

Are you ready for the Cosmetics Regulation?

The new [Cosmetics Regulation EC 1223/2009](#) ('Regulation') is upon us. From 11 July 2013, the Regulation comes into direct effect in the UK and the rest of the European Union ('EU'). The Regulation is intended to harmonise cosmetics and personal care products across the EU.

Dr Rosanna Cooper gives an overview of the key aspects of the Regulation. It aims to protect consumers' health and to give them confidence in cosmetics and personal care products that they purchase, by enabling them to be well informed and be able to monitor the ingredients of such products, especially regarding label claims that are made on such products. Consumers should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products. There are provisions in the Regulation on product safety and safety assessments that must be conducted to show that the products are safe and would not harm human beings. **Animal testing is banned** on any cosmetic products placed on the market in the EU.

The **free movement** of a cosmetic product in the EU is permitted only if it complies with this Regulation.

At a glance

As a manufacturer or supplier of a cosmetic product, there must be compliance with the Regulation:

- **Ingredients** - a cosmetic product must contain a list of ingredients and must not contain prohibitive products. Only certain restricted products such as colorants and preservatives can be contained in a cosmetic product.
- **Labelling** - there are specific labelling requirements under the Regulation for a product label, packaging, advertising, marketing and promotional materials.
- **Notification** - a cosmetic product must be notified before it is placed on the market.
- **Product Information File ('PIF')** - each cosmetic product placed on the market in the EU must have a PIF.

- **Responsible Person** - a responsible person has to be appointed who has a number of responsibilities under the Regulation including, reporting to the competent body if any adverse reactions are reported for the cosmetic product and being in charge of all PIF requirements under the Regulation.
- **Safety** - safety assessments for a cosmetic product have to be conducted and a safety assessment report has to be available for each cosmetic product.
- **Animal Testing** - no animal testing on a finished cosmetic product is allowed.
- **Distributors** - there are certain obligations on distributors under the Regulation.
- **Good Manufacturing Practice** - every cosmetic product must be manufactured in accordance with good manufacturing practice.

What is the definition of a Cosmetic Product?

Under the Regulation, a cosmetic product is defined as:

'...any substance or mixture intended to be placed in contact with the various 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, correcting body odours, protecting them or keeping them in good condition, except where such cleaning, perfuming, protecting, changing, keeping or correcting is wholly for the purpose of treating or preventing disease.'

The Regulation defines a 'cosmetic product intended to come into contact with the mucous membranes' as:

'...[A]...cosmetic product intended to be applied in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs, and does not include any cosmetic product which is intended to come only into brief contact with the skin.'

Meaning of Hair Product

A hair product means a cosmetic product which is intended to be applied on the hair or head or face, except eye lashes.

Meaning of Eye Product

An eye product means a cosmetic product which is intended to be applied in the vicinity of the eyes.

Can Aromatherapy Products be classed as Cosmetic Products?

Certainly, aromatherapy products can be cosmetic products. The determining factor is the intended use of the product, in which case, it could even be classed as a

medicine. A number of aromatherapy products may also fall under the provisions of the [General Product Safety Regulations 2005](#).

Ingredients

A cosmetic product must contain a [list of its cosmetic ingredients](#) on the label and/or packaging (under the heading "INGREDIENTS") in descending order of weight. It is worth noting that the weight of the ingredients will be measured at the time the ingredients are added to the product.

There is a requirement for each ingredient to be [identified by its common name](#), as listed in the International Nomenclature of Cosmetic Ingredients.

In addition, there are substances that are listed in the Regulation that cannot be included in cosmetics products or their uses are restricted:

- **Prohibited substances** such as petrolatum (petroleum), hydro treated or carbon-treated or silicic acid-treated or clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen, certain Colouring agents, Oestrogens, Iodine and Progestogens.
- **Restricted substances** for example thioglycolic acid and its salts, hydroquinone or potassium or sodium hydroxide have to be used in accordance with the restrictions laid down in the Regulation.
- **Colorants** other than those listed in the Regulation and colorants which are listed there but not used in accordance with the conditions laid down in the Regulation, except for hair colouring products. Under the Regulation, colorants mean '*...substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants.*'
- **Preservatives** other than those listed in the Regulation and preservatives which are listed there but not used in accordance with the conditions laid down in the Regulation. Under the Regulation, preservatives mean '*...substances which are exclusively or mainly intended to inhibit the development of microorganisms in the cosmetic product.*'
- **UV-filters** other than those listed in the Regulation and UV-filters which are listed there but not used in accordance with the conditions laid down in the Regulation.
- **Hair colouring products** that contain colorants in accordance with the conditions laid down in the Regulation will be compliant (those hair colouring intended to colour hair fall outside the Regulation).

Labelling

There are specific labelling requirements under the Regulation for a cosmetic product. The label and/or packaging must contain the name and address of the manufacturer or supplier of the product. **All** containers or packaging must bear written information in indelible, easily legible and visible lettering.

In circumstances where the product is manufactured outside the European Economic Area ('EEA'), the country of origin must also be stated on the label and/or packaging.

Product claims

Any label claims for a cosmetic product must be substantiated.

Notification

Before a manufacturer or supplier can place a cosmetic product on the EU market (and for products already on the market) a product notification must be completed with the European Commission central notification system. It is envisaged that each poison centre across Europe would have access to details of a cosmetic product on the market in the EU in the event of the occurrence of poisoning and/or medical incidents involving the cosmetic product.

The notification procedure requires every product placed on the market to be notified to the European Commission using the Cosmetics Product Notification Portal.

http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/cpnp_new_en.pdf. Further guidance is available at

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

Cosmetic Products Notification Portal (CPNP)

There is a duty on a manufacturer and/or supplier of a cosmetic product to notify using **CPNP** the product marketed by the responsible business.

The process is as follows:

- The manufacturer or supplier must first register with the European Commission Authentication Service (ECAS) to obtain a unique login; and
- Details of the product will then be notified via the CPNP, including images of the packaging and details of labelling and formulation.

The 'responsible person' will be able to do one notification in relation to one cosmetic product (for identical items).

Notification by distributor

From 11 July 2013, when a distributor makes available on a national market a cosmetic product already available in another Member State, and for that purpose translates at its initiative the elements of labelling in order to comply with national law, then the distributor is responsible for notification. This simplified notification will be linked in the **CPNP** to the original notification made by the 'responsible person' for the same cosmetic product.

This will allow the competent authorities and the anti-poison centre of the Member State where the distributor has introduced the product, to have access to the complete information related to this product.

Notification of a Cosmetic Product containing Nano materials

There has to be an additional notification for a cosmetic product containing nanomaterials that are not already listed in the Regulation. This has to be done six months prior to placing the product on the EU market.

The list of ingredients for a cosmetic product must contain the nano-form. Under the Regulation, nanomaterial means *'...an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.'*

The notification of a cosmetic product containing nanomaterials is the **responsibility of the 'responsible person'**, except in case of delegation.

Product Information File

The **PIF must contain specific information** including, all ingredients and concentrations of the cosmetic product (except for perfumes, where the name and code number and identity of the perfume supplier is sufficient). The method of manufacture and safety assessment reports for each cosmetic product must be comprised in the PIF.

The PIF is applicable to both new and existing products. The PIF for a new cosmetic product may be retained for ten years. PIFs for products currently on the market must be kept until 11 July 2020.

The name and address of where the PIF can be readily accessible must be stated on the cosmetic product.

Responsible Person

Only a cosmetic product for which a legal or natural person is designated within the EU as 'responsible person' shall be placed on the market. This means that there must be a **'responsible person'** for each product placed on the EU market. In particular, the 'responsible person' must ensure compliance with the Regulation, in particular, requirements relating to human health, safety and consumer information.

A 'responsible person' may be a manufacturer, a manufacturer's agent, a person for whom the manufacturer is making the product, or the first importer of the product into the EEA. A 'responsible person' who is a manufacturer or first importer must possess an *appropriate level of experience or relevant professional qualification(s)*.

A **'responsible person'** may also be an individual within the EU that:

- Manufactures a cosmetic within the EU; or
- Imports a cosmetic product into the EU.

A manufacturer or importer may by **'written mandate'** designate a person established within the EU as its 'responsible person' to carry out all of its legal obligations in relation to the Regulation, including safety assessments, maintenance of product files, registration etc.

There is a huge obligation on the 'responsible person' in relation to a manufacturer, agent or importer putting a cosmetic product on the EU market. For instance, the 'responsible person' must maintain specific information on every cosmetic product that are readily accessible to nominated authorities, (usually Trading Standards in the UK), such as an up-to-date PIF, including the [cosmetic product safety report](#).

If a cosmetic product is being placed on the market from outside of the EU, a 'responsible person' must be designated within the EU for any export into the EU.

The information must be in English or on another language easily understood by the nominated authorities.

Trade secrecy

The 'responsible person' has a choice whether to list all of the ingredients of a cosmetic product or not. The full composition could remain a trade secret by making an application to the [Department for Business Innovation and Skills \(BIS\)](#) for confidentiality.

BIS may allow the 'responsible person' to omit certain ingredients from the list. There is an option to list the omitted ingredient(s) as a registration number instead of a name.

Non-compliance by distributors

Where there is non-compliance, a distributor is required to take all appropriate measures as laid down by the Regulation:

- All corrective actions in bringing a cosmetic product into conformity.
- The withdrawal of the product from the market.
- Recall of the product within a given reasonable time limit, commensurate with the nature of the risk.

Market surveillance

Product traceability is a requirement under the Regulation and in order to ensure such [product traceability](#), a 'responsible person' must identify the distributors of a cosmetic product for a period of three years following the date on which the batch of the cosmetic product was made available to the distributor. All other persons in the supply chain for that cosmetic product must also be identifiable.

Under the Regulation, the 'responsible person' must keep an up-to-date file of all [reported adverse reactions](#) to the cosmetic product and must notify the EU of:

- All serious adverse reactions to the cosmetic product.
- The commercial name of the product.
- Actions taken by the 'responsible person' to remedy the issue (see below).
- The EU will then make the information available to the relevant Member States.

There are measures that the 'responsible person' has to take in case of non-compliance to render the product compliant, including:

- Withdraw of the product from the market; or
- Recall of the product to the manufacturing company in all Member States where the product is on sale

Where the responsible person does not take all appropriate measures, the competent national authority may take the necessary corrective measures. In the event that a cosmetic product which complies with the requirements of the Regulation presents or could present a serious risk to human health, the competent national authority has the authority to take all necessary provisional measures to withdraw, recall or restrict the availability of the product on the market.

Good Manufacturing Practice (GMP)

Under the Regulation, the manufacture of a cosmetic product must comply with GMP. There are standards laid down in the Regulation which a manufacturer can comply with.

Safety Assessment and Safety Assessment Reports

A cosmetic product that is available on the EU market must be safe. A **safety assessment** of a product must be performed and this safety must be demonstrated through a **product safety report**.

Safety assessment of the ingredients of a cosmetic product and how the product will be used must be conducted as a requirement of the Regulation. There must be a Cosmetic Product Safety Report (CPSR) for each cosmetic product held in the PIF. The Regulation gives the details that are required when conducting a safety assessment.

With regard to the **CPSR**, suppliers of raw material may have to provide information under the Regulation.

The 'responsible person' will be allowed under the Regulation to perform one safety assessment and have one product information file in relation to one cosmetic product (for several identical items).

Is it an offence to conduct Animal Testing on a finished Cosmetic Product?

It is an offence to conduct animal testing on a finished cosmetic product to determine whether the product might comply with the Regulation. There are a number of restrictions in relation to animal testing, as follows:

- The testing on animals of the final formulation or any ingredient or combination of ingredients of cosmetic products; and
- The supply of cosmetic products where the final formulation, or any ingredient or combination of ingredients, have been tested on animals is restricted;
- See further restrictions [here](#).

Is it an offence to claim that no Animal Testing has been done on a Cosmetic Product, if this is incorrect?

It is an offence for a manufacturer or supplier to claim that no animal testing has been done on a cosmetic product, if this is in fact incorrect.

It is worth noting that a cosmetic product must not contain any ingredients that have been tested on animals by other manufacturers for the purpose of developing new cosmetic products.

Conclusion

The regulation of a cosmetic product will be carried out centrally. The public will have access to information about a cosmetic product although certain trade secrets may be kept confidential. Nevertheless, consumers will have access to:

- The qualitative composition of the cosmetic product.
- The name code number and supplier of any fragrances in the product.
- Information on any reported adverse reactions.
- The quantitative information on the content of any ingredients.

There is a huge burden on the 'responsible person' to ensure a cosmetic product is compliant under the Regulation.

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