



# WP2 Selection of Case Studies

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## List of abbreviations

<b>CA</b>	Consortium Agreement
<b>CC</b>	Consortium Committee
<b>DOA</b>	Description of Action
<b>GA</b>	Grant Agreement
<b>PCG</b>	Project Coordination Group
<b>PO</b>	Project Office
<b>WP</b>	Work Package

## Table of Contents

<b>1. WP2 Selection of Case Studies</b>	<b>2</b>
<b>1.1 Intro</b>	<b>2</b>
<b>1.2 The Case Selection Process</b>	<b>3</b>
<b>2. Case study descriptions</b>	<b>5</b>
<b>2.1 Case-study 1: New Gene-Editing techniques</b>	<b>5</b>
<b>2.2 Case-study 2: Genetically Modified organisms (GMO's)</b>	<b>6</b>
<b>2.3 Case-study 3: Endocrine Disruptors</b>	<b>7</b>
<b>2.4 Case-study 4: Neonicotinoid insecticides</b>	<b>8</b>
<b>2.5 Case-study 5: Nano-technologies</b>	<b>9</b>
<b>2.6 Case-study 6: Glyphosate</b>	<b>10</b>
<b>2.7 Case-study 7: Financial risks and urban planning</b>	<b>11</b>
<b>2.8 Case-study 8: Artificial Intelligence in Health Care</b>	<b>12</b>
<b>2.9 Case study 9: Microplastics in food products and cosmetics</b>	<b>13</b>
<b>3 References</b>	<b>14</b>

# 1. WP2 Selection of Case Studies

*Note: This document fulfils delivery Delivery 2.3 and explains the case study selection process which was undertaken to arrive at the eight cases studies to be carried out in WP2. Delivery 2.1 Literature research on multi-case study analysis covers the theoretical component of criteria for multi-case study analysis. Those criteria are presented in delivery 2.2 as the comparative multiple-case design, which is the methodological framework developed in task 2.2. Thus deliveries 2.1 and 2.2 are tightly linked, and should be taken together as the overall case study framework for WP2. The comparative multiple-case design contains the practical methodological framework required by each partner to execute the case study analysis for task 2.3.*

## 1.1 Intro

This short document will introduce the RECIPES WP2 case studies and explain the case study selection process that was used to select the cases.

The overall aim of WP2 is to understand and explain the differences in the application or potential application of the precautionary principle in eight different case topics, in a way that reflects the particular context of the case study topic. The multiple case study component of the RECIPES project is one of the key analytical phases of the project.

As discussed in the case study conceptual framework (D2.1), a variety of methods exist for selecting the unit to be studied across the scientific disciplines. It is useful to consider the most common method from statistical analysis, random sampling. Suppose random sampling was used to select the WP2 case studies. Selecting from the population of existing EU precautionary principle cases would have been skewed towards topics which have existing legal cases, and those which have the most legal history. This would have potentially biased towards more clear-cut PP cases or ones which for various political reasons received more attention, as well as older technologies which have had time for PP legal activity to take place, at the expense of more pressing and potentially difficult to navigate technologies.

In multiple case study research the case selection method that is most often employed is known as theoretical sampling, whereby each case is carefully selected rather than randomly selected from the pool of possible cases. The most common method is to employ theoretical replication logic, where cases are select according to their appropriate fit with one another (Yin 2018). Theoretical replication describes intentionally choosing cases that replicate, counter, add to, or challenge the preliminary theoretical types and framework (Meyer, 5). Here, case selection is directed at pursuing informational richness, rather than representativeness. In other words, cases are not selected for their similarity with one another, but rather their potential to add to the overall understanding of a phenomenon.

As such, RECIPES used a theoretical replication logic to select the eight cases. This approach is has resulted in cases that can provide a more informed appreciation of how and why the precautionary principle has been applied successfully or failed in certain contexts..

## 1.2 The Case Selection Process

As discussed above, the RECIPES Consortium has selected eight case-studies by means of theoretical sampling, and a ninth case may still be added. The first seven cases were selected as part of the RECIPES project design, while the eighth case was designated as a stakeholder case study, and was selected at a later stage in the project. Afterwards, a ninth case study was added.

The eight case studies are:

1. New gene-editing techniques (i.e. CRISPR-Cas9)
2. Genetically Modified Organisms (GMOs)
3. Endocrine disruptors
4. Neonicotinoid insecticides
5. Nanotechnologies
6. Glyphosate
7. Financial risks and urban waste planning
8. Artificial Intelligence in Health Care (stakeholder case selected case)
9. Microplastics

A more detailed description of each of the case studies is given below in section 2 below. Nonetheless, it is immediately clear that this list presents a rich subset of case topics spanning EU geographies across a variety of cases – some with national and EU legal case histories, others where the appropriateness of the PP is only now being considered.

### *Initial seven cases*

The first seven cases were selected as follows. Maastricht University performed preliminary database research which showed that the most common areas where the precautionary principle is applied are health, environment and food. This finding was also later confirmed in the WP1 report. However, the RECIPES Consortium recognized the need to cover a broad spectrum of issues, and thus cases were selected to represent issues with high stakes, and which are therefore particularly suited for illuminating the complexity and controversies around the application of the precautionary principle.

The Consortium also stressed that co-creation would also mean that the final selection of the case-studies will also depend on the information obtained in WP1, in particular with respect to the public discourse. In line with full co-creation, **an eighth case-study** was then selected in a co-creative way together with the RECIPES advisory board.

### *Eighth Case study*

The eighth case was selected by means of input from stakeholders, whereby we used a selection process meant to tap into the insights of the RECIPES advisory board and partners, both in terms of their insight regarding relevant case topics and in filling in gaps in coverage from the seven initial cases. The steps for selecting the eighth case were as follows:

- 1) At the kick-off conference in January 2019, the consortium agreed to focus on a case involving technological innovation. Several preliminary case topics were then gathered in brainstorming session.
- 2) The advisory board was then contacted to vote on their suggestion for a few relevant cases.
- 3) 2 cases were selected as possible topics – Artificial Intelligence (AI) and Electric Pulse Fishing. These were then communicated to the RECIPES consortium for further deliberation.
- 4) Given the majority support for AI from the Advisory Board, as well as further preference for AI among the RECIPES partners, AI was selected as the 8th case study topic.
- 5) The Rathenau Institute then performed more in-depth research into the topic to narrow the case study topic, and the urgent topic of the use of AI in Health Care was selected.

#### *Ninth Case Study*

In order to further broaden the set of case study topics to be analyzed, the consortium added a ninth case study, microplastics. This topic is important both politically and environmentally, and expands the pool of precautionary principle cases to be evaluated.

## 2. Case study descriptions

The following describes each of the RECIPES case studies.

### 2.1 Case-study 1: New Gene-Editing techniques

Partner: Rathenau Institute

#### **Case-study introduction**

Since their discovery in the 1970's, recombinant DNA techniques have been a topic of international debate. More recent and ongoing discussions focus on the advent of new gene-editing techniques, such as CRISPR-Cas9. These techniques increasingly blur the distinction between classical breeding approaches, based on random mutations that occur in natural mating and recombination, and targeted editing on the DNA level.

#### **Relevance to the precautionary principle**

These new techniques give rise to a re-examination of the regulatory landscape. This discussion is in need of an evaluation of the effectiveness and results of current policies.

#### **Potential impact**

Gene Editing techniques encompass any method that enables the alteration of genetic material that is used by a living organism in a way that does not occur naturally. Accidental or intentional release of such organisms or genetic material that has been altered may result in all kinds of harm. The harm may include reduction of biodiversity, disruption or collapse of ecological systems or complete extinction of a targeted or wide range of species including humankind. The technology brings forward dual use of concern, including weaponization of biological agents into weapons of mass destruction or precision attacks and cause harm to humans, livestock, agricultural crops and/or ecology. On top of that Gene Editing brings moral values into question such as the dignity of life, freedom of choice, equality and autonomy, leading to societal unrest. The technique also enables privatization of organisms, which impacts the distribution of benefits and power.

#### **Likelihood**

The recognition of CRISPR Cas9 as a versatile genetic modification technique was established in 2012, and discovery of similar or enhanced methods followed consecutively. The characteristics of the precision and reliability remain to be set. Meanwhile the availability and use of the technology is wide-spread across the biotechnology sector and across the world. Therefore the degree of uncertainty is high.



## 2.2 Case-study 2: Genetically Modified organisms (GMO's)

Partner: Applied Research and Communications Fund (ARC)

### Case-study introduction

Genetically modified organisms (GMOs) are a heavily debated topic. According to EU law, a GMO is "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally and/or natural recombination"<sup>1</sup>.

GMO's are developed to enhance the yield of food production through plant disease resistance or herbicide tolerance.

Proponents argue that GMO's are key elements for solving problems caused by global population growth; opponents on the other hand maintain that the use of GMO's will open up Pandora's box and threaten the future of mankind and the environment.

### Relevance to the precautionary principle

GMO's are controversial as the technique involves two kinds of systemic risks: the widespread impact on the ecosystem and the widespread impact on health.

Ecologically, in addition to intentional cultivation, GMOs have the tendency to spread uncontrollably, and thus their risks cannot be localized. The cross-breeding of wild-type plants with genetically modified ones prevents their disentangling, leading to irreversible system-wide effects with unknown disadvantages. Furthermore, the ecological implications of releasing modified organisms into the wild are not tested empirically before release.

With respect to the impact on health, the modification of crops impacts everyone. Corn, one of the primary GMO crops, is not only eaten fresh or as cereals, but is also a major component of processed foods in the form of high-fructose corn syrup, corn oil, corn starch and corn meal. Foods derived from GMOs are not tested in humans before they are marketed<sup>2</sup>.

The potential widespread impacts of GMOs on ecologies and human health imply they are in the domain of the PP.

### Potential impact

Understanding of the risks is very limited and the scope of the impacts is potentially very large and global both due to an engineering approach replacing an evolutionary approach, and due to the use of monoculture.

### Likelihood

The use of GMO's is characterised by high uncertainty with respect to both the likelihood and degree of potential impacts of the GMO risks described above.

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<sup>1</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration, article 2

<sup>2</sup> Taleb, N., et. al., The Precautionary Principle (with Application to the Genetic Modification of Organisms)", Extreme Risk Initiative – NYU School of Engineering Working Paper Series, October 2014

## 2.3 Case-study 3: Endocrine Disruptors

Partner: Maastricht University (UM)

### Case-study introduction

Endocrine disruptors or endocrine disrupting chemicals (EDCs) are at the centre of a scientific controversy. As such (even) the definition of such chemicals is very much contested. To define which chemicals or substances are in fact to be considered as EDCs is, however, key as this in turn has important implications for how they are regulated. EDCs are suspected to be found in chemicals that are used on a daily basis such as paint, toys, clothing, cosmetics, medicines and pesticides.

### Relevance to the precautionary principle

The precautionary principle is of utmost relevance for this case. Relevant actors in this field such as the World Health Organisation (WHO) and the UN Environmental Programme (UNEP) but also NGOs and the European Parliament (EP) see the need to act in order to reduce or curb serious consequences for human health and the environment. In a context of scientific uncertainty more research is of utmost importance (European Parliament 2013).

### Potential impact

When it comes to **risks and severity of potential harm**, there seems to be a causal link between some of these chemicals and disorders within the endocrine (hormonal) system. Certain of these endocrine disruptors could also interfere with developmental processes of humans and wildlife. Children are seen to be at a higher risk of exposure than adults (WHO and UNEP 2012). Thus, EDCs could especially, when they are combined, be the cause of serious harm for human health. They are seen to play a role in both chronic diseases, including hormone related cancers, infertility, obesity, diabetes, cardiovascular disease (European Parliament 2013).

The European Consumer Organisation (BEUC) also stresses that these chemicals can cause 'severe and irreversible effects on humans and wildlife.' Due to the fact that EDCs are found in products one uses on a daily basis, this is 'seen as a risk that concerns us all' (BEUC 2016).

### Likelihood

This issue is characterized by a high degree of uncertainty. As the WHO and UNEP point out, around 800 chemicals are known or suspected to interfere with the hormonal system. Note however, only a small percentage of these chemicals have in fact been examined in tests. This lack of data is seen to lead to great uncertainties about the degree and extent of risks arising from EDCs (WHO and UNEP 2012).

## 2.4 Case-study 4: Neonicotinoid insecticides

Partner: University of Bergen (UiB)

### **Case-study introduction**

The introduction to the market in the early 1990s of the systemic insecticides imidacloprid and thiacloprid opened the neonicotinoid era of insect pest control. Since their market introduction in 1992 neonicotinoids (further abbreviated to neonics) have rapidly become the most widely used class of insecticides with a global market share of more than 40%. At present, 6 neonics are in use in Europe, both as plant protection product and as biocide: imidacloprid, clothianidin, thimethoxam, thiacloprid, acetemiprid and sulfoxaflor. They are used prophylactically in almost all food crops, forestry, and ornamentals. Acting systemically, these neurotoxic chemicals are taken up by plants making plants toxic to insects from the inside. Unintendedly, neonics also end up in pollen and nectar in non-lethal, yet harmful concentrations, by which not only plague insects are exposed but also beneficial insects such as pollinators. Their wide application, persistence in soil and water and potential for uptake by succeeding crops and wild plants make neonics bioavailable to pollinators at low dose year round. Widespread contamination of surface waters has been documented at levels that frequently exceed water-quality guidelines.

### **Relevance to the precautionary principle**

The main concern is the contribution of neonics to the global environmental problem of pollinator decline, which poses risks to food production and ecosystem functioning. Pollinator decline has a multitude of causes and drivers and the scientific assessment of the relative importance of neonics in the complexly interlinked set of causal factors is contested and plagued by uncertainty. There are emerging concerns that continued use of neonics can cause a collapse of the entomofauna (all insects) and species that feed on insects (e.g. birds). There is emerging concern and preliminary yet inconclusive evidence that prenatal neonic exposure is linked to human neurodevelopmental disorders such as autism. This has led to precautionary action and world-wide controversy in science and society on whether a complete phase-out of neonics is justified.

### **Potential impact**

Over the past decades pollinators are in dramatic decline. Globally, 35% of the volume of food crop production depends on pollinators (mainly wild and domesticated bees). Pollinator mediated crops are indispensable for essential micronutrients (e.g. vitamins) in the human diet. Many crops for fibre, fodder, biofuels, timber and phytopharmaceuticals and ornamental plants also depend on insect pollinators. The present pollinator crisis threatens global and local food security, can worsen the problems of hidden hunger (deficiencies of vitamins etc.), erodes ecosystem resilience, and can destabilise ecosystems that form our life support system.

### **Likelihood**

The main uncertainty stems from multi-causality in the interacting causes that together produce the ongoing global trend of pollinator decline. The scientific assessment of the importance of neonics in pollinator decline is highly contested with deep uncertainties.

## 2.5 Case-study 5: Nano-technologies

Partner: Österreichische Akademie der Wissenschaften (OEAW)

### **Case-study introduction**

A particular challenge to the precautionary principle is posed by fields of new and emerging technologies such as nanotechnology and advanced materials, which are characterized by manifold applications and display particularly high difficulty to anticipate effects. These technologies are defined by uncertainties rather than risks, with standard risk assessment methods oftentimes not being applicable. A new wave of early engagement can be observed in these fields, including nanotechnology, nanobiotechnology, enhancement technologies and synthetic biology.

### **Relevance to the precautionary principle**

In the aftermath of the controversies surrounding genetically modified foods, nanotechnology faced calls for moratoriums and the need for a different approach to regulating new technologies with risks which cannot be fully characterized has become apparent.

### **Potential impact**

The severity of potential harm regarding the use of nanomaterials depends very much on the physical and chemical nature of the used materials (metal oxides, carbon-based materials, silica), their processing (powder, paste, solid compounds) and the nature of their use (or misuse). In a toxicological sense there is no risk if no person is exposed to the material.

The first activities to control the use of nanomaterials focussed very much on determining the use of nanomaterials on workplaces, to assess the different types of workplaces and to prepare suitable workplace safety guidelines (Gazsó and Piringner 2012). Potential hazards for the living environment concern the fate of nanomaterials in water-bearing environments and in waste streams (Greßler et al. 2014).

### **Likelihood**

Uncertainties are always connected to new developments because we do not have very much experience with the long term behaviour of these materials and technologies. The uncertainties are mainly stemming from three sources: (1) there is now clear definition of the fields of application, in the case of the nanomaterials there is even no general definition, yet, although the European Commission introduced a recommendation 7 years ago. The discussion is still going on and can be doubted that there will be an agreement on binding definition during the next few years. At least there have been several working definitions included into the actual directives (cosmetics, novel food) which are sector specific and offer some basis for legislation. Additionally, a wide range of ISO and CEN standard projects exist or are under development which use common terminology. (2) The second source for uncertainties is stemming from the very diverse research on nano safety issues, mainly in human and environmental toxicology and toxicokinetics. The involved projects are normally of long duration and require very many resources. Therefore, their results are (a) not immediately available for the regulators. So, they have to base their decisions on other than toxicological findings. In

many cases the results are (b) ambiguous because the scientific discussion is not completed or they are (c) uncertain in a statistical sense (lack of data, high variance, non-standardised tests).

## 2.6 Case-study 6: Glyphosate

Partner: Maastricht University (UM)

### Case-study introduction

Glyphosate is one of the world's most widely used broad-spectrum herbicides. Glyphosate was first introduced in 1974 under the trade name "Roundup". In European agriculture, glyphosate-based herbicides are used to control weeds in a wide range of crops including cereals or sugar beet.

On 27 November the EU Member States agreed to renew glyphosate's license for a further five years after two years of dispute and hard negotiations. The renewal of the licence raised controversy. At the end of October 2017, the European Parliament had adopted, by a large majority, a resolution which requested the gradual banning of - glyphosate<sup>3</sup>. Furthermore, a "European Citizen Initiative" which requested its banning and clear European objectives for a reduction in the use of pesticides and a reform of their evaluation, obtained more than 1.3 million signatures.

Even though glyphosate's licence has been renewed, Member States will be able to refuse national marketing authorisations in favour of products based on glyphosate, as it is shared competence.

### Relevance to the precautionary principle

The renewal of glyphosate is causing so much debate, as glyphosate's harmfulness is highly controversial. In March 2015, the International Agency for Research on Cancer (IARC), an agency affiliated with the World Health Organisation (WHO) confirmed that the substance is "probably carcinogenic" for humans due to "*limited evidence of cancer in humans*" but that evidence of cancer in laboratory animals is "*sufficient*"<sup>4</sup>.

Subsequently, other reports have disproved these findings: the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) in November 2015 and the French Agency for Food, Environmental and Occupational Health & Safety

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<sup>3</sup> European Parliament resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011

<sup>4</sup><http://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Evaluation-Of-Carcinogenic-Risks-To-Humans/Some-Organophosphate-Insecticides-And-Herbicides-2017>

(ANSES) have ruled that there is no carcinogenic threat. However, the independence of the latter is called into question by some of the scientific community and by environmental NGOs, following the scandal of the "*Monsanto Papers*". As safety of glyphosate has not been established with certainty, the precautionary principle applies.

**Potential impact**

Glyphosate could have ecological consequences and health risks. It is argued that glyphosate is so non-selective that it can be destructive to wild and semi-natural habitats, and to biodiversity. Furthermore, there is fear that glyphosate is carcinogenic to humans.

**Likelihood**

There is significant controversy with respect to the likelihood of the potential impacts of glyphosate.

## 2.7 Case-study 7: Financial risks and urban planning

Partner: Humboldt-Universität Berlin

**Case-study introduction**

Many European cities are facing the challenges of massively overhauling their urban water infrastructures. This is due both to the requirements of the European Urban Waste Water Treatment Directive (UWWTD), and the fact that most of their main water infrastructures were installed in the 19th century and now have an outdated structure (exacerbated by climate change, especially in coastal locations). We will focus on the specific role and risks of financial R&I in these city investments, and conduct a case study involving two cities (London, Milan).

**Relevance to the precautionary principle**

Struck by the experience of the 2007/2008 financial crisis, cities must exercise precaution in major infrastructural investments, which involve exceptionally high costs and planning risks.

In major infrastructural city investments, cities are heavily dependent on innovation and advice from the financial and legal professions, in particular financial R&I (e.g., municipal bonds). European cities have experience of resolving practical problems and exercising precaution through citizen involvement. Thus, there is a 'wisdom' of cities that might provide a specific perspective on how to balance PP and IP.

**Potential impact:**

The potential impacts include overleveraged city balance sheets, less resilient infrastructural solutions with added vulnerabilities (climate change; city budgets), overpricing of projects, and the risk that eventually the costs will be socialized (city), while the profits will be realized individually (financial actors).

**Likelihood**

High market risk, increased resilience risk, high obfuscation risk, combined with asymmetric complexity risk: high for the city; low for the financial actors.

## 2.8 Case-study 8: Artificial Intelligence in Health Care

Partner: Rathenau Institute

### Case-study introduction

This case study will consider the use of Artificial intelligence (AI) in the health care sector. AI refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals’ (EU High-Level Expert Group on Artificial Intelligence, 2019). AI employs decision-systems based on data. Some well-known examples include self-driving cars, search engine recommendations, and health-apps.

In the health care sector, AI applications have already used since the 1970’s (MYCIN), and are currently used in a.o. diagnosis, prognosis, prevention, allocating resources, organizing files and automated operations. The use of AI in healthcare has intensified due to the rise of big data and machine learning techniques (ML). ML is the field of AI that currently receives the vast majority of R & I investment, as is sometimes used interchangeably with AI in common discourse. However, ML is only a subset of AI, which also included a variety of other fields such as symbolic representation AI.

In terms of healthcare and the precautionary principle, the PP is almost never mentioned in combination with AI. However, AI is a possible candidate for invoking the PP because of:

- A high level of ambiguity about what AI and how it relates to existing norms healthcare, and the nature of the risks (safety, privacy, human rights). This provides various ethical dilemmas particularly relevant in the medical field.
- Inherent complexity as a variety of systems interaction with one another. In particular, self-learning AI can be partly autonomous and constantly changing.
- Serious and systemic risks if AI systems are centralized and integrated in socio-economic systems

As such, the case study will provide a theoretical-ethical analysis, which should be relatively novel as the PP has not been explicitly applied in this domain at the EU level. The topic will take a broad approach to healthcare and health (care, cure, prevention and social domain).

### Potential Impact

Healthcare is often mentioned as one of the domains in which AI will have the most impact. AI is often seen as a solution for growing problems in healthcare (increasing health expenditures, deficits in personnel). In particular, under AI systems in healthcare a wide variety of (intimate, personal) data might be assembled. The use of AI may be accompanied by discrimination, profiling and exclusion.

### Likelihood

It is difficult to estimate how AI will develop in coming years. One area which is yet to become clear is the extent to which societies want to preserve human agency in the field of care and the governance that will be implemented to do so.

## 2.9 Case study 9: Microplastics in food products and cosmetics

Partner: Maastricht University

### Case study introduction

Microplastics are small pieces of plastics, usually defined as smaller than 5 millimetres, but with a large variety in terms of material, shape and solidity. As part of the wider discussion on plastic pollution, microplastics are a cause for concern. Microplastics end up in the environment via two routes, which are divided into primary and secondary microplastics. Primary microplastics are intentionally added to products, as is often done in cosmetic products, to increase certain product characteristics. Secondary microplastics, which constitutes the biggest part of the environmental pollution, are pieces of plastic that break down from larger plastics as used for example in packaging materials. Under the influence of temperature and light, the structure of the plastic particles is likely to change, making it even more difficult to detect and measure microplastics.

### Relevance to the precautionary principle

A wide range of stakeholders, including the European Commission, recognise the presence of microplastics in the environment as an undesirable situation. However, at this moment, the use of microplastics is not yet regulated at the European level. With regard to primary microplastics some countries, such as France and Denmark have implemented bans on intentionally added microplastics. The European Chemical Agency is currently working on a proposal to ban additionally added microplastics in the EU via the REACH regulation. This regulation is based on the precautionary principle. Regulating the presence of secondary microplastics in foods is more difficult. Complicating factors in this sense are the absence of a measurement tool, to detect microplastics in food products, and the wide variety of microplastics present in the environment. This would make it very complex to check for compliance with imposed thresholds.

### Potential impact

As part of the plastic pollution in the ocean, also known as the Plastic Soup, microplastics constitute to a large environmental problem. The abundant presence of microplastics in the environment, together with its very long degradation time, makes it very a harmful situation in light of environmental effects. Additional to consequences for the environment and animal life, microplastics might impact human health. It is known that microplastics end up in the intestinal tract of humans, via inter alia the consumption of polluted sea food and drinking water. Nevertheless, evidence on potential human health effects is very slim and almost entirely based on animal studies.

### Likelihood

Once in the environment, microplastics can spread very easily and have a very long degradation time. This makes them persistent in the environment with unknown effects on the long term. The lack of scientific evidence on human health effects adds to this uncertainty.



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