Cosmetics Europe Nano Guidance Package

Part II: Interpretation of the Definition of the Term "nanomaterial" according to the EU Cosmetic Regulation 1223/2009

Guidance developed and shared with Commission in April 2011
Status of context and regulatory background July 2012
FINAL

CONTEXT AND REGULATORY BACKGROUND

While the current Cosmetics Directive does not specify any requirement with regards to nanomaterials, the legislator has introduced several articles into EU Regulation 1223/2009 that will have implications for products containing nanomaterials.

A nanomaterial is defined according to the Regulation EC 1223/2009 as follows: "*an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm*"

It has to be noted that in a horizontal activity the Commission has in addition issued a broad, multi-sectorial definition, which includes a very large variety of nanomaterials, regardless of their origin (natural, accidental or manufactured). However, the EU Commission, in line with SCENIHR recommendations, allows the possibility of maintaining sectorial-specific definitions of the term "nanomaterial" (e.g. cosmetic products).

Consequently, as far as cosmetic products and ingredients are concerned, the two regulatory definitions of nanomaterials can coexist in the EU: the multi-sectorial definition and the specific definition included in EU Cosmetic Regulation 1223/2009.

In order to ensure the correct implementation of the Cosmetics Regulation, some general guidance is needed on practical aspects of the interpretation of this regulatory definition. Cosmetics Europe has decided to issue the present guidance to help cosmetic companies justifying their decision whether or not they consider that an ingredient falls under the regulatory definition "nanomaterial" in the Cosmetics Regulation.
Various sectors working with or producing such materials have also put forward positions on how to interpret the term "nanomaterial".

In the international arena there also have been some harmonization attempts through ISO standards (all industrial sectors) and through the ICCR (cosmetic sector,

International Cooperation on Cosmetics Regulation). ICCR defined a set of criteria for determining whether or not a material should be considered as a nanomaterial for regulatory purposes.

A cut-off is currently not part of the cosmetics definition. It can be expressed in different ways, based on particle mass or particle number. The Commission Recommendation proposes a cut-off based on number, which poses practical problems for the implementation in a routine setting. The present document provides arguments for a cut-off of 10% based on particle mass based on current pragmatic industry practice.

The European Commission has launched discussions in a stakeholder working group on the inclusion of a cut-off level in the nano definition and an interpretation of the existing elements. However, a first recommendation from this working group is expected at the earliest in autumn 2012 with translation into legislation and guidelines expected long after the deadline for legal compliance of products with the Cosmetics Regulation (July 2013).

This timeline allows the cosmetics industry to continue to implement the nano-related requirements for the 2013 deadline according to industry practice and to make the transition to the potentially new definition in a controlled and reasonable manner.

The present guidance has been prepared by Cosmetics Europe in order to provide assistance to its membership for this currently ongoing implementation work to meet the 2013 deadline.

- **INTENTIONAL MANUFACTURE**

A material is considered to be a nanomaterial if it is manufactured -*via* a physical or chemical process- **with a view to intentionally obtaining nanometric-scale objects or structures**.

Therefore, the following materials can be considered to be excluded from the scope of the definition of the term "nanomaterial":

- By-products of reactions that could contain nanometric scale material/elements
- Nanomaterials of natural origin (e.g. natural clays, chitin) that have not been intentionally transformed by a physical or chemical process with a view to intentionally obtaining nanometric-scale objects or structures or associated properties

- **INSOLUBILITY - BIOPERSISTENCE**

Insoluble, non-degradable materials are generally associated with a greater risk of accumulation and biopersistence. This is related to the fact that insoluble material cannot be digested, metabolised, or excreted *via* normal biological processes, although other mechanisms, like phagocytosis, play an important role in the elimination of such materials. This view is shared by the SCENIHR that considers that "*Insoluble, non-degradable nanomaterials would have a high priority for risk assessment as (bio)persistence/accumulation may be associated with chronic hazardous effects".* (SCENIHR, 2010).

To address these potential concerns the Cosmetic Regulation focuses regulatory requirements on insoluble or biopersistent nanomaterials, which is also consistent with recent recommendations from the EU JRC (Lövestam, 2010), and meets the principal objective of the Cosmetic Regulation EC 1223/2009, which is consumer safety.

Accordingly, objective criteria for insolubility and/or biopersistence of nanomaterials in use conditions have to be agreed. Generally, a material is considered to be insoluble if it remains in the same shape and size and does not disintegrate into ionic or molecular forms in solution. Additionally, within EU Reach and Classification, Labeling and Packaging (CLP) regulations, poorly soluble substances are defined as substances of water solubility < 1 mg/L (10^{-6}, w/v). Finally, criteria for biopersistence/ degradability are defined in the Annex XIII of the Reach regulation.

Consequently, **soluble or non-biopersistent materials should not be considered as nanomaterials. Likewise materials that cannot release insoluble or biopersistent nanometric-scale structures or objects should also not be considered as nanomaterials** (e.g. labile vesicular structures, microemulsions, latex in the form of labile structures).

- **SCALE: 1 - 100 nm**

A material is considered to be a nanomaterial if at least one of its dimensions is between 1 and 100 nm. These lower and upper limits of 1 nm and 100 nm are arbitrary but are used in most definitions of the term “nanomaterial”.

Molecules

In accordance with the recent recommendations from the SCENHIR and the JRC, materials for which the only “nano” feature is their molecular size **should be excluded from the scope of regulatory definitions of the term “nanomaterial”**.

Thus, macromolecules with a three-dimensional structure or in the form of molecular associations that may be used as cosmetic ingredients should not be considered as nanomaterials (e.g. globulin, myoglobin, casein).

Size Distribution - Threshold

As powder materials are generally characterised by a particle distribution, this parameter must be taken into account when deciding whether a given material should be considered as “nano” or not. This aspect is highlighted by most recent opinions (SCENIHR 2010, ICCR 2010). To illustrate this, the JRC specifies that: “*If a specific size range is to be established for the definition of nanomaterial, it is therefore important to clarify how characteristic values can be extracted from a size distribution, which then can be used to decide whether a material meets the definition of nanomaterials*” (Lövestam et al, 2010).

Accordingly, a threshold (“cut-off”) must be determined in order to help decide whether a material should be regarded as “nano”. **The thresholds of 0.15% and 1% of the number of particles proposed by the SCENIHR and the DG Environment, respectively, are in our view technically inapplicable and scientifically unfounded**, on the basis of the following arguments:

- Such thresholds when converted to mass fraction correspond approximately to 0.00015% and 0.001% *i.e.* 1.5 and 10 ppm, respectively. As a consequence most pigment grade materials would fall under such a definition of a naomaterial. This conservative, maximalist approach is not compatible with an adequate distinction between “nano” and “non-nano” materials, and would render the information given to the consumer meaningless

- In addition, according to the present state of our knowledge and that of our suppliers, there is no robust, reproducible and reliable method that can measure a concentration expressed as number of particles at such low values. According to certain authors, at these levels of precision, experimental uncertainties are so high that practically all grades of substances in the form of particles (including pigment-grade powders or coarsely pulverised raw materials) would have to be considered as nanomaterials. No distinction could be made between nanomaterials and non-nanomaterials.

- To put these levels into a proper perspective, much higher regulatory thresholds have been set for substances of toxicological concern. For example, the CLP regulation sets a classification threshold for mixtures containing a substance classified as CMR (carcinogenic, mutagenic, reprotoxic) 1A at 0.1% weight (1000 ppm). In contrast, the 100- to 1000-fold lower thresholds proposed by the SCENIHR and the DG Environment would apply to all nanomaterials, regardless of their toxicological profile.

- If the size distribution follows a normal distribution, this distribution can be described by its mean ± Standard Deviation (SD). A threshold of [mean -3 SD] (corresponding to 0.15%) as proposed by the SCENIHR is not usable for the aforementioned reasons.

- In the specific case of certain toxicological endpoints applied to certain specific nanomaterials, a dose unit expressed as surface area or number of particles would be more appropriate than the mass unit traditionally used. However, in the majority of cases, the mass unit will remain the most suitable dose metric. This was recently acknowledged by an OECD working group on "*Dosimetry for the safety testing of nanomaterials"* that stated that ***"dosimetry should always report mass concentration (…)",*** **the other dose metrics being optional (OECD 2010)**.

- Thresholds expressed as a fraction of the number of particles are not relevant for polydispersed materials.

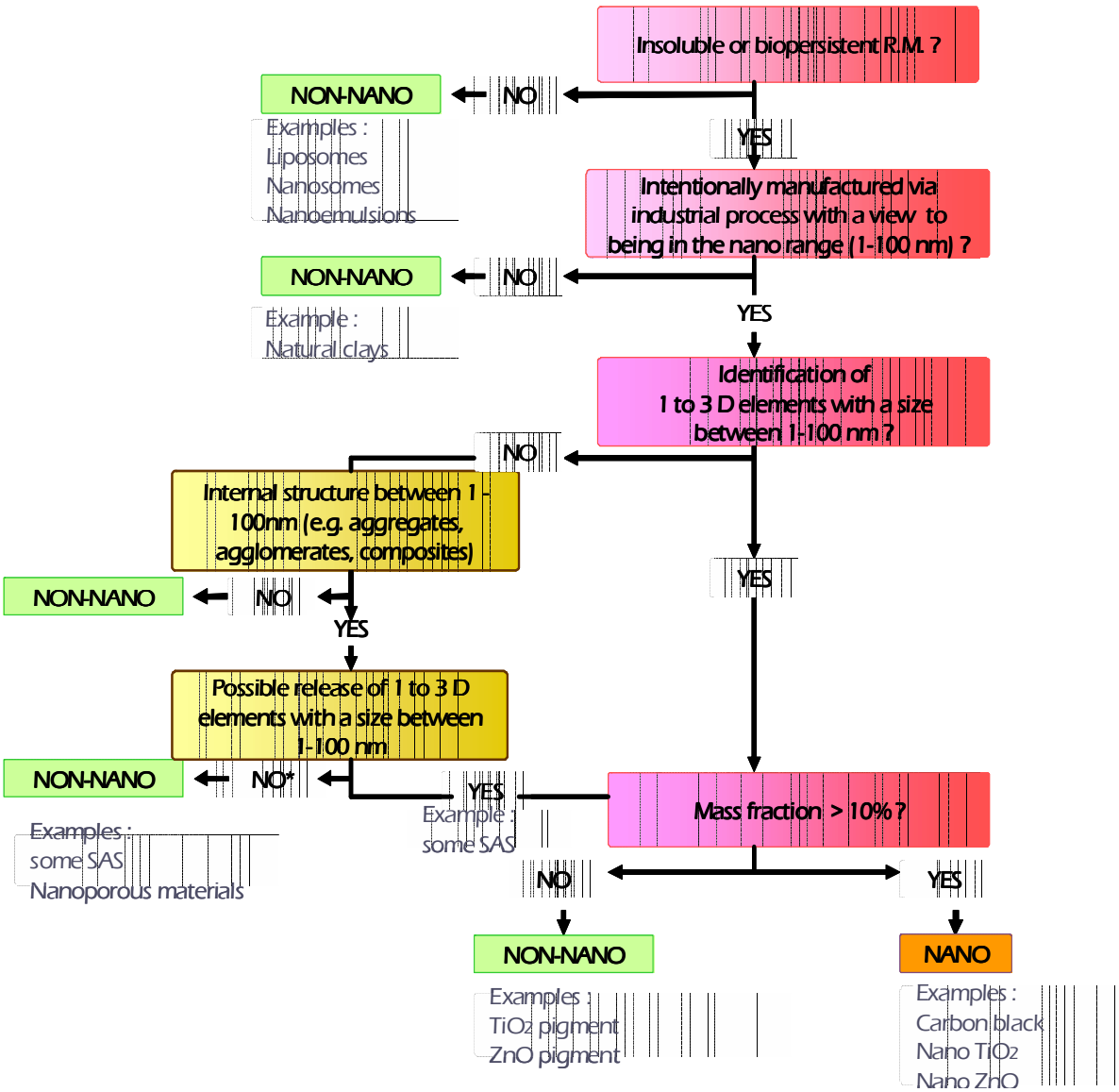
Accordingly, in order to meet regulatory obligations laid down in the Cosmetic Regulation EC 1223/2009, **we follow the suggestion of the chemical industry (e.g. VCI 2010) that a threshold of 10% of the mass fraction of a material should be used in order to determine whether a given material should be considered as a nanomaterial or not**. This threshold is realistic and accessible by current measuring techniques.

- **<u>INTERNAL STRUCTURE</u>**

Nanomaterials can be found in several physical forms, from isolated nanoparticles (primary particles, nano-objects) to aggregates and agglomerates (nano-structured materials). Aggregates and agglomerates are defined by the SCENHIR (2007) as "*groups of particles held together by strong forces such as those associated with covalent or metallic bonds*" and "(…) *by weak forces such as Van der Waals forces, some electrostatic forces and surface tension*", respectively. Additionally, some composites and nano-porous materials may be considered to have internal structures in the "nano" range.

In our view the regulator's intention is to focus on materials that may be present in the form of free elements between 1-100 nm. Thus, **materials with constitutive elements having a dimension in the nano-range** (e.g. aggregates, agglomerates, composites) **but that are themselves greater than 100 nm in size should not be considered as nanomaterials unless they release nano-objects or aggregates of less than 100 nm in size** in cosmetic products under normal use conditions. It should be noted that the cycle that should be considered for possible release of such entities should correspond to the "use cycle" of such materials and not their "life cycle".

The flowchart below summarizes the present Colipa guidance on the definition of the term “nanomaterial” included in the EU Cosmetic Regulation:



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