Memo on the Regulation of Nanoplastics: REACH and the Cosmetics Regulation

Heidi Kaarto
Hanna Leisti

Supervision
Esther Kentin, project leader LAPP

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Abstract
In recent years, concerns have been raised as regards the presence of nanoplastics in cosmetic products and their possible health and environmental impacts. The purpose of this memorandum is to present the current state of regulation of nanoplastics at the European Union level. Due to the lack of references on 'nanoplastics' in the legislation, the focus will be on nanomaterials in general. Firstly, the Union strategy on plastics in general is introduced. Secondly, the current stage of the regulation of nanomaterials in REACH will be discussed and analysed. Finally, this paper will look at the Cosmetics Regulation. The important concepts will be introduced after which the requirements in relation to nanomaterials are presented. Additionally, the process by which the European Commission prohibits substances is examined. This paper will end with an analysis of the effectiveness of the current regulation of nanomaterials.

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Introduction

In the past few years, research has revealed the implications of nanometre-sized plastic particles, 'nanoplastics' on the environment.[1] Nanoplastics are added to various cosmetic and personal care products (hereinafter cosmetic products), such as skin creams, sun protection products, eye make-up, shampoo and shower products.[2] Concerns have been raised regarding the lack of regulations on the use of nanoparticles in cosmetic products in Europe.[3] This memorandum concerns regulation of nanoplastics at the European Union level. The purpose is to track down whether and how nanoplastics are regulated in the European Union internal market. The focus of this paper is on the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH),[4] Regulation on the Classification, Labelling and Packaging (CLP)[5] and on the Regulation on Cosmetic Products (Cosmetics Regulation).[6] However, due to the lack of references to nanoplastics in these regulations, this paper has analysed the regulation of nanomaterials in general.

Firstly, the Union strategy on plastics in general is introduced. Secondly, the current stage of the regulation of nanomaterials will be discussed and analysed. Finally, this paper will look at the Cosmetics Regulation. The relevant concepts will be introduced after which the requirements in relation to nanomaterials are presented. Additionally, the process by which the European Commission prohibits substances is examined. This paper will end with an analysis of the effectiveness of the current regulation of nanomaterials.

1. The Relationship between REACH and Cosmetics Regulation

The aim of REACH is to improve the protection of human health and the environment through registration, evaluation, authorization and restriction of chemicals.[7] It places responsibility

[1] Albert A. Koelmans, Ellen Besseling, Won J. Shim, 'Chapter 12 Nanoplastics in the Aquatic Environment. Critical Review' Publisher: Springer, Eds. Bergmann M, Gutow L, Klages M. Marine Anthropogenic Litter 325-340, 325.
[2] Catalogue of nanomaterials used in cosmetic products placed on the market <http://ec.europa.eu/docsroom/documents/24521> accessed on 16.3.2018.
[3] S. F. Hansen, A. Baun, 'European Regulation Affecting Nanomaterials – Review of Limitations and Future Recommendations' [@012] Dose-Response 10, dose-response 1.
[4] 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 (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC, and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EEC and 2000/21/EC. OJ L 396/1, 30.12.2006.
[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (1). OJ L353/1, 31 December 2008.
[6] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59.
[7] Article 1 REACH.

on industry to deal with risks caused by chemicals and to provide information on the substances. To this end, REACH requires manufacturers and importers to gather information on the properties of chemical substances and to register the information in a central database of European Chemicals Agency (ECHA). Thus, the manufacture or sale of any substances[8] on their own, or in preparations[9] or articles[10] in the European Union that has not been registered with the ECHA is prohibited.[11] However, there are quite some exemptions on the obligation to register.[12] The group of polymers is one of them, and therefore the registration of nanoplastics as a polymer substance is not required.

The Cosmetics Regulation creates a separate legal framework for cosmetic products. Substances prohibited and restricted in the Cosmetics Regulation are not necessarily restricted in REACH.[13] This is because REACH does not apply to the use of substances in cosmetic products with regard to restrictions that address the risks to human health.[14] Those risks are assessed by the Cosmetics Regulation.[15] On the other hand, environmental risks of cosmetics products are dealt with within REACH.[16]

2. Plastics in General

2.1. A European Strategy for Plastics in a Circular Economy

In December 2015, the European Commission presented an action plan for the circular economy in which plastics were identified as a priority.[17] As part of the action plan, the European Commission published on 16 January 2018 the long-awaited European Strategy for Plastics in a Circular Economy, the EU Plastics Strategy, the aim of which is to protect the environment from plastic

[8] 'Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition' (Article 3(1) REACH).
[9] 'Preparation: means a mixture or solution composed of two or more substances' (Article 3(2) REACH)
[10] 'Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition' (Article 3(3) REACH).
[11] Article 5 REACH (entitled 'No data, no market'), which states 'Subject to Articles 6, 7, 21 and 23, substances on their own or in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.'
[12]
[13] Recital 13 REACH.
[14] Article 1(1) REACH.
[15] Recital 3 of the Cosmetics Regulation.
[16] Recital 5 of the Cosmetics Regulation.
[17] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Closing the loop – An EU action plan for the Circular Economy. COM(2015) 614 final. Brussels, 2.12.2015.

pollution while, at the same time, fostering growth and innovation.[18] Its object is to address the whole plastics supply chain from design to usage and to make the business case for plastic recycling. In addition, the European Commission will explore fiscal and legislative measures to achieve these aims, including the target that all plastic packaging on the EU market will be recyclable by 2020.[19]

The EU Plastics Strategy calls for efforts and greater cooperation by all key players including plastic producers, recyclers, retailers and consumers.[20] The strategy mostly relies on voluntary industry commitments, for example, to increase the use of recycled plastics. Additionally, it includes actions to address microplastics, such as the proposal for the restriction of the intentional use of microplastics and reducing plastic pellet spillage.[21] The European Agency for Chemaical Substances (ECHA) under REACH has been requested to prepare a dossier on the restriction of microplastics.[22] The strategy does not mention nanoplastics specifically, or any particular plans regarding nanoplastics.

The EU Plastic Strategy has been positively received by the industry, which has expressed its support for improved extended producer responsibility and the goal of ensuring that all plastic packaging is recyclable by 2030.[23] On the other hand, the strategy has been criticized, in particular, for the lack of mandatory requirements. For example, the Swedish environmental minister Karolina Skog pointed to the lack of concrete action and concrete legislative measures.[24] The effectiveness of the EU Plastic Strategy in tackling the problem of plastic pollution will depend on action on the part of the Commission and the member states to implement the proposals.[25]

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[18] European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A European Strategy for Plastics in a Circular Economy' COM(2018) 28 final, 1.
[19] Ibid 5.
[20] Ibid 17.
[21] Ibid 13.
[22] European Commission, Note for the Attention of Mr. G. Dancet, Executive Director, ECHA, 'Request to the European Chemicals Agency to prepare a restriction proposal conforming to the requirements of Annex XV to REACH, Ref. Ares(2017)5463573 – 09/11/2017.
[23] Rob Cole, 'EU Plastics Strategy focus on EPR and recycling targets welcomed by industry' (Resource, 18 January 2018) < https://resource.co/article/eu-plastics-strategy-focus-epr-and-recycling-targets-welcomed-industry-12358> Accessed on 25.1.2018.
[24] Irene Banos Ruiz, 'Not enough action from EU on plastic' (DW, 17 January 2018) < http://www.dw.com/en/not-enough-action-from-eu-on-plastic/a-42178451> Accessed on 25.1.2018.
[25] 'EU Plastics Strategy positive but requires implementation'(IUCN, 16 January 2018) <https://www.iucn.org/news/europe/201801/eu-plastics-strategy-positive-requires-implementation> accessed on 24.1.2018.

3. Nanomaterials

3.1. REACH and CLP Regulation

Transparency and traceability of nanomaterials on the internal market can be provided by labelling of products containing nanomaterials and by gathering information in a register or inventory.[26] The European Commission has identified REACH and CLP as the most relevant legal framework for nanomaterials.[27] In both REACH and CLP, there are no explicit requirements for nanomaterials. However, the European Commission and the Member States and Competent Authorities (MSCAs) have taken the stance that nanomaterials meet the regulations' definition on 'substance' and, therefore, the provisions of the regulations are applicable to nanomaterials. Whether a nanomaterial is hazardous is to be determined as part of a risk assessment.[28] Nanomaterials fulfilling the criteria for classification as hazardous under CLP are to be classified and labelled.[29]

What comes to the definition of 'nanomaterial', the Commission released, in 2011, a specific recommendation on the definition of a nanomaterial.[30] That recommendation is to be used in different European regulations, including REACH, Cosmetics Regulation and CLP.[31] However, because of the non-binding nature of the recommendation, there is no mandatory definition for the term 'nanomaterial' at place. Additionally, the Commission has prepared with the Competent Authorities for REACH and CLP guidelines on how to manage nanomaterials in accordance with REACH and CLP.[32] Finally, research has been ongoing for almost a decade relating to methodologies for assessing risks associated with nanomaterials.[33]

To be legally manufactured or imported in the EU, all substances within the scope of REACH, including nanomaterials, must be registered. Depending on the volume placed on the market, manufacturers and/or importers, as part of their registration, are to submit information on both human health and environmental effects, and hazardous nanomaterials. When substances have

[26] Aschberger K et al, 'Considerations on Information Needs for Nanomaterials in Consumer Products: Discussion of a Labelling and Reporting Scheme for Nanomaterials in Consumer Products in the EU' JRC Science and Policy Reports April 2014 51.
[27] European Commission, 'Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Second Regulatory Review on Nanomaterials', COM(2012)572 final, < http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0572&from=EN>.
[28] European Commission, 'Questions and Answers on the Commission Recommendation on the definition of Nanomaterial' (Environment, 8 June 2016) <http://ec.europa.eu/environment/chemicals/nanotech/faq/questions_answers_en.htm> (14.11.2017).
[29] European Commission, 'Nanomaterials' (Growth. Internal Market, Industry, Entrepreneurship and SMEs, 14 November 2017) <https://ec.europa.eu/growth/sectors/chemicals/reach/nanomaterials_en> (14.11.2017).
[30] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, OJ L 275/38.
[31] European Commission (n 24).
[32] European Commission, 'CARACAL Subgroup on Nanomaterials' (Environment, 8 June 2016) <http://ec.europa.eu/environment/chemicals/nanotech/reach-clp/caracal_en.htm> (14.11.2017).
[33] European Commission, 'Environment: RIPoN' < http://ec.europa.eu/environment/chemicals/nanotech/reach-clp/ripon_en.htm> accessed on 16.3.2018.

hazardous properties, CLP requires them to be notified to ECHA and be labelled and packaged so that the substances can be used safely. Companies are required to be transparent in their REACH registration to clearly indicate how the safety of nanomaterials has been addressed.[34]

Together with the member states, ECHA conducts two different evaluation processes under REACH, namely dossier and substance evaluation. Under dossier evaluation, ECHA carries out compliance checks for registration dossiers. The purpose is to verify that all the information requirements have been fulfilled. If they are not, ECHA can ask for further information or testing. The aim of the substance evaluation is, in turn, to clarify whether a substance poses a risk to human health or the environment. To verify concern, ECHA can request further information or testing. The substances subject to the substance evaluation are listed in the Community rolling action plan.[35]

In the event of non-compliance, Member States are to sanction the non-compliance with effective, proportionate and dissuasive penalties.[36] According to the Report on Penalties Applicable for Infringement of the Provisions of the REACH Regulation in the Member States, the level of penalties and the methods of enforcement differ from one country to another.[37] Member states have included fines in their penalty systems that vary, in general, between 50,000 and 1 million Euros.[38] Some countries have adopted lower fines, while others have adopted much higher ones.[39] These variations demonstrate a lack of consistency as to the level of penalty.[40] Other types of penalties include injunctions, prison sentences and name-and-shame methods.[41] The report concludes that the monitoring of REACH is still at its early stages. It seems that the principle of dissuasiveness is not respected due to the lack of adaptation of the amount of fine to the peculiarities of the REACH system of tonnages.[42]

3.2. The proposed regulation for the revision of REACH Annexes - Evaluation

Due to the absence of explicit references to nanomaterials in REACH, the Commission has launched the process of revision of the Annexes of REACH for the registration of nanomaterials. It has proposed an amendment to REACH, which adds obligations for risk assessment of the

[34] European Union Observatory for Nanomaterials, 'Regulation' <https://euon.echa.europa.eu/regulation> (8.12.2017)
[35] Ibid.
[36] Article 126 REACH
[37] Directorate General Environment, 'Report on Penalties Applicable for Infringement of the Provisions of the REACH Regulation in the Member States' March 2010, 69.
[38] Ibid 69.
[39] Ibid 69.
[40] Ibid 69.
[41] Ibid 3.
[42] Ibid 69.

nanoforms of the substance[43]. The Commission has identified that 'nanoforms may have specific toxicological profiles and exposure patterns and may therefore require specific risk assessment and adequate sets of risk management measures'.[44] The purpose of the amendment is to set additional legal requirements for chemical safety assessment when registering nanoforms of substances under REACH and to improve ECHA's ability to implement REACH for nanomaterials by making it more effective.[45] The draft regulation lays down the specific registration duties and obligations on manufacturers, importers and downstream users to generate data on substances they manufacture, import or use to assess the risks related to these substances and to develop and recommend appropriate risk management measures.[46] The new registration requirements are planned to come into effect in 2020.

The proposed regulation amending the Annexes of REACH has received a lot of feedback through the public consultation procedure. It has been praised for bringing more clarity and legal certainty for nanomaterials' registrants and their downstream users[47] and it is seen as 'a step in the direction for achieving a greater legitimacy for nanotechnology'.[48] However, there are also major critical notes to place. Due to the enormous delays that have took place since the beginning of the revision in 2011, the specific requirements on nanomaterials are not going to be available for the last REACH Registration deadline taking place in 2018. This registration deadline applies for registering phase-in substances[49] manufactured or imported at 1 to 1000 tonnes a year. The result is that at this moment nanomaterials are free to enter the market without the possibility of ECHA's

[43] Commission Regulation (EU) …/… of XXX 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. Ref. Ares(2017)4925011-09/10/2017.
[44] Ibid, Recital 5.
[45] European Union Observatory for Nanomaterials, 'Public consultation – amendments of the Annexes to REACH for registration of nanomaterials' <https://euon.echa.europa.eu/view-article/-/journal_content/title/public-consultation-amendments-of-the-annexes-to-reach-for-registration-of-nanomaterials> (14.11.2017).
[46] Commission Regulation (EU) …/… of XXX 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. Ref. Ares(2017)4925011-09/10/2017.
[47] Carolin Kranz, 'BASF Comment on Commission Regulation (EU) of XXX amending Regulation (EC) No 1907/2006 (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI and XII to address nanoforms of substances. 6 November 2017' (Policies, information and services, 6 November 2017) <https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011/feedback/F7542_en> (14.11.2017).
[48] Asalie Hartmanis, 'Feedback from SwedNanoTech' (Policies, information and services, 6 November 2017) <https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011/feedback/F7538_en> (14.11.2017).
[49] Phase-in substance denotes to substance that was already manufactured or placed on the market before REACH entered into force. Substances that fulfil at least one of the following criteria may be considered as phase-in substances in accordance with REACH: substances listed in the European Inventory of Existing Commercial Chemical Substances; substances that have been manufactured in the EU (including the countries that joined on 1 January 2007) but have not been placed on the EU market after 1 June 1993; and substances that qualify as 'no-longer polymer'.

assessment of their safety in light of adequate data.[50] Moreover, at present, REACH includes no definition of the term 'nanomaterial'. The importance of having a finalized definition of the concept of 'nanomaterial' has been raised and it is noted that the amendment of REACH should be only a subsequent step.[51] The uncertainty relating to the definition of a 'nanomaterial' increases the overall uncertainty as regards the process and is liable to constitute a significant barrier to achieving compliance by 2020.[52] If the review and potential revision of the definition of 'nanomaterial' laid down by the Commission Recommendation would have been finalized before amending REACH, this could have been prevented. Finally, the proposed regulation has also been criticized for the use of vague notions such as 'where relevant'[53] and for its technical deficits.[54]

All in all, from 2020, both for new and existing substances additional requirements for nanoforms are included in the safety assessment provisions of REACH. Due to the delayed proposal, these requirements do not have to be included in the registration dossier of existing substances in the latest phase of registration of substances 1 to 1000 tonnes a year. No specific and mandatory definition of the term 'nanomaterials' or measurement method for 'nanomaterials' has been adopted yet,[55] so it remains to be seen how manufacturers will include nanoforms into their registration of substances. A further uncertainty is the exemption of registration of polymers. The amendments do not consider any, in general, exempted substances, so without further regulation it seems that nanoforms of plastics are not included.

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[50] Tatiana Santos, 'EEB Comments on the Draft Regulation – Amendments of the Annexes to REACH for Registration of Nanomaterials' (Policies, information and services, 6 November 2017) <https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011/feedback/F7548_en> (14.11.2017).

[51] Angelika Hartl, 'Feedback from Eckart GmbH. 6 November 2017' (Policies, information and services, 6 November 2017) <https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011/feedback/F7535_en> (14.11.2017); Nathalie Kinga Kowalski, 'Feedback from Eurometaux' (Policies, information and services, 3 November 2017) <https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011/feedback/F7508_en> (14.11.2017).

[52] Jay West, 'Feedback from American Chemistry Council' (Policies, information and services, 6 November 2017) <https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011/feedback/F7551_en> (14.11.2017).

[53] Santos (n 43).

[54] See, for example, Valérie Xhonneux, 'Feedback from Inter-Environnement Wallonie' (Policies, information and services, 6 November 2017) <https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011/feedback/F7534_en> (14.11.2017).

[55] Shinya Sasaki, 'Feedback from Japan Business Counsil in Europe' (Policies, information and services, 6 November 2017) <https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011/feedback/F7531_en> (14.11.2017); Jan van der Meulen, 'Feedback from European Council of the Paint, Printing Ink and Artists' Colours Industry' (Policies, information and services, 6 November 2017) <https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011/feedback/F7524_en> (14.11.2017).

3.3. The European Union Observatory for Nanomaterials

At this moment, the European Commission has decided not to establish a mandatory registry for nanomaterials[56] but to first set up, on the basis of a delegation agreement between the ECHA and the European Commission, the European Union Observatory for Nanomaterials (EUON).[57] The EUON is part of the measures that were announced in the Second Regulatory Review on Nanomaterials intended to improve their regulation. It will be implemented in a stepwise approach and will integrate and expand the existing Commission information sources on nanomaterials. On 14 June 2017, ECHA launched the first version of the EUON.[58]

The objective of the EUON is to make available information on nanomaterials, their safety and related research activities. It also aggregates, interprets and evaluates data and communicates the results to decision-makers, public and authorities in an easily understandable manner. Thereby, the focus is on nanomaterials that are already present in the Union market.[59]

The creation of the EUON is very welcome considering that a lot of concerns were expressed by the policy makers and stakeholders concerning the lack of information on nanomaterials in the Union market, on articles sold to consumers and in workplaces which, in turn, renders effective risk assessment, management and enforcement of nanomaterials more difficult.[60] A recent overview conduced on the EUON notes that it is dependent to a large extent on information that is already available from other resources, such as REACH.[61] For this reason, ECHA has published guidance documents aiming to aid registrants to prepare REACH dossiers covering nano forms. Nevertheless, these documents are of limited legal power as long as nano-specific requirements are not covered by REACH Annexes.[62] Moreover, the aforementioned lack of a horizontal regulatory definition of nanomaterials has resulted in different definitions in the different sources the EUON uses (such as in cosmetics and food regulations) which, in turn, hampers comparisons of the available data.[63] Overall, it is expected that consumers will find it

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[56] NanoSafetyCluster, 'A Critical Overview at the European Union Observatory for Nanomaterials' (News and Events, 11 December 2017) https://www.nanosafetycluster.eu/news/245/66/A-critical-view-at-the-European-Union-Observatory-for-Nanomaterials.html (12.12.2017).
[57] Delegation Agreement on the European Union Observatory for Nanomaterials and the European Union Chemical Legislation Finder (hereinafter: the Delegation Agreement).
[58] European Commission, 'Nanomaterials' (Sectors, last update 12 December 2017) <http://ec.europa.eu/growth/sectors/chemicals/reach/nanomaterials_en> (12.12.2017).
[59] The Delegation Agreement (n 56).
[60] European Commission (n 57).
[61] National Institute for Public Health and the Environment. The European Union Observatory for Nanomaterials – A Step Forward? November 2017. Accessed on < http://www.rivm.nl/dsresource?objectid=72410ea8-7d00-4b72-91d5-c1ff4a78c34f&type=pdf&disposition=inline> (12.12.2017) 15.
[62] Ibid.
[63] Ibid.

difficult to detect whether they are using a 'nanoproduct' and what are the potential health risks.[64] The conclusion of the analysis is that the EUON web portal is, therefore, most relevant for expert, industry and competent authorities rather than for consumers.[65] Finally, the overview supports the conclusion that urgent action is required so that a binding definition on 'nanomaterial' will be made available and the REACH Annexes revised. Without these, the EUON will only emphasize the possible uncertainties related to the safety of nanomaterials rather than minimize them, for instance, by indicating lack of details in the information that aims to improve transparency.[66]

Meanwhile, member states have started to introduce their own regulations for nanomaterials that require companies to notify nanomaterials or products containing them to their national products register or nano register.[67] First of these schemes was launched by France in 2013.[68] Most recently, the Swedish Chemicals Agency (KEMI) announced on 5 December 2017 that it has introduced the requirement for manufacturers and importers to provide information on nanomaterials contained in chemical products. The requirement came into effect on January 1, 2018, and the first reports will be due in February 2019.[69] Without doubt, these diverging nanoregistries will increase fragmentation of the Union internal market. Therefore, the question arises whether the European Commission should reconsider the introduction of a Union wide registry for nanomaterials.

3.4. Prospects

In the beginning of 2018, ECHA's Management Board noted the urgent need for explicit requirements in the legal texts for nanomaterials. ECHA is going to increase its collaboration with the member states to amend OECD Test Guidelines to ensure that they will generate reliable and relevant data also for nanomaterials. These actions together with the proposed revision of technical information requirements in REACH Annexes specifically for nanomaterials will be published as updates in the ECHA's guidance documents for nanomaterials. In parallel, the recommendation for

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[64] Ibid.
[65] NanoSafetyCluster (n 55).
[66] National Institute for Public Health and the Environment (n 60) 15.
[67] 'Regulations on Nanomaterials in EU and Nano Register 2016' (LittlePro, 2 September 2018) <http://www.chemsafetypro.com/Topics/EU/Regulations_on_Nanomaterials_in_EU_and_Nano_Register.html> Accessed on 10.2.2018.
[68] More information about the national nanomaterial schemes can be found from 'Repoting Schemes for Nanomaterials' (SafeNano)< http://www.safenano.org/knowledgebase/regulation/substances/reporting-schemes-for-nanomaterials/>accessed on 23.2.2018.
[69] Lynn L. Bergeson, Carla N. Hutton, 'Sweden Announces Product Registration Requirement for Nanomaterials' (Nano and Other Emerging Chemical Technologies Blog, 7 December 2017) < https://nanotech.lawbc.com/2017/12/sweden-announces-product-registration-requirement-for-nanomaterials/> Accessed on 10.2.2018.

a definition of a nanomaterial is also being reviewed. Provided that these changes are conducted successfully, it will clarify the identification of nanomaterials under legal frameworks.[70]

4. The Cosmetics Regulation

The Cosmetics Regulation states that cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, risk-benefit reasoning should not justify a risk to human health.[71] For environmental concerns, the Regulation refers to REACH.[72] Article 16 of the Cosmetics Regulation is specifically dedicated to the safety of nanomaterials. The Article states that high level of human health must be ensured, therefore additional information on nanomaterials should be provided when entering the market. In addition, the Cosmetics Regulation presents special procedures to respond on safety concerns. In order to assess safety of nanomaterials the SCCS (Scientific Committee on Consumer Safety) should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials.[73] And based on the test results, the SCCS should give opinions on the safety of use of nanomaterials in cosmetic products. If potential risk to human health occurs, the Commission may restrict or prohibit the nanomaterial in cosmetic products.[74]

The Cosmetics Regulation notes that transparency is needed regarding the ingredients used in cosmetic products.[75] Such transparency should be achieved by indication of the ingredients used in a cosmetic product on its packaging. Where for practical reasons it is impossible to indicate the ingredients on the packaging, such information should be enclosed so that the consumer has access to this information.[76] The Cosmetic Regulation also recognises that the use of nanomaterials in cosmetic products may increase in the future and that a uniform definition for nanomaterials at international level is needed, thus the definition of nanomaterials in this Regulation should be adapted accordingly.[77]

[70] European Chemicals Agency, 'ECHA strategy on substances in nanoforms' MB/57/2017 final.
[71] Recital 9 of the Cosmetics Regulation.
[72] Recital 5 of the Cosmetics Regulation.
[73] Recital 30 of the Cosmetics Regulation.
[74] Article 16(6) of the Cosmetics Regulation.
[75] Recital 46 of the Cosmetics Regulation.
[76] Recital 46 of the Cosmetics Regulation.
[77] Recital 29 of the Cosmetics Regulation.

4.1. Key concepts of the Cosmetics Regulation

4.1.1. Responsible Person

The Cosmetics Regulation states that all cosmetic products must have a responsible person. The responsible person shall ensure compliance with the relevant obligations set out in the regulation. There are four different scenarios defining the responsible person.[78] First, for a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer established within the Community shall be the responsible person. Secondly, where, the manufacturer is established outside the Community, but a cosmetic product is manufactured within the Community and not subsequently exported and imported back into the Community, the manufacturer shall designate a person established within the Community as the responsible person. Thirdly, for an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market. Fourthly, the distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected. In addition, the manufacturer or the distributor may designate, by written mandate, a person estab-lished within the Community as the responsible person who shall accept in writing.

Responsible persons shall ensure compliance with Articles, inter alia, on good manufacturing practice, safety assessment (see safety assessment below), product information file, sampling and analysis, notification to the Commission, making sure that products do not contain restricted substances (in the Annexes), making sure that products do not contain prohibited substances (certain exceptions), compliance with Article 16 on nanomaterials, access to information for the public.[79] The responsible person has an obligation to take necessary corrective measures if a product is not in conformity with the Cosmetics Regulation.[80]

4.1.2. Safety assessment

The cosmetic product must comply with safety requirements set in the regulation. The responsible person must ensure that the cosmetic product has undergone a safety assessment, and the safety report is set up in accordance with the minimum requirements, see below. Further, the responsible person must ensure that the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety

[78] Article 4 of the Cosmetics Regulation.
[79] Article 7(1) of the Cosmetics Regulation.
[80] Article 5 of the Cosmetics Regulation.

assessment and that an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources. In addition, the responsible person must ensure that the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.[81]

According to Annex I, a cosmetic safety report should include, as a minimum, the following items:

Part A – Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product;
2. Physical/chemical characteristics and stability of the cosmetic product;
3. Microbiological quality;
4. Impurities, traces, information about the packaging material;
5. Normal and reasonably foreseeable use;
6. Exposure to the cosmetic product;
7. Exposure to the substances
8. Toxicological profile of the substances;
9. Undesirable effects and serious undesirable effects;
10. Information on the cosmetic product.

Part B – Cosmetic product safety assessment

1. Assessment conclusion;
2. Labelled warnings and instructions of use;
3. Reasoning;
4. Assessor's credential and approval of part B.

4.1.3. Implementation

The Cosmetics Regulation imposes clear and detailed rules that do not give room for diverging transposition by member states. It ensures that the Regulation is implemented at the national level at the same time in all member states.[82] Member states are required to take all necessary steps to adopt legislation on penalties applicable for infringements of the Cosmetics Regulation. Those penalties should be effective, proportionate and dissuasive.[83]

[81] Annex I Cosmetic Product Safety Reports of the Cosmetics Regulation.
[82] Recital 2 of the Cosmetics Regulation.
[83] Article 37 of the Cosmetics Regulation.

4.2. Nanomaterials

Article 16 of the Cosmetics Regulation regulates the use of nanomaterials in cosmetic products. In addition to the general notification requirement contained in Article 13, Article 16 requires that 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, except where they have already been placed on the market by the same responsible person before 11 January 2013.[84]

According to Article 16(3) of the Cosmetics Regulation, the information notified to the Commission shall contain at least the following:[85]

(a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI;

(b) the specification of the nanomaterial including size of particles, physical and chemical properties;

(c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;

(d) the toxicological profile of the nanomaterial;

(e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;

(f) the reasonably foreseeable exposure conditions.

The provisions of the Article 16 of the Cosmetics Regulation do not apply to nanomaterials used as colorants, UV-filters or preservatives regulated under Article 14.[86] These substances are already restricted by the Annexes II to VI. Nanomaterials can be restricted on initiative of the Commission, if there are safety concerns. Furthermore, Article 16 provides for a publicly available catalogue of all nanomaterials used in cosmetic products.[87] Article 16 concludes with the obligation for the Commission to review the regulation of nanomaterials in the light of scientific progress and stipulates the option of amendments. The first review is foreseen by 11 July 2018.[88]

4.2.1. The Procedure to Prohibit and Restrict Nanomaterials

According to Article 16(4), the Commission shall request the SCCS to give its opinion on the safety of a nanomaterial, if there are concerns regarding the safety.[89] The SCCS shall deliver its opinion

[84] Article 16(3) of the Cosmetics Regulation.
[85] Article 16(3) of the Cosmetics Regulation.
[86] Article 16(2) of the Cosmetics Regulation.
[87] Article 16(10) of the Cosmetics Regulation.
[88] Article 16(11) of the Cosmetics Regulation.
[89] Article 16(4) of the Cosmetics Regulation.

within six months of the Commission's request. Stakeholders will be consulted for the completion of the scientific opinion. 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. The SCCS shall deliver its final opinion within six months of submission of additional data. The opinion of the SCCS shall be made publicly available.[90] 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 (List of substances prohibited in cosmetic products) and III (List of substances which cosmetic products must not contain except subject to the restrictions laid down).[91] This procedure does not prohibit the use of a substance in products when the review by the SCCS is ongoing. So far, four requests for a scientific opinion on nanomaterials in cosmetics products have been made.[92]

In 2015, the Commission expressed concern on the nano form of Styrene/Acrylates copolymer and Sodium styrene/Acrylates copolymer, both nanoplastics, and it called for relevant scientific information on the substances from manufacturers and other interested parties. The SCCS was requested to give its opinion on the safety of the nanoplastics when used in leave-on cosmetics products up to a concentration of 0.06% and to express 'any further scientific concerns'. In its report adopted in February 2018, the SCCS concluded that there was insufficient data to evaluate possible toxicity, and therefore no conclusion could be drawn on the safety of the nanoplastics in cosmetics products. The SCCS noted in its toxicological evaluation that for many toxicity aspects information was not provided. It stated that it is also 'imperative' that the safety assessment should consider 'the safety of all components when put together in the form of a nano-sized entity', information that was not provided by the manufacturers.[93] The next step in this procedure is a consultation phase of eight weeks in which applicants and other interested parties may give comments to provide additional perspective and/or clarification. After discussion of these comments, the SCCS will finalise its opinion. This opinion is the first opinion on a nanoplastic of the SCCS. Earlier opinions have addressed the safety of Titanium Dioxide (nano) as UV-filter in creams and sprays. Also in these opinions the SCCS stresses the insufficiency of information and knowledge gaps on nano forms, in particular with regard to exposure to lungs and penetration of the (compromised) skin.[94] At the moment, the use of Titanium dioxide, normal and nano form, in

[90] Ibid.
[91] Article 16(6) of the Cosmetics Regulation.
[92] SCCS Mandates, https://ec.europa.eu/health/scientific_committees/consumer_safety/requests_en.
[93] SCCS, Opinion on Styrene/Acrylates copolymer (nano) and Sodium styrene/Acrylates copolymer (nano), SCCS/1595/18 preliminary opinion, 23.
[94] SCCS, Opinion on Titanium Dioxide (nano form) as UV-Filter in sprays, SCCS/1583/17, 38;

cosmetic products is limited to 25%, with some additional requirements for the nano form,[95] and subsequent SCCS reports have not lead to further restrictions, despite or due to knowledge gaps.

After the SCCS has issued a final opinion and when the Commission decides that a restriction would be necessary, the next step would be the start of the amendment procedure. In this procedure, the Commission shall be assisted by the Standing Committee on Cosmetic Products (SCCP), which is composed of representatives of the Member States and chaired by the representative of the Commission.[96] The SCCP will decide by the double majority on whether the Commission may proceed with the amendment procedure.[97] The draft measure will be scrutinised by the European Parliament and the Council, however, the focus of the scrutiny will be on the procedural matters.[98]

An example of the cosmetics products meeting of the Standing Committee is provided for in the Annex of this report.

4.2.2. The Catalogue

Article 16(10) provides that the Commission should compile a catalogue which should include all nanomaterials used in cosmetic products placed on the market.[99] Although the first version was foreseen on 11 January 2014, the first catalogue was published only in June 2017.[100] The catalogue includes all nanomaterials, including those used as colorants, UV-filters and preservatives, and indicates the categories of cosmetic products and the reasonably foreseeable exposure conditions. The catalogue is based on information notified electronically by responsible persons to the European Commission, through the Cosmetic Products Notification Portal (CPNP).[101] The catalogue lists of every substance its category of cosmetic products, such as eye shadow and face mask, and its exposure (dermal, oral, inhalation).[102] It further explicates whether it is use in a rinse-

SCCS, Opinion on Titanium Dioxide (nano form) coated with Cetyl Phosphate, Manganese Dioxide or Triethoxycaprylylsilane as UV-filter in dermally applied cosmetic, SCCS/1580/16 final, 24.

[95] Commission Regulation (EU) 2016/1143 of 13 July 2016 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. OJ L 189, 14 July 2016.

[96] Article 5a(1) of Decision 1999/468/EC.

[97] European Commission, Meeting of the Standing Committee on Cosmetic Products 14 March 2017, 17-GROW-COS-COSCOM-03.

[98] Article 7 of Decision 1999/468/EC.

[99] Article 16(10)(a) of the Cosmetics Regulation.

[100] Catalogue of nanomaterials used in cosmetic products placed on the EU market, Version 1 (31.12.2016), published June 2017.

[101] The CPNP is a free of charge online notification system created for the implementation of Regulation (EC) No 1223/2009 on cosmetic products. Accessed on <http://ec.europa.eu/growth/sectors/cosmetics/cpnp/index_en.htm> (12.12.2017)

[102] Catalogue of nanomaterials used in cosmetic products placed on the EU market, Version 1 (31.12.2016), published June 2017.

off and/or leave-on product. At present, the catalogue lists 43 nano substances, among which one nanoplastic, styrene/acrylates copolymer.[103]

The European Commission explicitly notes that it does not take responsibility for the content and the scientific qualification of the notifications made in the CPNP.[104] The catalogue is a 'work in progress' subject to modification. It should be regularly updated and made publicly available.[105] In addition, it is stipulated that the catalogue has 'an informative value only and is not in any case a list of authorised nanomaterials.'[106]

On 14 March 2018 the European Ombudsman issued its recommendation on a request regarding the public access to the catalogue. The Ombudsman concluded that stakeholders should have access to any notifications that can be extracted from the database of notification even if an update of the catalogue is not published yet.[107]

Conclusion

Considering the objectives of the REACH that include the protection of the environment and human health, the current status of regulation of nanomaterials at the Union level is limited. At the moment, the most significant problem is that there are no explicit requirements for nanomaterials within REACH. Furthermore, there is a lack of knowledge of the impact of nanomaterials on human health and the environment. This constitutes a barrier to the effective risk assessment of the nanomaterials which, in turn, enables the entrance of nanomaterials to the Union market even if they are hazardous. Despite the fact that the use of nanomaterials increases with the further development of technology,[108] any action regarding restriction is slowed down by the lack of knowledge regarding the effects on human health and the environment. A revision of REACH introducing compulsory registration of nano forms of substances before introduction on the market could repair this deficiency. In the meantime, the Observatory provides only information on nano forms of substances on a voluntary basis, without any mandate for further action, and is therefore no serious alternative for regulation.

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[103] Ibid.
[104] Ibid 15.
[105] European Commission, Nanomaterials, Catalogue of nanomaterials <http://ec.europa.eu/growth/sectors/cosmetics/products/nanomaterials_en> accessed 12.11.2017.
[106] Ibid.
[107] European Ombudsman, Recommendation of the European Ombudsman in case 1336/2017/JAS on the European Commission's refusal to grant access to its catalogue of nanomaterials used in cosmetics, as well as to related notifications from cosmetics manufacturers, Case: 1336/2017/KT, 14 March 2018.
[108] Recital 29 of the Cosmetics Regulation; European Chemicals Agency, 'Nanomaterials' <https://echa.europa.eu/regulations/nanomaterials> accessed on 16.3.2018.

The Cosmetics Regulation requires notification of the use of nanomaterials in cosmetic products six months prior to being placed on the market. It provides the Commission with tools to prohibit nanomaterials, if they are harmful for the human health during normal and daily use. However, during the restriction procedure the use of nanomaterials in cosmetic products remains possible. Due to the lack of information and long procedures, products with nanomaterials may be introduced and remain on the European market during this time, till nanomaterials are banned via an amendment to the Cosmetics Regulation.

No specific regulation concerning nanoplastics exists. As polymers are exempted from registration under REACH, less information will be available on nano forms of polymers. However, nanoplastics in cosmetic products have to be notified according Article 16 of the Cosmetics Regulation and can be restricted for human health concerns. It is to be noted that the detection, quantification and characterization of nanoplastics is methodologically challenging which, in turn, limits the abilities to draw conclusions about their potential consequences.[109]

Due to the lack of knowledge and uncertainties relating to the possible impacts of nanomaterials – including nanoplastics – on human health and the environment, it is challenging for the legislator to lay down specific technical requirements and restrictions applying to nanomaterials. Despite the principle of precaution, which is particularly included as an underpinning principle in REACH, it remains to be seen whether REACH and the Cosmetic Regulation can effectively restrict the use of nanomaterials if there are gaps in knowledge on the effects on human health and the environment.

[109] Hernandez LM et al, 'Are There Nanoplastics in Your Personal Care Products?' (2017) 4 Environemtnal Science and Technology Letters 280-285, 280.

Annex: Example of Standing Committee on Cosmetic Products meeting

21 September 2016
Issues for discussion: Nanomaterials

Catalogue of nanomaterials
COM informed that the draft catalogue has been technically finalized and internal approval is awaited for its publication. Once the approval is given, COM will send letters to Permanent Representations and to industry associations regarding the publication of the catalogue, in order for them to prepare for any reactions. COM will then inform Member States and industry associations of the exact date of publication.

The catalogue of nanomaterials now contains 44 colorants, 9 preservatives, 9 UV-filters and 247 other substances. Despite the remedial actions taken in 2014 and 2015 (contacts with the industry, market surveillance actions by Member States) and some improvements, the draft catalogue still shows a significant level of inconsistency.

Other substances:
Draft Regulation on Methylisothiazolinone (MI) - rinse-off

COM updated that a measure to ban the use of MI as a preservative in leave-on cosmetic products had been adopted on 22 July 2016. COM presented a draft Regulation with a proposal aiming at restricting the use of MI as a preservative in rinse-off cosmetic products from 100 ppm to 15 ppm.

A 12-week public consultation took place from 1 April to 1 July 2016 where 24 contributions were submitted from industry, consumer organizations, research institutes, patient organizations and individual citizens. A summary of the feedback received will be posted on DG GROW's website in the coming days.

COM prepared a draft Regulation which was circulated in advance of today's meeting.

A Member State asked for longer transitional periods to allow SMEs enough time to adapt to the restriction. Another Member State also supported longer transitional periods.

Several Member States strongly supported the current transitional period of 6 months for placing on the market and 9 months for withdrawing from the market. This measure has been discussed on numerous occasions and should be implemented as soon as possible.

Measures for vote
COM reminded the group of the new voting rules applicable since 1 November 2014 ("double majority" voting). No request to apply the former voting rules was made.

Regulation on Benzophenone-3
COM reminded of this draft Regulation aiming at reducing the maximum authorised concentration for Benzophenone-3 used as a UV-filter in cosmetic products from the current 10% to 6%, following the last SCCS opinion.

Before the vote, some Member States suggested introducing specific restrictions for the use of Benzophenone-3 as a UV absorber to protect cosmetic product formulations in line with the conclusions of the SCCS opinion on this substance. The Committee agreed that the maximum concentration of 0,5% of Benzophenone-3 for its use to protect product formulations against UV radiation should be introduced in its entry in Annex VI in the column 'h' (Other conditions). In addition, 'w/w' ('mass/mass') should be added after '%' of authorised concentrations.

After the discussion, the Committee voted according to the new "double majority" voting as follows: 24 MS voted in favour, representing a population of 93,7% and 4 MS were not represented (6,3%). The 65 % population threshold was met. A Member State voted on behalf of another Member State.