

COMPLIANCE WITH REGULATION
1223/2009 ON COSMETIC PRODUCTS

COSMETICS EUROPE GUIDELINES ON THE
PRODUCT INFORMATION FILE (P.I.F.)
REQUIREMENT

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I. INTRODUCTION

Regulation (EC) n°1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products (the “Cosmetics Regulation” or the “Regulation”) was published in the Official Journal of the European Union on 22 December 2009 (OJEU, L 342, p. 59). The Cosmetics Regulation will replace Directive 76/768/EEC (the “Cosmetics Directive” or the “Directive”), which has been governing the composition, labelling and packaging of finished cosmetic products in the European Union since 1976. This replacement will be fully effective on 11 July 2013 when all provisions of the Regulation become enforceable.

With more than 30 years of existence, the Directive had undergone numerous amendments and technical adaptations and was no longer considered as meeting the highest standard of good regulation in terms of clarity, consistency and user-friendliness.

The Cosmetics Regulation is a recast of the Cosmetics Directive and does not introduce fundamental changes to the product information requirements of the Directive.

The requirement for cosmetic manufacturers and importers to hold product information was first introduced by the 6th Amendment to the Cosmetics Directive (Directive 93/35/EEC). The 7th Amendment (Directive 2003/15/EC) introduced further requirements related to:

- ❑ the safety assessment of cosmetic products for children and of products for external intimate hygiene
- ❑ data on animal testing, and
- ❑ information on product composition and on undesirable effects to be made easily accessible to the public.

The Regulation goes further with the introduction, for the first time, of the wording “Product Information File” (the P.I.F.), under its Article 11:

[...] When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market. [...]

The concept and general content of the product information are maintained, as well as the public availability of certain 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. This Annex consists of the Cosmetic Product Safety Information (Part A) and the Cosmetic Product Safety Assessment (Part B), which combines all safety-related product information.

This document has been produced by Cosmetics Europe to facilitate industry’s compliance with the P.I.F. requirement. It is aimed at all companies manufacturing cosmetics within the EU and all companies importing cosmetics from outside the EU. This document provides guidance on how industry can meet this requirement in a pragmatic way by providing coherent and professional support.

Above all, it should be remembered that Article 3 of the Regulation remains the fundamental requirement to make safe products available on the market. The text of this Article reads:

[...] A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

- (a) presentation including conformity with Directive 87/357/EEC;*
- (b) labelling;*
- (c) instructions for use and disposal;*
- (d) any other indication or information provided by the responsible person defined in Article 4.*

The provision of warnings shall not exempt persons defined in Articles 2 and 4 from compliance with the other requirements laid down in this Regulation. [...]

The ultimate responsibility for ensuring compliance with these legal requirements lies with responsible persons operating within the EU market.

II. DEFINITIONS

To clarify the context in which certain words and expressions are used, the following definitions are given below. Some definitions are official (included in the Cosmetics Regulation) and for these the number of the relevant Article is indicated; some definitions are not official and are provided for clarification.

Cosmetic product: 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. *(Art 2.1 (a))*

Substance: a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. *(Art 2.1 (b))*

Mixture: a mixture solution or solution composed of two or more substances.
(Art 2.1 (c))

Manufacturer: any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark. *(Art 2.1 (d))*

Distributor: 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. (*Art 2.1 (e)*)

Making available on the market: any supply of a cosmetic product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge. (*Art 2.1 (g)*)

Placing on the market: the first making available of a cosmetic product on the Community market. (*Art 2.1 (h)*)

Importer: any natural or legal person established within the Community, who places a cosmetic product from a third country on the Community market. (*Art 2.1 (i)*)

Harmonised standard: a standard adopted by one of the European standardisation bodies listed in Annex 1 to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services on the basis of a request made by the Commission in accordance with Article 6 of the Directive N°1223/2009. (*Art 2.1 (j)*)

Responsible person: a legal or natural person based within the Community who is responsible for the placing on the EU market of a cosmetic product and who has been designated as such. The responsible person shall ensure compliance with the relevant obligations set out in the Regulation. (*Art.4 1 and 4.2*). The responsible person can be one of the following:

- Manufacturer within the EU
- Person designated by a manufacturer from outside the EU
- Distributor if he modifies a product already on the market in such a way that compliance with the Regulation may be affected (according to Article. 4.6) or if he places a cosmetic product on the Community market under his name or trademark
- Importer(s) (according to Article 4.5)
- Third party with a written mandate from manufacturer or importer.

Additional information on the identification of the Responsible Person can be found in Cosmetic Europe's Guidance Document on Roles & Responsibilities along the supply chain.

Safety Assessor: a natural person who carries out the cosmetic product Safety Assessment, and who is 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 similar discipline, or a course recognised as equivalent by a Member State. (*Art 10.2*)

Product Information File (P.I.F.): the information needed to meet the requirements of Article 11 of the EC Regulation.

Readily accessible: The P.I.F. shall be accessible to the competent authority of the Member State where the P.I.F. is kept, in electronic or other format and in a language which can be easily understood by the competent authority.

The P.I.F. should be available to control officers at the address of the responsible person labelled (or, in case of several addresses, highlighted) on the product, within a reasonable time period. The expectation by authorities may differ whether the control is part of a routine inspection, which is typically announced at last some days in advance, or whether it is triggered by an immediate health concern over a product on the market, in which case an inspection can be spontaneous. Whilst many



items may be rapidly accessible through electronic media, there may be a short delay when information is accessed by other means.

Place of manufacture: any premises where cosmetic products are manufactured, including premises where processing and filling in containers of cosmetic products take place. This includes filling of sachets and free samples. It also includes contract manufacture and private label manufacturing operations. A product that is part-manufactured outside the EU (e.g. concentrate manufactured in a non-EU state) is still subject to a manufacturing process within the EU if it is diluted, and/or filled and assembled into primary packaging in the EU.

Undesirable effect: an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product. (*Art 2.1 (o)*)

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. (*Art 2.1 (p)*)

Competent authority: national authority, designated by the respective Member State, in charge of the application and enforcement of the Regulation.

Good Manufacturing Practice (GMP): guidance that outlines the aspects of production and testing that can impact the quality of products. GMP guidelines are not prescriptive instructions on how to manufacture products; they are a series of general principles that must be observed during manufacturing.

Cosmetic Product Safety Report (CPSR): part of the Product Information File, documentation showing that a safety assessment has been conducted. The CPSR shall, as a minimum, contain the information requested in Annex I of the Cosmetics Regulation.

III. QUICK GUIDE TO ESTABLISHING A P.I.F.

This chapter provides an outline of responsibilities, tasks and requirements relevant to establishing a P.I.F.

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.

Product Information File

A description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product

Cosmetic Product Safety Report

A description of the method of manufacturing and a statement on compliance with good manufacturing practice

Where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product

Data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries

Part A – Cosmetic Product Safety Information

- Quantitative and Qualitative composition of the product
- Physical / chemical characteristics and stability of the cosmetic product
- Microbiological quality
- **Impurities, traces, information about the packaging material**
- **Normal and reasonably foreseeable use**
- Exposure to the cosmetic product
- Exposure to the substance
- Toxicological profile of the substance
- Undesirable effects **and serious undesirable effects**
- Information on the cosmetic product

Part B – Cosmetic Product Safety Assessment

- Assessment conclusion
- **Labelled warnings and instructions of use**
- **Reasoning**
- Assessor's credential and approval of part B

III.1 Responsibilities within the P.I.F.

The following persons carry responsibilities in the context of the P.I.F. requirement:

- the responsible person;
- the safety assessor;
- the distributor.

Duties of the responsible person with regard to the P.I.F.:

- ensure that a cosmetic product placed on the EU market is safe for human health under normal or reasonably foreseeable conditions of use;
- maintain specific information on the product that he places on the market, as specified under Article 11 of EU Cosmetic legislation P.I.F.;
- be in a position to demonstrate upon request that the product he has placed on the market meets the requirements laid down by the EU cosmetics legislation (Article 5.3);
- ensure that the Cosmetic Product Safety Assessment has been performed by a safety assessor, i.e. a person with appropriate qualifications and expertise considering the specific requirements described in Chapter IV.2 of this document and in Annex I of the Regulation;
- keep the product's safety assessment as well as the data upon which it is based as part of a "Cosmetic Product Safety Report" in the P.I.F. and update it in view of additional relevant information generated subsequent to placing the product on the market (Article 10.1(c) of the Regulation);
- ensure that he has a P.I.F. available in order to answer the enquiries made by the competent authority where the P.I.F. is kept and to bring evidence that the product is in compliance with the Regulation;
- be the first point of contact for the enforcement authorities should there be any enquiry on the product he has placed on the market.

Duties of the distributor with regard to the P.I.F.:

- collaborate with the responsible person and the national competent authorities whenever necessary to ensure compliance with the Regulation (Articles 6(3), 23 and 26); for further details, please refer to the Cosmetics Europe guidelines on Roles & Responsibilities along the supply chain.

Duties of the safety assessor with regard to the P.I.F.:

- assess the safety of the cosmetic product before it is placed on the market;
- depending on his contractual agreement with the responsible person, the safety assessor may also have to:

- gather all the necessary information to document the safety assessment as laid down in the Cosmetics Regulation (Annex I);
- collaborate with the responsible person to ensure that the safety assessment is readily accessible to the competent authority and kept up to date.

III.2 Products for which a P.I.F. must be kept

Article 11.1 reads:

“When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it.”

For every product that falls within the definition of a cosmetic product (Article 2 (1)(a)) and that is placed on the EU market, the responsible person must gather specific information, keep it and make it accessible to the competent authority of the Member State where the P.I.F. is kept.

Article 11.4 reads:

“The requirements provided in paragraphs 1 to 3 of this Article shall also apply to cosmetic products that have been notified under Directive 76/768/EEC.”

The P.I.F. requirements of the new Cosmetics Regulation apply equally to new products and to existing products that continue to be placed on the EU market as of 11 July 2013. The P.I.F. for existing products needs to be revised and made accessible in its new structure from this time (also see chapter III.4).

The European Commission recommends that companies begin to revise existing product information as early as possible to ensure compliance with the new Regulation. To prevent further rework, it is also recommended that the P.I.F. for new products be prepared according to the new requirements (for further guidance on this, please see Chapter III.8).

III.3 The information required

Article 11 of the Regulation specifically defines the information that needs to be contained in the P.I.F.. In addition, the Regulation states that the data within the P.I.F. shall be updated as necessary. Briefly, the P.I.F. must contain the following 5 types of information:

- Product description (Article 11.2.a)
- Cosmetic Product Safety Report (Article 11.2.b)
- Method of manufacture and a statement of GMP compliance (Article 11.2.c)
- Proof of effect for the product (Article 11.2.d)
- Data on animal testing (Article 11.2.e)

In general, no major content changes have occurred between the Cosmetic Directive and the Cosmetic Regulation.

III.3.a Product Description

Article 11.2.(a) reads:

“a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;”

The text of Article 11.2 of the Regulation differs from the text in the Cosmetics Directive. The emphasis of Article 11.2 is on clearly relating the finished product with the P.I.F.. The P.I.F. should include the product name, code name, identifying code or any other product identifier that would enable the responsible person or competent authority to attribute the P.I.F. to the cosmetic product placed in market. For example, formula numbers or code numbers used during the development of the product should be cross-referenced with the product name or other identifier.

III.3.b The Cosmetic Product Safety Report

Article 11.2.(b) reads:

“the cosmetic product safety report referred to in Article 10(1);”

Article 10.1 reads:

“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 in accordance with Annex I.”

Article 10 describes the new structure and content for the safety assessment of a cosmetic product placed on the market. Because the safety assessment is more explicit with regard to content and structure in the new Regulation (Annex I), a separate guidance document has been devoted to this section. Please see section IV.2 of this document for more detailed information.

III.3.c Method of Manufacture and Statement of GMP Compliance

Article 11.2.(c) reads:

“a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;”

Article 8 states that:

- (8.1) *“The manufacture of cosmetic products shall comply with good manufacturing practice with a view to ensuring the objectives of Article 1.”*
- (8.2) *“Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonised standards, the references of which have been published in the Official Journal of the European Union.”*

In this section of the P.I.F., a brief overview of the method of manufacture including bulk storage and filling for the manufacturing site(s) concerned is expected. There should be a summary of the process and a cross-reference to the detailed manufacturing documentation within any specific manufacturing site.

Article 8 of the Cosmetics Regulation requires that the manufacture of cosmetic products complies with cosmetic Good Manufacturing Practice (GMP). Companies must demonstrate compliance by including a statement in the P.I.F. The Cosmetics Regulation does not require external certification to be obtained; only compliance is expected.

Section IV.3 of this guidance document has more detailed information relevant to the manufacture.

III.3.d Proof of Effect

Article 11.2.(d) reads:

“where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;”

The requirement in the Cosmetics Regulation remains the same as described in the Cosmetics Directive.

The P.I.F. should contain support information or at least a short summary of the technical support for the claimed effects. The short summary should be cross-referenced to more detailed support information which, however, would not necessarily be held as part of the P.I.F.

III.3.e Animal Testing Data

Article 11.2.(e) reads:

“data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.”

The official text basically remains the same as in the Cosmetic Directive. Thus, the 7th Amendment of the Directive remains the basis for fulfilling this requirement.. The scope of this element of the 7th Amendment should be interpreted taking into account the information that cosmetic companies can be aware of or can reasonably be expected to obtain. For further details, please see section IV.5.

III.4 Timing for establishing a P.I.F.

According to Article 40 of the Regulation, the P.I.F. requirement (Article 11) will apply on 11 July 2013. However, according to article 39, by way of derogation from the Directive, cosmetic products placed on the market before 11 July 2013 may already comply with the P.I.F.-related requirements of the Regulation. In this case, such products need not also comply with Article 7a of the Cosmetics Directive.

As a consequence, companies can choose whether to update the P.I.F. before 11 July 2013. Even if the cosmetic product was notified under the new Regulation between 11 January 2012 and 10 July 2013, the PIF does not have to be compliant with article 11 before 11 July 2013.

In any case, for cosmetic products placed on the market from 11 July 2013, the PIF must comply with requirements of Article 11.

In summary, on 11 July 2013, the following cases must be considered:

Product placed on the market before 11 July 2013 and complying with the Cosmetics Directive	Product placed on the market before 11 July 2013 and complying with the Cosmetics Regulation	Product placed on the market for the first time after 11 July 2013
If the product continues to be placed on the market in the EU as of 11 July 2013: Action required - new P.I.F. must be produced to comply with the Regulation.	P.I.F. complies. No further action is required except when updates to information in the P.I.F. occur.	P.I.F. must be produced according to the Regulation requirements.
If the product is no longer placed on the market in the EU as of 11 July 2013: No action required - P.I. does not need to be replaced with new P.I.F. structure but information must be retained.		
If the product is no longer placed on the market in the EU by the responsible person as of 11 July 2013, but it is made available in the EU by a distributor after 10 July 2013: no action required. Note: if the product is exported and re-imported into the EU from 11 July 2013, this is equivalent to a new placing on the market, and a new or updated P.I.F. is necessary.		

III.5 Format and language of the P.I.F.

Article 11.3 reads:

“The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept.

The information contained in the Product Information File shall be available in a language which can be easily understood by the competent authorities of the Member State”.

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 above advice applies to all the information covered under Article 11.2, points (a) to (e) inclusive (see pages 17 to 23 of these guidelines). However, any supporting documentation, be it laboratory reports, letters or publications will, of course, be retained in the language in which it was written, provided it is an official EU language. It would be disproportionate to translate such documents into the national language. Efforts should be made to assist control bodies by explaining the content of such documents when the need arises.

III.6 Location of and access to the P.I.F.

Article 11.3 reads:

“The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept.”

Thus, 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:

(a) the name or registered name and the address of the responsible person. Such information may be abbreviated in so far as the abbreviation makes it possible to identify that person and his address. If several addresses are indicated, the one where the responsible person makes readily available the product information file shall be highlighted (...).

Each company may choose a single place within the EU where the complete P.I.F. is accessible. This place need not be a manufacturing site.



Where there is more than one address on the packaging of a marketed product, the single point of access to the P.I.F. must be highlighted (e.g. underlined).

In the case of a product manufactured outside the EU, the P.I.F. must be accessible within the EU at the address on the label. If an abbreviated address is used on the label, it must be sufficient to allow the identification of and the access to the undertaking. The address may be abbreviated to a well-known city or town such that the normal postal service will deliver a letter to that address.

As the P.I.F. must be “readily accessible”, authorities will expect that it is made available within a reasonable period of time even if it does not have to be physically kept at the point of access (see the definition of “Readily accessible” in Chapter II).

Should the authorities request additional information, such as further supporting documentation, this may take a few days to be made available.

The support documentation for the P.I.F. may also not necessarily be on company premises, e.g. it could be at the office of a contract laboratory or consultant. It can also be kept outside the EU. If not held on company premises, the accessibility of the documentation has to be assured.

In addition, Art. 30 should be taken into account. It reads:

“The competent authority of any Member State where the cosmetic product is made available may request the competent authority of the Member State where the product information file is made readily accessible to verify whether the product information file satisfies the requirements referred to in Article 11(2) and whether the information set out therein provides evidence of the safety of the cosmetic product.”

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.

Any authority that is given access to such information must keep it confidential. Making the P.I.F. readily accessible does not imply providing copies of any part of the information to control officers. Under Article 5.3, in the exceptional case of a reasoned (i.e. motivated) request from a national competent authority, the responsible person shall provide it with particular pieces of information and documentation necessary to demonstrate that specific aspects of the product are in compliance with the Regulation. However, as Article 5.3 only refers to motivated questions concerning specific aspects, this provision may not be used by national authorities to circumvent the process foreseen in Article 30.

Ownership of all data comprising the PIF, either as hard copy or electronically, remains the property of the responsible person. 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.

III.7 Retention period and updating of the P.I.F.

III.7.a Retention period

Article 11.1 reads:

“The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.”

From 11 July 2013, the responsible person will need to retain the P.I. F. for ten years after the last batch of that product was placed on the market. This requirement only applies to existing products which are still placed on the market as of 11 July 2013 or to any new products placed on the market after 11 July 2013.

Article 38 reads:

“...responsible persons shall continue to keep readily accessible the information collected pursuant to Article 7a of that Directive until 11 July 2020.”

Thus, for products no longer placed on the market as of 11 July 2013, Article 38 applies whereby the information used in the P.I.F. must be retained by the responsible person until 11 July 2020.

III.7.b Updating an existing P.I.F. or establishing a new P.I.F.

Since all the information is readily available, most companies do not assemble printed documents for the P.I.F. as a matter of routine. However, whether retrieving existing ‘living’ data or keeping an assembled paper file, it is important that information is kept up-to-date.

Article 11.2 reads:

“The product information file shall contain the following information and data which shall be updated as necessary:”

If any aspect of the product information changes (e.g. re-formulation, serious undesirable effects, etc.) then the P.I.F. should be updated accordingly.

In some cases, e.g. when the change in formulation is significant, an update might not be sufficient and the responsible person may have to consider creating a new P.I.F.

III.8 Adapting an existing P.I.F. to the new requirements of the Regulation

The concept and general content of the P.I.F. as described in the Cosmetics Directive are maintained in the Regulation.

However:

- the text of the Regulation is more explicit with regard to content and structure;
- all safety-related product information (including safety assessment) has to be combined in a “Cosmetic Product Safety Report”;
- minimum qualifications for safety assessors are clearly defined.

The following table compares the requirements of the Cosmetics Directive with those of the Regulation:

Existing PIF (Cosmetics Directive)	New requirements (Cosmetic Products Regulation)
	Description of the cosmetic product
a) qualitative and quantitative composition of the product; in case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier.	<p>Qualitative and quantitative composition of the product, including chemical name, INCI, CAS, EINECS/ ELINCS, where possible, and their intended function; in case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier.</p> <p><i>To be included in the Cosmetic Product Safety Report, Part A, Cosmetic Product Safety Information (see Annex I of the CPR, Part A, 1).</i></p>
b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product.	<p>Physical and chemical characteristics of the substances or mixtures, as well as of the cosmetic product. The stability of the cosmetic product under reasonably foreseeable storage conditions.</p> <p><i>To be included in the Cosmetic Product Safety Report, Part A, Cosmetic Product Safety Information (see Annex I of the CPR, Part A, 2).</i></p> <p>Microbiological quality (results of preservation challenge tests).</p> <p><i>To be included in the Cosmetic Product Safety Report, Part A, Cosmetic Product Safety Information (see Annex I of the CPR, Part A, 3).</i></p>
c) the method of manufacture complying with the good manufacturing practice.	Description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8
d) assessment of the safety for human health of the finished product,	Cosmetic product safety assessment, consisting of: 1 – Assessment conclusion 2 – Labelled warnings and instructions of use 3 – Reasoning 4 – Assessor’s credentials and approval of part B

	To be included in the Cosmetic Product Safety Report, Part B, Cosmetic Product Safety Assessment (see Annex I of the CPR, Part B).
taking into account the general toxicological profile of the ingredients, their chemical structure and their level of exposure	To be included in the Cosmetic Product Safety Report, Part B, Cosmetic Product Safety Assessment (see Annex I of the CPR, Part A, 7 & 8).
e) the name and address of the qualified person or persons responsible for the assessment.	Name and address of the safety assessor. Proof of qualification of safety assessor. Date and signature of safety assessor. To be included in the Cosmetic Product Safety Report, Part B, Cosmetic Product Safety Assessment (see Annex I of the CPR, Part B, 4).
f) existing data on undesirable effects on human health resulting from use of the cosmetic product.	All available data on undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. Includes statistical data. To be included in the Cosmetic Product Safety Report, Part B, Cosmetic Product Safety Information (see Annex I of the CPR, Part A, 9).
g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.	Where justified by the nature or the effect of the cosmetic product, proof of the effect claimed.
g) data on any animal testing performed by the manufacturer, his agents or suppliers.	Data on any animal testing performed by the manufacturer, his agents or suppliers (...).
	In addition to the above, the following information must be included in the Cosmetic Product Safety Report (see Annex I, Part A): - Impurities, traces, information about the packaging material - Normal and reasonably foreseeable use - Exposure to the cosmetic product - Information on the cosmetic product.

IV. SPECIFIC GUIDANCE ON THE INFORMATION

REQUIRED

IV.1 Description of the cosmetic product:

Article 11.2(a) reads:

a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product.

The description of the product is required to enable the P.I.F. to be “clearly attributed to the cosmetic product”. Therefore, in the case where a product notification has been made (optional until 11 July 2013, compulsory thereafter for both new and existing products still placed on the market), it is recommended to include this product notification reference number in the product description. In addition, and until that time, the exact name of the product should be provided as well as an internal reference that uniquely identifies that product and formulation e.g. a formula card reference. Companies may wish to include any local language names for the product if marketed in other countries, and a description of the product function if it is not obvious from the product name. The product name should be consistent with the name used for notification according to Article 13.

IV.2 Cosmetic product safety report

IV.2.a Cosmetic Product Safety Report

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. The safety report is the responsibility of the responsible person.

The official text of Article 10 reads:

Article 10

Safety assessment

1.

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 in accordance with Annex I.

The responsible person shall ensure that:

(a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;

(b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;

(c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

[...]

3.

study should not be rejected purely on the grounds that it has not been carried out to GLP standards. It is not necessary to repeat such studies merely to meet P.I.F. requirements.

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.

Products intended for children under three years of age and products intended exclusively for external intimate hygiene do require special attention, particularly in light of their specific exposure characteristics.

The safety assessor may be a company employee or a consultant. The safety assessor need not necessarily be based within the EU. Responsible person and safety assessor should work closely together to ensure that the safety of the product is properly assessed, documented and kept up-to-date. The responsible person should gather all the necessary information, as required by either Annex I – Part A or the information should be gathered by the safety assessor himself, at the request of the responsible person. Safety assessors would generally be expected to report to the senior management of a company to preserve the essential independence and objectivity of the safety function. The responsible person must establish structures and processes in order to ensure that the safety assessor is aware of possible changes and information on undesirable effects, as listed above.

In order to enable undertakings, in particular small and medium-sized enterprises (SMEs), to comply with the requirements laid down in Annex I, the Commission, in close cooperation with all stakeholders, will publish appropriate guidelines, as stipulated by Article 10 (1) in its last subparagraph.

Further guidance on the safety assessment of cosmetic ingredients and finished products is provided by the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (7th revision, SCCS/1416/11) and the forthcoming Commission guidance on the Cosmetic Product Safety Report.

IV.2.b Qualifications of the Safety Assessor

Article 10.2 reads:

The cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person 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.

A qualified person with a diploma in a “similar discipline” could be, for example, a veterinarian, a biochemist or a chemist with appropriate background and experience. Further guidance on this is expected from the European Commission.



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 safety assessor need not necessarily be based within the EU.

IV.3 Method of manufacture, statement of compliance with GMP:

Article 11.2(c) reads:

a description of the method of manufacturing and statement on compliance with good manufacturing practice referred to in Article 8;

This would be expected to be a brief overview of the method of manufacture including bulk storage and filling and should be generally applicable to the manufacturing site(s) concerned. There should be a summary of the process and a cross-reference to the detailed manufacturing documentation within any specific manufacturing site.

Article 8 of the Regulation requires that the manufacture of cosmetic products shall comply with cosmetic Good Manufacturing Practices (GMP). The cosmetic GMP and aspects of manufacture should be addressed and cross reference should be made to the full cosmetic GMP documentation at the manufacturing site concerned.

Compliance will be presumed if GMP is in accordance with an established harmonised standard published in the Official Journal of the European Union. A harmonised standard is defined in Article 2.1.j of the Regulation as a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC. One such example is the CEN ISO 22716¹.

Compliance may also be demonstrated in other ways, for example via a reference to industry-recognised standards and codes. However, in such cases, there is no automatic presumed compliance.

The Cosmetics Regulation does not require a certification to be obtained; only compliance is expected. Companies must confirm compliance by including a statement in the P.I.F.

Furthermore, in Article 22 of the Cosmetic Regulation, Member States are explicitly required to monitor compliance with the principles of GMP.

IV.4 Proof of effect claimed;

Article 11.2(d) reads:

¹ Commission Communication in the framework of the implementation of Regulation (EC) N° 1223/2009 of the European Parliament and of the Council on cosmetic products (2011/C 123/04), OJEU C123, 21.04.2011.

where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product..”

claimed for

The P.I.F. should contain the technical data (or cross-references, if the data are not part of the P.I.F.) necessary for substantiating the claimed effect(s).

This concerns any claim made for a cosmetic product, irrespective of the communication medium or type of marketing tool used and irrespective of the target audience (consumers, professionals, etc.).

The choice of the adequate and appropriate way to substantiate a claim remains with the responsible person and depends on the type of product, the packaging, the claims and their context, etc. In cases where the effect is obvious (e.g. lipsticks to colour the lips or shampoos to wash the hair), there is no need to include data on performance in the P.I.F.

Regarding claims on the absence of tests carried out on animals, reference should be made to the European Commission Recommendation of 7 June 2006 (OJEC L 158, 10 June 2006).

In order to assist the cosmetics industry in its compliance with the requirements of the Cosmetics Regulation regarding the efficacy evaluation of cosmetic products, Cosmetics Europe has issued Guidelines for the Evaluation of the Efficacy of Cosmetic Products (2nd rev., 2008). Because the methodologically sound research is essential for the efficacy evaluation, these Efficacy guidelines provide an overview of established testing methodologies.

Specific requirements existing for sunscreen products² :

- Commission recommendation on the efficacy of sunscreen products and the claims made relating thereto. 22 September 2006 (2006/647/EC)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:265:0039:0043:EN:PDF>

- In vivo determination of Sun Protection Factor (SPF) : ISO Standard – ISO 24444-2010.

This International Standard is applicable to products that contain any component able to absorb, reflect or scatter ultraviolet (UV) rays and which are intended to be placed in contact with human skin.

<http://www.iso.org/iso/search.htm?qt=In+vivo+determination+of+Sun+Protection+Factor+&searchSubmit=Search&sort=relevance&type=simple&published=on>

- Cosmetics Europe In vitro Method for Determination of UVA protection, March 2011

<http://www.CosmeticsEurope.eu/publications-CosmeticsEurope-the-european-cosmetic-cosmetics-association/guidelines.html?view=item&id=33>

IV.5 Data on animal testing:

The 7th Amendment of the Cosmetic Directive established a regulatory framework with the aim of phasing out animal testing (see now Article 18 of the Regulation).

Article 11.2(e) reads:

² “Sunscreen product” means any preparation intended to be placed in contact with the human skin with a view exclusively or mainly to protecting it from UV radiation by absorbing, scattering or reflecting radiation.

V. ACCESS TO INFORMATION FOR THE PUBLIC

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

Article 21 reads:

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume and aromatic compositions, the name and code number of the composition and the identity of the supplier, as well as existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product are made easily accessible to the public by any appropriate means.

The quantitative information regarding composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances in accordance with Article 3 of Regulation (EC) No 1272/2008.

Who needs to make the information accessible to the public?

The obligation to make certain information easily accessible to the public is with the responsible person. Its presentation may be specifically adapted for the public, and thus differ from that of the product information.

What information needs to be made accessible to the public?

- ***Product identification: product name & company name should be clearly identifiable***
- ***Qualitative and quantitative composition of the product***
 - ◆ The list of ingredients, as labelled on the cosmetic package.

The qualitative information ought to be consistent with the ingredient list on the product's package (Article 19.1(g)).

- For those cosmetic ingredients present in the product that are also covered by Regulation 1272/2008 (the Regulation on Classification and Labelling of substances and mixtures³, also known as the "CLP"), the use concentration should be indicated. In particular, the use concentrations should be indicated only for those substances listed in Annex VI of the CLP Regulation and the classification and labelling inventory (when published by ECHA). When necessary in order to not compromise commercial secrecy or intellectual property rights, the value can be rounded up and indicated as "<x %" or, alternatively, concentration ranges can be used (x-y%).
 - Regarding perfume compositions and perfumes, Article 21 of Cosmetic Regulation refers to disclosing the name and code number of the composition and the identity of the supplier. The same information is required under Annex I, part A (1) as part of the CPSR, which in turn is part of the P.I.F. that the responsible person shall make readily accessible to the competent authority of the Member State in which the P.I.F. is kept.
- **Data on undesirable effects and serious undesirable effects related to the product (Annex I, part A (9))**
- 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.
 - As defined in article 2(1)(o) an "undesirable effect" *means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product* (please also see the Practical Guidance on Undesirable Effects, on page 19). There should be a demonstrable link between the affected person and the product; undesirable effects do not include anecdotal or ambiguously reported effects or those resulting from abuse or misuse of the product, and do not include those related to associated items, such as the packaging.
 - Undesirable effects include but are not limited to irritant or allergic reactions that can affect the skin or eyes; if other undesirable effects occur, they should be specified.
 - A "serious undesirable effect" *means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death* (Article 2.1(p) of the Regulation).
 - In order to ensure consistent information to the public, companies should generally compute a value for the number of (serious) undesirable effects per million units placed on the market (including all member states but excluding non-EU markets). However, in situations where the actual number of items

³ Regulation (EC) N° 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) N° 1907/2006.



placed on the market is small (such as a recent launch or sale through selective distribution), the actual number of undesirable effects may be provided.

How should the information be made accessible to the public?

This requirement had been already introduced by the 7th Amendment to the Cosmetics Directive. In order to help industry with its practical implementation, Cosmetics Europe issued a guidance document and created a public directory, allowing a harmonised approach for companies throughout the European Union.

To the same end, the European Commission issued a similar guidance document (http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/guide_access_info_en.pdf).

The directory is accessible on the Internet at the following address: <http://www.European-Cosmetics.info>. It contains the names and contact details (address, phone, fax, email, website) of companies placing cosmetic products on the EU market. It is a central listing of contact points and not the source where the product information can be obtained. Companies themselves provide the information to a member of the public on request.

Companies should decide the most appropriate contact points for themselves, remembering that the address on the packaging will always remain an option for the public to use.

Companies who are not members of Cosmetics Europe may elect to have their contact details added to the directory. Competent authorities should assist with informing these companies of the existence of the directory.

Consequently, consumers who wish to access this information, have one or more of the following options:

- write to the company, either at the address printed on the product's package or at the address(es) published in the central public directory;
- telephone the company at a number which can be either printed on the product's package or listed in the central public directory;
- contact the company via an e-mail address;
- visit the company's website at the address which is either printed on the product's package or listed in the central public directory.

For those companies (mainly SMEs) that do not have consumer help-line numbers or websites, the consumer always has the option of writing to the address indicated on the packaging.

Companies must ensure they have the ability to respond to consumers from anywhere within the European Union. Also, records should be kept of all requests received and responses given.

VI. FREQUENTLY ASKED QUESTIONS

Q.: *To whom does the requirement apply?*

A.: To the Responsible Person (company or physical person) placing a cosmetic product on the EU market [Article 11(1)].

Q.: *Are there special rules for small manufacturers?*

A.: No, the same legal requirements apply to all companies placing cosmetics on the EU market, be they large or small.

Q.: *Does the requirement apply to perfumery products and to soaps?*

A.: Yes, the requirement applies to all cosmetics as defined under Article 2 of the Cosmetics Regulation.

Q.: *Does the requirement apply to professional products?*

A.: Yes, it does.

Q.: *Does the requirement apply to free samples, promotional products, gifts?*

A.: Yes, it applies to all products, however they are placed on the market.

Q.: *Does the requirement apply to products imported into the EU?*



A.: Yes, those responsible for initial placing on the market of a product on EU territory must keep the P.I.F. accessible. There must be an address in the EU on the label of such products.

Q.: *Does the requirement apply to existing cosmetic products already on the market before the date of application (11 July 2013) of the Cosmetics Regulation?*

A.: Yes, it applies to all existing products still placed on the market as of 11 July 2013 and all new products subsequently placed on the market [Article 11(1) & 11(4)]. It does not apply to products still on shelves, but no longer being placed on the market after 10 July 2013.

Q.: *If marketing a product in several EU Member States, does one need to hold the P.I.F. in every one of these Member States?*

A.: No, the information should be accessible only in one of the Member States and at one single place. The choice of the location of the P.I.F. is at the discretion of the responsible person (as long as it is one of the responsible person's addresses).

Q.: *Should the P.I.F. be physically held at the address specified on the label of the marketed product?*

A.: Not necessarily, but the information must be readily accessible via the address specified on the packaging. "Readily accessible" means to be available within up to 72 hours.

Q.: *Where should the P.I.F. be accessible when there is more than one address on the packaging?*

A.: The information has to be accessible at one of the addresses. That address has to be highlighted. If there is no highlighted address, authorities may expect to have access to the information at each of the addresses.

Q.: *Can parts of the information specified under this legal requirement be held at different places?*

A.: Yes, but the information must be accessible in total at one single place in the EU. One may, of course, hold part of the information at additional places.

Q.: *Can an importer of cosmetics into the EU hold the information outside the EU?*

A.: Yes, but the P.I.F. must be readily accessible at the address in the EU specified on the packaging. The safety assessment has to be accessible at the same place.

Q.: *Can somebody else than the manufacturer or importer become responsible for the P.I.F. requirement?*

A.: Yes, the responsible person may, by written mandate, designate a person established within the Community as the responsible person who shall accept in writing. Furthermore, the responsible person can outsource tasks for collating and storing the P.I.F., but the overall responsibility always lies with the responsible person placing the product on the market.

Q.: *Can supporting data (particularly safety information) be held outside the EU?*

A.: Yes, provided that the CPSR is accessible at one place within the EU. If requested by the authorities, supporting data has to be made available at the same place.



Q.: *Who is allowed to check the P.I.F.?*

A.: The control officers of the competent authority of the EU Member State where the information is accessible.

Q.: *Can a control officer remove or copy any part of the P.I.F.?*

A.: No, since the P.I.F. belongs to the company.

Q.: *If a company engages a contract manufacturer to manufacture a cosmetic product which it sells under its own brand name, who must fulfil the P.I.F. requirement?*

A.: This responsibility always lies with the Responsible Person whose name and address is on the package.

Q.: *What are the main differences between the P.I.F. requirements of the new Cosmetics Regulation and the previous Cosmetics Directive?*

A.: The main change is the restructuring of some of the information, including the safety assessment, into a Cosmetic Product Safety Report (CPSR) as detailed in Annex I of the Regulation.

Q.: *Do I have to prepare a P.I.F. for a multi-product pack (e.g. a gift-set)?*

A.: A P.I.F. is required for each individual product comprised in the multi-product pack, namely the components of which are also sold individually.

Q.: *Do I have to prepare different P.I.F.s for different pack variations (e.g. tube, pump) and sizes?*

A.: No. Different pack variations and sizes of the same product only need one P.I.F.. However, relevant differences (e.g. packaging in tubes vs. pumps) should be addressed in this P.I.F.

Q.: *Do I have to prepare P.I.F. for a cosmetic product manufactured in the EU exclusively for being exported outside of the EU?*

A.: No. The requirement only applies to products placed on the market in the EU.

Q.: *Does the responsible person have to prepare the P.I.F. on his/her own?*

A.: No, the responsible person can draw upon the following sources of expertise to fulfil the P.I.F. requirements: in-house support from research & development, safety, quality assurance departments; literature review; data from suppliers, third party experts and consultants, trade associations and competent authority advice and support.

VII. LIST OF REFERENCES

- Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, 76/768/EEC, OJ L 262, 27.9.1976
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009
- Council Directive 93/35/EEC of 14 June 1993 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, *OJ L 151, 23.06.1993, p. 32 – 37*
- Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, *OJ L 66, 11.03.2003, p. 26 – 35*
- Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers, *OJ L 192, 11.07.1987, p. 49 – 50*

- Guidelines on Good Manufacturing Practices: *ISO 22716*
- Guidelines for the Implementation of the Cosmetic Regulation, Cosmetic Product Safety Report (CPSR) Safety Assessment guidance document, 21 April 2010
- SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (7th revision, SCCS/1416/11)
- Cosmetics Europe Guidelines on the Management of Undesirable Event Reports, 2005
- Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, *OJ L 204, 21.7.1998, p. 37–48*
- Commission Recommendation of 7 June 2006 establishing guidelines on the use of claims referring to the absence of tests on animals pursuant to Council Directive 76/768/EEC, *OJ L 158, 07.06.2006, p. 18 – 19*
- Cosmetics Europe Guidelines for the Evaluation of the Efficacy of Cosmetic Products, 2008
- Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto, *OJ L 265, 26.09.2006*
- Sun protection test methods - In vivo determination of the sun protection factor (SPF): *ISO 24444, 2010*
- Cosmetics Europe In vitro Method for Determination of UVA protection, March 2011
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, *OJ L 353, 31.12.2008*.