Plastics Fate and Effects in the Human Body

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Table of Contents

Executive Summary

The document provides an overview of current regulations, policies and markets that are relevant to micro- and nano-plastics (MNP) at the European level. It provides a first framework or orientation for the research to be undertaken in all the technical work packages of PlasticsFatE regarding regulatory, policy and market needs and requirements, including existing gaps that need to be addressed by the project.

Available definitions are first clarified and missing harmonised methods and risk assessment concepts are addressed. Relevant activities going on in these fields are summarised including various international and European networks.

1 Introduction

The unwanted presence of plastic products, fragments or particles in the environment is regularly described in public news and scientific literature: pieces of fishing gear found in fish and birds, plastic fragments in soils from agriculture foil products, particles in rivers and washing machine effluents as well as tiny particles transported by air to remote areas including the polar regions. The problem of plastic pollution has been apparent since the article of Thomson et al 2004[1] (although already described for the first time in the 1970's), however since about 2015, the topic has become a high priority in scientific research, public opinion, and finally politics.

The topic of plastics in the environment is prevalent in the media, as the use in daily life and the littering is obvious to everyone. To the public, their overall visibility is very closely linked to possible risks for human health. This includes the indirect impact on the environment, which is the prerequisite for good and healthy food (e.g. contamination of plant-based food products), accumulation in the food chain (e.g. when eating fish products or shellfish) but also direct uptake via food products (e.g. particles from plastic packaging, contamination of drinking water), breathing or through the skin. Although the presence of plastics in the environment[2] and in human blood and faeces[3,4] is well documented, classification of risks that may arise from plastic pollution is still very unclear. On the one hand plastics consist of a multitude of chemical compounds (include processing auxiliaries, additives, degradation products), and on the other hand the size, form and specific dimensions of plastic products and their resultant particles also lead to different risks. An additional risk is related to the fact that plastic fragments might act as a "Trojan horse" for other even more toxic environmental pollutants (such as salts, or organic micropollutants)[5] or that biological species (pathogens) may use the particle for "Hitch-hiking"[6].

For that reason, the fate and effect of micro- and nano-plastics (MNP) on human health must not be considered separately from the environment. This concept is not new and has been documented by the ONE-Health concept of the WHO[7]. For plastic pollution, it must cover a broad particle size range with a highly variable chemistry and shapes, provide exact quantification of the existing contamination, and assess a wide variety of direct and indirect risks and effects.

Definitions and classifications

For a meaningful understanding of the present situation, a clear scientific based regulatory definition of what we mean by "plastics" or "micro- and nano-plastics" is needed. Unfortunately, the definition of plastic particles in the macro-, micro- and nanoscale, including synthetic polymers and implemented additives, is still not harmonised. The following definitions have been suggested by following organisations:

- GESAMP/MSFD/UNEP[8]

Plastics are synthetic or semisynthetic non-soluble polymeric material (including monomers, degradation products, non-intentionally added substances, flame retardants, pigments, UV stabilisers, bioactive compounds, etc.). Megaplastic is defined as objects larger than 1 m. Macroplastic are plastic products or fragments larger than 25 mm. Mesoplastic are plastic products or fragments in the dimension of 5 – 25 mm. Microplastic particles are particles smaller 5 mm and bigger than 1 µm. Nanoplastic particles are smaller 1 µm. An additional differentiation is provided for shape and colour.

- ECHA / REACH[9]

The scope includes products containing more than 0.01% (weight/weight) of microplastic particles, which are defined as particles containing solid polymer, where more than 1% are below 5 mm in size. A lower limit of 100 nm is being debated. The scope also includes fibres of length between 3 nm to 15 mm, particles of any composition with a polymer content of ≥1% or with a continuous polymer surface coating of any thickness. The scope excludes polymers that are biodegradable or natural or soluble.

- ISO/CEN[10]

By definition, the term "plastics" covers only thermoplastics and thermosetting plastics. Materials and products based predominantly on synthetic polymers (e.g. elastomers, textile fibres, coatings, tyres) can also release microparticles that are identified as synthetic polymers. For simplification, all the materials mentioned above are colloquially summarised by the term "plastics".

Microplastics are defined as any solid plastic particle insoluble in water with any dimension between 1 µm and 1000 µm (=1 mm). Microplastics may have various shapes. The defined dimension is related to the largest dimension of the particle. Large microplastic: any solid plastic particle insoluble in water with any dimension between 1 mm and 5 mm. Nanoplastic: plastic particles smaller than 1 µm.

2 Market and Sources

Micro- and nanoplastic particles (MNP) can be intentionally produced and added to products to improve their properties, such as an abrasion agent or to alter the viscosity of liquids. For those kinds of materials, a "market" exists.

This kind of microplastic is also called "primary microplastics".

MNP can be formed in the environment by aging and fragmentation of plastic products, such as littered packaging. This degradation process is a property of the polymer materials and inevitably unavoidable. The scale of the process depends on the composition (polymer, additives) and the environmental stress on the material (irradiation, oxidation, hydrolysis, mechanics). Degradation occurs over the space of months up to several years with the formation of microplastics and nanoplastics probably taking place simultaneously. This is also a property of the type of polymer or its processing, however it can also take place successively through progressive degradation of the particles.

MNP can be also formed by "tolerated" mechanical degradation of plastics products such as from tyre abrasion or from washing synthetic textiles.

These types of microplastic (formed by degradation) are called "secondary microplastics".

2.1 Intentionally added microplastics

Intentionally added microplastics are found in the following broad product categories with their functional purpose summarised in brackets:

- Cosmetics (exfoliant, controlled release (e.g. fragrances), emulsifier, binding agent, film forming, colourants, anti-static agents, thickening agent)
- Personal care (exfoliant, controlled release (e.g. fragrances), emulsifier, binding agent, film forming, colourants, anti-static agents, fluid absorption)
- Detergents (exfoliant, controlled release (e.g. enzymes), emulsifier

- Paints/coatings/inks (emulsifier, binding agent, improved chemical and mechanical resistance, thickening agent, colourants, dispersing agent)
- Industrial abrasives, e.g. for removing paint and other contaminants (abrasives, polishing agents)
- Agriculture (controlled release, fluid absorption, dewatering)
- Pharmaceuticals (controlled release)
- Wastewater treatment (flocculant, dewatering)
- Construction (binding agent, filler, thickening agent)
- Other (e.g. beads in furniture, adhesives and sealants, oil and gas production applications)

In Europe, the amount of microplastics used in these different products and their release into the environment each year has been estimated as follows[11] (see Fig. 1):

- Personal care products estimated at 793 tonnes in 2015 for exfoliation and rinse-off products, which was estimated to have decreased by 82% since 2012. However, leave on cosmetic products (e.g. mascara) are much higher at 1,250 – 1,910 tonnes. Total release into the environment estimated at ~1,330 tonnes p.a.
- Paints estimated at ~220 tonnes (mainly microspheres of acrylic, and/or fibres of polyamide or polyacrylonitrile), due to washing down drains. Overall, it is estimated that ~25% (w/w) of paints consist of polymers, which equates to 14,000 tonnes of marine and 870,000 tonnes of construction paint (these will be subject to wear and degradation as described above). Total release into the environment estimated at ~896 tonnes p.a.
- Detergents estimated at 190 – 200 tonnes. Total release into the environment estimated at ~200 tonnes p.a.
- Agriculture applications estimated at up to 8,000 tonnes, mainly for the slow release of fertilisers, but also for the slow release of pesticides, and for water absorption, soil remediation, and to reduce drag in sprinkler irrigation systems. Total release into the environment estimated at ~1,040 tonnes p.a.
- Industrial abrasives estimated at 1,000 - 5,000 tonnes for a variety of purposes such as sandblasting buildings, machinery, etc. Total release into the environment estimated at ~3,125 tonnes p.a.
- Oil and gas applications. Total release into the environment estimated at ~160 tonnes p.a.

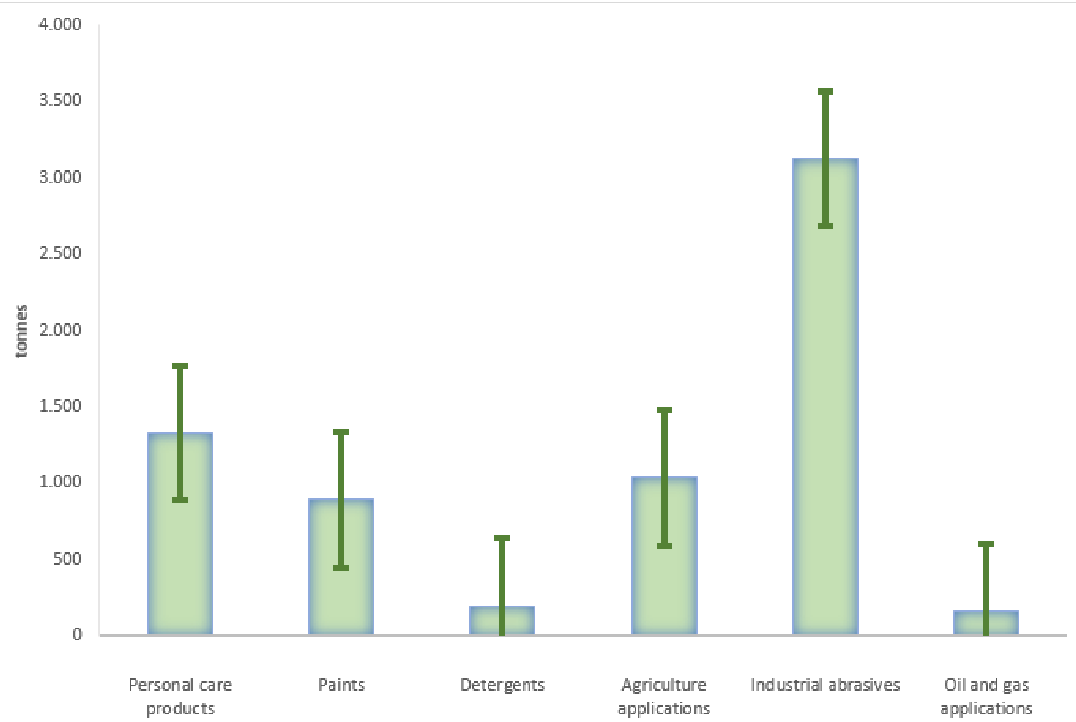

Figure 1: Overview of the total environmental release of intentionally added MNP in products p.a.

It should be noted that many countries have unilaterally banned the use of microplastics in certain products, including personal care products and cosmetics, however, as will be discussed further below, the EU has yet to enact the necessary REACH legislation to do so.

2.2 MNP from Degradation Processes

Estimates for the global manufacture of plastics vary from between 367[12] to 460[13] million tonnes (Mt) in 2020, and this is expected to double by 2050[14]. The OECD[13], estimate that in 2019 alone, 22 Mt of plastics leaked into the environment with 88% of these being macro and 12% microplastics. Around 5 billion tonnes of plastics are already in landfills and the environment[15], and it is estimated that by 2040, 380 million tonnes could be added to this each year, with around 10 million tonnes of this being microplastics[16]. This has a high potential to be dispersed throughout land, air and water. At least 8 million tonnes of plastics enter the oceans each year[17] and the majority of microplastics found in oceans are derived from the degradation of larger plastic objects. A recent study using nets with various size meshes (100, 333 and 500 µm) suggested that the prevalence of microplastics in oceans may be underestimated and could be as much as 3,700 particles per cubic metre[18].

A report for DG Environment by ICF and Eunomia[19] indicated the following main sources for environmental microplastics in Europe with calculated release of microplastics in tonnes per year (Figure 2):

- Automotive tyres: 503,586 tonnes per year. These are a complex mixture of different rubbers and polymers, most commonly styrene-butadiene rubber, plus additives such as carbon black and silica
- Plastic (pre-production) pellets (used to manufacture plastic goods): 16,888 - 167,431 tonnes per year, derived from losses due to spillages at production sites and during transport (e.g. at

ports). These comprise a variety of thermoplastics, most commonly polyethylene and polypropylene

- Road markings: 94,358 tonnes per year. These are a complex of different resins, plasticisers and thermoplastic elastomers with different pigments and fillers such as glass beads and calcium carbonate
- Artificial sports turf pitches (which contain a filler of crumbed, end-of-life tyres): 18,000 - 72,000 tonnes per year. These are mainly styrene-butadiene rubber
- Fibres released from the washing of clothing: 18,430 - 46,175 tonnes per year (between 100 and 600 quadrillion fibres). These are polyester, viscose, acrylic, polyamide and polypropylene, with polyester and viscose contributing the most
- Exterior building paints: 21,100 - 34,900 tonnes per year. These are mainly acrylics
- Automotive brake wear: 505 - 17,161 tonnes per year. These are composed of binders, fibres, fillers and friction modifiers, which can include a variety of polymer materials
- Marine paints (direct to surface waters): 1,194 tonnes per year. These are usually epoxy-resin based with a polyurethane overcoat to protect against UV, and also contain pigments, anti-corrosive and antifouling agents
- Fishing net wear emitted directly into oceans: 478 - 4,780 tonnes per year. These are composed of polyamide, polyethylene and polypropylene

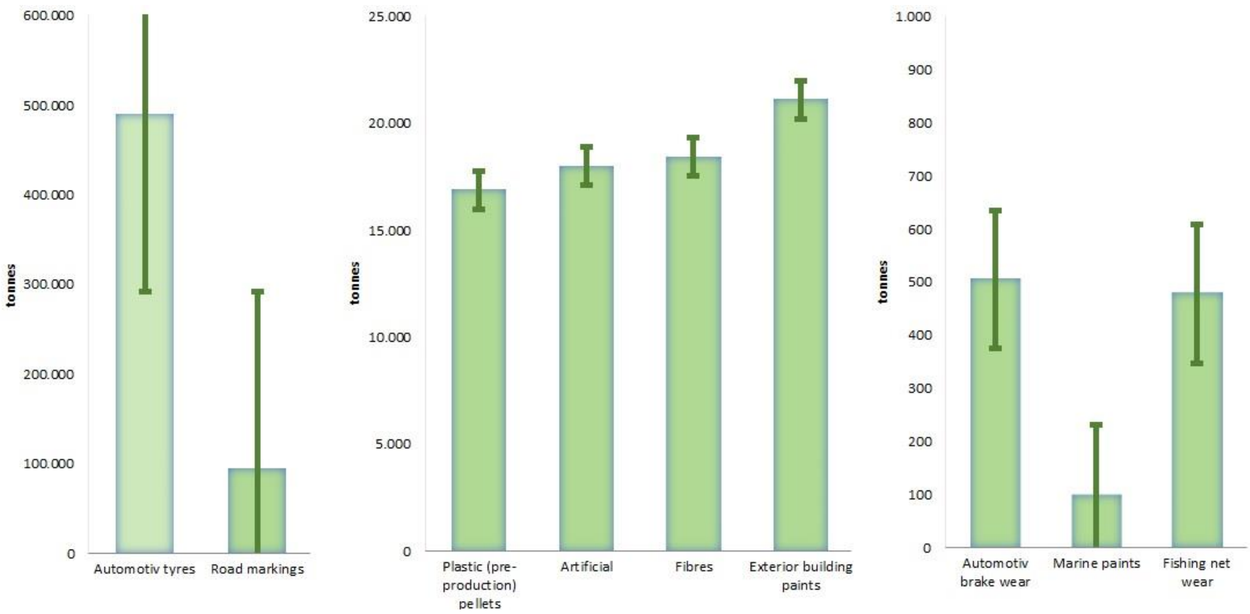

Figure 2: Overview of the estimated environmental release of MNP from larger plastic products p.a.

Figures 1 and 2 clearly illustrate, that the pathway in the environment is dominated by MNP degradation and that tyre abrasion dominates the overall amount. In contrast to MNP from packaging (controlled by food authorities) or construction materials (determined by the requirements of use), the composition of tyres is complex and not publicly disclosed. Additionally, the particles are difficult to detect[20].

2.3 Classification of MNP pollution and solution options

Thus, it is clear that there are many different sources of MNP in the environment. According to Mitrano et al.[21] MNP can be distinguished by their source as follows:

1. Microplastic lost through consumption (e.g. cosmetic beads, industrial abrasives).
2. Microplastic lost through accidents and transportation losses of industrial intermediates (e.g. plastic pellets, dispersions).
3. Microplastic formation through mechanical stress, creating hotspots for high release (e.g. tyre wear, brake wear, fibres from textile washing).
4. Microplastic formation of targeted applications (e.g. seed coatings, fertiliser capsules, paints and markings).
5. Microplastic formation by slow degradation over a period of months to years (e.g. uncollected mulch films, artificial sport turf pitches).
6. Microplastic formation from uncollected plastic waste, allowing degradation over time (e.g. littered packaging, fishing nets).

Entry pathways can be regulated by political bans (source 1), especially when less critical alternatives for these materials or products already exist (source 1). Politics can also regulate the unintentionally loss of raw materials (source 2) by improved control of processes and applications. Similarly, improved infrastructure (e.g. street run off filtration) can reduce entry for hotspots (source 3). These solutions are sometimes complex, but can be realised in the relatively short term, as solutions are often already known.

Alternative materials can be developed when plastic materials target applications in the environment, this means the degradation should result in nearly complete biodegradation / mineralisation – ultimately in uncritical compounds (source 4, 5). Or, alternative materials can be developed with high stability / quality and therefore meaningful reuse and recycling can reduce the plastic entry by slow degradation (source 6). The last examples mentioned could be ultimate solutions for the problem of MNP, but so far only the wishes of all involved parties (e.g. politics, industry, consumer) as no concepts for them exist yet.

It must be emphasised once again that a separation of "input into the environment" and "impact on human health" is not meaningful. Similarly, neither is a separation of primary and secondary microplastics nor a classification in terms of particle sizes or forms. In the short, medium or long term, all plastic in the environment becomes MNP and can enter the human body via ingestion of food and liquids, through respiration or even the skin. There, negative effects can occur – which are still unknown and will be analysed in PlasticsFatE. These effects can be caused by both the chemical composition of the particles and the particulate dimensions. Hence, regulations must also address the reducing entry into the environment, which will ultimately protect human health.

3 Current EU Regulation and Policy

Current regulation and policy at the EU level are summarised in this chapter. Analysis methods (including sampling, sample preparation, detection) are needed for successful control, and these should be based on standardised methods according to ISO or CEN. Here a number of projects exist in various (environmental) fields, however, there are still no finalised recommendations for analytical procedures. Therefore, these documents and activities are summarised in chapter 4.

To reduce the entry of plastics into the environment and subsequent exposure to humans, legal frameworks are needed. However, the formulation of legal measures is difficult due to the quantity of different plastic products and the multitude of possible sources, sinks and pathways, which is why different regulations are needed for these different pollution sources. Proposed solutions should therefore not only address the direct release of individual products or of the material itself, but all aspects of their life cycle, including production and processing, product design and use, reuse and recycling and should also consider use and consumer behaviour (see overview of existing regulations in Table 1).

At the European policy level, the "European Union Strategy for Plastics in a Circular Economy" (COM/2018/028)[22] and the "European Green Deal" (COM/2019/640)[23] with the EU Action Plan: "Towards a Zero Pollution for Air, Water and Soil" provide a framework for the regulation and safe and sustainable handling of plastics.

The first EU directives are addressing the consumption and ban of plastic carrier bags (EU2015/720)[24] and single use plastics (EU 2019/904)[25], as well as the collection of ship generated (plastic) waste. These aim to avoid/reduce the uncontrolled entry of plastics to the environment by carelessness or mismanagement. [26]

> *However, studies[27,28] have shown that the regulations addressing the consumption and ban of plastic carrier bags and single use plastics are not sufficient because significantly more and different plastic-containing products and packaging (including plastic pellets) are introduced into the environment by different actors.*

ECHA has produced Annex XV[29] as part of REACH, which proposes restrictions on intentionally added microplastics:

- restriction on placing microplastics on the market, with transitional periods for some products
- labelling requirement to minimise release (where risks can be minimised by appropriate conditions of use and disposal)
- reporting requirement to improve the quality of information to allow the assessment of potential future risks

> *However, various environmental NGOs believe that Annex XV is not aggressive enough and neglects the opinions of the independent committees set up to advise ECHA. In particular, it has been criticised for allowing longer than necessary transition periods to phase out microplastics in applications for cosmetics, detergents and agriculture, particularly as there are alternative materials that could be substitute MP. The authors also identify potential loopholes that would allow manufacturers to justify that microplastics will be contained within a product through technical means such as permanent modification or incorporation within a matrix, and thus not subject to the proposed restrictions[30].*

The Commission has received a proposal from ECHA to place certain plastics under the European chemical's legislation REACH (EG 1907/2006)[31]. Up to now polymers have not been regulated under REACH.

The revised version of the Drinking Water Directive (Directive (EU) 2020/2184)[32] entered into force on 12 January 2021. The new rules update quality standards and introduce a risk-based approach, including an obligation for Member States to improve or maintain access to safe drinking water for all, with a focus on vulnerable and marginalised groups. New substances will be placed on a watch list, including microplastics. The aim of the watch list is to identify potential risks to potable water at an early stage and to maintain drinking water quality by modifying the treatment process. Monitoring methods for microplastic detection should be established before 2025.

Furthermore, the European Commission has now launched two public participation processes[33] to help define measures to reduce the unintentional release of microplastics from tyres, textiles and plastic granules into the environment and to regulate the handling and use of biodegradable plastics. The results will be published at the end of 2022.

The EU's Marine Strategy Framework Directive (MSFD) also has international impacts as it has defined the input of (plastic) waste into the oceans as an indicator for assessing "good environmental status". For this, the MSFD has established specific thresholds for litter types after harmonisation of the methodology. With the concept for Healthy Oceans and Seas and Resilient Coastal Communities suggested at the G7 Summit in Charlevoix (2018), Germany together with other countries, has made a first international commitment to reduce the release of plastics into the oceans. The commitments adopted at this meeting have been taken up in principle by the United Nations Environment Assembly (UNEA). A resolution was adopted in Nairobi (March 2022) to conclude a multilateral agreement against plastic waste by the end of 2024.

In terms of Occupational Health, the Occupational Exposure Limit (OEL) is the maximum permitted concentration level of a gas, vapour and particles as aerosol, fibres or dust in the air in the workplace (8h-exposure (OEL) and/or short time exposure limit (STEL)). The basic principle is that the health of employees as well as that of their children must not be impaired (see also the German GESTIS database that collected OEL values from 28 countries: GESTIS International Limit Values (dguv.de).

Presently there are no occupational exposure limits for MNPs. In their absence workplace safety efforts should focus on minimizing potential exposure through appropriate risk management and engineering controls such as isolation cabinets, exhaust ventilation, training, utilizing good industrial hygiene practices.

Table 1 provides an overview of relevant EU legislation, while Table 2 provides an overview of international guidance and standards for occupational exposure monitoring.

Table 1: Existing and planned EU legislation that is relevant to MNPs

EU regulation	Main task
Directive 98/24/EC	**Council Directive 98/24/EC - on the protection of the health and safety of workers from the risks related to chemical agents at work** The directive lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents. The Directive provides for the drawing up of **indicative and binding occupational exposure limit values** as well as biological limit values at Community level above which certain chemical agents and activities involving chemical agents are prohibited. Member States may permit derogations from these prohibitions in special circumstances. Individual Directives add further **indicative occupational exposure limit values** for certain chemical substances: • Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values • Commission Directive 2006/15/EC establishing a second list of indicative occupational exposure limit values • Commission Directive 2009/161/EU establishing a third list of indicative occupational exposure limit values • Commission Directive 2017/164/EU establishing a fourth list of indicative occupational exposure limit values • Commission Directive 2019/1831/EU establishing a fifth list of indicative occupational exposure limit values
Directive 2004/37/EC -	**Directive 2004/37/EC - carcinogens, mutagens or reprotoxic substances at work** The Directive addresses the protection of workers from the health and safety risks related to exposure to carcinogens, mutagens or substances toxic to reproduction (CMR) at work. Hazardous medicinal products which contain one or several CMR fall under the scope of Directive 2004/37/EC. The Directive specifies **binding occupational exposure limit values** above which carcinogenic, mutagenic or reprotoxic agents are prohibited.
Reach 1907/2006/EC and CLP 1272/2008/EC	**This Regulation repealed Directives 67/548/EEC and 1999/45/EC as of 1 June 2015.** The purpose of this Regulation is to harmonize the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures. It also aims at establishing a classification and labelling inventory of substances. This Directive shall not apply to non-isolated intermediates, waste, medicines, cosmetics, food and feeding stuffs, and substances and mixtures that are either radioactive, or subjects to custom supervision, or used for scientific research and are non-marketed.

EU regulation	Main task
Directive 528/2012/EU	**Concerning the making available on the market and use of biocidal products Text with EEA relevance** The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment. Particular attention should be paid to the protection of vulnerable groups, such as pregnant women and children. This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment. With a view to removing, as far as possible, obstacles to trade in biocidal products, rules should be laid down for the approval of active substances and the making available on the market and use of biocidal products, including rules on the mutual recognition of authorisations and on parallel trade.
Directive 2009/148/EC	**Directive 2009/148/EC - exposure to asbestos at work** The Directive aims to protect workers health from risk of asbestos exposure, lays down limit values and specific requirements. The Directive prohibits activities in which workers are exposed to asbestos fibers in the context of the extraction of asbestos, the manufacture and processing of asbestos products or the manufacture and processing of products to which asbestos has been intentionally added. The treatment and disposal of materials that arise during demolition and asbestos removal work are excluded from this prohibition. Exposure to asbestos during demolition and asbestos removal must be reduced to a minimum, including minimising the number of persons exposed, prioritising dust-free work processes, cleaning buildings and ensuring that materials are properly stored, transported and labelled.
EU 2015/720	**Directive for reducing the consumption of lightweight plastic carrier bags**: Directive regards reducing the consumption of lightweight plastic carrier bags (2025, reduction about 80 % since 2010)
EU 2019/904	**Directive on Single-use plastics (SUPs)**: EU rules from 2021 on ten single-use plastic products to prevent and reduce the impact of certain plastic products on the environment. It includes also products of oxo-degradable materials and fish gear with plastic components. Furthermore, the Directive includes the labelling and aspects of product design. The use of intentionally added microplastics is not included.
EU 2019/883	**Directive on ship-generated waste**: Port reception facilities for the delivery of ship-generated waste, in particular plastic products and fishing nets.
EU 2020/2174	**Regulation on plastic waste shipments:** The rules ban the export of plastic waste from the EU to non-OECD countries from 2020, except for clean plastic waste sent for recycling. Exporting plastic waste from the EU to OECD countries and imports in the EU will also be more strictly controlled.

EU regulation	Main task
EU, in preparation	**Polymer** (including functional polymers and solid plastics): Exempted from REACH due to low bioavailability **Additives**: Proposed REACH restriction, potentially from 2022, banned if dispersed in environment
EU, in preparation	**Intentionally added microplastic particles**: proposed REACH restriction, potentially from 2022: banned if dispersed in environment, labeling & reporting if used only industrially and/or losing particle nature in application. Biodegradable, or natural, or soluble polymers exempted

Table 2: Standards and guidance for occupational exposure monitoring

Standard/Guidance	Description
EN 482:2021	Workplace exposure - Procedures for the determination of the concentration of chemical agents - Basic performance requirements
EN ISO 22065:2020	Workplace air - Gases and vapours - Requirements for evaluation of measuring procedures using pumped samplers (ISO 22065:2020)
EN 689:2018+AC:2019	Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values
EN ISO 13137:2013	Workplace atmospheres - Pumps for personal sampling of chemical and biological agents - Requirements and test methods (ISO 13137:2013)
EN 1540:2021	Workplace exposure - Terminology
EN 481:1993	Workplace atmospheres - Size fraction definitions for measurement of airborne particles
EN 13205:2014	Workplace exposure - Assessment of sampler performance for measurement of airborne particle concentrations
CEN/TR 15230:2005	Workplace atmospheres - Guidance for sampling of inhalable, thoracic and respirable aerosol fractions
ISO 15767:2009	Workplace atmospheres — Controlling and characterizing uncertainty in weighing collected aerosols
ISO 13138:2012	Air quality — Sampling conventions for airborne particle deposition in the human respiratory system

4 Gaps

The analysis of gaps must include aspects of exposure and release monitoring (for identification of entry pathways into the environment and the human body) and the understanding of effects (to arrive at an integrated risk assessment for MNP in the environment and in the human body). Connected to these points is the topic of meaningful / realistic reference materials and interlaboratory comparison tests. Additionally, also aspects of missing or insufficient regulatory and policy actions have to be considered, which is becoming obvious through the present public discussion about plastic pollution.

It is important to acknowledge that while the transfer of knowledge from the field of nanoparticles to MNPs may seem plausible at first glance, it does not work in practice.

The analysis of nanoparticles and their effects focuses very strongly on inorganic materials, the analysis of which is comparatively simple because they usually consist of atoms with complex electron shells (e.g. Ag, TiO2, etc). Thus, there is a completely different, much more diverse range of analytical methods that also cover the nanoscale range - also in-situ, e.g., to assess effects.

In the case of nanoplastics, these methods cannot be applied because nanoplastics are not organised atomically in the same way. In analytics, we are nowhere near as far advanced with nanoplastics as we are with nanoparticles.

In addition, the atomic structure determines the properties of the particles. Among other things, they can be chemically much more stable, more toxicologically relevant (since they are also composed of toxic ions) or have completely different mechanical properties.

Therefore, it is not possible to directly transfer knowledge gained from nanoparticle research to nanoplastics, without some adaptation/modification and then only when there is reliable knowledge available about the effects.

4.1 Harmonisation of Monitoring Tools

In order to assess the type and extent of MNP in the human body and in the environment and to identify relevant sources and exposure pathways for human health; harmonised and standardised methods are needed to obtain a realistic assessment of their occurrence.

In general, two analytical principles exist: particle detection tools (determining the particle type, size, numbers, and forms) and mass fraction detection tools (determining the particle type and the mass fraction of particles). The application of the two detection strategies depends on the goal of the investigation and the nature of the samples.

A number of initiatives and organisations are engaged in harmonisation of the analytical tasks on a general level (a selection is given in Table 3). Furthermore, standardisation documents from ISO and CEN exist, however, they also only address more general aspects or are still in progress with specified recommendations (Table 4). Existing ASTM documents are not summarised here. Practical recommendations from OECD are not known.

Table 3: Existing method harmonisation / recommendations of established organisations regarding the analysis of microplastics (selection)

Initiative / Program	Task	Outcome
GESAMP / UN (since 2010)	Guidelines for monitoring plastics in environment	Sources, fate and effects of microplastics in the marine environment: a global assessment
EFSA – European Food Safety Authority (2016)	Report about existing knowledge of microplastics and nanoplastics in food	There is no legislation for microplastics and nanoplastics as contaminants in food. Methods are available for identification and quantification of microplastics in food, including seafood. Occurrence data are limited. In contrast to microplastics no methods or occurrence data in food are available for nanoplastics. Research is recommended, especially for particles < 150 µm
WHO (2019)	Report about microplastic in drinking water	No overt health concerns for MP in drinking water, but increasing amount might be critical, especially of NP.
Ellen MacArthur initiative "Alliance to End Plastic Waste" (since 2019)	Alliance of companies	Group of companies, which support advanced infrastructure in waste management, innovation in recycling, education of behaviour and clean-up of plastic pollution hotspots.
UNEP (2020)	Guideline for the harmonisation of metrologies	Monitoring plastics in rivers and lakes
FAO (2021)	Status of knowledge microplastics in fisheries and aquaculture	Occurrence and implications for aquatic organisms and food safety

Table 4: Existing standardisation activities regarding the analysis of microplastics

Committee	Title	Description
ISO/TC 61/SC 14/WG 4	Plastics – Environmental aspects – State of knowledge and methodologies **CEN ISO/TR 21960: 2020**	General document about state of knowledge.
ISO/TC 61/SC 14/WG 4	Principles for plastic and microplastic analysis present in the environment **ISO/CD 24187.2: 2022**	Document about general aspects for microplastic analysis
ISO/TC 38/WG 34	Microplastics from textile sources. Part 2: Qualitative and quantitative evaluation of microplastics. **ISO EN/ISO/WD 4484:2020**	Focus on microplastics from textiles
ISO/TC 147/ SC 2 / JWG 1	Water quality — Analysis of microplastics -Part 1: General and sampling **ISO/WD 16094-1: 2022**	First part of series for specific procedure for microplastic sampling
ISO/TC 147/ SC 2 / JWG 1	Water quality — Analysis of microplastics -Part 2: Methods using vibrational spectroscopy in drinking water and groundwater **ISO/WD 16094-2: 2022**	Second part of series for specific procedure for microplastic detection using spectroscopic methods
ISO/TC 147/ SC 2 / JWG 1	Water quality — Analysis of microplastics -Part 3: Thermoanalytical methods in waters with low content of natural suspended solids **ISO/WD 16094-3: 2022**	Third part of series for specific procedure for microplastic detection using thermoanalytical methods
ISO/TC 147/ SC 6	Water quality — Sampling — Part 27: Sampling for microplastic particles and fibres in water **ISO/CD 5667-27:2022**	Specific procedure for microplastic sampling of water
CEN / TC 249 / WG 24	Plastics — Environmental Aspects — Vocabulary **EN 17615: 2022**	Document about definitions
CEN / TC 444	Sludge, treated biowaste, soil and waste — Sampling, pre-treatment and analysis of microplastics **CEN/TS Draft**	Specific procedure for microplastic sampling of solid samples and sample preparation

The recommendations given by these initiatives / norms address mainly microplastic particles, as for nanoplastics no routine methods yet exist. The present recommendations address particles in (clear) water phase, but not for analysis of samples in air, solids (i.e. soil, fertiliser) and biological matrices. Especially the harmonisation of sample preparation in such complex matrices is still missing. Also, no harmonised/standardised protocols for MNP in human tissues exist, nor a proper sampling strategy or sample preparation. For nanoplastic particles, the first detection approaches have been developed, but they are often complex to implement and only a few address sampling collection and effective isolation or extraction of the particles [34,35].

4.2 Harmonisation of Hazards / Risks Assessment Tools

The development of appropriate methods must accelerate for determining the hazard and impact of MNP on the environment and human health, including possible Trojan horse (adsorption of co-contaminants) or Hitch-hiking effects (adverse vector). While the field of analytical chemistry has advanced in recent years (including the harmonisation of monitoring tools), there are few regulations that address the human and eco-toxicology of MNP.

This research field needs, in particular, defined protocols and test methods that can be used for regulation, and which include particle size, shape, chemical composition, material properties and suitable end-points for assessing resulting toxic or chronic effects. Recent, especially scientific studies[36] show great differences in experimental approach, for example in the particle size, or different polymer types. In addition, a wide range of test species, exposure durations, exposure concentrations and response variables have been used, all prompting the question, 'how can the published data be compared and reproduced, to make sure that the data is robust and reliable when used for regulatory purposes?' Within OECD, standardised and harmonised ecotoxicological test protocols have been developed to assess fate and effects of chemicals in the environment, for example OECD 201[37] (Freshwater Algae and Cyanobacteria, Growth Inhibition Test), OECD 211[38] (Daphnia magna Reproduction Test) and OECD 236[39] (Fish Embryo Acute Toxicity Test with Danio Rerio). Originally developed for soluble chemicals, it may not be easy to apply these protocols to polymer particles which show different behaviours and biological responses[40].

As a consequence of the constantly changing ecosystem, most endpoints are not very sensitive due to limitations of the applied ecotoxicology testing methods and the challenge to detect very small particles. Endpoints could be incorrectly determined by false-positive results because of leaching of the fluorescent dye, dislocation of particles during histological processing and general contamination[40]. Tests could be affected by leaching of additives or monomers from the plastic matrix or released sorbed co-pollutants. In general, exposure studies should be more environmentally realistic under relevant conditions (media, temperature, pH, etc.)[41] and more focused on transformation processes (oxidation/reduction, interactions with macromolecules, light exposure, biological transformation) that potentially influence the MNPs in the ecosystem[42,43].

Concerning toxicity data, a wide range of particle types, particle sizes and amounts of plastic have been tested in a wide variety of species. A large number of studies have published using microplastic sizes from 1 – 10 and 10 – 100 µm, followed by 100 – 1000 and 1000 – 5000 µm size ranges [44]. Biological tests have mainly been performed in crustaceans, followed by fish, molluscs (snails and bivalves), sediment-dwelling organisms (chironomid larvae, nematodes and annelids), different prokaryotes, plants and invertebrates[45,36]. A variety of toxicological endpoints have been addressed, for example mortality, morphological alterations, growth, reproduction, behaviour, and different cellular, immunological, as well as metabolic parameters and stress indicators, or food web experiments have been studied. Unfortunately, highly inconsistent information is used to establish exposure conditions, particle concentrations/size, environmental relevance and the use of very high particle concentrations, all of which makes it difficult to translate the experimental findings into real situations[36].

Both microplastics and nanoplastics may have direct ecotoxicological impacts. They could also function as vectors for sorbed environmental contaminants and pathogens. Through the sorption of co-contaminants, they could function as additional vectors or sinks for other pollutants[46]. Also, additives released from the polymer matrix may cause additional and still unknown adverse effects. Last but not least, the different properties of polymers, like surface chemistry, polarity and density could change during aging or weathering processes.

So far, the complete degradation of synthetic polymer particles has not been demonstrated[47]. Adverse effects to human or environment have rarely been shown when environmentally relevant plastic concentrations were tested. The following aspects should be examined and correlated with the condition of aquatic biota and consequently human health in future research: the properties of the plastic during long term experiments (including composition, size); the interrelationship of plastic polymers, additives, and other pollutants; realistic analysis conditions; the fate of smaller particles with the potential for cellular uptake and the modulation of chemical toxicity.

In the future, the expected increase in MNP concentrations in the environment indicate that concentrations will also rise in seafood and other food and these levels should be assessed. For human health and food security it is important to quantify MNP in the edible tissues of marine species like fish, shellfish and algae for human consumption. There is a need for consecutive monitoring programs that evaluate the presence of MNP in different environmental compartments, potentially as a way to avoid the depletion of global fish and shellfish stocks. The studies should focus more on the chemical and microbiological hazards and risks associated with ingested microplastics and the development of new methods to evaluate the intake, translocation and presence of particles in the human body. The aquatic microplastic debris is an emerging issue for food security, food safety and human health so that research on analytical methods, toxicokinetic and toxicity of micro- and nano-sized polymers is important to improve the understanding of their potential impacts[48].

4.3 Reference materials / Interlaboratory Comparison tests

There are no reference materials available for the validation of methods needed for physicochemical characterisation, exposure and hazard assessment. These materials must include both raw or pristine and aged materials of the most relevant polymer types in both the micro- and nanoscale.
Up to now a limited number of published interlaboratory comparison (ILC) tests exists. The most well-known are the those of the NORMAN network[49] and the JRC[50], and some additional ILC exist on national level. The most limiting aspect is that these studies are restricted to particles larger than 20-50 µm, due to the lack of realistic reference particles in smaller (nano-) dimensions.

4.4. Gaps in Regulation

The current revision of the Urban Wastewater Directive (Directive 91/271/EEC)[51] and the Sewage Sludge Directive (Directive 86/278/EEC)[52] must address the issue of plastics. The EU Fertiliser Regulation (Regulation (EC) No. 2003/2003)[53] and the delegated acts of the Eco-Design Directive (Directive 2009/125/EC)[54] needs to be revised with the aim of reducing plastic inputs into the environment.

The new Circular Economy Action Plan (CEAP), adopted in March 2020, promotes circular economy processes, encourages sustainable consumption, and aims to ensure that waste is prevented. This action plan, which involves in particular improved recycling strategies, should also incorporate the topic of MNP. It is undisputed that increased material recycling makes sense from the perspective of resource conservation; at the same time, the plastic material gains a higher value through the necessary implementation steps (e.g. deposit systems, optimised design for recycling). However, it is also in the nature of plastics that they degrade very easily in the recycling process and the material composition can never be guaranteed to be free of contamination / pollutants. In the worst case, this leads to a restriction of the material quality, which can lead to an increased MNP formation with critical composition due to degradation in the use phase of plastic products. Such a “downcycling” must be avoided. In this context a declaration or labelling of a product’s plastic composition / stability would be useful to improve the quality of the resulting recyclates. Although PlasticsFatE will not explicitly address the issue of plastics recycling, the topic is closely linked to MNP, especially in standardisation work.

Plastic materials have besides low materials costs, other unique properties such as low weight, flexible design, and hygienic aspects. For the wider public, these properties are perhaps pushed more to the background in favour of the perceived ecologically better behaviour of alternative materials, such as glass or paper as packaging material. However, these too have disadvantages, e.g. in transport or processing costs (e.g. glass, metal) and the resulting greenhouse gas emissions. Another example is the modification of papers for improved resistance to food (e.g. perfluorinated hydrocarbons), which makes the recycling process of paper more difficult and increases the release of these contaminants into the environment. In certain applications, there are no alternatives to plastics, such as medical devices. A clear position on the ecological footprint of plastics, including their different recycling concepts for different sort of polymers, is therefore needed, as well as an objective debate on where plastics can be used as a sustainable material.

Ultimately the issue of plastic waste in the environment, entering the food chain and causing impacts on human health, is not just about regulations but wider societal behaviour. We need to understand and address the expectations of individuals as to how plastics and the products that they are made into should be used and dealt with at the end of their useful life.

5 PlasticsFatE Contribution to addressing Gaps

The outcome of this D6.3 report will primarily provide an overall framework in which the research work in the different technical Work Packages of PlasticsFatE will develop with regard to the specific current regulatory, policy and market situation, to address relevant existing needs and gaps that have been described above. The relevant activities in each work package are summarized in Table 5.

Table 5: Overview of how PlasticsFatE Contribution will address existing gaps

Work-Package	Contribution of PlasticsFatE
WP 1: Physicochemical Properties of MNP	Development of micro- and nanoscale reference materials and validated methods Organisation of ILC within VAMAS
WP 2: Exposure to MNP	Development of analytical detection, identification and quantification methods for exposure assessment of MNP in complex matrices (e.g., food, drinking water, inhalable air, human tissues etc.)
WP 3: Hazards Associated with MNP	Development of in vitro and in vivo test methods for hazard assessment of MNP in the human body
WP 4: Risks Associated with MNP	Development of a new risk assessment strategy for MNP integrating human and environmental risks
WP 5: Case studies to assess feasibility of methods developed for Regulation, Standardization and Policy implementation	Field studies to test suitability of PlasticsFatE methodologies for exposure, fate and hazard assessment and monitoring under real conditions (e.g., plastic bag production and waste water and waste recycling plants, FFF 3D printing)
WP 6: Exploitation of results achieved	Identify needs of relevant data / tools (PlasticsEurope, CEFIC, VCI) Prepare harmonised protocols, standardisation processes for monitoring (running activities in ISO/TC 147/SC2/ JWG), VAMAS) Sensibilisation for the need of harmonised risks assessment tools (ISO/TC 147/SC2/ JWG and on national level) Cross-linking topics of plastic recycling and environmental aspects (CEN 249/WG 24)

Abbreviations

ASTM	American Society for Testing and Materials
CD	Committee draft (in the context of ISO)
CEFIC	European Chemical Industry Council
CEN	European Committee for Standardization
ECHA	European Chemicals Agency
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GESAMP	Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (advises UN)
ILC	Interlaboratory Comparisons (in the context of VAMAS)
ISO	International Organization for Standardization
JRC	Joint Research Centre of the EU
MNP	Micro- and Nanoplastics
MSFD	EU Marine Strategy Framework Directive
NGO	Non-governmental organization
OECD	Organization for Economic Co-operation and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
UNEP	United Nations Environment Programme
TC	Technical committee
TR	Technical report
TS	Technical specification
VAMAS	Versailles Project on Advanced Materials
VCI	Verband der Chemischen Industrie (German Chemical Industry Association)
WD	Working draft (in the context of ISO)
WHO	World Health Organisation
WG	Working Group

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