic product under their name or trademark; or
- the importer who is importing a cosmetic product from outside of the Community Market; or
- a person or a company established within the Community mandated to act as the RP by the RP. In this situation, a mandate should exist and there should be acceptance from the designated person in writing.

3.2 Distributors

Article 2 of the Regulation defines a distributor as "*any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Community Market*". The definition covers any company or person supplying cosmetic products (in return for payment or free of charge) on the Community Market for distribution, consumption or use e.g.: wholesalers, retailers, shops, beauty or hair salons, telesales, outlets and internet selling.

Distributors have specific obligations established under Article 6 of the Regulation. They should verify that the name and address of the RP, the batch number and/or the list of ingredients are labelled on pack and, if applicable, any 'off pack ingredient notice' accompanies the product. Before supplying the product to any EU / EEA country, they must ensure that the product complies with the language requirement established by the relevant national law. They should not supply cosmetic products that have passed their minimum durability date. In certain situations, distributors should take appropriate measures, and communicate with competent authorities and the RPs. In certain circumstances, they have an obligation to notify cosmetic products on the Cosmetic Product Notification Portal (CPNP). This notification must be carried out when marketing a product in a new Member State and translating the label on their own initiative.

Distributors are not required to assess the safety of cosmetics by checking or asking to see the PIF or requesting a proof that the product has been notified via the CPNP. The RP is the one that should guarantee that the product is safe and makes the PIF accessible to the Competent Authority.

CTPA Distributor Guide:

http://www.ctpa.org.uk/content.aspx?pageid=483

4. Assessing Safety

4.1 Safety Assessment

Each cosmetic product must be the subject of a safety assessment performed by a duly qualified professional (hereafter the “safety assessor”) before it is placed on the market. In addition, the law requires that a specific safety assessment is carried out for cosmetic products intended for use on children under the age of three and for products exclusively used for external intimate hygiene.

The qualifications of the safety assessor are stated in the Regulation. The safety assessment can be performed in-house if the appropriate personnel are available. If this is not the case, the safety assessment must be performed by an appropriate qualified third party.

The safety assessor will take into account all relevant supporting information such as:

- the general toxicological profile of each ingredient used;
- the chemical structure of each ingredient;
- the level of exposure of each ingredient;
- the specific exposure characteristics of the areas on which the cosmetic product will be applied;
- the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended;
- the manufacturing process; and
- the directions for safe use labelled on the product.

In the case of perfumery raw materials, the composition may not be known because of confidentiality. If so, it is necessary to obtain a relevant safety assessment from the ingredient supplier.

Ingredients used in cosmetics are strictly regulated by the Regulation which requires cosmetic products to be safe under both normal and reasonably foreseeable conditions of use.

4.2 Ingredients

4.2.1 Annexes

The Regulation includes lists of prohibited (Annex II) and restricted (Annex III) substances. Restricted substances can only be used in accordance with the conditions laid down. The Regulation also requires that only the colours, preservatives and UV filters listed in Annexes IV, V and VI respectively can be used in cosmetics.

If a substance does not appear in Annex II or III then the ingredient can be freely used in a cosmetic product provided that:

- the ingredient is not used as a colour, preservative or UV filter;
- the substance is not classified as a Carcinogenic, Mutagenic or Reprotoxic (CMR) substances by the Classification, Labelling and Packaging Regulation (CLP); and
- the manufacturer has the appropriate safety data to ensure the ingredient and the final product is safe.

4.2.2 Carcinogenic, Mutagenic or Reprotoxic (CMR)

In addition to the specific list contained in Annex II of the Regulation, any substance classified as CMR by the Classification, Labelling and Packaging Regulation (CLP) is also prohibited from being intentionally added to a cosmetic product, unless specifically permitted for use in cosmetic products according to the Regulation. These will be listed in Annexes III, IV, V or VI as allowed for use under specific conditions. CMR substances are listed in Table 3.1 of Annex VI to the CLP Regulation.

4.3 Ensuring quality: Good Manufacturing Practice (GMP)

GMP means having procedures in place to ensure that products are prepared in a clean environment and that the products do not become contaminated in production. Microbial contamination can be quite common as many micro-organisms live freely in the atmosphere around us. Contamination of products can lead to degradation and, in severe cases, could cause harm to the consumer.

Companies are presumed compliant with the Regulation if they abide by the International Standard Organisation (ISO) Guidelines on Good Manufacturing Practices ISO 22716. Following ISO 22716 is not a legal requirement: companies are free to use whatever GMP they wish. However, they would be required to demonstrate their own system achieved the same objective as that of the ISO 22716 Guidelines.

4.4 Product Information File (PIF)

According to the Regulation each cosmetic product must have its own PIF containing information about the product. This is a legal requirement and the files are open to inspection by the Competent Authority where the PIF is located.

The PIF must include the following:

- the product description;
- the Cosmetic Product Safety Report;
- details of methods of manufacture in accordance with GMP;
- proof of the effect claimed for the cosmetic product, where justified by the nature or the effect of the cosmetic product; and
- data on animal testing.

Detailed guidance is available from Cosmetics Europe, the European personal care association.

Guidelines on Product Information File (PIF) Requirement, 2011:

https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=85%3Aguidelines-on-product-information-file-pif-requirement-2011&catid=46%3Aguidelines

4.5 Labelling

The labelling requirements for cosmetic products are detailed under Article 19 of the Regulation and are summarised in the following table:

Cosmetics Regulation	Labelling Requirement	Container (a bottle, jar…)	Packaging (a carton, box…)
19.1(a)	EU Address of the Responsible Person	Yes	Yes
19.1(a)	Country of origin*	Yes	Yes
19.1(b)	Declared quantity of contents*	Yes	Yes
19.1(c)	Date of minimum durability*	Yes	Yes
19.1 (c)	Period After Opening (PAO)*	Yes	Yes
19.1(d)	Warning statements and precautionary information*	Yes	Yes
19.1(e)	Batch code	Yes	Yes
19.1(f)	Function of the product* Declaration of the ingredients	Yes	Yes
19.1(g)	Declaration of the ingredients	No**	Yes

Notes:

* Where required

** Ingredient labelling is required on the primary packaging where there is no secondary packaging

4.5.1 Date of minimum durability

Products that remain durable for 30 months or less are required to be labelled with a date of minimum durability.

The Regulation introduces a new symbol for the requirement to label the date of minimum durability. Companies have now the choice to either using the words: "*best used before the end of*" or the hourglass symbol.

4.5.2 Period after Opening (PAO)

A product that remains durable for more than 30 months may be required to be labelled with a PAO if, after its opening, the deterioration of the product may lead to harm to the consumer.

An indication of PAO is not relevant for:

- products presented in containers where there is no possibility of contact between the product in the container and the external environment (e.g. aerosols);
- single-use products, which are designed to be used only once (e.g. samples); and
- products for which the manufacturer has assessed that there is no risk of deterioration impacting the safety following the first use by the consumer.

To label the PAO the 'open jar' symbol followed by the period in months or years can be used. The period of time can be inside or alongside the symbol. The industry practice it to label the period in months only ,indicated by an uppercase 'M'.

4.5.3 Ingredient labelling

The purpose of the ingredient listing on a cosmetic product is to provide the consumer with information in the case of known allergies to any ingredients. All ingredients added to the product should be listed. Perfume and aromatic compositions do not need to be fully disclosed and shall be referred to by the terms 'parfum' or 'aroma'. However, certain fragrance ingredients must also be labelled individually even if they form part of a perfume composition or essential oil in addition to 'parfum' or 'aroma'. These 26 potential allergens are listed in Annex III of the Regulation. The threshold levels for declaration are 0.001% for leave-on products and 0.01% for rinse-off products.

For example, a lavender shower gel would be labelled with 'parfum' and if it contains any of the potential fragrance allergens listed in Annex III, for example linalool, at a concentration above 0.01%, then linalool must also be labelled in the ingredient list.

The ingredient list should start with the word 'INGREDIENTS' in upper or lower case and then follow with each ingredient in descending order of weight. However, ingredients of less than 1% may be listed in any order after those of 1% or more. Colouring agents may be listed in any order after the other ingredients using their Colour Index (CI) number.

This listing must use the common name published in the International Nomenclature for Cosmetic Ingredients known as the INCI name. In the absence of an INCI name, companies can use an alternative as listed below:

- the International Cosmetic Ingredient Dictionary and Handbook published by the Personal Care Product Council (PCPC);
- chemical name;
- European Pharmacopoeia name;
- international non-proprietary name as recommended by the World Health Organisation; or
- EINECS, IUPAC or CAS identification reference.

All ingredients present in the form of nanomaterials shall be indicated in the list of ingredients immediately following the INCI name of the ingredient in question. This is done by adding '(nano)' after the ingredient name.

For decorative cosmetics marketed in several colour shades, all colouring agents used in the range may be listed preceded by the words 'may contain' or the symbol '+/-'. For example:

INGREDIENTS: Aqua, Cyclomethicone, Mica, Tris-Biphenyl Triazine (Nano), Polybutene, Triisostearin, Prunus Persica, Betula Alba, Paraffinum Liquidum, Propylene carbonate, Methylparaben, Phenoxyethanol, Propylparaben, Lecithin, Alcohol Denat., BHT, Cinnamyl Alcohol, Parfum, Aroma, [+/– CI 15580, CI 45430]

There is no defined listing style for the ingredient list, accordingly it may be linear, portrait, boxed (or not), around the circumference etc., in upper case, lower case or mixed case. However, text must be indelible, legible and visible. Contrasting colours and durability should therefore be considered with care.

The Regulation does not recommend any particular font size but labelling should be easily legible. There is no definition of 'easily legible'. Generally it will mean the information should be of sufficient size which ensures it can be read by a person with normal vision at a distance of about 30cm without having to resort to aids such as magnification.

4.5.4 'Peel-and-read' Label

'Peel and Read' labels have been in common use worldwide for over 25 years, and used by the cosmetics industry for 10 to 15 years, because of the increase in statutory information required on product labels. When using a 'Peel and Read' label, it is advisable to use a symbol to indicate to the consumer that further information is available underneath. By doing so the company is ensuring that the relevant information is visible. There is currently no official symbol.

5. Claims

5.1 Article 20

Article 20 of the Regulation states that "In the labelling, making available on the market and advertising of cosmetic products, text, names, trademarks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have".

In evaluating whether claims are appropriate, it is essential to consider the final impression that the average, well-informed and circumspect consumer would form from the presentation or advertising of the cosmetic product in its proper context. It is therefore very important to address the following questions:

- What is the nature of the claim (or consumer message) to be made?
- Will the available information provide appropriate and sufficient evidence to substantiate reasonable consumer expectations of that claim?
- What are the requirements for quality of tests within the supporting information and does the available information meet the quality criteria?

5.2 Common Criteria

Six Common Criteria for the justification of claims used in relation to cosmetic products have been developed and published as Commission Regulation (EU) No 655/2013 Common Criteria for Justification of Claims. Commission Regulation (EU) No 655/2013 is not aimed at defining and specifying the wording that can be used for cosmetic product claims. The main objective of laying down common criteria is to guarantee a high level of protection for end-users, in particular from misleading claims in relation to cosmetic products. A common approach at the Community level should also ensure better convergence of actions taken by the Member States' Competent Authorities, and prevent distortions in the internal market.

Regulation (EU) No 655/2013 Common Criteria for Justification of Claims

Legal compliance

Claims that indicate that the product has been authorised or approved by a Competent Authority within the community market shall not be allowed. The acceptability of a claim shall be based on the perception of the average end-user of a cosmetic product, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors in the market in question. Claims which convey the idea that a product has a specific benefit when this benefit is mere compliance with minimum legal requirements shall not be allowed.

Truthfulness

If it is claimed on the product that it contains a specific ingredient, the ingredient shall be deliberately present. Ingredient claims referring to the properties of a specific ingredient shall not imply that the finished product has the same properties when it does not. Marketing communications shall not imply that expressions of opinions are verified claims unless the opinion reflects verifiable evidence.

Evidential support

Claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them, including where appropriate expert assessments. Evidence for claim substantiation shall take into account state of the art practices. Where studies are being used as evidence, they shall be relevant to the product and to the benefit claimed, shall follow well-designed, well-conducted methodologies (valid, reliable and reproducible) and shall respect ethical considerations. The level of evidence or substantiation shall be consistent with the type of claim being made, in particular for claims where lack of efficacy may cause a safety problem. Statements of clear exaggeration which are not to be taken literally by the average end user (hyperbole) or statements of an abstract nature shall not require substantiation. A claim extrapolating (explicitly or implicitly) ingredient properties to the finished product shall be supported by adequate and verifiable evidence, such as by demonstrating the presence of the ingredient at an effective concentration. Assessment of the acceptability of a claim shall be based on the weight of evidence of all studies, data and information available depending on the nature of the claim and the prevailing general knowledge of the end-users.

Honesty

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

Fairness

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

Informed decision-making

Claims shall be clear and understandable to the average end-user. Claims are an integral part of products and shall contain information allowing the average end-user to make an informed choice.

Marketing communications shall take into account the capacity of the target audience (population of relevant Member States or segments of the population, e.g. end-users of different age and gender) to comprehend the communication. Marketing communications shall be clear, precise, relevant and understandable by the target audience.

To provide guidance for the application of Commission Regulation (EU) No 655/2013, the Commission published Guidelines. Annex I to these Guidelines provides a detailed description of the common criteria established by Commission Regulation (EU) No 655/2013, including illustrative and non-exhaustive examples of claims. In particular, the EU Commission Guidelines established that "free from" claims should be used for information only and not to denigrate an ingredient legally and safely used. It is also recognised that claiming that a product is compliant with the Regulation is not acceptable. Pre-existing guidance from the Commission says that claims relating to animal testing should be possible. However, the Common Criteria Regulation now specifically covers legal compliance claims and animal testing of cosmetic products and their ingredients has been banned. Revision of the Commission Guidelines relating to animal testing claims in the light of the Common Criteria is expected.

The Responsible Person has a duty to ensure that the wording of the message communicated is in compliance with the Common Criteria and is consistent with the documentation in their possession for supporting the claim. Annex II to the Common Criteria Guidelines provides for best practices specifically related to the type of evidential support used for the justification of cosmetic claims.

5.2.1 Natural and Organic Claims

The terms "natural" and "organic" are not defined in the Cosmetics Regulation and neither are they specifically regulated therein. However, claims must not mislead or misinform the consumer and all claims must comply with the common criteria.

In the absence of a legal definition for natural and/or organic as applied to cosmetic products and their ingredients, standards have been developed by non-mandatory certification bodies. However, these standards differ between different organisations and are not specifically backed by law. Their common aim is to promote the use of a high proportion of organic ingredients, natural ingredients or ingredients chemically derived from natural ingredients in cosmetic products making claims to be natural or organic. Each set of standards applies restrictions on the processing of raw materials allowed and which synthetic ingredients may or may not be used according to that specific standard.

Because the various standards differ, the consumer may find it difficult to make an informed choice. The International Standards Organisation (ISO) is developing standards in this area to ensure a common basis of understanding. The adoption of ISO standards will not prevent any organisation promoting their own standards if they feel such standards offer specific additional benefits but ISO will ensure a common basis for claims for cosmetic products or ingredients claiming to be organic or natural.

Common Criteria Regulation:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.o?uri=OJ:L:2013:190:0031:0034:EN:PDF

Common Criteria guidance:

http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/guide_reg_claims_en.pdf

5.3 Cosmetics Europe Charter

Advertising is an important part of the interaction brands have with their consumers. It is very important therefore that the consumer is given a clear understanding to make informed choices and decisions. The cosmetics industry is committed to acting in a transparent and trustworthy manner. During 2012, the European cosmetics and personal care association, Cosmetics Europe, launched a 'Charter and Guiding Principles on responsible advertising and marketing communication'. Whilst embodying the key principles of advertising – to be legal, decent, honest and truthful - they look in depth at areas that might cause concern such as: airbrushing, taste and decency, advertising to children, as well as respect for the human being.

The Charter and Guiding Principles set out the benchmark for the responsible advertising of cosmetic products in Europe. Cosmetics Europe is actively promoting these across all European countries, tailoring where necessary to reflect national and cultural expectations.

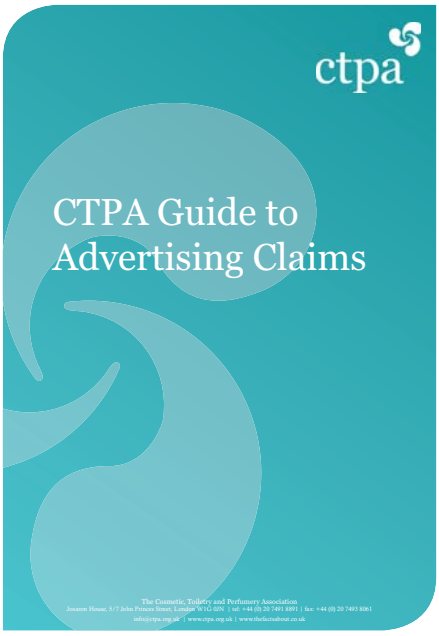
CE Guiding Principles on responsible advertising:

https://www.cosmeticseurope.eu/news-a-events/statements/54-launch-of-the-cosmetics-europe-guiding-principles-on-self-regulation-in-advertising.html

5.4 CTPA Guide to Advertising Claims

The CTPA Guide to Advertising Claims, endorsed by the Advertising Standard Agency (ASA) and Clearcast, was published in 2008. Reference to the Cosmetics Directive has been changed to refer to the Cosmetics Regulation and further revisions are envisaged to incorporate the Common Criteria and the Cosmetics Europe Charter.

http://www.ctpa.org.uk/publications.aspx?pageid=277



6. Notification (European) - CPNP

The Cosmetic Product Notification Portal (CPNP) is the online notification system.

The RPs and, under certain circumstances, the distributors of cosmetic products must submit through the CPNP some information about the products they place or make available on the European market.

The CPNP number is not required to be labelled on the cosmetic packaging.

The European Commission has issued Guidance on the CPNP:

http://ec.europa.eu/growth/sectors/cosmetics/cpnp/index_en.htm

7. Nanomaterials

A material is defined as a nanomaterial under the Regulation if it is considered to be "*an **insoluble** or biopersistant and **intentionally manufactured** material with one or more external dimensions, or an internal structure on the scale from 1 to 100nm*". This definition, given in Article 2 of the Regulation, should be used to determine whether a substance is considered a nanomaterial in the context of the Regulation.

7.1 Colours, preservatives or UV filters

As is the case in general for colours, preservatives and UV filters, nano-forms of these ingredients must be specifically included in the appropriate Annex to the Regulation in order to be used in cosmetic products.

7.2 Notification

All nanomaterials present in a cosmetic product must be indicated in the main product notification made under Article 13, regardless of function. Only materials meeting the nanomaterial definition given in Article 2 should be indicated as being a nanomaterial. No other definition should be applied.

Any product containing a nanomaterial not already regulated in Annexes III, IV, V and VI must be notified under Article 16, in addition to the product notification made under Article 13, six months before placing the product on the market.

7.3 Safety assessment

Specific consideration of particle size should form part of the safety assessment of the product.

7.4 Labelling

See section 4.5.

7.5 Annexes

It should also be noted that an entry in any Annexes III-VI does not include the nano-form of a material unless specifically stated.

8. Serious Undesirable Effects (SUEs)

Serious Undesirable Effects (SUEs) and the number of Undesirable Effects (UE) attributable to a cosmetic product are required to be kept in the PIF. Additionally, the RP and distributors must report a SUE to the Competent Authority of the Member State where the SUE has occurred. A report can also come from a consumer or a healthcare professional.

Article 2 of the Regulation provides definitions of both UEs and SUEs.

Undesirable Effect: an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product

Serious Undesirable Effect: an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death

Guidelines on the reporting SUEs can be found at:

http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance/index_en.htm

8.1 Reporting

The safety assessor needs to consider any SUE as part of the Cosmetic Product Safety Report and therefore will need to be informed when a SUE has occurred.

In case of SUEs attributable to a cosmetic product in the UK, companies should send their form A to their local Trading Standards. If SUEs happen in another Member State the company should send their form A to the relevant national Competent Authority of the Member in which the SUE occurred.

The report must be completed “without delay”. The guidance defines this as 20 calendar days. This is 20 days from when anyone in the company is informed of a possible SUE, or could be reasonably expected to be aware of an SUE.

Important:

This guide does not constitute legal advice and must be read in conjunction with the legal texts as outlined in Section 1. It constitutes industry understanding of the requirements and has been provided as an *aide memoire* to the Regulation as at June 2015.

Further information can be obtained from your local Trading Standards. Find your local Trading Standards Office at: https://www.gov.uk/find-local-trading-standards-office.