European Changes and the news on the Cosmetics Regulation

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New Cosmetics Regulation

- Adoption: expected 26. Nov. 2009
- Application date: 42 months (3 ½ years) after adoption; except *inter alia* CMR:1.12.2010
- Implementation work has started (CPNP) Nano (SCCS)
- Guidelines

The Cosmetics Regulation (Recast)

- New Cosmetics legislation in the form of a Regulation
- Introduction of new definitions
- Cosmetics Products Safety Assessment
- New rules on substances: CMR and nanomaterials
- Simplified notification
- Enhancement of market surveillance

Main aspects not changed (Recast)

- Animal testing provisions
- Labelling requirements [cmr, nano]
- Responsible person has the responsibility of the safety of cosmetic products made available on the market

New definitions

- "End user" means either consumers or professionals using the cosmetic product
- "Serious undesirable effect" means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death

Safety Assessment

- Safety assessment (Art. 10)
- Responsible person:

✓ Cosmetic product safety report

✓ Intended use and anticipated systemic exposure

✓ Weight of Evidence (review data)

✓ Updated Report

- Guideline (SME),
- Diploma,
- GLP

Product information file (Art. 11)

Product Information file

(a) description of the product
(b) cosmetic product safety report
(c) description of manufacturing method GMP
(d) proof of claim, when relevant
(e) data on animal testing (3. country)

10 years last batch placed on the market

Annex I -
Cosmetic Products Safety Report

- Part A CP safety information

1. Qualitative/quantitative composition of product
2. Physical/chemical characteristics and stability of the cosmetic product
3. Microbiological quality - challenge test
4. Impurities, traces, information about packaging material
5. Normal and reasonable foreseeable use

Annex I -
Cosmetic Products Safety Report II

- Part A CP safety information

6. Exposure to the cosmetic product
7. Exposure to the substances
8. Toxicological profile of the substances
9. Undesirable effects and serious UE
10. Information on the cosmetic product

Annex I - Cosmetic Products Safety Report III

- Part B CP safety assessment

1. Assessment conclusion
2. Labelled warnings and instructions of use
3. Reasoning
4. Assessor's credentials and approval of part B

CMR substances

- No change for CMR 2 (old 3)
- CMR 1A and 1B - use possible by way of exception:
  - ✓ The substance complies with the food safety requirements
  - ✓ They are no suitable alternatives
  - ✓ The request is for a particular use in cosmetic product with known exposure
  - ✓ The substance is found safe by the SCCS
  - ✓ Re-evaluation every 5 years
- Only for newly classified substances
- Specific labelling to avoid misuse

Nanomaterials

- DEF (Art. 2 (k)): “Nanomaterial" means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm

Cosmetics Regulation on nano materials (II)

Control Mechanism

For cosmetic products containing nano materials used as colorants, UV filters or preservatives:

→Current mechanism of authorisation through listing in positive annexes is preserved.

For cosmetic products containing nano materials for other function:

- For new cosmetic products containing nano materials

→6 months before placing them on the market, notification to COM with submission of safety data.

- For cosmetic products containing nano materials already available on the market.

→6 months before the date of application of the Regulation, notification to COM with submission of safety data.

Cosmetics Regulation on nano materials (III)

Notifications will allow the Commission, in case of concern, to consult the SCCS. Taking into account the scientific opinion, the Commission may then amend the respective annexes of the Regulation

On the basis of the notification received, the Commission will publish a catalogue of nano materials used in cosmetic products

Simplified notification for all cosmetic products

- One centralized notification system at the EC level
- For Competent Authorities and Anti-poison Centres
- Managed by the EC
- Obligation to update

Market Surveillance

- Member States are responsible for the surveillance of their market
- Obligation to communicate serious undesirable effects to competent authorities
- Communication on request of the list of products containing a specific substance and its concentration, if such substance raises concerns
- Cooperation and exchange of information through Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC)

Main aspects changed/introduced I

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

Main aspects changed/introduced II

- Alignment with “New Approach
- Nanomaterials
- Environmental aspects
- Counterfeit aspect
- Internet sales ?
- Claims

Committees

- Standing Committee on Cosmetic Products (Member States)
- Working Group on Cosmetics (Member States + Industry, Consumers' Groups and Animal Protection Groups → transparency)
- Scientific Committee for Consumer Safety, SCCS (scientific experts)

Thank you !

http://ec.europa.eu/enterprise/cosmetics/index_en.htm

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

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