

# Guide to Cosmetic products for responsible persons

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## 1 SCOPE

This document is designed to offer guidance to cosmetic product manufacturers, importers and any other designated parties in understanding their obligations when acting as the responsible person (RP) as described in Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as amended ('the Cosmetics Regulation').

A 'cosmetic product' means 'any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours'.

This definition is quite specific and does not encompass products presented as having properties for treating or preventing disease in human beings. Such activities are more in keeping with medicinal product intent. Neither does it include any products used by injection for aesthetic purposes, or products that are inhaled or ingested.

More information on this topic is included on the European Commission Website: [Borderline products - European Commission \(europa.eu\)](#).

## 2 INTRODUCTION

The role of the Health Products Regulatory Authority (HPRA), as the competent authority for cosmetic products, is to help ensure that cosmetic products on the Irish market meet the requirements of cosmetic product legislation and in doing so, do not compromise the health and safety of the consumer and any other person using or coming into contact with such products. For example, products for professional use expose both the professional and the client to the cosmetic product.

Cosmetic products made available on the Irish market must comply with the Cosmetics Regulation, which aims to ensure consumer safety and facilitate the free movement of cosmetic products within the European Union's internal market. It does this by establishing strict safety requirements for cosmetic products, simplifying regulatory procedures, and adapting to scientific and technical advancements.

Responsible persons should be aware of the Irish national legislation, the European Union (Cosmetic Products) Regulations 2013 (S.I. 440 of 2013), which has some additional requirements, for example in relation to language obligations of the labelling and product information file (PIF).

There are a number of other legislative frameworks outside the above-mentioned cosmetics regulations, such as those referenced in section 6.4 of this guide, which responsible persons

should make themselves aware of to ensure that they are meeting all the relevant requirements when placing a cosmetic product on the market.

### 3 ECONOMIC OPERATORS IN THE SUPPLY CHAIN OF COSMETIC PRODUCTS

There are a number of different actors in the supply chain of cosmetic products. The HPRA regulates the manufacture, sale and supply of cosmetic products in Ireland and collaborates with the National Environmental Health Service (NEHS) to monitor the market to identify and address cosmetic product quality and safety issues.

Actors in the supply chain include:

- The manufacturer, who is the natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured and markets that cosmetic product under its name or trademark.
- The importer, who is any natural or legal person established within the EEA who places a cosmetic product from a third country on the Union market. Please note that the importer of a cosmetic product is considered the RP, if no other entity is designated as the RP.
- The distributor, who is any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the market. This includes the retail sale of cosmetics.

However, there must be a designated RP for each cosmetic product placed on the market within the EEA, as stated in Article 4 of the Cosmetics Regulation. The RP may be a natural or legal person; therefore, it is acceptable for the RP to be named as a company.

### 4 THE RESPONSIBLE PERSON

In general, the RP for a cosmetic product is one of the following:

- The manufacturer of the product:
  - o If the product is manufactured **within the EEA**, the manufacturer established within the EEA is considered the RP.
  - o The manufacturer may designate another entity within the EEA to act as the RP, once this is agreed in writing between both parties.
  - o If the manufacturer is established **outside the EEA**, the importer in the EEA acts in the capacity of RP.
  - o Any cosmetic product sourced from outside the EEA for placing on the market is classified as importation. Even if a cosmetic product has a European name and address on the label of the imported products, the importer of the product shall be the RP. In order for the importer to not act as RP for such products, they (as importer) must have a mandated agreement in place with the RP in the EEA. It should be noted, it is not

sufficient for the importer to have an agreement only with the supplier/manufacturer located outside the EEA. The entity based outside the EEA cannot act as or designate the RP.

- If the manufacturer or importer within the EEA designates another party within the EEA to act as the RP, this designation and the acceptance of the role by the RP must be formally set out in writing.
- If a distributor of a cosmetic product modifies a cosmetic product in a way which compromises its compliance with the legislation and/or markets a cosmetic product under its name or trademark, the distributor takes on the role of RP. However, translation of existing information is generally not considered to be modification.

The RP must always be based within the EEA. Since Brexit, the RP cannot be based in Great Britain; however, it may be based in Northern Ireland. Their address should appear on the cosmetic labelling.

## **5 OBLIGATIONS OF THE RESPONSIBLE PERSON**

The responsible person (RP) is legally obliged to ensure compliance with the Cosmetics Regulation. Article 5 of the Cosmetics Regulation states that the RP shall ensure compliance in relation to:

- Article 3: Safety
- Article 8: Good manufacturing practice
- Articles 10 and 11: Safety assessment and product information file
- Article 12: Sampling and analysis
- Article 13: Notification
- Articles 14, 15 and 17: Restrictions for substances listed in the Annexes, substances classified as CMR substances, and traces of prohibited substances
- Article 16: Nanomaterials
- Article 18: Animal testing
- Article 19: Labelling
- Article 20: Product claims
- Article 21: Access to information for the public
- Article 23: Communication of serious undesirable effects
- Article 24: Information on substances

The RP must ensure they are familiar with their legal obligations to fulfil the requirements of the Cosmetics Regulation. It is the HPRA's expectation that, should an RP not have adequate experience or knowledge to fulfil their duties, they should seek appropriate assistance from experts in the field. More information relating to the RP can be found on the [HPRA website](#).

## **6 PRODUCT INFORMATION FILE**

Cosmetic products must be safe for use. The safety and quality of cosmetics must be documented by the responsible person in a product information file (PIF), which must be prepared prior to placing a cosmetic product on the EEA market. This RP must maintain this PIF throughout the life cycle of the cosmetic product at the address which appears on the product's label.

In the event a cosmetic product is no longer to be placed on the EEA market, the PIF must be kept for a period of 10 years following the date on which the last batch of cosmetic product was placed on the market.

The information that must be contained within the PIF is outlined in this section.

### **6.1 Product name and description**

Each product should have a product name and description which allows the consumer to identify what product they are purchasing. Each product must be described in a way that clearly attributes the PIF to the cosmetic product; it is recommended that a product or formulation code is assigned for internal referencing.

### **6.2 Cosmetic Product Safety Report**

The safety assessment is an account of the scientific reasoning to support the safety of the cosmetic product. It should be noted that the requirements of the cosmetic product safety report (CPSR) are specific, and documents known as Material Safety Data Sheets (MSDS) are not sufficient.

A safety assessment should be conducted by a suitably qualified natural person who may be a consultant or an employee. The name, address and qualifications of the safety assessor must be maintained in the safety report. If the safety assessor has obtained their formal qualifications from outside the EEA, evidence of equivalence of their qualification with one of that of a Member State of the EEA should be included in the safety report.

The Scientific Committee on Consumer Safety (SCCS) notes of guidance for testing of cosmetic ingredients and their safety evaluation offers useful guidance. In addition, the European Commission has published a Commission Implementing Decision (2013/674/EU) on how to comply with the requirements of Annex I (Cosmetic Product Safety Report) of the Cosmetics Regulation. The Commission Implementing Decision is available on the [European Commission's website](#).

The RP and safety assessor should work closely together to ensure that the safety of the product is properly assessed, documented and kept up to date. The RP should ensure that the safety assessment is adequately detailed to demonstrate that the product is safe.

It is recommended that the RP puts in place a technical agreement or contract with its safety assessor outlining the roles and responsibilities of the safety assessor in relation to the following (this list is not exhaustive):

- access to all the technical and scientific skills necessary
- access to safety information
- ongoing review and updates to the CPSR
- consideration of serious undesirable effects (SUEs) in the CPSR

It may be necessary to involve the suppliers of raw materials, and other technical experts to fully evaluate the safety of the cosmetic product. The safety assessor should have access to the details and quality standards of the raw materials used, so they can consider the potential presence of contaminants. It is not considered sufficient to evaluate each of the ingredients in isolation; the product formulation should also be evaluated, taking into consideration possible interaction between ingredients.

If essential oils are used in the manufacture of the product, it is considered useful to consult the '[Guidance on essential oils in cosmetic products](#)', published by the Council of Europe.

A specific safety assessment should be carried out for cosmetic products intended for use on children under the age of three. The physiological, metabolic and behavioural characteristics of infants should be taken into account, such as the fact that the skin surface of infants and children relative to their body weight is larger than in adults. When assessing the safety of cosmetic products intended for infants, attention should be paid to possible toxicological effects on the nervous, immune, respiratory and endocrine systems. Further information is available in the guidance '[Safe Cosmetics for Young Children – A Guide for Manufacturers and Safety Assessors](#)', published by the Council of Europe.

### **6.3 Method of manufacture**

An overview of the method of manufacture; the level of detail to be included should be commensurate to how complicated the manufacturing process is. The manufacturing phases, speeds and timeline should be included in a manner that protects any manufacturing intellectual properties. A declaration of compliance with good manufacturing practices (GMP), or an ISO 22716 certificate, should be included in the PIF. See section 7 of this guide for further information.

### **6.4 Label claims and proof of effect**

Commission Regulation (EU) No. 655/2013 lays down common criteria for the justification of claims used in relation to cosmetic products.

Label claims including the product name and description should not be misleading and should be supported by sufficient, sound and relevant evidence. The benefits delivered by the product should be consistent with reasonable consumer expectations created by the claims, and scientific, technical or consumer perception studies performed. There are a number of methods that can be used to substantiate label claims, as outlined below.

### 6.4.1 Methods of substantiating label claims

#### Literature review

Evidence of claims that are widely accepted may be substantiated using independently peer-reviewed supporting data. Additional product-specific data may be required to accompany this literature review. Where claims are based on ingredient efficacy, data should ensure that the ingredient is effective at the concentration present in the finished product and that its activity is maintained in the product.

#### Sensorial approach

These are user tests taking into account the perception of product efficacy based on factors the volunteers can observe or feel. Tests are based on an appreciation of product performance made through the senses of either panellists or experts. They give information mainly on observed or perceived parameters. An example of such a claim is '8 out of 10 women felt their skin was smoother after just one week.'

#### Instrumental approach

These tests are performed with instruments which can accurately measure given parameters, according to a defined protocol, following the application of a product on human subjects, for example, skin hydration tests conducted in a laboratory or colorimetric tests for the measurement of colour.

Studies conducted on volunteers should adhere to ethical guidelines and products tested should have previously undergone a safety assessment. For further information, refer to the World Health Organisation's [Handbook for good clinical research practice \(GCP\)](#) and/or the World Medical Association's [Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects](#).

### 6.4.2 Nature of claims

Care should be taken to ensure that product claims are consistent with that which is considered reasonable and consistent with the definition of a cosmetic. In particular, borderline claims with other classes of products must be considered carefully. The European Commission has published a number of guidance documents which are available on their website in the [Borderline Manual](#). Medicinal products and biocidal products are examples of classes which can commonly have a border with cosmetics.

#### Medicinal claims

Promoting a product with claims that it treats or prevents disease or otherwise affects the structure or any function of the body may render the product a medicinal product. For more information on medicinal claims, refer to the HPRA 'Guide to the definition of a human medicine', available on the HPRA website under '[Regulatory guidance documents](#)'.

## 6.5 Data on animal testing

A ban on testing finished cosmetic products on animals has been applied since 2004. A similar testing ban on ingredients or combinations of ingredients has been applied since 2009 where alternative validated methods to animal testing have been available. A marketing ban on finished products or ingredients tested on animals, where alternative methods are available, was imposed in 2009.

As of 11 March 2013, a ban on all animal testing of finished products and ingredients applies, even if there are no alternative non-animal tests. The SCCS outlines available alternative validated methods to animal testing ([SCCS safety testing guidelines](#)).

Data on any animal testing performed by the manufacturer, agents or suppliers and any animal testing performed to meet the regulatory requirements of third countries should be included in the PIF. Where no animal testing has been conducted, a statement indicating this should be included in the PIF. Therefore, where an animal test has been performed, the following information should be contained within the PIF:

- identification of the animal test carried out
- identification of the ingredient tested
- date of the animal test
- location of the animal test
- information on the entity (or entities) that carried out the test and the entity that commissioned it
- legislative purpose of the animal test and substantiation of the stated purpose

In the case of the last point, a clear reference to the legislation in question, a short description of the scope and of the need for the testing under that legislation should be included. Substantiation of the stated legislated purpose can also take the form of the listing of the respective ingredient under other legislation (e.g. in a positive list), and it can be demonstrated by labels of products including the respective ingredient.

## 7 GOOD MANUFACTURING PRACTICES

Article 8 of the Cosmetics Regulation establishes ISO 22716 or equivalent as the requirements for good manufacturing practice (GMP).

ISO 22716 is the GMP standard and provides organisational and technical guidance on the management of the human, technical and administrative factors affecting cosmetic product manufacture and product quality.

The documentation system implemented should incorporate the following (this list is not exhaustive):

- procedures
- instructions
- specifications

- protocols
- reports (such as complaints, deviations, investigations and recalls)
- methods
- records

For more information on GMP for cosmetic products, refer to the HPRA 'Guide to good manufacturing practice of cosmetic products' available on the HPRA website under '[Regulatory guidance documents](#)'.

## **8 CONSUMER INFORMATION**

The following information should be made available to the public on request but does not have to be published:

- qualitative and quantitative list of ingredients
- the name and code number of the composition and the identity of the supplier of fragrances
- data on undesirable and serious undesirable effects (UE/SUEs)

## **9 COMMUNICATION OF SERIOUS UNDESIRABLE EFFECTS**

The Cosmetics Regulation is the basis for a uniform approach to the communication of SUEs attributable to the use of cosmetics. It provides for notification of SUEs to the competent authority of the member state where the SUE occurred, without delay, as well as the notification of any corrective measures taken by the RP or distributor.

To facilitate the implementation of a harmonised communication and management system on SUEs throughout the EU, [SUE Reporting Guidelines](#) were developed.

As the safety report requires the safety assessor to consider any trending of UE and SUEs, it is important that the RP has a system in place to manage, investigate and appropriately record reports of both UE and SUEs.

## **10 TRACEABILITY WITHIN THE SUPPLY CHAIN**

Traceability of a cosmetic product throughout the entire supply chain is necessary, owing to the free movement of goods within the EEA. Accordingly, the RP should keep records of the distributors (including retailers) they supply, including contact details and dates of supply. In turn, distributors should document who they receive a cosmetic product from i.e. their suppliers, and details of all operators to whom they supply.

Good systems of traceability will make market surveillance more efficient, and this has benefits to the free movement of goods. For example, a consignment of cosmetic product may be detained by market surveillance authorities whilst they identify the economic

operators involved. An efficient traceability system facilitates the task of tracing economic operators and thereby speeds up the entire process resulting in the prompt release of the consignment to the market.

This obligation with respect to identification within the supply chain must be met for three years after each batch of product was made available to the distributor. Further information is available in the HPRA 'Guide to distribution of cosmetic products in Ireland', available on the HPRA website under '[Regulatory guidance documents](#)'.

## 11 LABELLING

All cosmetic products are required to be appropriately labelled. The image below shows an example of a cosmetic product label for a shampoo. It should be noted that not all of the items depicted are obligatory. Guidance for cosmetic labelling is provided in this section.

Example:



### 11.1 Name and address of the RP (EEA Address)

Article 19 of the Cosmetics Regulation stipulates that the name and address of the RP must be on the container and packaging of the cosmetic product. The RP address must be within the EEA or Northern Ireland. The cosmetics legislation allows for the address to be abbreviated as long as the abbreviation makes it possible to identify that person and address. For the HPRA to accept an address, it must be sufficiently detailed to accurately describe the location of the PIF. It must also be an address that permits a letter to be delivered through the postal service. The name of the company accompanied by a phone number, PO box and/or email address would not be acceptable; however, the appropriate use of an Eircode

could be acceptable. Where a product is being manufactured at a residential property, the full address is not required on the label, but the company name should be accompanied by contact details as listed above. Where there is more than one EEA address on the product label, the address at which the PIF is located should be indicated (usually by underlining the address).

## **11.2 Nominal weight or volume**

A cosmetic product should display the nominal content at the time of packaging, given by weight or by volume. The following products are exempt from this requirement:

- free sample products (the weights and measures legislation only covers products for sale);
- products containing less than 5 g or 5 ml;
- products intended for single application, e.g. sachets;
- products for which the details of weight or volume are not relevant, for example, bath balls, (however, the number of items within packaging should be stated if it is not obvious from the product presentation)

## **11.3 Date of minimum durability or period after opening**

The date of minimum durability or period after opening (PAO) is assigned to a cosmetic product and must be supported by stability study data. A date of minimum durability (best before date) is required unless stability data indicate that the product is stable for more than 30 months. The PAO refers to the time within which the product may be used, once opened by the consumer. An open jar symbol is used to indicate 'the period' (Annex VII (2) of the Cosmetics Regulation). There are some exceptions where the period is not required, and this should be justified in the PIF, for example, if the product is single use only, there is no physical opening or there is no risk of deterioration which could lead to a risk to the consumer.

## **11.4 Precautions for use**

The conditions of use and warnings which must be printed on the label are generally related to the ingredient list. A search for each ingredient on the European Commission database, [CosIng](#), will give information on warnings. Precautions and warnings should be verified in the most recent publication of the Cosmetics Regulation. The safety assessor should identify precautions which should appear on the label while drafting the CPSR, and state the required precautions in the CPSR. The safety assessor should consider the product's method of use and presentation, for example, restricting a product to professional use only (see section 11.5 of this guide).

## **11.5 Professional use only (if applicable)**

The restriction to professional use ensures that certain products are used by a professional only.

The restriction applies to cosmetic products which:

- contain certain substances, or

- contain substances in a higher concentration than for general use

A professional is more familiar with the health risks of a specific substance or its concentration in the cosmetic product than a consumer or has more professional expertise in applying cosmetic products correctly on the consumer, for example, products intended to be applied to the nails or on the hair, but which must not come into contact with the skin.

Where a restriction to professional use is required, it will be stated in Annex III of the Cosmetics Regulation and should be taken into consideration in the safety assessment.

It is the HPRA expectation that if a product is intended for professional use only, the RP ensures that supply is only provided to the appropriate customer base.

### **11.6 Batch number for traceability**

The batch number should be a unique identifier relating to the manufacture of a single batch allowing traceability of the cosmetic product. A product code or barcode does not constitute a batch number unless a new code is generated for each batch of product manufactured. It should be clear which code on the cosmetic product identifies the batch.

### **11.7 Product function**

The function or instructions for use are required where they are not obvious from the way the product is presented. In some instances, instructions may be necessary to ensure that the cosmetic product is used correctly. For example, a mouthwash product may require instructions such as 'rinse around teeth and gums for 30 seconds, then spit out'.

### **11.8 List of ingredients**

A full list of ingredients must be given on the outer packaging headed or preceded by the word 'INGREDIENTS'. An exception applies if it is impractical to label the product with a list of ingredients due to size or shape. In such cases, the product may refer to the ingredients being on display at retail level. The open book symbol (Annex VII of the Cosmetics Regulation) can be used to indicate that the information is given elsewhere.

The name given in the Common Ingredients Nomenclature known as the INCI name (International Nomenclature for Cosmetic Ingredients) should be used to list ingredients. The ingredients should be listed in decreasing order of weight. Ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of more than 1%.

### **11.9 Suitable languages**

English, or English and Irish, are suitable languages for labelling of cosmetic products on the Irish market. Products which are not labelled in English, or English and Irish, must be appropriately translated prior to being placed on the Irish market.

## **12 SAMPLING AND ANALYSIS**

Quality control checks including sampling and analysis must be performed in a reliable and reproducible manner. A number of test methods are provided in Commission Directives 80/1335/EEC, 82/434/EEC, 83/14/EEC, 85/490/EEC, 93/73/EEC, 95/32/EC and 96/45/EC. In the absence of a legislative method, test methods are presumed reliable and reproducible if they are in compliance with the relevant ISO or CEN standards. Relevant records of sampling and analysis plans and results should be maintained.

## **13 NON-COMPLIANT PRODUCT**

In the event of a non-compliance being identified, the RP must take all appropriate measures to bring the product into conformity. If a cosmetic product poses a risk to consumers, measures must be taken to prevent risk to the consumer, such as adequate and effective warning of the risk to consumers, recall of the product or affected batch from consumers or withdrawal of the product from the market. Market action including recall and withdrawal should take place when other measures are not considered adequate to prevent the risk to the consumer.

If a cosmetic product on the market is considered to be a risk to the consumer, the RP must inform the HPRA without delay. Where a decision is taken by the RP to take market action on the Irish market, the HPRA should be informed in advance by contacting [cosmetics@hpra.ie](mailto:cosmetics@hpra.ie).

### **13.1 Corrective and preventative actions**

Corrective actions required to address non-compliance(s) can vary in terms of severity. Measures taken to bring the product into conformity may include but are not limited to:

- Re-labelling or over-labelling
- Marketing the product with appropriate warnings
- Making the marketing of the product subject to prior conditions
- Reformulation

The PIF should be updated to reflect any changes made to the product. Substantial changes such as reformulation generally require a new PIF.

### **13.2 Recalls and product withdrawals**

There should be established written procedures, regularly checked and updated as required, to organise any recall or withdrawal activity. The HPRA's 'Guide to distribution of cosmetic products in Ireland', available on the HPRA website under '[Regulatory guidance documents](#)', provides detailed information on expectations in relation to product recall and withdrawal. These expectations also apply to RPs. For further information refer to ISO 22716.

## 14 NOTIFICATION

Prior to placing on the market, the RP must notify the cosmetic product to the European Commission (EC). The Cosmetic Product Notification Portal (CPNP) is a centralised database for the notification of cosmetic products. It should be noted that for some cosmetics containing nanomaterials, they require notification to CPNP six months in advance of marketing. Further information on the CPNP is available on the [European Commission website](#).

The information submitted by RPs (and in some cases distributors) via the CPNP is made available electronically to the competent authorities (for the purposes of market surveillance, market analysis, evaluation and consumer information) and to the poison centres (for the purposes of medical treatment). The National Poisons Information Centre has been appointed as the body responsible for receiving emergency health response information relating to cosmetic products. Further information can be found on the [National Poisons Information Centre website](#).

Please note that the CPNP is managed by the European Commission, and any queries or issues associated with the website should be sent directly to them.

## 15 MARKET SURVEILLANCE BY THE HPRA

As part of our obligations as competent authority in Ireland for cosmetic products, the HPRA, in conjunction with the National Environmental Health Service (NEHS), carry out an annual sampling and analysis plan of cosmetics on the Irish market.

This surveillance involves proactive and reactive activities which include:

- cosmetic product sampling and analytical testing
- review of cosmetic product labelling
- review of cosmetic PIFs and associated safety data
- inspection of RPs, manufacturers, importers and distributors of cosmetic products

The HPRA may receive requests from competent authorities for cosmetics in other Member States in relation to cosmetic products where the RP is located in Ireland. The HPRA may contact the RP for information in relation to products as necessary.

The HPRA conducts inspections of cosmetic product RPs, in relation to verifying if there are controls of processes in place that ensure the obligations of the RP are consistently met. The HPRA considers that, for an RP to consistently meet their obligations, there should be a documented quality management system in place. Further information is included in the HPRA's 'Guide to distribution of cosmetic products in Ireland', available on the HPRA website under '[Regulatory guidance documents](#)'.

## **16 FURTHER INFORMATION**

Further guidance on cosmetic products is available on the HPRA website, under the 'Regulatory guidance documents' and the 'Cosmetics' sections.

For queries relating to the responsible person for cosmetic products, contact the HPRA via email at [cosmetics@hpra.ie](mailto:cosmetics@hpra.ie), or use the '[contact us](#)' form on the HPRA website.