European Commission
DG Enterprise and Industry
Unit F/3 Cosmetics and Medical devices

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'Acquis' in the cosmetics field

- Council directive 76/768/EEC of 27.07.1976 on the approximation of the laws of the Member States relating to cosmetic products (Cosmetics Directive)
  - 7 amendments
  - 37 technical adaptations
  - 2 directives on postponement of animal testing
- 7 Directives on analytical methods
- Directive on confidentiality of ingredients (Directive 95/17/EC)
- Commission decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products

Other tools

- Guidelines on borderline aspects (biocides, medicinal products)
- Guidelines on the notion ‘professional use’
- Guidelines on ‘period after opening’, article 6.1(c) of Cosmetics Directive

Other tools

- In the near future:
  - Guidelines on claims not tested on animals (art. 6.3 2nd paragraph of Cosmetics Directive)
  - Guidelines on access to information (art. 7a.1(h)2nd paragraph of Cosmetics Directive)
  - Good Manufacturing Practice (art. 7a1(b): adoption of CEN standard in parallel to the ISO.

Aims of the Cosmetics Directive

- Ensuring free circulation of cosmetic products
- Safeguarding public health

Free circulation of cosmetic products

- No pre-market authorisation/in-market control by Competent authorities
- Member States may not refuse, prohibit or restrict the marketing of any cosmetic product which complies with the Directive's requirements.

Guarantee safeguard of public health

- A clear definition of cosmetic products
- Manufacturer' responsibility for safety
- Product Information file
- Regulation of ingredients in specific cases
- Safeguard mechanism

Definition of a cosmetic product

- Article 1.1 of the Cosmetics Directive
  - Application-related: substance intended to be placed in contact with external parts of the human body/teeth/mucous membranes of the oral cavity,
  - Purpose-related: main purpose is cleaning, perfuming, changing the appearance, correcting body odours, protecting them ok keeping them in good conditions.
- Indicative, non-exhaustive, list of Annex I

Manufacturer liability

- Article 2 of the Cosmetics Directive

  "*A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market*".

Product Information file

- Article 7a.1 of the Cosmetics Directive
- File showing the safety of the product
- Should be readily accessible for control purposes
- Located at the address indicated on the product
- Should be in the national language(s) of the Member States concerned or in a language readily understood by Competent authorities.

Regulation of ingredients in specific cases

- « negative lists »
  - Annex II: prohibited substances
  - Annex III: substances subject to restrictions and conditions
- « positive lists » only listed substances are allowed:
  - Colouring agents (Annex IV)
  - Preservatives (annex VI)
  - UV filters (annex VIII)

Safeguard mechanism Art.12

- Provisional measure by Member State
- On the basis of substantiated justification
- Measure concerns a cosmetic product
- Product complies with Cosmetics directive requirements but may represent a hazard to health.

Labelling requirements (1)

Purpose: informing consumer and facilitating enforcement

- Address of manufacturer/importer (country of origin only when manufacturing in third countries)
- Date of minimum durability (and not expiry date) when durability is less than 30 months
- When durability is more than 30 months, period after opening.

Labelling requirements (2)

- Ingredients (in language easily understood by the consumer/ INCI names).
- Nominal content, date of minimum durability, particular precautions to be observed in use and function of the product may be required to be in National language(s).

Animal testing (1)

- Since September 2004:
  - Testing ban on finished cosmetic products
- As soon as an alternative method is listed in Annex V of Council Directive 67/548/EEC or Annex IX of the Cosmetics Directive, animal testing is prohibited and product cannot be marketed on the Community market.

Animal testing (2)

- In March 2009 even if no alternative methods are available :
  - Testing ban of ingredients used in cosmetic products
  - Marketing ban of cosmetic products tested on animals or which ingredients have been tested on animals
    - Except for 3 end-points (repeated dose toxicity, reproductive toxicity and toxicokinetics) deadline is 2013.

Questions?

Website:
http://europa.eu.int/comm/enterprise/cosmetics/index_en.htm

Functional mail box:

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