



Cosmetics Europe Nano Guidance Package

Part I: Compliance with the legal requirements related to nanomaterials in the EU Cosmetic Regulation 1223/2009

Final 3-10-2012

Regulation 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products (the “Cosmetics Regulation” or the “Regulation”) was published in the Official Journal of the European Union on 22 December 2009 (OJEU, L 342, p. 59). The Regulation will replace Directive 76/768/EC (the “Cosmetics Directive” or the “Directive”).

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

This guidance document is intended to give an overview of these new requirements and to clarify the obligations of companies placing products containing nanomaterials on the EU market.

Many of the practicalities of the requirements are still to be decided. Discussions at the European Commission are continuing. This document will be updated and elaborated in light of the outcome of these discussions.

Definition of “Nanomaterial”

To clarify which ingredients and products are subject to the Regulation nanomaterial requirements, a “nanomaterial” must be defined. The definition of nanomaterial, for the purposes of the Cosmetics Regulation, is provided under Article 2.1 (k) as:

“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”

To aid cosmetic companies in their decision whether or not an ingredient falls under the regulatory definition, in October 2011 (revision January 2012) Cosmetics Europe issued general guidance **“INTERPRETATION OF THE DEFINITION OF THE TERM “NANOMATERIAL” ACCORDING TO THE EU COSMETIC REGULATION 1223/2009”**. This guidance, based on the industry interpretation developed in April 2011, is inspired by and is consistent with opinions and recommendations of the JRC

(June 2010), the SCENIHR (July 2010) and the European Commission (DG Environment, October 2011).

It is the responsibility of the company manufacturing the product to decide whether any ingredients they are using are nanomaterials. Cosmetics Europe strongly invites companies to establish a dialogue with their suppliers to gather the necessary information to take such a decision.

Obligations for companies marketing cosmetic products containing nanomaterials

1. Article 13 declaration of nanomaterial usage

Article 13 of the Cosmetics Regulation requires that the responsible person submits a notification to the European Commission before placing each cosmetic product on the EU market. Products already existing on the market must also be notified before 11 July 2013. This should be done through the Commission's Cosmetics Product Notification Portal (CPNP). Guidance is available on the European Commission website:

http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/cpnp_user_manual_en.pdf

Included in the information to be declared under this general notification scheme (Article 13 (1)) is the presence of any substance in the form of nanomaterials, including information on their identification and the reasonably foreseeable exposure conditions. This requirement applies to all nanomaterials without exception.

2. Article 16 nano-notification

Article 16 of the Regulation introduces the requirement for the responsible person to notify to the Commission cosmetic products containing certain nanomaterials. This is separate and in addition to Article 13 notification.

For products already on the market before 11 January 2013, this nano-notification is required to be submitted between 11 January 2013 and 11 July 2013. From 11 July 2013, this nano-notification must be submitted six months in advance of placing the product on the market.

The information that should be submitted is listed in the Regulation Article.

Exemptions from Article 16 requirements:

Products containing nanomaterials that are used as colorants, preservatives or UV filters, and which therefore need to be listed on annexes IV to VI to be allowed for use, are never subject to the nano-notification requirements, irrespective of the size of these ingredients. In these cases the positive listing supersedes the need for nano-notification. Products containing ingredients listed on annex III in the form of a nanomaterial need not be notified.

3. Article 19 "(nano)" labelling

A new requirement introduced by the Regulation is the obligation to inform the consumer when nanomaterials, as defined under Article 2.1(k), are used in cosmetic

products. To this end, the suffix “nano” shall be placed after the INCI name of the ingredient concerned. The requirement applies to all nanomaterials without exception.

All cosmetics products made available on the market, , shall be compliant from 11 July 2013. For further information on this issue see Part V (Legal Note), section I of the Cosmetics Europe Nano Guidance Package.

Further practical guidance on nano-labelling is available in section III (g) 5 of the 2011 **COSMETICS EUROPE GUIDELINES ON COSMETIC PRODUCT LABELLING**.

This labelling enables consumers to make an informed choice whether or not to use products containing nanomaterials, but has nothing to do with the safety of the product, nor is it a warning.

4. Safety assessment of nanomaterials

The consideration of material particle size is not a new requirement under the Regulation; the Cosmetics Directive already required the consideration of any ingredient characteristic that may impact the safety assessment of a product. However specific references are now included in the Regulation:

Article 16 (1)

“For every product that contains nanomaterials as defined in Article 2, a high level of protection of human health shall be ensured.”

Annex I Part A (8)

“Particular consideration shall be given to any possible impacts on the toxicological profile due to...particle sizes, including nanomaterials.”

The Scientific Committee on Consumer Safety (SCCS) has published guidance on the safety assessment of nanomaterials in cosmetics. The guidelines are publically available for free and can be downloaded from this link:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf

5. Annex entry coverage of the nano-forms of ingredients

In the current Cosmetics Directive, entries in the annexes do not distinguish between nano and non-nano form of ingredients. Ingredients listed in the annexes are therefore allowed under the specified use conditions in their nano and non-nano form.

However, in the new Regulation, paragraph 3 of the preamble to annexes II to VI states that the entries do not cover nanomaterials, except when specifically mentioned.

Assuming the new Cosmetics Regulation would enter into force with the annex entries worded as in the current Directive, no nanomaterial forms of ingredients listed in the annexes would be allowed for use in cosmetic products.

Considering only those ingredients listed in the positive lists are allowed to be used for these purposes, dossier submission and evaluation by the SCCS of positive listed substances in products already on the market have to be completed at the latest when the new annex structure applies, in order to allow use of the nano-forms of these ingredients under the new Regulation.

Dossiers are being/have been prepared to support the following nanomaterials: titanium dioxide, zinc oxide, carbon black and methylene bis-benzotriazolyl tetramethylbutylphenol.

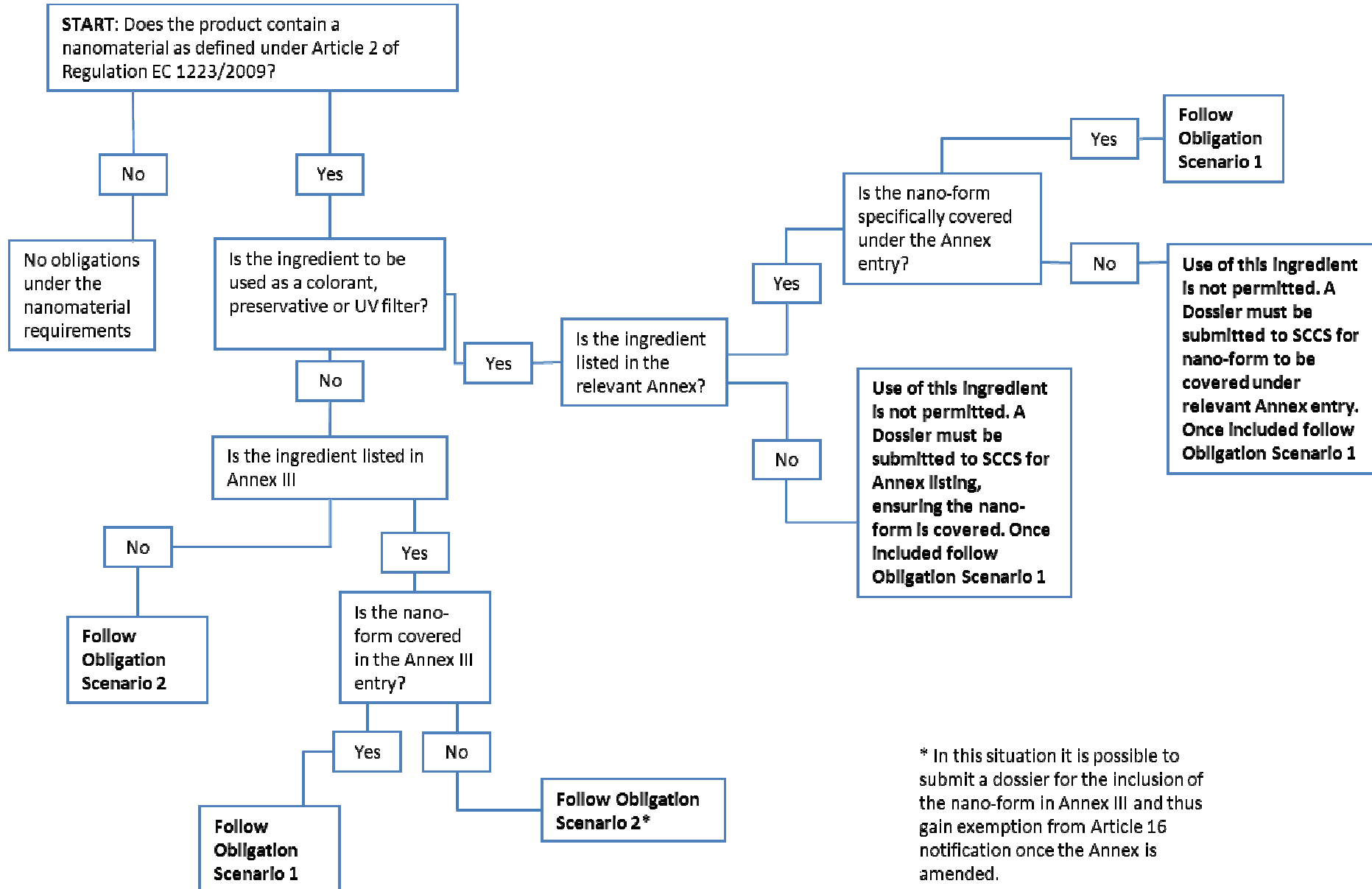
Companies using nanomaterials of any other substance listed in the Annexes, who are prepared to support the continued use under the Regulation through the preparation of a safety dossier, are advised to contact Cosmetics Europe or their national associations.

Nano obligations summary table

| Regulation Reference | Requirement | Applicable to: | Also affects existing products? |
|-----------------------------|---|--|--|
| Article 13 | Declaration of nanomaterial use under the general notification procedure (CPNP) | All products containing nanomaterials | Yes, CPNP notification for existing products by 11 July 2013 |
| Article 16 | Nano-notification of products containing nanomaterials six months prior to placing on the market. | Products containing nanomaterials not listed in Annex IV, V or VI and not listed as the nano-form in Annex III | Yes, nano-notification of affected existing products between 11 January and 11 July 2013. |
| Article 19 | Nano labelling | All products containing nanomaterials | All cosmetics products made available on the market shall comply from 11 July 2013. Also see Part V (Legal Note), section I of the Cosmetics Europe Nano Guidance Package. |
| Article 16 and Annex I | Ensure a high level of safety and consider particle size as part of the safety assessment | All products containing nanomaterials | Yes, this is not a new requirement and already applies under the Directive. |

Nano Obligations Decision Charts

These decision charts should be used as a guide to company obligations under the new Regulation requirements for nanomaterials, depending upon the regulatory status of individual nanomaterials under the Regulation Annexes.



Obligation Scenario 1

1. Declare under the CPNP the presence of the nanomaterial in the cosmetic product.
2. Label the nanomaterial with the suffix “(nano)” after the INCI name in the ingredients list.

Obligation Scenario 2

1. Declare under the CPNP the presence of the nanomaterial in the cosmetic product.
2. Submit an Article 16 nano notification for the product, six months prior to placing on the market. For existing products notify between 11 January and 11 July 2013.
3. Label the nanomaterial with the suffix “(nano)” after the INCI name in the ingredients list.