

**LEGISLATION OF COSMETICS IN THE EU**  
**Key Features of Regulation 1223/2009/EU**

DR. G. RENNER

Cosmetics Europe, Brussels, B

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## 1. History and objective of harmonised EU legislation of cosmetics

The Single Market - the term used to describe the free movement of goods, capital, people and services within the Member States of the European Union - is a cornerstone of the European Union. In order for it to work for a specific product sector, there must be similar legislation in place in all the Member States. For example, if a product is to move freely within the European Union, the same labelling, packaging and safety regulations must apply.

In the early 1970's the Member States of the European Economic Community (now called the European Union - EU) decided to harmonise their national cosmetic regulations in order to enable the free circulation of cosmetic products within the Community, on the basis of commonly agreed safety standards. As a result of numerous discussions between experts from all member countries, the Cosmetics Directive was adopted on 27 July 1976 and published in the *Official Journal of the European Communities* (OJEC) on 27 September 1976 with the reference 76/768/EEC.

Although harmonising the legal principles and requirements for cosmetics across the EU, the EU Cosmetics Directive still needed to be transposed into the national legislation of each Member State in order to become the applicable law at local level. This process is slow and not always perfect, i.e. leaving room for (small) national divergence creating additional costs for industry without contributing to product safety. Furthermore, since 1976, the EU Cosmetics Directive was amended seven times<sup>1</sup> and its Annexes updated to technical progress more than 50 times<sup>2</sup>. This resulted in a patchwork of individual pieces of legislation representing over 3500 pages of legal text (in 21 languages) without coherent logical flow and terminology.

In 2007, the EU Commission finally considered the Cosmetics directive as "a piece of EU legislation that is ripe for simplification" and proposed to modernise and simplify it. After intensive stakeholder consultation, the EU Council and Parliament adopted in 2009 the EU Cosmetics Regulation (1223/2009/EU).

The new Regulation confirmed the principle approach of its predecessor and most of its specific requirements but brings them together into one coherent text, using consistent terminology and bringing better compatibility with other pieces of EU safety legislation. There are obviously some new requirements, but the real main change over the EU Cosmetics Directive is in the full level of harmonisation that is achieved by the fact that the EU Regulation is a directly applicable law in all Member States, that no longer requires transposition into national legislation.

More than thirty years of experience with this approach under the Cosmetics Directive have shown that it is effective, safe and meets the needs of 27 EU governments, consumers and industry and remains the principle model under the EU Cosmetics Regulation.

For more information see :

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0049:FIN:EN:PDF>

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<sup>1</sup> An amendment to the Cosmetics Regulation is a fundamental change, involving a lengthy consultation procedure and votes by the Member States and the European Parliament.

<sup>2</sup> An adaptation to technical progress relates to the regulation of ingredients (annexes of the Cosmetics Regulation) and is voted only by the Member States.

## 2. The Philosophy of the Cosmetics Regulation

The philosophy of the Cosmetics Directive is that all products meeting the requirements of the Directive should have **equal** and **immediate access** to the market and should be able to circulate freely throughout the European Union. In the EU, it is strongly believed that for fast moving consumer products, such as cosmetics, an in-market control system (also known as *post-market control*) is more effective than pre-market approval procedures.

Article 9 states:

Member States shall not, for reasons related to the requirements laid down in this Regulation, refuse, prohibit or restrict the making available on the market of cosmetic products which comply with the requirements of this Regulation.

The key principle of the EU Cosmetics Directive is that the person or company who places the cosmetic product on the market is responsible for that product (so called 'Responsible Person'). It is the responsibility of that person or company (usually the manufacturer or the importer) to ensure that the product is safe and in meets the requirements of the Cosmetics Regulation.

Article 4 states:

- 1. Only cosmetic products for which a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market.*
- 2. For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Regulation.*

In order for products to have immediate access to the market, it has to be assumed that they are safe for human use, and that an assessment of this safety has been carried out and is accessible to the competent authorities. This assumption is at the heart of the Cosmetics Regulation.

Article 3 and 10 state:

*A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use ...*

*In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up ...*

There is no pre-market registration for cosmetic products at Member State or EU level. A product may go on the market immediately as long as the manufacturer, importer or distributor is certain that it complies with the requirements of the Regulation. Control of cosmetic products within the EU is assured through an in-market surveillance system. Inspectors appointed at national level visit department stores, supermarkets, small shops and market stalls to check the products being sold. These inspectors may take any product from the market to official laboratories to be tested for compliance with EU regulations. If necessary, they may also have access to the product information together with the manufacturer. In cases where there may be any irregularity, the person or company responsible will be penalised, as explained above.

Article 22 obliges EU Member State Authorities to :

*monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market. They shall perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples. Member States shall also monitor compliance with the principles of good manufacturing practices.*

### 3. The Layout of the Cosmetics Regulation

Chapter	Title	Articles
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### 4. The Scope of the Cosmetics Regulation

The Cosmetics Regulation covers a well-defined product sector. Article 2.1 gives a clear definition of what is meant by a cosmetic product:

*'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;*

The definition is based on three fundamental criteria, which allow a clear delineation of cosmetics against 'neighbouring' products<sup>3</sup>:

- **Physical/chemical form** must be substances or mixtures; articles - even if applied to the skin with a cosmetic function - are not cosmetic products. Substances/mixtures released from an article can be cosmetics (e.g. lotion in a cosmetic wipe)
- **Intended application site** is limited through the definition; the Regulation further specifies 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." (§ 2.2). However, a certain degree of dermal penetration, inhalation or accidental ingestion is acknowledged and accepted.
- **Primary function** must be a cosmetic function; secondary, non-cosmetic functions are acceptable. To determine the primary function, one should consider : *Manufacturer intention, Presentation / Labelling / Advertising / Claims, Mode of action, Composition, Consumer perception*

Consideration (7) of the Regulation provides an illustrative, non limited list of product categories within the meaning of this definition. Products for professional use and products for consumers are treated equally under the Directive.

<sup>3</sup> e.g. pharmaceuticals, medical devices, biocides, toys, food

## 5. Roles and Responsibilities

The Regulation requires the designation, in the European Union, of a Responsible Person for every cosmetic product placed on the EU market. This person must take responsibility to ensure that every cosmetic product it/he places on the EU market complies with all the requirements of the Regulation. Once the product has been put on the market, if any questions about its safety, its packaging or its labelling arise, the responsible person will be considered liable. If it is found that the requirements of the Cosmetics Regulation have not been properly met, this person or company may be penalised. Corrective actions and penalties vary according to the severity of the infraction and are commensurate to the risk that the infraction has created for the consumer. A formal labelling infraction may simply result in a fine and an obligation to correct the label for future productions. Incorrect safety procedures could result in imprisonment. In case of substantiated risk, the product will be immediately removed from the market resulting in bad publicity and lost revenue.

The Responsible Person may be a natural or a legal person. His/its name (or style) and address must be printed on the primary (container) and secondary packaging of each product for which he/it takes responsibility.

The concept of a single person responsible for ensuring compliance with the cosmetic legislation was already a key pillar of the Cosmetics Directive. With the Regulation, the central role of the Responsible Person remains and is further specified.

Depending on whether the product is manufactured or imported in the EU, the Responsible Person can be the manufacturer or the importer or a mandated person. As a default, the manufacturer is the responsible person for products manufactured in the EU and the importer is the responsible person for the products he imports into the EU. In practice, manufacturers and importers have some flexibility to decide who shall fulfil the role of Responsible Person for their products. Under certain circumstances they may mandate any person to assume this role, provided this person is:

- registered and located in the EU;
- adequately mandated;
- in a position to assure compliance under the Cosmetics Legislation including competent authorities' access, as and when appropriate, to the Product Information File at the address mentioned on the cosmetic products by the Responsible Person.
- indicated as the Responsible Person on the label with his name and address

The term 'manufacturer' has a wide definition under the cosmetics legislation and includes the entity which has a product designed or manufactured, and markets that cosmetic product under his name or trademark. Therefore, unless he has explicitly been mandated as such in writing, a contract manufacturer / filler will normally not be considered as the Responsible Person as he is providing services for a third party and not in his own name.

It is the responsibility of the Responsible Person to ensure that every product he/it places on the EU market complies with the requirements of the Cosmetics Regulation. His duties relate to all aspects regulated under the EU cosmetics legislation: Article 3 (safety), Article 8 (good manufacturing practice), Article 10 (safety assessment), Article 11 (product information file), Article 12 (sampling and analysis), Article 13 (notification), Article 14 (restrictions for substances listed in Annex), Article 15 (substances classified as CMR substances), Article 16 (nanomaterials), Article 17 (traces of prohibited substances), Article 18 (animal testing), Article 19(1)(2) and (5) (labelling), Article 20 (product claims), Article 21 (access to information for the public), Article 23 (communication of serious undesirable effects) and Article 24 (information on substances).

The Regulation imposes a general **duty of care** upon distributors and requires that *“in the context of their activities, when making a cosmetic product available on the market, distributors [act] with due care in relation to applicable requirements”* (Article 6(1)). The Regulation specifically points to the distributor’s responsibility to check certain elements of the products’ labelling (Article 6(2)), to ensure appropriate transport and storage conditions for the products (Article 6(4)) and to collaborate with the Responsible Person and the national competent authorities whenever necessary to secure compliance with the Regulation (Articles 6(3), 23 and 26). Under certain circumstances, distributors may take over specific responsibilities, that were originally allocated to the responsible person, if they alter the product (e.g. changes to labelling).

For more information see : Cosmetics Europe Guidelines on Roles and Responsibilities [www.cosmeticseurope.eu](http://www.cosmeticseurope.eu)

## 6. Good Manufacturing Practice

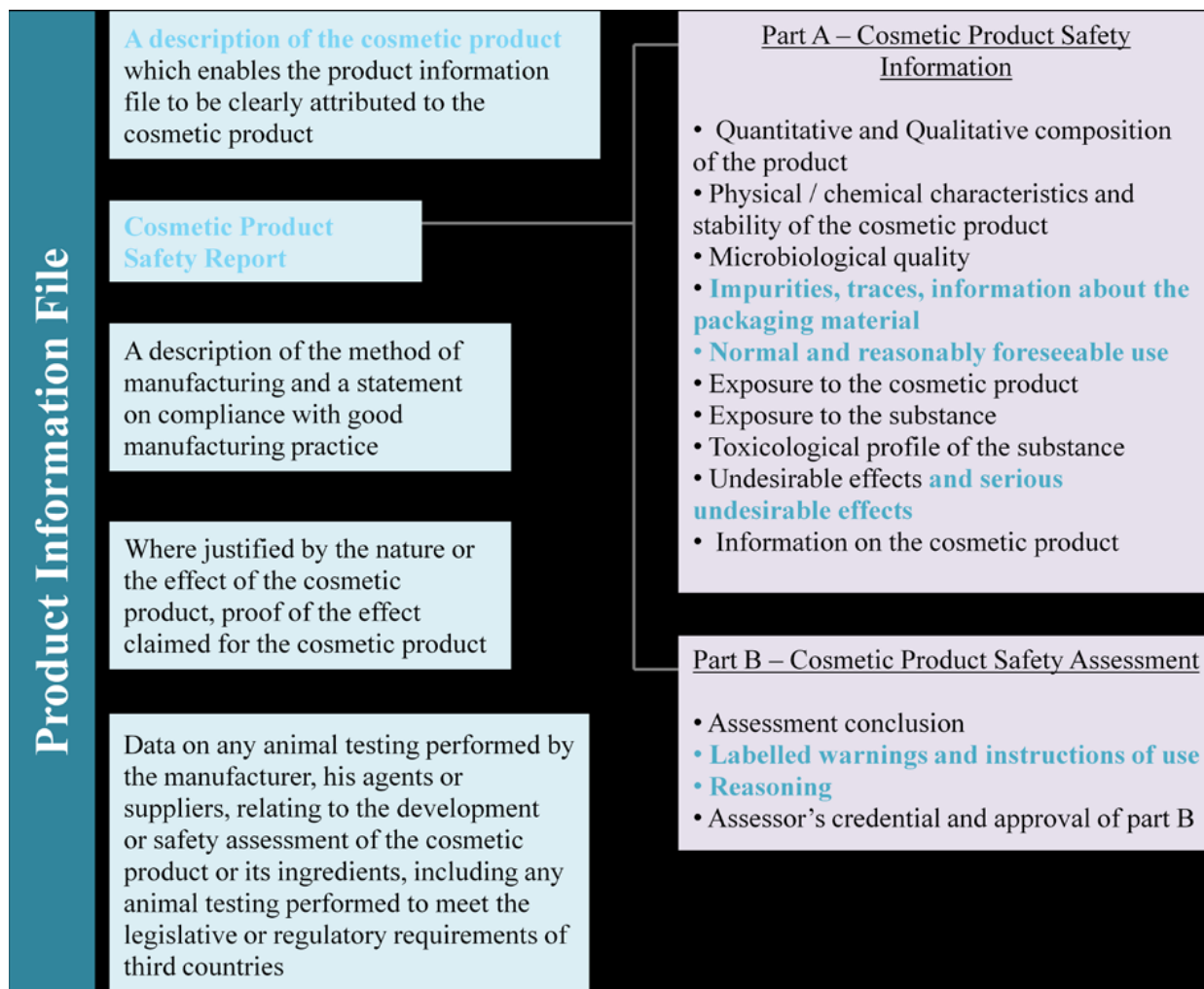
Like under the Cosmetics Directive, Cosmetics placed on the EU market under the Cosmetics Regulation need to be manufactured according to cosmetics-Good manufacturing Practice (cGMP).

The choice of the cGMP is in principle voluntary, but the Cosmetics Regulation provides an incentive to follow the European Standard CEN 22716:2007 (similar to the ISO 22716). If a product follows this standard, which is recognised as a harmonised standard by the EU, it benefits from a presumption of compliance with the Cosmetics Regulation’s cGMP requirement. If another standard is followed, the responsible person may be required to demonstrate that the standard provides an equal or higher level of rigour than the CEN/ISO 22716.

It is not necessary to obtain external, official certification according to the cGMP standard used. It is sufficient for the responsible person to include in the Product Information a statement identifying the cGMP standard that has been used. However, external CGMP audits or formal cGMP certification according to a recognised standard can facilitate cGMP inspections by authorities and reduce the level of detailed proof and documentation that the responsible person would be expected to show as justification of his GMP statement.

## 7. Product Information and Safety Assessment

The requirement for responsible persons to hold specific product and safety information accessible to control authorities was first introduced by the 6th Amendment to the Cosmetics Directive in 1993. The concept and general content of the product information (P.I.F.) are maintained under the EU Cosmetics Regulation, as well as the public availability of part of the information. The main change is the restructure of some of the information, including the safety assessment, into a Cosmetic Product Safety Report (CPSR), as detailed in Annex I of the Regulation. The following diagram is a short summary of the information that needs to be included in the P.I.F. The items that are highlighted in **blue** are new requirements in the Cosmetics Regulation. The items that are in black were already included in the Cosmetics Directive.



The main element of a P.I.F., as required by Article 11 of the Regulation, is the **Cosmetic Product Safety Report (CPSR)**, as described in Article 10 and Annex I.

It is understood that the CPSR is an expert report, made of several components or modules, which may be stored in different databases. The report should contain, as a minimum, all the information indicated by the headings of Annex I to the Regulation, which should be retrievable under those or similar headings for ease of reference of the competent authorities. It is, however, also understood that it may be sufficient that under each heading a clear reference is made to the document, in electronic or other format, which contains the information and which is directly available. The CPSR must be drawn up in a transparent way; it must be well-argued and easily understandable. If any of the information required by Annex I is not provided, this should be duly justified in the CPSR.

Part A of the CPSR aims at gathering the data necessary to clearly identify and quantify, from the identified hazards, the risks that a cosmetic product may present to human health. The hazard may arise, for example, from the raw materials, the manufacturing process, the packaging, the conditions of use of the product, microbiology, quantities used, the toxicological profile of the substances, etc. If data are inadequate to make a proper assessment, the safety assessor may require additional tests to be carried out.

Part B of the CPSR is a safety assessment leading to a conclusion about the safety of the product. The assessment conclusion should be a statement on the safety of the cosmetic product in relation to the

safety requirement of Article 3 of the Regulation. In his or her reasoning, the safety assessor must take into account all hazards identified and the intended exposure conditions of the product. This reasoning is based on the data compiled in part A and takes into account the safety evaluation of substances and/or mixtures (done by the Scientific Committee for Consumer Safety, in case the substances appear in the annexes to the Cosmetics Regulation, by other competent scientific committees or panels or by the safety assessor himself), and the safety evaluation of the cosmetic product.

The safety assessor must be in *possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a Member State*. He does not necessarily need to be based within the EU. It is most obviously in a company's interest that the safety assessment should be sound and supportable. It is recommended that substantial experience – in addition to formal qualifications – may be appropriate for this function to be adequately fulfilled. Training programs on risk assessment exist at European as well as at Member States' national level, some of them particularly focusing on cosmetic products.

The Responsible Person must

- Establish and maintain a Product Information File - available for answering enquiries by control authorities - for all products (new and existing), including imported, professional, promotional gifts
- Ensure that a safety assessment has been performed by a qualified safety assessor
- Keep and update the P.I.F. according to relevant new data
- Open specific parts of the P.I.F. to interested members of the public

The Regulation requires the P.I.F. to be kept in electronic format or any other format (e.g. paper), as long as it is readily accessible to the competent authority in the Member State where the P.I.F. is kept. The text concerning the language used for the P.I.F. states that the information should be easily understood by the controlling officer when he/she comes to verify the P.I.F. in the country where it is kept. Therefore, it is obviously in the interest of the company concerned to make the P.I.F. available in the national language(s) for the country where the P.I.F. is held, unless it has been previously established that the competent authority is equally willing to accept another language. In many Member States, English will be "a language easily understood by the competent authorities".

The point of access to the P.I.F. for the competent authorities is the address of the responsible person specified on the packaging of the marketed product. This address must be indicated on the product, as required under Article 19.1a of the Regulation. This place need not be a manufacturing site. The P.I.F. is accessible in one of the Member States, at the discretion of the responsible person. Should a justified request for information be made by another Member State, such a request is transmitted through the competent authorities of the country where the P.I.F. is accessible. These competent authorities will report the results of their consultation to the competent authority of the EU Member State which made the request. (administrative co-operation procedure, Art. 30 of the Cosmetics Regulation). All the information contained in the P.I.F. is the intellectual property of the Responsible Person (or of other parties, depending on contractual arrangements) and it is to be made readily accessible to the competent authority upon request. Under the Cosmetics Regulation, it should not be expected that an enforcement officer removes from the premises of the responsible person any documents of the P.I.F. However, if there are reasonable grounds to suspect an offence has been committed the officer may have the power to require the responsible person to produce any records relating to his business and seize and detain goods or records.

The P.I.F. is not to be made public. However, some of the information contained in it needs to be made accessible to members of the public upon request :



- The list of ingredients, as labelled on the cosmetic package.
- For those cosmetic ingredients present in the product that are classified as hazardous under Regulation 1272/2008, the use concentration should be indicated. When necessary in order to not compromise commercial secrecy or intellectual property rights, the value can be rounded up, indicated as “<x %” or, alternatively, concentration ranges can be used (x-y%).
- Appropriate information, on a European basis, on the frequency and nature of undesirable effects linked to the product placed on the market in the Member States of the EU. (e.g. number of (serious) undesirable effects per million units placed on the market)

For more information on P.I.F. and Cosmetic Product Safety Report, see

- Cosmetics Europe Guidelines on P.I.F. [www.cosmeticseurope.eu](http://www.cosmeticseurope.eu)
- European Commission Guidelines on Annex I - Cosmetic Products Safety Report (publication expected Q2 2013) : [http://ec.europa.eu/consumers/sectors/cosmetics/index\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/index_en.htm)
- SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (8th revision, 2012) [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm)

## 8. Product Notification

The Cosmetics Regulation introduced a significant simplification of cosmetic product notifications across the EU. The Cosmetics Directive had left the content and processes for product notifications to the discretion of national authorities, leading to a number of different and incompatible notification requirements to competent authorities and poison control centres across the EU.

The Cosmetics Regulation replaces all national product notification schemes by single, central electronic notification requirement at the European Commission, called Cosmetic Products notification Portal. The CPNP makes relevant parts of the notified information available electronically to the competent authorities (for the purposes of market surveillance, market analysis, evaluation and consumer information) and to the poison centres, or similar bodies established by Member States (for the purposes of medical treatment in case of accidental poisoning).

Article 13 of Regulation (EC) N° 1223/2009 lists the information that the responsible persons and, under certain circumstances, the distributors of cosmetic products shall notify through the CPNP about the products they place or make available on the European market.

- Product category
- Product name(s)
- Responsible person - *name and address*
- Country of origin (import only)
- Member State where product is placed on the market
- Details of physical contact person in case necessity
- Nanomaterials – identification, exposure conditions
- CMRs (1A & 1B) – identification
- Original labelling (only once)
- Photograph of original packaging - if reasonably legible (only once)
- Final formulation

For more information see : <http://ec.europa.eu/consumers/sectors/cosmetics/cnpn/>

## 9. Product Composition

EU cosmetics legislation does not impose standards of formulae which constitute, per category, a framework of composition to which the manufacturer must adhere. The approach on ingredient regulation arises from the principle of 'responsible person' and safety assessment. The choice of safe ingredients and use levels is in the primary responsibility of the responsible person (advised by his safety assessor, and subject to in-market control by the national authorities).

For some classes of substances, however, the legislator has identified the need to introduce EU-harmonised restrictions. These are laid down in the Annexes II to VI of the Cosmetics Regulation, providing a set of lists, limiting the use of some ingredients to guarantee the safety of the final preparation:

**Annex II** lists substances which may not be used;

**Annex III** lists substances which may be used subject to certain conditions and restrictions;

**Annex IV** is a positive list of colouring agents (currently still excluding hair dyes);

**Annex V** is a positive list of preservatives; and

**Annex VI** is a positive list of UV filters.

The Annexes of the EU Cosmetics Directive are normally updated once a year. However, if there is a really urgent safety matter, it may occur more often. The methodology for adding new cosmetic ingredients to the existing positive lists or for modifying the current restrictions for ingredients already listed is the following:

- prepare a file (complete toxicological data, according to SCCS Guidelines requirements) as well as a standardised summary (abbreviated form of the safety data available in the form of toxicological reports from testing laboratories or of information coming from the literature or databases or of reports of clinical studies) ==> file + summary = full dossier
- the full dossier is submitted to the appropriate department at the European Commission
- European Commission transmits the full dossier to the SCCS - the scientific advisory body of the European Commission
- SCCS refers the dossier to its subgroup dealing with this type of ingredient for evaluation and opinion which is then discussed by the full committee before being approved. Their opinion is then transmitted to the Commission
- final SCCP opinion is discussed at the AHWP (Ad Hoc Working Party: working group notably composed of the Ministry of Health representatives of the Member States, of industry delegations including Cosmetics Europe and of a delegation representing European consumers)
- if SCCS opinion is accepted by AHWP, European Commission drafts a proposal to include the new ingredient/new restrictions for an ingredient in the Annexes of the Cosmetics Regulation
- proposal is then approved by the COSCOM (Standing Committee on Cosmetics for Adaptation to Technical Progress, same membership as for AHWP but without industry or consumer representatives)
- if proposal is accepted, European Commission finalises the amendment and publishes it in the *Official Journal of the European Communities* (OJEC) with appropriate transition times.

However, via the Safeguard Clause (i.e. Article 27 of the EU Cosmetics Regulation), a Member State can temporarily and immediately ban the a product for presumed serious health risk. In this case, the State has to inform the Commission and the other Member States, providing them with the precise reasons. The Commission has to evaluate whether the national measure was justified (and be applied across the EU) or not (and be repealed).

Two classes of ingredients have additional regulatory requirements :

- Article 15 states that substances classified as CMR (carcinogenic, mutagenic or toxic for reproduction) under EU Chemical legislation are banned for use in cosmetics as soon as their chemical hazard classification becomes applicable. Exemptions can be granted based on certain conditions (no suitable alternatives, demonstrated safety, compliance with food law) but they need an implementing act under the Cosmetics Regulation which must be completed in time before the automatic ban enters into force.
- Article 16 introduces specific requirements for products containing nanomaterials (see next chapter)

## 10. Nanomaterials

While the Cosmetics Directive did not specify any requirement with regard to nanomaterials, the legislator introduced several articles into the Regulation that have implications for products containing nanomaterials. Many of the practicalities of the requirements are still to be decided. Discussions at the European Commission are continuing. This chapter will be updated and elaborated in light of the outcome of these discussions.

To clarify which ingredients and products are subject to the Regulation nanomaterial requirements, a “nanomaterial” must be defined. The definition of nanomaterial, for the purposes of the Cosmetics Regulation, is provided under Article 2.1 (k) as:

*“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”*

To aid cosmetic companies in their decision whether or not an ingredient falls under the regulatory definition, in October 2011 (revision January 2012) Cosmetics Europe issued general guidance “INTERPRETATION OF THE DEFINITION OF THE TERM “NANOMATERIAL” ACCORDING TO THE EU COSMETIC REGULATION 1223/2009”.

Article 16 of the Regulation introduces the requirement for the responsible person (or a delegate) to notify to the Commission cosmetic products containing certain nanomaterials. This is separate and in addition to the CPNP (Article 13) notification and needs to be carried out six months in advance of placing the product on the market. However, the notification can be made using the CPNP Webportal. The six-month prenotification allows the European Commission to identify whether the use of the nanomaterial raises particular concerns and the placing on the market of the product should be discouraged.

The information that should be submitted is listed in the Regulation Article 16 :

- the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI;
- the specification of the nanomaterial including size of particles, physical and chemical properties;
- an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;
- the toxicological profile of the nanomaterial;

- the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;
- the reasonably foreseeable exposure conditions

The European Commission has issued a manual for this notification which can be found here : [http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/cpnp\\_16\\_user\\_manual\\_en.pdf](http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/cpnp_16_user_manual_en.pdf)

Products containing nanomaterials that are used as colorants, preservatives or UV filters, and which therefore need to be listed on annexes IV to VI to be allowed for use, are never subject to the nano-notification requirements, irrespective of the size of these ingredients. In these cases the positive listing supersedes the need for nano-notification. Products containing ingredients listed on annex III in the form of a nanomaterial need not be notified.

A new requirement introduced by the Regulation is the obligation to inform the consumer when nanomaterials, are used in cosmetic products. To this end, the suffix “nano” shall be placed after the INCI name of the ingredient concerned. The requirement applies to all nanomaterials without exception. (see chapter below on labelling).

This labelling is meant to enable consumers to make an informed choice whether or not to use products containing nanomaterials, but has nothing to do with the safety of the product, nor is it a warning. The Scientific Committee on Consumer Safety (SCCS) has published guidance on the safety assessment of nanomaterials in cosmetics:

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_s\\_005.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf)

## **11. Animal Testing and Alternative Methods**

The Cosmetics Regulation provides the regulatory framework for the phasing out of animal testing for cosmetics purposes. It establishes a prohibition to test finished cosmetic products and cosmetic ingredients on animals (testing ban), and a prohibition to market in the European Union finished cosmetic products and ingredients included in cosmetic products which were tested on animals for cosmetics purposes (marketing ban).

A testing ban on finished cosmetic products applies since 11 September 2004; a testing ban on cosmetic ingredients or combination of ingredients applies since 11 March 2009. A marketing ban for products containing ingredients tested outside the EU applies since 11 March 2013, irrespective of the availability of alternative non-animal tests.

It is important to note that the bans cover tests that were carried out after these deadlines and were « carried out in order to meet the requirements of the Cosmetics Regulation». In March 2013, the EU Commission clarified in a communication the situation of tests made in other fields of legislation or to carried out to meet requirements of the third countries' legislation :

- Animal tests performed after 11 March 2013 on ingredients exclusively used in cosmetic products would trigger the bans
- Animal data generated to comply with third country cosmetics regulations do not trigger EU bans but cannot be relied on in the EU safety assessments
- Use of non-cosmetics data, generated for EU- and non-EU regulatory regimes is allowed
- No derogative scheme for new cosmetics-unique ingredients
- Current Member State derogation scheme for existing ingredients remains available

## 12. Consumer Information/ Labelling

The information that must be printed on cosmetic product labels (containers and packaging) is regulated under Article 19 of the Cosmetics Regulation. New requirements introduced by the Regulation are a symbol for “date of minimum durability” (Annex VII, point 3) and the indication of ingredients present in the form of nanomaterials. The Regulation also acknowledges that a “period after opening” is not required when the concept of durability after opening is not relevant: for single-use products, products presented in containers that do not allow contact between the product and the external environment and products for which there is no risk of deterioration that could lead to non-conformity of the product with the safety requirements of the Regulation. Labelling requirements apply to all cosmetic products, be they sold in shops, through vending machines, by mail order, via the internet, applied by professionals, or made available in hotels, spas etc. The following table contains an overview of the compulsory labelling requirements of the Regulation:

Article	Requirement
Art 19.1(a)	Name or registered name and the address of the responsible person
Art 19.1(a)	Country of origin for cosmetic products imported into the EU
Art 19.1(b)	Nominal content at the time of packaging by weight or by volume. <i>Exceptions: for pre-packaged items, number of items if weight or volume are not relevant; packaging containing less than five grams or five millilitres, free samples and single-application packs</i>
Art 19.1(c)	Date of minimum durability preceded by an hourglass symbol or the words: ‘best used before the end of’. Indication of the date of minimum durability is not mandatory for products with a minimum durability of more than 30 months. For such products except where the concept of durability after opening is not relevant an indication of the period of time after opening has to be indicated for which the product is safe and can be used without any harm to the consumer. This information shall be indicated by an open jar symbol, followed by the period (in months and/or years, but usually in months as “x M”);
Art 19.1(d)	Information regarding possible precautions to be observed in use. Note especially the compulsory information listed in Annexes III to VI.
Art 19.1(e)	Batch number or reference to identify the final cosmetic product. When products are too small, such information need appear only on the packaging.
Art 19.1(f)	Function of the cosmetic product, unless it is clear from its presentation
Art 19.1(g)	List of ingredients (INCI). May be indicated on the packaging only. Must be preceded by the term ‘ingredients’.

Note that for cosmetic products packaged in aerosol dispensers there are additional requirements specified by Directive 75/324/EEC

The Regulation refers to two types of packaging for cosmetic products:

- the **container** (also known as primary package or inner package) is the packaging designed to come into direct contact with the product;
- the **packaging** (also known as secondary package or outer package) is the packaging designed to contain one or more containers, including protective materials, if any.

The information required by Article 19.1, items (a) to (f) of the Regulation must appear on the label of both the container and the packaging of each individual cosmetic product. The list of ingredients (Article 19.1 item (g)) may be printed on the packaging only.

Except for the ingredient list, the language of the information printed on a cosmetic product's label shall be determined by the law of the Member State where the product is made available to the end user. The list of ingredients shall be expressed in INCI (as published in the Official Journal of the European Union). In the absence of an INCI name, a term as contained in a generally accepted nomenclature can be used.

In particular cases (e.g. small packaging), the information may not have to be indicated or can be made available to the consumer by other means.

For more information see : Cosmetics Europe Labelling Guidelines at [www.cosmeticseurope.eu](http://www.cosmeticseurope.eu)

### 13. Claims / Misleading Advertisement

Article 20 of the Regulation prohibits text, names, trade marks, pictures and figurative or other signs that are used to imply that a product has characteristics or functions which it does not have. A very similar requirement existed already under the Cosmetics Directive.

Furthermore, where justified by the nature or the effect of the cosmetic product, the Product Information File needs to contain proof of the effect claimed for the cosmetic product.

The European Commission is obliged to establish an action plan on claims for cosmetics, including adoption of a list of common criteria for claims and a report the European Parliament and Council in 2016. Based on the findings the Commission shall then take further measures to ensure compliance, if necessary.

The following common criteria for claims were identified by the Commission and will be formally published in Q2 2013 as a EU Regulation together with more detailed guidance, examples and a guideline on best practice for claim substantiation

( [http://ec.europa.eu/consumers/sectors/cosmetics/regulatory-framework/index\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/regulatory-framework/index_en.htm) ) :

- Legal compliance
- Truthfulness
- Evidence support
- Honesty
- Fairness
- Allow informed decisions

At a later stage additional criteria for certain categories/types of claims can be envisaged where the common criteria prove to be insufficient. However, the Regulation does not foresee a positive/negative list approach on claims.

## 14. Market Surveillance / Cosmetovigilance

The EU Cosmetics Regulation requires products “to be safe”, but this does not mean a “zero risk” approach. Even after a state of the art safety assessment, a small proportion of consumers will inevitably experience undesirable effects when using a product. Such products are still considered safe if the rate / nature of the undesirable effects remains within acceptable limits.

Undesirable effects from normal use of cosmetics are generally local (itching/ burning, irritation, allergic skin reaction), transient and successfully addressed by patient self-management without medical intervention. Very rarely, more serious effects may occur – but do not necessarily mean that the products are unsafe. Concerns arise if the type or frequency of reactions create a safety signal.

- «Undesirable effects» are defined as adverse reactions for human health attributable to the normal or reasonably foreseeable use of a cosmetic product
- «Serious undesirable effect» are defined as undesirable effects which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies, or an immediate vital risk or death

The Cosmetics regulation requires that non-serious cases need to be recorded as summary information in the product information file (P.I.F.). Serious undesirable effects need to be actively reported to the authorities :

### **Who ?**

*Responsible Person (and Distributor)*

### **What ?**

*All SUE cases , except those classified as “excluded”*

### **Where ?**

*Country where serious undesirable effect occurred*

### **When ?**

*Initial report : Without delay (understood as calendar 20 days)*

*Follow-up report : When new relevant information is obtained*

### **How ?**

*Standardised reporting forms, following EU Commission Guidelines*

European Commission, with Member States and Industry has developed **guidance and template report forms** [http://ec.europa.eu/consumers/sectors/cosmetics/documents/guidelines/sue\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/documents/guidelines/sue_en.htm) addressing:

- Causality Assessment method
- Scope of notification of SUEs
- Requirements for notification and transmission of SUEs
- Principles of interaction between the Responsible Person, Distributor and National Competent Authority
- Subsequent actions by Responsible Person and Competent Authority