



COSMETICS

Legal & Regulatory Aspects

Audrey Anne Anastasi

Foodstuffs, Chemicals, Pesticides & Cosmetics Unit

Regulatory Affairs Directorate

Malta Standards Authority

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OUTLINE

- ◆ Current Regulations
- ◆ General Information
- ◆ Ingredients/Composition
- ◆ Labelling
- ◆ Notification to the MSA
- ◆ Product Information File
- ◆ Cosmetics & Animal Tests
- ◆ Roles & Functions of MSA
- ◆ Proposal for a Regulation on Cosmetics

Current Regulations

- ◆ National Legislation: L.N. 424 of 2004 (as amended)
- ◆ Transposes Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (as amended)

Aims & Objectives...

- ◆ Aims at ensuring the **free circulation** of cosmetic products in the internal market and safeguarding the **safety** of cosmetic products placed on the EU-market.
- ◆ This safety relates to **composition, packaging** and **information** and it falls totally under the responsibility of the producer or the importer into the EU who is responsible for the marketing liability.
- ◆ There is **no pre-market control** for cosmetic products at Member State or EU level.
- ◆ Control of cosmetic products within the EU is assured through the **responsibility of the person who places the product on the market**, a simple notification of manufacturing/importing site, and an in-market surveillance system.

What falls under the definition of a Cosmetic Product?

A *'cosmetic product'* shall mean any substance or preparation intended to be placed in contact with:

- ◆ the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or
- ◆ the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to:
 - ◆ cleaning them,
 - ◆ perfuming them,
 - ◆ changing their appearance and/or correcting body odours and/or protecting them or
 - ◆ keeping them in good condition.

ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS

- ◆ Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).
- ◆ Face masks (with the exception of peeling products).
- ◆ Tinted bases (liquids, pastes, powders).
- ◆ Make-up powders, after-bath powders, hygienic powders, etc.
- ◆ Toilet soaps, deodorant soaps, etc.
- ◆ Perfumes, toilet waters and eau de Cologne.
- ◆ Bath and shower preparations (salts, foams, oils, gels, etc.).
- ◆ Depilatories.
- ◆ Deodorants and anti-perspirants.
- ◆ Hair care products.
- ◆ Shaving products (creams, foams, lotions, etc.).
- ◆ Products for making up and removing make-up from the face and the eyes.
- ◆ Products intended for application to the lips.
- ◆ Products for care of the teeth and the mouth.
- ◆ Products for nail care and make-up.
- ◆ Products for external intimate hygiene.
- ◆ Sunbathing products.
- ◆ Products for tanning without sun.
- ◆ Skin-whitening products.
- ◆ Anti-wrinkle products.

Borderline Products

- ◆ **Cosmetic/Biocide?**
- ◆ **Cosmetic/Medicine?**
- ◆ **Cosmetic/Medical Device?**

- ◆ **Type of product**
- ◆ **Application site**
- ◆ **Effect Site**
- ◆ **Intended Cosmetic Purpose**
- ◆ **Absence of pharmacological, immunological or metabolic action**

Examples of Borderline Products

- ◆ Glue for artificial nails
- ◆ Sculptured nails
- ◆ Nail hardeners/strengtheners
- ◆ Products intended to remove corns and callosities or soften callosities
- ◆ Products for foot-care containing antimycotic or other antimicrobial substances
- ◆ Products reducing hair loss and stimulating hair growth
- ◆ Anti-dandruff products
- ◆ Products to whiten teeth
- ◆ Products for sensitive teeth
- ◆ Exfoliants
- ◆ Anti-cellulite products
- ◆ Skin whitening products
- ◆ Products with essential oils
- ◆ Insect repellents
- ◆ Products for external intimate hygiene
- ◆ Etc.

Example 1: Products with antimicrobial/antiseptic properties

Function: Keeping in check the dermal flora and thus protecting the good condition of the skin

- ◆ A product which presents itself as “antiseptic” or “antibacterial” may be a biocidal product, a cosmetic product, a medicinal product or a medical device.
 - ◆ Biocide: claims refer to antifungal activity, microbicidal or antiseptic properties
 - ◆ Cosmetic: prevent excessive proliferation of the skin flora
 - ◆ Medicine: claims referring to antiseptic/antibacterial properties
 - ◆ Medical Device: Disinfectants intended for use with medical devices if intended for general use

Example 2: Products against impure and blemished skin

Function: Improving blemished and impure skin; regulating the secretion of the sebaceous glands, constricting dilated pores and diminishing comedons and white spots

- ◆ Medicinal or Cosmetic? It depends on:
 - ◆ Claims referring to function
 - ◆ Non-cosmetic: Preventing, alleviating, treating of acne
 - ◆ Composition
 - ◆ Non-cosmetic: Retinoic acid and derivatives, such as tretinoin; benzoyl peroxide; resorcinol; salicylic acid >2%

Ingredients/Composition

- ◆ Substances which cosmetic products must not contain and substances which can only be used subject to restrictions and conditions laid down
- ◆ Substances provisionally allowed
- ◆ Colouring agents provisionally/allowed
- ◆ Substances excluded from the scope of the regulations
- ◆ Preservatives & UV filters allowed

Inventory of Ingredients

- ◆ On 8 May 1996, the Commission adopted Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products, amended by Commission Decision 2006/257/EC of 09.02.2006
- ◆ The inventory is divided into a general introduction, a section 1 (cosmetic ingredients other than perfume and aromatic raw materials) and a section 2 (perfume and aromatic raw materials).

International nomenclature of cosmetic ingredients (INCI)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:097:0001:0528:EN:PDF>

CosIng

<http://ec.europa.eu/enterprise/cosmetics/cosing/>

EU
CION
Database

The screenshot shows the CosIng website interface. At the top, there is a navigation bar with the CosIng logo and the text "COSMETIC INGREDIENTS & SUBSTANCES". To the right, there is a language selector set to "English (EN)". Below the navigation bar, there is a breadcrumb trail: "EUROPA > European Commission > Enterprise and Industry > Cosmetics > CosIng". On the left side, there is a sidebar menu with sections: "SEARCH" (containing "Simple Search" and "Advanced Search"), "REFERENCE DATA" (containing "Directives", "Annexes", "Functions", and "Abbreviations"), and "Important legal not" (with a dropdown for "English (EN)"). The main content area is titled "Simple Search" and contains a "Welcome to CosIng" message. The message states: "CosIng is the European Commission database with information on cosmetic ingredients contained in the: - 'Cosmetics Directive' 76/768/EEC (Cosmetics Directive), as amended; - Inventory of Cosmetic Ingredients, as amended; and - Opinions on cosmetic ingredients of the Scientific Committee for Consumer Products. CosIng also allows for search for the relevant CAS, ELINCS or EINECS numbers. CosIng includes all data since the adoption of the Cosmetics Directive in 1976. Therefore the current data are mentioned as 'active' and the historical data as 'not active'." Below the message, there is a search instruction: "You can search a substance (entry in the directive) or an INGREDIENT (entry in the inventory) by: Name [i] or CAS/EINECS/ELINCS # [input field]".











Important note: The *inventory of ingredients* and the *CosIng database* are purely indicative and do not constitute a list of the substances authorized or banned for use in cosmetic products.

For safety-related restriction of ingredients you have to consult the Cosmetics regulations!

Labelling

- ◆ Container & packaging:
 - ◆ Name/style & address of manufacturer or responsible person
 - ◆ Country of origin
 - ◆ Nominal content (wt/vol)
 - ◆ Date of minimum durability '*best used before the end of*' (M/Y-D/M/Y)
 - ◆ Period after opening symbol (M &/or Y) (DMB – not mandatory)
 - ◆ Particular precautions (on label accepted + symbol)
 - ◆ Batch no. (on packaging alone accepted)
 - ◆ Function of the product (unless clear from presentation)
 - ◆ 'Ingredients' (on packaging alone accepted; on label accepted + symbol)
 - ◆ INCI nomenclature
 - ◆ 'Parfum' or 'Aroma'
 - ◆ Claims

Cosmetic Label: Sample

 LOGO	 <p>Apply to areas of the face where needed.</p>  <p>Caution: Avoid Eye Area</p>  <p><i>Ingredients:</i> ALCOHOL DENAT.-FRAGRANCE (PARFUM)-WATER (AQUA PURIFICATA) PURIFIED-LINALOOL- CINNNAMIC ALCOHOL-LIMONENE.</p> 
 <p>Facial Moisturizer</p>	 <p>© Cosmetic Co. <u>London WIK 38Q</u> Paris-Milano</p>
 <p>Net Wt. 30mL</p>	 <p>Made in USA</p>
 <p>Batch No: 25819</p>	

Notification to the MSA

- ◆ The Regulatory Affairs Directorate within MSA is the notification point for cosmetic products manufactured in Malta or imported into the Community for the first time through Malta
- ◆ Cosmetic Product Registration Form:
 - ◆ Company Name & Address
 - ◆ Manufacturing Site Address
 - ◆ Parent Company's Name & Address if product under licence
 - ◆ Range name & the product names
 - ◆ Contact person/address/email/telephone no. & fax no.
- ◆ Final Label or copy

Cosmetic Product

Registration Form

COSMETIC PRODUCT REGISTRATION FORM FCC001

Date: ___/___/___

Company Name: _____

Company Address:

Manufacturing Site Address¹:

This product is manufactured: Under Licence Locally

If produced under licence, please give the address of the parent company:

Range Name²: _____

Products that are marketed under this range:

Contact Person: _____

Address:

Email:

Tel:

Fax:

Signature: _____

Product Information File (PIF)

- ◆ The responsible person must keep PIF readily accessible (upon request - within 72 hours) with the following information:
 - ◆ Qualitative & quantitative composition
 - ◆ Compliance with GMP
 - ◆ Human health safety assessment of finished product carried out according to GLP (Directive 87/18/EEC):
 - ◆ Name & address of qualified person/s responsible for the human health safety assessment
 - ◆ Existing data on undesirable effects on human health resulting from use of the cosmetic product
 - ◆ Proof of the effects claimed
 - ◆ Data on animal testing
 - ◆ Methods of analysis necessary for checking the composition of cosmetic products
 - ◆ The criteria of microbiological and chemical purity for cosmetic products and methods for checking compliance with those criteria

Cosmetics & Animal Tests

- ◆ Regulations establish a prohibition:
 - ◆ to test finished cosmetic products - *11 September 2004* - and cosmetic ingredients - *11 March 2009* - on animals (testing ban); and
 - ◆ to market in the EC, finished cosmetic products and ingredients included in cosmetic products which were tested on animals (marketing ban)-
 - ◆ *This marketing ban will be introduced on 11 March 2009, for all human health effects with the exception of repeated-dose toxicity, reproductive toxicity and toxicokinetics. For these specific health effects, the deadline is on 11 March 2013, irrespective of the availability of alternative non-animal tests.*

Roles & Functions of MSA

- ◆ Notification point
- ◆ Guidance on compilation of product information and labelling of cosmetic products
- ◆ Inspection of product information dossiers
- ◆ Site visits
- ◆ Free Sales Certificate

MSA Website

<http://www.msa.org.mt/rad/cosmetics/>

Malta Standards Authority -

Regulatory Affairs Directorate

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Cosmetics

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Overview

[Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products](#) ("Cosmetics Directive") is the main regulatory framework which aims at ensuring the free circulation of cosmetic



products in the internal market and safeguarding the safety of cosmetic products placed on the EU-market. The principles laid down in the Cosmetics Directive take into account the needs of the consumer while encouraging commercial exchange and eliminating barriers to trade. For example, if a product is to move freely within the EU, the same labelling, packaging and safety regulations must

Links

- ◆ **Borderline Products:**
http://ec.europa.eu/enterprise/cosmetics/html/cosm_borderline_docs.htm
- ◆ **Colouring agents:**
http://ec.europa.eu/enterprise/cosmetics/html/cosm_colouring_agents.htm
- ◆ **Cosing Database:** <http://ec.europa.eu/enterprise/cosmetics/cosing/>
- ◆ **Guidelines:**
http://ec.europa.eu/enterprise/cosmetics/html/cosm_guidance_docs.htm
- ◆ **Hair Dye Products:**
http://ec.europa.eu/enterprise/cosmetics/html/cosm_hairdyes.htm
- ◆ **Importing in the EU:**
http://ec.europa.eu/enterprise/cosmetics/html/cosm_import.htm
- ◆ **Inventory of Ingredients:**
http://ec.europa.eu/enterprise/cosmetics/html/cosm_inci_index.htm
- ◆ **'Period after opening' label:**
http://ec.europa.eu/enterprise/cosmetics/html/cosm_open_label.htm
- ◆ **Sunscreen Products:**
http://ec.europa.eu/enterprise/cosmetics/sunscreens/index_en.htm



Proposal for a Regulation of the European Parliament and of the Council on Cosmetic Products

(COM(2008)49)

(Recast)

Audrey Anne Anastasi

Foodstuffs, Chemicals, Pesticides & Cosmetics Unit

Regulatory Affairs Directorate

Malta Standards Authority

4th June 2008

OUTLINE

- ◆ Purpose & Objectives
- ◆ Public Consultation
- ◆ Impact Assessment
- ◆ Changes Proposed
- ◆ Labelling Requirements
- ◆ Views & Possible Impacts

Purpose of Proposal...

- ◆ To join together the 63 amendments in 1 legal text.
- ◆ Regulation - facilitates a harmonised application and removes the need for transposition of the highly detailed provisions of the Cosmetics Directive.
- ◆ This proposal pursues three objectives:
 1. To remove legal uncertainties and inconsistencies;
 2. To avoid divergences in national transposition which do not contribute to product safety but instead add to the regulatory burden and administrative costs;
 3. To ensure that cosmetic products placed on the EU market are safe in the light of innovation in this sector.

Public Consultation...

- ◆ The consultation confirmed:
 - ◆ That the Cosmetics Directive needed to be **recast** and that many provisions required **clarification**;
 - ◆ That in order to ensure a high level of protection of **human health** throughout the EU and to ensure an **internal market** for cosmetic product, a recast Cosmetics Directive should take the form of a **Regulation**.
 - ◆ In terms of product safety, the need to sharpen the focus on the **manufacturer's responsibility** for the **safety** of cosmetic products placed on the market .

Impact Assessment...

- ◆ The impact assessment supports:
 - ◆ The amendment of the Cosmetics Directive as the only effective means of increasing legal certainty thereby reducing the regulatory burdens considerably.
 - ◆ The clarification and streamlining of various provisions facilitates compliance without compromising product safety.
 - ◆ A recast into the form of a Regulation.
 - ◆ Striking a better balance between “manufacturer responsibility” and “prescriptive regulation of individual ingredients”.

Impact Assessment...(2)

- ◆ Manufacturer responsibility and in-market control aspects need to be strengthened to make sure that cosmetic products will be safe in the future. This includes:
 - ◆ **clear minimum requirements** for the cosmetics safety assessment;
 - ◆ a system of administrative cooperation of competent authorities;
 - ◆ an obligation of industry to actively report serious undesirable effects to competent authorities for risks for human health caused by cosmetic products; and
 - ◆ a notification requirement which provides information to all competent authorities of the internal market through one single notification portal.

Changed Aspects...

- ◆ Codification and adoption of text as Regulation
- ◆ Introducing a set of definitions
- ◆ Reference to standardisation
- ◆ Strengthening in-market control
- ◆ Substances/Annexes
- ◆ Inventory replaced by a glossary for names of ingredients and in parallel database with information contained in the current inventory
- ◆ **Clarification regarding the responsible person**
- ◆ **Cosmetics safety assessment**
- ◆ **Centralised notification**

Responsible Person

<i>Cosmetic Product...</i>	Responsible Person...
<i>Manufactured within Community</i>	Manufacturer or Person established within Community
<i>Imported</i>	Importer or Person established within Community
<i>Made available on the market directly to consumer from outside Community in absence of importer</i>	Designated person within Community by person placing the product on the market

Product Information File & Cosmetics Product Safety Report

- ◆ The responsible person shall keep a product information file for the cosmetic product for which he is the responsible person. It shall contain:
 - ◆ a description of the cosmetic product
 - ◆ **the cosmetic product safety report**
 - ◆ *safety assessment in accordance with Annex I of the proposal*
 - ◆ a description of the method of manufacturing and a statement on compliance with GMP
 - ◆ proof of the effect claimed for the cosmetic product;
 - ◆ data on any animal testing relating to the development or safety assessment of the cosmetic product or its ingredients.
- ◆ The product information file must be kept up-to-date & readily accessible in electronic or other format at his address to the competent authority of the Member State where the file is kept.

Annex 1 – Cosmetic Product Safety Report

- ◆ Part A - Cosmetic Product Safety *Information*
 - ◆ Quantitative & qualitative composition of product
 - ◆ Physical/chemical characteristics & stability of product
 - ◆ Microbiological quality
 - ◆ Impurities, traces, information about packaging material
 - ◆ Normal & reasonably foreseeable use
 - ◆ Exposure to substances & product
 - ◆ Toxicological profile of substances
 - ◆ Undesirable effects (also serious)
 - ◆ Information on product
- ◆ Part B - Cosmetic Product Safety *Assessment*
 - ◆ Assessment Conclusion
 - ◆ Labelled warnings & instructions of use
 - ◆ Reasoning (including margins of safety; possible interactions; stability impacts; etc.)
 - ◆ Safety Assessor - Name/address/proof of qualification/ date & signature

Centralised notification

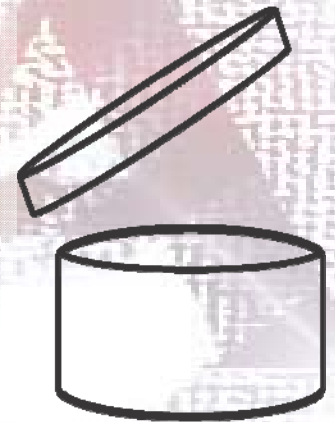
- ◆ The responsible person shall submit, prior to placing the cosmetic product on the market, the following information to the CION:
 - ◆ category of cosmetic product & its complete commercial name;
 - ◆ name & address of responsible person where product information file is made readily accessible;
 - ◆ Member State where cosmetic product is placed on the market;
 - ◆ contact details of a physical person to contact in the case of necessity;
 - ◆ presence of substances in the form of micronised particles other than substances listed in Annexes III to VI to this Proposal;
 - ◆ ***presence of substances classified as CMR, of category 1 or 2; &***
 - ◆ ***frame formulation.***

Labelling Requirements

- ◆ The container & packaging of cosmetic products shall bear:
 - a) the name/style & address or registered office of the manufacturer or the responsible person. *If several addresses are indicated, the one where the responsible person makes readily available the product information file shall be highlighted;*
 - b) the nominal content at the time of packaging;
 - c) The “date of minimum durability” (month & year or the day, month & year) shall be preceded by **symbol no. 1** or the words: “**best used before the end of**”. For products, with a minimum durability of > 30 months **symbol no. 2** followed by the period (in months &/or years) shall be used;
 - d) particular precautions;
 - e) the batch number;
 - f) the function of the cosmetic product;
 - g) a list of ingredients preceded by the term ‘ingredients’ which may be indicated on the packaging alone.



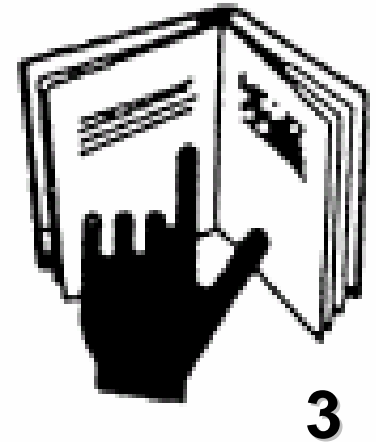
1



2

Labelling Requirements...(2)

- ◆ When it is impossible for practical reasons to label the **precautions & ingredients**, an enclosed or attached leaflet, label, tape, tag or card can be used; Unless impracticable, this information shall be referred to by abbreviated information or the **symbol no. 3**.



- ◆ The list of ingredients shall be expressed by using the common ingredient name set out in the glossary provided for in Article 28. In the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.

Views on the Proposal...

- ◆ Four Working Parties were held between February and May 2008.
- ◆ The main objectives for Malta:
 - ◆ To ensure the protection of the interests of consumers; &
 - ◆ To ensure that any rules adopted do not constitute any unjustified burdens, such as labelling requirements and the requirements of the safety assessment on manufacturers and importers.
- ◆ Financial repercussions for importers and manufacturers are expected to mainly be incurred due to the potential requirement for re-labelling and for the preparation of a product safety assessment in accordance with requirements as laid down in Annex I. The most significant cost is expected to be related to the cosmetic product safety assessment.

Thank you for your attention.

For any other information or advice you can always contact MSA:

***Malta Standards Authority,
Second Floor,
Evans Building,
Merchants Street,
Valletta, VLT1179***

Tel no: +(356) 21242420

Fax no: +(356) 21242406

Email: helpdesk.msa@msa.org.mt