AVICENN
Association de veille et d'information civique
sur les enjeux des nanosciences
et des nanotechnologies

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(The document has been very slightly edited on March, 24
in order to improve the layout and clarity of one sentence on page 4)

Feedback for the Call for evidence from the European Commission regarding the Cosmetic Products Regulation (CPR) – evaluation

AVICENN is grateful for the opportunity to comment on the Cosmetic products regulation (CPR)[1], and more specifically on its nano-related provisions.

We would like to highlight the need for:

- **a better definition of the term 'nanomaterial'**

and

- **a thorough assessment of nano-specific risks in cosmetics.**

→ Both aspects must be revised, in the light of the latest scientific developments and technical progress, in order to properly ensure consumers' information and protection which have been partially deficient so far.

1 – Since the early 2000s', serious concerns about health issues related to human exposure to nanosubstances have emerged and CPR has included provisions to tackle them.

Because of their very small size[2], nano-substances can cross physiological barriers[3] and penetrate human bodies, organs, and cells, where their high reactivity can exert a higher toxicity than bulk substances[4]. That's why significant scientific concerns have been rising regarding their safety[5], especially in cosmetics, where human exposure can be specifically high. Indeed, nanoparticles from cosmetics can come into contact with the body not only through dermal exposure but also through inhalation (hair sprays, makeup powders, …) and ingestion (*via* lipsticks or toothpaste for example).

That's why European institutions included nano-related provisions in CPR, with a dedicated definition of the term 'nanomaterial' and a specific evaluation and authorization process. Some of these provisions have already proven effective and led to the restriction of twelve nanomaterials in cosmetics, which we can only commend[6].

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14433-Cosmetic-Products-Regulation-evaluation

[2] 1 nanometer (nm) = 10^{-9} meter = 0.000 000 001 m = 1 billionth of a meter

[3] Cf. https://veillenanos.fr/en/dossier/nanos-and-health/nanos-entry-and-fate-human-body

[4] Cf. https://veillenanos.fr/en/dossier/nanos-and-health/nanos-health-risks

[5] Cf. https://veillenanos.fr/en/news/?type=post&limit=12&type_nano=598

[6] Cf. https://veillenanos.fr/en/twelve-nanomaterials-banned-and-one-restricted-in-european-cosmetics

2 – Yet many pigments in cosmetic products on the market contain nanosubstances that are neither authorized nor labelled [nano].

In addition to generic examples from the European Observatory on nanomaterials (EUON)[7], national authorities[8] as well as consumers' and citizens' organisations which have tested cosmetic products have systematically found unlabelled – and most of the times also unauthorized – nanoparticles in cosmetics.

- In 2018, the consumer association Que Choisir revealed the presence of nanoparticles (among which, titanium dioxide and iron oxides) in 6 cosmetics[9]. Except for one sunscreen, where titanium dioxide nanoparticles are allowed for their anti-UV properties, the other nanoparticles were present although neither authorized (as pigments), nor labelled [nano].
- In 2022, AVICENN disclosed the results of new tests[10] on 6 unlabelled [nano] cosmetic products in which titanium dioxide (TiO2) nanoparticles were again identified (3 of them contained around 25 % of TiO2 particles less than 100 nm, 2 around 40% and 1 around 100%) as well as iron oxides nanoparticles (from 63 to 85% particles less than 100 nm).

→ The implementation of the nano-related provisions within the CPR is clearly lacking.

3 – The definition of the term 'nanomaterials' and whether or not it should include the 50% threshold have been implemented in a detrimental way regarding consumers' information and safety

Some brands have argued that they have/had been using these nanosubstances – and doing so without labelling them as [nano] – because they were not 'nanomaterials' since they contain fewer than 50% of particles smaller than 100 nm.

However, although recommended twice by the European Commission[11], this arbitrary 50% threshold has no scientific basis*, it was – and is still – not legally binding as it is not included in the CPR, and its inclusion in Novel Foods regulation has been objected by the European Parliament (in 2014 and again in 2024[12]).

* It is based on the fact that a substance that contains fewer than 50% of particles with a size less than 100 nm is not made of a 'majority' of nanosubstances… but this does not prevent it from containing a very large quantity of nanosubstances. Deliberately ignoring the fact that, except for carbon black, pigments are not authorized if their size is less than 100 nm goes against the law and against citizens' demand for *"better labelling of everyday products containing nanomaterials"* that has been reiterated in a 2020 study commissioned by the European Chemicals Agency (ECHA)[13]. Above all, this 50% threshold does not guarantee in any way the absence of potential risks.

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[7] Cf. https://euon.echa.europa.eu/cosmetics

[8] Cf. https://www.economie.gouv.fr/dgccrf/laction-de-la-dgccrf/les-enquetes/nanomateriaux-dans-les-produits-solaires-la-dgccrf-agit-en, https://www.economie.gouv.fr/dgccrf/laction-de-la-dgccrf/les-enquetes/controles-2021-sur-les-substances-reglementees-dans-les, https://www.economie.gouv.fr/dgccrf/laction-de-la-dgccrf/les-enquetes/quand-les-cosmetiques-ont-des-imperfections-corriger, …

[9] Cf. https://www.quechoisir.org/actualite-nanoparticules-video-une-opacite-generalisee-n50832

[10] Cf. https://veillenanos.fr/wp-content/uploads/2023/01/Rapport-test-EN-20230113.pdf

[11] Cf. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0696 and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022H0614(01)

[12] https://www.europarl.europa.eu/doceo/document/B-9-2024-0225_EN.pdf

[13] Cf. https://euon.echa.europa.eu/documents/2435000/3268573/nano_perception_study_en.pdf

4 - In spite of growing questions about their safety, the risk assessment of nanosubstances in cosmetics is still incomplete and lagging

Another issue is that, as the SCCS has reminded us in July 2024[14], data provided by manufacturers are very often not robust enough to properly assess the toxicity of nanoparticles in cosmetics, particularly (but not only) regarding TiO2.

The SCCS has called several times for more data and the European Commission has granted manufacturers additional time to this end.

Meanwhile, against the precautionary principle, European consumers and workers thus continue to be exposed to a wide range of nanoparticles whose safety is not established.

→ This situation is incompatible with the objective of the CPR, namely a *"high level of protection of human health".*

5 – Toxicity, authorization, and labelling of nanoparticles used in trendy pearlescent pigments must be urgently scrutinized

In addition to what has been mentioned above, a specific attention must be paid to pearlescent pigments that have been increasingly marketed for a few years now and have become a popular craze among young people, with millions of views on Tik Tok[15].

Many of these sparkling pigments are made of micrometric mica flakes covered by very small metal oxide nanoparticles, whose combinations are considered as nanocomposites. As such, even if many more than 50% of them are smaller than 100 nm, they are excluded from the 2022/C 229/01 EC definition. Cf. Recital 11 of EC 2022 Recommendation on the definition of the term 'nanomaterial':

> *"The definition should **not** cover large solid products or components, even when they have an internal structure or a surface structure at the nanoscale, such as coatings, certain ceramic materials and complex nanocomponents, including nanoporous and **nanocomposite materials**. Some of these products or components may have been manufactured using nanomaterials and **may even still contain them**"* [16].

Cosmetic brands use this 2022/C 229/01 recommendation to justify that they use these TiO2 nanoparticles in their pearlescent pigments without authorisation nor [nano] labelling, even though the size distribution shows above 50% of particles less than 100 nm. Granted, they would no longer be considered as 'nanomaterials' if this recommendation of definition were to be integrated into the CPR.

We would like to highlight two problematic assumptions here.

1) First, the belief that the 2022/C 229/01 EC definition will necessary be copied and pasted within the CPR in the short term and without any other nano-specific risk management measures.
   → Scientific expertise, public authorities, NGOs and Members of the European Parliament have different perspectives on this issue that need to be openly and fully taken into consideration. Substances that do not meet the 'nanomaterials' definition but still exhibit nanosizes and/or nanoproperties should not be overlooked.

[14] Cf. https://health.ec.europa.eu/publications/scientific-advice-titanium-dioxide-tio2-casec-numbers-13463-67-7236-675-5-1317-70-0215-280-1-1317-80_en

[15] Cf. Glamour's article published in March 2024: *Pearl Skin Is The Spring Makeup Trend That TikTok's About To Blow Up*.

[16] Cf. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX%3A32022H0614%2801%29

2) Second, the hypothesis that the metal oxide nanoparticles (TiO2, iron oxides, etc.) contained in many pearlescent pigments are all very strongly attached to the mica.
   →However, these bonds, supposed to be very strong by manufacturers are absolutely not scientifically demonstrated. What is more, we are currently compiling evidence of the contrary. It turns out that they do contain a multitude of very small nanoparticles of metal oxides (mainly titanium dioxide, and iron oxides also but in much smaller proportions), not only on the mica plates, but also outside of the mica plates. Some are isolated, of a size clearly less than 100 nm (their average size being around 30 to 50 nanometers, twice as small as the size of more common pigmentary TiO2 particles). Others are agglomerated/aggregated in the close vicinity of the edges of the mica flakes (with agglomerates' and aggregates' sizes also less than 100 nm in many cases). There is a very significant release of nanoparticles from the mica flakes, leading to an important human exposure to nanomaterials/nanosubstances.
   This shows not only that the brands do not comply with the CPR in force but also that the 2022 recommendation on definition promoted by the European Commission, even if it were integrated as is in the Cosmetics Regulation (i.e. with its recital 11 which excludes nanocomposites) would not protect them from prosecution for non-compliance.

The presence of such unlabelled [nano] substances in products that can be inhaled and spread on the body on a daily basis shows that the legal framework does not adequately protect the information nor the health of consumers... who are, for the vast majority of them, female consumers. Most of them are very young (see the millions of views on Tik Tok mentioned above), chronically and repeatedly exposed to these nanoparticles and their agglomerates detached from mica flakes. Due to their particularly small size, these TiO2 and iron oxide nanoparticles penetrate deeper into the pulmonary alveoli than usual pigmentary TiO2 nanoparticles. Thus, they are more likely not only to generate increased inflammation in the lungs, but also to be distributed throughout the body in various organs where their accumulation could cause other worrisome adverse effects.

Last but not least, the use of TiO2 nanoparticles is expected to intensify– not only due to fashion trends but also as a result of the European restriction on microplastics adopted in 2023[17], with a potential risk of 'regrettable substitution'. This advocates for risk assessment and mitigation measures to be taken in the shortest possible time, as safety concerns are at stake, which consumers are not aware of.

We thank you for your taking our feedback into consideration.

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[17] Cf. https://echa.europa.eu/hot-topics/microplastics