HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Cosmetic Products Information Pack

FOR PLACING PRODUCTS ON THE IRISH MARKET

Checklist

Before placing a cosmetic product in the market, the RP must address the following:

- RP as per Article 4
- Notification to CPNP as per Article 13
- PIF in place as per Article 11
- - To include CPSR as per Annex 1
- Labelling as per Article 19
- Claims as per Regulation (EU) 655/2013
- Reading list

Articles and Annex refer to Regulation (EC) No. 1223/2009 on cosmetic products

Introduction

This information pack outlines the legal requirements for placing cosmetic products on the European Economic Area (EEA) market, including Ireland, and contains:

- concise information to guide you through placing a product on the market
- checklist to help ensure all tasks are completed before placing cosmetic products on the market

This pack is useful to anyone who has placed or plans to place a cosmetic product on the market.

Regulation (EC) No. 1223/2009 on cosmetic products (the Regulation) is the main piece of legislation concerning cosmetic products in Europe. Every cosmetic product placed on the market in Europe must meet the requirements set out in this Regulation and must be safe for use. In particular, every cosmetic product on the market in Europe must have a **Responsible Person (RP)**.

An RP is responsible for ensuring that the cosmetic product they place on the market complies with the Regulation. An RP can be an individual or a legally registered company and they must be located in the EEA. There must be an RP for every cosmetic product placed on the market in the EEA.

Before placing a cosmetic product on the market, an RP must ensure that requirements for the following have been met in accordance with the Regulation:

- Responsible Person (RP)
- Product Information File (PIF) including a Cosmetic Product Safety Report (CPSR)
- Labelling
- Claims substantiation
- Notification to cosmetic product notification portal (CPNP)

After placing a cosmetic product on the market, the RP must:

- Update the PIF with new information that comes to light (e.g. undesirable effects, ingredient information)
- Update the PIF and CPNP when there is a change in formulation
- Amend the PIF according to any changes to the Regulation

Responsible Person (RP)

An RP is responsible for ensuring that the cosmetic product they place on the market complies with the Regulation. An RP can be an individual or a legally registered company and they must be located in the European Economic Area (EEA). There must be an RP for every cosmetic product placed on the market in the EEA.

A cosmetic product is defined in the Regulation as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair systems, nails, lips and external genital organs) or with the teeth and the mucous membranes or 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".

Before placing a cosmetic product on the market in the EEA, the RP must ensure that the cosmetic product is safe for use and meets the requirements of the Regulation. The name and address of the RP must be on the label of the cosmetic product and in the **product information file (PIF)**. The PIF must be available at the address on the label.

A cosmetic product does not require approval or a licence before being placed on the market. However, the RP must ensure the cosmetic product meets the requirements of the Regulation.

If you perform any of the following activities, you may be considered the Responsible Person for the cosmetic products you place on the market:

	Responsible Person
• Manufacture & sell cosmetic products under your own brand or trademark	✓
• Import cosmetic products from outside the EEA and sell them in the EEA	✓
• Alter the packaging and/or labelling of a cosmetic product which is already on the market, such as rebrand it	✓
• Use a contract manufacturer to make cosmetic products and you sell them under your own brand or trademark	✓

Article 2, 4 & 5 of Regulation (EC) No.1223/2009 on cosmetic products

Cosmetic Product Notification Portal (CPNP)

Before placing a cosmetic product on the market, a **responsible person** (RP) must notify the product to the cosmetic product notification portal (CPNP). One notification is sufficient to place that cosmetic product on the market in any Member State of the EEA.

In general, the RP is the only entity required to notify cosmetic products to CPNP. However, distributors are required to notify CPNP if they translate the language of a cosmetic product label into another language.

In order to notify products to CPNP an account is required. This CPNP account can be obtained by completing the following steps:

Step 1: EU Login

EU login, formally known as the European Commission Authentication Service (ECAS) is an authentication service managed by the European Commission.

- Go to EU Login* and create an account
- Chose username and password
- Click link in email in order to validate account and login

Step 2: SAAS

- Go to SAAS** (while logged into EU Login)
- Select CPNP from dropdown menu and request access
- Create an organisation on SAAS

Step 3: CPNP

- Log into CPNP
- Create user profile as RP
- Begin notifying products

The European Commission provide a tutorial to explain the procedure further. It is available via the following web link:
https://webgate.ec.europa.eu/cpnp/public/tutorial.cfm

*EU login address: **https://webgate.ec.europa.eu/cas**

SAAS: **https://webgate.ec.europa.eu/saas/requestAccess/application/21/create.html

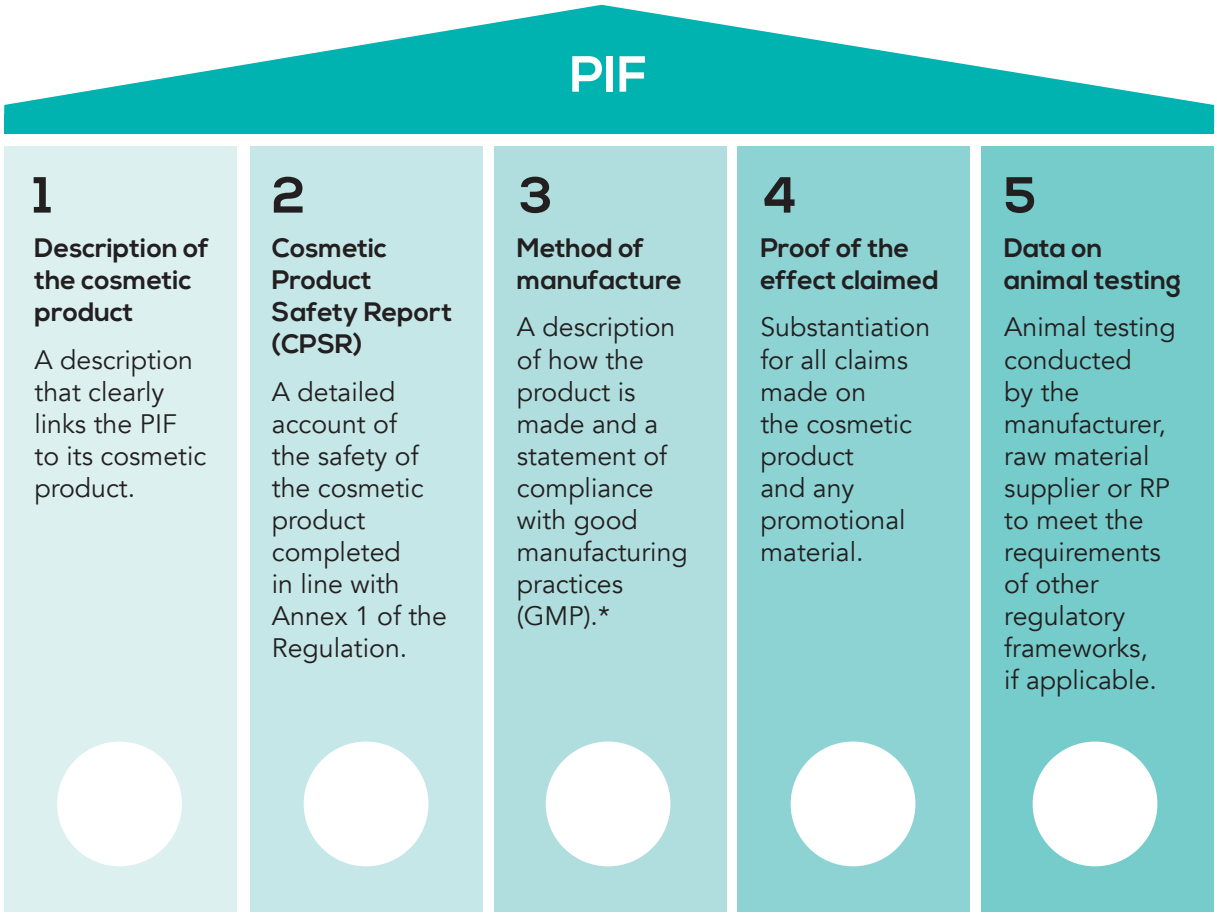
Article 13 of Regulation (EC) No. 1223/2009 on cosmetic products

Product Information File

The product information file (PIF) demonstrates the safety of a cosmetic product for reasonably foreseeable use and must be in place before placing a cosmetic product on the market.

The PIF must be made available by the **responsible person** (RP) at the address displayed on the label of the cosmetic product in accordance with the Regulation.

The RP must keep the PIF for ten years after placing the last batch of it on the market.



* *EN ISO 22716:2008. It is acceptable to use other GMP standards once they are equal or superior to EN ISO 22716:2008 and this is demonstrated in the PIF.*

Article 11 of Regulation (EC) No.1223/2009 on cosmetic products

Cosmetic Product Safety Report (CPSR)

The CPSR is a component of the **product information file (PIF)** and is a critical scientific review of the safety of the cosmetic product.

The CPSR is composed of two parts: Part A – Cosmetic product safety information and Part B – Cosmetic product safety assessment, which must be completed in accordance with Annex 1 of the Regulation.

Part A must contain:

1. Quantitative and qualitative composition of the cosmetic product
2. Physical/chemical characteristics and stability of the cosmetic product
3. Microbiological quality
4. Impurities, traces, information about the packaging material
5. Normal and reasonably foreseeable use
6. Exposure to the cosmetic product
7. Exposure to the substances
8. Toxicological profile of the substances
9. Undesirable effects and serious undesirable effects
10. Information on the cosmetic product

Part B must contain:

1. Assessment conclusions
2. Labelled warnings and instructions for use
3. Scientific reasoning for the conclusions drawn
4. Assessors credentials and approval of Part B

Part B of the CPSR should be carried out by a suitably qualified safety assessor

Annex I of the Regulation and Guidelines on Annex I to Regulation (EC) No. 1223/2009 outline exactly what is required in a CPSR under specific headings and it is important that an RP familiarises themselves with and understands these requirements.

Article 10 & Annex 1 of Regulation (EC) No. 1223/2009

Annex 1 Guidelines

Labelling

The label of a cosmetic product must display certain information as set out in Article 19 of the Regulation.

For the Irish market, the label of cosmetic products should be in English or Irish and English.

Example:

Function of the cosmetic product, if not apparent from the presentation of the product.

List of ingredients
All substances added to the formulation must appear in the list of ingredients from largest quantity to smallest. The INCI name† for each ingredient should be used.

Precautions for use (if applicable)
The **CPSR** should examine the need for precautions for use. All precautions identified should appear on the label of the cosmetic product, unless otherwise justified.

Minimum date of durability or period after opening (PAO)*

RP name and address
Must be based in Europe.

Batch number.

Weight or volume.

***Minimum date of durability** is the date the cosmetic product will remain safe for use if stored under appropriate conditions. If a cosmetic product has a minimum date of durability of over 30 months, then a **period after opening (PAO)** is required.

PAO is the length of time after opening for which the product is considered fit for use by the consumer. An 'open jar' symbol followed by the period (in months and/or years) shows the PAO.

Minimum date of durability and PAO are not random figures. Rather, they are determined as part of testing required to be detailed in the cosmetic product safety report (CPSR) and evidence to support the declared minimum date of durability and PAO must be included in the CPSR.

† International Nomenclature for Cosmetic Ingredient (INCI)

Article 19 & 33 of Regulation (EC) No. 1223/2009

Claims

The claims made on cosmetic products must not be misleading to consumers nor should they imply the cosmetic product has a characteristic or function which it does not have.

Regulation (EU) No. 655/2013, and associated guidance were developed to provide further clarity on the criteria claims must meet to be considered acceptable under Regulation (EC) No. 1223/2009. These requirements apply not only to on-pack claims but to all advertising material, such as advertisements, promotional leaflets and posters and websites.

The six common criteria claims must meet in order to be considered acceptable are as follows:

Legal compliance

Claims that suggest:
- approval of a cosmetic product
- a product has a particular benefit when that benefit is just a requirement of the Regulation are not allowed.

E.g.: 'Approved for sale in Europe' or 'Does not contain lead'*

**Lead is prohibited for use in cosmetic products.*

Fairness

Claims should be objective and should not criticise competitor products.

E.g.: 'Our product X has a superior formulation to leading product Y'.

Evidential support

All claims made in respect of cosmetic products, whether stated or implied, must be supported by evidence. It is acceptable to substantiate a claim using different types of evidential support, such as literature, consumer or clinical studies.

Truthfulness

If a product claims to contain an ingredient, then the ingredient must be present in the product. Similarly, if the product claims to have a particular effect due to the presence of an ingredient, then the finished product must have that specific effect.

E.g.: for the claim 'contains aloe vera which has moisturising effects', the finished product must contain aloe vera and exhibit moisturising effects.

Informed decision making

Claims should be clear and understandable to the average consumer.

Honesty

All claims made on cosmetic products must be honest. For example, if an effect claimed is attributable to many different products, then one product cannot claim the benefit in the absence of the other products. A shampoo product cannot claim to detangle hair when it has been shown that the detangling occurs following use of both a shampoo and conditioner and not the shampoo alone.

The common criteria are in place to ensure claims made on cosmetic products are not misleading to consumers. The common criteria should be applied from the perspective of a consumer who is reasonably well-informed. The RP must give consideration as to how a consumer would interpret the claim.

Article 20 of Regulation (EC) No. 1223/2009

Reading List

The following documents are available from the European Commission website (https://ec.europa.eu/growth/sectors/cosmetics_en)

- Regulation (EC) No. 1223/2009 on cosmetic products
- Guidelines on Annex I to Regulation (EC) No. 1223/2009
- Regulation (EU) 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products
- Guidelines to Commission Regulation (EU) 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products
- Serious Undesirable Effects Reporting Guidelines

The following documents are available from the HPRA website (www.hpra.ie/homepage/cosmetics)

- HPRA Guide to Cosmetics
- HPRA Guide to Cosmetic Products for Responsible Person
- HPRA Guide to Good Manufacturing Practice of Cosmetic Products (To be read in conjunction with ISO 22716:2007)
- HPRA Guide to Distribution of Cosmetic Products in Ireland

Contact cosmetics@hpra.ie for further information

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