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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the use of nanomaterials in cosmetics

and

on the review of Regulation (EC) No 1223/2009 on cosmetic products as regards nanomaterials

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Glossary

Cosmetics Regulation	Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
CPNP	Cosmetic Products Notification Portal
ECHA	European Chemicals Agency
EU	European Union
EUON	European Union Observatory for Nanomaterials
ICCR	International Cooperation on Cosmetics Regulation
INCI	International Nomenclature of Cosmetic Ingredients
Responsible person	Legal or natural person designated in the EU in accordance with Article 4 of the Cosmetics Regulation
REACH (Regulation)	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SCCS	Scientific Committee on Consumer Safety

INTRODUCTION

Nanomaterials consist of very small particles[1] that cannot be observed by the human eye. These materials are present in nature, such as in beach sand and milk (natural colloids), but they are also manufactured and added to consumer products to provide specific properties.

The very small size of nanomaterials provides special physical and chemical properties: nanomaterials may change colour compared to their macroform or may gain antioxidant properties. However, the small size can also influence the hazard properties of a specific nanomaterial. Some of the nanoforms of substances could thus potentially present intrinsic hazards not displayed in their non-nano form.

Cosmetic products containing nanomaterials must follow specific regulatory provisions for nanomaterials, and every day, approximately 10 new such cosmetic products are placed on the EU market; this represents only small fraction (between 1.2% and 1.5%) of the total number of new products (see Paragraph 1.2).

Regulation (EC) No 1223/2009 (hereinafter the "Cosmetics Regulation") addresses the specificities inherent to nanomaterials used in cosmetic products: Article 16 provides an ad-hoc regime that applies to cosmetic products that contain nanomaterials, as described more in detail in Section 1.

Pursuant to Article 16 (10) and (11) of the Cosmetics Regulation, the Commission is required to submit to the European Parliament and the Council an annual status report on the use of nanomaterials in cosmetic products and to review the provisions concerning nanomaterials of this Regulation.

This document aims to implement the provisions mentioned above and is structured as follows:

- Section 1 – Status **Report** on developments in the use of nanomaterials in cosmetic products (Article 16 (10) (b));
- Section 2 – **Review** of the Provisions Concerning Nanomaterials of the Cosmetics Regulation (Article 16 (11).

[1] Article 2(1)(k) of the Cosmetics Regulation refers to a material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm (nano-meter).

SECTION 1 –STATUS REPORT ON THE USE OF NANOMATERIALS IN COSMETIC PRODUCTS

1.1. The provisions governing nanomaterials in the Cosmetics Regulation

The Cosmetics Regulation provides a specific regime governing cosmetic products that contain nanomaterials, defined in Article 2(1)(k) of this Regulation as "*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'*"*.*

In particular, Article 16(1) clarifies that "[for] *every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured*" and the subsequent paragraphs in Article 16 govern the procedures that apply to cosmetic products that contain nanomaterials:

1. cosmetic products with nanomaterials are subject to a specific notification procedure, "[i]*n addition to the notification under Article 13, products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market* […]" (Article 16(3) of the Cosmetics Regulation). The notification submitted by the applicant shall include the information listed in Article 16(3) of the Cosmetics Regulation;
2. in the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission shall, without delay, request the SCCS (the Scientific Committee for Consumer Safety)[2] to give its opinion on the safety of this nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure;
3. the SCCS shall deliver its opinion within six months of the Commission's request. Where the SCCS finds that any necessary data is lacking, the Commission shall request the responsible person to provide such data within an explicitly stated reasonable time, which shall not be extended;
4. SCCS shall deliver its final opinion within six months of submission of additional data;
5. Article 16(6) of the Cosmetics Regulation eventually provides that: "[taking] *into account the opinion of the SCCS, and where there is a potential risk to human health, including when there is insufficient data, the Commission may amend Annexes II and III'*'[3].

Article 16(2) provides that the provisions of this Article do not apply to nanomaterials used as colorants, UV-filters or preservatives regulated under Article 14 of the same Cosmetics Regulation, unless expressly specified[4], since they are already subject to specific ex ante authorisation requirements.

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[2] The SCCS is an expert body that provides independent scientific advice to the European Commission on the safety of non-food consumer products, including cosmetic products.

[3] Annexes II and III of the Cosmetics Regulation provide, respectively, the list of "substances prohibited in cosmetic products" and the list of restrictions to the use of substance ("List of substances which cosmetic products must not contain except subject to the restrictions laid down").

[4] In accordance with Article 14 of the Cosmetics Regulation, these nanomaterials can only be used in accordance with the conditions laid down in the relevant Annex (IV; V or VI).

1.2. Notification procedure of the nanomaterials placed on the EU market

Article 13 of the Cosmetics Regulation provides that, prior to placing a cosmetic product on the market, the responsible person shall submit, by electronic means, specific information on that cosmetic product to the Commission (including the presence of nanomaterials when relevant). This notification requirement is carried out via the Cosmetic Product Notification Portal[5] (CPNP).

The data extracted from the CPNP provide valuable information on cosmetic products: ***every day about 800 new cosmetic products are notified and placed on the EU market (almost 290.000 cosmetics were notified in 2019)***.

Article 16(3) of the Cosmetics Regulation provides that, in addition to the notification under Article 13, cosmetic products that contain nanomaterials shall be notified to the Commission by the responsible person, by electronic means, six months prior to being placed on the market. Hence, the CPNP also contains a separate module for cosmetic products containing nanomaterials.

The notification shall include the information listed in Article 16(3) of the Cosmetics Regulation. In case of ingredients used to colour, preserve or as UV–filter and listed in Annexes IV, V or VI as nanomaterials, the notification under Article 16 does not apply; nevertheless, the general notification requirement under Article 13 would continue to be applicable.

Therefore, the notifications submitted under Article 13 to CPNP allow assessing the total amount of cosmetic products containing nanomaterials.

Considering the data collected from the CPNP, it is possible to assess how the use of nanomaterials in cosmetic products has evolved over time. In particular, since the establishment of the CPNP for nanomaterials (period 2013 - 2020) a total of:

- over 2.5 million cosmetic products have been placed on the EU market;
- 37 647 cosmetic products were notified with nanomaterials (in accordance with Article 13 procedure), this corresponds to about 1.5% of all notifications;
- 1 445 notifications were made in accordance with Article 16 procedure.

More specifically, Table 1 below provides an overview of the submitted CPNP notifications received for the period 2016 – 2020:

Year	Article 13 Notifications	Article 16 Notifications
2020	3 444	137
2019	3 926	175

[5] See https://ec.europa.eu/growth/sectors/cosmetics/cpnp_en

2018	3 557	200
2017	3 626	131
2016	3 556	265

Table 1: 2016-2020 CPNP notifications on cosmetic products containing nanomaterials (both Article 13 and Article 16 notifications).

This corresponds to an average of about 3 620 new products containing nanomaterials per year that are notified on the CPNP (data 2016-2020): ***every day, about 10 new cosmetic products containing nanomaterials are placed on the EU market.***

The use of nanomaterials in cosmetic products is limited (1.5% of all products) and seems to be rather stable over the past five years (2016-2020).

Nanomaterials used as colorants, preservatives or UV filters and listed, respectively, in the Annexes IV, V and VI to the Cosmetics Regulation are not subject to the notification requirements under Article 16 of that Regulation, since they are already subject to the pre-market authorisation regime. Their presence can be, however, retrieved via the general notifications submitted in accordance with Article 13 of the Cosmetics Regulation.

There are five nanomaterials included in the Annexes IV, V and VI to the Cosmetics Regulation (see Table 2):

Annex	INCI	CAS number
IV (Colorants)	Carbon Black (nano)	1333-86-4/7440-44-0
V (Preservatives)	-	-
VI (UV Filters)	Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano)	103597-45-1
	Titanium Dioxide (nano)	13463-67-7/1317-70-0/1317-80-2
	Tris-biphenyl triazine (nano)	31274-51-8
	Zinc Oxide (nano)	1314-13-2

Table 2: Nanomaterials included in the Annexes to the Cosmetics Regulation

In 2020, 3 444 notifications were submitted under Article 13 of the Cosmetics Regulation for nanomaterials listed in the Annexes IV, V and VI; for all other nanomaterials only 137 notifications were made in accordance with Article 16 of the Cosmetics Regulation.

The figures above confirm that the vast majority of the nanomaterial notifications are related to authorised uses of colorants and/or UV filters (currently there are no authorized nanomaterials with a preservative function listed in Annex V nor notified in the CPNP); only

a minority of all notifications are not related to such uses (in 2020, 137 notifications corresponding to about 3.9% of all notifications of that year).

Most of the cosmetic products containing nanomaterial ingredients are related to ingredients with a colorant or UV filter function (about 96% of notifications in 2020).

The four most used chemical substances, accounting for over 70% of all CPNP nanomaterial notifications, are:

- Titanium Dioxide
- Silica Dimethyl Silylate, Silane, dichlorodimethyl-, reaction products with silica
- Carbon Black nano (CI 77266)
- Silica.

The most common product categories[6] associated with a cosmetic containing nanomaterials are:

1. Sun protection;
2. Nail varnish/Nail make up;
3. Oxidative hair care;
4. Foundation;
5. Lip care products and lipstick.

Significant differences were found on the percentage of cosmetic products containing nanomaterials in different countries. Table 3 below provides an overview of notifications in the five EU countries with the highest number of total CPNP notifications (France, Germany, Italy, Spain and Poland). It is plausible to assume that this divergence may result from differences in the implementation by national authorities and/or economic operators of the nanomaterials definition and, consequently, of the relevant notification obligations.

Country of the responsible person	Total CPNP notifications	CPNP notifications for Nanomaterials	Percentage of notifications for Nanomaterials in that country	Country contribution to total EU notifications for nanomaterials
France	328 041	16 459	5.0%	43.7%
Germany	291 269	4 326	1.5%	11.5%
Italy	528 340	4 569	0.9%	12.1%
Spain	315 850	2 550	0.8%	6.7%
Poland	123 966	2 463	2.0%	6.5%

Table 3: CPNP notifications in the five largest EU countries

There is a significant difference in the percentage of cosmetic products containing nanomaterials notified in the five EU countries with the highest number of total CPNP

[6] The reported five uses account for about 64% of all Nanomaterials notifications.

notifications (from 0.8% up to 5%) and in the country's contribution to the total EU notifications of nanomaterials (from 6.5% (Poland) to 43.7% (France)).

1.3. Inventory of the nanomaterials present on the EU market

To improve transparency, the Commission has published two catalogues of nanomaterials used in cosmetic products placed on the EU market, as notified through the CPNP. Article 16 (10) requires that this information concerns all nanomaterials used in cosmetic products – not only those notified under Article 16, but also those used as colorants, preservatives or UV-filters.

The Commission published the first catalogue in June 2017 ("2017 Catalogue" with data collected until end of 2016)[7]. The second version was issued in 2019 ("2019 Catalogue" with data collected until end of 2018)[8].

The catalogues include a list of International Nomenclature of Cosmetic Ingredients (INCI) names of nanomaterials used in cosmetics, as notified in CPNP. The catalogue further specifies into nanomaterials used as colorants, as UV-filters and other nanomaterials notified under Article 16 of the Cosmetics Regulation.

It is important to highlight that the Catalogue is based on the information provided solely by the responsible person and there is no validation of the quality of the information. The responsible person holds the responsibility for the content of the notification. For this reason, the catalogue is for information only and does not represent a list of authorised nanomaterials.

A comparison of both catalogues issued with a two years interval allows identifying trends in the use of nanomaterials in cosmetics. Apart from illustrating the market trends, it also reflects rectification of incorrect listing of substances as nanomaterials:

- The 2017 Catalogue contains 43 entries (even though some nanomaterials appear there multiple times in their different functions – i.e. as colorants, UV-filters and other functions).

- The 2019 Catalogue contains 29 entries (titanium dioxide and zinc oxide are listed twice as both colorants and UV-filters).

The total amount of cosmetic ingredients qualifying as nanomaterials has declined over the observed period from 43 to 29.

In order to explain this difference, it is relevant in particular to assess the colorants category:

- The 2017 Catalogue contains 12 nanomaterial substances notified in CPNP as Colorants; however, only one substance (Carbon black nano) is present in the related Annex IV (only colorants listed in Annex IV can be used for this purpose as cosmetic ingredients).

[7] Catalogue of nanomaterials used in cosmetic products placed on the market – version 1. Available at: https://ec.europa.eu/docsroom/documents/38164

[8] Catalogue of nanomaterials used in cosmetic products placed on the market – version 2. Available at: https://ec.europa.eu/docsroom/documents/38284

- In the 2019 Catalogue there are only 3 nanomaterial substances notified in CPNP as Colorants (Carbon black, Titanium oxide and Zinc oxide); Titanium oxide and Zinc oxide are not authorized for colouring purposes but are inserted in Annex VI as authorized UV filters in nanomaterial form.

Furthermore, two nanomaterial substances from the list of UV-filters[9] and six from the list of nano-substances with other functions[10] were removed. Nano-copper, Gold and Silver moved from nano-colorants to nanomaterials with other functions.

The above seems to support the finding that ***many notifications on nanomaterials included in the 2017 first catalogue were made by mistake or as a precaution and that the 2019 Catalogue represents a more accurate picture of the market.*** For instance, Titanium dioxide and Zinc oxide are not authorized as colorants in Annex IV and, therefore, should not have been notified for colouring purposes.

The differences between the nanomaterial definitions in the Cosmetics Regulation and in the Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU) ("Commission Recommendation on the definition of nanomaterial")[11] (see Section 2) might be at the origin of some difficulties encountered by economic operators in the past in implementing some notifications obligations.

Overall, there are no "new" chemical substances, qualifying as nanomaterials, featured in the 2019 Catalogue that had not already appeared in some form (e.g. used in a different category of cosmetics) in the 2017 Catalogue.

1.4. Safety assessment of nanomaterials used in cosmetic products

As mentioned in Section 1.1, Article 16(4) of the Cosmetics Regulation provides that in the event that the Commission has concerns regarding the safety of a nanomaterial, it shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure.

The SCCS must deliver its opinion within six months of the Commission's request. Where the SCCS finds that any necessary data is lacking, the Commission requests the responsible person to provide such data within an explicitly stated reasonable time, which should not be extended.

The SCCS has to deliver its final opinion within six months of submission of additional data.

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[9] Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine; Ethylhexyl Methoxycinnamate.

[10] Cellulose; Platinum powder; Retinol; Sapphire Powder; Tin Oxide; Tocopheryl Acetate.

[11] The Cosmetics Regulation provides a sector specific definition of "nanomaterial" in Article 2(1)(k*): "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".*
The 2011 Commission Recommendation provides the following definition of nanomaterial by*: "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 accordance with Article 16(5) of the Cosmetics Regulation, the Commission may also, at any time, consult the SCCS in accordance with the procedure described above in case safety concerns arise.

Following the mandates provided by the Commission[12], in the last 10 years, SCCS issued over 20 opinions and guidance documents[13] on nanomaterials used in cosmetic products[14].

The draft conclusions of the SCCS are subject to public consultation and, once finalised, constitute the scientific basis for the Commission decision to amend the Annexes to the Cosmetics Regulation.

The assessment conducted by the SCCS on the safety of a nanomaterial is, therefore, mainly based on the information provided by the notifier, both in the original notification (Article 16(2) and Article 16(3) of the Cosmetics Regulation) and in the additional information requested by the SCCS, as applicable, pursuant to Article 16(4) of the Cosmetics Regulation.

Normally the SCCS should conclude whether a safe use of a nanomaterial can be established, including with relevant limitations or restrictions, as applicable. However, in some cases SCCS might not be in a position to conclude on the safety. This might be due to the insufficient information/data, as submitted to the SCCS by the applicants and/or as available in scientific literature.

Considering ***the most recent (2015 to 2020) SCCS opinions on CPNP-notified nanomaterials, the majority are inconclusive***. In particular, in seven out of ten opinions, the SCCS could not conclude on the safety of the relevant nanomaterial based on the information available in the CPNP system or when the responsible persons were requested to provide clarification or additional information/data.

Finally, it should be noted that ***the availability of data on specific nanomaterial substances could improve in the future via the implementation of the REACH Regulation***. In fact, the Commission adopted nano-specific clarifications and new provisions for REACH registrants[15]. The proposed amendments (applicable since 1st January 2020) require characterisation of nanoforms of substances (i.e. nanomaterials in their different forms). They also clarify REACH information requirements with regard to nanomaterials and are expected to over time increase the availability of related data (e.g. through updates of REACH registration dossiers).

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[12] See https://ec.europa.eu/health/scientific_committees/consumer_safety/requests_en

[13] See Guidance on the safety assessment of nanomaterials in cosmetics; SCCS/1611/19 – 30-31 October 2019; Checklists for Nanomaterials in Cosmetics; Revision of the memorandum on Relevance, Adequacy and Quality of Data in Safety Dossiers on Nanomaterials, SCCS/1524/13 – 12 December 2013 – revision of 27 March 2014

[14] The final SCCS opinions are public and can be consulted at https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions_en#fragment2

[15] On 3 December 2018 the Commission adopted Commission Regulation (EU) 2018/1881 to modify REACH Annexes I, III and VI-XII, introducing nano-specific clarifications and new provisions in the chemical safety assessment (Annex I), registration information requirements (Annex III and VI-XI) and downstream user obligations (Annex XII).

1.5. Assessment methods

The assessment whether a particulate material is a nanomaterial or not according to the definition of nanomaterial in the Cosmetics Regulation often requires that specific measurements (e.g. to confirm the size range) are carried out, as well as to duly consider additional elements of the definition (e.g. insolubility, intentionality of the manufacturing, etc.). The assessment of the risks associated with nanomaterials also requires specific considerations.

Recital 30 of the Cosmetics Regulation provides that:

> "*At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety the SCCS should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials*".

The Cosmetics Regulation acknowledged, therefore, that, at the moment of its adoption there was "*inadequate information on the risks associated with nanomaterials*" and mandated the SCCS to adopt a guidance on test methodologies to assess their risks. Such guidance has been adopted by the SCCS in 2012 ("Guidance on the Safety Assessment of Nanomaterials in Cosmetics", SCCS/1484/12) and it was followed by a SCCS Memorandum on Relevance, Adequacy and Quality of Data in Safety Dossiers on Nanomaterials (SCCS/1524/13).

The Guidance was originally adopted in 2012 and was revised in 2019[16] to reflect new scientific findings and update data requirements, such as the animal testing ban that has meanwhile come into force and requires obtaining data from alternative methods[17].

The current Guidance on the Safety Assessment of Nanomaterials in Cosmetics takes into account specific characteristics of nanomaterials and details various safety considerations to be taken into account (such as physicochemical characterisation, exposure assessment, hazard identification and dose-response characterisation and risk assessment). Checklists for the applicants' dossiers are also available[18].

In addition, the EU Joint Research Centre (JRC) issued in 2019 a *Report on Identification of nanomaterials through measurements*[19], which addresses identification of nanomaterials according to the Commission Recommendation on the definition of nanomaterial. Even if there is no full coherence between the 2011 Commission Recommendation on the definition of nanomaterial and the definition of "nanomaterial" in the Cosmetics Regulation, the JRC report contains useful elements on the analytical methodologies to be followed. Relevant information can also be retrieved on the ECHA Guidance *"Appendix for nanoforms*

[16] Guidance on the Safety Assessment of Nanomaterials in Cosmetics, SCCS/1611/19, as revised in October 2019. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_233.pdf

[17] https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/citizens_guidance_nano_en.pdf

[18] See Checklists for Nanomaterials in Cosmetics section in the: Checklists for Applicants submitting dossiers on Cosmetic Ingredients to be evaluated by the SCCS, SCCS/1588/17, as revised in May 2018. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_210.pdf

[19] See https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/identification-nanomaterials-through-measurements

applicable to the Guidance on Registration and Substance Identification" (December 2019)[20].

1.6. International cooperation and regulatory harmonisation in the field of nanomaterials in cosmetic products

The EU is the first jurisdiction to have regulated the use of nanomaterials in cosmetics in order to ensure their safety for human health. However, using nanotechnology to improve the performance of cosmetic products is a global trend not limited to EU. Some other countries followed this approach by adopting a regulatory framework specifically covering the use of nanomaterials in cosmetics[21].

Contrary to this, other jurisdictions did not adopt specific regimes reflecting the distinct chemical and biological characteristics of nanomaterials (e.g. United States, Australia, Brazil, Canada and Japan[22]).

Efforts towards harmonisation of the "nanomaterial" definition and alignment on the nano-specific safety assessment is ongoing at a number of international fora[23]. Therefore, when the ICCR (International group of cosmetics regulatory authorities from Brazil, Canada, the European Union, Japan and the United States)[24] was established in 2007, the use of nanotechnology in cosmetics was considered as one of six priority areas for international cooperation[25]. Since then, steps are being taken to find a common approach towards nanomaterials in cosmetics.

In its standardisation efforts, ICCR worked toward a consensus on safety approaches to nanomaterials in cosmetics and to harmonise experimental procedures. It has issued reports on standard nanoparticle detection and characterisation methods, followed by the latest report on safety approaches to nanomaterials in cosmetics[26].

As the notion of "nanomaterial" varies among different jurisdictions, already in its first report on nanotechnology, the ICCR invited the cosmetic industry to develop common definitions

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[20] See https://echa.europa.eu/documents/10162/13655/how_to_register_nano_en.pdf/f8c046ec-f60b-4349-492b-e915fd9e3ca0

[21] By way of example, New Zealand has a notification and labelling requirement comparable to those in the EU Cosmetic Regulation. In Israel and South Korea, nanomaterials are also regulated – specific requirements are in place to verify the safety of a cosmetic product containing nanomaterial ingredients and the use of nanomaterials in the product has to be indicated on the product label.

[22] Report of the ICCR Working Group: Safety Approaches to Nanomaterials in Cosmetics. Annex 2: Regulatory Considerations relating to nanomaterials in cosmetics (2013). Available at: https://www.iccr-cosmetics.org//downloads/topics/2013-11_safety_approaches_to_nanomaterials_in_cosmetics.pdf

[23] See e.g. the standardisation work of the Technical Committee 229 on Nanotechnologies of the International Standardization Organization (ISO) (https://www.iso.org/committee/381983.html).

[24] International Cooperation on Cosmetics Regulation (ICCR) is a voluntary international group of cosmetics regulatory authorities from Brazil, Canada, the European Union, Japan and the United States. see the ICCR website available at: https://www.iccr-cosmetics.org/.

[25] ICCR-2. *Association Panel Report Nanotechnology in Cosmetics* of October 31, 2008. Available at: https://www.iccr-cosmetics.org/files/2814/3350/5427/2008-10_Association_Panel_Report_on_Nanotechnology_in_Cosmetics.pdf.

[26] ICCR. *Report of the ICCR Working Group on the Safety Approaches to Nanomaterials in Cosmetics*. ICCR/NANOSAFETY1/R/FINAL/. 2013. Available at: https://www.iccr-cosmetics.org//downloads/topics/2013-11_safety_approaches_to_nanomaterials_in_cosmetics.pdf

for nanotechnology in the field of cosmetics[27]. In the interim, the ICCR's Ad Hoc Working Group on Nanotechnology identified a set of criteria to help determine if a specific substance used in cosmetics is considered "nanomaterial" based on set criteria and methods of detection.

The ICCR working definition[28] is broadly aligned with the definition in Article 2(1)(k) of the Cosmetics Regulation, thus defines a nanomaterial as a substance which, amongst other criteria, is of the size 1 to 100 nanometres. Similarly to the Cosmetics Regulation, the ICCR also does not include the nanoparticles emerging naturally or incidentally in the nanomaterial definition.

1.7. Main findings Section 1

- ***On average, 10 new cosmetic products containing nanomaterials are placed on the EU market every day; this is only a fraction of the 800 new cosmetic products notified daily in CPNP. Overall, the use of nanomaterials concerns a rather limited number of all cosmetic products (about 1.5% of the total) and has been rather stable over the last five years.***

- ***Most of the cosmetic products notified in the CPNP correspond to nanomaterials with a colorant or UV-filter function.***

- ***There are differences in the percentage of newly notified cosmetic products containing nanomaterials among EU countries (from 0.8% to 5.5%) as well as in the share of the overall notifications of nanomaterials (from 6.5% to 43.7%).***

- ***The 2019 Commission catalogue of nanomaterials represented a rather accurate picture of the market, albeit with the inherent limitations stemming from the notification process.***

- ***Most of the SCCS opinions on the safety of CPNP-notified nanomaterials were inconclusive due to the lack of or insufficient data. Therefore, there is a need for responsible persons to provide information as accurate as possible when notifying nanomaterials which are present in cosmetic products.***

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[27] *Ibid*., p. 2.

[28] *"For purposes of the International Cooperation on Cosmetic Regulation, a substance used in a cosmetic is considered a nanomaterial if it is an insoluble ingredient, intentionally manufactured, with one or more dimensions in the realm of 1 to 100 nanometers in the final formulation and is sufficiently stable and persistent in biological media to allow for the potential of interaction with biological systems."* see: https://www.iccr-cosmetics.org/files/2814/3350/5840/2010-07_Nanotechnology_in_Cosmetics_Criteria_and_Methods_for_Detection.pdf. (See the *Association Panel Report Nanotechnology in Cosmetics, ibid, p. 5).*

SECTION 2 – REVIEW OF THE PROVISIONS CONCERNING NANOMATERIALS

2.1. Purpose of the review

As mentioned in Section 1.1, Article 16(11) of the Cosmetics Regulation provides that the Commission shall "*regularly review the provisions of this Regulation concerning nanomaterials in the light of scientific progress and shall, where necessary, propose suitable amendments to those provisions"*[29].

The current review intends to assess whether the provisions of the Cosmetics Regulation concerning nanomaterials are still fit for purpose in the light of technical and scientific progress, including the information shared in Section 1 of this document.

In particular, four main elements of the provisions governing nanomaterials in the Cosmetics Regulation are assessed in the light of technical and scientific progress:

1. Definition of "nanomaterial"
2. Notification of nanomaterials
3. Scientific assessment of nanomaterials
4. Labelling of cosmetic products containing nanomaterials

2.2. Definition of "nanomaterial" in the Cosmetics Regulation

In 2009, when the Cosmetics Regulation was adopted, an internationally agreed definition of nanomaterials was not yet available. The Cosmetics Regulation acknowledged, therefore, that there was a lack of consensus on a definition of nanomaterials at EU and international level and thus expressly envisaged the possibility to review and update its related provisions.

In this respect, Recital 29 of the Cosmetics Regulation provides that:

> "*The use of nanomaterials in cosmetic products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Community should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly."*

The Cosmetics Regulation currently provides a sector-specific definition[30] of "nanomaterial" in Article 2(1)(k): "*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"*.

[29] The need to review the provisions on nanomaterials of the Cosmetics Regulation is also reflected in Recital (31) "*The Commission should regularly review the provisions on nanomaterials in the light of scientific progress*".

[30] Other sectorial nanomaterial definitions are provided in EU: for instance, the Novel Food Regulation (Regulation 2015/2283 Article 3 (f): https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&from=en) and in the Biocidal Products Regulation (Regulation 528/2012 Article 3(z) Reg. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528&from=en)

Therefore, when establishing the nanomaterial status of a cosmetic ingredient, the following main elements must be considered:

- Insolubility or biopersistence
- Intentional manufacture
- One or more external dimensions on the scale from 1 to 100 nm.

A more horizontal definition of nanomaterials became available after the publication of the Cosmetics Regulation with the Commission Recommendation of 2011 on the definition of nanomaterial [31]:

"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."

It is worth noting that the cross-sectorial REACH Regulation applies the 2011 Commission Recommendation on the definition of nanomaterial[32].

There are two main differences between the two definitions: the threshold of the particle size distribution and the concept of natural, incidental or engineered nanomaterial.

1. Particle size distribution – the absence of a threshold of the size distribution in the Cosmetics Regulation should be regarded with caution. In fact, considering that most of the materials are not mono-modal in size (i.e. not all particle dimensions are the same) and that no size distribution is requested, this could create unwanted situations (i.e. the detection of one single particle of a cosmetic ingredient in the scale from 1 to 100 nm could cause the applicability of the nanomaterial classification)[33]. This is also somewhat confirmed by the 2019 SCCS *"Guidance on the Safety Assessment of Nanomaterials in Cosmetics"* that acknowledged the 50% distribution size threshold in the 2011 Commission Recommendation and suggested that *"it should be kept in view by the Applicants when assessing the safety"* of a substance used in a cosmetic product.

2. Incidental and intentional– similarly, the concept of "intentionally manufactured" of a nanomaterial used in a cosmetic product is difficult to be established only based on analytical test methods. The "intention" is something that goes beyond an objective and measurable fact.

The differences between the Cosmetics Regulation definition and the Recommendation create some discrepancies across different sectors concerning the classification of materials as nanomaterials (i.e. some materials are considered nanomaterials under REACH and not under

[31] The general relevance of this definition is clarified in point 1 of the Recommendation: *"Member States, the Union agencies and economic operators are invited to use the following definition of the term 'nano-material' in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies*."

[32] See COMMISSION REGULATION (EU) 2018/1881 of 3 December 2018

[33] Some authors argued that the nanomaterials definition in Cosmetics Regulation refers implicitly to a significant size distribution. Miernicki, M., Hofmann, T., Eisenberger, I. et al. Legal and practical challenges in classifying nanomaterials according to regulatory definitions. Nat. Nanotechnol. 14, 208–216 (2019). https://doi.org/10.1038/s41565-019-0396-z

the Cosmetics Regulation), which might generate questions and divergent approaches amongst Competent Authorities and economic operators (see footnote 32).

Further to the divergence mentioned above, it is important to underline that as mentioned in Section 1.4, following adaptations of the REACH annexes[34], it is expected that REACH registrants will soon start to produce new data on the safety of nanomaterials and update their registration dossier. Such data would be based on the nanomaterials definition provided in the 2011 Recommendation. In order to fully exploit the new scientific data from the cosmetics regulatory perspective (e.g. in the safety assessment of specific nanomaterials used in cosmetics by SCCS), it could be beneficial to adopt the same nanomaterial definition also for cosmetic products.

The possibility of aligning the nanomaterial definition of the Cosmetics Regulation with the 2011 Commission Recommendation and its planned future update should be thoroughly assessed in order to evaluate its potential effects.

Furthermore, the EU Chemicals Strategy for Sustainability published on 14 October 2020[35], has identified several elements also relevant for the cosmetic sector, including the revision of the horizontal definition of nanomaterials by 2021 (such a revision will follow the Better Regulation rules, including public consultation). In particular, and in order to allow a coherent approach across the EU acquis, it is provided that the Commission will "*review the definition of nanomaterial and ensure its coherent application across legislation using legally binding mechanisms*"[36]. ***The cosmetics definition of nanomaterials might, therefore, be adapted to the upcoming revised general definition to be presented in 2021***.

2.3. Notification process for nanomaterials

As mentioned in Section 1.1, further to the notification obligations that apply to all categories of cosmetic products under Article 13 of the Cosmetics Regulation, Article 16(3) provides specific notification obligations applying to cosmetics products that contain nanomaterials. Therefore, cosmetic products containing nanomaterials are subject not only to the notification under Article 13, but also to the notification under Article 16:

"For every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured. In addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market […]."[37]

Following the notification and the relevant information made available via the CPNP, the Commission may request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable

[34] See COMMISSION REGULATION (EU) 2018/1881 of 3 December 2018 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances.

[35] Communication on "Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment" (COM(2020) 667 final).

[36] Communication on "Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment" (COM(2020) 667 final), Page 17.

[37] Article 16(3) of the Cosmetics Regulation

exposure conditions. On the basis of SCCS findings and if there is a potential risk, including when there is insufficient data, the Commission can prohibit or restrict the use of such a nanomaterial in cosmetic products (see Section 1.1 and Article 16 (4) to (6) Cosmetics Regulation).

There are a few important elements to be highlighted in this respect:

- First, Article 16 states that '*in the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial…'*. The identification of concerns by the Commission might require special scientific consideration in order to fully implement this provision. For that reason, the Commission has requested from the SCCS to draft a priority list based on relevant concerns for the notified nanomaterials as published in the 2019 catalogue[38].

- Second, it is evident from Article 16 that it is not the nanomaterial itself that is notified to the Commission via CPNP, but each cosmetic product containing the relevant nanomaterial. However, the safety assessment is carried out at ingredient level by SCCS (see next Paragraph). This observation has some direct consequences, since the same nanomaterial ingredient can be used in multiple applications by many responsible persons. Thus, the Commission and SCCS need to check numerous notifications containing similar or the same information (especially in the case where the same responsible person is notifying multiple products). It should be noted that in the last three years over 500 CPNP notifications were made under Article 16 notification procedure. Although this process is a time consuming exercise, it must be concluded in a relatively short period of time (6 months).

- Third, the current approach does not appear optimal for the economic operators that need to plan in advance their business activities. A cosmetic product notified under Article 16 can be marketed after the period of six months, regardless of whether the safety assessment has been concluded or not. The expiry of this period in fact does not mean *per se* that the nanomaterial was approved nor that it may not be regulated in the future. Contrary to the substances authorised under Annexes IV to VI, the expiry of the 6 months 'standstill period' does not necessarily result in a conclusive assessment on the safety of the concerned products.

The notification process of the nanomaterial and, in particular, its duration and the effect of the expiry of the deadline provided in the Cosmetics Regulation would deserve special further analysis in order to consider possible improvements and adaptations in light of the experience gained so far.

[38] See the Commission's mandate to SCCS "Request for a scientific advice on the safety of nanomaterials in cosmetics" adopted by written procedure by SCCS on 5 February 2020, available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs2016_q_044.pdf

2.4. Scientific assessment of nanomaterials and regulatory measures

The approach followed in the nanomaterials assessment[39] is based on a preliminary screening of CPNP notifications operated by the Commission on the basis of a potential concern. Once such a concern has been identified, the SCCS is mandated to issue an opinion on the safety of the nanomaterial. Based on the SCCS opinion and where there is a potential risk to human health, the Commission may act by prohibiting or restricting such nanomaterial via the modification of Annexes II or III.

With over 7 years since the applicability date of the nanomaterials notification, ***experience shows that the application of the Article 16 has revealed some aspects which should be further analysed in order to strengthen the safety assessment of nanomaterials***.

As reported in Section 1, a total of 1 445 notifications were submitted to CPNP under Article 16 for new cosmetic products containing nanomaterials. The establishment of concerns for specific nanomaterials has to be carried out by the Commission on the basis of the information provided within each notification. This is challenging from an administrative and scientific point of view, in particular, in the absence of specific information/data on the safety of those nanomaterials used.

Following the preliminary screening by the Commission, the SCCS issued 10 opinions on the safety of the CPNP-notified nanomaterials in the last five years (2015-2020). Seven out of these ten SCCS opinions were inconclusive due to lack of data, therefore the SCCS could not provide any conclusions on whether these nanomaterials are safe for use and under which conditions.

On one hand, the lack of conclusive SCCS opinions indicating a potential risk for human health hampers the ability of the Commission to proceed with regulatory measures. On the other hand, the responsible persons are allowed to place their products on the market once the 6-months are lapsed, irrespective of the SCCS outcome.

The current situation is expected to improve to a certain extent with the publication of the 2021 scientific advice on the safety of nanomaterials in cosmetics[40] by the SCCS. The identification of safety concerns within this scientific advice, after the previously inconclusive SCCS Opinions specifically for three groups of nanomaterials, may pave the way to the adoption of regulatory measures. In addition, the SCCS advice proposes a scoring system that will help the Commission in the screening phase and during the selection of the materials most likely to cause concerns. Furthermore, new data from the REACH registration dossiers on the safety of nanomaterials are expected to become available in the coming years (see Paragraph 2.3) that may further contribute to the safety assessment of cosmetic ingredients.

Nevertheless, further improvements might be examined to also address other features of the current system, such as the disproportionate number of notifications per single nanomaterial to be checked and the lack of reassurance on the safety of the concerned products in case of inconclusive SCCS opinion.

[39] Article 16 notification process and SCCS role are discussed in Par. 1.3.

[40] The scientific advice SCCS/1618/20 is available https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_239.pdf

At the same time it is important to recall that the Cosmetics Regulation has already in place a well-functioning "authorisation process" whereby the safety of an ingredient has to be demonstrated via a dedicated dossier submission by the applicant to the SCCS for evaluation. Only substances that were assessed and found safe are listed in Annexes IV, V and VI (Article 14 Cosmetics Regulation).

The possibility to extend the authorisation system for nanomaterials (as provided in Article 14 of the Cosmetics Regulation) beyond colorants, preservatives and UV Filter) could be further explored.

2.5. Labelling of cosmetics containing nanomaterials and consumer awareness

In order to inform consumers about the composition of a specific product, every cosmetic product has to indicate the list of its ingredients in indelible and visible lettering either on its container or packaging[41]. Furthermore, when it comes to cosmetic products including nanomaterials, the Cosmetics Regulation further extends the labelling obligation:

"All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets." (Article 19(1)(g) of the Cosmetics Regulation).

This labelling applies to all cosmetic products containing nanomaterials, regardless whether they are subject to the nanomaterial notification under Article 16, or the authorization procedure as colorants, preservatives or UV-filters under Article 14(1)(c), (d) and (e) respectively. ***In the consumer product sector, only cosmetic products have a specific labelling requirement on the presence of nanomaterials***[42].

The label should indicate all ingredients in INCI nomenclature and the ingredients in nano-size should be followed by a word 'nano' in brackets (e.g. Titanium dioxide(nano)). As with other ingredients, also nano-ingredients should be listed in the descending order of weight compared to other ingredients in the product[43].

With regard to consumer perception of nano-enabled cosmetic products, it remains unclear how the above 'nano' labelling facilitates the consumer awareness about the cosmetic products containing nanomaterials and their buying behaviour. However, interesting findings were published in 2020 by a study conducted for the European Union Observatory for Nanomaterials (EUON) and ECHA "*Understanding the Public's Perception of Nanomaterials and How Their Safety Is Perceived in the EU*"[44]. This report found that almost 9 out of 10 respondents, from a representative number of EU citizens from different Member States, consider it important to be informed when buying a product containing nanomaterial.

The study also showed that if consumers were presented with clear information that a product contains nanomaterials, the majority would take a cautious stand of either not buying such a product, or decide based on the category of the product. The negative or rather negative

[41] See Article 19 (1)(g) of the Cosmetics Regulation.

attitude towards nanomaterials was clearly linked to the level of knowledge of respondents about nanomaterials. The lower the level of knowledge about nanomaterials, the less likely the respondent is to buy a product containing nanomaterials. Furthermore, as a general observation, consumers tended to be more aware of the use of nanomaterials when it came to cosmetics than with a number of other surveyed areas.

Finally, it should be recalled that the use of digital technologies to purchase consumer goods, and cosmetic products in particular, has increased significantly (e.g. during the Covid-19 health crisis). This provides novel challenges and opportunities that deserve to be further explored. For instance, market control of on-line purchase can be challenging; on the other hand, digital means can contribute to a more effective and targeted communication to the user of cosmetic products (e.g. an electronic label could also include information on the use of cosmetic ingredients qualifying as nanomaterials).

Most EU citizens considers important to be informed on the presence of nanomaterials when they purchase a product (as required by the Cosmetics Regulation) and the potential use of digital technologies should also further explored to that extent.

2.6. Main conclusions

This review has assessed whether the provisions of the Cosmetics Regulation concerning nanomaterials are still fit for purpose in the light of technical and scientific progress. In particular, the review has focused on the definition of 'nanomaterial', the notification of nanomaterials, the scientific assessment of nanomaterials, as well as the labelling of cosmetic products containing nanomaterials.

As regards the **definition**, this review has highlighted the differences between the definition of nanomaterials in the Cosmetics Regulation and the 2011 Commission Recommendation on the definition of nanomaterial. This was also recognised in the EU Chemicals Strategy for Sustainability, where a revision of the horizontal definition of nanomaterials by 2021 was announced. Aligning the nanomaterial definition of the Cosmetics Regulation with a horizontal definition could increase coherence between legislation but should be thoroughly assessed in order to evaluate its potential effects.

Shortcomings have been identified in the **notification of nanomaterials**. For instance, while the safety assessment is carried out at ingredient level, notifications are made at product level. Furthermore, the timeline for assessment is relatively short and does not appear optimal for economic operators that need to plan their business activities in advance. Therefore, the effectiveness of the current notification process of nanomaterials via the Cosmetic Products Notification Portal (CPNP) merits specific attention, in particular the duration and effect of the expiry of the deadline as laid out in the Cosmetics Regulation.

The scientific safety assessment of nanomaterials could be strengthened, in particular as experience has shown that the majority of the completed assessments by the Scientific Committee on Consumer Safety were inconclusive due to lack of data. While the current situation is expected to improve to a certain extent through improved implementation, further improvements could be explored, such as the possibility to extend to nanomaterials the existing authorisation system, as provided in Article 14 of the Cosmetics Regulation for colorants, preservatives and UV Filter, which works well.

Finally, as regards **labelling**, as most EU citizens consider it important to be informed about the presence of nanomaterials in products they buy, digital labelling could be considered to complement and further improve the labelling of nanomaterials in cosmetic products.