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## COSMETICS EUROPE

# COMPLIANCE WITH REGULATION 1223/2009 ON COSMETIC PRODUCTS \_ ROLES AND RESPONSIBILITIES ALONG THE SUPPLY CHAIN

A PRACTICAL GUIDE

2016

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*This Practical Guide has been prepared by Cosmetics Europe to assist its member associations and companies, as well as other interested persons and is for information purposes only. This document has no legally binding force. Where doubt exists, the original legal texts, published in the Official Journal of the European Union, prevail.*

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## Glossary

### - Affiliates –

Within this Practical Guide, affiliates refer to companies affiliated in the same group, meaning they are generally under the partial or full control of a common corporate parent.

### - Common Criteria Regulation –

The Common Criteria Regulation is the Regulation 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products.<sup>1</sup> The Common Criteria Regulation entered into force on 11 July 2013.

### - Community, Community market, EU, EU market, market, EEA –

As the Cosmetics Regulation was adopted in 2009, the legislation still makes reference to the “Community”. However, since the entry into force of the Lisbon Treaty, the “Community” should be understood as the “European Union (EU)”.

The Cosmetics Regulation is a text with European Economic Area (EEA) relevance. Therefore, any reference in the Cosmetics Regulation to the “Community” or “Community market” means the 28 countries of the European Union plus Iceland, Norway and Liechtenstein.

**For the purpose of this Practical Guide, any references to the EU or the Community mean the 28 countries of the EU plus Iceland, Norway and Liechtenstein.**

### - Cosmetics Directive –

The Cosmetics Directive is the Directive 76/768/EC which has been governing the composition, labelling and packaging of finished cosmetic products in the European Union since 1976 and which is now replaced by the Cosmetics Regulation.<sup>2</sup>

### - Cosmetics Regulation –

The Cosmetics Regulation is the Regulation 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products, replacing since 11 July 2013 the Directive 76/768/EC.<sup>3</sup>

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<sup>1</sup> Commission Regulation (EU) N° 655/2013 of 10 July 2013 laying down common criteria for the justification used in relation to cosmetic products, *O.J.*, L. 190, 11 July 2013, p. 31.

<sup>2</sup> Council Directive of 27 July 1976 on the approximation of laws of the Member States relating to cosmetic products (76/768/EEC), *O.J.*, L. 262, 27 September 1976, p. 16.

<sup>3</sup> Regulation (EC) N° 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, *O.J.*, L. 342, 22 December 2009, p. 59.

- General Product Safety Directive (GPSD) –

The General Product Safety Directive is the Directive 2001/95/EC.

- Natural person – legal person –

A natural person refers to an individual.

A legal person refers in particular to a company. A legal person is a non-human entity regarded by law to have the status of a legal person (e.g. a corporate entity). Like a natural person, a legal person has rights, protections, privileges, responsibilities, and liabilities under law.

- Packaging –

This Practical Guide shall refer, for packaging elements, to ‘container’ (primary packaging) and ‘packaging’ (secondary packaging).

- Practical Guide –

The ‘Practical Guide’ refers to this non-binding Practical Guide on the Roles and Responsibilities along the supply chain prepared by Cosmetics Europe to assist its members and any interested persons and which is for information purposes only.

- RAPEX –

RAPEX is the EU rapid alert system that facilitates exchange of information between Member States and the European Commission in particular on cosmetics products posing a serious risk to the health and safety of professional users or to other public interests protected with relevant EU legislation. This system is regulated by the General Products Safety Directive (GPSD). The Cosmetics Regulation makes an explicit reference to that regulation (Article 25(7)).

## I. INTRODUCTION

### - A new Regulation in force since 11 July 2013 –

The **Cosmetics Regulation** (1223/2009), published in the Official Journal of the European Union on 22 December 2009, replaces the **Cosmetics Directive** (76/768/EC), which has been governing the composition, labelling and packaging of finished cosmetic products in the European Union since 1976. This replacement is fully effective since 11 July 2013 when all provisions of the Cosmetics Regulation became enforceable.

As of the same date, 11 July 2013, the **Common Criteria Regulation** (655/2013) entered into force laying down common criteria for the justification of claims used in relation to cosmetic products putting into effect provisions under Article 20(2) of the Cosmetics Regulation.

### - Continuity and improvement –

The Cosmetics Regulation essentially consists of a recast of the Cosmetics Directive and did not introduce fundamental changes to the regulatory framework of the Directive, in particular with regard to the allocation of responsibilities along the supply chain.

After more than 30 years in force, the Cosmetics Directive had undergone numerous amendments and technical adaptations. Despite this patchwork of amendments, the Directive demonstrated its effectiveness to achieve its principal goals: guaranteeing a high level of protection to the European consumer and facilitating the free movement of cosmetic products within the EU. Given this good legislative record, the Cosmetics Regulation continues to rely on a similar approach and confirms the Responsible Person's<sup>4</sup> primary responsibility to guarantee the safety of cosmetic products and the major role to be played by the Member States' authorities to survey the market and ensure the proper enforcement of the European legislation.

Being in the form of a Regulation - i.e. immediately applicable legislation that does not need to be transposed into the laws of the Member States – the new EU cosmetic legislation has gained in precision and clarity, notably as a result of the definition of key concepts and a more explicit delineation of the roles and responsibilities in the supply chain, from the placing on the EU market of cosmetic products to their distribution and sales to end users.

Prior to the Cosmetics Regulation, the **General Product Safety Directive (GPSD)** (Directive 2001/95/EC) and the laws of the Member States provided the principles and rules under which Distributors<sup>5</sup> responsibilities were addressed. The Cosmetics Regulation now offers an integrated and detailed framework at EU level that renders the application of the GPSD largely superfluous,

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<sup>4</sup> For a definition of the "Responsible Person", please see Section II, point 8 of this Practical Guide.

<sup>5</sup> For a definition of the "Distributor", please see Section II, point 4 of this Practical Guide.



except for RAPEX which remains of particular relevance for the implementation of the Cosmetics Regulation.<sup>6</sup>

- *Purpose of this Practical Guide –*

This Practical Guide has been developed by Cosmetics Europe to assist its members and other industry partners to further clarify their respective roles and responsibilities for ensuring compliance with the Cosmetics Regulation. Where appropriate, the Guide offers practical guidance for the implementation of certain provisions of the Cosmetics Regulation, including the necessary collaboration that needs to take place between Distributors<sup>7</sup> and Responsible Persons<sup>8</sup>.

Additional guidance has been developed by Cosmetics Europe and the European Commission on other key provisions of the Cosmetics Regulation, which are useful and complementary references to this Guide. These publications can be found on <https://www.cosmeticseurope.eu/> or [http://ec.europa.eu/growth/sectors/cosmetics/index\\_en.htm](http://ec.europa.eu/growth/sectors/cosmetics/index_en.htm).

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<sup>6</sup> See Article 25(7) of the Cosmetics Regulation.

<sup>7</sup> For a definition of the “Distributor”, please see Section II, point 4 of this Practical Guide.

<sup>8</sup> For a definition of the “Responsible Person”, please see Section II, point 8 of this Practical Guide.

## II. KEY TERMS OF THE COSMETICS REGULATION

### 1. COSMETIC PRODUCT

The Cosmetics Regulation applies to cosmetic products defined as: *“any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours”* (Article 2(a) of the Cosmetics Regulation).

Any product placed on the EU market that falls under this definition is subject to the requirements of the Cosmetics Regulation irrespective of its channel of distribution.

### 2. MANUFACTURER

A Manufacturer is *“any natural (i.e. an individual) or legal person (i.e. a company) who manufactures a cosmetic product or has such product designed or manufactured, and markets that cosmetic product under his name or trademark”* (Article 2(d) of the Cosmetics Regulation).

### 3. IMPORTER

An Importer is *“any natural (i.e. an individual) or legal person (i.e. a company) established within the Community, who places a cosmetic product from a third country on the Community market”* (Article 2(i) of the Cosmetics Regulation).

### 4. DISTRIBUTOR

A Distributor is *“any natural (i.e. an individual) or legal person (i.e. a company) in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Community market”* (Article 2(e) of the Cosmetics Regulation).

### 5. END USER

‘End users’ are *“either the consumers or professionals using the cosmetic product”* (Article 2(f) of the Cosmetics Regulation).

### 6. MAKING AVAILABLE

‘Making available’ means *“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”* (Article 2(g) of the Cosmetics Regulation).

## **7. PLACING ON THE MARKET**

‘Placing on the market’ means “*the first making available of a cosmetic product on the Community market*” (Article 2(h) of the Cosmetics Regulation).<sup>9</sup>

## **8. RESPONSIBLE PERSON**

A Responsible Person is a natural (i.e. an individual) or legal person (i.e. a company) established within the European Union who shall ensure compliance with the relevant obligations set out in the Cosmetics Regulation. Only cosmetic products for which a Responsible Person has been designated could be placed on the EU market (Article 4 of the Cosmetics Regulation).

## **9. PRODUCT INFORMATION FILE (“PIF”)**

The Product Information File (hereinafter referred to as the “**PIF**”) is a set of information and data in relation to a cosmetic product to be placed on the EU market kept by the Responsible Person. The PIF has to be made readily accessible in electronic or in other format by the Responsible Person at his address indicated on the label to the competent authority of the Member State in which the file is kept (Article 11 of the Cosmetics Regulation).

For further information on the PIF obligations please refer to Cosmetics Europe Guidelines available on Cosmetics Europe website.<sup>10</sup>

## **10. COSMETICS PRODUCT NOTIFICATION PORTAL (“CPNP”)**

The Cosmetics Product Notification Portal (hereinafter referred to as the “**CPNP**”) is a European centralized system of notification into which each cosmetic product has to be notified by the Responsible Person before being placed on the EU market (Article 13 of the Cosmetics Regulation).

The main objective of the CPNP is to provide an effective tool for in-market controls by the national competent authorities of products on the EU market and for the poison control centres. In particular it allows easy access by the Market Surveillance authorities to the contact details of the Responsible Person and the address where the PIF is accessible.

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<sup>9</sup> Please refer to the European Commission’s interpretative document clarifying the concept of ‘first making available’ in the context of the medical devices legislation, such concept being harmonised across EU legislation applicable to industrial goods, including the Cosmetics Regulation. ([http://ec.europa.eu/consumers/sectors/medical-devices/files/guide-stds-directives/placing\\_on\\_the\\_market\\_en.pdf](http://ec.europa.eu/consumers/sectors/medical-devices/files/guide-stds-directives/placing_on_the_market_en.pdf)) and the “Blue Guide” (EC, The “Blue Guide” on the implementation of EU product rules 2014, version 1.1, 15 July 2015, Section 2.3, Placing on the market, p. 20 <http://ec.europa.eu/DocsRoom/documents/12661?locale=en> ).

<sup>10</sup> Cosmetics Europe Guidelines on the Product Information File (P.I.F.) requirement, 15 December 2011, 29 pp., available on the following link: <https://www.cosmeticseurope.eu/>

Please note that in particular cases the notification of certain information has to be done by the Distributor (see Section III, point 3(b) and Section IV, point 3(b) of this Practical Guide for further information).

### III. ALLOCATION OF RESPONSIBILITIES WITHIN THE SUPPLY CHAIN – THE CENTRAL ROLE OF THE RESPONSIBLE PERSON

#### 1. A Responsible Person for each cosmetic product

The Cosmetics Regulation requires the designation, within the EU, of a Responsible Person for every cosmetic product placed on the EU market. This person (who may be a natural (i.e. an individual) or legal person (i.e. a company)) must take responsibility to ensure that every cosmetic product he places on the EU market complies with all the requirements of the Cosmetics Regulation.

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

By default, the Manufacturer established in the EU is the Responsible Person for the cosmetic products he manufactures within the EU and the Importer is the Responsible Person for the cosmetics he places on the EU market. However, this responsibility could be transferred to another person established within the EU based on a written mandate (please see Section III, point 3(a) of this Practical Guide).

There is only one single Responsible Person per cosmetic product. In case a cosmetic product is imported in the EU by several Importers, each Importer becomes the Responsible Person for the unit products he imports (unless he designates a mandated person), hence different CPNP numbers and Responsible Person's names/addresses as well as separate PIFs.

#### 2. Identification of the Responsible Person on the product label

The name (or style) and address of the Responsible Person must be printed on the container and packaging of each product for which he takes responsibility.

##### (a) **Abbreviation of the name and address of the Responsible Person**

The name and address of the Responsible Person may be abbreviated in so far as the abbreviation makes it possible to identify that person and his address (Article 19 (1)(a) of the Cosmetics Regulation). The possibility to abbreviate the information shall be evaluated on a case by case basis in the country where the address is located, with the goal of ensuring that the consumer can identify the Responsible Person's name and address.

##### (b) **Several addresses on the label**

If several European addresses are indicated on the label, the address where the Responsible Person makes the PIF readily available must be highlighted (Article 19(1)(a) of the Cosmetics Regulation). This allows, for example, a group of companies to designate one of its European legal entities as the Responsible Person by highlighting the address where the PIF is available on the label while also

providing the locations of other Affiliates. Companies using this approach generally underline the address where the PIF is accessible.

**(c) Consistency between the details on the container and the packaging with the CPNP notification**

The Responsible Person details on the container and packaging should coincide with the details recorded in the CPNP. As described in Section IV, point 3(a) of this Practical Guide, the Cosmetics Regulation requires that the Responsible Person notifies his finished cosmetic products via the CPNP before placing them on the EU market (Article 13 of the Cosmetics Regulation). However updates of the packaging may sometimes create temporary discrepancies between notification and marketed product.

**3. Who is the Responsible Person?**

Article 4 of the Cosmetics Regulation considers different situations as to who must or can take responsibility for ensuring compliance with the Cosmetics Regulation.

**(a) Manufacturer, Importer or a mandated person as Responsible Person**

Depending on whether the product is manufactured or imported in the EU, the Responsible Person (a natural (i.e. an individual) or legal person (i.e. a company)) is the Manufacturer, the Importer or a mandated person. In any case the Responsible Person must be established within the EU.

Cosmetics Regulation – Article 4 – Responsible person

3. For a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer established within the Community shall be the responsible person.

The manufacturer may designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

4. Where, for a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer is established outside the Community, he shall designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

5. For an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market.

The importer may, by written mandate, designate a person established within the Community as the responsible person who shall accept in writing.

### ▪ **Manufacturer or Importer**

The Manufacturer established within the EU will be the Responsible Person unless he designates someone else by mandate to serve as the Responsible Person. A Manufacturer is free to appoint an EU Affiliate as Responsible Person if that Affiliate does not itself meet the definition of “Manufacturer”.

For products imported into the EU market, the Importer, if established within the EU, will usually assume the role of Responsible Person, unless he designates by written mandate another person.

### ▪ **Choice to mandate a person**

Manufacturers and Importers may choose, under the conditions laid down in the Cosmetics Regulation, to mandate a person who shall fulfil the role of Responsible Person for their products.

They may appoint any person (either natural (i.e. an individual) or legal (i.e. a company)) to assume this role, provided this person is:

- registered and located in the EU;
- adequately mandated (in writing); and
- in a position to ensure the compliance with the requirements incumbent to the Responsible Person.

Please note that some Member States from the EU market may impose specific conditions for the validity of the mandate (e.g. the mandated person has to be able to assume his responsibility, to have the necessary capability, information and budget to execute his duties).

When mandated as Responsible Person, the name and address of the mandated person must appear as the Responsible Person on the label.

In situations where the Responsible Person mandated by the Manufacturer/Importers is not one of its Affiliates, appropriate contractual arrangements need to be anticipated so as to ensure, that all the requirements incumbent upon the Responsible Person under the Cosmetics Regulation are assigned to, and can be fulfilled by the mandated person, and in particular, that the PIF can be made readily accessible to the competent national authorities upon request (see Section III, point 4 of this Practical Guide).

### ▪ **The particular case of subcontractors**

The Responsible Person may delegate some tasks to a sub-contractor. For instance the filling of a product, cosmetovigilance or CPNP notification.

A sub-contractor unless he has explicitly been mandated as Responsible Person under the abovementioned conditions and has accepted the mandate in writing, will not be considered as the Responsible Person as he is acting on behalf of the Manufacturer or the Importer. The Responsible Person remains responsible for the obligations described in the Cosmetics Regulation.

**(b) Distributor as Responsible Person**

The Cosmetics Regulation also envisages that a Distributor shall be considered as the Responsible Person in specific circumstances (Article 4(6)).

Cosmetics Regulation – Article 4 (6)

The distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already placed on the market in such way that compliance with the applicable requirements may be affected.

The translation of information relating to a cosmetic product already placed on the market shall not be considered as a modification of that product of such a nature that compliance with the applicable requirements of this Regulation may be affected.

A Distributor shall be considered as the Responsible Person when he:

- ***“places a cosmetic product on the Community market under his name or trademark”, or***

In this capacity, and provided no other person is mandated, Distributor will need to ensure that he can fulfil all obligations imposed on the Responsible Person.

- ***“modifies a product in such a way that compliance with the applicable requirements may be affected”***

A Distributor may be considered as a Responsible Person in those circumstances where he modifies the product at his own initiative without the Manufacturer’s prior consent.

It should be noted that not only may such modifications affect the compliance of the product with the Cosmetics Regulation, but it may also infringe upon intellectual property rights.

Whether a modification to a cosmetic product may affect compliance with the Cosmetics Regulation must be **evaluated on a case-by-case basis**. Please see below some illustrations.



- An accurate translation of information/claims  
(under certain conditions, it is not a modification of the product that may affect compliance with Cosmetics Regulation)

Provided it is accurate, the translation of the information labelled on a cosmetic product already placed on the market – in particular the information required under Article 19(5) – is not considered as a modification of the product affecting the compliance with the Cosmetics Regulation, and the Distributor shall not be considered as the Responsible Person (Article 4(6) of the Cosmetics Regulation; Section IV, point 2(b) of this Practical Guide).

It must be noted that an accurate translation of the label of a cosmetic product requires a lot of know-how and the use of the wrong terms may even put the classification of the product (under the Cosmetics Regulation) into question.

It is advisable that Distributors inform the Responsible Person to ensure an accurate translation.

In case the claim is translated, the Guidelines to Commission Regulation 655/2013 on common criteria address the fact that Distributors should translate any claim provided by the Responsible Person in a way that keeps the essence of the claim, otherwise they become the Responsible Person under Article 4(6) of the Cosmetics Regulation.

- Distributor making available in a Member State a cosmetic product already placed on the market in another Member State and translating elements of the labelling to comply with national law  
(under certain conditions, it is not a modification of the product that may affect compliance with Cosmetics Regulation)

A Distributor who makes available in a Member State a cosmetic product already placed on the market in another Member State and translates, on his own initiative, any elements of the labelling of that product in order to comply with national law, although not becoming the Responsible Person, has to comply with the notification obligation described in Article 13(3) of the Cosmetics Regulation (see Section VI, point 3(b) of this Practical Guide).

With regard to this Article 13(3) notification to the Commission, the Cosmetics Regulation does not contain any obligation for the Distributor or the Commission to inform the Responsible Person of such notification. However, depending on the context, it may be relevant, as a business to business practice, that the Distributor informs the Responsible Person of such notification. The Responsible Person shall therefore be able to fully comply with his obligations, particularly those related to market surveillance.

- Modifications to a cosmetic product by Distributor that may affect compliance with the Cosmetics Regulation  
(non-exhaustive list of examples)

For instance, compliance may be affected when the modification consists of:

- an improper translation which changes the claims in such a way that they are no longer supported;
- a change in the product name or function;
- incorrect or incomplete usage instructions or warnings;

In these examples, the Distributor might be considered as the Responsible Person and shall therefore have to ensure that he fulfils all obligations imposed on the Responsible Person.

- Label of Distributor  
(risk of modification of the product that may affect compliance with Cosmetics Regulation)

The Distributor is not required to label his name and address on the container and/or the packaging. If the Distributor labels his name and address, he risks becoming the Responsible Person.

#### **4. The duties of the Responsible Person**

##### Cosmetics Regulation

##### Article 4(2) – Responsible Person

For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Regulation.

##### Article 5(1) – Obligations of Responsible Persons

Responsible persons shall ensure compliance with Articles 3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, Article 19(1),(2) and (5), as well as Articles 20, 21, 23 and 24.

##### Common Criteria Regulation – Article 2

The responsible person referred to in Article 4 of Regulation (EC) No. 1223/2009 shall ensure that the wording of the claim in relation to cosmetic products is in compliance with the common criteria set out in the Annex and is consistent with the documentation proving the effect claimed for the cosmetic product in the product information file referred to in Article 11 of Regulation (EC) No. 1223/2009.

It is the responsibility of the Responsible Person to ensure that every product he places on the EU market complies with the requirements of the Cosmetics Regulation. His duties relate to all aspects regulated under the Cosmetics Regulation: Article 3 (safety), Article 8 (good manufacturing practice), Article 10 (safety assessment), Article 11 (PIF), Article 12 (sampling and analysis), Article 13 (notification), Article 14 (restrictions for substances listed in the Annexes), 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 Common Criteria Regulation provides that the Responsible Person ensures that the wording of any claim in relation to cosmetic products is in compliance with the common criteria set out in its Annex and is consistent with the documentation supporting the effect claimed for the cosmetic product in the PIF.

Altogether, these provisions primarily aim to guarantee a high level of consumer protection and ensure that any cosmetic product placed on the EU market is safe for human health under normal or reasonably foreseeable conditions of use.

The Responsible Person must be in a position to demonstrate at any time that the product he has placed on the market meets these requirements. In order for the Responsible Person to fulfil this role, he needs to maintain specific information on the product in the PIF.

The PIF contains the information that enables the Responsible Person to answer most of the enquiries made by the competent national authorities and to provide evidence that his product is in compliance with the Cosmetics Regulation. The PIF has to be kept by the Responsible Person for 10 years after the last batch of the cosmetic product is placed on the EU market by the Responsible Person.

This obligation does not mean that the PIF must be physically located at the address indicated on the product label. The address is only a point of access to the information in the Member State where the Responsible Person makes the PIF accessible to the competent national authorities in any format, including an electronic format.

Information contained in the PIF is proprietary and most of the data are confidential. Consumers and the public in general can only have access to a few limited elements of the PIF (Article 21 of the Cosmetics Regulation). This confidentiality is also protected by the provisions of the Cosmetics Regulation which limits the access to the entire file to the authorities of the Member State where the Responsible Person makes the PIF readily accessible (Article 30 of the Cosmetics Regulation).

For further information on the PIF, please refer to the Cosmetics Europe Guidelines on the PIF.<sup>11</sup>

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<sup>11</sup> Cosmetics Europe Guidelines on the Product Information File (P.I.F.) requirement, 15 December 2011, 29 pp., available on the following link: <https://www.cosmeticseurope.eu/>

#### IV. COMPLIANCE WITH THE COSMETICS REGULATION: WHAT ROLE FOR DISTRIBUTORS?

##### Introduction

##### - Role defined in the Cosmetics Regulation –

As was the case under the GPSD, the Cosmetics 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) of the Cosmetics Regulation).

In addition to this general duty of care, the Cosmetics Regulation defines specific duties of the Distributor (see Section IV, points 1 to 8 of this Practical Guide).

The scope of the Distributors’ responsibilities and their practical applications need to take into account the respective role, activities and expertise of the participants involved in the supply of the products in the EU.

##### - Distribution agreements –

Distribution agreements concluded with suppliers may also contain references concerning the responsibilities provided by the Cosmetics Regulation. Nevertheless, despite the commitments undertaken by the supplier under these agreements, the obligations of the Distributor cannot be transferred to the supplier. Thus, the Distributor remains responsible for fulfilling the duties described below.

#### 1. Product safety

It is the Responsible Person’s responsibility to perform the safety evaluation of his products or to have such evaluation made on his behalf. However, Distributors have also specific duties with respect to the safety.

##### (a) **Product Safety must be assessed by the Responsible Person**

###### Cosmetics Regulation – Article 3 – Safety

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

The safety of every cosmetic product made available on the EU market must be assessed prior to marketing. It is the Responsible Person’s responsibility to perform the safety evaluation of his products or to have such evaluation made on his behalf. The product safety assessment, as well as the data upon which it is based, are kept by the Responsible Person as part of the PIF in the form of a “cosmetic product safety report”.

The Responsible Person has to ensure that the product safety assessment is made by a safety assessor, i.e. a person with appropriate qualifications and expertise<sup>12</sup>, considering the specific requirements of Chapter III and Annex I of the Cosmetics Regulation<sup>13</sup> and the *Notes of guidance for the testing of cosmetic ingredients and their safety evaluation* published by the Scientific Committee for Consumer Safety (SCCS)<sup>14</sup>.

The safety evaluation of a product is a complex process which involves expert knowledge with respect to the product composition, the chemical and physical properties of its ingredients, manufacturing processes and the site and method of application of the product. The standards used for this assessment will correspond to a high level of consumer protection based on the best scientific methods and techniques available.<sup>15</sup>

In-market experience with the product or similar formulations will also be relevant for the Responsible Person to determine the steps that are necessary to perform a proper safety evaluation of his product. Distributors have an important role to play in recording in-market experience with the cosmetic products they sell and transmitting this information to the Responsible Person, since the latter has the necessary expertise to assess the information and process it accordingly (see Section III, point 4 of this Practical Guide).

#### **(b) Specific duties of the Distributor with respect to safety**

##### Cosmetics Regulation – Article 6 - Obligations of distributors

1. In the context of their activities, when making a cosmetic product available on the market, distributors shall act with due care in relation to applicable requirements.

3. Where distributors consider or have reason to believe that:

- a cosmetic product is not in conformity with the requirements laid down in this Regulation, they shall not make the product available on the market until it has been brought into conformity with the applicable requirements,

- a cosmetic product which they have made available on the market is not in conformity with this Regulation, they shall make sure that the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate, are taken.

<sup>12</sup> The safety assessor must, in accordance with Article 10(2) of the Cosmetics Regulation, hold a diploma in pharmacy, toxicology, medicine or a similar discipline.

<sup>13</sup> Annex I of the Cosmetics Regulation specifies the content of the cosmetic product safety report. This report includes safety information on the product and the safety assessment carried out by the safety assessor.

<sup>14</sup> The Scientific Committee on Consumer Safety is the advisory Committee that assists the European Commission in the evaluation of cosmetic ingredients and the regulation of their use in cosmetic products.

<sup>15</sup> Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

Furthermore, where the cosmetic product presents a risk to human health, distributors shall immediately inform the responsible person and the competent national authorities of the Member States in which they made the product available, giving details, in particular, of the non-compliance and of the corrective measures taken.

4. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in this Regulation.

▪ **Product Safety of cosmetic products is not assessed by Distributors**

Distributors are not required to assess the safety of cosmetic products nor to check the PIF, as the Cosmetics Regulation makes it clear that the product safety is assessed by the Responsible Person.

However, if the Distributors consider or have a reason to believe that a cosmetic product is not in conformity with the Cosmetics Regulation, they shall not make the product available. If the product is already available on the market, they shall make sure that - where necessary - appropriate and proportionate corrective measures are taken.

▪ **Importance of the cooperation between Distributors and the Responsible Person**

In most instances, close collaboration with (and reliance upon) the Responsible Person will be necessary for Distributors to be able to fulfil these obligations, especially when the duties to be met relate to the product's safety. Article 6(3) of the Cosmetics Regulation highlights the necessary cooperation between Distributors and the Responsible Person by requiring that Distributors, in case they consider that a cosmetic product presents a risk to human health, should immediately inform the Responsible Person. Indeed, the Responsible Person has the necessary qualification and capabilities to assess whether such a risk really exists and – if necessary – to determine the appropriate corrective measures in coordination with the national competent authority.

## **2. Labelling of cosmetic products**

Distributors must check certain labelling information on the packaging of the products and verify that specific information is present on the label, including whether certain information is in the language required under the applicable national law (See Annex III of this Practical Guide).

However, Distributors cannot be considered responsible for the overall compliance of the product labelling, notably when it relates to the accuracy of the information that can only be verified with data held by the Responsible Person (such as for example the correctness of claims on the product label or of an ingredients list).

If Distributors have concerns regarding the correctness of a product label, they should contact the Responsible Person and refrain from offering the product for sale until the status of the product under the labelling rules of the Cosmetics Regulation is clarified or, where relevant, corrective measures have been taken.

The Distributor is not required under Article 19(5) of the Cosmetics Regulation to label his name and address on the container and/or the packaging. If the Distributor labels his name and address, he risks becoming the Responsible Person (see Section III, point 3(b) of this Practical Guide).

#### **(a) The general labelling requirements**

Article 19 of the Cosmetics Regulation sets out detailed rules for the labelling of cosmetic products. The Responsible Person must make sure that all products under his responsibility meet the following requirements:

- (i) (Abbreviated) name and address of the Responsible Person (Article 19(1)(a))
- (ii) The country of origin for products imported into the EU (Article 19(1)(a))
- (iii) Content (Article 19(1)(b))
- (iv) A date of minimum durability or a Period after opening (PaO) where appropriate (Article 19(1)(c))
- (v) Precautions of use (Article 19(1)(d))
- (vi) The batch number of manufacture or the reference for identifying the cosmetic product (Article 19(1)(f))
- (vii) The function of the product (Article 19(1)(f))
- (viii) The list of ingredients (Article 19(1)(g))
- (ix) Small products (Article 19(3))
- (x) Unpackaged products (Article 19(4))

The list of ingredients will be on the outer packaging only as this information is particularly useful to the consumer at the time of purchase. All other information needs to appear on both the container and packaging.

When the size and shape of the product do not allow that, the list of ingredients and precautions for safe use may be given to the consumer in a leaflet or a card enclosed with, or attached to, the product.

Alternatively, in the case of a small product, the list of ingredients may be made available on the retail shelves in a notice placed in the immediate proximity to the product concerned. Under certain conditions, a batch code may be labelled on the outer packaging only.

A summary of these requirements as well as additional details are provided in Annex II of this Practical Guide. Please see also the Cosmetics Europe Guidelines on Cosmetic Product Labelling.<sup>16</sup>

**(b) The responsibilities of the Distributor: verification of correctness of labelling**

Cosmetics Regulation Article 6 (2) - Obligations of distributors

2. Before making a cosmetic product available on the market distributors shall verify that:

- the labelling information provided for in Article 19(1)(a), (e) and (g) and Article 19(3) and (4) is present,
- the language requirements provided for in Article 19(5) are fulfilled,
- the date of minimum durability specified, where applicable under Article 19(1), has not passed.

As set out in Article 6(2) of the Cosmetics Regulation, the Distributors' verification obligations cover the following aspects:

▪ **The conformity of the product label with Article 19(1)(a), (e) and (g) and with Article 19(3) and (4) of the Cosmetics Regulation**

○ Contact details

Article 19(1)(a) of the Cosmetics Regulation requires that cosmetic products bear the name and address of the Responsible Person. This information may be abbreviated, provided the abbreviation makes the identification of the company and its address possible.

A Distributor can easily check that an address is present on the packaging. However, the Distributor will not be able, and cannot be expected, to verify the accuracy of the address(es) on the label, especially where several addresses are shown and one of them is being highlighted (see Section III, point 2 of this Practical Guide). The Distributor must rely on the information included on the label by the Responsible Person.

○ Country of Origin

Article 19(1)(a) of the Cosmetics Regulation also requires cosmetic products manufactured outside the European market to be labelled with the country of origin (usually with the reference "made in...").

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<sup>16</sup> Cosmetics Europe Guidelines on Cosmetic Product Labelling, 2011, 33 pp., available on the following link: <https://www.cosmeticseurope.eu/>



The Distributor cannot be expected to check where the product was actually manufactured and he has to rely on the information printed on the label by the Responsible Person.


- Identification numbers

All cosmetic products must bear a batch number of the Manufacturer or a reference for the identification of the cosmetic product (Article 19(1)(e) of the Cosmetics Regulation). For packaged products, such a number or reference needs to be placed on the container and the packaging.

Article 19(1)(e) of the Cosmetics Regulation, however, allows for the reference not to appear on the container when practically impossible due to the small size of the product.

- Ingredients list

A list of ingredients complying with the requirements of Article 19(1)(g) of the Cosmetics Regulation, must appear on the products' outer packaging.

When this is not possible for practical reasons, Article 19(2) of the Cosmetics Regulation allows for the information to be on an enclosed or attached leaflet, side label, paper tape or card, provided this is indicated on the packaging by a short explanation or by the following 'hand in book' symbol referred to in Annex VII of the Cosmetics Regulation (unless this is also impossible for practical reasons):  .

Where, in the case of soap, bath balls and other small products, the list of ingredients cannot be indicated either on the packaging or on a label, tag, tape or card, it must be on a notice to be found in the immediate proximity of the shelves where the cosmetic product is exposed for sale. The Responsible Person must, therefore, put at the Distributor's disposal the documents (e.g. a booklet or a catalogue) that contain the necessary information and that can be placed in immediate proximity of the cosmetic product.

The Distributor is responsible for ensuring that the documentation provided by the Responsible Person for the labelling of ingredients in accordance with Article 19(3) of the Cosmetics Regulation, remains in immediate proximity of the products.

- **Conformity of the product label with Article 19(5) of the Cosmetics Regulation**

Article 19(5) of the Cosmetics Regulation provides that *"the language of the information mentioned in point (b), (c), (d) and (f) of paragraph 1 and in paragraph (2), (3), and (4) [of Article 19] shall be determined by the law of the Member States in which the product is made available to the end user"*.

The Distributor must verify that product labels comply with the language requirements of the Member State(s) where the products will be offered for sale. Such verification must be done before the products are made available to end users.

Annex III to this Practical Guide provides a table indicating the language requirements applicable in the various Member States.

The Cosmetics Regulation does not require that Distributors verify the translation of the country of origin for imported cosmetic products from non EU-countries. Indeed, the term ‘made in ...’ does not require translation into local language.

The translation of a product label is a complex exercise. Distributors who take the responsibility to translate a label must ensure that the translated information is accurate and does not affect the compliance of the products with the Cosmetics Regulation (see Section III, point 3, b of this Practical Guide).

- Article 19(1)(b) of the Cosmetics Regulation: Nominal content at the time of packaging

According to Article 19(1)(b), cosmetic products need to be supplied with their nominal content at the time of the packaging.

When the nominal content represents the weight or the volume of the product, it is expressed across the EU with the abbreviation “g” or “ml”, which renders a language verification unnecessary.

The nominal content only needs to be indicated in the relevant national language when the number of items must be mentioned on the packaging (and not the weight or volume).

- Article 19(1)(c) of the Cosmetics Regulation: “Date of minimum durability” and “Period after Opening”

Depending on the characteristics of the products, the Cosmetics Regulation requires the labelling of a date of minimum durability, a period after opening (PaO) or no durability-related information.

The indication of a date of minimum durability is mandatory only for products with a durability of 30 months or less. For products with a durability of more than 30 months, the indication of a PaO is required, except when the concept of durability is irrelevant<sup>17</sup>.

It is the responsibility of the Responsible Person to determine when the requirements of Article 19(1)(c) of the Cosmetics Regulation apply to their products.


When a date of minimum durability is necessary, it will be indicated with the words “Best used before end of...” or with the ‘egg-timer’ symbol referred to in Annex VII of the Cosmetics Regulation:



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<sup>17</sup> See Recital 48 of the Cosmetics Regulation and the European Commission Guidance on the practical implementation of Article 6(1)(c) of the Cosmetics Directive: the PaO is not required for single-use products; products presented in containers that do not allow a 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.

It is only when the date of minimum durability is expressed by the mention “Best used before end of...” that the Distributor will need to verify that it is in the language(s) required by the Member State(s) where the products are made available to end users.

When a PaO is necessary, it is indicated with the ‘open jar’ symbol referred to in Annex VII of the Cosmetics Regulation, with an indication of the period (usually in months, abbreviated as “M”, e.g. “12 M”): 

There is no language requirement applicable to the PaO, which renders verification by the Distributor superfluous.

- Article 19(1)(d) of the Cosmetics Regulation: Particular precautions to be observed in use

Specific precautions to be observed by end users of cosmetic products may be labelled on cosmetic products. These precautions are either required by the Cosmetics Regulation or printed on the label under the responsibility of the Responsible Person.

When specific precautions for use are mentioned on a product in accordance with Article 19(1)(d) of the Cosmetics Regulation, they must be in the language(s) required by the Member States in which the products are made available to end users.

- Article 19(1)(f) of the Cosmetics Regulation: Function of the product

The Cosmetics Regulation requires that the function of the product appears on the label when it is not clear from the presentation of the product.

When the labelling of the function is necessary, it needs to be in the language(s) required by the Member States in which the product is made available to end users.

In many instances, however, the overall presentation of the products, including EU-wide well understood terms (e.g. aftershave, eyeliner, perfume, eau de toilette) makes a translation of the product’s function superfluous.

- Article 19(3) of the Cosmetics Regulation: Alternative placement of product information when product labelling is impractical

When, for practical reasons, the ingredient list is on a leaflet, side label, paper tape or card, this separate labelling will generally be indicated on the product by the ‘hand in book’ symbol (see above).

If this is not the case, and instead of the symbol, a short (written) notice is provided on the label, only this notice must be in the language(s) required by the Member State(s) in which the product is made available to end users. The language of the notice will, therefore, need to be verified by the Distributor.

Such verification does not concern the content of the ingredients list which, according to Article 19(1)(g) of the Cosmetics Regulation, is performed consistently throughout the EU with the word “Ingredients” followed by the name of the ingredients using the common denomination laid down in the European Glossary referred to in Article 33 of the Cosmetics Regulation.

- Article 19(4) of the Cosmetics Regulation: Cosmetic products that are not pre-packaged

According to Article 19(4) of the Cosmetics Regulation, it is up to the Member States to decide how the ingredients list must be made available to end users for cosmetic products that are not pre-packaged. Distributors must ensure compliance with these specific rules when they exist.

- **Verification of the date of minimum durability**

When a Distributor receives a cosmetic product bearing a date of minimum durability in accordance with Article 19(1) of the Cosmetics Regulation, Article 6(2) requires that the Distributor verifies that this date is not expired at the time the product is offered for sale. This verification can only be carried out at the point of sale by the Distributor.

### **3. Notification of information to the European centralized data base**

#### **(a) Notification system for Responsible Persons (Article 13(1) of the Cosmetics Regulation)**

##### Cosmetics Regulation – Article 13 – Notification

1. Prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, (...) information to the Commission (...)

The Cosmetics Regulation introduced a standard cosmetic product notification system, the CPNP, across the EU. The CPNP is a centralized system which replaced all the former national product notification schemes by a single, central electronic notification requirement to the European Commission.

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, as well as to poison centers (or similar bodies established by Member States), for the purposes of medical treatment in case of accidental poisoning.

Article 13 of the Cosmetics Regulation lists the information that the Responsible Persons 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)
- Frame formulation

For more information, please see the EU Commission's CPNP User Manual.<sup>18</sup>

The CPNP notification information is made accessible only:

- to competent national authorities for the purposes of market surveillance, market analysis, evaluation and consumer information; and
- to poison centers for the purposes of medical treatment.

Under the Cosmetics Regulation, Distributors do not have a right to access to the CPNP notifications made by a Responsible Person and there is no obligation for the Responsible Person to provide the notification number, or any other notification information to Distributors.

Indeed, the notification number has no value to the Distributors as it does not guarantee either that the product has been notified or that the product is fully compliant. Further, Distributors have no access to the notification portal.

**(b) Particular cases: Notification of certain information by the Distributor (Article 13(3) of the Cosmetics Regulation)**

In principle and as per above, the notification needs to be carried out by the Responsible Person. In exceptional cases, in addition to the Responsible Person's notification, the Distributor will have to notify certain information to the Commission.

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<sup>18</sup> The EU Commission's CPNP User Manual is available on the following link:  
[http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/cnpn\\_new\\_en.pdf](http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/cnpn_new_en.pdf)

Article 13(3) of the Cosmetics Regulation envisages a specific situation where a Distributor makes a product available in a Member State for which the marketing of the product was not foreseen by the Responsible Person and the original product label is not in the language(s) of that Member State.

In such a situation, the Distributor of the product must notify certain information to the Commission's centralized database. This notification may take place without cooperation of the Responsible Person, as the Cosmetics Regulation does not provide for such cooperation. However, although it is not compulsory, the Distributor may consider to also inform the Responsible Person so that the Responsible Person is made aware of the new country(ies) where the product is made available.

#### Cosmetics Regulation – Article 13(3) – Notification

As from 11 July 2013, a distributor who makes available in a Member State a cosmetic product already placed on the market in another Member State and translates, on his own initiative, any element of the labelling of that product in order to comply with national law, shall submit, by electronic means, the following information to the Commission:

- (a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;
- (b) the Member State in which the cosmetic product is made available;
- (c) his name and address;
- (d) the name and address of the responsible person where the product information file is made readily accessible.

Article 13(3) of the Cosmetics Regulation aims to ensure that the Member State's authorities are informed when a person other than the Responsible Person takes responsibility for introducing products on their market.

This provision, however, does not exhaustively regulate the permissibility of such activities. Distributors who translate, on their own initiative, information of the product label must also consider other areas of legislation, including the rules protecting intellectual property rights. For example, Article 13(3)(a) of the Cosmetics Regulation does not confer a right to change the name of a cosmetic product.

Article 13(3) of the Cosmetics Regulation applies to products that are still placed on the market by the Responsible Person after the entry into force of the Cosmetics Regulation. For products which are no longer placed on the market after the entry into force of the Cosmetics Regulation, the provisions of Article 13(4) of the Cosmetics Regulation apply.

**(c) Notification and communication along the supply chain (Article 13(4) of the Cosmetics Regulation)**

Cosmetics Regulation – Article 13(4) – Notification

Where a cosmetic product has been placed on the market before 11 July 2013 but is no longer placed on the market as from that date, and a distributor introduces that product in a Member State after that date, that distributor shall communicate the following to the responsible person:

- (a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;
- (b) the Member State in which the cosmetic product is made available;
- (c) his name and address.

On the basis of that communication, the responsible person shall submit to the Commission, by electronic means, the information referred to in paragraph 1 of this Article, where notifications according to Article 7(3) and Article 7a (4) of Directive 76/768/EEC have not been carried out in the Member State in which the cosmetic product is made available.

Article 13(4) of the Cosmetics Regulation regulates a situation where a product is no longer placed on the EU market by the Responsible Person (i.e. no new batches of the product are further supplied by the Responsible Person) after the entry into force of the Cosmetics Regulation, and a person, other than the Responsible Person, introduces this product in a Member State where it was not previously made available.

In such a situation, the Distributor must contact the Responsible Person and provide the information mentioned in Article 13(4) of the Cosmetics Regulation so as to allow the Responsible Person to perform a notification under the CPNP for this product if the product has not previously been notified, under the (repealed) Cosmetics Directive, in the Member State(s) in which the cosmetic product is made available by the Distributor.

This notification is intended to ensure that the relevant poison control centres may have access to the information that is necessary for medical treatment in case of emergency (e.g. when a product is misused).

#### 4. Transport and storage of cosmetic product – Distributor’s responsibility

##### Cosmetics Regulation – Article 6(4) – Obligations of distributors

Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in this Regulation.

When the products are under the Distributor’s responsibility, appropriate steps must be taken by the Distributor to ensure that the safety of the products cannot be jeopardized.

Article 6(4) of the Cosmetics Regulation reproduces the general recommendations laid down in the EC *Blue Guide on the implementation of EU product rules 2014* and the international practices under the *United Nations Convention on Contracts for the International Sale of Goods* (a.k.a. CISG or “Convention of Vienna”, 1980).

##### EC, The “Blue Guide” on the implementation of EU product rules 2014, version 1.1, 15 July 2015, Chapter 3, The actors in the product supply chain and their obligations, 3.4, Distributors, p.34:

“The distribution conditions (for example transportation or storage) may have an impact on maintaining the compliance with the provisions of the applicable Union harmonisation legislation. Thus, the person in charge of the distribution conditions must take the necessary measures to protect the compliance of the product. This is to ensure that the product complies with the essential or other legal requirements at the moment of first use within the Union.”

##### United Nations Convention on Contracts for the International Sale of Goods:

###### Article 32

(2) If the seller is bound to arrange for carriage of the goods, he must make such contracts as are necessary for carriage to the place fixed by means of transportation appropriate in the circumstances and according to the usual terms for such transportation.

###### Article 36

(1) The seller is liable in accordance with the contract and this Convention for any lack of conformity which exists at the time when the risk passes to the buyer, even though the lack of conformity becomes apparent only after that time.

(2) The seller is also liable for any lack of conformity which occurs after the time indicated in the preceding paragraph and which is due to a breach of any of his obligations, including a breach of any guarantee that for a period of time the goods will remain fit for their ordinary purpose or for some particular purpose or will retain specified qualities or characteristics.



For some products, guidance regarding specific storage requirements may be obtained from the information intended for the end users in relation to the product's durability.

Distribution agreements concluded with the suppliers may also contain specific references or requirements concerning the appropriate conditions for the storage of cosmetic products.

Where relevant, these recommendations should be taken into account by the Distributor as well as any other guidance that may have been developed by national cosmetics associations.

### **5. Identification within the supply chain (Article 7 of the Cosmetics Regulation)**

Before the adoption of the Cosmetics Regulation, the GPSD and related Guidelines already required that producers of consumer products take appropriate measures to prevent risks associated with the products they supply.

#### Cosmetics Regulation – Article 7 – Identification within the supply chain

At the request of a competent authority:

- responsible persons shall identify the distributors to whom they supply the cosmetic product,
- the distributor shall identify the distributor or the responsible person from whom, and the distributors to whom, the cosmetic product was supplied.

This obligation shall apply for a period of three years following the date on which the batch of the cosmetic product was made available to the distributor.

As emphasized by Recital 12 of the Cosmetics Regulation, Art. 7 “*helps to make market surveillance simpler and more efficient*” and to facilitate the competent authorities’ task of tracing economic operators.

In a situation where there is a serious risk associated with the use of a product, an efficient traceability system will facilitate the withdrawal of the product and enable interested parties to be provided with specific and accurate information for identifying the products concerned.

The Cosmetics Regulation leaves flexibility to the Responsible Person and the Distributors to determine the system that will allow them to trace the products.

Article 7 of the Cosmetics Regulation aims at ensuring that businesses are at least able to easily identify the immediate supplier of the product in question and the immediate subsequent recipient, with the exception of final consumers (*one step back - one step forward*).

Developing a traceability system does not necessarily mean that companies involved in the distribution of cosmetic products must have a dedicated system: it is the information itself which is important, not the format in which it is kept.

The obligation of Article 7 of the Cosmetics Regulation can therefore be met by keeping invoices or providing delivery statements. Importers are subjected to the same obligation and are required to be able to identify from whom the product was imported.

This information must be kept for a period of 3 years, starting after the last delivery of the respective batch of products was made available to the Distributor.

If the traceability of a product cannot be ensured, some Member States have considered the last identifiable Distributor as the Responsible Person, although the Cosmetics Regulation provides no legal basis.

## **6. Information to consumers (Article 21 of the Cosmetics Regulation)**

### Cosmetics Regulation – Article 21 – Access to information for the public

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.

The obligation to inform consumers falls on the Responsible Person only. Any related query received by Distributors should therefore be referred to the Responsible Person.

## **7. Post-marketing surveillance (Articles 6 and 23 of the Cosmetics Regulation)**

Market surveillance after the products are placed on the market or sold to consumers is an important feature of the Cosmetics Regulation. The competent national authorities and the Responsible Persons are obviously key players for the practical implementation of such surveillance. Distributors also have an important role to play in the context of their activities and several provisions of the Cosmetics Regulation are dedicated to the cooperation that is needed within the supply chain and with the national authorities for the management of exceptional circumstances where a product presents a risk to human health or where a consumer experiences a serious undesirable effect.

The conclusion of contractual arrangements between the Responsible Person and the Distributors foreseeing the exchange of information and the collaborative steps that are necessary to ensure the implementation of the market surveillance provisions of the Cosmetics Regulation, can facilitate the enforcement of these obligations.

### (a) Cooperation with the authorities when a product presents a risk to human health

As was the case under the Cosmetics Directive and the GPSD, the Cosmetics Regulation contains a general obligation for the Responsible Person and the Distributors to cooperate, as appropriate, with competent surveillance authorities to ensure a safe market place.

Such cooperation is particularly warranted when a product represents a risk to human health, i.e. when consumers are likely to be exposed to a risk due to the use of a cosmetic product.

#### Cosmetics Regulation – Article 6 – Obligations of distributors

3. (...) Where the cosmetic product presents a risk to human health, distributors shall immediately inform the responsible person and the competent national authorities of the Member States in which they made the product available, giving details, in particular, of the non-compliance and of the corrective measures taken.

5. Distributors shall cooperate with competent authorities, at the request of the latter, on any action to eliminate the risks posed by products which they have made available on the market. In particular, distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2, in a language which can be easily understood by that authority.

When such a situation arises, Article 6 of the Cosmetics Regulation provides that the Responsible Person and/or the Distributors must inform the competent national authorities of where the product is sold.

In order to meet this obligation, a close collaboration between the Responsible Person and the Distributors is indispensable, in particular for the assessment of the actual risk<sup>19</sup>, the identification of the product concerned and the markets affected, including, where necessary, the implementation of corrective measures.

In addition to the corresponding provisions of the GPSD, for Distributors, the obligation was added in Article 6(3) of the Cosmetics Regulation to immediately contact the person responsible for placing the product on the market. This provision is very useful as the Responsible Person has the expertise required to assess the actual risk situation in a given context and, in cooperation with the competent national authority, to decide where appropriate on the necessity of taking corrective measures.

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<sup>19</sup> The Council of Ministers and the European Parliament have requested that the European Commission provides guidelines for the uniform interpretation and application of serious risks. The guidelines issued by the European Commission in the context of the GPSD serve this purpose.

### (b) Communication of Serious Undesirable Effects (SUEs)

The Responsible Person and Distributors must also participate in the market surveillance system established under Article 23 of the Cosmetics Regulation for serious undesirable effects.

A serious undesirable effect (hereinafter referred to as “SUE”) is distinct from the concept of “risk to human health” envisaged under Article 6 of the Cosmetics Regulation. In most instances, SUEs are linked to the underlying conditions of the individual (e.g. allergies to certain substances) and the occurrence of a SUE does not necessarily mean that the product is defective or that there is a risk to human health.

A SUE is a serious adverse reaction experienced by an individual consumer with the normal or reasonably foreseeable use of a product and is defined by the Cosmetics Regulation as “*an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death*” (Article 2(p) of the Cosmetics Regulation).

#### Cosmetics Regulation – Article 23 – Communication of serious undesirable effects

In the event of serious undesirable effects, the responsible person and distributors shall without delay notify the following to the competent authority of the Member State where the serious undesirable effect occurred;

- a) all serious undesirable effects which are known to him or which may reasonably be expected to be known to him;
- b) The name of the cosmetic product concerned, enabling its specific identification;
- c) The corrective measures taken by him, if any”.

When an adverse effect is reported, the following 3-step assessment will have to be carried out in order to establish whether it is a SUE within the meaning of Article 23 of the Cosmetics Regulation that must be communicated to the authorities<sup>20</sup>:

- (1) Verification of the existence of the undesirable effect and the conditions under which the product was used (misuse or not).
- (2) Verification of the level of causality between the product and the undesirable effect (i.e. assessment of whether the adverse effect can be attributed to the use of the product). This step is strictly individual, applied to a specific claim of undesirable effects and confirmed on the individual consumer claiming that effect.
- (3) Determination of the seriousness of the undesirable effect (i.e. whether the case is serious within the meaning of the Cosmetics Regulation).

<sup>20</sup> For further information on the SUE, please refer to the Cosmetics Europe Guidelines: “Cosmetics Europe Guidelines on the Management of Undesirable Effects and reporting of Serious Undesirable Effects in the European Union”, 2016, available on the following link:

<https://www.cosmeticseurope.eu/>

Assessing these three parameters requires expert knowledge, including expertise and experience with the substances used in the products. The Responsible Person will generally be the most qualified reference person to determine the causality and the seriousness of an undesirable effect.

In order to ensure coordination for the notification of the serious effects to the competent national authorities (avoiding repetitions), it may be advisable to foresee a collaboration contract between the Responsible Person and the Distributor. Such a contract could then be concluded through an *addendum* to the contract setting the frame for the distribution, foreseeing prior sharing of the information.

## **8. Cooperation with the national competent authorities (Articles 5, 6, 24, 25 and 26 of the Cosmetics Regulation)**

### **(a) Obligations of Responsible Persons**

- **Obligation to provide information upon a competent national authority's request**
  - Reasoned request from a national competent authority

#### Cosmetics Regulation – Article 5(3) – Obligations of Responsible Persons

Responsible persons shall cooperate with these authorities at the request of the latter, on any action to eliminate the risks posed by cosmetic products which they have made available on the market. In particular, responsible persons shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product, in a language which can be easily understood by that authority.

According to Article 5 of the Cosmetics Regulation, upon a reasoned (i.e. motivated) request from a competent national authority, a Responsible Person must be in a position to provide the information and documentation necessary to demonstrate that specific aspects of the product are in compliance with the Cosmetics Regulation.

This obligation covers all the areas of responsibility set out in Article 5(1) of the Cosmetics Regulation (Please see Section III, point 4 of this Practical Guide).

However, this provision must be read together with Article 22 of the Cosmetics Regulation (In-market-control) and Article 30 of the Cosmetics Regulation (Cooperation regarding verification of product information files), i.e. such information request from a competent authority must not replace appropriate checks through the Product Information File.

- Serious doubt of a competent national authority regarding the safety of a substance contained in cosmetic products

#### Cosmetics Regulation – Article 24 – Information on substances

In the event of serious doubt regarding the safety of any substance contained in cosmetic products, the competent authority of a Member State in which a product containing such a substance is made available on the market may by reasoned request require the responsible person to submit a list of all cosmetic products for which he is responsible and which contain this substance. The list shall indicate the concentration of this substance in the cosmetic products.

- **Obligation to take all appropriate measures, including corrective actions, to bring a cosmetic product into conformity**

#### Cosmetics Regulation – Article 25 – Non-compliance by the Responsible Person

Without prejudice to paragraph 4, competent authorities shall require the responsible person to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within an expressly mentioned time limit, commensurate with the nature of the risk, where there is non-compliance.

In case of non compliance with the requirements listed below, the Responsible Person must take appropriate measures to remedy the situation, commensurate with the nature of the risk involved, for all products made available on the EU market. Such measures will have to be implemented within the time limit expressly mentioned by the competent national authorities.

Non-conformity that can trigger enforcement measures by the competent national authorities can be related to:

- The good manufacturing practice referred to in Article 8 of the Cosmetics Regulation;
- The safety assessment referred to in Article 10 of the Cosmetics Regulation;
- The requirements for the product information file referred to in Article 11 of the Cosmetics Regulation;
- The provisions on sampling and analysis referred to in Article 12 of the Cosmetics Regulation;
- The notification requirements referred to in Articles 13 and 16 of the Cosmetics Regulation;
- The restrictions for substances referred to in Articles 14, 15 and 17 of the Cosmetics Regulation;

- The animal testing requirements referred to in Article 18 of the Cosmetics Regulation;
- The labelling requirements referred to in Article 19(1), (2), (5) and (6) of the Cosmetics Regulation;
- The requirements related to product claims set out in Article 20 of the Cosmetics Regulation;
- The access to information for the public referred to in Article 21 of the Cosmetics Regulation;
- The Communication of the serious undesirable effects referred to in Article 23 of the Cosmetics Regulation;
- The information requirements on substances referred to in Article 24 of the Cosmetics Regulation.

#### **(b) Cooperation obligations of Distributors**

Articles 6(5) and 26 of the Cosmetics Regulation subject Distributors to two specific obligations vis-à-vis the competent national authorities. Firstly, Distributors must make the information and documents necessary to demonstrate the conformity of certain aspects of the products, available to the authorities. Secondly, they must take corrective or other appropriate measures in case of non-conformity of a product.

##### **▪ Obligation to demonstrate the conformity of the products upon request by an authority**

###### Cosmetics Regulation – Article 6(5) – Obligations of distributors

Distributors shall cooperate with competent authorities, at the request of the latter, on any action to eliminate the risks posed by products which they have made available on the market. In particular, distributors shall, further to a reasoned request from a competent national authority, provide it with all information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2, in a language which can be easily understood by that authority.

Distributors shall, further to a reasoned request from a competent national authority, provide the latter with the information and documentation necessary to demonstrate the conformity of the product with the following requirements:

- the labelling information required under Article 19(1)(a), (e) and (g) and Article 19(3) and (4) of the Cosmetics Regulation (see Section IV, point 2(b) of this Practical Guide);
- the language requirements as specified by Article 19(5) of the Cosmetics Regulation (see Section IV, point 2(b) of this Practical Guide);

- the requirements regarding the date of minimum durability under Article 19(1) of the Cosmetics Regulation, notably if the latter has not expired (see Section IV, point 2(b) of this Practical Guide).

The Distributors' obligation under Article 6(5) (second sentence) of the Cosmetics Regulation is limited to the *"information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2"*, e.g.: copy of the labels when the authority requests proof of labelling compliance.

▪ **Obligation to take appropriate measures in case of non-conformity of a product**

Cosmetics Regulation - Article 26 – Non-compliance by distributors

Competent authorities shall require distributors to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within a given reasonable time limit, commensurate with the nature of the risk, where there is non-compliance with obligations laid down in Article 6.

When the product does not comply with the obligations mentioned in Article 6 of the Cosmetics Regulation, the Distributor shall take all necessary measures within a given reasonable time limit, including corrective measures, to bring the product in conformity with the Cosmetics Regulation. The measures to be taken will depend on the nature of the risk and may include corrective measures, withdrawal or recall of the product from the market.

For example, such a situation may arise when a Distributor makes a product available in a Member State, whilst this was not foreseen by the Responsible Person, without ensuring that the mandatory information printed on the product is in a language accepted by that Member State.


Measures to be taken by Distributors in the context of these provisions will often necessitate information or collaboration with the Responsible Person. Contractual arrangements with the Responsible Person should be envisaged, as appropriate, to facilitate such collaboration or delineate more specifically respective roles and responsibilities in this context.



## ANNEX I – Checklist for Distributors


This checklist can be used in case a Distributor has questions concerning his **obligation to check the labelling of the packaging** according to the Cosmetics Regulation.

➔ Check the **presence on packaging** (regardless the correctness of the information) of the following:

- Name and address of the Responsible Person (both may be abbreviated):
  - on packaging (secondary packaging);
  - on container (primary packaging).
  
- Batch number or reference:
  - on packaging (secondary packaging);
  - on container (primary packaging) unless there are practical reasons.
  
- Ingredient list:
  - on packaging (secondary packaging) only unless there are practical reasons or small packaging (e.g. soap, bath balls and other small products). In such a case, the hand-in-book pictogram (  ) can be present;
  
  - in immediate proximity to the container at the point of sale for small products, where the other labelling options are impossible for practical reasons.

➔ For products with date of minimum durability (Expiry date):  
check that **Expiry date has not passed**

➔ Check that **national language requirements** have been observed for the following:



- Precautions to be observed in use.
  
- Function of the product, *only where the function is not clear from the whole presentation of the product.*
  
- Nominal content, *only when the number of items is indicated on the packaging. It is not needed if the number of items is easy to see from outside or if the product is normally only sold individually.*
  
- The words “best used before the end of” preceding date of minimum durability, *only when a date of minimum durability is present and the symbol “egg-timer” (  ) is not used.*

<b>Explanatory note</b>
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The check list may help Distributors to check the labels according to their obligations laid down in Article 6 of the Cosmetic Regulation.


Important to note that there can be specificities and exemptions to the labelling requirements as provided by Article 19 of the Cosmetics Regulation.

Those specificities and exemptions are detailed below.

- Name and address of the Responsible Person:
  - both can be abbreviated
  - no translation needed
  - in case of several addresses, one address shall be highlighted (it is the one where the PIF is readily accessible)
  
- Precautions to be observed in use:
  - some products do not have any precautions in use
  - in case of small products, the precautions can be on an enclosed or attached leaflet, label, tape, tag or card and can be referred to by the “hand-in-book” () pictogram
  
- Function of the product:
  - in some cases, the overall presentation of the product is clear enough and the labelling of function is not needed
  - some EU-wide well understood terms (e.g. aftershave, eyeliner, perfume, eau de toilette) make a translation of the product’s function superfluous
  
- Date of minimum durability:
  - when there is one, which is not the case for the great majority of products, the symbol “egg-timer” () or the words “**best used before the end of**” can be used. In the latter case, those words shall be translated
  - validity of the date of minimum durability when making the product available on the market:
    - this provision is only relevant for products with such a labelling
    - checks must be organized by the Distributor

**ANNEX II – Labelling Requirements**

Requirements	Container	Packaging	Comments
Name and address of the RP	Yes	Yes	Both can be abbreviated as long as it is still possible to identify the person and his address  When several addresses are indicated, highlight the one where the Responsible Person makes readily available the PIF
Country of origin	No *	No *	* Except for imported cosmetic products (from outside the EU)
Nominal content	Yes	Yes	Except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs
Date of minimum durability if minimum durability ≤ 30 months	Yes	Yes	Several possibilities: -  or the sentence: " <b>Best used before the end of</b> " followed by the date (Month, Year) or (Day, Month, Year); or - if the expiry date is not printed next to the symbol or the sentence, an indication needs to be given on where the date is printed
Minimum durability > 30 months and PAO if relevant	PaO to be labelled	PaO to be labelled	 <b>Months</b> and/or years (usually in months as "x M")
Particular precautions to be observed in use	Yes	Yes	Where it is impossible for practical reasons to label, the information shall be mentioned on an enclosed or attached leaflet, label, tape, tag or card  and shall be referred to by 
Batch number	Yes*	Yes	* Except where this is impossible for practical reasons because the cosmetic products are too small

Function of the product	Yes*	Yes*	* Unless it is clear from its presentation
Ingredients list	No *	Yes	<p>* Except if there is no packaging</p> <p>Where it is impossible for practical reasons to label, the information shall be mentioned on an enclosed or attached leaflet, label, tape, tag or card and shall be referred to by </p> <p>For small products, when the above solutions are not possible, this information shall appear on a notice in the immediate proximity of the product at the point of sale. (“Hand in book” symbol not needed)</p>

**ANNEX III – Labelling compulsorily expressed in national language<sup>21</sup>**

This overview reflects Cosmetics Europe’s current knowledge.

COUNTRY	LANGUAGE
AUSTRIA	German
BELGIUM	Dutch and French and German
BULGARIA	Bulgarian
CZECH REPUBLIC	Czech
CYPRUS	Greek/English
DENMARK	Danish
ESTONIA	Estonian
FINLAND	Finnish and Swedish
FRANCE	French
GERMANY	German
GREECE	Greek
HUNGARY	Hungarian
IRELAND	English
ITALY	Italian
LATVIA	Latvian
LITHUANIA	Lithuanian
LUXEMBURG	French or German or Luxemburgish
MALTA	Maltese/English
NETHERLANDS	Dutch
NORWAY	Norwegian
POLAND	Polish
PORTUGAL	Portuguese
ROMANIA	Romanian
SLOVAKIA	Slovak
SLOVENIA	Slovenian
SPAIN	Spanish
SWEDEN	Swedish
UNITED KINGDOM	English

<sup>21</sup> Courtesy of FEBEA (*Fédération des Entreprises de la Beauté*)

**COSMETICS EUROPE IS THE EUROPEAN TRADE ASSOCIATION REPRESENTING  
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