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Summary

The cosmetics industry uses a range of nanomaterials to improve the properties of products. Whilst there are no or only minor health concerns with soluble and biodegradable nanomaterials, such as those used to transport active ingredients into the skin, it is primarily the insoluble and persistent nanoparticles that give cause for concern. These are substances that are used, for example, as UV filters or dyes, or because of their antibacterial or antioxidant properties. To ensure the highest possible level of consumer protection, the EU Cosmetics Regulation was adapted in 2009, with special provisions introduced for nanomaterials. These include the notification of cosmetic products containing nanomaterials to the European Commission, a comprehensive safety assessment, and the labelling of nanoscale ingredients on the product label. Cosmetics are the only consumer products with such regulations in the EU. In the USA, for example, there are no such regulations to protect consumers. Technical progress, but also the experience gained during the implementation of the provisions for nanomaterials in the EU Cosmetics Regulation over the recent years, now necessitate their adaption and update. The definition of the term “nanomaterial” in the regulation, the safety assessment and notification procedures, and the labelling method are now subject to review at EU level.

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Nanomaterials in cosmetics – regulation and safety assessment in the EU

Introduction

The cosmetics industry is constantly developing new products for different requirements, drawing on developments from the latest research, including the field of nanotechnology. The market for cosmetic products is growing continuously. In 2017, the global market was estimated at around US\$530 billion. In 2023, it is expected to reach a volume of US\$800 billion.¹ By using nanomaterials, it is possible to improve the properties of cosmetics and overcome their limitations. For example, nanomaterials enable better skin penetration and controlled release of active ingredients, increase their stability and solubility, and offer improved UV protection.

A distinction must be made between soluble and biodegradable nanomaterials such as liposomes, nanoemulsions or lipid nanoparticles, which are used primarily to transport active ingredients into the skin, and insoluble, persistent nanoparticles such as pigments and particles of precious metals or oxides, which are used as UV filters, colourants and fillers, flow agents or, for example, because of their antibacterial or antioxidant properties.

With regard to consumer safety, substances used in cosmetic products warrant particular caution. Cosmetic products are so-called “consumer-oriented” applications, i.e. consumers come into direct contact with the substances used. Skin and mucous membranes, such as eyes, mouth or intimate areas, can come into contact with creams, shampoos, deodorants, decorative cosmetics, toothpaste, mouthwash, etc. However, inhaling spray-type agents or accidentally ingesting various substances used in cosmetic products is also possible. Nanosized materials can have different properties than the same material in larger form, which makes nanomaterials so interesting for use in cosmetic products. The downside, however, is that nanosized particles (1-100nm) – when they enter the body – can reach organs that are inaccessible to larger particles and trigger adverse effects there, especially if they are insoluble and persistent nanoparticles. Because of their small size and the resulting larger sur-

face area relative to volume, nanosized particles also exhibit greater reactivity than particles of the same material in a larger form. Insoluble or poorly soluble nanoparticles, in particular should therefore be investigated in great detail concerning health risks, as they may accumulate in the body.²

The topic of nanotechnology in cosmetics was already addressed in NanoTrust Dossier No. 008³ (December 2010), which provided an overview of the applications of nanomaterials in cosmetics and possible associated adverse health effects in line with the state of knowledge at that time. Much has happened in this sector since then, both in research and development, but also in the area of regulation. This dossier mainly provides an insight into activities at EU level aimed at ensuring the highest possible level of consumer protection. This dossier focuses on the regulatory aspects of insoluble or persistent nanoparticles in the EU, which are used in cosmetic products and which raise particular safety concerns. Soluble and biodegradable nanomaterials, such as those based on lipids or polymers, are widely used in cosmetics but pose little or no risk to consumers' health when assessed against currently available information. These materials are also not covered by sectorspecific regulations in the EU and, therefore not addressed in this dossier. For an overview, please refer to the NanoTrust Dossier³ from 2010.

The road to the new EU Cosmetics Regulation

Environmental and consumer protection organisations have been pointing out possible risks of nanomaterials in cosmetics since the mid-2000s and have called for the labelling of nanomaterials in cosmetic products (see³). In 2009, the European Parliament also criticised the lack of information on the use and safety of nanomaterials already placed on the market, especially in the case of applications involving direct exposure to consumers. The European Parliament, therefore, called on the European Commission to re-

view all relevant legislation within two years to ensure the safety of workers, consumers, and the environment.⁴ It also called for a uniform definition of the term nanomaterial and for the labelling of nanomaterials in consumer products. A recommendation for a definition⁵ was published by the European Commission in October 2011 (see also⁶). This was evaluated several times between 2013 and 2021 and presented in a revised form in June 2022.⁷

The EU regulation on cosmetic products was also revised in 2009 in line with the demands of the EU Parliament. Following a transitional period, all cosmetic products – whether manufactured in the European Union or in third countries – have had to comply with the new EU Cosmetics Regulation (EC) No. 1223/2009⁸ since 11 July 2013. Nanomaterials were explicitly included in this. At the time of the revision of the EU Cosmetics Regulation, the Commission's recommendation for a definition of the term "nanomaterial" was not yet available, and as there are safety concerns especially concerning the use of insoluble and persistent materials, the regulation defines "nanomaterial" 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 100nm*". A threshold at which nanoparticle content of a material would be considered a nanomaterial, as set out in the Commission's definitional recommendation, cannot be found in the definition of the EU Cosmetics Regulation.

According to the EU Cosmetics Regulation, an authorisation procedure is required for substances used as UV filters, colourants or preservatives, regardless of whether they are nanomaterials or not. Only those listed in the annexes of the regulation may be used. Dyes and mixtures used for tattoos or permanent make-up are not covered by the EU Cosmetics Regulation, but have been subject to restrictions and bans under Annex XVII of the EU Chemicals Regulation REACH (Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) by regulation since 2020 because of their health risks.⁹ The EU Cosmetics Regulation also contains a list of substances that may only be used in cosmetic products to a limited extent or are banned altogether. All cosmetic products – irrespective of whether they are subject to authorisation or not – must be notified to the European Commission by the manufacturer or importer via a dedicated portal (Cosmetic Products Notification Portal, CPNP) in accordance with Article 13 of the EU Cosmetics Regulation.⁸

In addition to this notification, Article 16 requires cosmetic products containing nanomaterials to be notified six months before they are placed on the market. In doing so, information on the spec-

ification of the nanomaterial (size of the particles, physical and chemical properties), the quantity of nanomaterial contained in cosmetic products to be placed on the market per year, the toxicological profile, and the foreseeable exposure conditions must also be provided to the Commission, as well as safety data of the nanomaterial related to the category of the cosmetic product in which it is used. As a result, the European Commission hopes to gain a better overview of which nanomaterials are used in which products and in which quantities.⁸

Cosmetic products are thus far the only consumer goods for which a labelling obligation for nanomaterials has also been introduced. Unlike textiles, paints and varnishes or cleaning agents, nanomaterials in cosmetic products must be labelled in the list of ingredients according to the regulation. Since July 2013, the ingredient in question must be followed by the word "nano" in brackets. Labelling obligations otherwise only exist for food¹⁰ and biocidal products.¹¹

Only a few other countries regulate nanomaterials in cosmetic products as is done in the EU. The legislation in New Zealand, Israel, and South Korea, for example, is comparable. Countries such as the USA, Australia, Brazil, Canada or Japan have not introduced specific regulations. However, there are international efforts towards harmonisation and alignment of nano-specific safety assessments.¹³

Nanomaterials in cosmetics on the EU market

Article 16 of the EU Cosmetics Regulation No. 1223/2009 stipulates that the European Commission shall inform the public regularly about all notified nanomaterials, including those used as colourants, UV filters, and preservatives, and for which there is a separate authorisation procedure. This list should also include the categories of cosmetic products and foreseeable exposure conditions. The first catalogue was to be made available by January 2014, but publication was delayed until 2017. The second and so far latest version was made available to the public in 2019.¹² The catalogue is based solely on information manufacturers provide during notification, which is not validated.

A summary status report was presented by the Commission to the European Parliament and the Council in July 2021.¹³ According to this report, over 2.5 million cosmetic products were placed on the EU market in 2013-2020. Of these, only 37 647 products containing nanomaterials were notified via the CPNP reporting portal in accordance with the Article 13 procedure of the EU Cosmetics Regulation, including those containing na-

nomaterials for which there is a specific authorisation procedure, i.e. UV filters, preservatives, colourants, and which are not subject to the notification requirements referred to in Article 16. According to Annex IV, only "carbon black" is currently approved as a nanoscale colourant. Annex V of the EU Cosmetics Regulation does not contain any nanomaterial as a preservative, and Annex VI contains four UV filters in nanoform: methylene bis-benzotriazolyl tetramethylbutylphenol, titanium dioxide, tris(biphenyl) triazine, and zinc oxide.

1445 notifications were made between 2013 and 2020 in accordance with the Article 16 procedure, i.e. products containing all other nanomaterials except UV filters, preservatives, and colourants. This included 22 different nanomaterials, most commonly silica (silicon dioxide) and surface-modified forms of this material, but also alumina, colloidal gold, copper, platinum, and silver.¹²

The number of cosmetic products containing nanomaterials notified annually remained relatively stable over the period 2013-2020, and these numbers make it clear that the majority of products containing nanomaterials that are subject to mandatory authorisation are UV filters or colourants. According to the status report, the most common categories of cosmetic products containing nanomaterials are 1) sun protection, 2) nail varnish/nail make-up, 3) oxidative hair care, 4) foundation, and 5) lip care products/lipstick.¹³

Safety assessment of nanomaterials in cosmetics

Manufacturers of cosmetic products containing nanomaterials must submit a safety dossier in accordance with the guidelines of the Scientific Committee on Consumer Safety (SCCS) at the time of notification.¹⁴ If there are concerns about the safety of a nanomaterial, the European Commission may ask the SCCS to carry out a risk assessment for the nanomaterial in question. The basis for this is the information provided by the manufacturers during notification as well as information gathered from scientific literature. If there is scientifically proven evidence of health risks, the use of these materials can be restricted or banned in the EU. However, the safety dossiers submitted by companies are incomplete in most cases. Important information, such as on the physicochemical properties of the nanomaterial and on experimental toxicity studies, is often missing. In these cases, the SCCS cannot carry out a conclusive risk assessment. The EU Cosmetics Regulation stipulates that in such a case, manufacturers are given a grace period to submit the missing data. After that, the SCCS has another six months to check the data and carry out an assessment. During this time, the

products may be traded even if a safety assessment is missing. However, if manufacturers submit insufficient data once more so that the SCCS cannot perform a risk assessment, the European Commission can ban or impose restrictions on the use of the nanomaterial in question in cosmetic products. National bans would also be possible in such a case.

The SCCS issued ten opinions on the safety of CPNP-notified nanomaterials between 2015 and 2020. For seven nanomaterials, no conclusive statement was possible because of a lack of information and data.¹³ Without a conclusive result, manufacturers or distributors can continue to place their products on the market. This highlights a current discrepancy between the provisions in Article 16 of the EU Cosmetics Regulation, according to which the use of nanomaterials in cosmetic products can be restricted or banned if there is a potential risk to human health, including in the case of missing information at notification, and current practice. Since information and safety data are often not even submitted by manufacturers or distributors during the grace period, the European Commission is now interpreting the provisions of the EU Cosmetics Regulation to mean that evidence from the scientific literature is also sufficient to both identify a risk from nanomaterials in cosmetic products

and to adopt appropriate regulatory measures in accordance with Article 16.¹⁵ In addition, there are considerations to possibly extend the authorisation procedure for UV filters, preservatives, and colourants as provided in Article 14 of the EU Cosmetics Regulation to nanomaterials that do not fall into these three areas of application in order to be able to carry out a comprehensive risk assessment.¹³

To obtain an overview of nanomaterials for which there are currently safety concerns, the European Commission has asked the SCCS to identify those nanomaterials in notified cosmetic products for which there are the most significant uncertainties in terms of health risks. As a basis for safety concerns, the SCCS has identified specific aspects of nanomaterials:

- **Other aspects** including: novel properties, activity or function of the nanomaterial, and specific concerns arising from the type of application.
- Based on these aspects, the SCCS lists nanomaterials in cosmetic products in the January 2021 report¹⁵ in order of priority regarding their health risks (see Table 1).
- For three nanomaterials (colloidal silver; styrene/acrylates copolymer and sodium styrene/acrylates copolymer; silica, amorphous silica, and silica surface-modified with alkyl silane), for which the SCCS has not been able to carry out a final safety assessment in the past because of a lack of information, the Committee was mandated by the Commission to conduct a risk assessment in accordance with Article 16 of the EU Cosmetics Regulation based on the scientific literature and its own expert assessment. For all three nanomaterials, the SCCS identified certain aspects that raise safety concerns.¹⁵ This could pave the way for regulatory measures for the three nanomaterials.¹³
- **Physicochemical properties:** small size of particles, solubility/persistence, chemical composition and toxicity, physical/morphological properties of particles, surface chemistry and characteristics (modifications, coatings);
 - **Exposure of consumers** depending on: the type of products, frequency and amount of use, and the potential for systemic exposure to nanoparticles and potential accumulation in the body;

Table 1:
Nanomaterials in cosmetics notified via CPNP, ranked according to their priority in terms of health risks.¹⁵

Nanomaterial	Function	Products	Concerns
Copper/ Colloidal copper	Dye other function	Body, face, and lip care, mouthwash, soap, make-up, nail modelling, hair shampoo, foot care, bath and shower products.	Copper is insoluble but can release ions; both copper and copper ions can enter the bloodstream and organs. There are indications in the scientific literature that copper has toxic potential. The safety of copper when used in cosmetics warrants further safety evaluation.
Methylene bisbenzotriazolyl tetramethylbutylphenol	UV filter	Sun protection, body, face, lip, and hand care, face masks, exfoliating products, eye contour products, self-tanning products.	Insoluble, persistent material that can accumulate in the body. There is a positive opinion by the SCCS when used as a UV filter, provided it is only applied to the skin. However, some of the applications raise concerns about possible absorption via the lungs or orally, as there are still uncertainties about the genotoxicity and carcinogenicity of the material.
Silver/ Colloidal silver	Dye other function	Skincare, soap, toothpaste, perfume, bath and shower products, face masks, foot care, eye contour products, skin cleansing products, soap, exfoliating products, mouthwash, hair shampoo, antiperspirant, pre- and after-shaving products.	Silver particles slowly release silver ions which may be problematic because they can bind to proteins and enzymes, for example. There are indications for genotoxicity, immunotoxicity, and developmental toxicity of nanosilver. Especially those products that are used orally give cause for concerns.
Tris-biphenyl triazine	UV filter	Sun protection, facial care, foundation, skin lightening products.	This material is insoluble and has already received a positive SCCS opinion for products applied to the skin. However, as it can cause inflammatory reactions, there are concerns for applications that may involve absorption via the lungs.
Platinum/ Colloidal platinum	Antimicrobial, antioxidant, skin nourishing, exfoliating	Face, body, and hand care, make-up, foundation, face masks, make-up remover, eye contour products.	Platinum is insoluble and persistent. Nanoparticles can act as catalysts for chemical reactions that may have adverse effects. For this reason, there are concerns about possible absorption into the bloodstream when used in cosmetics.
Styrene/ acrylates copolymer	Encapsulation material	Body and face care, nail varnish, eye contour products.	The material is a polymer that is used as an encapsulation material for other [bioactive] ingredients. Concerns exist regarding a health risk of the encapsulated, nanoscale substances which may be transported to unintended body parts.

Nanomaterial	Function	Products	Concerns
Titanium dioxide	Dye, UV filter	Body and face paint, sun protection, bath and shower products, body, face, foot, hand, lip, and nail care, exfoliating products, concealer, eyeliner, lid contour pencils, eye shadow, hair conditioner, lipstick, make-up, self-tanning products, depilatories, soap, toothpaste, tooth whiteners, skin cleansing products, antiperspirant.	Titanium dioxide is practically insoluble and persistent. A positive SCCS opinion for use as a UV filter is available, since this material cannot be absorbed through the skin. However, there are concerns about inhalation absorption, which is why use in cosmetic products where absorption via the lungs would be possible [e.g., in spray form] is not permitted.
Silicon dioxide [silica] and various surface-modified forms	Abrasive, absorptive, anti-caking agent, opacifier, superplasticiser	Body and face paint, bath and shower products, body, face, foot, hand, lip, and nail care, lipsticks, nail varnish, toothpaste, skin cleansing products, hair dye, sun protection, exfoliating products, concealer, eyeliner, lid contour pencil, eye shadow, eye contour products, foundation, mascara, hair styling products, antiperspirant, nail varnish remover.	SiO ₂ is insoluble and potentially persistent. Different forms have already been evaluated by the SCCS. However, no final conclusion for or against the safety could be drawn because of inadequate data. Until conclusive evidence for safety is available, concerns remain, especially for applications where absorption via the lungs or orally is possible.
Gold thioethylamino hyaluronic acid	Skin-caring qualities	Eye contour products, facial care, make-up remover, soap.	Complex from the reaction of hyaluronic acid with thioethylamine and colloidal gold; insoluble and persistent. The absorption of gold nanoparticles through the skin may be increased in this form [see "Colloidal gold"].
Carbon black	Dye	Body and face paint, bath and shower products, eye contour products, eyeliner, lid contour pencil, eye shadow, face mask, foundation, mascara, nail varnish, make-up, hair colouring products, soap products, tooth whiteners.	Insoluble; a positive SCCS opinion for dermal applications is available. However, carbon black must not be used in products where lung absorption is possible. Concerns also exist for products where oral ingestion would be possible. Additional information is needed on the use of carbon black with a particle size smaller than 20nm, as data are only available for particle sizes greater than 20nm.
Gold/ Colloidal gold	Dye, skin-caring qualities, surface modifier, antimicrobial	Body and face care, foundation, perfume, make-up, skin cleansing products, bath and shower products, eye contour products, hair conditioner, make-up remover, exfoliating products, hair shampoo, soap, scalp care, hair straightening products.	Insoluble and persistent; studies have shown that colloidal gold can penetrate the skin, and some data on toxicity are also available. In particular, the possibility of inhalation of gold nanoparticles from some products raises health concerns.
Alumina [aluminum oxide]	Abrasive, absorptive, anti-caking agent, opacifier, superplasticiser	Facial care, nail varnish, sun protection, face masks.	Insoluble and potentially persistent; alumina has not yet undergone safety evaluation by the SCCS. Concerns exist regarding uptake into the bloodstream.
Hydroxyapatite	Abrasive, oral care, skincareing qualities, filling powder	Mouthwash, dental care, tooth whiteners, toothpaste.	A natural material that is a component of bones and teeth; a safety evaluation by the SCCS has not yet been completed. There are concerns about absorption through the oral mucosa and possible adverse effects.
Lithium magnesium sodium silicate	Absorptive, filling powder, superplasticiser	Bath and shower products, body care, depilatories, cuticle removers, eye contour products, facial care, face masks, hair conditioner, mascara, nail varnish, skin cleansing products, hair styling products.	There is little information in the scientific literature on this material, both for the nanoparticulate and the larger form. Therefore, the same safety concerns apply as described under "Silicon dioxide".
Sodium propoxy-hydroxypropyl thiosulfate silica	Other function	Nail care products, nail hardener.	There is little information in the scientific literature on this material, both for the nanoparticulate and the larger form. Therefore, the same safety concerns apply as described under "Silicon dioxide". Because of the surface modification, absorption into the body and systemic availability may be higher, resulting in a higher health risk.
Sodium magnesium fluorosilicate	Abrasive, absorptive, superplasticiser, opacifier	Body and face care, eye contour products, make-up, skin cleansing products, pre- and after-shaving products	Soluble; in the larger form it has no or low toxicity. The safety of the nanoform has not yet been evaluated by the SCCS.
Sodium magnesium silicate	Binder, filler, superplasticiser	Body, face, and hand care, eye contour products, nail varnish.	Soluble; in the larger form it has no or low toxicity. The safety of the nanoform has not yet been evaluated by the SCCS.
Zinc oxide	Dye, UV filter	Bath and shower products, sun protection, concealer, eye shadow, eye contour products, face, hand, foot, and lip care, lipstick, skin cleansing products, depilatories, scalp care, skin lightening products, antiperspirant	ZnO is an insoluble material that releases ions that are not problematic at low concentrations because zinc performs biological functions in the body. The material has already received a positive SCCS opinion for its use as UV filter because it cannot penetrate the skin. The evaluation of ZnO nanoparticles with different surface modifications has not yet been completed.

Review of the EU Cosmetics Regulation

Technical and scientific progress and the associated latest findings make a review of the EU Cosmetics Regulation just as necessary as does the practical experience gained in recent years since its implementation.¹³ As has been demonstrated and outlined above, the approach to the **safety assessment** of nanomaterials in cosmetic products, which has so far been carried out by the SCCS primarily based on the information and data provided during notification, is proving problematic and in need of reform.

However, the **notification procedure** according to Article 16 of the EU Cosmetics Regulation also showed weaknesses and a need for improvement in practice, because it is not the nanomaterials themselves that have to be notified, but the individual cosmetic products. This means that one and the same nanomaterial is often notified in many different products, and the Commission as well as the SCCS have to review a large number of notifications, all containing similar or the same information. This process is complex and must be completed in a relatively short period of six months. The situation is also not ideal for the companies submitting the notification, because if a safety assessment has not yet been completed and a cosmetic product is nevertheless allowed to continue to be on the market, this does not mean that a nanomaterial could not still be regulated at a later date.¹³ Unlike the authorisation procedures for UV filters, preservatives or colourants, companies therefore face uncertainty whether a nanomaterial that does not fall into one of the three categories may also be used in the long term.

The differences between the **definition** of the term “nanomaterial” in the EU Cosmetics Regulation and the corresponding Commission Recommendation (see above) lead to certain discrepancies between the different sectors regarding the classification of materials as nanomaterials.¹³ The EU Cosmetics Regulation only contains a reference to particle size of 1-100nm but no threshold for the number size distribution of particles. In the Commission’s definition proposal, a material is considered a nanomaterial if at least 50% of the particles in the number size distribution have one or more external dimensions in the range of 1-100nm. This could mean that if even one particle in a cosmetic ingredient is nanosized, it would be classified as a nanomaterial. This fact is also addressed in the SCCS guidelines for the safety assessment¹⁴ of nanomaterials in cosmetics where the threshold in the Commission proposal is recognised, even though it is not part of the definition in the EU Cosmetics Regulation. The definition of the term “nanomaterial” in the EU Chemicals Regulation REACH follows the Commission’s proposal. This means that according to REACH, some materials are considered nanomaterials, but not according to the EU Cosmetics Regulation. Following the adaptation of the REACH regulation¹⁶ to take account of nanofoms of substances, it can be expected that new data on the safety of nanomaterials will soon be provided by REACH registrants and that this information could also be used for the safety assessment of specific nanomaterials used in cosmetic products. Thus, it would be beneficial if the same definition were to be used in both regulatory provisions.¹³ Another difference between the definition in the EU Cosmetics Regulation and the Commission proposal is that the former includes only “intentionally manufactured” nanomaterials. However, determining whether a material is “intentionally” manufactured based on analytical test methods remains chal-

lenging. “Intent” cannot be reduced to an objective and measurable fact.¹³ This terminology in the EU Cosmetics Regulation will also need to be reviewed. A future update and alignment of the nanomaterials definition in the EU Cosmetics Regulation to that of the Commission proposal would be desirable in any case, but this would have to be assessed in advance in order to be able to evaluate possible effects.¹³

Another point of discussion is currently the form of **labelling** of nanomaterials in cosmetic products. A study conducted in 2020 has shown how important it is for EU citizens to be informed when buying a product as to whether it contains nanomaterials, with nine out of ten respondents confirming this.¹⁷ The labelling of nanomaterials in cosmetic products is essential for consumers to be able to make an informed purchasing decision. Yet how this labelling is done could be adapted to technical progress. For example, a digital list of ingredients in the form of an “electronic label” could be introduced, which could also provide information about any nanomaterials in the product.

Notes and references

- Oliveira C., Coelho C., Teixeira, J.A., Ferreira-Santos P. & Botelho C.M. (2022): Nanocarriers as Active Ingredients Enhancers in the Cosmetic Industry—The European and North America Regulation Challenges. *Molecules* 2022, 27, 1669. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8911847/pdf/molecules-27-01669.pdf>.
- Scientific Committee on Consumer Safety (SCCS) (2021): Scientific Advice on the safety of nanomaterials in cosmetics. SCCS/1618/20. https://health.ec.europa.eu/system/files/2022-08/sccs_o_239.pdf.
- Greßler S., Gazsó A., Simkó M., Fiedeler U. & Nentwich M. (2010): Nanotechnology in Cosmetics. NanoTrust Dossier No. 008en, December 2010. <http://epub.oew.ac.at/ita/nanotrust-dossiers/dossier008en.pdf>.
- European Parliament (2009): Report on regulatory aspects of nanomaterials (2008/2208(INI)). A6-0255/2009. https://www.europarl.europa.eu/doceo/document/A-6-2009-0255_EN.pdf.
- European Commission (2011): Commission recommendation (2011/696/EU) of 18. October 2011 on the definition of nanomaterial. (OJ L 275 of 20.10.2011. Official Journal of the European Union L 275/38. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0696>.
- Greßler S. & Gazsó A. (2013): Definition of the term “nanomaterial”. NanoTrust Dossier No. 039en, May 2013. <http://epub.oew.ac.at/ita/nanotrust-dossiers/dossier039en.pdf>.
- European Commission (2022): Commission Recommendation of 10 June 2022 on the definition of nanomaterial (2022/C 229/01). Official Journal of the European Union C 229/1. [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022H0614\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022H0614(01)).

Conclusion

The regulatory measures for nanomaterials in cosmetic products in the EU, which were introduced in 2009 with the amendment of the relevant regulation, have brought about improvements by introducing mandatory labelling for consumers. The obligatory notification of products containing nanomaterials provides an overview of the market situation and the nanomaterials used in cosmetics, which also requires data and information to be submitted to the Commission for a safety assessment. However, practice in recent years has shown that the documentation submitted by registrants is often deficient and incomplete, so that in many cases a final risk assessment of nanomaterials in cosmetic products is not possible. There is a need for improvement here. This also applies to some of the regulation’s other provisions and terminology, such as the notification procedure itself, the definition of the term “nanomaterial” or the way of labelling, which are currently subject to review and will lead to an update and adaptation of the EU Cosmetics Regulation in the future.

- ⁸ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (OJ L 342, 22.12.2009, p. 59). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1223-20221217&from=EN>.
- ⁹ European Commission (2020): Commission Regulation (EU) 2020/2081 of 14 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up. Official Journal of the European Union L 423/6. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R2081&from=EN>.
- ¹⁰ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers. Official Journal of the European Union L 304/18 of 22.11.2011. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169&from=EN>.
- ¹¹ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. Official Journal of the European Union L 167/1 of 27.06.2012. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528>.
- ¹² European Commission (2019): Catalogue of nanomaterials in cosmetic products placed on the market, as notified to the European Commission by Responsible Persons. Version 2: 31.12.2018. <https://ec.europa.eu/docsroom/documents/38284/attachments/1/translations/en/renditions/native>.
- ¹³ European Commission (2021): 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. COM(2021) 403 final. 22.07.2021. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0403&from=EN>.
- ¹⁴ Scientific Committee on Consumer Safety (SCCS) (2019): Guidance on the Safety Assessment of Nanomaterials in Cosmetics. October 2019. https://health.ec.europa.eu/system/files/2020-10/sccs_o_233_0.pdf.
- ¹⁵ Scientific Committee on Consumer Safety (SCCS) (2021): Scientific Advice on the safety of nanomaterials in cosmetics. SCCS/1618/20. Corrigendum of 8 March 2021. https://health.ec.europa.eu/system/files/2022-08/sccs_o_239.pdf.
- ¹⁶ European Commission (2018): Commission Regulation (EU) 2018/1881 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. Official Journal of the European Union L 308/1. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1881>.
- ¹⁷ Tengler M., Hamanová J., Novotný T., Popelková S., Holomek J., Kováčová V., Oliva F., Trávníčková J., Bašič D. & Dibusz K. (2020): Understanding public perception of nanomaterials and their safety in the EU. Final Report. European Chemicals Agency (ECHA). November 2020. https://euon.echa.europa.eu/documents/2435000/3268573/nano_perception_study_en.pdf.

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