New regulation on cosmetic products- more stringent requirements for safety assessment

Safety assessment of cosmetic products

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Important news in Regulation 1223/2009 on cosmetic products

- **Cosmetic Products Notification Portal (Art 13)**
- **Nanomaterial– labelling and authorization (Art 16)**
- **Cosmetic product safety report (Art 10)**
- **Serious undesirable effects- communication (Art 23)**

Safe for human health (art 3)

- **Safety assessment (Art 10)**
- **Cosmetic product safety report set up as Annex I**
- **Substances (Art 14)**

  prohibited

  restricted

  allowed colorants, preservatives, UV-filters
- **CMR substances (Art 15)**
- **Nanomaterials (art 16)**

Cosmetic Product Safety Report

Responsibel person responsible to draw up the report

Safety assessment as set up in part B carried out by a qualified safety assessor

Responsibel person and safety assessor work closely together

Annex I part A

gather the data necessary

data listed a minimum- discrepancy justified

safety assessor can use additional data

any reliable sources

1. quantitative and qualitative composition

provide exact composition starting from raw materials

useful to indicate suppliers

indirectly added by raw materials

2. physical/chemical characteristics and stability

relevant specifications for substances used and the final product

may influence the safety

acceptable from quality view

assessment of the stability

3. microbiological quality

acceptable microbiological specifications

original levels and possibility of growth

finished product (low risk, single use , all other)

4. impurities, traces, packaging material

assess whether the product contain substances not intentionally added which may have an impact in its safety

5. normal and reasonably foreseeable use

determine the relevant exposure scenario

communicated to the consumer

6. exposure to product

quantify the amount into contact with the body and the frequency of use

useful information in SCCS Notes of Guidance but do not contain daily exposure for a specific product, other ways may be used

insufficient data- assume worst case

7. exposure to substances

determine the amount for each substance

8. toxicological profile of the substances

describe the toxicological hazard of each substance

safety assessor choose which endpoints are relevant and justify why not relevant

comply with the requirements concerning animal testing

decribed in detail in part A and assessed in part B

intrinsic properties from different sources

for appropiate endpoints NOAEL/LOAEL identified

systemic exposure calculated from the different routes of exposure and the absorption

route-to- route extrapolation

9. undesirable effects and serious undesirable effects

monitor the safety of the product and take corrective actions if necessary

10. information on the cosmetic product

any additional information

Annex I part B

1. assessment conclusion

state safe in relation to Reg 1223/2009

2. labelled warnings and instructions for use

the need to label warnings

in additon to the listed in Annex III-VI

3. reasoning

clearly and accurately explain

ensure that all information is available

justify absence of data

individual substances and final formulation

local and systemic exposure

reassessed regularly

4. assessor´s credentials and approval of part B

name, adress, dated, signed, proof of qualifications

Medical Product Agency part B 2013-2014

- **no clear statements on 1 and 2**
- **wellknown ?**
- **not enough information in 3 to understand that all endpoints were assessed for all substances**
- **too much referrals to part A**
- **unclear for which substances MoS was calculated and not clear justifications for the other**
- **not clear assessments of both local and systemic effects for all substances**
- **proof of qualification not included**
- **(dated- safety assessment before that date ?)**

SUE communications

about 80 reports July 2013 – April 2014

sub-group Cosmetovigilance meetings in May and June 2014

references :

Regulation 1223/2009 on cosmetic products Annex I

Guidelines on Annex I (2013/674/EU) 25 Nov 2013

” these guidelines should assist the responsible person, not meant to replace the knowledge and expertise of the qualified safety assessor”