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# Overview of Cosmetics Legislation

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Cosmetics Information Day , September 15<sup>th</sup> 2010

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# Overview

- Definition of a cosmetic?
- What legislation applies?
  - Specific legislation
  - Parallel legislation



# Definition of a Cosmetic Product

## Directive 76/768/EEC – Article 1

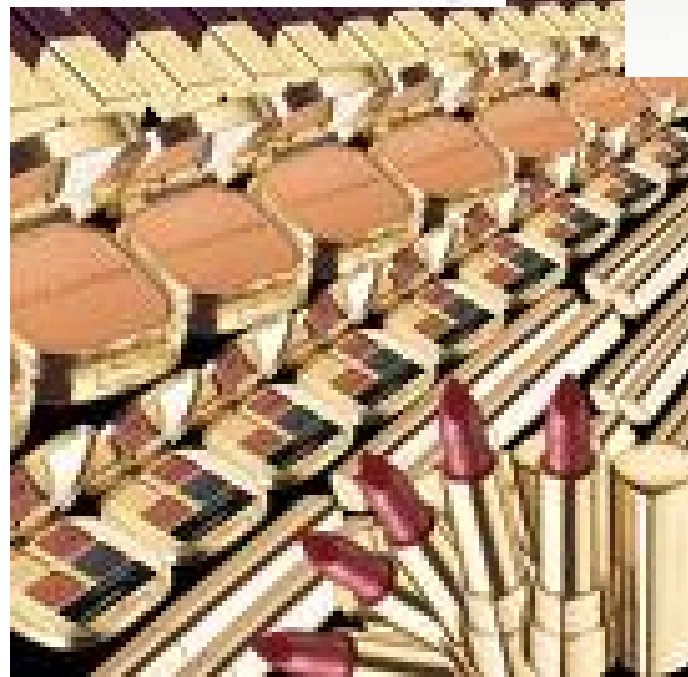
- ...substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with teeth and the mucous membranes of the oral cavity,

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...**



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# Some examples...

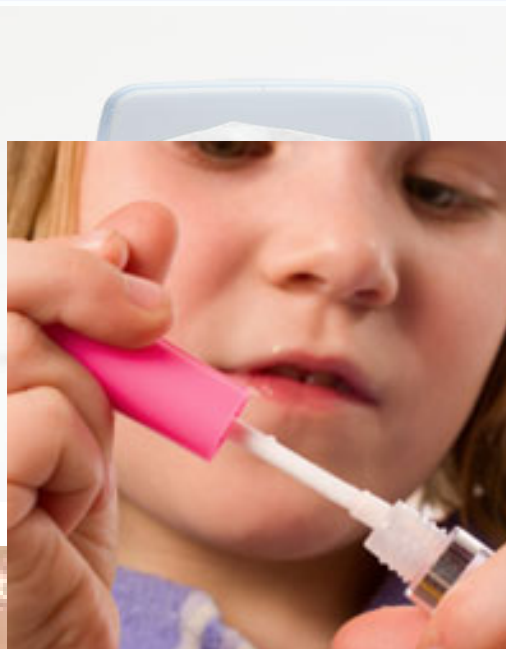


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# Borderline cases...



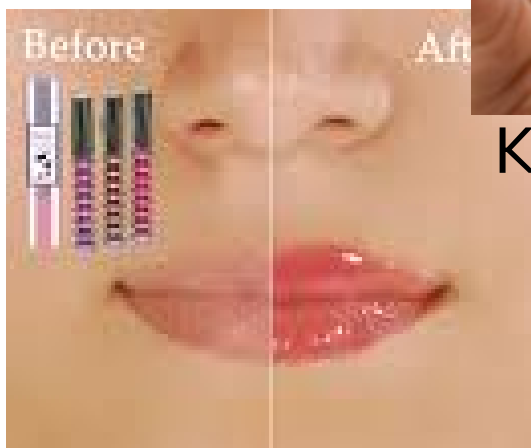
Dental Floss



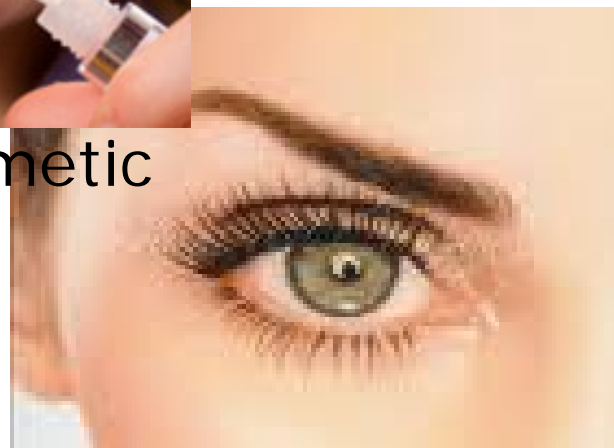
Kids Cosmetic



Dermal Patch



Lip Plumper



Eyelash Growth  
Enhancer



# Why regulate?



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# Regulatory Framework

- **Cosmetics Directive 76/768/EEC**

SI 870 of 2004, European Communities (Cosmetic Products) Regulations, 2004, as amended

- **General Product Safety Directive 2001/95/EC (GPSD)**

SI 199 of 2004, European Communities (General Product Safety) Regulations, 2004

- **Regulation (EC) No 1223/2009** of the European Parliament and of the Council on cosmetic products (Recast)

- **Regulation 765/2008** – part of the New Legislative Framework (NLF)



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# Cosmetics Directive 76/768/EEC

- Adopted in 1976
- Ensure the free circulation and safety of cosmetics placed on the market
- 7 amendments and > 50 adaptations
- Transposed by SI 870 of 2004
- Responsible Person (RP) must ensure products meet the requirements of the Directive
- **NO** Premarket Approval



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# Who has to comply?

## *Directive 76/768/EEC Art 7a*

- Manufacturer of the product
- Manufacturer's agent
- The person to whose order a cosmetic product is manufactured
- The person responsible for placing an imported cosmetic product on the Community market

*i.e.* **The Responsible Person** as defined in Regulation 4 (1) of SI 870 of 2004



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# Key elements of Directive 76/768/EEC

- Labelling requirements (article 6)
- Product Information File Requirements (art 7a)
  - Safety assessment (art 7(a) 1(d))
  - Claim substantiation (art 7(a) 1(g))
  - Existing data on undesirable effects (art 7(a)1(f))
- Notification requirements (article 7a(4))
- Composition in compliance with Annexes (art 4)
- [http://ec.europa.eu/enterprise/sectors/cosmetics/cosmetology/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/cosmetics/cosmetology/index_en.htm)



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# Applicability of GPSD

- Directive 2001/95/EC on General Product Safety – to ensure products placed on the market are safe (GPSD Art 1)
- applies to consumer products where not all aspects of safety or categories of risk are covered by sector legislation

***NO GAPS ... NO OVERLAP***



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# GPSD – key provisions

- **Producers and distributors** to inform the CA if a product placed on the market poses a risk  
(GPSD Art 5(3))
- **Distributors** - keep documentation to ensure traceability. Cooperate with Mfr and CA in case of risk
- **CA's** of Member States - entitled to take measures for any product where appropriate  
(GPSD Article 8)
- Community Rapid Information System - **RAPEX** is established under Art 12

# Specific Articles that apply to cosmetics

GPSD Article applicable	Short Description	Responsibility
<b>Article 5.1, subpara 3, 4 and 5</b>	<b>Post-marketing obligations for producers (active steps e.g. complaints, information to distributors, sample testing)</b>	<b>Producer and Distributor</b>
<b>Article 5.3</b>	<b>Obligation to inform competent authorities about certain measures</b>	<b>Producer and Distributor</b>
Article 5.4	Obligation to co-operate with the CA	Producer and Distributor
Articles 5.2, 5.3 and 5.4	Distributors obligations	Distributor
Article 7	Rules on penalties to be adopted	Member States
<b>Article 8.1</b>	<b>Establishment of powers for CAs to require information and to ban or recall products</b>	<b>Member States</b>
Article 9	Adopt approach on market surveillance	Member States
Article 13	Rapid Intervention	Member States

# Applicable articles continued ...

<b>GPSD Article applicable</b>	<b>Short Description</b>	<b>Responsibility</b>
<b>Article 11</b>	<b>Notification of measures taken based on health and safety considerations</b>	<b>Member States</b>
<b>Article 12</b>	<b>RAPEX Notifications – emergency situations</b>	<b>Member States</b>
Articles 14 and 15	Committee procedures for decisions taken under the GPSD	Member States
Article 16	Access to information and confidentiality when carrying out actions (some limitations apply)	Member States
Article 17	Relationship with the Directive on liability for defective products	
Article 18.1	Administrative requirements (some limitations apply)	Member States
Articles 18.2 and 18.3	Access to justice and relationship to assessment of liability (some limitations apply).	Member States

## Reason for Recast

- Significant amendments to 76/768/EEC
- Regulation removes diverging transposition
- Simplifying procedures and streamlining terminology



# What's new?

- Definitions (Art 2 & 4)
- Obligations of Responsible Person (Art 5)
- Obligations of Distributors (Art 6)
- Identification within the supply chain (Art 7)
- Compliance with GMP (Art 8)
- Notification requirements (Art 13)
- In-market control (Art 22)



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# Who is the RP?

- Manufacturer within EU
- Manufacturer outside EU – shall designate an RP within the EU
- Each Importer is RP for specific products
- Distributor is RP where he places product on the market under his name or modifies a product already on the market



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# Obligations of RP

- Shall ensure compliance with all aspects of regulation
- For product not in conformity – take corrective measures
- Where product presents a Risk – notify the CA where product is made available & where PIF is available
- In case of non-compliance where serious risk – CA uses provisions under RAPEX



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## Article 6 – Obligations of Distributor

- Verify labelling is compliant
- Language requirements are fulfilled
- Date of minimum durability
- Shall not make non-conforming product available
- Storage and transport conditions met
- Where a product presents a risk, inform the RP and the CA where the product is made available



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# Article 7 – Identification within Supply Chain

- RP shall identify Distributors they supply
- Distributor shall identify those distributors (or RP) from whom and the distributors to whom the product was supplied
- Obligation applies for 3 years after the batch was made available to Distributor



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# Article 13 - Notification

- Notification directly to the Commission
- Centralised database – Cosmetic Product Notification Portal (CPNP)
- Name and category of cosmetic
- Name & address of RP where PIF held
- Member State in which the cosmetic product is to be placed on the market
- When placed on market – RP to notify the original labelling + photograph of packaging



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# Notification requirements ...

- Presence of substances in form of Nanomaterials & exposure conditions
- Name of CMRs of category 1A or 1B
- Frame formulation for prompt medical treatment
- DTR obligation – where a cosmetic is no longer on the market from 11 July 2013, DTR introduces that product in a MS – DTR must communicate to the RP:



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# Article 22 – In-market control

- MS shall monitor compliance via in market controls
- Perform checks through PIF, physical and laboratory checks
- MS shall monitor compliance with principles of GMP
- MS shall entrust to market surveillance authority necessary powers, resources and knowledge
- MS shall periodically review and assess functioning of surveillance activities

# Art 40 – Entry into force

- Regulation applies from 11<sup>th</sup> July 2013
- Exception – Article 15 (1) and (2) which applies from 1<sup>st</sup> Dec 2010 (use of CMRs)
- Article 16 (3) shall apply from 11<sup>th</sup> Jan 2013 – notification of nanomaterials



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# Impact of new Regulation 1223/2009

- Clarification on obligations of RP and distributors
- Mandatory compliance to GMP and introduction to the new ISO EN 22716 cosmetic GMP standard
- Mandatory communication of 'undesirable effects' to the CA (cosmeto-vigilance)
- Provision for in-market control and sampling analysis
- Cooperation between member states



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# New Legislative Framework (NLF)

- Revision of New Approach in 2008 – led to the NLF
- NLF fills in missing chapters of market surveillance and accreditation
- New provisions in NLF bring market surveillance requirements in line with those in GPSD



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# Legal texts

- Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State
- **Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products**
- Decision No 768/2008/EC on a common framework for the marketing of products



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# Regulation 765/2008

- Chapter III applicable to cosmetics
- Member states – periodically assess and review the functioning of surveillance activities – at least every 4<sup>th</sup> year
- Documentary, physical and laboratory checks
- Ensure products presenting a serious risk are recalled, withdrawn or prohibited
- Market surveillance & information exchange system in GPSD Article 12 shall be used



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# Summary

- Cosmetics - Consumer Products
- Compliance verified through in-market control
- Legislation addresses roles of RP (Manufacturer, Importer), Distributor and CA
- Recast – roles more clearly defined - effective from July 2013



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