Memo on Banning Microbeads in the European Union

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Summary

This memo departs from the Eunomia study on EU regulation of microplastics and explores the Cosmetics Regulation, the REACH Regulation and the Ecodesign Directive as possible instruments for banning microbeads. The Cosmetic Regulation is aimed at human health and safety and therefore less suitable. The REACH Regulation could lead to an all-encompassing prohibition from certain products or even in general, but its procedure requires multiple (scientific) evaluations and stakeholder participation rounds. The Ecodesign Directive is primarily designed for reducing energy consumption and would require amendments before waste generation issues could be included as a standard.
In the second section the legislative procedures are explained, in particular the competence of the EU in environmental policy and the procedures for adopting and amending legislation. The third section explains the difficulties of adopting a voluntary code banning microbeads in the light of EU competition law.

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Introduction

Microbeads in cosmetic and other rinse-off consumer products have been widely acknowledged as damaging to the environment (insert source). Our world's oceans being the largest victim with increasing numbers of pollution found in sea-creatures like shrimps and oysters (source), off shores and in the seawater itself. One of the major causes are the billions of (almost) microscopic plastic particles.

The Plastic Soup Foundation is advocating a ban on the use of microbeads in cosmetics through its campaign Beat the Microbead. In the US the Microbead-Free Waters Act was adopted in 2015 to phase out microbeads in cosmetic products by the year 2017. While several calls have been made by EU Member States to initiate EU regulations on the use of microbeads, so far the European Commission has not started any legislative procedure. Recently, it has commissioned a study to investigate measures to combat marine litter and in particular microplastics from cosmetic products.[1] The study distinguishes three possibilities of banning microbeads within existing legislation: the Cosmetics Regulations, the REACH regulation and the Ecodesign directive. This memo builds upon this study and provides further legal guidance regarding these options. Next to that, the possibility of voluntary agreements with the industries has been examined, in particular with regard to a possible clash with European competition law.

Banning microplastics within existing EU legislation

The Plastic Soup Foundation started its campaign Beat the Microbead in 2012 when it became clear that thousands of cosmetic products contained microplastics. Cosmetics are the main products including microplastics although there are several other sources such detergents and other cleaning agents, and paints. Next to products containing microplastics, microplastics also enter our environment by the use of specific products, such as synthetic clothing and car tyres. While our research is focussed on microplastics in cosmetics, we will point out whether the regulations may also suit a ban on microplastics in other products.

[1] Eunomia, *Study to support the development of measures to combat a range of marine litter sources: Report for the European Commission DG Environment* (2016 Eunomia).

The Cosmetics Regulation

Regulation 1223/2009, the Cosmetics Regulation, is more of less applicable to all cosmetics products due to the broad definition of cosmetic product in Article 2.[2] The regulation focusses on the working of the internal market and consumer safety, in particular human health.[3] Article 1 prescribes 'a high level of protection of human health.'[4] The Cosmetics Regulation in particular refers to the REACH regulation, discussed below, for regulating environmental concerns.[5] Although a ban on microplastics was initially inspired by environmental considerations, new research has identified severe human health risks of exposure by microplastics.[6] People may be exposed to microplastics by consumption of seafood and other food products, drinking water and via the air. Since the Cosmetics Regulation only regulates the safety of the product during normal use,[7] and thus not indirectly via the food chain or water, the product itself should pose a risk to the human health of the user. Some cosmetic products, such as toothpaste and lip gloss may be swallowed, while other products, such as creams, penetrate into the skin. If such exposure can be proven to pose a risk to human health,[8] according to Article 3 a product cannot be placed on the market. The manufacturer has to carry out a safety assessment according Article 10, including reviewing data from all existing sources.

There are also substances that are prohibited in cosmetics in any case. Annex II includes over 1300 substances that are prohibited. In addition, Article 14 prescribes that only colorants, preservatives and UV-filters that are listed in respectively Annex IV, V and VI can be used. Annexes can be amended by the European Commission according to the procedure described

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[2] Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) [2009] OJ L342/59 (Cosmetics Regulation).
Article 2(1)(a) reads:

> Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

[3] Cosmetics Regulation, Recital 3.
[4] Cosmetics Regulation, art. 1.
[5] Cosmetics Regulation, Recital 5 reads:

> The environmental concerns that substances used in cosmetic products may raise are considered through the application of 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) and establishing a European Chemicals Agency, which enables the assessment of environmental safety in a cross-sectoral manner.

[6] See research done by Plastic Soup Foundation; A. Dick Vethaak and Heather A. Leslie, 'Plastic Debris Is a Human Health Issue' *Environ. Sci. Technol.* 2016, 50, 6825−6826.
[7] Cosmetics Regulation, Article 3, 10 and Annex I.
[8] Research suggests that nanoplastics may pass cell membranes, Tamara S. Galloway, 'Micro- and Nano-plastics and Human Health' in Melanie Bergmann, Lars Gutow, Michael Klages, *Marine Anthropogenic Litter* (2015 Springer), ..

in Article 31. An advisory role is foreseen for the Scientific Committee on Consumer Safety (SCCS).[9]

Also substances classified as CMR substances are prohibited according to Article 15. CMR substances are substances that are carcinogenic, mutagenic, or toxic for reproduction and are classified as such under Part 3 Annex IV of the CLP Regulation.[10] A substance can be put on this list by proposal of the Commission, Member States, manufacturers, importers and downstream users. The procedure includes a risk assessment in the form of a scientific opinion by the Committee for Risk Assessment (RAC) of the European Chemical Agency before the European Commission decides.[11]

A special procedure is foreseen regarding nanomaterials in cosmetics.[12] Before being placed on the market the manufacturer has to notify the Commission at least six months before. If the Commission has concerns it will request a scientific opinion of the SCCS. Such request was made on 1 September 2016 regarding Sodium styrene/Acrylates copolymer (nano) and Styrene/ acrylates copolymer (nano).[13] The SCCS has to deliver its opinion within six months. In March 2015, the Commission invited interested parties to submit any relevant information on these substances before 30 June 2015, so the notification of manufacturer must have been received before. Therefore, it could be possible that the product is already placed on the market during the procedure.

Banning microbeads in cosmetics or a particular category of cosmetics under the Cosmetics Regulation would follow the same approach as the national bans on microbeads. However, since the Cosmetics Regulation is based on the working of the internal market and protection of human health, the prohibition of microbeads in rinse-off products under the regulation would depart from its legal basis and therefore be a more unlikely route.

[9] Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC [2008] OJ L241/21.

[10] Regulation (EC) 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 [2008] OJ L353/1 (CLP Regulation).

[11] CLP Regulation, art. 37.

[12] Cosmetics Regulations, art. 16.

[13] European Commission, *Request for a scientific opinion to SCCS: Styrene/Acrylates copolymer (nano) CAS No 9010-92-8, EC No 927-710-1 and Sodium styrene/Acrylates copolymer (nano) CAS No 9010-92-8*, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs2016_q_002.pdf.

The REACH Regulation

The purpose of the REACH Regulation is 'to ensure a high level of protection of human health and the environment, [...] as well as the free circulation of substances on the internal market'.[14] This is done by the four processes, namely the registration, evaluation, authorisation and restriction of chemicals. The REACH Regulation contains 141 Articles and 17 Annexes, making up for 849 pages. A further 37 amendments have been made since 2006 and an unofficial consolidated version which includes the amendments has been published, covering over 500 pages.

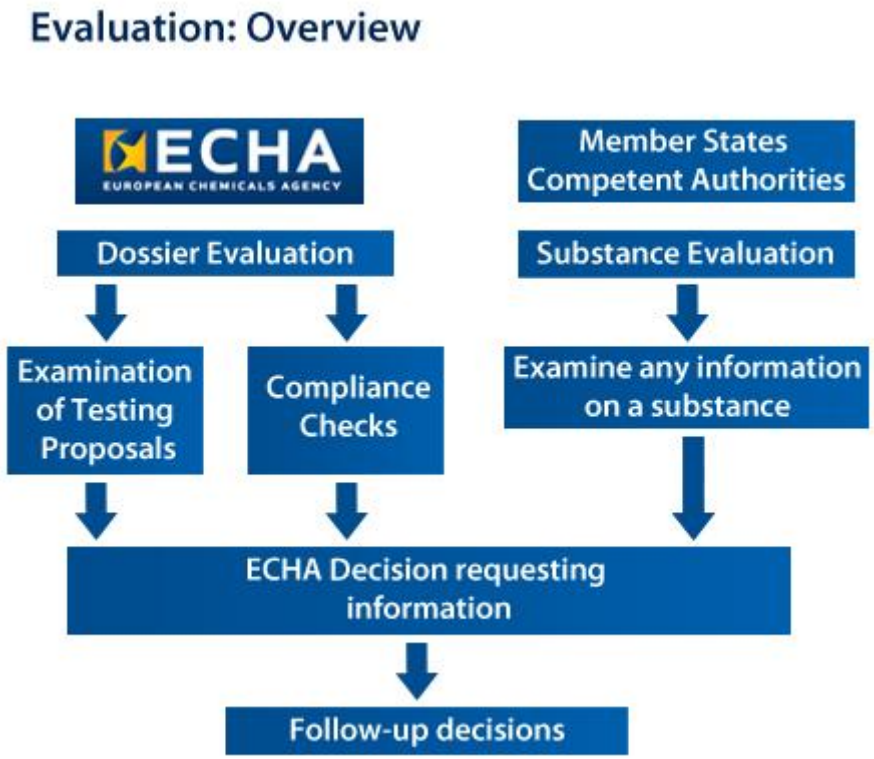
According to the Preamble REACH places product manufacturers, importers and, ultimately, the users under certain obligations regarding the production, sale and use of goods.[15] Recital 16 explicitly stipulates that the REACH Regulation is 'based on the principle that industry should manufacture, import or use substances or place [substances] on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected'.[16]

REACH distinguishes four processes: registration, evaluation, authorisation and restriction.

The general obligation regarding registration of a substance is included in Article 5 called 'No data, no market', which requires the registration of a substance before it is placed on the internal market.[17] Generally, this has to be done for substances in quantities above a tonne.[18] Although nanomaterials are not explicitly regulated by REACH, substances do fall under the general provisions of REACH. There is however special attention for the risks for human health and the environment for the nanoforms of registered substances. The procedure for registration starts with compiling a dossier by the registrant, which has to be submitted to the European Chemicals Agency (ECHA).[19] The registration dossier is then published by the ECHA.[20] The ECHA will evaluate the dossier and if there are any risks for human health or

[14] Regulation (EC) 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/EC and 2000/21/EC [2006] OJ L396/1 (REACH Regulation).
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0049:FIN:EN:PDF.
[15] REACH Regulation, Recital 16.
[16] id.
[17] REACH Regulation, art. 5.
[18] REACH Regulation, art. 6.
[19] REACH Regulation, art. 7.
[20] REACH Regulation, art. 20.

the environment expected it will assign a competent authority of a Member State for a substance evaluation.[21]



Depending on the outcomes of the evaluation the ECHA may take a decision to propose the labelling of the substance as a CMR substance, to propose identifying the substance as a substance of very high concern (SVHC) or to propose a restriction of the substance.

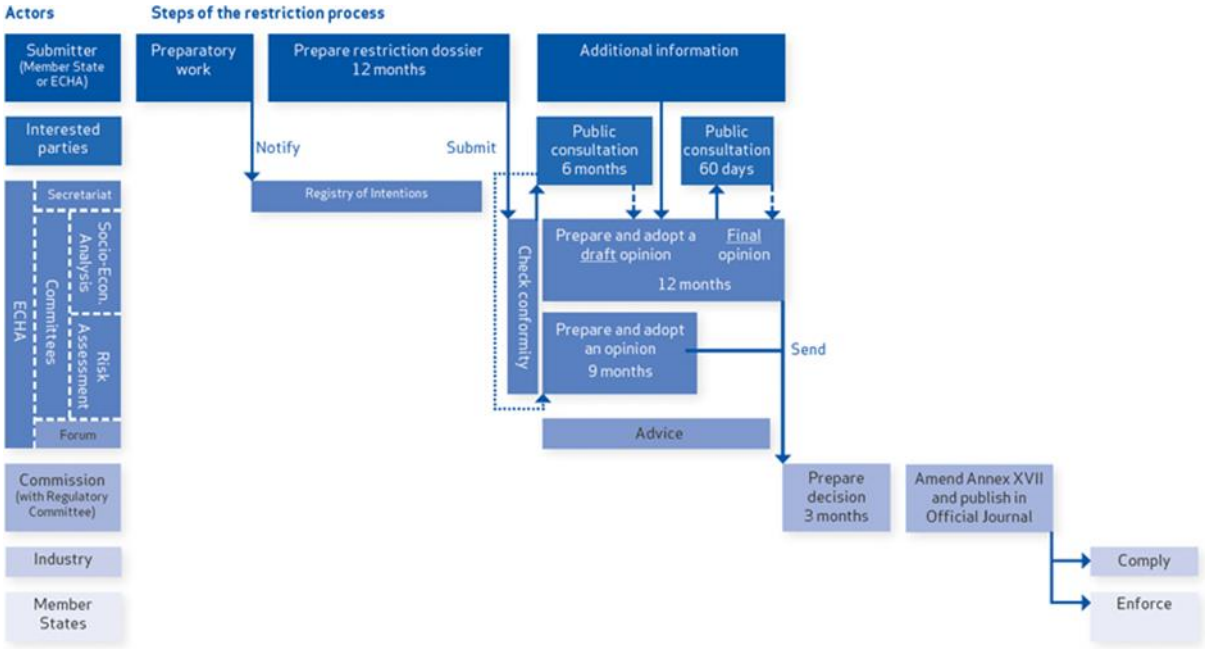
A CMR substance is regulated by the CLP Regulation. A SVHC substance will be placed on the Candidate List if it fulfils the criteria of Article 57,[22] and, if indeed identified, eventually in Annex XIV. These substances fall under the regime of authorisation, which means that manufacturers, importers and downstream users may apply for authorisation for placing on the market or using. The aim of the authorisation regime is 'that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and

[21] REACH Regulation, art. 40, 44 and 45.
[22] Article 57 lists substances in the CMR category as well as persistant and very persistant or/and bioaccumulative and/or toxic.

technically viable'.[23] Currently there are 31 substances on the Annex XIV list, 169 on the Candidate list and 192 submitted proposals of SVHC substance.[24]

When a substance is considered to pose 'an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances' it may be restricted and be included in Annex XVII of REACH.[25] Restriction may mean that the substance may be used under certain conditions such as not be used in a product category, or for the most dangerous substances, not to be placed in the market or used at all. The European Commission may ask the ECHA to prepare a dossier but also Member States can prepare a dossier on its own initiative. Both the Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC) of the ECHA will give their opinion, after which the Commission has to take a decision. The inclusion of a substance in Annex XVII is a formal amendment of REACH which has to be adopted by the European Commission after submission of the proposal to the European Parliament. From a cursory examination of this list, it appears that most of the substances are placed on the restriction list for reasons pertaining to risk to human health, primarily due to the substances being carcinogenic or toxic for reproduction. This gives rise to further indications that plastic may not reach the severity threshold required by the REACH Regulation. However, scientific analysis is outside the scope of this report and REACH is not limited to these categories. Compiling a dossier regarding the risks for human health and the environment is a starting point for each procedure of REACH and all stakeholders are allowed to contribute. Further scientific research regarding the toxicity of microplastics is therefore in our view a priority for banning microplastics as a substance under REACH.

[23] REACH regulation, art. 55.
[24] REACH regulation, annex XIV; https://echa.europa.eu/candidate-list-table; https://echa.europa.eu/registry-of-submitted-svhc-intentions. Inclusion of microplastic in the current lists seems highly unlikely, but review is beyond our research.
[25] REACH Regulation, art. 68.



source: ECHA website[26]

The Ecodesign Directive

The Ecodesign Directive was adopted in 2010 with the aim to improve the energy efficiency of products.[27] The Ecodesign Directive is mentioned as a core instrument of European environmental product policy: it establishes mandatory minimum requirements for product design from the moment products are placed on the EU market and thus apply to products both produced within and imported into the EU.[28] While adopted in the first place regarding energy efficiency, Recital 39 of the Directive explicitly refers to 'extending its scope beyond energy-related products.'[29] The European Environmental Bureau has suggested that the Ecodesign Directive is also well suited to improve a product's resource efficiency.[30] By setting minimum standards regarding waste treatment and recycling, the use of microplastics may be banned in certain product groups. Also in the Green Paper on a European strategy on

[26] https://echa.europa.eu/home.
[27] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products [2009] OJ L285/10 (Ecodesign Directive).
[28] Ecodesign Directive, art. 1, 4 and 5.
[29] Ecodesign Directive, recital 39
[30] EBB *Delivering resource-efficient products: how Ecodesign can drive a circular economy in Europe?* (2015 EBB) 7.

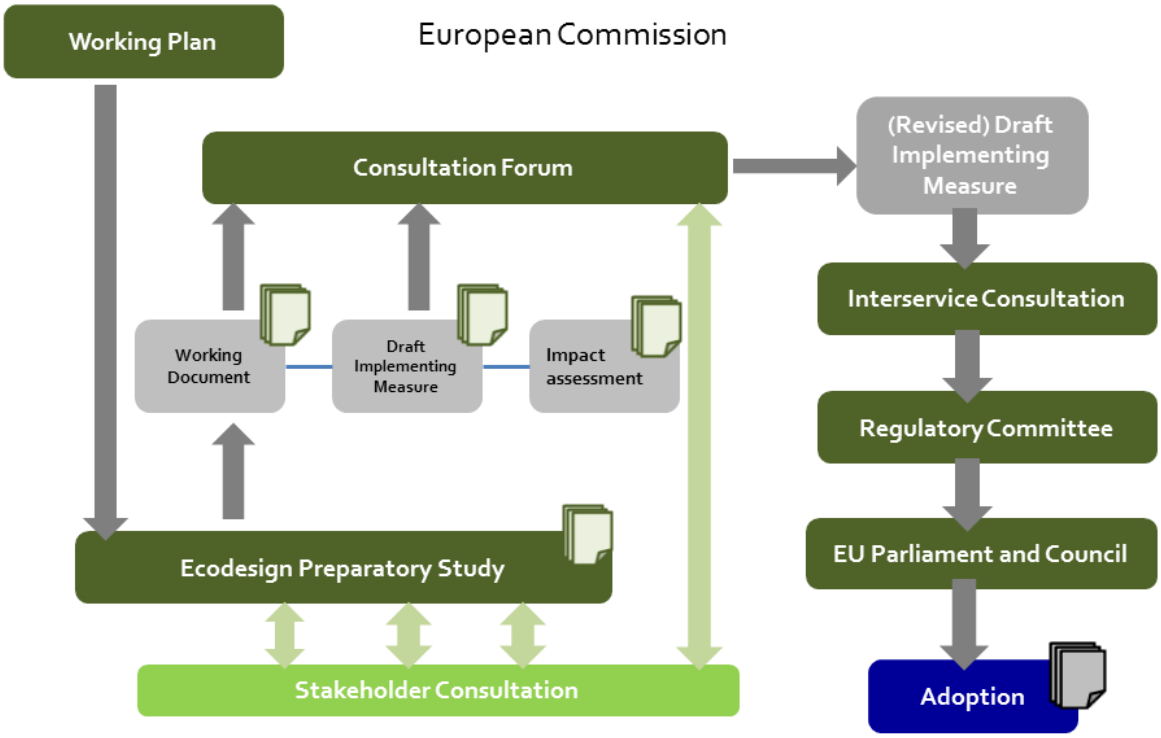
plastic waste in the environment ecodesign is called pivotal in minimizing waste.[31] Microplastics and nanoplastics are considered to require special attention.

Article 15 is the central provision of the Directive: it sets the requirements and procedure for the implementing measures.[32] Implementing measures are the measures that will specify the energy efficiency standards for a product group. Implementing measures can be taken if:

a) more than 200 000 units of the product a year are sold or traded within the Community.
b) the product shall have a significant environmental impact within the Community.[33]
c) the product shall present significant potential for improvement in terms of its environmental impact without entailing excessive costs.[34]

According Annex I not only energy consumption, but also other resource consumption such as of water and material should be assessed, as well as anticipated emissions and expected generation of waste material. In Annexes II and VII further requirements and procedural rules are included.[35] So far 23 implementation measures, from air conditioners to water pumps, have been adopted, focussing mainly on energy consumption in the use phase.[36] The process of adopting an implementation measures starts with the Commission making a working plan setting priority for product groups.[37] A Preparatory Study will be made which is followed by a consultation phase. Energy standards are then included in a Commission regulation which gives detailed specifications for the product, for example that 'power consumption of televisions in any off-mode condition shall not exceed 1,00 Watt.'[38]

[31] 103rd plenary session, 7-9 October 2013, *Draft Opinion:* Green Paper on a European strategy on plastic waste in the environment. http://www.retorna.org/mm/file/CDR3751-2013_00_00_TRA_PAC_EN.pdf, 7.
[32] Ecodesign Directive, art. 15.
[33] As specified in the Community strategic priorities as set out in Decision No 1600/2002/EC.
[34] Taking into account in particular: the absence of other relevant Community legislation or failure of market forces to address the issue properly or a wide disparity in the environmental performance of products available on the market with equivalent functionality. (i, ii article 15 c).
[35] Ecodesign Directive, Annexes I, II and VII.
[36] List of Ecodesign regulations, https://ec.europa.eu/energy/sites/ener/files/documents/list_of_ecodesign_measures.pdf.
[37] Ecodesign Directive, art. 16.
[38] Commission Regulation (EC) No 642/2009 of 22 July 2009 implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for televisions [2009] OJ L191/42, Annex I, 2.1.a.



source: Task 1 Draft Final Report[39]

The Commission has been studying 'the possibility of enhancing material efficiency aspects of the Methodology for Ecodesign of Energy-related Products (MEErP), as used in the framework of the Ecodesign Directive (2009/125/EC)', but this would only apply on those product groups that fall under the Ecodesign Directive because of their energy consumption.[40] Next to the implementing measures it is also possible to conclude voluntary agreements under the Ecodesign Directive. Three energy related product agreements have been concluded so far.

The banning of microplastics via the Ecodesign Directive would first of all require an amendment to the Ecodesign Directive itself, as it now only provides requirements and parameters mainly specified for energy consumption. Additional standards, such as on minimizing waste generation, can be set, but only as supplementary requirements to the energy-related specifications. A second step would be to place product groups entailing

[39] BIO by Deloitte, Oeko-Institut and ERA Technology, *Preparatory Study to establish the Ecodesign Working Plan 2015-2017 implementing Directive 2009/125/EC – Task 1 Draft Final Report prepared for the European Commission (DG ENTR)* (2014) 7.

[40] BIO Intelligence Service, *Material-efficiency Ecodesign Report and Module to the Methodology for the Ecodesign of Energy-related Products (MEErP), Part 1: Material Efficiency for Ecodesign – Draft Final Report. Prepared for:European Commission - DG Enterprise and Industry* (2013) 15.

microplastics on the Working Plan. This could be rather challenging as most product groups of the Ecodesign Directive and Working Plans are quite specific, for example making a distinction between a refrigerator and a wine storage refrigerator. Therefore, a complete ban of microplastics in all cosmetic products and other consumer products would require multiple procedures and implementing measures.

The legislative procedures of the EU

Competence of the European Union

It must first be noted that the European Union does not have sole and exclusive legislative competence in all policy fields. The European Union is an international organisation based on international treaty and it 'can only act within the limits of the powers assigned to it.'[41] Legislative measures can only be taken if the competence in the policy area is included in Treaty on the Functioning of the European Union. Furthermore, competences are divided in three categories: exclusive competence, shared competence and supporting competence. This may limit the scope of EU legislation in some policy areas.

According to Article 4(2) TFEU, the EU and the individual Member States have shared competence in respect of the environment.[42] This means that the EU Member states may exercise their own competence if the EU has not exercised or decided not to exercise its own competence. The overarching rule in exercising shared competences is that the EU has the right of pre-emption.[43] Simply put, the European Union has the priority in exercising competence in this area. This however does not mean that Member States do not have, after the EU undertook certain action in this area, any space for adopting its own initiatives. That said, the EU 'shall act only if and in so far as the objectives of the proposed action (…) can (…) be better achieved at Union level.'[44] Furthermore, as per the principle of proportionality, the EU may only legislate to the extent that it is necessary to achieve the policy objective.[45] The EU measures discussed in this report, the Cosmetics Regulation, the REACH Regulation and the Ecodesign Directive, have all been validly adopted in accordance with the EU legislative process. The Cosmetic Regulation was adopted to further the development of the

[41] P Craig and G de Búrca, *EU Law, Text Cases and materials (6th* edition, Oxford University Press 2015) 74.
[42] Division of Competences within the European Union. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3Aai0020 accessed 24 June 2016.
[43] According to Art. 2(2) TFEU "The Member States shall exercise their competence to the extent that the Union has not exercised its competence The Member States shall again exercise their competence to the extent that the Union has decided to cease exercising its competence".
[44] Article 5(3) TEU.
[45] Article 5 TEU.

internal market and to ensure protection of human health, a supporting competence and supplementary competence.[46] The legal basis of the REACH Regulation pertains to the functioning of the internal market in addition to 'ensur[ing] a high level of protection of human health and the environment.'[47] Finally, the Ecodesign Directive was drafted under the competency on environment: 'to ensure the functioning of the internal market by requiring products to reach an adequate level of environmental performance.'[48] This competence suggests that Member states are not allowed to set further standards if the substance is regulated by REACH or the Ecodesign Directive. However, microbeads are not regulated by any regulation so far. France is now the first EU Member state that has notified its proposed ban of microbeads in rinse-off cosmetic products to the EU, based on, among others, the EU Marine Strategy Framework Directive, but no further information is available yet.[49]

The legislative process

The question being frequently asked is why does it take so much time to enact certain measure or to change certain legislative act. Firstly, there are several different but interconnected aspects – political, economic and legal. There needs to be certain policy which must be pushed either by the European Commission, the Council[50] or by strong group in the European Parliament.[51] Such policies must also in conformity with the rules of the internal market. Finally, there is also legal process which may last year, despite many modifications towards facilitating a faster procedure. In the following part the procedures, concentrating on the main actors, time frames and practice in the legislation and decision-making will be described.

[46] Cosmetics Regulation, Recital 71.
[47] REACH Regulation, Recital 1.
[48] Ecodesign Directive, Recital 41.
[49] Notification Detail, Decree prohibiting the placement on the market of rinse-off cosmetic products for exfoliation or cleaning that contain solid plastic particles, provided for in the third paragraph of point III of Article L541-10-5 of the Environmental Code, Notification number 2016/543/F, received on 12 October 2016, <http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search. detail&year=2016&num=543>.
[50] One of the possible options if certain policy or particular actions is needed to be adopted is lobbying through the country holding the presidency. The Council, institution composed of national ministers for particular areas (there are approximately 10 Council configurations), presiding by the Member State holding the presidency may propose certain initiatives which it considers to be its priority. This allows for more quick adoption of certain measure.
[51] An impulse for adoption or amendment of certain EU measure does not have to come only through European institution but also by the activity of citizens of the EU. The Lisbon Treaty has introduced the citizens' initiative in Art. 11 (4) TFEU which provides that no fewer than one million citizens who are nationals of a significant number of Member States may take initiative addressed to the European Commission. The European Commission should then submit an appropriate proposal.

Most measures, including those pertaining to the environment, are adopted by means of the ordinary legislative procedure.[52] According to Article 289 TFEU, a proposal is initiated by the European Commission and must be jointly adopted by the European Parliament and the Council. This is applicable to the adoption of legislative acts, in case of environmental measures notably in the form of regulations and directives. Article 294 TFEU provides a more detailed outline of process as follows:

1. First Reading:

At this stage, the European Parliament must determine the positon it adheres to and inform the Council in this regard.[53] In the event that the Council concurs with the Parliament, the measure is adopted.[54] However, if the Council disagrees with the Parliament, it shall inform the Parliament of its position and its reasons for adopting the position.[55]

2. Second Reading:

Three months subsequent to the communication between the Parliament and Council, the measure will be deemed to have been adopted if Parliament's approves of Council's position or fails to make a decision in this regard.[56] The wording would be that decided by the Council.[57] On the other hand, if after the three month period, Parliament rejects Council's position, the measure will not be adopted.[58] In addition, the Parliament also has the option of drafting amendments to the measure which are then forwarded to the Council and the Commission.[59] The Council has a further three months to either accept or reject the amendments.[60] Rejecting the amendments serves to bring about a meeting of the Conciliation Committee.[61]

3. Conciliation:

It is the purpose of the Conciliation Committee to 'reach … agreement on a joint text, by a qualified majority of the members of the Council or their representatives and by a majority of the members representing the European Parliament within six weeks of its being convened.'[62]

[52] For a comprehensive overview, see <http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers>.
[53] Article 294(3) TFEU.
[54] Article 294(4) TFEU.
[55] Article 294(5)-(6) TFEU.
[56] Article 294(7)(a) TFEU.
[57] Article 294(7)(a) TFEU.
[58] Article 294(7)(b) TFEU.
[59] Article 294(7)(c) TFEU.
[60] Article 294(8) TFEU.
[61] Article 294(8) TFEU.
[62] Article 294(10) TFEU.

The Commission may also have a role in this process.[63] As mentioned above, the process is limited by a temporal restriction of six weeks. If approval is not achieved in this period, the measure will not be adopted.[64]

4. Third Reading:

If a joint text of the Conciliation Committee is approved, the following occurs:
The European Parliament, acting by a majority of the votes cast, and the Council, acting by a qualified majority, shall each have a period of six weeks from that approval in which to adopt the act in question in accordance with the joint text.[65]

5. Formal Adoption:

For formal adoption, the measure must be signed into law by the President of the European Parliament and the President of the Council and published in the Official Journal of the European Union.[66] As per Article 297(1) TFEU, the measure 'shall enter into force on the date specified in [the Official Journal] or, in the absence thereof, on the twentieth day following that of their publication.'

Amending existing measures

Amending existing measures is often foreseen in regulations. However, any such amendments can only occur by means of the ordinary legislative procedure, so exactly the same procedure as described above. So, an inclusion of a new substance on Annex XVII of the REACH (list of restricted substances) is only achieved by adopting an amending regulation.[67] Similarly, a directive is altered by the adoption of a subsequent directive which has the objective of amending the former measure.

Status of regulations and directives

As this report outlines the suitability of existing EU measures to address the possibility of regulating the presence of microbeads in various substances, it is helpful to outline the status of these measures in the individual Member States. As mentioned *supra,* this report will focus on secondary legislation, namely the Cosmetics Regulation, the REACH Regulation and the Ecodesign Directive.

(i) Regulations

[63] Article 294(11) TFEU.
[64] Article 294(12) TFEU.
[65] Article 294(13) TFEU.
[66] Article 297 TFEU.
[67] See <http://ec.europa.eu/environment/chemicals/reach/legislation_en.htm>.

Regulations, as defined in Article 288 TFEU, are binding EU instruments and must be applicable in their entirety in each individual Member States in the EU. In addition, a regulation has direct effect and can be relied upon by persons in any Member State. A comprehensive definition of a regulation can be found in Recital 2 of the Cosmetics Regulation which reads as follows:

> A Regulation … imposes clear and detailed rules which do not give room for diverging transposition by Member States … [and] ensures that legal requirements are implemented at the same time throughout the Community…

Due to their uniform application, regulations leave no room for discretion of individual Member States in relation to the implementation of a regulation in that Member States. The universal applicability of regulations make them an attractive legal instrument for adopting uniform measures across the EU, particularly regarding environmental standards for products.

(ii) Directives

In accordance with Article 288 TFEU, a directive, on the other hand, is only binding upon the Member States to which it is addressed. Furthermore, 'the choice of form and methods' of implementation of a directive is left to the authorities of each Member State. That is, directives must be transposed into national law to be relied upon. National transposition 'must achieve the objectives set by the [D]irective [and] [n]ational authorities must communicate these measures to the European Commission.'[68] Proceedings can be instigated in relation to late or insufficient transposition.

Directives can be praised for their 'flexible' nature and their aim of harmonising national law.[69] However, this flexibility can in turn cause problems since the EU is then dependent upon the actions of individual Member States to implement directives accurately and without delay. For this reason, it is our view that a directive is not the ideal instrument to regulate microbeads in products. But, regulation in the form of directives might be suitable to regulate microbeads in the disposal of sewage water and in relation to the quality of fresh water. This topic requires further study before substantive conclusion can be drawn.

Voluntary agreements banning microplastics and EU competition law

Self-regulation by manufacturers may anticipate a ban on microplastics which may take several years to implement. However, branch organisation Cosmetics Europe has stated that 'it cannot provide specific guidance to their members that encourages the removal of

[68] European Union Directives, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al14527>.
[69] European Union Directives, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al14527>.

microplastics from their products.'[70] Also the Plastic Soup Foundation has reported that the *Nederlandse Cosmetica Vereniging* (NCV) will not actively support a voluntary agreement between manufacturers to ban microplastics as it may be in violation with European competition law.

European competition law forbids agreements between manufacturers and other market players that would restrict competition.[71] Exceptions to this rule are possible but only if it would improve the production of goods or lead to technical or economic progress and consumers would benefit from these improvements.[72] The requirement that consumers have to benefit from these agreements has been interpreted strictly by the European Commission, meaning that consumers have to benefit financially. The Commission has actually been warning that even if national authorities are encouraging companies to enter into voluntary agreements for public purpose objectives, such as environmental protection, it does not mean that these agreements are permissible under Article 101 TFEU.[73] The strict interpretation has been confirmed in the *Consumer Detergents* Decision of the Commission.[74] In this case, three major detergent manufacturers, Henkel, Unilever and Procter & Gamble, were fined for activities related to an environmental initiative to promote a sustainable dosage of detergent powder and corresponding packaging. The environmental initiative was launched by the

[70] Eunomia (n 1) 330.

[71] Consolidated version of the Treaty on the Functioning of the European Union, art. 101.
Article 101 TFEU reads:
1. The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:
(a) directly or indirectly fix purchase or selling prices or any other trading conditions;
(b) limit or control production, markets, technical development, or investment;
(c) share markets or sources of supply;
(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.
2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.
3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:
- any agreement or category of agreements between undertakings,
- any decision or category of decisions by associations of undertakings,
- any concerted practice or category of concerted practices,
which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:
(a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;
(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

[72] Eunomia (n 1) 330 .

[73] Commission, 'Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements' (Communication) 2011/C 11/01, 7 (Commission Guidelines).

[74] *Consumer Detergents* (COMP/39579) Commission Decision C(2011) 2528 final [2011] OJ C193/14.

International Association for Soaps, Detergents and Maintenance Products (AISE), the European trade organisation to which Henkel, Unilever and P&G were associated. The voluntary agreement did not foresee in price agreements, but the manufacturers organised side meetings to stabilise prices leading to indirect and direct price increases for the consumer. The Commission did not assess the voluntary agreement organised by AISE, but concluded that the side meetings and the price agreements between the three largest manufacturers consisted a infringement of Article 101 TFEU, and set a fine of 130 million Euro.
So, although the AISE initiative itself was not considered in violation of European competition law, the decision has led to extreme carefulness regarding voluntary agreement between companies.[75] When a voluntary agreement could lead to price increases, for example due to increased costs for the manufacturer, the agreement may potentially infringe European competition law. The Commission has issues guidelines on horizontal co-operation agreements, that is agreements between competitors in the same market.[76] An agreement between manufacturers banning microplastics from cosmetic products would qualify as a standardisation agreement.[77] It would set a standard not to use microplastics in certain products. These agreements could potentially lead to a restriction of competition for example by reducing price competition and exclusion or discrimination of companies. According to the Commission this may be caused by anti-competitive discussions associated with the agreement or by limiting effective access of certain companies to the standard setting process.[78] The Commission provides examples of standardisation agreements that may restrict competition, of which we list the most relevant ones:

- For instance, an agreement whereby a national association of manufacturers sets a standard and puts pressure on third parties not to market products that do not comply with the standard [...].
- Any standard terms containing provisions which directly influence the prices charged to customers (that is to say, recommended prices, rebates, etc.) would constitute a restriction of competition by object.[79]

[75] Interview with Tom Ottervanger, Professor of European Law and Dutch Competition Law, Leiden Law School, Leiden University (Leiden 5 July 2016).
[76] Commission Guidelines (n 50) 4.
[77] ibid 55.
[78] ibid 57.
[79] ibid 58.

However, the Commission has also listed a number of conditions that would make agreement normally not restrictive of competition:

> 280. Where participation in standard-setting is **unrestricted** and the procedure for adopting the standard in question is **transparent**, standardisation agreements which contain **no obligation to comply** with the standard and provide **access to the standard on fair, reasonable and non-discriminatory terms** will normally not restrict competition within the meaning of Article 101(1).[80]

The Commission adds that '[t]he standard-setting organisations would also need to have objective and non-discriminatory procedures for allocating voting rights as well as, if relevant, objective criteria for selecting the technology to be included in the standard.'[81] Furthermore, a binding standard obligatory for the industry will not be allowed anyway. In addition, if the agreement would have negative effects on the price of products it is qualified as restricting competition in any case. In that case, it should be assessed whether the agreement could fall under the exceptions of Article 101(3) TFEU. Essential is that the 'efficiency gains' should be passed on to the consumer. Efficiency gains can be in the form of price, quality and innovation, though price is considered the deciding factor.[82] The example given by the Commission is an agreement aimed at reducing energy consumption of washing machines.[83] Such an agreement may lead to restriction of competition due to increased prices, but through a lower energy use during its lifetime, the consumer benefits in the end.[84]
Some concluding remarks. A voluntary agreement between manufacturers of cosmetic products banning microplastics may infringe European competition law. First of all, participation to the standard-setting agreements should be open to all and transparent, while compliance should be strictly voluntary. If the agreement would lead to an increase of prices, the agreement may fall under the exceptions, but essential is that the agreement would lead to efficiency gains, read economic gains, for the consumer. Agreements regarding prices, either to stabilize or to increase, between manufacturers will violate the law and may be punished. Due to the strict interpretation of the Commission manufacturers and trade organisations are

[80] ibid 59 (emphasis added).
[81] ibid.
[82] Tom Ottervanger, 'Maatschappelijk verantwoord concurreren: mededingingsrecht in een veranderende wereld' (Inaugural lecture, Leiden University 2010), 9.
[83] ibid 68.
[84] ibid.

hesitant to enter into agreements.[85] Involvement of national authorities, as with the Agreement on Sustainable Garment and Textile, may help to fulfil the criteria of the Commission to stay within the limits of Article 101.[86] Guidance of the Dutch Social and Economic Council by its programme on Agreements on international responsible business conduct may also contribute to the dispelling of doubts and uncertainties.[87]

[85] In the *Consumer Detergents* case Henkel, Unilever and Procter & Gamble were involved. They are also large manufacturers of cosmetic products and members of Cosmetics Europe.
[86] Email conversation with Barbara Cooreman, Lecturer EU Law, Leiden Law School, Leiden University (Leiden 3 August 2016).
[87] Sociaal-Economische Raad, *Agreements on International Responsible Business Conduct* (abbreviated version, Den Haag 2014); the orginal Dutch version is also available via the website: <https://www.ser.nl/en/publications/publications/2014/international-responsible-business-conduct.aspx>.