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Addendum – July 2021

NANOMATERIALS :
Cosmed separates the real from the fake

Many manufacturers turn to Cosmed following inspections that reveal the presence of nanomaterials, even though the person responsible did not think they were using them. The person responsible is often dependent on the data and analysis of suppliers. And yet, in the event of non-compliance, it is this person who will be affected by sanctions, including the withdrawal of the products concerned from the market.
It is therefore appropriate to recall the obligations, rules and practices regarding nanomaterials.

Some substances may be nano in terms of the R-nano obligation and not nano from the point of view of the Cosmetic Regulation (EC) No 1223/2009, and vice versa

TRUE

The European Cosmetics Regulation defines a nanomaterial as "*an insoluble or biopersistent material, intentionally manufactured and characterised by one or more external dimensions, or internal structure, on a scale of 1 to 100 nm;*"
This definition is different from the one used in the French decree n°2012-232 to which it is appropriate to turn for the French R-nano declaration "*substance intentionally manufactured at the nanometric scale, containing particles, unbound or in the form of an aggregate or in the form of an agglomerate, of which a minimum proportion of the particles, in the size distribution by number, have one or more external dimensions between 1nm and 100 nm.* ».
Differences are thus based on the notions of intentionality, insolubility, bio-persistence and consideration of internal structure.
Similarly, the European Commission's Recommendation No. 2011/696 gives an even different definition by referring to a threshold of 50%: "*a natural, incidentally formed or manufactured material containing free particles, in aggregate or in agglomerate form, of which at least 50% of the particles, in numerical size distribution, have one or more external dimensions between 1 nm and 100 nm.* ».

The definition of nanomaterial will soon be harmonised

TRUE

The European strategy for sustainability in the field of chemical products published on 14 October 2020 foresees to review and harmonise the definition of nanomaterials with an indicative deadline of 2021 in order to ensure consistency in the different legislations. To this end, discussions are underway within European working groups, such as the "nanomaterials" working group on cosmetic products, which met on January 28th, a meeting in which Cosmed participated as a member.

Silicas are partly soluble and therefore considered non-nano

FALSE

The SCCS, in its opinion on silica (SCCS/1606/19[1]), specifies the solubility threshold to be taken into account: 33.3g/L *(*defined according to USP 38 and USP 38NF33[2]), whereas the threshold of 100mg/L is frequently used by manufacturers, leading to non-compliance. The SCCS specifies that given the solubility values of the silicas evaluated in the SCC/1606/19 opinion, none of them can be considered as soluble with regard to Regulation (EC) No 1223/2009.

[1] SCCS/1606/19 OPINION ON solubility of Synthetic Amorphous Silica (SAS)
[2] USP 38 and USP 38 - NF 33: The Pharmacopeia of the United States of America (USP), Thirty-Eighth Revision and the National Formulary (NF) Thirty-Third Edition - General Notices and Requirements.

There are no official test methods for detecting nano TRUE

There is no official method, but there are opinions expressed by the JRC, OECD and other publications that address this issue; the test protocols used to define the nano criterion as well as the sample preparation have, in some cases, a strong influence on the results. Above all, an appropriate method(s) should be used. In order to ensure reliable results, it is recommended to combine different analytical techniques.

Many suppliers claim a non-nano form of their raw material on the basis of DLS (dynamic light scattering) or laser particle size analysis. However, these analyses do not allow differentiation between aggregates/agglomerates and primary particles and generate false negatives due to overestimation of particle sizes. This analysis alone will not defend the non-nano nature of a substance.

Scanning Electron Microscopy (SEM) is a reference technique for nanometric characterisation TRUE FALSE

This technique makes it possible to observe the presence of nano particles through a direct measurement of the size of the primary particles. It also takes into account the notion of criterion in number that indirect techniques do not provide or provide incorrectly.

As for the sp-ICPMS technique, it can also be used by the control authorities for certain matrices, certain elements and certain particle shapes. However, it cannot be applied to all nanomaterials, as it may present biases, such as not being able to distinguish between subpopulations of different size characteristics.

Addendum July 2021: SEM is the preferred tool of French authorities to characterize nanos. However, following a control, analyses conducted separately by the administration and by an industrialist, on the same raw material (TIO2), in two analysis centers by SEM technology revealed different results. The SEM technology is affected by a variability of results; Cosmed, like the SCCS and the JRC, recommends to couple a SEM analysis and an sp-ICPMS analysis in order to make the results more reliable.

Aggregates and agglomerates are not considered as nano FALSE

To confirm the nano status it is necessary to look at the primary particle or internal structure. Aggregates of nanoparticles (strong bonds) or agglomerates of nanoparticles (weak bonds) are considered to fall within the definition of a nanomaterial. considered to fall under the definition of a nanomaterial.

There is currently no technique capable of telling whether the bonds between particles are strong (covalent) or weak (electrostatic). For example, titanium nanoparticles grafted onto the surface of mica wafers are nanostructured materials that can release nanoparticles.

Some methods of sample preparation, including sonication, can create nano particles by breaking up the material TRUE FALSE

On metal oxide materials such as TiO2, ZnO, iron oxides or even silica, sonication will simply deagglomerate the particles. This method is not powerful enough to break a particle in two. It only breaks up the agglomerates. This is very important to have a good preparation of the samples for SEM analysis.

On the other hand, on certain materials such as hydroxyapatite platelets, clays or naturally extracted calcium carbonate, sonication can cause the appearance of nanometric fragments.

There is a threshold at which a substance contained in a mixture is considered nano FALSE

The definition of "nanomaterial" in the cosmetics regulation does not include a minimum threshold: "*an insoluble or biopersistent material, intentionally manufactured and characterised by one or more external dimensions, or internal structure, on a scale of 1 to 100 nm*".
Thus any ingredient with a particle size distribution curve with values below 100 nm should be considered a nanomaterial, subject to information on its solubility and bio-persistence.
However, the DGCCRF applies a tolerance of 10% in terms of the number of nanoparticles to the results of analyses carried out on products sampled during controls. This approach makes it possible to cover measurement uncertainties and to guard against the situation where the presence of nanoparticles results from environmental contamination.

The person responsible cannot be held liable the presence of nano if the supplier certifies the opposite FALSE

The nano nature of a raw material is to be determined on a case-by-case basis according to the characteristics of the substance. It is the responsibility of the person responsible for placing the cosmetic product on the market to analyse all the data in order to conclude on the nano character or not of the ingredient he uses. The supplier as well as the safety assessor should "participate" in this analysis in order to make a fair and complete study.

If my supplier certifies that the substance is non-nano I don't have to check anything FALSE

Given the current state of knowledge and available data, a simple statement of "no nanomaterial" without proof that adequate analyses have been carried out is not likely to meet the requirements of the Regulation. A particle size distribution curve, expressed as a number of particles, should support the supplier's reasoning.
If the ingredient supplier is unable to provide this evidence, it is the responsibility of the responsible person to conduct the appropriate analyses.

The Cosmed trade association brings together more than 920 companies in the cosmetics industry; following the findings of **the national authorities** and in order to take action to address the issues that make the use of nanomaterials and compliance with the resulting regulations difficult today, **it has set up a Nanomaterials Working Group**.

Cosmed now advocates that the availability and quality of data should be the responsibility of the ingredient supplier, a position shared by the DGCCRF.
Suppliers of ingredients who, as part of the obligations under the Chemicals Regulation, have to provide more and more information on qualification as a nanomaterial and more analysis.

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