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Nano-materials in cosmetic products: definition needs to effectively protect consumers

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Ref.: X/2012/066 - 28/08/2012

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Summary

The EU Commission is planning to align two differing definitions used for the term 'nano-material', one contained in the EU Regulation on cosmetic products and the other in the EU Commission recommendation for the term 'nano-material'. The Commission's aim is to apply the updated definition to cosmetic products as soon as the nano-specific requirements enter into force.

In this position paper BEUC outlines which elements such a definition should contain in order to effectively protect consumers from unknown hazards that may be related to cosmetic products which use new materials at an infinite small scale.

In our point of view, a definition of nano-materials in cosmetic products needs to:

- include all materials in which more than 0,15 % of the number of particles are present in the nano-size range;
- cover by-products which are not intentionally manufactured but which are present in the nano-range;
- include soluble nano-particles and nano-structures which have specifically been designed to carry encapsulated substances that will be released to the systemic circulation;
- include nano-particles below 1nm such as fullerenes;
- add a criterion on volume specific surface area as particle size distribution alone is insufficient to give information about the surface area which has an impact on the reactivity of the particles.

Introduction

The cosmetics sector was among the first ones to research and develop patented applications using nano-technologies and nano-materials. Applications cover the product formulation, the packaging as well as the manufacturing equipment for cosmetics. In cosmetic products, nano-materials are used as 1) active substances, 2) carriers and 3) formulation aids with the aim to enhance the efficacy of the product[1].

When the EU adopted in 2009 a new Regulation for Cosmetic Products (EC/ 1229/2009)[2] it contained for the first time specific requirements for nano-materials including a technical definition of this term. As there was a need for a horizontal definition which could be applied across sectors, the EU adopted in 2011 a general definition for the term 'nano-material' in a Commission recommendation[3].

In 2012 the EU Commission has set up a small working group which is mandated to work out first ideas of how these two definitions can be aligned and finally made applicable to cosmetic products before the new legal requirements for cosmetics containing nano-materials will enter into force in 2013.

In this position paper we make concrete proposals on the scope and elements which a definition for the term 'nano-material' for cosmetics should comprise based on the Commission recommendation. The most important aspects will be setting the right threshold for percentage in particle distribution and to interpret the meaning of what means "intentionally manufactured". In addition, we have to look into solubility and bio-persistence very carefully.

1. The future definition in the Cosmetics Regulation should set a low threshold (0.15% number of particles)

According to recital 30 of the Cosmetics Regulation there is at present inadequate information available on the potential risks associated with nano-materials. Therefore additional provisions for nano-materials have been introduced. The identification of cosmetic ingredients falling under the definition for nano-materials will trigger:

- a specific notification of manufacturers to the regulator prior to marketing the product;
- the possibility of a nano-specific risk assessment by the Scientific Risk Assessment Committee (SCCS);
- the labeling as nano-materials in the list of ingredients.

[1] Mihranyan, Albert; Ferrez, Natalia und Maria Strømme (2012): Current status and future prospects of nanotechnology in cosmetics, in: Progress in Materials Science 57 (2012), pp. 875-910.

[2] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

[3] Commission Recommendation of 18 October 2011 on the definition of nano-material (2011/696/EU)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

As cosmetic products are per definition intended to come in contact with the human skin and as we cannot exclude that consumers use cosmetic products on vulnerable skin such as using sun protection products on irritated skin, we have to ensure that the definition for nano-materials captures definitely all materials of concern. Moreover, it has to be kept in mind that parts of the cosmetic products could be unintentionally inhaled or ingested or being released to an open environment.

Although both definitions have the same size range of 1-100nm, some elements need clarification:

Cosmetics Regulation	**Commission Recommendation**
'Nano-material' 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	2. 'Nano-material' 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. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %. 3. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nano-materials.
Covers only "intentionally manufactured" NM and does not clarify if it is mass or number based	Covers manufactured and unintentionally and naturally occurring NM such as particles deriving from combustion engines or volcanic ash based on number distribution
Covers only insoluble and biopersistent particles	Does not make a distinction between insoluble and soluble particles. Moreover nothing regarding bio-persistency is stated.
Covers one or more external dimensions as well as internal structures	Covers one or more external dimensions

While the Commission recommendation on nano-materials foresees that 50% or more of the number of particles have to be in the size range of 1-100 nm to be in the scope of the definition, a lower threshold of as little as 1% can be set if this seems to be justified to ensure protection of human health and the environment.

As cosmetic products are directly applied to the skin, we are of the opinion that the 50% threshold is far too high to ensure safety based on the precautionary principle. We argue that even the 1% threshold is too high for cosmetic products because the Commission definition covers all materials including naturally occurring ones whereas the Cosmetics Regulation only covers intentionally manufactured materials.

We recommend that a percentage of "0.15% of particles, in an unbound state or as aggregate or as agglomerate or an internal structure with a size below 100 nm"[4] should be introduced as deciding threshold for the size distribution of nano-materials. This number is recommended by SCENHIR 2009. This value is derived from the mean plus/minus three times the Standard Deviation (indicating 99.7% of the data set of measured nano-particles).

As the current scientific knowledge is not sufficient to determine a threshold for cosmetic ingredients below which the fraction of nano-materials does not require a nano-specific risk assessment, the threshold should be as low as possible, i.e. 0.15%, in accordance with the precautionary principle foreseen in recital 36 of Cosmetics Regulation N°1223/2009. We therefore strongly recommend following the SCENIHR approach.

When setting the definition, it has also to be kept in mind which impact a certain definition could have on exposure of humans and the environment. The Dutch National Institute for Public Health and the Environment (RIVM) explicitly points out that materials which do not qualify as "nano-materials" according to the Commission recommendation are not automatically safe. For example, a material with a majority of particles being larger than 100nm could still mean that the exposure to particles in the nano-range could be considerable if they are also present in that material[5].

In the light of the above, we recommend setting the threshold for nano-particles in cosmetics at 0.15%.

2. The term "intentionally manufactured" needs to cover by-products in the nano-range

When a material is deliberately manufactured with nano-scale dimensions, we call it "intentionally manufactured" or "engineered" nano-particles. However, there is a grey area in case a manufacturer intends to produce a nano-material which is slightly beyond the boundaries of the nano-size range (e.g. 120 nm) but which contains as unintented by-product also particles in the nano-range.

[4] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR: Scientific Basis for the Definition of the Term "nanomaterial", 8 December 2010, http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf

[5] Bleeker et al. (2012): Interpretation and implications of the European Commission Recommendation on the definition of nanomaterial, National Institute for Public Health and the Environment, RIVM letter report 601358001/2012, http://www.rivm.nl/dsresource?objectid=rivmp:181801&type=org&disposition=inline

As from a safety perspective the decisive factor is not the process or the intention of the manufacturer but the resulting material which will be finally used in cosmetics, we strongly recommend also covering all materials in the nano-range resulting as by-products of manipulating a material. While impurities which may be present at a very minor level may be negligible, it will be crucial to require a nano-specific safety assessment without exception if the threshold that qualifies a material as 'nano' will be overstepped.

3. Soluble nano-materials need to be covered

Although the definition in the Cosmetics Regulation restricts itself to non-soluble and bio-persistent particles, the Commission recommendation does not contain such a limitation. Moreover, such a distinction is not made in many other definitions for the term 'nano-material' in technical standards or other regulatory contexts. As the terms 'non-soluble' and 'bio-persistent' are not defined in the Cosmetics Regulation, this provision leads to legal uncertainty and therefore is not useful.

Looking into the available applications of nano-materials in cosmetic products, we urge the Commission to also include soluble nano-particles.

We consider that cosmetic products which use permeability enhancers require special attention.

While passive diffusion is the most common way of delivering active ingredients through the skin, we also consider it important to look at cosmetic nano-carriers which are designed for example to release vitamins, antioxidants, chemical UV filters and anti-aging substances[6] with caution. Some of the nano-carriers are designed as depo-type nano-carriers which means they release their load of active ingredients which are contained in the inner core after the outer nano-capsule dissolved. This may be important for people which are already sensitized. Research on allergies related to micro- and nano-ingredients suggests that in some cases contact allergens encapsulated in ethosomes showed significantly enhanced patch test reactions compared to a control group[7].

4. Nano-size range needs to cover certain structures below 1nm such as fullerenes

In line with the Commission recommendation, we recommend including certain structures below 1nm into the scope of the definition such as fullerenes. As these materials seem to be used in cosmetics it will be crucial to include them into the definition.

The RIVM[8] points out however, that a future revision of the Commission recommendation needs to clarify why certain carbon substances which are generally considered to be nanomaterials have been specifically mentioned in the recommendation but not other substances which may need to be covered as well.

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[6] Mihranyan et al.

[7] Jakob Torp Madsen (2011): Microvesicle formulations and contact allergy - Experimental studies in-vitro, mice and man, Ph.D. Thesis, Department of Dermatology and Allergy Centre, Odense University Hospital, http://www.videncenterforallergi.dk/userfiles/files/ph.d-afhandlinger/phd-madsen.pdf

[8] Bleeker et al., p. 20.

5. New definition should include volume specific surface area as well as agglomerates and aggregates

The Commission Recommendation foresees as one additional criterion the volume specific surface area and included also agglomerates and aggregates. We recommend including these specifications also into the future definition for cosmetic products because particle size distribution alone is insufficient to give information about the surface area which has an impact on the reactivity of the particles. Porous materials and particles with a very small diameter react at much faster rates than compact materials because more surfaces are available to react.

It should however be noted that the RIVM points out that the wording in the Commission recommendation on agglomerates or aggregates could be misinterpreted. As the sentence reads as follows "a material containing particles, in an unbound state or as an aggregate or as an agglomerate, where for 50% or more of these particles (…)", it could be understood as 50% or more of aggregates. We share the recommendation of RIVM to clarify this wording when the 2014 revision of the recommendation is due[9].

END

[9] Bleeker et al., p. 16.