Case study 9: Microplastics in food products and cosmetics

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Abstract

In the current case study we will analyse if the conceptual core of the precautionary principle, and in particular scientific uncertainty, complexity and ambiguity, is present in the case of microplastics in cosmetics and food. Additionally, we aim to understand the complexities and controversies around the potential application of the precautionary principle in the risk governance of microplastics in cosmetics and foods in the European Union.

Microplastics are synthetic polymers with a size smaller than 5 mm. Cosmetic products contain intentionally added microplastics, which are directly released into wastewater. Additionally, large amounts of microplastics develop in the environment as a side effect of plastic pollution, where they remain for a long time. Via consumption of i.a. molluscs, microplastics end up in food. Scientific evidence on human health effects coming from microplastics is very scarce. This makes it a potential candidate for the precautionary principle.

With this study, we found that the case of microplastics in food and cosmetics does adhere to the key precautionary concepts of complexity, uncertainty and ambiguity. Microplastic is a diverse group of materials, leading to high complexity and difficulties in performing scientific research and defining regulations. This is caused i.a. by a lack of one uniform definition and a lack of standardized measurement tools. Especially scientific evidence for human health effects of microplastics is very thin and its scientific quality is debated. This is particulary important in dealing with microplastics in food products. The presence of intentionally added microplastics in cosmetics is mostly related to environmental issues. In this regard, the mere presence of high amounts of microplastics in the environment is unwanted, regardless of the specific risks caused. Therefore legislation is in the making to ban intentionally added microplastics in cosmetics. This drives innovation in the direction of biodegrable microplastics and natural alternatives with the function to scrub and exfoliate the skin.

Concluding, microplastic has attracted a lot of societal attention and is surrounded with complexities. Lack of a common definition and lack of standardized measurement methods contribute to the complexity and uncertainty on health and environmental effects. Legal actions to reduce microplastics in cosmetics take form via the REACH regulation, which is based on the precautionary principle. Via this route, the Commission and relevant agencies aim to deal with the abundant presence of microplastics in the environment. Health effects due to microplastics in food require more scientific research and are more difficult to regulate. Nevertheless, with the EU Plastic Strategy policy is directed to reduce plastic pollution altogether, including microplastics.

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List of abbreviations

EFSA	European Food Safety Authority
ECHA	European Chemical Agency
EC	European Commission
FAO	Food and Agriculture Organisation of the United Nations
SAM	Scientific Advice Mechanism
SAPEA	Science Advice for Policy by European Academies
SCHEER	Scientific Committee on Health Environmental and Emerging Risks
WHO	World Health Organisation
WWTP	Wastewater treatment plants

1 Introduction

1.1 Introduction

This case study will discuss the potential use of the precautionary principle in regulating the occurrence of microplastics in food products and in cosmetic products throughout the European Union.

Microplastics, mostly defined as polymer particles smaller than 5mm, can be divided into two groups: primary and secondary microplastics. Primary microplastics are intentionally added to products, and are widely applied in cosmetics, such as scrubs, lotions, toothpaste or bath gels (Leslie, 2014). Their function varies among products, e.g. to improve exfoliation, bulking, viscosity control, film formation and skin conditioning (United Nation Environment Programme, 2015). Because many of these products are so-called 'rinse off products', these small plastic particles are directly released into the sewage system. Although part of the microplastic particles do get filtered out of the water in the wastewater treatment plants, some particles are released into the freshwater stream. Another important route for primary microplastics to end up in the environment is by being captured in the sewage sludge. This sludge is often used as a fertilizer on agricultural land (Duis & Coors, 2016). Via this route, cosmetic products contribute to the spread of microplastics in both the aquatic environment and on soil.

The bulk of the microplastics present in the (aquatic) environment is not coming from cosmetics, but is so-called secondary microplastic. Secondary microplastics are not intentionally added, but they breakdown from plastic litter in the environment, under the influence of heat, light and oxygen (Van Wezel, Caris, & Kools, 2016). This process mainly takes place in the oceans, where the bulk of plastic pollution exists. Additionally, washing of synthetic fabrics and wearing down of tyres are important contributors to secondary microplastic pollution in the (aquatic) environment (Boucher & Friot, 2017). Fibres from synthetic fabrics, which are released in the washing process, are even estimated to account for 35% of all microplastics fibres in the oceans (Prata, 2018).

The existence of microplastics in the environment is therefore mostly a consequence of the currently widespread use of plastics in all kinds of applications and the widespread plastic pollution. This plastic pollution, and the question how to deal with plastic debris, has attracted attention of both researchers and the general public over the last years (Schirinzi et al, 2017). In the media, most attention goes to microplastic pollution in the marine environment. This is indeed an important issue, since microplastic is estimated to account for 94% of the number of plastic pieces of the Great Garbage Patch in the Pacific ocean (Lebreton et al, 2018). However, this does not cover the complete microplastic pollution. Also freshwaters, air and soil have shown pollution with primary and secondary microplastics (Koelmans et al, 2019). Since microplastic particles are widespread through the environment, together with their small size and large variation in appearances, they are difficult to be filtered out of the environment. Given their very slow degradation, its pollution is a reason for concern. Potential harmful effects are expected for the environment, but also animal and human health should be carefully considered. The reason for this is as follows: microplastics in the marine environment get eaten by fish and other sea animals. Via this route, also humans get exposed to microplastics, when consuming polluted seafood, such as mussels or oisters. Because these animals are eaten as a whole, including their intestines, the consumption of microplastics by humans is very likely (Santillo, Miller & Johnston, 2017). Other food products that have been reported to contain microplastics are honey, seasalt, water and beer (Koelmans et al, 2019). Additionally, human exposure to microplastics can occur via food packaging, for example plastic water bottles, which can leak small particles into the foods.

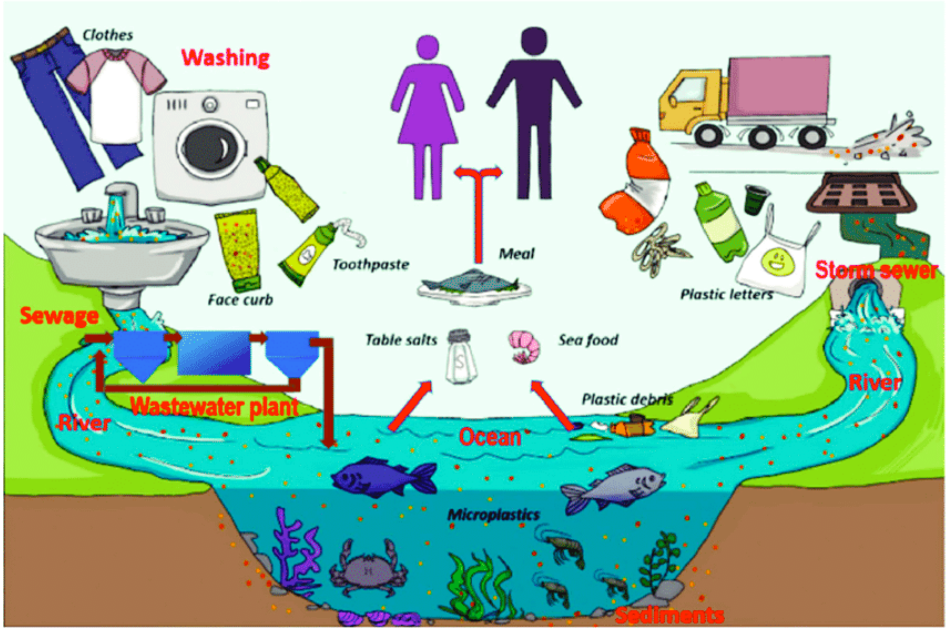

Figure 1: Overview of microplastic pollution in the aquatic environment and in food sources, including the main routes of exposure (Westphalen & Abdeirasoul, 2017; Wu, Yang & Criddle, 2017)

Thus far, very little is known on how the human body processes microplastic particles and which health effects might be caused. An important factor to take into account in assessing the human health risk is not only the plastic particles themselves, but also the chemicals that are present on its surface. This often includes endocrine disrupting chemicals, such as bisphenol A, which are added to the plastics to improve certain characteristics such as their flexibility or water resistance (Campanaie, Massarelli, Savino, Locaputo & Uricchio (2020). But also coloring chemicals and fire retardants are often added to the surface of (micro)plastics. While the microplastics stay in the water for a long time, these chemical substances soak off and leak into the water, where they are even more difficult to be measured and removed (Campanale et al, 2020). It is especially problematic when these chemicals are released into the food chain, since scientific literature has suggested associations between endocrine disruptors and a large variation of health effects in humans (Rochester, 2013).

The environmental burden of microplastic pollution is widely recognised as a global problem nowadays (United Nation Environement Programme, 2009). Looking at the large amount of microplastic released in the environment, its very slow degradation and consequently uncertain effects on the environment and animal and human effects on the long term, action is required. Since their specific harmful, long-term effects with regard to the environment and animal and human health are difficult to study because of the variation in materials and the interdisciplinary nature of the subject, this might be a suitable topic for the precautionary principle to be applied.

Many documents have been written to understand the issue of microplastic pollution, potential consequences for the environment, animal and human health and finally to provide policy advice to adequately deal with potential risks. Relevant international bodies with regard to risk assessment and risk management are the European Commission, European Chemical Agency (ECHA), European Food Safety Authority (EFSA), SAPEA (Science Advice for Policy by European Academies) and UNEP (United Nations Environment Programme). Relevant parties in this discussion are also industry parties like PlasticsEurope and environmental NGO's such as the Plastic Soup Foundation. At the moment, various (policy making) activities are taking place, on national and international level, to reduce the amount of plastic pollution and deal with its potential consequences on the long term. An important document in this regard is the EU Plastic Strategy, which was launched by the European Commission in 2018. This policy to reduce plastic litter in the environment, shows an interesting social as well as political development to work towards a circular economy and thereby reduce plastic waste (European Commission, 2018). The potential, but sometimes uncertain, long-term effects for environment and animal and human health of microplastics played a large role in designing this document. Namely, this uncertainty needs to be balanced with all the benefits that plastic brings to our daily lives and translated into proportionate measures. Although the EU Plastic Strategy concerns plastic pollution in a broad sense, it does specifically address microplastic as a rising problem that needs to be researched and that requires innovation.

Because of the growing public concern worldwide on the magnitude and potential harms caused by the plastic pollution, it would be expected that the release of microplastics into the environment had been regulated already in various legal documents. Examples of relevant European legislation could be the regulation on contaminants in foodstuffs (EC 1881/2006), the regulation on cosmetic products (EC 1223/2009) or the regulation on food contact materials (EC 1935/2004). However, at this moment, none of these EU regulations mention the regulation of microplastics specifically. In the current research we will address the factors that make microplastics a difficult field to regulate, or whether specific regulation is not needed.

Apart from the EU level, several EU Member States, have introduced legislation to ban intentionally added microplastics in cosmetics. France has taken the lead in this, followed by countries like Denmark and Belgium, with a ban on microplastics in rise-off cosmetic products in 2016 (Kentin & Kaarto, 2018). As a response to these national actions, the European Commission has asked the European Chemical Agency (ECHA) to perform a risk assessment and provide advice on how to deal with this issue. ECHA is currently working on a proposal for the European Commission to limit the use of intentionally added microplastics via the REACH regulation. REACH stands for Registration, Evaluation, Authorization and Restriction of Chemicals. This regulation is the founding regulation of ECHA, enacted in 2006, and has the goal to achieve a high level of protection of consumers and the environment. REACH therefore uses the precautionary principle as its guiding principle, to ensure safety on the long term, also in complex and uncertain situations (European Commission, 2006). By restricting the use of intentionally added microplastics via the REACH regulation, it seems to be recognised that a precautionary approach is appropriate to deal with, at least intentionally added, microplastics. However, it should be recognised that intentionally added microplastics are only a small proportion of all the microplastic pollution in the environment. This leaves open the potential regulation of secondary microplastics, which develop from the degradation of larger plastic particles.

Research question

In the current case study we will analyse if the conceptual core of the precautionary principle, and in particular scientific uncertainty, complexity and ambirguity, is present in the case of microplastics in cosmetics and food in relation to human health risks. Additionally, we aim to understand the complexities and controversies around the potential application of the precautionary principle in the risk governance of microplastics in cosmetics and foods in the European Union.

1.2 Key timeline

Political	*Legal*	*Science/risk assessment*	*Public debate*	*Other*

Year	Event	Relevance to case study
1950s	Industrial development led to large scale plastic production	Plastic pollution in the environment started to take problematic forms, leading also to the development of secondary microplastics.
1990s	Cosmetics industry introduced microplastics in their products	Primary microplastics started to get released directly into the wastewater and build up in fresh water and sewage sludge.
2008	EU Marine Strategy Framework Directive (Directive 2008/56/EC) went into force	Goal of this directive is to achieve a Good Environmental Status of the marine environment by 2020. Reducing pollution is one important aspect of this goal.
2013	'Green paper on a European Strategy on plastic waste in the environment' got published by the European Commission	Aim of the green paper is to learn the views of citizens and other stakeholders on how to make plastic products more sustainable, how to reduce generation of plastic waste and how to decrease the impact of any plastic waste that does enter the environment.
2015	Danish Environmental Protection Agency published a report on occurrence, effects and sources of release to the environment of microplastics in Denmark	This report by the Danish authority was one of the first risk assessments by EU countries, on primary and secondary microplastics.
2015	'Opinion of the Committee of the Regions on the better protecting of the marine environment' got published	The Committee of the Regions recognized the long-term impact of microplastic pollution on the (marine) environment.
2015	USA released the Mircobead-Free Water Act	USA is the first country worldwide to ban intentionally added microplastics in cosmetics

2016	France bans intentionally added microplastics in cosmetics	France is the first EU Member State to ban intentionally added microplastics in cosmetics. Reason for this ban is to protect the environment.
2016	'Statement on presence of microplastics and nanoplastics in foods, with particular focus on seafood' was released by EFSA	The EFSA panel on contaminants in the food chain (CONTAM) prepared a statement, based on a scientific assessment, on the presence of microplastics in food. It is concluded that more scientific research is needed.
2018	The European Commission released the European Strategy for Plastics.	EU-wide policy to reduce single-use plastic, together with other actions attempting to limit the formation of secondary microplastics, are based in this strategy
2018	European Parliament called for a ban on intentionally added microplastics in inter alia cosmetic products.	Following the French ban of 2016, the EP is looking into options to ban intentionally added microplastics across the EU.
2019	European Chemical Agency (ECHA) wrote a restriction proposal for intentionally added microplastics via the REACH regulation	Based on a risk assessment, ECHA concludes that intentionally added microplastics should be limited.
2019	Public consultation was opened as a response to ECHA's restriction proposal	A public consultation was held for a period of six months, for the public to respond to ECHA's restriction proposal. In this consultation period, input was mainly provided by industry and environmental NGO's.
Expected June 2020	Final opinions on the restriction proposal by the Risk Assessment Committee and the Socio-Economic Assessment Committee of ECHA	Based on these documents, the European Commission will take a decision on the limitation of intentionally added microplastics in cosmetics.

2. Microplastics

As mentioned previously, microplastics is a name for a collection of synthetic polymers, with a large variety of characteristics but all with a size of smaller than 5 mm. Microplastics have not been developed on purpose, as a solution to one clear issue. Rather, it is a side effect of the growing use of plastic in a wide variety of uses. The mass production of synthetic polymers, better known as plastics, has started in the 1950s (Duis & Coors, 2016). The innovation and mass production of plastics has been a great contributor to the growing wealth in the western world. Because plastic is, in comparison to other materials, low costs, low weight and highly resistant to heat and chemicals. This makes plastic suitable for many applications (Thompson, Swan, Moore & vom Saal, 2009). These benefits have resulted in its wide applications and big success all over the world. For example, in cars and planes, the use of plastic reduces the weight of the vehicle, leading to lower CO2 emission and fuel costs. In packaging materials, plastic is a good alternative for other materials such as glass and metals, because of its flexibility and low weight. In clothing and other fabric applications, polymers are used for their high durability and ability to take up dye while being waterresistent. In some of these examples, plastic could actually be seen as a more sustainable alternative to the traditional materials, because of its lower weight and longer life span compared to its traditional alternatives (Andrady & Neal, 2009). However, with the wide application of plastic came not only wealth, but also potential disadvantages and criticism. To a large extent, these downsides are related to the great amount of plastic waste ending up in the environment. This includes spreading of (micro)plastic particles through the air, water and sewage systems. Ultimately these particles pile up in the environment, for example in the Great Garbage Patch, where they stay around for a very long time, due to their very low degradation rate. Given the large amount of plastics used over the years, together with a low attention for correct plastic waste disposal, the pollution of plastic in the environment has become a well-known problem of global proportion (Sun, Dai, Wang, van Loosdrecht, 2019). So interestingly, where the sustainability and longevity of plastic were initially mentioned as a benefitial product characteristic, these characteristics are a disadvantage when it comes to plastic waste ending up in the environment. Over the last years, these downsides of the widespread use of plastics have gained more and more attention in the public debate, also attracting scientific and regulatory attention.

From the widespread plastic pollution develops the issue of secondary microplastics. Secondary microplastics are defined as microplastics particles that have not been intentionally produced as such, but have developed as a breakdown product from other applications of plastics (Branhey, Hallerud, Heim, Hahnenberger, Sukumaran, 2020). A large part of the microplastic particles in the (aquatic) environment develops through this breakdown from bigger pieces of plastic pollution. Additionally, washing of synthetic textiles and wearing of tyres are important contributors to microplastic pollution, via various routes. Washing of synthetic textiles releases many microfibres, which end up in the wastewater and later on in freshwater. Microplastic particles released from tyres spread mostly via the air and pile up in the water stream. Already in the 1970, the occurrence of microplastic as breakdown product from bigger pieces of plastics was recognised as a problem in the aquatic environment (Carpenter, Anderson, Harvey, Miklas & Peck, 1972). In the meantime several regional sea conventions and action plans have been put into place to limit the amount of (micro)plastic pollution. This includes i.a. The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989), The UN Open-Ended Informal Consultative Process on Oceans and the Law of the Sea (1999) and the G20 Action Plan on Marine Litter (2017). Most of these actionplans focus on the environmental burden of plastic pollution and appeal to the moral obligation to not polute the oceans any further. Zooming in on the human health effects, these documents recognise that there are many knowledge gaps with regard to specific harmful effects (United Nation Environment Programme, 2016). Therefore, uncertainty with regard to microplastics relates mostly to the health effects for humans and animals. This provides potential room for the application of the precautionary principle.

Apart from the microplastics that develop from the breakdown of bigger pieces of plastic, there are intentionally added microplastics. This is a more recent development, which started around the 1990's in cosmetic products (Kentin & Kaarto, 2018). Microplastics are added to a wide range of cosmetic products, e.g. shower gels, toothpaste and scrubs. Their role to provide specific product characteristics, such as exfoliating, cleansing, tooth polishing or modifying viscosity of the product (Leslie, 2014). In the past, these functions where performed by natural substances such as sand or sugar. They were replaced by microplastics as cheaper and more constant alternatives (Guerranti, Martellini, Perra, Scopetani & Cincinelli, 2019). Since this mostly concerns wash-off products, the microplastics are directly released into the wastewater system. Although a large part of them are filtered out, they do end up in large scale in sewage sludge and fresh water. Since sewage sludge is used as fertiliser on land, this is an additional route of exposure for microplastics to be spread through the environment (Mahon, O'Connell, Healy, O'Connor, Officer, Nash & Morrison, 2017).

Currently, the exact amount of microplastics present in the environment is still debated. Recent insights, published in May 2020, from the Plymouth Marine Labortory in the UK suggested that the amount of microplastics has been underestimed until now (Lindeque et al, 2020). This underestimation can be seen as an illustration of how difficult it is to adequately measure microplastic particle once they are in the environment. This difficulty relates to the large variation in particles, with regard to its size, shape and materials, and the sensitivity of the measurement tools. Since there is no clear universal definition of a microplastics, different stakeholders advocate a different way of measuring microplastic pollution.

The developing attention for microplastics over the last years could be seen in line with the growing attention for climate change, sustainability and plastic pollution in general. Where in the past the focus was mostly on economic growth and development, the public opinion seems to have shifted in a way that is also focused on long-term effects for the environment. The European Green Deal can be seen as a concrete expression of this development. Consequently, also more and more research funding and research effort has been going to studying the long-term potential harmful effects of microplastics pollution. This can be seen in the increased number of scientific publications over the last ten years.

Although the attention for microplastics is growing in academia as well as in society, regulations to deal with the widespread appearance of microplastics is not yet in place. Dealing with microplastics on EU level is a complex policy area, with many different facets and disciplines involved. Potential consequences take place in the environment, with regard to human and animal health, but also there is an economic and sustainability perspective to the discussion. The perception and explanation of the risks and benefits of microplastics can depend of the specific angle that various stakeholders take. Several of these perspectives will be discussed in this report.

3 Scientific uncertainty about risks

3.1 Risk/threat

3.1.1 Potential risks

From a scientific perspective, the concept of risk constitutes of two parameters; namely, hazard on the one hand and probability of this hazard to happen on the other hand (Stirling, 2008). To gain insight in the potential risks of microplastics, we need knowledge on the hazards potentially caused by microplastic and the likelihood that these hazards happen, looking at the current exposure level in the environment and in the human body. In this paragraph we will discuss the scientific literature on the potential risks of microplastics in cosmetics and food products, by looking at the literature on hazards and exposure.

Both primary and secondary microplastics have a different route of exposure and involve other potential hazards. Where primary microplastics are directly released into the sewage system with the use of cosmetic products, secondary plastics are more present in the marine environment via breakdown of bigger pieces of plastic pollution. All these microplastics can lead to a disruption of the aquatic ecosystem and potential health risks for humans and animals, when being ingested.

Microplastics are known for their very slow degradation and therefore they can stay in the environment for an undefined period of time. This combination of being present in large amount and for such a long time creates a build up of microplastic particles and leads to high exposure of microplastics in the environment. Mere presence of microplastics creates an unpredictable situation for the environment and is generally perceived as undesirable. Determining the exact amount of microplastics present in the environment is however very complicated, due to several reasons. It was already mentioned that no general definition of a microplastic exists, and that a great variety in materials, shapes and sizes is present, which might correspond to different consequences. Additionally, the structure and size of the microplastic particles changes under the influence of high temperature or UV radiation, which is especially likely to happen over such a long exposure time. Depending on the specific polymer, this can include all kinds of changes, making the particles more brittle and vulnerable to breakdown into nanoparticles (World Health Organisation, 2019). These changes make it harder to measure the presence of microplastics, which is necessary to calculate the risks of microplastic exposure in the environment. Additional to the changing *amount* of microplastic particles, the alteration of the structure and composition of the particles might also change their hazardous properties.

Although the exact amount is uncertain, the presence of large amounts of microplastics in the environment has been established conclusively (Mrowiec, 2018). Potential risks resulting from this presence can be found in different directions. Because of their small size and wide spread across the aquatic environment, sea animals can easily consume them. Of course primarily this can lead to consequences for these animals, such as risk of suffocation. These consequences are often depicted in the media, when reporting on plastic pollution (De-La-Torre, 2020). Subsequently, the consumption of microplastics by sea animals, can potentially lead to human risks as well. Namely, via the consumption of seafood, especially when eating whole animals such as mussels, the human intestinal tract gets exposed to microplastics (De-La-Torre, 2020). However, scientific literature on specific human health effects is very slim at the moment. A small research, including only eight participants from various countries, showed the presence of microplastics in human stool samples (Schwabl et al, 2019). Although this research was very small in terms of number of participants, it does provide proof for the hypothesis that humans carry pieces of microplastics in their intestines and is a motivation for future research.

With the growing public attention for (micro)plastic pollution, the research into human health effects is also developing. At this moment it is known that humans get exposed to microplastics via several routes of consumption, coming from sea food, but also from beer, table salt and drinking water and via air (Kosuth, Mason & Wattenberg, 2018). However, the fact that microplastics are found in the intestinal tract does not directly mean that humans necessarily experience harmful effects from this exposure. Namely, as we have described before, the risk arises from the hazard in combination with exposure. At the moment, scientific uncertainty prevails when assessing the potential hazardous consequences of these ingested particles on human health (Koelmans et al, 2019). To get a better understanding of potential health effects, it is important to know whether particles pass through the first cell layer of the intestine and have the ability to enter tissues or cells. This is crucial information to understand where microplastics can interact with cell mechanisms and potentially cause a variety of health problems. At the moment, little is known about the route that microplastics travel inside the human body. Assessments by the European Food Safety Authority (EFSA) and the Food and Agriculture Organisation of the United Nations (FAO) carefully estimated that only a very small percentage of the microplastics consumed by humans are actually absorbed by the intestine (EFSA Panel on Contaminants in the Food Chain, 2016; Lusher, Hollman & Mendoz-Hill, 2017). The majority of the microplastic particles, especially the relatively large particles, are expected to directly pass through the body. In this estimation, it needs to be taken into account that there is large variation in the size of microplastic particles and that the intestinal epithelium (the first cell layer of the intestinal wall) functions as a natural barrier to avert foreign substances (Stock et al, 2019). Therefore, it is expected that only relatively small microplastics can be absorbed in the body and bigger particles will be directly excreted via faeces.

But even when looking past the potential low absorption rate of actual particles, academic literature is not consistent with regard to the hazards caused by microplastic consumption in humans, eventhough associations have been suggested with a variety of health outcomes. A recent review on the human health effects of microplastics mentioned a large number of outcomes potentially being related to microplastic ingestion, including oxidative stress, cytotoxicity, chronic inflammation and increased risk of cancer, neurodegenerative diseases and autoimmune diseases (Prata, Da Costa, Lopes, Duarte & Rocha-Santos, 2019). However, evidence for these health effects has come solely from in vitro studies and animal studies, inter alia in zebra fish and mice (Lu et al, 2016; Furukuma & Kujili, 2016). The level of evidence provided by this methodology cannot directly be translated to the human level and is therefore limited to provide certainty. At this moment, human evidence with regard to long-term health effects on population level is lacking. On a mechanistic level, an explanation for the relationship between microplastics and these health outcomes can partly be found in the increased production of reactive oxygen species and free radicals, which cause damage to cells in the body. Already in the 1990's animal research showed that orally administered pieces of microplastics had the ability to travel from the intestine to the blood stream (Eyles, Alpar, Field, Lewis & Keswick, 1995). Additionally, research has suggested that the health consequences caused by microplastic intake can in theory take contradicting forms. On the one hand, ingestion of microplastics has been linked to deficit of digestive enzymes in fish, which resulted in lower nutrient uptake (Wen et al, 2018). On the other hand, research suggests that ingestion of microplastics might actually lead to more energy intake, by means of increased energy demand, which was demonstrated in mice (Deng, Zhang, Lemos & Ren, 2017). All this information contributes to the situation of uncertainty with regard to animal and human health effects of microplastics.

Apart from the potential risks caused by the pieces of microplastics themselves, microplastic particles carry other chemical substances on their surface or inside the particle. Via degradation, these additives can leak into the intestine and potentially lead to all kinds of problems (Smith, Love, Rochman & Neff, 2018). In this way, also relatively large microplastic particles can still potentially cause harm when they pass through the body (Toussaint et al, 2019). These chemicals include endocrine disrupting chemicals

(EDC), such as bisphenol A and phthalates, but also coloring substances and flame retandants. These substances are frequently applied to plastics for various reasons, such as improving the flexibility of the plastic. Since these chemicals are smaller than the microplastic particles, they are capable to travel through the bloodstream. EDC have been linked to a large variation of different health effects for men and women, although the scientific evidence for specific health effects is still not conclusive (Rochester, 2013; Tsai, 2006). As the name indicates, EDC have the ability to interact with hormone receptors. Potential health risks are therefore mostly related to the hormonal system. In women this exposure might lead for example to breast cancer, whereas for men it has been linked to prostate issues (Lynn, Rech & Samwel-Mantingh, 2017). However, the fact that the link with hormone receptors is possible, does not directly translate in the development of specific health effects. Additional to the potential health effects, EDC also add to the environmental burden of the plastic contamination. Because of the long time that the plastic particles are in the water, it becomes inevitable that the chemical additives leak into the water, where it gets very complex to be detected and removed. In the same way, it has been suggested that pieces of microplastics can carry micro-organisms, such as bacteria and viruses, which have the ability to cause all kind of diseases (Padervand, Lichtfouse, Robert & Wang, 2020). This again leads to uncertain risks for the environment and for animal and human health.

Although the scientific base for health risks caused by microplastic exposure in foods is still thin, there is no reason to believe that the exposure or hazards are specific for certain groups of people in society. Microplastic pollution is a widespread problem and the food products that transport microplastics from the environment into the human body are consumed in all layers of society. Although no difference in the exposure to microplastics are expected for specific local communities, there is specific concern for future generations (Galloway & Lewis, 2016). Additional to the wide spread of potential health risks that might relate to microplastic pollution, this concern is fed by the fact that microplastic pollution is so widespread and once in the environment, not many options are available to get them removed. The United Nations has even referred to the microplastic pollution as growing concern to a number of human rights, such as the right for future generation to have a clean, healthy and sustainable environmet (Galloway & Lewis, 2016).

3.2 Scientific analysis

Scientific research, which functions as the basis of the risk assessment process, on the health effects of microplastics is relatively new. In earlier decades, research on (micro)plastics was focussed on environmental effects and the amount of pollution. Since approximately ten years, scientific research has shifted towards potential human health effects. Consequently, not much long-term evidence is available yet and no definitive, scientific answer has been provided with regard to the relation between microplastics exposure via food or cosmetics and harmful effects on human health. As described in paragraph 3.1, most available evidence has been collected via animal models and in vitro studies.

Apart from research at universities and research institutes, European agencies and other regulatory bodies have written scientific analyses on microplastics. Aim of these analyses is to map the potential consequences of microplastic pollution for health and the environment. In 2016 the European Food Safety Authority (EFSA) reported a statement on microplastics in food, with a focus on seafood (EFSA Panel on Contaminants in the Food Chain, 2016). This focus on seafood was justified because the highest level of exposure to microplastics is coming from seafoods, since these animals are consumed together with the intestinal tract. Using a conservative scenario, EFSA estimated that consuming a portion of 225 grams of mussels could lead to the ingestion of 900 microplastic particles, which corresponds to approximately 7 micrograms (EFSA Panel on Contaminants in the Food Chain, 2016). Although EFSA states mussels as the food source that contains the most microplastics per unit, there can be an accumulative effect of multiple food sources. Microplastics have been found in beer, drinking water, table salt and honey. Additionally, fishmeal is often fed to poultry and pigs, and via this route microplastic can end up in non-fish food products as well. With regard to the toxicity of microplastics and consequently the human health effects, EFSA comes to the conclusion that a large knowledge gap exists. No reference methods for sampling or analysing microplastics are available yet, which can explain big differences among studies. Additionally, sampling and analysing harmful effects gets complicated by potential contamination with microplastics coming from the air, clothes or even the measurement tool itself. Ultimately, EFSA concluded that toxicological data on human health effects of microplastics are not available, which makes a human risk assessment not possible at this moment (EFSA Panel on Contaminants in the Food Chain, 2016).

In 2019 'a scientific perspective on microplastics in nature and society' was written by SAPEA (Science Advice for Policy by European Academies) (Koelmans et al, 2019). SAPEA is part of the European Science Advice Mechanism of the European Commission (SAM) and brings together scientific evidence from all kinds of scientific disciplines. In their 2019 report, microplastics are discussed from the perspective of natural science, social science and regulatory science. Interestingly, the report has marked all collected evidence as 'what is known', 'what is partially known' and 'what is unknow', related to the level of uncertainty. This approach increases transparency and makes it well organised for interested readers. SAPEA comes to the conclusion that, although the information on effects of microplastics is growing, it will remain a complex topic. This complexity is explained, inter alia, by its great variability in substances. They also conclude that scientific uncertainty on human health effects remains, as not enough evidence is available to perform a human risk assessment. Different than the EFSA report, SAPEA stresses the high excretion rate in humans. Since most microplastics leave the body directly, SAPEA seems to see less reason for direct concern. As part of that argument, they refer also to the fact that much of the research on toxicological effects has been performed with microplastic concentrations much higher than normally present in the natural situation. This leads to a potential overestimation of the harmful effect and, more important, limits the reliability of the risk assessment (Koelmans et al, 2019).

Additional to SAPEA and EFSA also the European Chemical Agency (ECHA) has performed a risk assessment on intentionally added microplastics in 2019. They have concluded the accumulation of primary microplastics is mostly a problem on the land, where sewage sludge is spread as fertilizer (Corradini, Meza, Eguiluz, Casado, Huerta-Lwanga & Geissen, 2019). Sewage sludge contains a high amount of intentionally microplastics, because the microplastics in cosmetic products are directly released into the wastewater stream, where they pile up in sewage sludge. To limit this spread of microplastics, ECHA has put forward a proposal to restrict the use of intentionally added microplastics (European Chemical Agency, 2019). This proposal focuses is very much on the exposure of microplastics in the environment, instead of the potential hazards, which are both needed to determine the risk. ECHA argues that the long-term presence of microplastics, with unknown hazardous effects for the environment, is undesirable in itself. Intended goal of this restriction is therefore to limit the emission of microplastics by approximately 85% in the next 20 years (European Chemical Agency, 2019). The proposed restriction by ECHA only involves synthetic polymers and specifically excludes biodegrable polymers. Before this proposed restriction can go into force, several steps need to be taken. First, this initial proposal has been subject to a public consultation, with mostly comments of industry and NGO's. Often heard comments relate to the definition of the microplastics. Several comments mentioned that a differentiation should be made between different types, sizes and shapes of microbeads. Other parties argue that the definition of 'microbead' is too specific and should also concider other microplastic particles. At the moment, ECHA's Risk Assessment Committee and the Socio-Economic Assessment Committee are evaluating the ECHA proposal, to come to a conclusion on the proposed limitation. The outcome of these committees will be forwarded to the European Commission, who has the role of risk manager. Following a comitology procedure, involving the Member States, a final decision will be made on the restriction of intentionally added microplastics.

3.3 Scientific uncertainty

Scientific uncertainty is one of the key components in applying the precautionary principle. To study the level of scientific uncertainty in the case of microplastics in food products and cosmetics in relation to the environment and human health, the current paragraph will assess the strongly linked risk properties of complexity, uncertainty and ambiguity.

3.3.1 Complexity

We use the definition of complexity as provided by Renn, Klinke and Van Asselt (2011): "the difficulty of identifying and quantifying causal links between potential candidates and specific adverse effects" (Renn, Klinke & van Asselt, 2011). To understand the case of microplastic, we can observe complexity on different levels. For example, complexity in relation to its appearance forms, different routes of exposure and potential measurement tools.

Research has indicated that toxicology of microplastic depends largely on the polymeric composition, shape of the plastic particle, the surface area, density of the material and the added chemicals on the plastic particle surface (Hale, 2018). However, large variation exists in the complete group of microplastic with regard to many of these characteristics. Consequently, no general definition exists of what a microplastic is.

As mentioned previously, plastic particles are classified as microplastics if they have a size between 0.001mm and 5 mm, with smaller pieces being referred to as nanoplastics (Koelmans, Nor, Hermsen, Kool, Mintenig & De France, 2019). This size range makes a big difference when it comes to human exposure, the way in which the particles are potentially taken up by the body and consequently the health effects that might be caused. This size variation does not only lead to complexity when it comes to making and enforcing regulations, but also in adequately comparing evidence coming from academic studies (Frias & Nash, 2019). The type of measurement tool that is available is one of the deciding factors in the quality of the scientific study. Namely, measurement tools can vary greatly in their specificity and validity. A clear illustration of this issue is the measurement of microplastic on a sandy beach or in sewage sludge, which are well-known places for plastic litter to accumulate. Relatively large pieces of microplastics, up to 1 mm, are often visually identified and picked by hand. However, given the context of the sandy beach or sewage sludge, it can be very difficult to correctly distinguish between plastic particles and e.g. sand grains (Duis & Coors, 2016). To identify smaller pieces of microplastics, fine sieves and density separation are often applied techniques. However, the accuracy of the measurement has shown to depend on the type of measurement tool that is used. For example, the specific size of the sieve can lead to an over- or underreporting of the quantity of microplastics, compared to other sieves (Duis & Coors, 2016). Since not one standardized measurement tool is available, this is a well-know issue that reduces the generalisability of scientific evidence and makes it difficult to compare studies (Directorate-General Research and Innovation, 2019).

Another factor contributing to the complexity of microplastics is the fact that there is a wide variety in materials. Most microplastic particles are some kind of synthetic polymer, such as polyethylene, polypropylene, polyvinyl chloride and polyurethane (Koelmans et al, 2019). All these particles have different shapes and characteristics on molecular level. Also, microplastics are available in a variety of forms, such as pellets, fragments, fibres, ropes, foams and film (Frias & Nash, 2019). These variations add to the measuring issue as described above, since different measurement tool might detect other shapes and materials of microplastic. Additionally, with regard to human health effects due to microplastics in food items, all these variations might lead to different interaction with human cells and tissues and therefore different health outcomes (Weithmann, Moller, Loder, Piehl, Laforsch & Freitag, 2018). Animal research has already shown that the polymer type, size, shape, water solubility and surface charge are crucial in relation to the uptake of microplastics into different body compartments and thereby to the level of toxicity inside the human body (Smith, Love, Rochman & Neff, 2018).

3.3.2 Uncertainty

Apart from the complexity relating to determining the risks of microplastics, there is a lot of uncertainty concerning the potential health and environmental effects of microplastics. Uncertainty can take two directions: uncertainty with regard to the specific hazards and uncertainty with regard to the likelihood of these hazards to happen (European Commission, 2017). A large part of the uncertainty and complexity can be traced back to the lack of consensus on one scientific or regulatory definition of microplastics. This makes that various stakeholders have different understandings of what is a microplastic and thus what are potentially relevant hazards. Interestingly, this variation in definitions is already seen in rules and regulations that are put into place by various countries around the world, in an attempt to lower microplastic pollution. The lack of one clear definition, together with the lack of standardized measument techniques, makes it complicated to do research and make general statements on the potential health effect of microplastics in a general sense. Namely, different materials and different shapes and sizes will lead to other relevant hazards, for example by interacting with certain enzymes and cell structures in the body. Also the exposure to microplastics in humans will vary between different types of microplastics. Therefore, the lack of one clear definition leads to uncertainty when it comes to defining the risk of microplastics as one general outcome.

Reaching consensus on one uniform definition and develop standarized measurement tools for microplastic particles will be an important step in reducing the uncertainty of the microplastics discussion. Setting such standards will help in the collection of scientific evidence and later on in performing a risk analysis. However, when focussing on the potential risk of microplastics for human health, this will not completely solve the scientific uncertainty. The important point that needs to be taken into account in understanding the risk is to know whether the alleged health outcomes are actually caused by exposure to microplastic, and not by other substances. Especially in the case of food intake this is challenging, since many confounding factors, such as other nutritients or physical activity level, can potentially explain health outcomes like inflammation or problems related to metabolism (Willet, 2012). Additionally, it can be argued that it is not ethically acceptable to expose people deliberately to high concentrations of microplastics and its adhesive endocrine disruptors in a randomised controlled trial. Consequently, research on human health effects of microplastics is largely depending on observational research designs.

Finally, uncertainty is caused by an absolute lack of data with regard to the exact hazard and exposure of microplastics (Koelmans et al, 2019). This lack of data can be explained by the previously mentioned complicating factors such as no universal definition, large variety in size, materials and added chemicals. Especially with regard to human health effects, the scientific evidence base is very thin and mostly based on animal studies (Koelmans et al, 2019). Nevertheless, there is a clearly growing research interesting over the last few years, with a rapidly growing number of publications. Potentially this research interest is driven by the overall societal interest for plastic pollution and conversion towards a more sustainable world.

3.3.3 Ambiguity

The third risk property that is relevant for the precautionary principle is ambiguity, which refers to different interpretations of identical assessment results (Renn, Klinke & van Asselt, 2011). In the risk assessment of microplastics there is some discrepancy in how serious the uncertain human health risks are interpreted in the reports of EFSA and SAPEA. Where EFSA sees the lack of human toxicological data as reason to be cautious, SAPEA concludes that, due to the low uptake level in the body, this lack of toxicological data gives no direct reason for concern. Additionally, the risk assessment of microplastic is surrounded by a discussion on different types of bias, which were described previously in chapter 3.2 and will be further discussed on chapter 4. Shortly, it is known for long time that in many research fields, studies with null results (suggesting there is no harmful effect of microplastic on health) are more difficult to publish, giving a skewed presentation of the evidence. Studies reporting positive findings (suggesting there *is* a harmful effect of microplastic on health) are more likely to be published, regardless of their scientific method and quality (Easterbrook et al, 1991). Additionally, researchers have argued that a substantial part of the research has been performed with concentrations of microplastics that are unrealistically high (Koelmans et al, 2017). Both of these issues lead to a misinterpretation of the evidence, potentially resulting in an overestimation of the harmful effect whilst disregarding the harmless outcomes. This is especially complicated, because the amount of unpublished work and the effect sizes found by these studies are not known and cannot be taken into account in establishing the level of misinterpretation.

Additional to interpretative ambiguity, on how to interpret the scientific data, we can also look at normative ambiguity. Normative ambiguity refers to different perspectives on the tolerability of the risk (Johansen & Rausand, 2015). In this regard it is interesting to look at the different perspectives of stakeholders such as industry and environmental NGOs. In the discussion on banning microplastics and reducing its presence in the environment, industry refers often to the differences between microplastics. Because particles are different in i.a. shape, size, polymer composition and water solubility, their potential toxicity for the environment and for human health might be different. Especially since not much scientific evidence is present of its exact harmful effects, industry argues that there is no reason for all microplastic particles to be banned in the same way. Additionally, the plastics branch organisation PlasticsEurope stresses the benefits of plastic product for our current state of welfare and actually mentions it as a contributor for sustainable solutions (PlasticsEurope, 2019). On the other hand, they do recognise the problem of marine litter and stress that action needs to be taken to reduce this (PlasticsEurope, 2018). In terms of a risk-benefits analysis, the high benefits that are attributed to (micro)plastics should put its potential risks in a more tolerable daylight, according to the argumentation of the plastic industry.

On the other hand there are environmental NGO’s which have a much lower tolerability to the potential risks caused by microplastic pollution. In November 2019 a group of environmetal NGO has published a position paper to urge the European Commission to ban intentionally added microplastics in cosmetics (European Environmental Bureau et al, 2019). Their view is as follows: although specific hazardous effects for human health are scientifically uncertain at this moment, the mere presence of the large amount of microplastics in the environment is undesired. One of their main arguments in the requested ban is that the function of the microbeads in cosmetic products can be replaced by natural subsitutes. In the past, natural products such as sand, clay or sugar performed the function of microplastics in cosmetics. Therefore the environmental NGOs argue that intentionally added microplastics in cosmetics pose risks to the environment and to human and animal health that are unnecessary and can relatively easily be avoided by going back to these natural alternatives. Looking back at the risk-benefit analysis, the environmental NGOs come to a substantially different conclusion when weighing the potential risks with the benefits of microplastics in cosmetics.

3.4 Relevance of the precautionary principle to the case

The precautionary principle has been defined in different ways by various (international) institutes/organisations. Scientific uncertainty with regard to potential harm is one clear comon denominator in these working definitions. As described in this chapter, the discussion on microplastics is surrounded by scientific uncertainty. Only little scientific evidence on harmful health effects for humans is present and the quality of this evidence is debated. This scientific process is seriously complicated by the lack of a clear definition of what a microplastic is and large variation in the type and shape of microplastic particles. Another aspect that is mentioned in some definitions of the precautionary principle is the irreversibility of the potential harm. This is for example mentioned by the European Environment Bureau and in the Rio declaration on Environment and Development of 1992. Irreversible harm seems to be very much applicable to the case of microplastics and its pollution in the environment. Once microplastic particles are being released into the environment, they will remain there for a long time. In this regard there is is no difference between primary and secondary microplastics. On the other hand, with regard to human health, there might be too little evidence to already speak about irreversible damage. The working definition of the precautionary principle as used by the World Commission of the Ethics of Scientific Knowledge and Technology (COMEST), which is part of UNESCO, mentions not only uncertain risks in the current situation but also uncertain risks for future generations. Given the very long durability of plastic particles, as mentioned in the previous paragraph, future generations are a realistic concern when dealing with microplastics.

We learned that all three characteristics of the precautionary principle, complexity, uncertainty and ambiguity, are applicable to the case of microplastics in food and cosmetics. Uncertainty on potential health risks is mostly caused by a lack of evidence and difficulties with regard to the definition and measurement tools of microplastics. Due to the complexity caused by the types of polymers, their size, added chemicals and other characteristics, it is difficult to make general statements on the potential consequences of microplastic pollution in food. Consequently, it is at this moment not possible to define concrete hazardous effects. Additionally, no long-term studies are available at this moment to assess the effect of microplastics in the human body. Therefore, the likelihood that a harmful effect will occur in a population cannot be determined. On the other hand, the persistence of (micro)plastic particles in the environment is well-known. Although the specific consequences of this presence are not yet known, this persistence in itself is undesired. Therefore, dealing with microplastics might not only be a matter for the precaution, but also a matter of the prevention.

Ideally, when performing a risk assessment, this should combine all information on the hazard and likelihood and conclude in a quantative expression of the risk. Based on this conclusion, an acceptable threshold for the risk can be determined and can function as a basis for policy measures. From interviews with highly placed officials in EFSA and ECHA, we learned that, based on the limited amount of scientific evidence available, and its debatable scientific quality, it is not yet possible to set such an acceptable risk level. This is visible in the lack of specific microplastic regulations.

In the end, the precautionary principle is a balancing exercise between the level of risk and the societal risk tolerance. Although the level of risk is not yet clear in this moment, scientific research is currently being conducted to create this knowledge. With this knowledge, it might be feasible to develop an acceptable threshold for the risk, which can be used in regulations. On the other hand there is the societal risk tolerance, which might change over time due to societal developments. In that light, the application of the precautionary principle might change over time, with developments in the tolerance to a risk. This is a very interesting realisation in the case of microplastics in cosmetics and food products. With the growing attention to climate change, sustainability and plastic pollution in the environment, the reduced societal risk tolerance, especially with regard to microplastics in cosmetic products, might explain the use of the precautionary principle to limit this type of environmental pollution.

4 Risk governance and the precautionary principle

4.1 Political/legal dynamics

When discussing the risk governance of microplastics, it is important to stress once more the difference between primary and secondary microplastics. Since primary microplastics are added intentionally, these will be easier to regulate compared to secondary microplastics, which are not intentionally added but develop as breakdown product of bigger plastic pieces. Expecially determining who is responsible for the plastic pollution and its potential consequences in the long term is a complex issue. Thus far, there is no European legislation in place to regulating the existence of microplastics, in cosmetics or in food, on the market on European level. Nevertheless, there are several documents that critically assess the way in which microplastics in food and cosmetics could be regulated. Additionally, some EU Member States and other countries, such as the United States, have undertaken action to ban the use of intentionally added microplastics. The current paragraph describes what these different forms of regulation look like and what is the role of the precautionary principle in these regulations.

One regulation where secondary microplastics might be expected is the regulation on Food Contact Material (Regulation (EC) No 1935/2004). This regulation aims to regulate i.a. "materials that can reasonably be expected to come into contact with food". From this very general description, it would be expexted that microplastics are covered by this regulation. Nevertheless, the regulation does not once refer to microplastics specifically. Potentially this can be explained because the regulation already dates from 2004, and the knowledge concerning microplastics was even more limited back then. However, in the mean time the existence of microplastics in food, especially in seafoods has been clearly proven. The regulation states that, before a substance can be used as food contact material, it needs to be granted community authorisation. To reach this authorisation, it is the task of the applicant to submit a technical dossier, containing all relevant information for the safety assessment, to their national authority. EFSA then reviews this provided information and comes to a conclusion on its safety in an opinion, which can lead to community autorisation. Implicitally, this procedure makes clear that food contact materials always concern materials that are intentionally used. This could be a reasonable explanation for not including secondary microplastics in this regulation. Since the microplastics in food are not intentionally added, this would complicate the enforcement of the regulation. Namely, it can be debated who is responsible for the presence of microplastics in food, e.g. the initial plastic producer, the government who is responsible for the level of plastic pollution or the merchant bringing poluted seafood on the market. Knowing who is responsible is an important decision to enforce the regulation and actually limit the amount of microplastics in food products. Since this cannot be determined, and together with the lack of a clear definition of microplastics and lack of reliable measurement tools, it seems not possible to regulate microplastics in food products via the food contact material regulation.

To develop more suitable regulations to deal with microplastics in cosmetics and food, the European Commission has various committees of scientists and other stakeholders in place to provide advice on the risks surrounding microplastics. One of the main Directorate Generals responsible in this field is DG Research and Innovation. In 2018 an initial statement by the group of Chief Scientific Advisors of the European Commission, who are part of the Scientific Advice Mechanism (SAM), was written with a scientific perspective on microplastic pollution and its impact (Directorate-General Research and Innovation, 2019). After a thorough assessment, including scientific and societal arguments, they have provided several recommendations on how to deal with microplastics on European level. Firstly, they stress the need to not only focus on microplastic pollution in the marine environment, which is often the case in this discussion, but give equal attention to pollution in air, soil and freshwater. With regard to regulating microplastic pollution, it was recommended to explore options within already existing legal instruments before developing new directives and regulations. Focussing on microplastic pollution in the environment, relevant documents can be the Water Framework Directive and directives with regard to wastewater treatment, application of sewage sludge as fertilizer and air quality. Apart from these legal instruments, it is emphasized that also softer voluntary measures, such as economic measures, can be taken to promote more responsible behaviour with regard to the use and waste management of microplastics. These activities stress the *prevention* of further plastic pollution, since it is known with certainty that the presence of microplastic in the environment is undesired. Also in designing these measures it is important to realise that microplastics is a very diverse group of polymers, with large variety in composition, shape and added chemicals. Legal as well as non-legal instruments to limit microplastic pollution in the environment need to be as specific as possible, to make enforcement of the rules possible.

To prevent microplastic pollution most efficiently, it was recommended by the Chief Scientific Advisors to target first specifically high-volume and high-emission sources of microplastics. This could include e.g. stringent standards for washing machines to reduce microplastic pollution from synthetic textiles, which is known to be a big contributor to the pollution. Interestingly, the Chief Scientific Advisors addressed that prevention of microplastic pollution should be politically and socio-economically feasible. E.g. lifecycle assessments, substitution alternatives and cost-benefit analyses should be taken into account when developing legal measures, to avoid the measures to be worse than the problem. It should not be forgotten that plastic also has numerous benefits over its alternatives, such as its flexibility, low weight and long durability. These pros and cons should be weight with respect to environmental issues, but should also include a social, economic and human aspect. In line with this approach, taking action to reduce microplastic pollution should be seen in the light of other environmental issues, such as the use of pesticides and heavy metals. In light of all these environmental issues related to sustainability and the future of the planet, various parties debate the priority that should go to microplastic pollution. Namely, according to the Scientific Committee on Health Environmental and Emerging Risks (SCHEER) of the European Commission, microplastic pollution is indeed one out of fourteen health and environmental risks currently faced by the European Union (Scientific Committee on Health, Environmental and Emerging Risks, 2018). On the other hand, the World Health Organisation requests more research, to get a better idea of the impact of microplastic on the environment and health before placing it as a top priority (World Health Organisation, 2019).

As a final yet very important recommendation, the Chief Scientific Advisors addressed the issue of low quality scientific studies and a lack of standardized measurement tools. This compromises the value of the scientific evidence and actually contributes to the uncertainty, especially regarding the human health consequences after consuming microplastics via food. These methodological issues need to be tackled in order to get to reliable and validated evidence, which is needed to base new policy on (Directorate-General Research and Innovation, 2019).

Zooming in on the legal framework concerning cosmetic products on EU level, it would be relevant to look at the Cosmetics Regulation, which is in place since 2009 (Regulation (EC) 1223/2009). The objective of this regulation is to assure the functioning of the internal market and a high level of protection of human health (article 1). Remarkably, this regulation does not mention intentionally added microplastics. It does refer to the related topic of nanoplastics. However, due to its much smaller size, these have a different way of spreading through the environment and potentially impacting human health. Namely, due to their smaller size, nanoplastics can migrate through the first layer of the intestine into the blood stream and interfere with cell mechanisms. Although the reason for excluding microplastics is not made explicit, this might relate to the idea that microplastics in cosmetics mostly cause issues for the environment and not so much for human health, which is the focus of the regulation. Due to its relatively large size, it is not likely that microplastic particles pass though the skin, in order to cause human health effects (De-La-Torre, 2020). Additionally, not mentioning microplastics in the Cosmetics Regulation can relate to the earlier mentioned issue that, without a clear definition of microplastics, the regulation could not be enforced.

Nevertheless, also without being included in the cosmetics regulation, legal actions are being taken to reduce the presence of intentionally added microplastics in the environment. At this moment, the European Commission is working on the decision to regulate the existence of intentionally added microplastics via the REACH regulation (European Chemical Agency, 2019). This regulation aims to register, evaluate, authorise and restrict chemicals in the EU, with the goal to ensure a high level of human health and the environment. The decision whether or not to include intentionally added microplastics in REACH will largely depend on the advice reports that are currently (summer 2020) being prepared by two ECHA committees, namely the Committee of Risk Assessment and the Committee of Socio-Economic Analysis. This decision might change the current situation in individual EU Member States. According to the REACH regulation, regulating chemicals that potentially pose a risk to the population should be harmonized across the EU, to avoid fragmentation within the European market. This means that once intentionally added microplastics are regulated via REACH, the opportunities for individual Member States to follow their national rules will be limited (Kentin & Kaarto, 2018). This is interesting in the light that several EU Member States and other countries have taken actions to limit the use of intentionally added microplastics in cosmetics in recent years. The United States was the first country worldwide to put a ban on intentionally added microplastics in rinse-off cosmetic products. The basis for this ban was found in the Microbead-Free Water Act. After a brief phase out period, the sale of cosmetic products containing intentionally added microplastics is prohibited since July 2018 (Strifling, 2016). This example was followed by a number of other countries, such as Canada, United Kingdom, Taiwan and South Korea. Since several years also individual Member States within the European Union have taken action to ban intentionally added microplastics. This started with France in 2016 and was followed by Italy, Denmark, Belgium and Sweden. The basis for these national bans is often the Marine Strategy Framework Directive (directive 2008/56/EC). This directive states that all Member States have the obligation to achieve Good Environmental Status, which relates to the marine environment being clean, healthy and productive. Therefore this directive does not only account for intentionally added microplastics, but for limiting plastic litter in the environment altogether. Interestingly, not all countries that have a ban in place apply the same definition of microplastic in their ban. Some countries only use a size restriction, whereas others also specify the shape, excluding soluble particles (Kentin & Kaarto, 2018).

Further analyzing the application of the precautionary principle in dealing with microplastics in cosmetics and food, we will now describe some key element of the principle, namely the threshold of damage, cost effectiveness, reversibility of the measure and the reversibility of the burden of proof.

Threshold of damage

Following from the little amount of scientific evidence, no threshold of damage for human health effects has been established yet. The lacking standard in measuring (the effects of) microplastics leads to large variation between studies and potentially leads to misinterpretation of results and miscommunication between researchers. Also, it is shown that research has been conducted with unrealistically high concentrations of microplastics, which leads to more spectacular results (Koelmans et al, 2017; Lenz, Enders & Nielsen, 2016). Especially when studying microplastics in a laboratory setting, in animals or cell lines, this can easily go undetected. Related to this problem of testing unrealistic exposure levels, is the problem of publication bias. This means that studies that show a harmful effect are more likely to be published compared to studies showing no effect. Since the studies with very high exposure levels are most likely to show harmful effects, compared to studies using a more realistic approach, these unrealistic studies are more likely to be published compared to its more realistic counterparts. In a topic such as microplastics, publication bias is especially problematic. It does not only impact the development of scientific knowledge, but it also impacts the opinion of the general public (Koelmans et al, 2017). By only publishing studies showing harmful health effects, without providing a clear explanation on how the study was conducted, this can easily make the public belief that there is a serious problem, whereas actually scientific uncertainty remains.

Another reason why setting a threshold of damage has not been established yet, has to do with the large variation in microplastic particles. As described before, there is no clear definition on what microplastic is. Microplastics in cosmetics do have some properties in common, for example that they are made from solid particles, insoluble in water and nondegradable (Leslie, 2014). Nevertheless, still much variation exists with regard to the specific polymer structure and the substances that adhere to their surface, such as endocrine disruptors. These variations between microplastic particles may lead to different levels of toxicity (Bhattacharya, 2016). This makes it very complex, to define one threshold of damage that can be applied to microplastics in general. As long as there is not more scientific evidence on the health effects caused by microplastics, it is not possible to set a threshold of damage. These problems could potentially be tackled by making use of more standardized research methods, setting realistic limits for the exposure of microplastics and the use of valid measurement tools and make use of a more critical publication process. Finally, more research is needed before a treshold of damage can be set, which is needed to formulate regulations on microplastics.

Cost effective/proportionality

The second important aspect of the precautionary principle is the measurement needs to be cost effective; the legal measure to prevent potential harmful effects of microplastics needs to be in proportion to the benefits brought by microplastics. When it comes to microplastics in cosmetics, these are added on purpose to enhance certain characteristics of the cosmetics. Prohibiting the use of these primary microplastics is relatively easy, yet can be very expensive for industry (Cosmetics Europe, 2019). Although the benefits of microplastics in terms of product characteristics are real, alternatives are available. For example, natural, degradable particles or fibres like coffee, sugar or salt can be used as replacement to synthetic polymers (Petsitis, 2018). Additionally, the industry does invest in the development of biodegradable microplastics.

With regard to secondary microplastics, the microplastics that break down from bigger pieces of plastic and end up in the food stream, establishing the cost effectiveness of restrictive measures is more difficult. Secondary microplastics break down from bigger parts of plastics, in all kind of applications, or develop in the washing of synthetic fabrics. More and more policies are put into place to reduce the use of (single-use) plastic and its waste in the environment. Indirectly, these policies also contribute to the limitation of secondary microplastics in the environment. Proportionality plays a role in these policies, to balance unnecessary plastic waste and environmental pollution with the beneficial aspects of plastics such as its low weight and long lifespan (Koelmans et al, 2019). For example, replacing plastic packaging materials with glass or paper can lead to disadvantages such as higher costs and weight, which also leads to more emission during transportation. In this way, plastic might be favourable, but extra attention is needed for disposing plastic waste. Additionally, plastic is used in many technical and medical applications, which have created also large benefits for society. Since it is not realistic in the current society to ban all plastic products, yet we need to find a way to deal with potential negative effects, a cost-benefit analysis needs to have a central place in this discussion (Eriksen, Thiel, Prindiville & Kiessling, 2018).

Reversibility of the measure

Another aspect to take into account when applying the precautionary principle is the question whether the measure is reversible. This should allow for new evidence on the potential risks to be collected, for a new risk assessment to come to a different conclusion, which consequently requires different (legal) measures. In the application of the precautionary principle it is therefore often seen that the measures are only put into place for a certain amount of time. After this period of time the newly collected evidence will be reviewed and this allows for a new conclusion on the risk or a prolonging of the precautionary measure. Looking at the proposal for intentionally added microplastics in cosmetics to be taken up in the REACH regulation, there is no end date included. Although the REACH regulation as a whole is based on the precautionary principle, allowing for measures to be changed when new scientific evidence comes to light, the measures concerning microplastics in cosmetics might therefore also be seen as a preventive measure instead of a precautious measure.

Reversibility of the burden of proof

In case the precautionary principle is applied, the reversed burden of proof indicates that a harmful situation exists unless proven otherwise. The burden of proof is therefore on the producer of the product surrounded with uncertainty, to proof that the product does *not* lead to risk for the environment or human health. For intentionally added microplastics in cosmetics, this is a very clear situation. The producer of cosmetics has the responsibility of showing its products are safe. Once the intentionally added microplastics are added to the REACH regulation, the burden of proof is on cosmetic companies accordingly. In order for a product with intentionally-added microplastics to be approved under REACH, the company has to provide evidence to ECHA showing the safety, for both environment and health, of the product.

With regard to secondary microplastics and the occurrence of microplastics in foods, such as seafood, it is much more difficult to allocate where the burden of proof should be. Following the General Food Law, each food producer has the responsibility to make sure the food that is put on the market is safe (Van der Meulen, Van der Velde, Szajkowska & Verbruggen, 2008). However, no measurement tools are available to establish the amount of microplastics in a validated and standardized way. It is therefore not realistic to pose this responsibility on the food producer, or merchant of the seafood. Also putting the burden of proof on the initial producer of the plastic might be difficult, since this producer has no controle over the plastic ending up in the environment and developing into microplastics.

4.2 Other governance dynamics

Microplastic pollution has gained much public attention in recent years. To a large extent, this movement has been generated by environmental NGOs, who put pressure on policy makers and industry to reduce the use of microplastics (Henderson & Green, 2020). With regard to intentionally added microplastics, the "beat the microbead" campaign of the Plastic Soup Foundation is a good example of this (Plastic Soup Foundation, 2012). By making use of an app, European consumers were asked to scan barcodes of cosmetics products. In this way, information was collected on a large scale on how many cosmetic products actually contained microplastics. It was found that the percentage of products containing microplastics varies per product group, with the highest percentage in facial cleaners. Moreover, it was found that producers of many of these cosmetic products indicate that they are working on phasing them out (European Commission, 2017). This gives support for the recommendation of the Scientific Advice Mechanism, stating that limitation of microplastics does not rely only on legal standards, but can also be promoted in a more voluntary way. Namely, with this campaign of the Plastic Soup

Foundation, awareness for the presence of microplastics in cosmetic products was raised in the general public. Consequently, cosmetic industry will feel more incentives to work on the replacement for microplastics, as the consumer demand for natural alternatives grows.

The growing public attention for the issue of microplastic pollution can be seen in a wider context of public movements. For example, the growing attention for climate change, circular economy, organic food consumption and reduced use of (single-use) plastic come together in the European Green Deal (European Commission, 2019). As part of this societal movement, behaviour of consumers and companies has been shifting towards more sustainable alternatives. A clear example of this can be seen in the reduced use of single-use plastic bags (Angus & Westbrook, 2019).

From a societal point of view, scientific assessment is not the only factor taken into account in adequately dealing with potential risks of microplastics. The mass media, including social media, has also taken up a great role in raising public awareness for the potential health effects caused by microplastics (Scientific Advice Mechanism, 2019). This is seen to impact the public behaviour, for example in reducing the use of single-use plastics and cosmetic products containing microplastics. Also research has shown, that not many people deny the plastic pollution problem and there is a feeling of co-responsibility in the public with regard to limiting the development of plastic pollution (Koelmans et al, 2019). Of course, only recognising the issue is not sufficient to accomplish behaviour change. When looking at the similar situation of climate change, it is known that not many people deny climate change. However, still the use of cars and planes has not been reduced. Nevertheless, recognising the problem is an important first step in coming to actual behaviour change.

Apart from performing scientific studies, scientists have also engaged in the public discussion on how to deal with the risks concerning microplastics. Several scientists have expressed the criticism that there is mismatch between the state of affairs in science and how this is presented in the media (Koelmans et al , 2017; Rist, Almroth, Hartmann & Karlsson, 2018). When microplastics are discussed in the general media, it is often mentioned in relation to ‘potential risks’, without clear stating of the situation of scientific uncertainty and lack of scientific data. Due to this type of framing, a mismatch might develop between the scientific understanding of the risk and the public perception.

5 Precautionary principle and its future

5.1 Reflection on the precautionary principle in the literature

In general, the precautionary principle seems relevant to deal with microplastics, given its upcoming regulation via the REACH regulation. The widespread and very long persistence of the microplastics in the water and soil, make microplastics undesired from the environmental perspective, and asks at least for the proportionality principle to be envoked (Verschoor, 2018). Especially the large unknowns with regard to animal and human health and specific environmental consequences on the long-term, ask for a precautious approach.

Although consensus exists on the *abundance* of microplastics in the environment and the complexity and uncertainty with regard to its consequences are widely understood, there is some criticism on the upcoming rules to deal with microplastics in cosmetics. This criticism is specifically coming from the Italian cosmetics industry. They are a large producer of products containing intentionally added microplastics. They mainly argue that limiting the use of microplastics as proposed in the REACH regulation is too cautious, by not making any distinction between different types of microplastics. Essentially, their criticism refers to the fact that not one definition of microplastics exists and therefore much variation exists between microplastics with regard to their potential effect on human health. Because of the lack of one definition, and because microplastics can change under influence of light and temperature, REACH uses a very broad definition, including all kinds of polymers. The rational behind this, is that all synthetic polymers are non-degrable and stay in the environment for a very long time. The Italian cosmetics industry argues that many differences exists between different types of microplastics and that it is therefore not a correct application of the precautionary principle to cover them as one and the same product in REACH (Chemical Watch, 2019). By being too cautious, industries could have to look for alternatives unnecessarily. Especially for small companies, it is argumented by the Italian cosmetics industry, finding alternatives to the microplastics can be a costly activity. In light of the cost-benefit analysis, the industry argues that the balance between the costs for changing to natural alternatives is not in balance with the potential harmful effects for some of the microplastics (Chemical Watch, 2019).

On the other hand, environmental NGOs argue that the precautionary principle is not applied strict enough and see loopholes for industry in the proposed ban for intentionally added microplastics in cosmetics via REACH (Plastic Soup Foundation, 2012). This loophole refers mostly to the way the proposed regulation deals with biodegradable microplastics. Namely, biodegradable polymers are excluded from the definition of microplastics and are therefore not subject of the proposed ban (European Chemical Agency, 2019). Although ECHA stresses that biodegradable microplastics are tested for their half-time in the marine environment and sediment, concerns from environmental NGOs remain. Additionally, NGO allegiance Rethink Plastics argues that the transition period, which allows industry to find replacement for intentionally added microplastics, is too long and thereby leads to unnecessary duration of plastic pollution (Chemical Watch, 2019).

5.2 Effect of the precautionary principle on innovation pathways

An interesting tension can be observed when looking at (micro)plastics and innovation. Initially, the development of plastics has actually been an important innovation in itself, which provided many benefits on a global level. It has replaced many products as a cheaper and multifunctional alternative in the i.e. fields of electronics, construction, food preservation and many medical applications (Scientific Advice Mechanism, 2019). Thereby, plastics are a good example of how quickly an innovation can integrate into an essential part of society, given that nowadays plastics are an indispensable part of our modern way of living. Also adding chemicals, such as bisphenol A and phthalates, to plastics was done as an innovation. These substances add certain product characteristics, such as flexibility, to the plastic in order to improve their use and sustainability. For instance in the use of tubes to transport fuel in vehicles or in medical equipment, these characteristics are of crucial importance. Unfortunately, the formation of secondary microplastics is an undesired side-effect of the great amount of plastic used and the lack of an adequate disposal system.

Now that plastic pollution has become a clear issue worldwide, innovation plays again a big role in this discussion. In 2018 the European Commission launched the 'European Strategy for Plastics in a Circular Economy', as one of the initiatives to help reach the Sustainable Development Goals (European Commission, 2018). This strategy aims to reduce the presence of plastic in the environment and contribute to a more circular economy. Thereby, the EU Plastic Strategy can be seen as a precautionary effort to reduce secondary microplastics, in an indirect way. Innovation plays a big role in reaching these goals. According to the press release by the European Commission in 2018 the reduction of plastic use is not seen as a problem, but actually a big business opportunity (European Commission, 2018). The European Commission recognises that the plastic industry is a big driver for European economy. Improving its sustainability will bring forward new business opportunities and accordingly create new jobs, while reducing the plastic pollution that stays around in the environment for a very long time.

Since the regulation under development, following the REACH regulation, focusses on intentionally added microplastics, most innovation is nowadays expected in this area. It is interesting to see that the use of microplastics in cosmetics has actually been introduced quite recently. They have a number of functions, inter alia to improve exfoliation and cleaning properties. In the past, these roles were fulfilled in most cosmetics by more natural products, which did not pollute the environment. Therefore, consumer organisation BEUC described these intentionally added microplastics an example of a 'regrettable innovation' (European Consumer Organisation, 2019).

Since the discussion on microplastics has been going for some years now, the cosmetics industry already took action to find replacement products. In 2015 the branch organisation Cosmetics Europe recommended to discontinue the use of microbeads in wash-off products. CosmeticsEurope phrased this recommendation as part of their responsibility to the environment. However, it is likely that it was already a preparation for the upcoming legal rules and changing societal needs. A survey among their members in 2018 showed that the use of microbeads in these specific wash-off products was already reduced with 97% (Cosmetics Europe, 2019). Potentially pressured by the societal discussion on plastic pollution and climate change and driven by the prospect of EU wide legislation, also other large cosmetic producers such as Unilever have been looking for alternatives for several years (Unilever, 2014).

5.3 Innovation principle

The innovation principle has been suggested by several industry partners, lead by the European Risk Forum, as an alternative to the precautionary principle (Business Europe et al, 2015). They argue that the precautionary principle is often applied in a way that is too precautious, thereby blocking innovation and reducing the competitiveness of European companies compared to their counterparts in other continents. The innovation principle is derived from the precautionary principle, but with a specific attention for the potential impact on innovation. Although the innovation principle has not been defined as a legal principle, several official documents by the European Commission have made mention of it (Renda &Simonelli, 2019). As mentioned in paragraph 3.5, Italian cosmetic producers mentioned that the role of industry is not represented sufficiently in the current proposal to limit the use of microplastics via REACH. Implicitely here a link is made with the innovation principle, by saying that the industry perspective should be weighted in setting boundaries for specific microplastics. However, in official documents this view is not discussed.

6 Synthesis

Microplastics is a highly relevant societal and scientific issue that is surrounded with complexity and uncertainty. Plastic litter in the oceans has been a growing problem for approximately the last fifty years (Andrady, 2015). The attention for microplastics has only peaked in the last decade. This growing attention seems to be not solely based in scientific insights, since the harmful effects of microplastics were already known in the 1970s. Although the presence of microplastics has been known for such a long time, academic research into human health effects due to microplastic exposure thrived more recently. Thereby, we can see that development of scientific knowledge does not happen in a complete vacuum, but is driven by societal attention for a subject. The growing attention for microplastic pollution seems therefore to be based in a broader societal development, with growing attention for the environment, climate change and organic food consumption. Especially the abundance of microplastics available in the environment, its very long persistence and the lack of scientific evidence with regard to human health effects, create an undesirable situation. We have found that the lack of knowledge and lack of legislation, especially with regard to microplastics in food and its consequences for human health, can be explained by several factors.

First, performing scientific research and setting a threshold of damage is complicated given that no uniform definition on microplastic exists. There is a great variability of nondegradable polymers and their structure changes in the environment, under the influence of light, water and temperature. Second, no standardized measurement tools for microplastics are available. In terms of scientific research, this makes it difficult to compare results from different studies. With regard to making legislation, valid and reliable measurement tools are needed in order to check for compliance with the rules. Overall, the scientific evidence on potential health effects for humans is very scarce. Additionally, in the case of microplastics in food, it is very complex to assign who is responsible for the potential risks on human health. This needs to be clearly defined before legislation can be enforced. Looking beyond the microplastics in food, we *do* know with certainty that microplastics are present in large amounts in the environment, in water, air and soil. The combination of their very long durability and the fact that they might leak chemical substances make it an unwanted situation for the environment, even regardless of the potential, consequential risks for animal and human health, now and in the future.

In the current European regulatory framework, microplastics in cosmetic products and in food are not yet specifically regulated. At the moment, efforts are being made by the European Commission to include microplastics in cosmetics in the REACH regulation, which is based on the precautionary principle. In 2019 ECHA published a proposal to restrict intentionally added microplastics, as their presence in the environment is so widespread and persistent over the very long term. Although this restriction is still under consideration with the European Commission, several Member States have already put similar bans in place, with the purpose to pursue a good environmental status. ECHA's proposal to include primary microplastics in REACH is found to be in line with the EU Plastic Strategy, as defined by the European Commission. This strategy is also largely based on the precautionary principle and has the goal to work towards a more circular economy. This strategy can be seen as an indirect attempt to reduce the development and release of secondary microplastics, coming from plastic litter or washing of synthetic textiles. Via this route, also the presence of microplastics in food products, with unknown consequences for human health, should be reduced. ECHA's proposal has been welcomed by various environmental NGO's, such as the European Environmental Bureau and the Rethink Plastic Alliance (European Environmental Bureau et al, 2019). Before the proposed limitation can be installed, the Committee on Risk Assessment and the Committee on Socio-economic Analysis of ECHA are still preparing an advice report for the European Commission. These documents are expected by the end of 2020.

It is interesting to see that the main focus of regulating microplastics is currently on intentionally added microplastics in cosmetic products. This could be expected from the perspective that primary microplastics are directly released into the environment and it is relatively easy to stop this route of pollution. However, primary microplastics account for only a small percentage of the complete worldwide microplastic pollution. Figures differ among countries, but the vast majority of microplastic pollution is not coming from cosmetics, but from other sources such as synthetic textiles, tyres and other plastic pollution. When it comes to secondary microplastics, coming from pollution in the environment, regulating their presence in foodstuff will be more difficult to target. This should be seen in the bigger context of plastic pollution, as secondary microplastics develop as a side-effect thereof. The EU Plastic Strategy is a clear attempt to discourage single-use plastics and work towards a circular economy. Via this route the development of secondary microplastics will be reduced over time, which could lead to a reduction in microplastics in food products. Additionally, as recommended by the Chief Scientific Advisors of the Science Advice Mechanism of the European Commission, microplastic pollution can be integrated in existing legislation regarding (waste)water, soil and air quality.

Looking at the different components of the precautionary principle, the risk characteristics of scientific uncertainty, complexity and ambiguity seem to be met. Zooming in on the legal practice and the key components of the precautionary principle, actually applying and enforcing the principle seems to be rather complicated, especially with regard to microplastics in food.

Learning from the literature and from interviews with high-placed officials at the European agencies dealing with microplastics, it seems that uncertainties and complexities mostly play a role in relation to the environment and human health. Relating to the specific topic of this case study, this uncertainty is expected to be bigger in relation to seafood in comparison to cosmetic products. Focussing on cosmetic products, it is mostly the *amount* of microplastics ending up in the environment that is the reason for putting in place regulations. In seafood, the presence of microplastics has been shown, but the potential consequences for animal and human health remain highly uncertain, due to different theories and very limited scientific evidence. When envoking the precautionary principle to deal with microplastics in foods, it should however be kept in mind that plastic actually was introduced in the Western world as an innovation that brought great advantages. In many situations (micro)plastics have been used as a replacer of other materials, which will have other disadvantages. In applying the precautionary principle it is therefore important to focus not only on the 'better safe than sorry principle', but also take into account the proportionality principle, substitution strategies, cost-benefit analyses and life-cycle assessments. This trade-off between plastics and other materials should be performed at different levels, in order to act responsibly with regard to the social, economical, environmental and human perspective.

7 Conclusion

We started this report with the aim to understand the complexities and controversies around the potential application of the precautionary principle for the case of microplastics in cosmetics and foods. Additionally we analysed if the conceptual core of the precautionary principle, and in particular scientific uncertainty, is present in the case of microplastics in cosmetics and food in relation to human health risks and how the precautionary principle has been applied in practice.

The discussion on microplastics is surrounded with scientific complexity and uncertainty. Although microplastics are known to be widespread through the environment, they are difficult fields to regulate. Firstly, there is no universal definition of a microplastic. There is a wide variety in materials, shapes and adhering substances, which might lead to different risks for the environment and human health. Secondly, once microplastics are in the environment, their structure and hazardous properties might change under the influence of light, water and temperature. Thirdly, the lack of high quality measurement tools makes it a complex field to study and to regulate. Finally, and crusial to the application of the precautionary principle: only very limited scientific evidence is present on the human health effects caused by microplastics consumed via food products. Although it does not seem likely that microplastic particles are taken up as a whole by the human body, no sufficient quality scientific evidence is present on this. On the other hand, there *is* certainty on the abundant presence of microplastics in the environment. This is the reason why the European Commission is currently working on a proposal to limit the use of microplastics in cosmetic products via the REACH regulation. The REACH regulation is in line with the conceptual core of the precautionary principle, in order to protect the environment from long-term, unknown harms. However, there is only a thin line between precaution and prevention in the regulation of microplastics in cosmetics. Namely, the integration of microplastics in REACH does not have an end date and requires no further data collection. Therefore, this might be more of a prevention measure instead of precautionary measure. Especially given that the abundant presence of microplastics will not be changed with new scientific insights.

When zooming in on microplastics in food, the focus is more on health effects instead of the environmental burden. Thus far, there is no regulation in this field. There is lack of scientific evidence with regard to the hazards and likelihood of these hazards in relation to human health. Based on these findings, the use of the precautionary principle would be justified. However, the lack of a definition, uncertainty on the treshold of damage and difficulty in appointing the party responsible for the microplastic in the food product make it impossible to formulate and enforce specific regulation. Nevertheless, the societal demand is growing to limit the presence of microplastics all through the environment, including in food products. Via the EU Plastic Strategy the use of single-use plastics will be discouraged. Resulting from this policy, over time also the formation of secondary microplastics and the microplastics in food should be reduced. These actions can be seen as more soft implications of the precautionary principle, in order to achieve a Good Environmental Status.

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