Nanomaterials in Europe - Regulations and Obligations
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Ina Höfgen-Müller, Global Regulatory Affairs Cosmetics, Merck KGaA
Agenda

- Definition of Nanomaterials
- EU Commission Activities
- Industry Guidance Papers
- Obligations for the Cosmetic Industry in the EU
- Notification and Labelling of Nanomaterials in the EU
- Nanomaterials - Documents of Interest
• A variety of definitions for the term ‘Nanomaterial‘ exist - final versions and drafts → all of them showing differences for the same term:

  • Standard ISO/TS 27687:2008
  • ICCR
  • SCENIHR 2007 / 2010
  • SCCP / SCCS
  • JRC
  • *Cosmetics Regulation (EC) No 1223/2009*
  • *EU Commission Recommendation 2011*
  • …
EU Cosmetics Regulation 1223/2009

The Cosmetics Regulation defines the term “nanomaterial“ [Art 2, 1.(k)] as:

“nanomaterial“ means an insoluble or biopersistent and intentionally manufactured material with one or more dimensions, or an internal structure, on the scale from 1 to 100 nm.“
EU Commission Recommendation (October 2011)

‘Nanomaterial‘ means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm.
**Definition**

“Nanomaterial”

**Chemical Industry**

- CEFIC

**Consumer Organisation**

- BEUC

**Cosmetic Raw Materials**

- JRC

**Cosmetic Industry**

- EFFCI

**Cosmetics Europe**

**Cosmetics Regulation**

EC No. 1223/2009

**EU Member State**

- EU Member State
  - EU Member State
  - EU Member State
  - EU Member State
  - EU Member State

**European Commission**

- DG ENV
- DG ENTR
- DG SANCO
‘nanomaterial’ Definition:

- Aiming for one definition applicable in all EU legislations!

- Discussion to adopt elements of the EU “Commission Recommendation into sectorial legislations, e.g. Cosmetic Regulation.


- Involvement of various stakeholders.
What is discussed in detail:

- **Threshold**: 50 % of particles (number size distribution) in the nano range

- **Criteria**:
  - intentionally manufactured, incidental
  - insoluble, biopersistent
  - external or internal structure
  - constituent particles
  - additional parameter (e.g. volume specific surface area)
  - measurement techniques

- **Applicability**: Raw materials / finished cosmetic products?
Aspects to be viewed at in advance to a revised Definition

- reliability of ‘nano’ – classification in general
- use of validated and suitable measurement techniques
- feasibility of implementation, also for SMEs
- increase of paperwork at industry and COM
- economical aspects
- product safety assessment at SCCS
- enforcement process

“Clear and enforceable definition for safe consumer products!”
Timeline

- Currently no timeline is defined for a revised definition of the term ‘nanomaterial’ within the EU Cosmetics Regulation.

- Originally a final wording of the revised definition was planned for submission to Parliament in the 4 Q 2012.

- There may be a transition period for cosmetic products in the market to comply with the new elements of the revised definition.

At present only the criteria of the ‘nanomaterial’ definition as published in the EU Cosmetics Regulation (No) 1223/2009 are valid!
Industry “Guidance” Papers

COLIPA / Cosmetics Europe

• Discussion Paper – Interpretation of the Definition of the term “nanomaterial” according to the EU Cosmetic Regulation 1223/2009”, 14 April 2011

EFFCI

• Guidance Paper on Nanomaterials in Cosmetics, January 2012

Both papers are a guidance document for the industry and discuss the implications of the term ‘nanomaterial’ as described in the EU Cosmetics Regulation 1223/2009 but do not have any legal relevance!
(29) The use of nanomaterials in cosmetic products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Community should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly.

(30) At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety the SCCS should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials.

(31) The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

(35) The SCCS should give opinions where appropriate on the safety of use of nanomaterials in cosmetic products. These opinions should be based on full information being made available by the responsible person.

(65) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of certain measures relating to CMRs, nanomaterials and potential risks to human health.
What has been new with respect to ‘nanomaterials’?

→ Definition

→ Notification Process → Cosmetic Industry for finished cosmetic products containing nanomaterials from 11\textsuperscript{th} January 2013 on.

→ Labelling → Cosmetic Industry of \textit{all} nanomaterials in the list of ingredients from 11\textsuperscript{th} July 2013 on.
**Notification** to the European Commission

- obligatory for all finished cosmetic formulations prior to placing on the market

- Detailed requirements are defined in
  
  Art. 13 1.(f) → general product notification and
  
  Art. 16.ff → notification of nanomaterials
Requested Information with respect to Nanomaterials (acc. to Art. 16.ff):

- Identification
- Specification and information about particle size
- Quantity
- Safety data
- Toxicological profile
- Foreseeable exposure conditions

In case of safety concerns with respect to the nanomaterial the SCCS is requested for an Opinion on such nanomaterial within 6 months.

Note: “Where the SCCS finds that any necessary data is lacking, the Commission shall request the responsible person to provide such data within an explicitly stated reasonable time, which shall not be extended. The SCCS shall deliver its final opinion within six months of submission of additional data.”
Exemptions from Notification (acc. to Art. 16.ff)

- Colorants (Annex IV)
- Preservatives (Annex V)
- UV-filters (Annex VI)

Note: These exemptions do not apply if not specifically mentioned that the listing of a substance in the Annex cover the nanoform as well.

[Preamble to Annexes II to VI (3)]

“(3) Substances listed in Annexes III to VI do not cover nanomaterials, except where specifically mentioned.”
Timeline for Notification

… of cosmetic products containing new nanomaterials
⇒ six months prior to marketing from 11th January 2013 on.

… of cosmetic products containing existing nanomaterials
⇒ between 11th January 2013 and 11th July 2013.
Labelling of all nanomaterials in the list of ingredients ("INCI" – list') of the final cosmetic product [Art. 19, 1. (g)].

- the name of the ingredient is followed by the word “nano“ in brackets
  e.g. “Titanium Dioxide (nano)“

Labelling = Consumer Information
≠ Warning
Nanomaterials - Documents of Interest

• **France**: Decree no. 2012-232 of 17th February 2012 concerning the annual declaration of substances with nanoparticle status
  – entry into force 1st January 2013
  – Declaration of quantities and uses of substances – all uses, not only cosmetics - with nanoparticle status until May 1st for the preceding year.

• **SCCS** Opinion (Scientific Committee on Consumer Safety of the European Commission):
  “Guidance on the Safety Assessment of Nanomaterials in Cosmetics”, adopted at the plenary meeting on 26th – 27th June 2012.

• **JRC** (Joint Research Center of the European Commission)
  “Requirements on measurements for the implementation of the European Commission definition on the term of ‘nanomaterial’ “. July 2012
But, what finally is a nanomaterial ... ???

Definition, Sample Preparation and Analytical Measurement are the basis to decide on ...

Thank you for your attention!