Analysis of governments' authority to mitigate micro- and nanoplastic releases through closed-loop design to inform the global plastics treaty negotiations.

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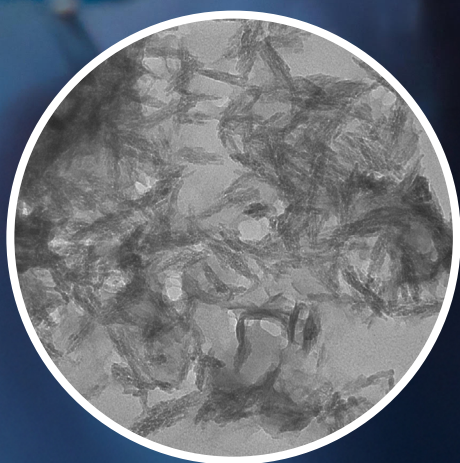

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Inset: Photo courtesy of Eliane El Hayek, PhD, University of New Mexico

Image of solid nanoparticle shards captured by Transmission Electron Microscopy (TEM) in digested and prepared brain tissue prior to Py-GCMS chemical analysis which reported polyethylene in these samples

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Summary

A global emergency is now recognized regarding society's reliance on plastic. The extensive dissemination of microplastics particles (MP) and nanoplastics particles (NP) (collectively MNP) within consumer goods, inside homes, in the workplace, circulating in the environment via atmospheric currents, aquatic systems, and biological vectors, facilitates their global dispersion, elevating all human exposure to plastic and its MNP to a genuinely worldwide concern. Compelling evidence, sufficient to satisfy the Precautionary Principle, demonstrates that the progressive accumulation rates of MNP in the environment increase the risk of MNP accumulation in humans due to exposure from increasing plastic loading, both through plastic use and plastics in the environment, as it degrades by fragmentation into micro- and then more hazardous nanoplastic particles. This human exposure to MNP can be mitigated through closed-loop design for plastic, plastic products, and processes involving plastic, including legacy plastic. This discussion explains how closed-loop design can mitigate human exposure to MNP, the legal authority available to adopt such design and how this can be considered in the development of a legally binding global instrument on plastic pollution, including in the marine environment (hereafter: plastics instrument).

Sources, exposure and impacts

Plastic is a perfectly imperfect material. Plastic consists of up to 70,000 different polymer formulations and relies on a complex array of 16,000 chemicals—4,200 of which are "of concern"—just to achieve functionality for which it is currently marketed. Plastics are used widely for "disposable" products despite their persistence and mobility in the environment. The complexity and heterogeneity of plastic formulations is maintained as larger plastic pieces break down into MNP. These plastic particles, generally from plastic that is hydrophobic and lipophilic, carry their plastic chemical burden with them as they find their way into biological organisms, including humans.

Direct exposure to MNP occurs through a wide range of sources in indoor and outdoor environments. Direct exposure to MNP occurs through consumer goods such as synthetic textiles, baby bottles, toothbrushes, and plastic food containers. This exposure is accelerated when plastics are heated. MNP have been found in municipal and bottled water, highlighting their pervasive presence. Key environmental sources include car tyres; coatings such as marine paints, road markings and architectural paint; personal care products; and agricultural practices that contribute MNP to ecosystems and the food chain. Industrial activities, such as plastic production and waste management, also generate significant MNP exposure, particularly in occupational settings. However, this occupational exposure is not limited to plastics facilities alone, but all industries that make use of plastic products, such as conveyor belts.

MNP enter biological organisms through routes of exposure occurring from all plastic including ingestion (bottled water, food), inhalation (microparticles in the indoor and outdoor air) or potentially through the lesser route of dermal absorption (from clothing). Studies show human exposure to be over 100,000 MNP per year through food consumption and inhalation alone. To date, MNP have been reported in peer reviewed research to be found in a wide range of human organs and tissues, including hair, saliva, lungs, liver, spleen, kidneys, colon, placenta, urinary tract, bladder, blood, male reproductive system and brains. Analytical methods continue to mature, including new imaging techniques for the very small particles, methods to evaluate relevant material characteristics such as heat content, size and shape; sample preparation methods such as proper digestion and refinement; and chemical identification methods including gas chromatography and mass spectroscopy and more, along with laboratory techniques to ensure and control data quality, are recognized and together support this body of work.

Beyond human studies, laboratory studies involving animals and in vitro in cells, and relevant modeling, have associated the presence of MNP in tissue with several disease processes including inflammation, oxidative stress, cancer, developmental impacts, respiratory health effects, cardiovascular effects, reproductive effects, biological obstruction and cellular damage. Alterations in gut microbiome composition and intestinal health have been reported. Studies also show that the smaller MNP may potentially pass through the blood-brain barrier.

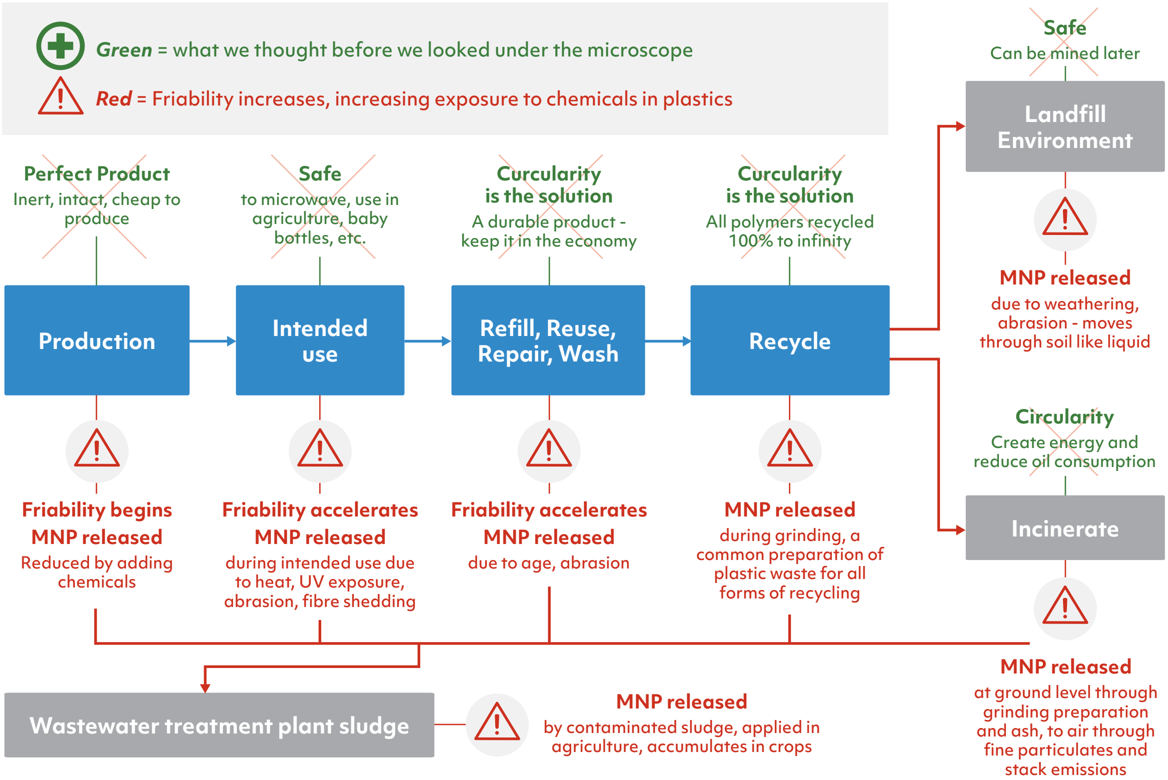


Figure A: *Historical perception of plastics compared to evidence of invisible emissions and releases*

With new methods, the specific risks posed by MNP particle, chemical and pathogenic hazards in biological and natural systems are being evaluated. For biological systems, evaluation is most advanced in laboratory models (in vitro, animal studies) which use manufactured, homogeneous and pristine particles of known size, shape composition and concentration. Evaluation of exposure to heterogeneous environmental MNP in biological systems including humans is an emerging field. These different methods of data collection, including human tissue sampling for accumulated MNP from environmental exposure, and laboratory-controlled animal studies utilizing manufactured prepared MNP to study MNP behavior at the cellular level, constitute multiple lines of evidence of the presence of, and harm from, human exposure to MNP. The current body of evidence represented by these human and animal studies are not unexpected given its coherence with early work as well as the known durable nature of plastic. Increasingly, the evidence indicates there may be no safe level of MNP exposure. However, without specific methods to conclusively quantify internal MNP exposure and effects, evaluating actual MNP safety criteria remains a critical goal.

Detection of smaller MNP (micron size range), referred to as nanoplastics (sub-micron size range) is an emerging technology, thus despite increasing pervasion of plastics throughout every aspect of our lives, it has not previously even been possible to directly assess the exposure and safety of these particles in humans. Therefore, the harm from these particles has historically gone unrecognized. Recent studies of human tissue utilizing newly available analytical techniques indicate MNP, a synthetic material not present in humans naturally, is now present, indicating that accumulation may now be occurring in populations not subjected to concentrated occupational exposures. While rates of bioaccumulation at variable exposures have yet to be quantified, due to the durable nature of plastic, the anticipated presence of MNP in human tissue, as reported in recent studies, is alarming. Further research is needed to confirm that the particles reported in the studies are conclusively MNP, while also determining the potential harm due to leaching or diffusion of plastic chemicals of concern into the specific locations where MNP may be deposited, and potentially accumulating, in the body.

In support of the need to prevent further exposure, it must also be recognized that the removal of MNP from the environment and human tissues, once released, is virtually impossible at scale either in the environment, or from human tissue. Meanwhile, MNP have proven so persistent that they present significant challenges in disposal processes. Recycling, incineration and landfilling of post-consumer plastic do not eliminate the formation and propagation of MNP through the environment. For instance, plastic waste is most often discussed in the context of recycling and its greenwashing issues. While recycling clearly produces fugitive emissions of MNP released at ground level due to crushing and shredding of waste plastic, recognition must also be given to current statistics showing more collected plastic waste is incinerated than recycled. Incineration processes also commonly prepare plastic waste feed by crushing and shredding to reduce waste volume, but the incineration processes themselves are generally not designed to completely destroy plastic. While purported to be the final fate of plastic, incinerators generate prolific amounts of MNP that are emitted and released without specific recognition of the risk of MNP, or even monitoring for MNP emissions and releases. All processes involving plastic, particularly combustion processes, must be modified and monitored to ensure complete mitigation of MNP emissions and, if incineration, complete destruction of plastic.

Microplastics as "delivery mechanisms" for other pollutants and disease vectors

The primary mechanism by which plastic chemicals of concern enter biological organisms from MNP is molecular transport phenomena, whereby plastic chemicals diffuse from the exposed surfaces of MNP particles, with higher rates of diffusion at newly exposed surfaces which had not previously had opportunity for release from diffusion before the fracture. Diffusion of plastic chemicals continues to increase as MNP fracture into smaller particles. Once in an organism, **MNP act as unintended "delivery mechanisms"** for these chemicals, increasing their biological impact. Chemical contaminants from the environment, such as POPs and heavy metals, also adsorb onto the surface of MNP. Of course, environmental chemicals (as opposed to plastic chemicals) are presented with greater opportunity to adsorb onto the surface of MNP (for later release through desorption) due to the increased surface area per mass for smaller particles.

Unique to MNP exposure is the likely direct chemical exposure to biological tissues from MNP, once within biological tissue, that would not otherwise have occurred. This is due to targeted delivery of the chemical through the particle surface after the particles become lodged in biological tissues and bioaccumulate. In this manner, chemicals delivered by MNP can **bypass normal metabolic processes that would typically eliminate these substances** from the body should they enter the body through other means. This bypassing mechanism resembles the use of MNP for targeted drug delivery, but differs in its unintentional nature, introducing potentially toxic chemicals into the body.

With recent research reporting MNP could potentially enter the brain through the blood brain barrier (BBB) and the human olfactory bulb, this new pathway presents a previously underappreciated or unrecognized route of possible toxic exposure that needs to be explored.

Similarly, MNP can enable microorganisms to "hitchhike" into the body when they bond to MNP surfaces. Once inside an organism, smaller MNP may find their way inside cells, where the MNP and their pathogenic burden may **evade normal immune defenses** (Katsumiti et al., 2021). These microorganisms may include many dangerous pathogens, such as Aeromonas, Rhodococcus, Pseudomonas, Enterobacter, Halomonas, Mycobacterium, Photobacterium, and Shigella, and certain fungi (Yang et al., 2023).

New toxicology data is needed based on the delivery of toxins via MNP transport mechanisms, especially where toxicity may persist and exposure risk may magnify as the particles fragment, due to greater surface areas of smaller particles relative to mass. Specifically, because many plastic chemicals have already been evaluated on their own for overall harm, this new research must address the potential for magnification of harm to humans from persistent exposure to these plastic chemicals. Such studies should consider MNP persistence and potential for long range transport, both contributing to the hazard posed by MNP and resulting risk following exposure to MNP, as well as potential bioaccumulation, none of which were likely considered in assessing risk posed by plastic chemicals in isolation.

Conventional risk assessment "dose-response" approaches are challenged due to the inherent variability of MNP. But, pursuant to the Precautionary Principle, current evidence is sufficient to both act as well as shift the burden of proof: sufficient evidence can be provided to support action through associations between human MNP tissue samples and plastic usage reflecting exposure rates, to disease rates and other health data.

System-wide approach towards a closed-loop for plastics

This scientific basis highlights the urgent need to mitigate MNP releases, primarily through an overall reduction in plastics production and use. This will need to be supported by a **system-wide approach** to firstly reduce plastic production, eliminate problematic plastic products, and minimize the number of plastic formulations while enhancing transparency along the supply chain. This is supported by eliminating problematic polymers, simplifying chemical plastic formulations and additives, and eliminating chemicals of concern from plastics. Secondly, mitigating MNP release and exposure is critical, through mandating best design practices for least shedding or other release potential, as well as prioritizing and regulating use practices of plastic products to avoid escalating both release and exposure.

The ultimate goal should be to create a closed-loop system through reduction of plastic production and removal of legacy plastic, along with redesign of plastic, plastic products and processes involving plastic to eliminate human exposure to MNP ("closed-loop design"). In such a closed-loop plastic system, plastics would not continue to accumulate in the environment only to result in MNP environmental exposure, and plastic would not be used (1) where MNP would be released as a planned element of design, or (2) if MNP release could not be mitigated where MNP release is incidental to design. This system could include agreeing on allowable critical uses, such as for some health care, automotive, aerospace, home construction, and moisture barrier applications, considering steps to mitigate MNP release and human exposure. Additionally, eliminated uses should be defined, in particular focusing on direct exposure and vulnerable population use. All plastic uses would require capturing plastic post-use for appropriate management or destruction.

Experiences from national and regional authorities

Despite comprehensive regulation of products, chemicals and environmental pollutants, as well as existing waste management infrastructure, there are few instances where existing national or regional authority or infrastructure specifically limits or otherwise mitigates human exposure to MNP. Examples from the EU, US and Tuvalu illustrate the varied approaches to tackling MNP.

The strength of precautionary principle implementation within regulatory frameworks determines the level of causal evidence required, with stronger implementations demanding **less compelling (or less demanding) evidence**, and weaker implementations **requiring higher levels of evidence of harm**. The EU has adopted MNP policies based on the precautionary principle, providing regulatory authority to effectively address intentionally added microplastics, as well as increasingly setting thresholds for secondary releases. While the US was among the first countries to ban microbeads in cosmetics, it has not expanded regulatory action to other MNP uses due to limited emphasis on the precautionary principle.

Tuvalu, a small island developing country, on the other hand, is an example of a country that does not manufacture plastic products and has high reliance on regional and global regulatory measures to mitigate MNP releases. **The only authority Tuvalu has for product and engineering design is to refuse imports.**

Where nations have not adopted the precautionary principle, as in the United States, litigation can drive development of legislation and regulation. Plastic litigation has surged in the United States over the past five years, with recent significant lawsuits filed by the State of New York, the City of Baltimore, and the State of California against major plastics-related corporations.

Without specific provisions for MNP in the plastics instrument, **harm to humans and the environment will likely escalate further**. This may necessitate widespread and disruptive litigation at all levels of government to mitigate damages and compel action, **diverting resources that could otherwise be utilized for effective governmental action**. Moreover, such litigation may drain plastic manufacturer corporate resources that could be better spent in **transitioning the current unmanaged plastics market to a safely designed, managed, and more sustainable closed-loop plastic market**.

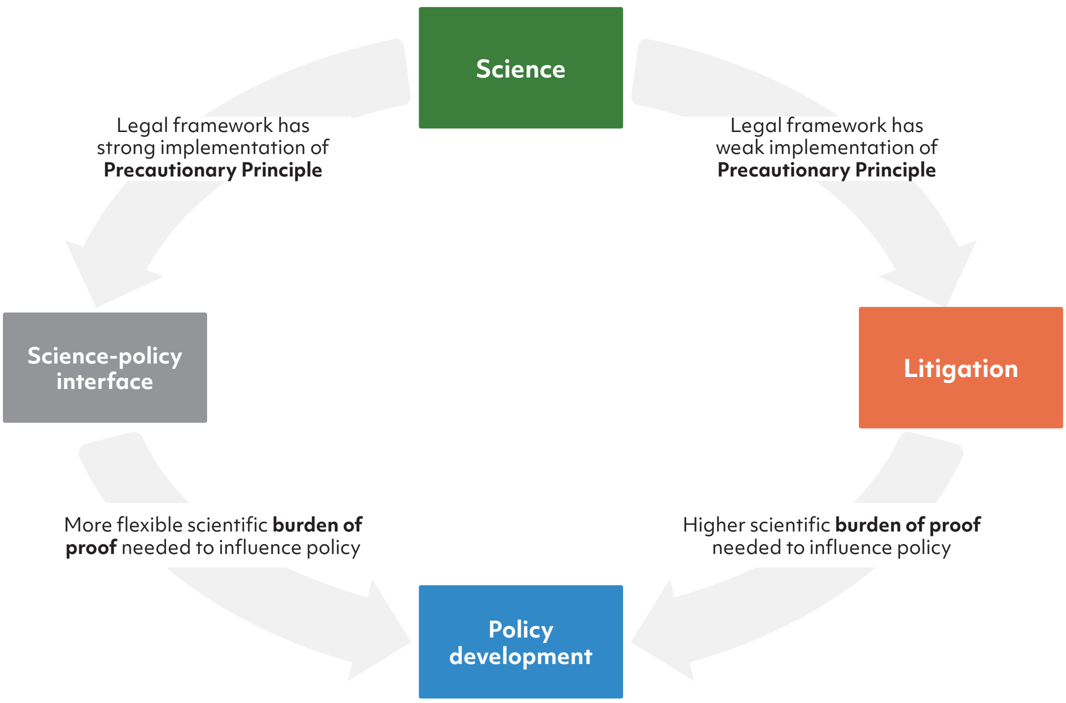


Figure B: *The role of the Precautionary Principle in policy development*

The role of the plastics instrument

Existing multilateral environmental agreements (MEAs) were developed before the problem of MNP surfaced on political agendas. The plastics instrument will have an important role to play in filling this global governance gap, in line with UNEA Resolution 5/14 that recognizes microplastics as a component of plastic pollution. The zero-draft developed for the third session of the Intergovernmental Negotiating Committee (INC-3) to develop an international legally binding instrument on plastic pollution, including in the marine environment, has been used as a basis for negotiations. This draft included consideration of microplastics in areas of identifying and avoidable problematic plastic products (focusing on intentionally added microplastics only), plastic product design, emissions and releases, and trade.

The Non-Paper 3 of the Chair of the Committee (hereafter referred to as "Chair's non-paper"), released late October 2024 in preparation for INC-5 suggests options for streamlining the text of the zero-draft with the aim of meeting the deadline for concluding negotiations at INC-5. Microplastics are specifically included in the proposed Article 2 on definitions, proposed Article 7 on emissions and releases, listing releases of microplastics during production of plastics, but also including microplastic and nanoplastic releases during use of products.

The new Article 19 on Health suggested in the Chair's non-paper provides an improvement in the recognition of the health impacts of human exposure to microplastics, including occupational exposure and the need for ongoing monitoring of health risks related to exposure. However, the specific regulation of microplastics has been weakened. Also, several important provisions for MNPs have been omitted, or may have been merged within other provisions, such as the provision II.13 of the zero-daft on transparency, tracking, monitoring and labeling.

The following recommendations are provided to effectively address MNPs, suggesting areas for inclusion across the provisions outlined in the Chair's non-paper:

Principles (Art. 2)

- Article 2 of the Chair's non-paper includes only definitions for the interpretation of the plastics instrument. Although a dedicated section for principles is not always included in MEAs, it is recommended that Part I.4 of the draft instrument be maintained, despite exclusion from the Chair's non-paper, to include key overarching principles that guide implementation and interpretation of the plastics instrument. Principles are no longer featured in the Chair's non-paper and could be included as a subsection of the proposed Article 2 of the Chair's non-paper.

- It is necessary to agree on a primary goal to minimize MNP releases, while endeavoring to achieve their elimination. This will require placing strong emphasis on mitigating all plastic pollution, with the **precautionary principle** explicitly embedded in the text of the convention, either in the preamble or, preferably, in a section dedicated to principles and approaches.

- Applying the **polluter pays principle** is also necessary for internalizing costs of MNP contamination. This can be done through EPR schemes that shift the cost of waste management and remediation from municipalities and consumers to producers. Establishing clear liability standards, including for legacy plastic, will further reinforce producer accountability and stimulate safe design of plastic materials.

Plastic products and chemicals of concern used in plastics (Art. 3)

- **Targeted mitigation measures** should recognize the existing risk of human exposure to MNP and include banning main sources of primary MNP release by design (including intentionally added MNP) and setting regulatory thresholds for secondary MNP release and emissions incidental to design for specific product and process groups. This could involve developing product and process lists with phaseout dates and release limits, outlined in an Annex to the plastics instrument.

- A comprehensive and efficient approach to identify and phase out plastic **polymers and chemicals of concern** will be critical to reduce impact of unavoidable MNP releases, given these particles function as vectors, reportedly carrying harmful chemicals deep into human tissues where they persist. This can be achieved by adopting polymer and chemical simplification including, for chemicals, and a grouping of chemicals approach based on structural similarities and shared characteristics.

- **Transparency and traceability** are essential and can be enhanced with mandatory product labeling and content disclosure of MNP profiles and associated chemicals of concern. Moreover, ensuring that industries report MNP releases will be critical to monitor progress. This could include development of mandatory plastic pollution release registers, or disaggregating data on plastic pollution, specifically MNP emissions and releases, within existing Pollutant Release and Transfer Registers (PRTRs).

Plastic product design (Art. 5)

- The plastics instrument could guide the **design of plastic products** by adopting design criteria that aim to first identify for elimination or replacement those products that are used in an intended manner constituting disposal, or otherwise highly likely to leak into the environment. Design of remaining plastic products must include improving product performance specifically by minimizing MNP releases. Such criteria could include safe material composition, polymer integrity, longevity, and transparency.

- The plastics instrument could also guide the **design of processes involving plastic** by adopting MNP release criteria that aim to minimize MNP release through design of both product and process. Such criteria could include identifying those processes that rely heavily on plastic, that could either replace these uses of plastic or contain all MNP releases, and properly manage this waste.

Supply (Art. 6)

- Agreeing on a **global cap on primary plastic production** could significantly enhance the effectiveness of targeted MNP measures indirectly, given MNP releases are inherent throughout the entire plastics life cycle, and likely can never be fully eliminated.

Emissions and releases (Art. 7)

- Agreeing on a primary goal to minimize MNP emissions and releases, while endeavoring to achieve their elimination, will be important to mitigate human health and environmental impacts across the life cycle of plastics.

- The plastics instrument has a role to play in enhancing **industrial regulatory measures** through the following measures:

    - Requiring adoption of best available technology design to eliminate MNP emissions and releases through evaluation of plastic use or processes involving plastic within industrial facilities, taking steps to reduce reliance on plastic while mitigating MNP release from such use or processes.
    - Regulating MNP releases, both stack emissions and fugitive ground level emissions, through existing environmental regulations which have generally not yet recognized MNP as fine particulate or consider its risk differently from dust or other sources of fine particulate. Also, while mitigating MNP releases.

  - Ensuring workers' safety from MNP exposure by requiring protective equipment, ventilation systems, emission controls, and worker training.
  - Requiring companies to disclose potential MNP emissions to ensure workers are informed of the risks and safety measures.

- Minimization of emissions and releases can also be promoted through other actions, as outlined for Articles 3 (plastic products and chemicals of concern used in plastics), 5 (plastic product design), 6 (supply) and 9 (existing plastic pollution).

Existing plastic pollution (Art 9.)

- **Remediation** measures will also be necessary, given all plastics eventually degrade into MNP. This could include both environmental and landfill remediation, with a focus on hot spots, while taking into account the need to minimize possible environmental damage from these efforts.

Human health (Art. 19)

- Give specific recognition of the health impacts of human exposure to microplastics, including occupational exposure and the need for ongoing monitoring of health risks related to exposure.

Conference of Parties, including ability to establish subsidiary groups (Art. 20)

- It is essential to establish a subsidiary scientific and technical body of the plastics instrument to better advise the COP on product restrictions. In this context, the review of **risk assessment** data for possible products and processes proposed for listing under the convention should move from a focus on causality to correlation, ensuring a comprehensive acknowledgment of the harm caused by MNPs.

1. Introduction

1.1 Objectives

The main objectives of this report include the following:

- Establish the technical foundation of risks caused by micro and nanoplastic plastic particles (MNP), in particular regarding human health based on the most recently available published research.
- Provide product and system design solutions for mitigating harm from MNP, focusing on plastic and plastic chemicals.
- Examine how national and regional MNP policies can inform mitigation efforts
- Provide recommendations for the legally binding instrument on plastic pollution, including in the marine environment (hereafter: plastics instrument) to address governance gaps in MNP control, including through specific measures, approaches and principles

The report also has the following specific objectives:

- Convey newly published data reporting the presence of MNP in human tissue resulting from persistence by design of plastic, including reliance on harmful chemicals, the harm resulting from both the particle and the chemicals, and the urgency of mitigating human exposure to these particles now.
- Convey new data on how persistence by design is fundamental to potential human exposure to MNP, as well as to hazard presented by MNP from all potential exposures.
- Explain the significance of plastic mass in planetary circulation as MNP and its source plastic, resulting in planetary overloading with MNP; how this previously

unrecognized or understudied class of particle is released from plastic throughout its existence; behaviour and chemical characteristics of these particles as influenced by conditions outside the plastic particle, whether during use or in the environment; chemical engineering systems approach for designing to mitigate MNP exposure from elimination of plastic mass flux to the environment, mitigation of MNP release from plastic production, use and waste management, and removing plastic MNP precursor from the environment.

- Demonstrate the necessary industry-wide design conditions to achieve closed-loop design and implementation for the manufacture, use, and end-of-life management and remediation of plastic.
- Demonstrate the authority of national and regional governments to regulate and mitigate risks to human health from MNP exposure resulting from plastic throughout its existence including during production, use, recovery, disposal and in the environment.
- Suggest the possibility, due to this authority, from manufacturing and consumer product safety through environmental protection, of litigation stemming from health effects.

1.2 Terms

The following terms are used in this report, as articulated below for this discussion specific to plastic product and system closed-loop design to mitigate human exposure to MNP.

- **Adsorb/adsorption**: The tendency of chemicals and pathogens encountered by the MNP to attach to and be held on or in the surface of the MNP.

- **Absorb/absorption**: The behaviour and result of chemicals and particles passing through a surface into and through a solid matrix by diffusion, such as chemicals being absorbed into a plastic, or plastic particles being absorbed across a biological barrier (i.e., uptake).

- **Emission**: MNP escaping to any media or environment as MNP by design, or incidental to design due to plastic's inherent friability, whether during production, operation of plastic-reliant processes, plastic or MNP use, plastic waste management or legacy remediation. MNP emissions generally constitute, or result in, MNP contamination or pollution.

- **Friable**: In terms of plastics, the characteristic of plastic particles becoming unbound by degradation from the plastic matrix emitting or releasing as MNP.

- **Micro- and nanoplastic particles (MNP)**: All plastic particles less than 5 mm in size including nanoplastic particles.

- **Microplastics (MP)**: Plastic particles less than 5 mm in size. MP can be intentionally manufactured (such as microbeads in cosmetics) or result from the breakdown of larger plastic items through environmental weathering.

- **Nanoplastics (NP)**: Generally considered plastic particles smaller than 1 µm (1000 nanometers), although nanotechnology is considered design within the lower end of that range, 1 to 100 nm. NP can be intentionally manufactured (e.g., specifically manufactured for testing medical devices or as medical devices for drug delivery; designed and used as abrasives in toothpastes and personal care products) or result from the breakdown of larger plastic items through environmental weathering or uses such as abrasion.

- **Precautionary Principle**: A principle promoted in the 1992 Rio Declaration, Principle 15, which states, "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

- **Primary Microplastic by Design**: Microplastic intentionally manufactured as microplastic.

- **Secondary Microplastic Incidental to Design**: Microplastic resulting from breakdown and fragmentation of larger plastic pieces.

- **Plastic**: Solid material incorporating one or more synthetic or semi-synthetic high molecular weight polymers. including thermoplastics, thermosets, elastomers and composite resins. Plastics are additionally characterized by typically including a diverse range of plastic chemicals, typically being hydrophobic, and typically being highly persistent in the environment while still degrading into MNP.

- **Plastic chemicals**: Includes the polymer, intentionally added substances such as monomers, processing aids and additives and, importantly, non-intentionally added substances (NIAS), such as impurities, reaction by-products, and degradation products. Contaminants sorbing to plastics during the use and end-of-life phase are not considered plastic chemicals (Wagner et al., 2024) but are important in terms of risks of MNP.

- **Persistence**: Regarding plastic, the tendency to remain in the environment or in landfills without fully biodegrading, but rather fragmenting into microplastic and nanoplastic, for a prolonged period of time. This is the key characteristic of current plastic formulations resulting from plastic polymer design with the current use of chemicals.

- **Release**: MNP emitted by design into or from any human, industrial, agricultural or natural environment, or incidentally from its initial solid plastic matrix due to plastic's friability, whether during production, operation of plastic reliant processes, plastic or MNP use, plastic waste management or legacy remediation. MNP releases constitute, or result in, contamination or pollution.

- **Thermoplastic plastic**: Plastic solid material made of strong polymer chains with primary bonds between carbons (or silicon atoms if silicone) in the polymer chain, but with only secondary bonds between carbons in adjacent polymer chains; can be melted and reformed. Includes thermoplastic elastomers.

- **Thermoset or cross-linked plastic**: Plastic solid material made of strong polymer chains with primary bonds between carbons (or silicon atoms if silicone) in the polymer chains, but that also has primary bonds between carbons in adjacent polymer chains; has been heat treated and/or chemically cross-linked and cannot be remelted. Includes thermoset elastomers.

2. The Human Body: MNP Sources, Pathways, Effects

Key Points

- Plastic is designed to be perfect, but remains perfectly imperfect, requiring a significant chemical burden for use as intended. This chemical burden does not render plastic impervious or permanent: while conventional plastic is specifically designed to not biodegrade, and in fact does not meaningfully biodegrade within any practical or meaningful human timeframe, all plastic is friable to some degree and degrades by fragmentation into MNP, resulting in MNP emissions and releases throughout its existence. Unmitigated plastic production has rendered plastic and MNP now ubiquitous in our environment, with new plastic production estimated to contribute to the planetary plastic burden at a rate of 1 to 1 (Cowger et al., 2024).
- Production caps, caps on problematic plastic products, polymers and chemicals, redesign of plastic production, use and environmentally sound waste management, and remediation of legacy plastic pollution will all reduce continuing contribution to overall planetary plastic burden and risk from plastic exposure. But the existing planetary plastic burden, along with current societal reliance on plastic products, constitutes a present, ongoing and exponentially increasing source of human MNP exposure to MNP emissions and releases.
- Plastic is a unique synthetic solid material, both designed to resist degradation while manufactured and sold for purely disposable uses.
- While resisting degradation, plastic has visually appeared to be physically inert given the earlier state of the relevant science, resulting in plastic historically being considered safe for most uses, including critical uses such as containers for pharmaceuticals, baby food and drinking water.
- Plastic has been considered cheap (due to failure to incorporate external cost of plastic, MNP and plastic chemical pollution), light, adaptable and persistent by design

to achieve specific properties with chemical additives. Plastic has also erroneously been considered generally safe. With ever increasing new uses, production continues to accelerate greatly, replacing natural materials, and creating unique disposable markets. However, mounting scientific evidence shows that many plastics, their additives, and MNP released from all plastic, pose significant risks to human health and the environment, requiring careful consideration of their safety on a case-by-case basis based on their composition, intended use, and disposal methods.

- The initially perceived attractive features of plastic, including cheap, light, mouldable, persistent by design and yet somehow safe, have driven increasing plastic production since the 1950's. Almost all plastic produced has become plastic waste that still exists today and is accumulating in our environment.
- As expected, given its design, while plastic does not biodegrade at meaningful rates within practical policy timeframes. Instead, it is inherently friable and fragments into smaller and smaller pieces, including MNP, resulting in emissions and releases of MNP, from any plastic, throughout its existence. Given its design, these MNP are expected to simply fragment into smaller particles without meaningful biodegradation.
- With new analytical techniques, as expected production, emissions and releases continue to increase, MNP are now found everywhere on the planet and in every environmental media. Where MP is found, NP is found at counts orders of magnitude higher, even while we remain limited in our ability to detect the smallest NP.
- MNP present hazards from both the particle itself, chemical additives and NIAS that they release, and additional chemicals or microorganisms transported by the MNP (Li et al., 2024b).
- Significant sources of direct MNP exposure from consumer goods include synthetic textiles, which shed microfibers at varying rates (Cui & Xu, 2022); plastic baby bottles emitting and releasing MNP when heating formula (Jeon et al., 2022); toothbrushes with plastic bristles shedding MNP through abrasion (Fang et al., 2023); plastic food containers, especially when heated, accelerating MNP release into food (Hussain, 2023).
- MNP has been detected in both municipal tap water and commercially bottled water (Gambino et al., 2022).
- Key ubiquitous sources of environmental MNP include car tyres emitting and releasing particles through abrasion, coatings (like marine paint, architectural coatings and road markings) fragmenting into MNP (Paruta et al., 2022), and personal care products with intentionally added MNP (Srivastava et al., 2022). Construction materials, such as geotextiles and astroturf, also degrade into MNP, while agricultural practices use time-release polymer capsules and plastic-coated irrigation pipes that contribute MNP to the food chain (Lewicka et al., 2024).

- Concentrated sources of MNP from industrial activities occur with plastic production, solid waste management and plastic recycling, including MNP laden municipal waste treatment plant sludge land application. This also results in significant human exposure in work environments (Murashov et al., 2021).
- MNP also present hazards from the chemicals and pathogens adsorbed onto the surface of the MNP from its presence in the environment. It appears that the smaller the MNP, the more hazardous it is, as it can cross cellular walls and release chemical additives at higher rates (Kaur et al., 2022; Junaid et al., 2022; Bowley et al., 2021).
- Using emerging scientific methods, researchers are only now beginning to systematically evaluate the true risks of MNP across biological and natural systems.
- MNP has been found accumulating, rather than biodegrading, everywhere we look, including sensitive ecosystems and our own individual environments, from our industrial and consumer use and waste management practices. MNP are being captured and are concentrating in the human ecosystem, resulting in daily human MNP exposure through ingestion, inhalation and, to a lesser degree dermal absorption, in home environments.
- Through our MNP exposure pathways, MNP appear to be present, and potentially concentrating, in various organs. MNP may become associated with various diseases including inflammatory and endocrine related diseases, sterility and other reproduction issues, cancer and possibly infant mortality. Research indicates that very small MNP may cross the BBB and possibly accumulating in brain tissue and potentially contributing to the incidence of Neurodegenerative diseases like Parkinson'ss disease.
- Due to the human health implications from MNP accumulation in human tissue, direct intervention to mitigate human MNP exposure through ingestion, inhalation and dermal absorption pathways is now necessary.

2.1 Overview

Chapter 2 encompasses:

- An in-depth look at plastic as ubiquitous source of human MNP exposure, its production, uses and fate
- Most direct sources of MNP resulting in human exposure
- A detailed examination of the various routes through which MNP enters the human body
- An analysis of how these particles move and persist within human biological systems
- A critical review of current research on the health effects of MNP exposure
- An exploration of the long-range transport mechanisms that distribute these particles globally

This chapter explores the complex journey of plastics from their production to their eventual fate as micro- and nano-sized particles. Sources of MNP in the human environment and the intricate pathways through which these particles enter the human body will be illustrated. This chapter will examine their behavior and persistence within our biological systems, and critically assess the emerging evidence of their health effects. Additionally, we will investigate the mechanisms of long-range environmental transport that contribute to the global spread of this pollution (Landrigan et al., 2023; (Bowley et al., 2021).

By building on and complementing the latest research findings, including those from the Minderoo-Monaco Commission on Plastics and Human Health, this chapter aims to provide a comprehensive overview of our current understanding of the MNP issue. It seeks to highlight the urgency of addressing MNP not just as an environmental concern, but as a pressing public health matter.

2.2 Plastic as a Ubiquitous MNP Source

Plastic is a unique synthetic material entirely originating from human design, typically formed into solid products but capable of existing in various physical states during processing. From its historical origins as a waste byproduct of the petroleum industry, waste hydrocarbon gas was chemically changed into plastic monomer feedstock which is polymerized into polymers used to produce plastic. Thus plastic, as a material, has historically always been considered very cheap relative to natural materials, although there are externalized costs that are not incorporated into the cost of plastic. Plastic is lightweight, mouldable and adaptable. In addition to design for a range of uses, plastic is designed specifically to persist, i.e., to resist a range of anticipated degradation pathways, such as sunlight (ultraviolet light or UV), oxidation, thermal and biological degradation, as well as to achieve specific desired plastic product properties, through use of plastic chemical additives, many of which are associated with their own hazards. Because plastic is cheap, lightweight, adaptable through design to achieve specific properties with chemical additives, and was historically mistakenly presumed to be safe, those uses have exploded, replacing natural materials, and creating unique disposable markets. These factors have driven acceleration of plastic production since the 1950's. Almost all plastic produced has become plastic waste that still exists today and is accumulating in our environment.

In recent years, the proliferation of microplastics (MPs) and nanoplastics (NPs) as MNP in the environment has emerged as a significant concern for both environmental scientists and health researchers. These tiny plastic particles, often invisible to the naked eye, have infiltrated virtually every aspect of our ecosystem and, consequently, human life (Li et al., 2023b). As our understanding of their ubiquity grows, so does the urgency to comprehend their potential impacts on human health (Landrigan et al., 2023). The pervasiveness of these particles in our air, water, and food supply has raised alarming questions about their long-term effects on human health and the environment (Thompson et al., 2024; Landrigan et al., 2023).

2.2.1 A History of Unlimited Plastic Production

Most plastic is made from fossil fuels, primarily oil and natural gas (Baheti, n.d.), where waste gases like ethane and propane are feedstock for chemical processes that create the basic building blocks of plastics – monomers like ethylene and propylene (Baheti, n.d.). These monomers are then polymerized, a critical step involving the application of heat in the presence of a catalyst, which facilitates the linking of small molecules into extended polymer chains (Samani, n.d.). The outcome is resin that serves as the foundation for plastic production to form long chains of molecules, that can be interconnected to create different types of plastic resins such as polyethylene (PE), polypropylene (PP), polyvinyl chloride (PVC), and polyethylene terephthalate (PET), as well as thermosets like polyurethane (PU), epoxy and phenolic plastics (Speight, 2011). Each type of resin has unique properties that make it suitable for specific applications. These resins can also be further treated thermally and/or chemically to convert thermoplastic into thermoset (or otherwise cross-linked) plastic that cannot be remolded. But, in addition to the specific properties of each resin, whether thermoset or thermoplastic, chemical additives are utilized to create specific characteristics. These additives, which may include colorants, stabilizers, and plasticizers, are crucial in determining the plastic's final characteristics, modifying both its physical and chemical properties to meet specific requirements (Samani, n.d.). But all conventional plastics are designed to perform as products, such that they are designed to resist environmental degradation. Thus, initial feedstocks of primary plastic pellets may be already laden with additives such as antioxidants, antimicrobials, flame retardants, UV absorbers and heat stabilizers (Wagner et al., 2024; UN Chemicals in Plastics, 2023). Over the history of plastic production, despite plastic's persistence, levels of plastic production have not been restricted. Due to its utility and lack of internalization of waste management costs, plastic production has only increased.

2.2.2 *Ubiquitous Plastic Uses and Presence in All Environments*

Different types of plastics require distinct manufacturing processes. Once produced, thermoplastic plastic can be moulded or otherwise incorporated into discrete products in many ways, whether injection (where molten plastic is forced into a mould under pressure), blowing (air pressure is used to shape molten plastic into hollow forms), or thermoforming (heated until pliable and then shaped over a mould) (Samani, n.d.). Thermoset plastics, in contrast, undergo irreversible chemical reactions during curing and are typically processed through compression moulding, resin transfer moulding, or casting. Elastomers, which are rubber-like polymers, are often manufactured through vulcanization or cross-linking processes to achieve their characteristic elastic properties. These materials can also be incorporated into difficult to recover composite materials (La Rosa et al., 2023). Thermoplastic can be further treated by heat and/or chemicals to become thermoset or cross-linked, leaving it no longer capable of reforming. The inert and durable nature, versatility, and low cost of plastics have led to their ubiquitous presence in modern life. Plastic use has grown to replace natural materials in a vast array of applications, including: packaging, replacing glass, metal, cardboard and wax paper food containers with plastic, including beverage bottles; replacing paper and cloth shopping bags and other single use items with plastic; replacing metal and wooden cutlery with plastic; creating new plastic items where they were not in wide use previously, such as lids and straws; developing new plastic or plastic infused construction materials, such as water pipes, insulation, window frames; integrating plastic into all forms of electronics, such as wiring insulation, and inventing new composite products like casings for devices, circuit boards; automotive, such as interior components, bumpers, fuel systems; innovating new uses for plastic in healthcare, such as medical devices, protective equipment, drug delivery systems; adapting plastic to replace natural fibres in textiles, including synthetic fibres and polymer coatings for clothing and furnishings; developing plastic technologies for coatings, such as latex paint and agriculture products, from weed control plastic sheeting, to irrigation piping and agricultural polymer time release insecticide applications (Lewicka et al., 2024).

Accelerating plastic production with ubiquitous use has been possible through creation of a disposable plastic goods market, advocating this false feature of disposability despite plastic's inherent durability and persistence (Bonta et al., 2024). Currently, plastic waste is managed poorly, given its persistence.

Conventional waste management methods, such as landfilling, incineration, and recycling were not designed for plastic, capture only a small fraction of plastic waste, allow leakage of plastic waste that is captured, while emitting and releasing significant amounts of MNP and plastic chemicals (Kabir et al., 2023;Hettiarachchi et al., 2023; Brown et al., 2023). The combination of ineffective waste management systems and the durability of plastic materials leads to the accumulation of plastic waste and MNP across various ecosystems, from the oceans, which have become major repositories for plastic pollution, (Kibria et al., 2023), to land and the soil column, (Sajjad et al., 2022) ambient air and precipitation (O'Brien et al., 2023), watersheds and rivers (Strokal et al., 2023) and our indoor environments at home (Kacprzak et al., 2022).

Continuing plastic production, spurred by the disposable plastic market, is contributing significantly to plastic pollution (International Union for Conservation of Nature, 2024), such that each kilogram of plastic produced has been recognized as potentially adding a kilogram of plastic to the planetary burden of plastic pollution (Cowger et al., 2024), while creating an environment where avoiding exposure to microplastic appears to be an impossible challenge (Gerretsen et al., 2024).

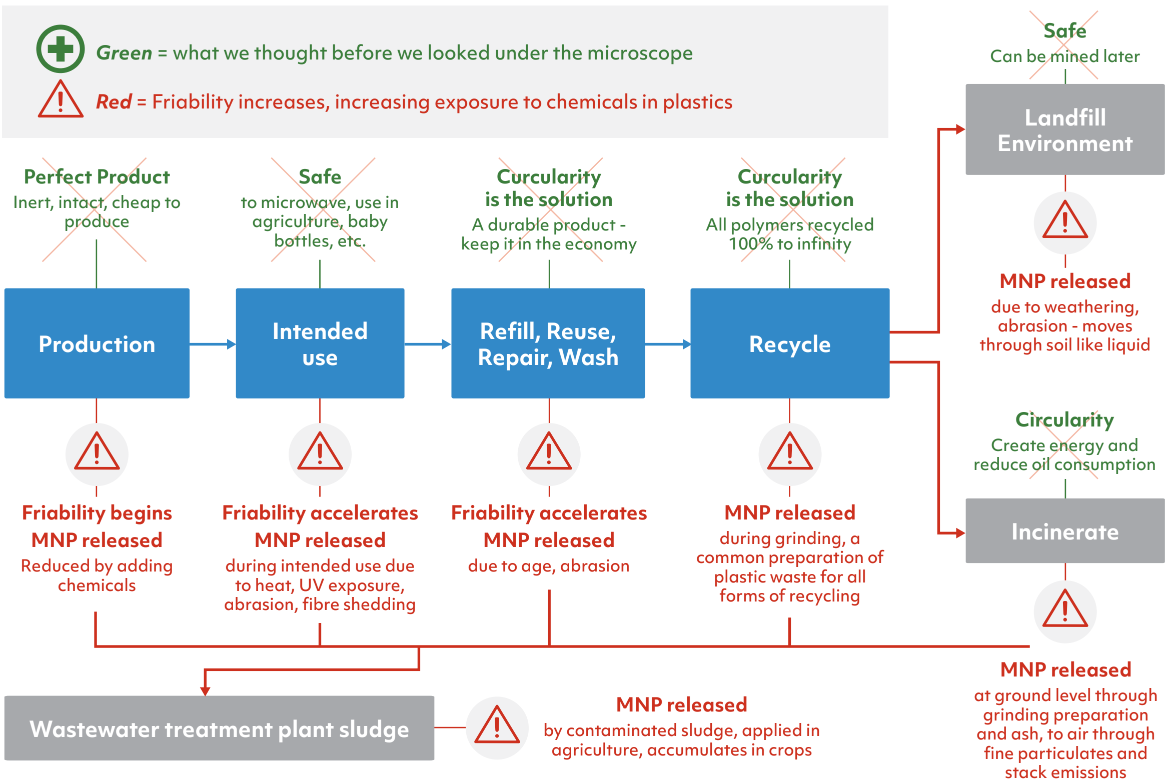


Figure 1: *Historical perception of plastics compared to evidence of invisible emissions and releases*

2.2.3 Significant Sources of MNP Human Exposure

Because all plastic will fragment and become a source of MNP as long as it exists, all plastic that is not destroyed or permanently sequestered can eventually become a source of MNP human exposure. Recognized significant sources of direct human exposure include consumer goods and environmental exposures to MNP sources from human activities.

When defined by shape and size, types of MNP include fragments, spheres, fibres, granules, and foam from expanded PS (Ziani et al., 2023). For intentionally manufactured MNP (primary MNP), the physical characteristics and chemical content are a function of their intended use. For example, long curly fibres and chemical content produced for use in the manufacture of synthetic fabrics, spheres and chemical content produced for use as microbeads in personal care items, or granules and chemical content manufactured for use as abrasives. MNP resulting from plastic use (resulting in wear and fracture) or from fragmenting in the environment (secondary MNP) have particle shapes resulting from their history of fracture and fragmentation. These include smaller fibres, multi-sided fragments, double pointed shards, and shred from tyres (Thompson et al., 2024).

Significant sources of direct MNP exposure through consumer goods include synthetic textiles which shed microfibers continuously at different rates depending on the tightness of the weave, use and fibre type, especially during washing (Cui & Xu, 2022). These microfibers which include MNP can be inhaled while worn, and then ingested later after MNP is released in the washing process into wastewater treatment plants ending up as biosolids applied to land as fertilizer for consumption as crops and ingestion through food (Sajjad et al., 2022). Specific examples of high-risk consumer uses include: plastic bottles used for baby formula, which release MNP when heating the formula (Jeon et al., 2022) to be ingested by vulnerable infant populations; toothbrushes with plastic bristles which release MNP through abrasion directly to oral cavities (Fang et al., 2023); plastic food containers, especially when heated (Hussain, K., 2023), which accelerates MNP shedding and concentration in food ingested; and single use plastic drinking water bottles shown to contain millions of MNP, (Quian et al., 2024), all which are ingested. Other direct human exposure through ingestion includes food, water and spices (Ziani et al., 2023). Additional significant human exposure occurs in work environments, where workers in both plastic manufacturing, and general industry, face high concentrations of MNP in industrial settings (Murashov et al., 2021).

Examples of ubiquitous sources of environmental MNP resulting in significant human exposure include car tyres, which release MNP of synthetic rubber (a plastic) during use through abrasion; coatings, such as architectural paint, marine paint and road markings, which fragment into MNP (Paruta et al., 2022); and MNP intentionally added to personal care products (Srivastava et al., 2022). Also, construction uses such as architectural fabrics and geotextiles like artificial turf all degrade and release MNP that can be inhaled. Some MNP is intentionally added to our environment, particularly in agricultural use of time release polymer capsules containing pesticides and herbicides, or agricultural piping for irrigation and plastic coating, which become MNP contributions to the food chain (Lewicka et al., 2024). These MNP are captured by natural water features such as deltas (Pellegrini et al., 2023) as well as infrastructure, emitted from waste incineration (Tsunematsu et al., 2022; U.S. EPA NSPS; Yang et al, 2021), while sequestering in wastewater treatment sludge that is applied to land only to concentrate in the food chain (Sadia et al., 2022).

All of these sources accumulate in indoor and outdoor environments, resulting in direct and indirect human exposures to MNP from these sources as well as city dust, ambient air, precipitation, drinking water and in homes. Oceans have become major repositories for plastic pollution, considering purely mass, resulting in severe consequences for marine life and, consequently, human health (Kibria et al., 2023)

2.3 Pathways into the Human Body

The current ubiquitous presence of plastic MNP in human indoor and outdoor environments is resulting in human exposure through inhalation, ingestion, and, to a lesser degree, dermal absorption, especially through high-risk consumer goods and other recognized MNP sources. Older research calculated MP intake by children and adults as more than 500 and 880 particles per day, respectively (Mohamed et al., 2021). However, newer data discussed in Chapter 3 suggests higher counts (Jadang, et al., 2024; Ziani 2023), indicating that the research is evolving, considering how MNP may break down into different rates depending upon outdoor and indoor exposure and respiration rates (Feng et al., 2023). Global estimates of modelled MNP mass intake from diet and inhalation, across 109 countries between 1994 and 2028, indicate a median ingestion and inhalation range of 1.98 grams per week MNP intake (Zhao et al., 2024).

While MNP exposure concentrations and potential intake will need to be studied for purposes of mitigating MNP exposure, the actual presence of the MNP in human tissue, and the potential for it to trigger disease processes, is of most concern. The risk from MNP is not just the physical obstruction posed by the particle in biological processes, but also the enhanced risk posed by plastic chemicals from the MNP's elevated ratio of surface area to volume, which enhances their ability to release chemicals (Costa, 2023; Gulizia, 2023), adsorb other substances (Joo et al., 2021; Mosca Angelucci et al., 2020), including pathogens (Zhang2024; Yang et al., 2023; Zhang Y. et al., 2022), and may increase their mobility and accumulation within the human body (Alijagic et al., 2024). Once MNP enters the body, it has been reported to cross impermeable barriers such as the intestinal mucosal barrier and potentially the BBB (Kopatz et al., 2023) and may alternatively potentially enter the brain through the olfactory bulb (Amato-Lourenco et al., 2024). The mechanism of transport of MNP through these barriers is a complex process with many implications (Li et al., 2024a). This process is reported as depending on several factors such as particle size, charge, surface chemistry and the type of cell with which they interact (Kopatz et al., 2023; Stock et al, 2022).

To mitigate the potential harm of MNP to human health and the environment, it is critical to limit exposure and reduce their use while continuing to study their effects (Mohamed et al., 2021). The pervasive nature of MNP in our environment has led to multiple routes of human exposure (Thompson et al., 2024; Landrigan et al., 2023). Understanding these pathways to human MNP exposure is crucial for assessing the potential health risks associated with plastic pollution (Sun & Wang, 2023).

2.3.1 Inhalation

Humans inhale MNP through exposure to airborne plastic particles originating from plastic, both indoors and outdoors, in any use, from contamination of goods or as plastic pollution. Currently plastic sources are not designed to eliminate MNP releases, where such design would achieve great reduction of MNP exposure, as discussed in Chapter 3. As discussed previously, and herein, MNP shed from textiles used in clothing, furnishings, architectural fabrics and other synthetic materials at relative rates depending on their weave and use, which MNP are inhaled and reach human tissues depending on their size and shape (WHO, 2022).

Outdoors, MNP are shed with tyre abrasion on road surfaces, creating tiny particles of synthetic rubber and plastic that can become airborne and inhaled in outdoor air. MNP are components of urban dust, which can be resuspended in the air by wind or human activities. Industrial activities utilize plastic, whether for packaging or process equipment, which can release MNP into the air, releases which are poorly or not regulated pursuant to existing environmental regulations. Concentrated sources of MNP from industrial activities occur with plastic production, solid waste management and plastic recycling, including MNP laden municipal waste treatment plant sludge land application. In addition to MNP sources from land application of sludge, agricultural activities include significant uses of plastic, which can release MNP, whether through pesticide use, plastic sheeting or plastic irrigation piping, where MNP can be carried as airborne emissions through wind erosion.

Due to their minuscule dimensions, these particles can remain airborne for prolonged durations and cover vast distances. Upon inhalation, the tiniest of these particles have the capacity to infiltrate deep into the respiratory system, potentially breaching the lung-blood barrier and entering the circulatory system. This ability of the particles to persist in the air and potentially access the bloodstream through the lungs raises significant concerns about their impact on human health through respiratory exposure (Landrigan et al., 2023). But inhalation also includes olfactory routes of exposure, where MNP have been reported in the olfactory bulb (Amato-Lourenco et al., 2024).

2.3.2 Ingestion

While any inhalation of MNP also poses the risk of ingestion through swallowing, the consumption of food and water contaminated with MNP is currently the most well-documented route for these particles to enter the human body. This occurs through ingestion of food, water and consumer products. MNP has been detected in a wide range of food products, including fish and shellfish, salt, fruits and vegetables where MNP can be taken up by plants from contaminated soil or water. Processed food may be produced with MNP contaminated ingredients, but also can be contaminated during food processing and from packaging.

MNP have been detected in both municipal tap water and commercially bottled water (Gambino et al., 2022). This contamination persists because many conventional water treatment facilities lack the specialized filtration systems necessary to effectively capture and remove these minuscule plastic particles, while drinking water distribution systems often utilize plastic pipe that degrades and releases MNP throughout distribution The standard purification methods employed by most water treatment plants are not adequately equipped to address the challenge posed by MNP, allowing these tiny pollutants to pass through and remain in public drinking water supplies. Also, physical wear and tear of the packaging, such as plastic water bottles, can cause small plastic particles to detach and mix with the food or water, while plastic exposed to heat or acidic conditions allow chemical components of the plastic to dissolve and transfer into the contents. This is particularly common with fatty or oily foods.

Over time, plastic chemical molecules can slowly move from the packaging material into its contents, especially in long-term storage situations where environmental factors like UV light or temperature fluctuations can break down the plastic, emitting and releasing particles into the contents. In this way, significant contamination can result from packaging, where MNP and its chemicals can migrate from plastic into its contents through plastic container abrasion, leaching and diffusion of chemicals, and material degradation, as discussed in more detail in Chapter 3. These migration processes are often accelerated when the food is exposed to heat (e.g., microwaving in plastic containers) or when the food itself is acidic. The type of plastic, food composition, storage conditions, and duration all play roles in determining the extent of MNP migration from packaging to food.

2.3.3 Dermal Absorption

While less studied than ingestion and inhalation, the potential for MNP as NP to be absorbed through the skin is an emerging area of concern. Possible routes of dermal exposure include personal care products, clothing and occupational exposures. Use of cosmetics and toiletries, such as exfoliating scrubs and toothpastes, which have historically contained plastic microbeads, are also a concern. While many countries have now banned these, other forms of NP may still be present in personal care products. Synthetic fabrics in direct contact with the skin may release nanofibers and their chemicals that could potentially be absorbed. The smallest fibers from clothing, as NP, can cross the skin cellular barriers through absorption, while larger fibers on the surface of the skin, as MP, can release chemicals onto the skin which can then be absorbed into the skin. Workers in certain industries, such as textile manufacturing or plastic production, may have increased dermal exposure to MNP. But also, MNP can be introduced intentionally through medical applications, particularly for drug delivery including transdermal drug delivery systems, where NP are used to enhance the penetration of drugs through the skin barrier (Lamparelli et al., 2023); and targeted drug delivery, where MNP are engineered to carry drugs to specific sites in the body, potentially entering through various routes including dermal, oral, or intravenous (Lamparelli et al., 2023). The long-term implications of such intentional exposures are an active area of research, balancing the immediate medical benefits against potential long-term risks.

The extent to which NP can penetrate the skin barrier is still a subject of ongoing research and is thought to be a route of lesser exposure. The implications are not yet understood but a study has reported that MNP may exploit oxidative stress pathways in skin to cause further harm (Li et al, 2024a) Factors such as particle size, shape, and surface chemistry likely play a role in determining the potential for dermal absorption (Aristizabal et al., 2024; Li et al, 2024b; Lamparelli et al, 2023; Landrigan et al., 2023). Understanding these pathways is crucial for assessing human exposure to MNP and for developing strategies to mitigate this exposure. As research in this field progresses, it’s likely that additional pathways and sources of exposure will be identified, further highlighting the pervasive nature of this pollution (Thompson et al., 2024; Landrigan et al., 2023).

2.4 Microplastics as delivery mechanisms for plastic chemicals

As discussed in more detail in Chapter 3, MNP acts as delivery systems for both its initial plastic chemical burden, as well as chemicals adsorbed from the environment and potential pathogens as well. Chemicals intentionally added to plastic to achieve specific plastic product performance characteristics include known toxins such as phthalates, bisphenols, chlorinated compounds, organometallics, and aromatics. These chemicals are known to contribute to thyroid disruption, neurodevelopmental deficits, and increased cancer risk (Seewoo et al., 2023). These chemicals, and other chemicals including unreacted monomer, processing aids, chemical reaction byproducts, up to 16,000 "plastic chemicals" (Wagner et al., 2024), are released from MNP throughout its existence, including inside human tissues following incorporation of MNP. In addition to plastic chemicals, persistent chemicals in the environment from past chemical uses can adsorb to the MNP adding to its chemical burden. These can include previously banned chemicals such as PCBs and some types of PFAS, where PCBs were historically used as dielectric fluid in electrical transformers, and PFAS was historically used in fire-fighting foam. Both compounds can also be present through environmental adsorption and in recycled plastics. For purposes of human health impact from MNP chemical content, recognized here is the fact that when MNP is ingested, inhaled or absorbed, these particles can serve as "delivery devices" for toxic chemical exposure. With the recent research showing that smaller MNP may enter the brain through the BBB and the human olfactory bulb, this potential new delivery mechanism presents a previously underappreciated or unrecognized route of toxic exposure that needs to be explored, a mechanism which is magnified as the particles fragment further exposing greater surface area of smaller particles relative to mass. These chemicals, their use, characteristics and behaviours are discussed in more detail in Chapter 3. Chapter 3 builds on the risk to human health from MNP presented herein to present chemical engineering concepts for comprehensive plastic design to mitigate human exposure to MNP that may support societies continued, but scaled back and carefully managed, reliance on plastic.

2.5 Movement of MNP and Persistence within the Body

Research has shown that the behavior and potential health effects of microplastics MNP in the human body are influenced by multiple variables. (Thompson et al., 2024; Campanale et al., 2020) These include the particles' dimensions, morphology, chemical makeup, and the biological mechanisms they interact with. To accurately evaluate the possible health hazards associated with these particles, it is essential to comprehend how they navigate through and remain within the human system. The complex interplay between these factors determines the ultimate impact of MNP on human health, making it a critical area of study for researchers assessing the risks of plastic particle exposure.

2.5.1 Fate of Larger MPs (>10 µm)

Particles larger than 10 micrometers (µm) are generally considered less likely to cross biological barriers (Landrigan et al., 2023). Through ingestion, larger MNP pass through the digestive system and are excreted in feces, through some may adhere to the mucus layer of the gastrointestinal tract, potentially leading to local inflammation or serving as a reservoir for the slow release of associated chemicals (Yee et al., 2021). Through inhalation, larger particles are typically trapped in the upper respiratory tract (nose, throat, and upper airways) and removed through mucus clearance mechanisms, such as coughing or sneezing (Campanale et al., 2020).

Although particles of larger size may not circulate in the bloodstream, their accumulation in the gastrointestinal and respiratory systems could still pose health risks. These risks include the possibility of causing localized irritation and inflammatory responses. Additionally, these larger particles might act as vehicles for transporting toxic substances or pathogenic microorganisms, potentially leading to adverse health effects even without entering systemic circulation.

2.5.2 Behavior of Smaller MPs and NPs (<10 µm)

Particles smaller than 10 µm, especially those in the nanoscale range, have a higher potential for distribution through the body and crossing biological barriers (Thompson et al., 2024; Landrigan et al., 2023; Stock et al., 2022). Administration of radio-labelled polystyrene MNPs (20nm - 5µm) in mice results in ~99% being excreted in the faeces (Keinänen et al., 2023). Nevertheless, through ingestion, some studies suggest that particles can be taken up by intestinal epithelial cells through multiple transport pathways: endocytosis (for particles <150 nm), paracellular transport, passive diffusion, micropinocytosis, and phagocytosis, with different pathways accommodating varying particle sizes (Deloid et al., 2024). Once inside these cells, the particles could potentially enter the bloodstream or lymphatic system (Yee et al., 2021). Through inhalation, nanoparticles can penetrate deep into the lungs, reaching the alveoli. From here, they may cross the air-blood barrier and enter systemic circulation (Campanale et al., 2020). Through dermal absorption, while the skin generally provides an effective barrier, some research indicates that nanoparticles may be able to penetrate the stratum corneum, especially through hair follicles or in areas where the skin barrier is compromised (Aristizabal et al., 2024; Li et al., 2024a; Lamparelli et al, 2023; Landrigan et al., 2023). A 2022 peer reviewed report recognized that the current science regarding very small nanoscale particles allows only speculation about the real effects of nanoscale particles inside the cells. But, even then, the report recognized that in in vitro studies, the size of the nanoplastic is more relevant to toxicity than larger microplastic. But both properties, size and surface chemistry contribute to the cellular uptake and impact of micro- and nanoplastic particles (Stock et al., 2022).

The ability of MNP to cross biological barriers is a key concern, especially for nanoparticles which have recently been reported to pass through the BBB, concentrating in the human olfactory bulb, potentially resulting in neurological effects (Amato-Lourenco et al., 2024; Kopatz et al., 2023). MNP have also been reported in human placentas, suggesting that maternal exposure could potentially lead to fetal exposure (Garcia et al., 2024; Medley et al., 2023; Weingrill et al., 2023). At the cellular level, some nanoparticles have been observed to enter cells and even penetrate the nuclear membrane (Lai et al., 2022).

Another key concern is MNP accumulation in various organs upon following systemic circulation (Sorci & Loiseau, 2022), such as in the blood and potentially the lymph system. When circulating in the blood stream, MNP can: interact with blood cells and plasma proteins, potentially affecting blood chemistry and function; be transported to various organs and tissues throughout the body, potentially cross other biological barriers, such as the blood-brain barrier or the placental barrier.

In summary, while several studies report MNP detection in human tissues (Thompson et al., 2024; Ziani et al., 2023, Leslie at al., 2022; Zarus, 2021), the most reliable evidence for tissue accumulation comes from controlled laboratory studies using labeled particles. These studies, using fluorescent-labeled MPs in animal models and cell cultures, demonstrate size-dependent tissue distribution and cellular uptake (Deng et al., 2017; Brynzak-Schreiber et al., 2024). MNP have been reported in studies identifying MNP in human colectomy specimens (Ibrahim et al., 2020) and human lung tissue (Jenner et al., 2022).MNP have also been reported as being found in the heart (Enyoh et al., 2023), the brain's olfactory bulb (Amato-Lourenco et al., 2024), as well as the urinary tract and bladder (Pironti et al., 2022). and the male reproductive system. In the male reproductive system, MNP has been found in the testes, epididymis, prostate gland, and semen (Hu et al., 2024; Demirelli et al., 2024; Hong et al., 2023). Human tissue findings should be interpreted cautiously due to current limitations in detecting and quantifying unlabelled particles. However, the reported accumulation identified throughout the male reproductive system in either human or animal studies raises concerns about potential impacts on male fertility, reproductive health, and possible alterations to genetic material in sperm. Also, when circulating in the bloodstream, MNP can: interact with blood cells and plasma proteins, potentially affecting blood chemistry and function; be transported to various organs and tissues throughout the body, potentially cross other biological barriers, such as the BBB or the placental barrier.

2.5.3 *Factors Affecting MNP Persistence in the Human Body*

Several factors can be expected to influence how long MNP may persist in the body, including factors unique to the individual human body and the physical and chemical properties of the particles themselves. Age, health status including known periods of vulnerability such as illness or pregnancy, and other individual characteristics may affect how the body processes and clears these particles. The material properties dictated by the chemical composition of the particles affect how they interact with biological systems and how quickly they may be degraded or excreted. Surface characteristics such as particle surface charge and any coatings on the particles can influence their interactions with cells and tissues. MNP may agglomerate, or tend to clump together differently, affecting their distribution and clearance from the body. Smaller, spherical particles may be more easily cleared than larger or irregularly shaped ones. The long-term behavior and distribution of MNP in human physiology continue to be subjects of ongoing scientific inquiry. Although animal studies and limited human-based research have provided some understanding, there are still significant gaps in our knowledge regarding the extended impact of these particles on human biological systems (Yee et al., 2021). Elucidating the mechanisms of how MNP persist and move within the body is essential for accurately evaluating the potential health consequences of prolonged exposure to these materials (Yee et al., 2021).

2.6 Evidence of Health Effects

With the growing recognition of MNP as ubiquitous environmental contaminants, combined with reported detection of MNP throughout the human body (Thompson et al., 2024; Ziani et al., 2023, Leslie at al., 2022; Zarus, 2021), scientific investigations into their impact on human health have gained momentum. Indeed, occupationally exposed synthetic textile workers show a wide range of respiratory symptoms as well as lung and bowel cancer (Prata, 2018). While epidemiological studies are still lacking, systematic reviews of controlled laboratory studies have revealed several concerning effects. For instance, research on human cells has demonstrated that MPs can affect cytotoxicity, immune responses, oxidative stress, and cellular barrier functions, with effects observed even at environmentally-relevant concentrations (Danopoulos et al., 2022). As discussed in Chapter 4 regarding evidentiary issues in regulatory and litigation contexts, animal studies, along with other evidence, can be relied upon as sufficient evidence of harm to human health, where the subject animal biology is sufficiently representative of human biology and the harm represented by the study is fairly representative of the harm to humans sought to be demonstrated. However, there remains a critical need for more extensive and prolonged research involving human exposure, in representative exposure scenarios with representative MNP, in order to fully understand potential health risks in real-world exposure scenarios.

2.6.1 Inflammation, Oxidative Stress and Cancer Responses

One of the most consistently observed effects of MNP exposure in cellular and animal studies is the induction of inflammation and oxidative stress (Danopoulos et al., 2022) with potential long-term effects (Li et al., 2023a; Barguilla et al., 2022). MNP have been shown to trigger the release of pro-inflammatory cytokines in various cell types. Chronic low-grade inflammation could potentially contribute to a range of health issues if sustained over time (Li et al., 2023a). MNP have also been associated with oxidative stress from an increase in reactive oxygen species (ROS) production, which can lead to damage of cellular components, including DNA, proteins, and lipids (Li et al., 2023a) as well as exacerbating existing processes such as alopecia (Li et al., 2024a). Chronic inflammation and oxidative stress are known to be underlying factors in various diseases, including cardiovascular disorders, cancer, and neurodegenerative conditions (Li et al., 2023a; Pironti et al., 2022).

2.6.2 Impacts on Gut Microbiome and Intestinal Health

The gastrointestinal system, being a primary site of exposure to ingested MNP, has been a focus of many studies (Fournier et al., 2021). These studies indicate MNP can result in alterations in gut microbiome composition, compromise of intestinal barrier function, and gastrointestinal inflammation. MNP can cause changes in the diversity and composition of gut bacterial communities. Given the crucial role of the gut microbiome in overall health, these alterations could have far-reaching effects (Fackelmann et al., 2023). MNP may also compromise the structural integrity of the gut's protective lining. Investigations have revealed that contact with these minute particles could potentially enhance the permeability of the intestinal wall, a condition commonly known as "leaky gut syndrome." This increased permeability might facilitate the unwanted transfer of detrimental substances from the gut into the circulatory system (Jeong et al., 2024). MNP may also trigger localized inflammatory responses, potentially contributing to a range of digestive system disorders. While some scientific investigations have suggested a possible connection between exposure to MP and the development of conditions like inflammatory bowel disease, the scientific community emphasizes the need for further research to definitively establish cause-and-effect relationships between these factors (Garcia et al., 2023, Preprint).

2.6.3 Endocrine Disrupting Effects

A considerable number of plastic materials incorporate compounds classified as endocrine disruptors - substances capable of interfering with the body's hormonal systems. These substances are often intentionally added to products, and increasing evidence highlights their risks. As a result, many countries and regions have initiated regulatory measures to restrict or ban their use. A major point of concern among researchers is the possibility that MNP might serve as carriers for these hormone-altering chemicals, potentially facilitating their introduction and distribution within biological systems. These endocrine disruptors are delivered through chemical leaching, (Campanale et al., 2020), potentially disrupting various endocrine-regulated processes in the body (Ullah et al., 2023).

2.6.4 Developmental Impacts

The developmental stages of fetuses and young children are considered especially vulnerable to the effects of MNP exposure, raising particular alarm among researchers and health professionals (Amran et al., 2022). Fetal development is a concern because MNP have been detected in human placentas and animal studies have suggested that prenatal exposure to certain plastic-associated chemicals can affect fetal growth and development (Pluciennik et al., 2024; Landrigan et al., 2023). Neurodevelopment is a particular concern according to some studies of early-life exposure to plastic-associated chemicals including possible associations between phthalate exposure and behavioral disorders (Braun, 2017). Recent evidence has demonstrated associations between a number of endocrine-disrupting plastic chemicals and neurodevelopmental differences, impairment and/or disability, with particularly strong evidence for chemicals such as BPA and its relationship with autism spectrum disorder in males (Symeonides et al., 2024a; Symeonides et al., 2024b). Additionally, significant concern is arising regarding consequences to childhood growth and development from prolonged exposure to MNP and their chemicals throughout childhood. These concerns include potential influence on multiple facets of a child's growth and maturation processes; possible effects on cognitive abilities; the development of the immune system; and the proper functioning of the endocrine system (Amran et al., 2022).

2.6.5 Respiratory Health Effects

Inhalation of airborne MNP is an area of growing concern and associated with lung inflammation, oxidative stress and respiratory diseases. MNP-caused lung inflammation can potentially exacerbate existing respiratory conditions or contribute to the development of new ones (Lu et al., 2022). MNP has been associated with increased oxidative stress in lung epithelial cells, which could lead to cellular damage over time (Hu & Palić, 2020). And while more research is needed, some scientists have hypothesized potential links between long-term exposure to airborne plastic particles and the development or exacerbation of conditions such as asthma and chronic obstructive pulmonary disease (COPD) (Lu et al., 2022).

2.6.6 Cardiovascular Effects

The potential for MNP to enter the bloodstream raises concerns about cardiovascular health (Mantel, 2024; Marfella et al., 2024; Zhu et al, 2023). MNP is associated with vascular inflammation, a key factor in the development of cardiovascular disease (Mantel, 2024). MNP are associated with platelet activation, which can potentially increase the risk of blood clot formation (Tran et al., 2022). MNP including polyethylene, polyvinyl chloride, and polyamide 66 have been found in blood clots (Wang et al., 2024). Atherosclerosis may result from long term exposure (Mantel, 2024) especially considering a recent study finding MNP in atheromas were linked with increased risk of subsequent cardiovascular events (Marfella et al., 2024).

2.6.7 Reproductive Effects

As discussed previously, MNP have been found in both the female and male reproductive systems. MNP have been reported in the male testes, epididymis, prostate gland, and semen (Hu et al., 2024; Demirelli et al., 2024; Hong et al., 2023). This accumulation raises concerns about potential impacts on male fertility, reproductive health, and possible alterations to genetic material in sperm. Given MNP are also detected in the placenta, it will likely also be found throughout the female reproductive system. Because MNP are detected in the blood and lungs, it will also likely be found in the breast.

There is concern that once MNP have entered the body through any route of exposure carrying their chemical (particularly endocrine-disrupting chemicals) and potential pathogenic burden, MNP may target the reproductive system in a size-dependent manner and disturb germ cell and other somatic cell development (Hong et al., 2023). Early studies have associated the presence of MNP in reproductive tissues and potential reproductive toxicity with implications for fertility (Hong et al., 2023; Yin et al., 2021). Additional research is needed to better characterize reproductive effects of MNP exposure.

2.6.8 Neurotoxicity

Neurotoxicity of MNP exposure is a new area of study. MNP fibres and polyethylene particles have been found in the human olfactory bulb (Amato-Lourenco et al., 2024), while animal studies suggest MNP may pass through the BBB (Kopatz et al., 2023). As discussed above, MNP are known to cause general oxidative stress and inflammation for human cells, while MNP are known to carry both chemical and potential pathogenic burdens as discussed below. One study reports that NP increased a number of symptoms similar to those of Parkinson's disease in C elegans and used the A53T α-syn-EGFP SH-SY5Y cell line, derived from human neuroblastoma to show NP caused an increase in the numbers of a-Synuclein aggregates (Jeong et al., 2024). And another reports that polystyrene beads induce α-synuclein aggregation, a hallmark of Parkinson's (Liu et al., 2023). The presence of MNP in mice brains was reported as changing behaviour in mice (Gaspar et al, 2023) and reported as inducing activation of microglia in the brains of mice (Shan et al., 2022). More work must be done to evaluate the neurotoxicity implications from human exposure to MNP.

The state of the science is provided below in Table 1, highlighting research considered as having strong evidence or emerging evidence.

Table 1: *State of MNP Science Regarding Human Health Impacts*

Health Concern	Emerging Evidence	Strong Evidence	Notes
General Inflammation, Oxidative Stress and Cancer		*	Consistently observed in multiple studies (inflammation) and various experimental settings (oxidative stress) (Li et al., 2024a; Marfella, et al., 2024; Li et al., 2023a; Pironti et al., 2022; Hu & Palić, 2020).
Cell Damage	*		Observed in laboratory studies, human impact unclear (Jeong et al., 2024; Marfella, et al., 2024; Landrigan, et al., 2023; Fackelmann et al., 2023; Fournier et al., 2021; Hu & Palić, 2020).
Cardiovascular health	*		Potential link through inflammation, oxidative stress (Marfella, et al., 2024; Landrigan, et al., 2023; ; et al., 2023; Zhu et al, 2023), as well as arterial plaque agglomeration Marfella et al., 2024), and blood clot formation and blood clot (Tran et al., 2022).
Metabolic Disorders	*		Possible connection, more research needed (Ullah et al., 2023).
Digestive System Health	*		Concerns due to ingestion of microplastics (Jeong et al., 2024; Fackelmann et al., 2023; Garcia et al., 2023, Preprint; Fournier et al., 2021).
Respiratory Issues	*		Linked to inhalation of MNP including emissions from plastic combustion, needs more study, (Lu et al., 2022; Hu & Palić, 2020).
Endocrine Disruption	*		Potential effects being investigated particularly given association of endocrine disrupting chemical burden of MNP (Campanale et al., 2020; Ullah et al., 2023.
Reproductive Health	*		Early-stage research, no definitive conclusions but negative associations implicated for fertility where MNP present in reproductive tissues (Hu et al., 2024; Demirelli et al., 2024; Hong et al., 2023; Yin et al., 2021).
Gut Microbiome Impact	*		Growing area of research, effects not yet fully understood but negative associations implicated between MNP presence and gut health (Jeong et al., 2024; Garcia et al., 2023, Preprint; Fackelmann et al., 2023; Fournier et al., 2021).
Neurotoxicity	*		New area of research, effects of MNP in brain not yet fully understood (Amato-Lourenco et al., 2024; Kopatz et al, 2023; Jeong et al., 2024; Liu et al., 2023; Gaspar et al, 2023; Shan et al., 2022).

2.6.9 MNP as Vectors for Other Pollutants

As discussed in Chapter 3, MNP pose additional risks beyond their potential as vectors for their own plastic chemicals. These tiny particles also attract and convey various environmental contaminants adsorbed onto their exterior (Mosca Angelucci et al., 2020). These characteristics transform MNP into environmental chemical transport mechanisms, facilitating the entry of additional toxic elements into organisms (Amelia et al., 2021). In essence, they might serve as unintended delivery systems for a range of harmful substances, introducing them into biological systems. Chemicals that are known to adsorb onto plastic particles in the environment include long banned persistent chemicals remaining in the environment such as persistent organic pollutants (POPs), including polychlorinated biphenyls (PCBs) and similar persistent brominated chemicals such as polybrominated diphenyl ethers (PBDE) and polybrominated biphenyls (PBBs), as well as persistent pesticides such as dichlorodiphenyltrichloroethane (DDT) (Joo et al., 2021). Toxic metals also accumulate on MNP on their surfaces, including lead, cadmium, and mercury (Amelia et al., 2021). As discussed in more detail in the Chapter 3, because plastic is such a beneficial environment for microbes, MNP can carry into the body harmful pathogens including bacteria, viruses and fungi (Yang et al., 2023; Tavelli et al., 2022). These potentially dangerous microbes adsorb onto the MNP preventing detection by the body's natural immune system entering the body through a trojan horse or sorts, which the human immune system does not recognize and cannot defend itself against (Yang et al., 2023; Katsumiti et al., 2021). Based on this research, and all the research demonstrating accumulation of MNP in human tissues including the brain and human olfactory bulb, it is crucial to carry out a risk evaluation of MNP on the human body and further explore their impact on the immune system (Lin et al., 2024). These MNP pathways can act as vectors for invasive alien species by providing a durable surface for organisms to attach and be transported across geographical boundaries (Zhang R. et al., 2024).

2.6.10 Challenges in Assessing Human Health Impacts and Strategies to Overcome

While the evidence from laboratory and animal studies is concerning, there are significant challenges in directly assessing the human health impacts of MNP exposure:

- **Largely Absent MNP Characterization Technology:** Historically there have been no sampling or analytical methods available, adopted by consensus or not, to capture and detect smaller MNP in various media such as air, water, soil and consumer products, as well as biological matrices from plants, animals and humans. But this technology is now developing quickly and may soon be useful in assessing MNP characteristics.

- **Highly variable, persistent, particle and chemical pollutant:** Conventional dose-response epidemiological studies are not representative given highly variable pollutant with differing polymer matrix, chemical content, potential environmental chemical pollutant/pathogenic burden, size, shape and behaviour within human biology, especially given variations in vulnerability to disease within different human populations.
- **Ubiquitous exposure:** The ubiquitous nature of MNP in our surroundings makes it problematic to identify truly unexposed populations for comparative studies. This widespread contamination hinders researchers' ability to establish proper control groups, complicating the assessment of potential health impacts.
- **Multiple exposure routes:** Accurately measuring an individual's total MNP exposure is challenging due to the diverse routes through which these particles can enter the body. This multiplicity of pathways complicates efforts to quantify overall exposure levels.
- **Long-term effects:** The health impacts of long-term exposure may only become evident after many years, making it challenging to conduct comprehensive studies on human populations. This extended latency period complicates efforts to establish clear links between exposure and health outcomes.
- **Confounding factors:** Isolating the specific health impacts of MPNP exposure is complicated by the myriads of environmental and lifestyle variables that also affect health. This complex interplay of factors makes it difficult to attribute observed health outcomes solely to plastic particle exposure.
- **Ethical considerations:** The potential risks associated with MNP exposure make it unethical to conduct controlled exposure studies in humans while also compelling ethical approaches to gaining access to human decedent tissue to assess MNP contamination in association with human disease and mortality. In addition, epidemiological studies will also be a more accessible avenue to compare associations between different MNP exposure levels and health outcomes when accurate quantitative measurement techniques are more available for complex biological matrices.

For all these reasons, conventional human health risk assessment approaches are limited when applied to MNP due to their variability and ubiquitous nature. Historical attempts to characterize risk from MPs were not representative of human exposure experience as they focused on intentionally added microplastic designed for specific uses. This conventional approach generally consists of the following four steps: (1) hazard identification from exposure to the pollutant; (2) dose-response assessment for the assessed pollutant; (3) exposure assessment for specific populations impacted by the pollutant, and (4) risk characterization considering the results of steps (1) through (3). In the case of MNP, regarding step (1), identification of hazards potentially posed by these particles has historically been hindered by the inability to sample for and detect these particles. The technology simply was not available until recently. Though at the cellular level, hazards have been demonstrated as discussed herein, regarding step (2), the variability of these particles in the environment and MNP sources precludes meaningful dose-response assessments. Regarding step (3), given the ubiquitous nature of MNP contamination throughout our indoor and outdoor environment, it is very difficult to identify specific populations that are impacted more or less than others. Finally, regarding step (4), any meaningful risk characterization is elusive given the inability to fully implement the prior three steps.

However, where there is broad exposure to large regional areas of population, associations between the prevalence of the source of the contamination and general health trends in that region can be useful in supporting use of the Precautionary Principle as well as the preponderance of the evidence threshold for civil litigation and damages recovery in the United States. For example, correlations between regional MNP exposures, human tissue concentrations and human health disease trends within MNP exposed populations can support new authority especially pursuant to the Precautionary Principle and preponderance of the evidence threshold for US litigation. This approach was employed recently to associate decline in bat populations from white nose syndrome and increases in infant mortality due to increased pesticide use (Frank, 2024). Such an approach allowed disease association with regional exposures to polyfluorinated compounds through class action compelled medical monitoring conducted during the DuPont PFAS litigation from 2005-2013 (C8 Science Panel). With global ubiquitous exposure to MNP, there would likely be no control group available. that has not been exposed to MNP However, a strict control group is not necessary to draw positive associations as long as there are other association trends available, such as plastic use, exposure, tissue accumulation and population disease trends., as well as representative and relevant animal data as discussed in Chapter 4.

In summary, current research indicates possible health risks from MNP exposure, but comprehensive understanding of long-term effects remains incomplete. The Minderoo-Monaco Commission on Plastics and Human Health advocates for more extensive research, particularly emphasizing studies on vulnerable groups and prolonged exposure impacts (Landrigan et al., 2023). As our understanding of these health impacts grows, it becomes increasingly clear that addressing plastic is not just an environmental issue, but a significant public health concern that requires urgent attention and action.

2.7 Long-Range Environmental Transport

Long-Range Environmental Transport of plastic debris, including MNP and their associated chemicals is a significant global concern and makes clear the urgent need for global action. Long-Range Environmental Transport is closely linked to international regulatory efforts, such as the Stockholm Convention on Persistent Organic Pollutants, which is considering the regulation of certain chemicals used in plastics, including UV-328, a common ultraviolet light stabilizer. The potential listing of UV-328 under the Stockholm Convention highlights the growing recognition of the need to address both MNP and the chemicals associated with plastics on a global scale. MNP are particularly problematic due to their capacity for long-range transport through diverse mechanisms, leading to their widespread presence in the environment. Understanding these dispersal processes is crucial for comprehending the global scope of plastic pollution and its potential health implications for humans (Bowley et al., 2021). The pervasive nature of MNP, facilitated by long-range transport, underscores the importance of international cooperation and regulatory measures to mitigate its environmental and health impacts.

2.7.1 Atmospheric Transport

Airborne MNP, from sources such as urban dust, tyre wear particles, fibres from synthetic textiles, and industrial emissions, as well as contaminated soil and waterbodies including the ocean, can travel vast distances through atmospheric circulation (Landrigan et al., 2023). Transport mechanisms include global wind patterns, vertical transport with convection currents, and deposition through rainfall and snow. MNP exhibit mobility potential depending on size, density and shape, where lighter and more aerodynamic particles can migrate further than heavier and less aerodynamic particles. Dispersion through global wind patterns are responsible for MNP detected in remote mountain areas and polar regions, far from any significant human activity (Evangeliou et al., 2020), transport enhanced by convection currents which lift plastic particles high into the atmosphere, where they can be transported over long distances before being deposited (Landrigan et al., 2023), and precipitation which can wash airborne particles out of the atmosphere, depositing them in areas far from their source (Landrigan et al., 2023).

2.7.2 Water Current Transport and Concentration

Oceans and rivers play a significant role in the long-range transport of plastic pollution through ocean currents, river systems and vertical transport in water columns. Global ocean currents circulate seawater like conveyor belts for buoyant plastic waste, dispersing it across extensive marine areas (Lebreton et al., 2018). Rivers also serve as crucial channels, funneling plastic debris from terrestrial regions into marine environments, where a few principal rivers contribute an outsized portion of the total plastic influx into our oceans. Water transport of plastic and MNP, like air transport (where air, like water, is a fluid) is affected by material characteristics, including density, such that some plastic remains buoyant, while other types descend and are carried by subsurface ocean flows. This stratified dispersion of plastic materials throughout various ocean layers presents significant challenges for remediation initiatives and heightens the risk of interaction between marine organisms and plastic debris across different depth zones.

Concentration through water transport occurs in many ocean gyres, including five major ocean gyres (North and South Pacific, North and South Atlantic, and Indian Ocean), known hotspots for plastic accumulation (Lebreton et al., 2018). Coastal areas are well known for concentrating along densely populated coastlines due to local inputs as well as isolated areas solely due to their location in proximity to ocean currents. MNP are accumulating in coral and the deep-sea sediments as well, suggesting that coral in shallow oceans and the deep ocean may be a major sink for plastic pollution (Jadang et al., 2024)

2.7.3 Biological Transport

Animals can inadvertently contribute to the long-range transport of MNP (CIEL 2019). Migratory species, including Birds, fish, and marine mammals that travel long distances can ingest plastic particles and smaller organisms contaminated with MNP in one location and excrete them in another, potentially thousands of kilometres away. As smaller organisms contaminated with MNP are consumed by larger predators, perhaps that migrate, plastic particles can be transferred up the food chain and across different ecosystems. Bioturbation can also occur, when sediment burrowing marine organisms redistribute MPs within the seafloor, potentially re-suspending them into the water column.

2.7.4 Implications for Human Exposure

Plastic is a synthetic material that does not meaningfully biodegrade, such that now MNP has famously been found everywhere on the planet, including in our food, our water and in the dust in our homes. But all plastics degrade by fragmentation into the more harmful form of MNP and spread through the environment, resulting in increased risk to human health. As plastics are transported through the environment, they undergo processes that can lead to the degradation into smaller particles (Landrigan et al., 2023) including: photodegradation, where UV radiation (sunlight) can break down plastic polymers, leading to fragmentation; mechanical weathering, including wave action, abrasion against sand or rocks, and freeze-thaw cycles which can physically break down larger plastic items into MNP; biodegradation, despite antimicrobial chemical additives, because some plastic can be partially broken down by microorganisms, especially after other degradation processes have altered their structure.

The long-range transport of MNP has resulted in global distribution, contaminating even the most remote areas. MNP are now falling with rain, contaminating soil and water, potentially affecting agriculture and drinking water and the food web, both land and marine based. Combined with direct exposure from highly shedding consumer products, such as textiles and tyre shred, highly processed foods and industrial and agricultural uses, environmental MNP has significant implications for human exposure.

Grasping the intricacies of these far-reaching micro and nano plastic distribution pathways is vital for comprehending the worldwide consequences of plastic contamination and crafting efficient remediation approaches. This knowledge underscores the necessity for global collaborative efforts in tackling this challenge, as the spread of plastic waste transcends national boundaries, impacting even the most isolated regions of Earth (Landrigan et al., 2023).

2.8 MNP Risk evaluation

As elaborated above, recent scientific studies have clarified the extent of MNP releases and emissions, demonstrating its ubiquitous presence in humans and the environment. These studies also reveal potentially progressive significant accumulation in biological tissues and environmental accumulation rates of plastics, due to continued plastic production, from waste management methods, food, water and consumer product production and use. While primary MNP is produced as MNP, secondary MNP is generated when larger plastic particles (macroplastics and microplastics) in the environment fragment into smaller pieces. This ongoing degradation of both primary and secondary MNP leads to an increasing presence of nanoplastics, which are potentially more toxic due to their extremely small size. Thus, it is with the aging and fragmentation, discussed above, that macro plastic's transition into microplastic contributes to exponentially escalating concentrations of the potentially more toxic form that are nanoplastics, a scenario which now constitutes a global emergency:

Earlier studies such as the 2022 World Health Organization inhalation study (WHO 2022) are interpreted as concluding that there is insufficient evidence of harm from micro and nanoplastic exposure to support legislative action. However, the WHO report:

- Recognizes the lack of classic dose-response epidemiological data clearly establishing pathological diseases from exposure, and states that such conventional studies will require future decades of effort while recommending limited workplace occupational exposure in the studies which will not reflect the general population.
- Even where such conventional approaches are clearly not effectively performed for a ubiquitous pollutant that presents so many inherent biologically relevant variables as MNP (Cunningham et al., 2023).
- And other risk assessment strategies, and approaches to demonstrating harm, are available to support policy action as discussed herein and addressed in more detail in Chapter 4.

More recent studies of human tissue utilizing newly available analytical techniques indicate accumulation may now be occurring in populations not subjected to concentrated occupation exposures. While accumulation in human tissue is reasonably believed to be occurring and may be demonstrated with the current body of work, MNP are still presumed to be excreted from the human body via bile into the small intestine. Yet newer studies report the ubiquitous baseline presence of MNP in the human population in just about all organs and tissues, (Thompson et al., 2024; Ziani et al., 2023, Leslie at al., 2022; Zarus, 2021), indicating associations with specific disease processes such as general inflammation, oxidative stress and cancer, and potentially other health impacts as discussed herein. At the time of this writing, this ubiquitous baseline presence may be progressively accumulating, possibly through magnification of exposures resulting from continually increasing concentrations in exposure pathways (Campen M. et al., 2024, Preprint).

Thus, the current body of data, demonstrating progressively increasing accumulation in both the world's human population and the environment, continually magnified by still escalating production and minimal, if any, degradation, supports utilizing different approaches to evaluating risk. Effective approaches to mitigating direct human exposure to micro and nanoplastics could be developed from different strategies including:

- Demonstrating for purposes of evidentiary sufficiency the representative nature of current animal studies and human tissue analysis as evidence of harm to human health;

- From the top down, developing environmental economic analytical approaches to establish correlations of plastic use to concentrations in human tissue. Use these concentrations to evaluate correlations between impacts to human health and the environment and prioritize regional hot spots of exposure for specific exposure mitigation strategies (Frank, 2024);
- From the bottom up, developing regional databases to support the top down work, while taking into account other possible disease drivers, including:
- Representative human tissue micro and nanoplastic concentrations.
- Human health trends, including diseases, fertility and infant mortality.
- Trends in plastic use and thus likely sources of micro and nanoplastic for use in the overall evaluation.

Initiate prioritizing methods for exposure mitigation. While environmental sources are likely currently catalogued, significant work must be done to inventory micro and nanoplastic shedding rates from consumer products to prioritize actions to ban or otherwise mitigate human exposure to these consumer sources, especially when the consumer product is food (Osuna-Laveaga et al., 2023; Zangmeister, C. et al., 2022; contra FDA Micro and Nanoplastics in Foods website).

2.9 Conclusion

The ubiquitous presence of MNP in our surroundings, coupled with their potential health ramifications, accentuates the pressing demand for additional scientific inquiry and proactive measures, including taking a precautionary approach to address microplastics. This should be a key component of international efforts to establish a global legally binding instrument on plastic pollution. This analysis has illuminated several crucial aspects:

- The entire plastic life cycle, from its inception to its eventual discard, contributes to the environmental accumulation of MNP. This issue is further compounded by suboptimal waste handling practices and the inherent durability of plastic materials.
- MNP can infiltrate the human body through various routes, including ingestion, inhalation and possibly skin penetration, as well as intentional medical drug delivery and shedding of plastic medical device components. The omnipresence of these minute particles in our food, water and air that we breathe, whether indoors or outdoors renders human exposure to MNP virtually inescapable.
- Upon entering the body, MNP exhibit the potential to traverse physiological barriers and accumulate within diverse organs. The precise behaviour and longevity of these particles within human biological systems remain subjects necessitating further investigation.

- Nascent research indicates potential health consequences linked to MNP exposure, encompassing inflammatory responses, oxidative damage, hormonal imbalances, and alterations in gut microbial communities, as well as more serious implications for reproductive issues, cancer and more. Additional studies are imperative to fully elucidate the enduring health implications, particularly within human populations, but the existing body of data is sufficient to support policy action now.
- The extensive dissemination of MNP via atmospheric currents, aquatic systems, and biological vectors facilitates their global dispersion, elevating plastic pollution to a genuinely worldwide concern.

The Minderoo-Monaco Commission on Plastics and Human Health has underscored the inequitable impact of plastic contamination, shedding light on the social equity dimensions of this worldwide challenge. Communities facing economic hardship frequently endure a disproportionate share of exposure and health hazards linked to plastic pollution including MNP.

As the complex relationships between MNP exposure and human health continue to be unravelled, several key areas for immediate action and future research emerge:

- Implementation of policy to mitigate human exposure to MNP, and risk from that exposure, by reducing overall plastic loading on the planet through plastic production caps; elimination of problematic plastic products, polymers and chemicals of concern; prevent release of MNP from plastic use, MNP contamination, waste management and legacy plastic.
- Development of standardized methods for detecting and quantifying MNP in human tissues and the environment.
- Reach consensus regarding MNP risk assessment strategy utilizing relevant evidence including animal studies, human tissue data and possibly medical monitoring in association with human health trends as discussed herein.
- Conduct long-term epidemiological studies to assess the health impacts of chronic, low-level exposure to MNP in human populations.
- Development of truly safe and sustainable alternatives to conventional plastics without adding to the global waste burden, including greenhouse gas or other pollution
- Increase public awareness and education about the potential health risks associated with plastic.

The evidence presented in this study accentuates the necessity of embracing a cautionary stance towards plastic utilization and disposal, due to the myriads of emerging human health challenges associated to microplastic releases. While plastics have undeniably transformed numerous facets of contemporary living, their potential enduring consequences on human wellbeing and environmental integrity cannot be disregarded.

Tackling the challenge of microplastic and nanoplastic contamination demands a comprehensive strategy involving diverse stakeholders: governmental decision-makers, corporate leaders, scientific researchers, and the broader populace. Through collaborative efforts aimed at curtailing plastic manufacturing, enhancing waste handling procedures, and innovating safer substitutes, prospective health hazards linked to MNP exposure can be alleviated and progress towards a more ecologically sound future can be made. The plastics instrument could facilitate enhanced collaboration, including by establishing necessary working groups for technical and scientific support.

As scientific inquiry in this domain continues to advance, it is imperative that a state of alertness and flexibility in the approach to this global predicament be maintained. The welfare of our planet and its denizens hinges on our capacity to confront the escalating menace of plastic pollution.

3. Product formulation and design for closed loop plastic manufacturing, use, and disposal

Key Points

- The planet and its ecosystems are overloaded with plastics. The release of MNP from plastic at all stages of its manufacture and use is inevitable as currently designed, including use as intended. The current planetary plastic loading is causing escalating mass flux of MNP from larger plastic pieces.
- Research suggests that MNP are now found to be accumulating in biological organisms at varying rates and risk potential depending on their size, shape and chemical/pathogenic loading and site of biological concentration while potentially crossing cellular walls interfering with cellular process, BBB which may introduce plastic chemicals of concern and pathogens directly into the brain which is a critical design consideration.
- The complexity and heterogeneity of plastic formulations are maintained as larger plastic pieces in the environment break down into MNP, all which adsorb persistent chemical pollutants and pathogens from the environment, that plastic chemicals diffuse out of MNP that have entered biological organisms via ingestion, inhalation, or dermal absorption.
- MNP amplify the effect of plastic chemicals of concern by functioning as the primary mechanism for plastic chemicals entering biological organisms via molecular transport phenomena, which is another critical design consideration.

- Setting design thresholds for MNP exposure is challenging due to variability and size. Traditional toxicology has historically failed to capture risk posed by MNP.

- It is possible that there is no safe design threshold for MNP exposure within certain size ranges, where smaller particles are likely more hazardous due to potential for interference in biological and cellular functions.

- With these design considerations, and given the current planetary loading, meeting the objective of mitigating risk to human health from MNP exposure involves issues of chemical engineering design including transport phenomena, chemical reaction engineering and system design principles.

- To mitigate sources of MNP and minimize the risk of human exposure, the plastic manufacture and use cycle must be redesigned, reprioritized, managed and remediated to ensure that a closed-loop system is maintained throughout the life cycle.

- To minimize hazards from MNP, reduction of unnecessary complexity of polymer formulations and mitigation of risk from MNP must be included in the system design of the plastics industry

3.1 Overview

This chapter encompasses an engineering overview of the steps that must be taken to minimize or eliminate human and environmental exposure to MNP, through manufacture, use, and end of life management. Based on the fact that all plastics eventually break down into MNP through environmental degradation or use as intended, the concept of closed-loop manufacturing and capture is proposed as a means to minimize or eliminate exposure to MNP. Using fundamental engineering principles, the redesign of the plastics industry must be based on simplifying formulations of plastics on the market, ensuring transparency along the supply chain, elimination or reduction of single use items, limiting plastic use to globally agreed upon critical uses, and closed-loop capture to safeguard the environment and public health.

3.2 Introduction

As stated, MNP is found everywhere on the planet. The release of MNP from plastic, either in use or in the environment, is inevitable, leading to significant human health concerns. Solving the current plastic pollution crisis requires the application of chemical engineering principles to understand the formation of, and the potential harm, caused by MNP. To effectively address this challenge, the formulation, manufacturing and use of plastics must be redesigned, reprioritized, managed and remediated to ensure that a closed loop system is maintained throughout the life cycle, including how post-consumer plastic is managed after use. Achieving these goals requires both an understanding of how MNP are formed through manufacturing, product use, and in the environment, and a systems-oriented approach to polymer design and use that result in a closed-loop cycle for plastics.

Exposure to MNP from plastic is a critical environmental and public health crisis. The planet is overloaded with MNP from the environment and the everyday consumer products we use. Whether in the environment or in landfills, all macroplastics will eventually break down into MNP. This has been recognized as an urgent environmental and public health crisis. The problem is more than the polymers themselves. Plastics for consumer and industrial use are complex formulations of polymer and chemical additives designed to tailor the material properties for specific uses. Plastic is known to release and emit MNP throughout its existence, from production, through use as intended, to its persistence in the environment. Plastic, by its nature, is friable and is known to ultimately break down into MNP which research suggests can make their way into biological organisms, including humans, through ingestion, inhalation, and potentially dermal absorption. Once in an organism, these particles may serve as delivery mechanisms for hazardous chemical exposure via molecular transport mechanisms, including molecular diffusion through the particle surface. The research discussed in Chapter 2 indicates that these particles may accumulate in organs and biological systems, and may initiate many disease processes through inflammation, obstruction, and interference with biological mechanisms (Płuciennik et al., 2024). As discussed in Chapter 2, previously unrecognized routes of transmission through barriers previously thought to be impermeable, such as the blood-brain barrier and the olfactory bulb, represent a different mechanism for toxic exposure that must be explored, considering the design implications for a mechanism that is magnified as the particles fragment further, exposing greater surface areas of smaller particles relative to mass. Specifically, because many plastic chemicals have already been evaluated for overall harm, this new approach to toxicological assessment to harm must address the magnification of potential harm due to the targeted delivery of the chemical additives through the particle surface after the particles become lodged in biological tissues, thereby avoiding the elimination of the chemical additive through otherwise normal metabolic processes present when exposure is to the chemical additive alone.

In response to this concern, in addition to overall reductions in plastic production and use, the manufacturing of plastic requires rethinking and redesigning to mitigate this known additional and potentially magnified risk. Achieving sustainable use of plastic requires a system wide approach considering all steps from polymer formulation to manufacturing, to use, to end of life. This redesign should be based on a reduction in the number of plastic formulations, reduction in unnecessary complexity of plastic additives on the market, transparency along the supply chain, elimination of problematic polymers, overall simplification of additives while eliminating hazardous and toxic additives, as well as mitigation of MNP release and exposure through mandating best design practices for least shedding potential, prioritizing and regulating uses of plastic products to avoid both release and exposure. The goal of this redesign should be to create a closed system for plastics whereby plastics that cannot be prevented from being released into the environment or shedding MNP through intended use are simply not produced. Achieving closed-loop design with respect to plastic, as will be described in this chapter, will result in a significant reduction in plastic production, plastic use, elimination of single use items, reduction in intentionally added plastic chemical use, elimination of intentionally added chemicals of concern, and reduction of MNP formation both through use and in the environment.

3.3 Background on MNP and the Complexity of Plastic Formulations

3.3.1 Micro and Nano Plastic Background

As discussed in Chapter 2, MNP have been reported throughout the human and animal tissues studied. For design purposes it is important to consider that these studies have associated the presence of MNP in tissue with several disease processes, including inflammation, biological obstruction, and cellular damage. MNP appear to be ubiquitous chemical delivery devices, accumulating throughout the human lifetime; where particle to chemical health associations have already been mapped (Costa et al., 2023; Seewoo et al., 2023; Mohamed et al., 2021). Meaning, there may be no safe MNP level of exposure. However, more study is needed to determine the potential harm from the MNP itself as well as leaching or diffusion of harmful plastic chemicals into the specific locations where MNP may be deposited in the body. There is now urgent concern regarding MNP due to their pervasive and widespread presence.

Characteristics of MNP

As defined earlier, but elaborated more here, MNP are divided into two categories:

1. Primary microplastics are intentionally manufactured products for use in cosmetics, personal care products, industrial processing (e.g. sandblasting), textile applications, synthetic clothes production, domestic and industrial washing processes of fabrics (Re, 2019).
2. Secondary microplastics are typically generated by the degradation and fragmentation of larger pieces of plastics (due to the exposure to ultraviolet light from the sun and/or by mechanical means such as tidal waves or tyre abrasion) (Re, 2019).

As described in Chapter 2, types of MNP include fragments, spheres, fibres, granules, and foam from expanded PS (Ziani et al., 2023). The configuration of primary MNP is a function of their intended use. For example, long fibres produced for use in the manufacture of synthetic fabrics, spheres produced for use as microbeads in personal care items, or granules manufactured for use as abrasives. Secondary MNP are produced in the environment with particle shapes resulting from their history of fracture and fragmentation. These include smaller fibres, multi-sided fragments, double pointed shards, and shred from tyres (Thompson et al., 2024). In addition to simple physical force causing shearing of the plastic matrix, secondary MNP can be formed through two primary mechanisms: cracks can form at the surface which penetrate the particle, causing breakup; fragmentation of the surface due to degradation which can release MNP directly (Thompson et al., 2024; Pfohl et al., 2022). Cracks and fragmentation can result from photo-degradation, thermal-oxidative degradation, thermal degradation, and hydrolysis (Thompson et al., 2024; Ziani et al., 2023).

Each MNP producing event exposes new surface area of the plastic with enhanced potential for release of plastic chemicals through diffusion from the newly exposed surfaces, as well as through adsorption of environmental pollutants and pathogens on the exposed surface of the newly formed MNP. Thus, as the particle becomes smaller and more biologically problematic, its potential to cause harm likely increases depending upon the chemicals in the source plastic as well as the chemicals and pathogens in the environment the particles have been exposed to.

MNP are so persistent that they present significant challenges even in disposal processes. Recycling, incineration and landfilling of post-consumer plastic do not eliminate the formation and propagation of MNP through the environment. First, these waste management methods only capture a small percentage of post-use plastic (Landrigan et al., 2023). Second, these methods themselves release MNP. Both chemical and mechanical recycling require shredding of sorted waste which releases significant amounts of MNP (Suzuki et al., 2024; Brown et al., 2023). Conventional solid waste incinerators and waste to energy processes are not designed to ensure complete destruction of plastic, thus emitting and releasing hundreds of tons of MNP particles per year per facility through air emissions, wastewater discharge and incinerator ash disposal (Tsunematsu et al., 2023; Yang et al., 2021). Even recent reports do not recognize the need to fully redesign incinerators to completely destroy the plastic matrix (Jelinek et al., 2024). Solid waste landfills are designed to compact and digest waste, including plastic, causing it to release MNP into the leachate (Zhang L. et al., 2024; Shi et al., 2023). Due to their small size, MNP are able to move like a liquid through the landfill. These MNP end up flowing with the leachate and are not effectively removed by wastewater treatment operations (Zhang L. et al., 2024; Shi et al., 2023).

Industrial processes can be designed to mitigate release of MNP but cannot fully eliminate their release. Thus, overall reduction of plastic production, along with mitigation of MNP releases through product and process design, and specific mitigation of MNP exposure, are all required to address the issue of MNP exposure.

Exposure to MNP

Humans are exposed to MNP through several routes of exposure as discussed in Chapter 2, including ingestion, inhalation and dermal exposure. Relative rates of MNP exposure are important in informing design strategies. Research reports that humans may ingest through food consumption at rates of 39,000 to 52,000 MNP per year (Ziani et al., 2023; Cox et al, 2019). This number rises to 74,000 when inhalation is included, while drinking tap water adds another 4000 particles per year, and bottled water adds 9000 particles per year (Ziani et al., 2023). However, this estimate may be conservative, as the study utilized analytical methods that are now considered potentially outdated and likely underestimate actual exposure. This exposure inventory did not include major contributors to human exposure, such as plastic fibres from synthetic fabrics used in clothing and home furnishings, or from consumer goods like the plastic bristles in toothbrushes, or other personal care products, or from tyre shred in the outdoor air. Also, due to the age of the data, nanoparticles are likely not represented.

Particle counts in the literature are only expected to grow as new sampling and analytical technologies allow tracking of smaller and smaller particles, as well as particles bound in other matrices, such as cellulosic material, minerals including coral and salt, and animal tissues (Jadang, et al., 2024; Ziani 2023). Thus, particle count inventories must continue to be updated to reflect newly assessed MNP sources with newly available sampling and analytical methods.

Additionally, particle count inventories will vary considerably between regions, countries and socio-economic groups. High-GDP countries with higher per-capita plastic consumption rates may be at higher risk during the plastic use phase than low-GDP countries with a lower per-capita consumption rate. Higher per-capita consumption leads to concentrating MNP in diet through highly processed foods and the home environment (Lin et al., 2023; Ziani et al., 2023). Countries with limited waste management infrastructure or high open landfill or open burning rates may experience higher rates of environmental MNP exposure from the waste phase through unmitigated fragmentation of uncontrolled sources of plastic waste in the environment and open landfills. Countries with high incineration and recycling rates have unknown exposure rates because known MNP emissions and releases from these processes and their impact on surrounding populations have not been historically assessed for MNP risk, where regulations generally rely on limits for merely fine particulate matter (PM2.5) and not MNP (EEA EMEP NFR 5.C.1.a.; U.S. EPA NSPS). Countries that use sophisticated high-yield agricultural methods relying on polymer chemicals and plastic will incorporate more MNP into crops (CIEL, 2022). Countries bordering oceans and relying on fish stocks for their diet may consume higher rates of MNP in seafood caught closer to highly populated and likely plastic contaminated shorelines (Hantoro et al., 2019).

Due to the hazards that MNP pose, plastic waste, including post-consumer waste, that is known to shed MNP during processing could be addressed per the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, Annexes II, VIII and IX. For example, Annex II could identify plastic waste that is friable and likely to generate MNP during transportation and processing as requiring special consideration. Annex VIII could identify MNP specifically as hazardous waste. Annex IX could ensure that "environmentally sound management" is defined to control MNP generation, mitigate MNP emissions and MNP exposure. Further discussion is available in Chapter 4 - National and regional legal authorities supporting Closed Loop Design to prevent human exposure to MNP, and Chapter 5 - The international legal landscape of relevance to micro- and nanoplastics.

Amplification effect of MNP

In considering design approaches, it is critical to understand material specific issues, such as the tendency for some factors to amplify the negative effect of MNP. High levels of exposure will compound the harmful effect of MNP's ability to act as carriers for other harmful substances, chemical and pathogen, not intentionally added to the plastic product itself but adsorbed from surroundings (Junaid et al., 2022; Kaur et al., 2022; Bowley et al., 2021; Mosca Angelucci et al., 2020). And as discussed previously, MNP have an elevated ratio of surface area to volume, resulting in an enhanced ability to adsorb other substances (Yang et al., 2023), as well as potentially enter the human body and cross typically impermeable barriers, such as the intestinal mucosal barrier and the BBB (Kopatz et al., 2023; Zhi et al., 2024). Design considerations must include particle size, charge, surface chemistry, and the type of cell with which the particles interact, which can all influence the ability of MNP to cross these barriers (Kopatz et al., 2023). Due to these amplification effects and many unknowns regarding MNP and their exact effects on the environment and public health, it is important to consider these issues when designing approaches to limit exposure to MNP in conjunction with a reduction in the overall use of plastics to prevent possible adverse effects to human health and the environment impacts while further studies continue (Mohamed et al., 2021).

3.3.2 Complexity of Plastic Formulations

Plastic Polymers

The production of plastics involves a wide range of plastic polymers. All plastics break down into MNP at rates depending on the degradation factors previously discussed. Additionally, all MNP pose variable risks depending on opportunity for direct human exposure, as well as size, shape, polymer type, leachable chemical content, including plastic chemicals as well as unreacted toxic monomers shown in Table 2, and experience in the environment resulting in adsorbed harmful substances such as environmental contaminants and pathogens. New polymers formulations and products are being created constantly without consideration of these issues. This unnecessary complexity and numerous trade names for identical chemical species confounds efforts to mitigate harm. The proliferation of trade names for identical plastic additives and minor changes to molecular structure to renew patent protection adds to this complexity. The primary categories of polymers are provided in Table 2, where all are concerning if they are used to manufacture a product that is leaked to the environment, mismanaged as waste or poses significant risk of MNP shedding during intended use.

Table 2: *General Plastic Polymer Groupings*

	Specific Additional Problematic characteristics	
Type	Hazardousl Air Pollutant Monomer*	Associated Plastic Chemicals
Polyvinyl chloride (PVC)	Vinyl Chloride	Phthalates used as plasticizers Heavy metals (like lead or cadmium) used as stabilizers Nonylphenol used as a stabilizer and antioxidant Dioxins and furans released during production and incineration (restricted under the Stockholm Convention)
Polystyrene (PS)	Styrene (aromatic hydrocarbon containing benzene ring)	Hexabromocyclododecane (HBCD) used as a flame retardant (restricted under the Stockholm Convention)
Polyethylene (PE) Low Density (LDPE) High Density (HDPE)	Ethylene	Benzophenone used to prevent photodegradation
Polypropylene (PP)	Propylene oxide	Antioxidants, including phenolics and phosphites UV stabilizers, including hinder light amines and benzotriols Flame retardants, including halogenated and phosphorous based compounds Anti-static agents Anti-slip agents Colorants and dyes including titanium dioxide Fillers including glass fiber and talc
Polyurethane (PUR)	Urethane (as ethyl carbamate)	Ozone depleting substances (ODSs) and hydrofluorocarbons (HFCs) used as blowing agents (restricted under the Montreal Protocol)
Polycarbonate		Bisphenol A as a residual monomer from polymerization Hindered mine light stabilizers Benzotriols Impact modifiers like acrylonitrile butadiene styrene and methacrylate butadiene styrene
Acrylonitrile Butadiene Styrene (ABS)	ABS, acrylonitrile, styrene and butadiene (all are HAPs)	Phenolic antioxidants used to prevent degradation of plastics
Silicone	Methyl Chloride	Methyl Chloride used in production

**Hazardous Air Pollutants as regulated by the U.S. EPA, 40 C.F.R. § 61.01 pursuant to the U.S. Clean Air Act.*

Plastic chemicals

The production of plastics involves a wide range of chemicals, which persist in MNP. Currently, more than 16,000 chemicals are used in plastic formulations, 4,200 of which are chemicals of concern due to their status as persistent, bioaccumulative, mobile, or toxic (PBMT) (Wagner et al., 2024). The study identified a high share of chemicals of concern (>40%) in 11 groups categorized by structural similarities and further highlighted 4 groups of chemicals of concern comprising a total of 15 chemicals, as shown in Table 3. These groups include, among others, phthalates, bisphenols, chlorinated paraffins, organometallics, and aromatics, which are associated with thyroid disruption, neurodevelopmental deficits, and an increased risk of cancer (Seewoo et al., 2023). Again, as discussed herein, these chemicals are used in the polymer formulation, including as additives and processing agents along with any unreacted hazardous monomers that remain in the MNP as plastic breaks down over time in the environment or through intended use. The presence of these plastic chemicals, along with any opportunistic adsorption of hazardous substances and pathogens from the environment, raises concerns about MNP and their levels of intake by people.

Table 3: *Plastic Chemicals of Concern and their Usage*

Chemicals of Concern (Wagner et al., 2024)	Purposes	Polymers	Typical Uses
Aromatic Amines	Curing agents and stabilizers, dyes and pigments	PUR	Epoxy resin, textiles
Aralkyl Aldehydes	Chemical intermediates, aromatic, crosslinker	Specialty polymers	Scented plastic
Alkylphenols	Stabilizers, antioxidants, plasticizers	PS, PVC	Detergents, cleaning products, lubricants, hair care products
Salicylate Esters	Antioxidant, Light stabilizer, Processing Aids, Plasticizer	PLA	Enhancing degradation in environment
Aromatic Ethers	Antioxidant, Colorant, Intermediate, Biocide, Flame retardant	High performance thermoplastics	Chemical resistance, strength, and stability in high performance polymers
Bisphenols	Makes polymers durable and clear	Polycarbonate	Linings for food and beverage cans.
Phthalates	Plasticizers	PVC	Flexible tubing, vinyl flooring, cables and wires, inflatable toys, packaging
Benzothiazoles	UV Light Stabilizer	PE, PP, PVC, PS, PET, PUR	Films and coatings
Benzotriazoles	UV light stabilizers	PE, PP, PVC, PC, ABS	Outdoor furniture, plastic films, packaging, automotive parts
Organometallics	Catalysts, stabilizers, modifiers, flame retardants, corrosion inhibitors, colorants	PVC, LDPE, HDPE, LLDPE, PEX, PC, ABS, Nylon, PTFE	Plumbing, home construction
Parabens	Preservative	PET	Cosmetics and personal care packaging
Azodyes	Colorant	PE, PP, PS, PVC, ABS	Consumer products, toys, packaging, textiles
Aceto/benzophenones	Antioxidant, Biocide, Catalyst, Colorant, Crosslinking agent, Filler, Initiator, Intermediate, Light stabilizer, Odor Agent, Processing Aids	PVC, PETE	Cosmetics, cleaning products, packaging
Chlorinated Paraffins	Plasticizers, flame retardants, lubricants	PVC, PE, PUR	Processing aid
Pre- & Polyfluoroalkyl substances (PFAS)	Fire retardants, coatings	HDPE, PE, PP	Non-stick coatings, moisture resistance

Chemicals, Pathogens and Very Small Particles

MNP in the human body behave in a similar way as nanopolymers used in drug delivery devices. These devices are designed and used to deliver specific therapeutic doses of a drug directly to the patient, specifically to targeted tissues, while preventing the body from metabolizing the drug on its way. These devices, also polymers in the nanoscale size, are an example of intentionally added MNP, that are purposefully designed for this specific application and intentionally introduced to the human body. In contrast, MNP may be produced by design, such as tyre particles which are necessarily created by the tyre overcoming inertia through abrasion, and MNP incidental to design, such as MNP shedding from textiles.

Drug delivery and nanotoxicology are two sides of the same coin:

- drug delivery is the intentional introduction of therapeutic pharmaceuticals into human tissues via administration of MNP, and
- nanotoxicology is the unintentional introduction of potentially toxic substances into human tissue, in this case via environmental MNP.

Also discussed in Chapter 2, but relevant here specifically for design, is the nature of plastic chemicals of concern to migrate both out of the particle, referred to as leaching, as well as within the particle itself, referred to as diffusion, through the mechanism of transport phenomena (Li et al., 2024b; Costa et al., 2023). Chemicals and microorganisms persisting in the environment can also attach onto the surface of the particle, referred to as adsorption, only to later desorb or leach off the particle when conditions experienced by the particle encourage that event (Junaid et al., 2022; Bowley et al., 2021; Mosca Angelucci et al., 2020). These chemicals may be hazardous, and the microorganisms may actually be dangerous pathogens. When toxic chemicals and pathogens migrate out of, or off of, MNP, through these mechanisms of diffusion, absorption, adsorption, and desorption, these particles may act as delivery mechanisms for hazardous chemicals and harmful pathogens to enter biological organisms, including humans.

For design purposes, the actual rate of diffusion of different chemicals within, and desorption out of a plastic polymer matrix is important, especially because it can vary for the same chemical even within the same polymer type. This chemical behavior as used with specific polymers is being studied, but the current literature is far from complete, especially given the numerous polymer formulations on the market. But priorities can be set. For example, a recent study on the diffusion of diethylhexyl phthalate (DEHP) has indicated that leaching of DEHP from PVC microparticles begins in less than 1 minute when immersed in agitated seawater (Gulizia et al., 2023), indicating that leaching is governed by surface area effects, and thus could be highly variable given surface area conditions. The same study, however, found that leaching of bisphenol A (BPA) from PVC occurs much more slowly under the same conditions, indicating that leaching of BPA from PVC is limited by how it diffuses within the polymer matrix (Gulizia et al., 2023).

Currently, available studies on the diffusion of chemical additives focus on diffusion into seawater and do not focus on diffusion as a mechanism for direct exposure to biological organisms. However, it also illustrates the potential, in polymer design, to consider the desirability of plastic chemicals based on their diffusion potential within the polymer matrix as a mitigation approach to reduce their potential to leach out of MNP. Consideration could include weighing the benefit of the plastic chemical in preventing fragmentation into MNP, versus the toxicity and resulting harm caused by the additive should it leach. This work also illustrates the potential to consider these dynamics in the context of waste management methods such as wastewater treatment, again for process design purposes. Of course, when plastic fragments, new surfaces are exposed which will leach, or desorb, without relying on diffusion through the matrix.

In addition to chemicals that may adsorb onto the surface of these particles from the environment, pathogens have been found to adsorb onto MNP as well. Plastic pathogenic contamination is such a recognized issue that there is a large group of antimicrobial additives intended to mitigate microbial proliferation. Many microorganisms have been found on the surface of MNP, including bacteria such as Aeromonas, Rhodococcus, Pseudomonas, Enterobacter, Halomonas, Mycobacterium, Photobacterium, and Shigella, and fungi (Yang et al., 2023; Junaid et al., 2022). Microorganisms can bond to the surface of MNP and hitch-hike into the body in nontraditional ways (Yang et al., 2023). In this way, microorganisms can overcome immune defence mechanisms that developed over the course of evolution to tackle them through traditional biological mechanisms (Yang et al., 2023).; Katsumiti et al., 2021) It is crucial to carry out a risk evaluation of MNP on the human body and further explore their impact on the immune system (Lin et al., 2024).

3.4 Background on Molecular Transport Mechanisms

The diffusion of chemicals discussed above, representing the rate of migration of chemicals through and out of MNP, is governed by Fick's Laws of Diffusion (Costa et al., 2023). Fick's First Law states that movement of particles from high to low concentration is directly proportional to the particle's concentration gradient (i.e., the difference in the concentration of particles between two areas relative to the particle itself). Fick's second law describes the change in concentration gradient with time due to diffusion. While stated in terms of particles, these laws are relevant to the diffusion of chemicals through MNP as well. Additionally, the rate of migration of organic chemicals like plastic chemicals through a plastic matrix is a function of particle size within a specific plastic polymer matrix (Costa et al., 2023; Gulizia et al., 2023). The migration of chemicals through the polymer particle follows four steps outlined in Table 4 (Costa et al., 2023) and illustrated in Figures 2 and 3.

Table 4: *Mechanisms for transport of chemicals in and out of MNP*

Migration of chemicals (Costa et al., 2023)	Mechanism
Diffusion through the polymer	Movement of chemical through the polymer matrix via mass diffusion mechanisms.
Desorption from the polymer surface	Release of the chemical from the polymer surface into the surroundings.
Sorption at the plastic/matrix interface	Binding of a chemical species from the surrounding material onto the polymer surface which may or may not penetrate into the particle.
Absorption/dispersion into the polymer	Penetration of chemical species from the surface into the polymer matrix.

The migration of chemicals through the polymer particle through the four steps above in Table 4 (Costa et al., 2023) is shown below, where Table 1 illustrates the transport mechanisms in MNP.

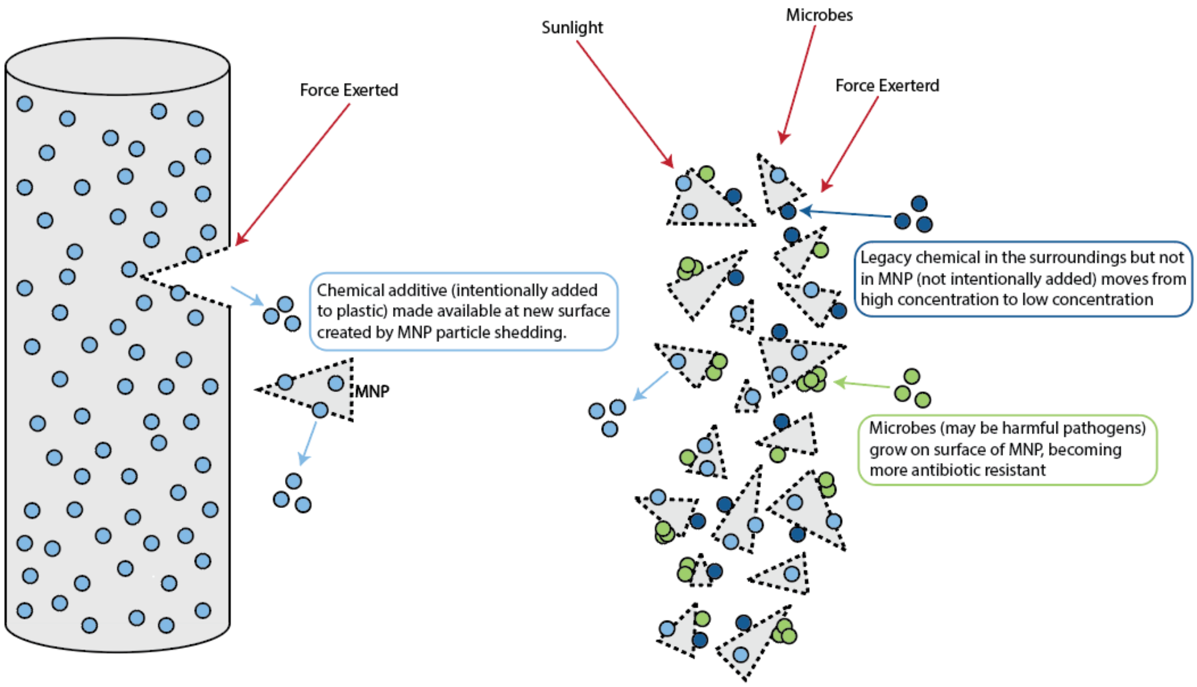


Figure 2: *Illustration of transport mechanisms in MNP*

The migration of chemicals through the polymer particle through the four steps above in Table 4 (Costa et al., 2023) is shown further below, in Figure 3.

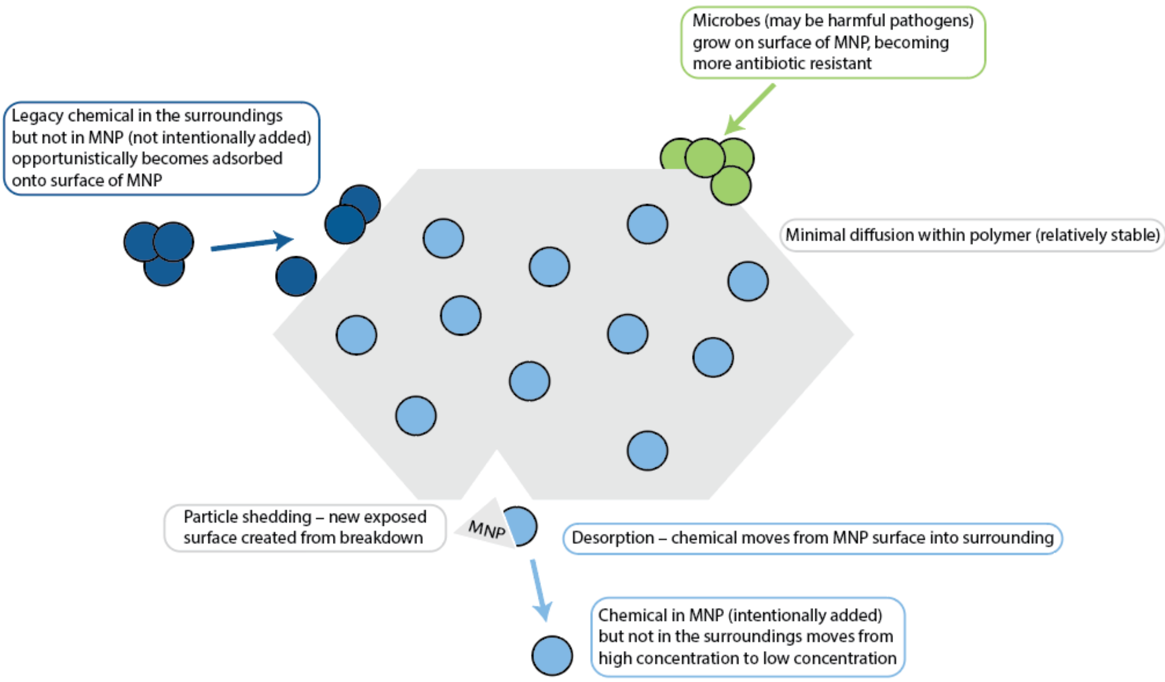


Figure 3: *Breakdown of MNP and release of plastic chemical in the environment*

3.5 Mitigating Risk

3.5.1 Current Approaches for Limiting Exposure

As discussed in Chapter 2, toxic and other harmful substances can enter biological organisms through 4 main pathways: ingestion, inhalation, injection, and transdermal absorption (Crowl & Louvar, 2019). Traditional dose-response risk assessment processes discussed herein consider these routes of exposure and assess the point at which exposure results in observable harmful effects. This observed response to a dose of a particular substance is used to set allowable exposure thresholds for that substance, which is then used to set environmental contamination thresholds for that substance in the context of environmental remediation. In occupational settings, exposure assumes worker exposure durations, such as 8 hours a day, 5 days a week. In human health settings considering exposure to substances in the home, and to substances in the outdoor environment, assumptions would be made regarding concentrations of substances in the indoor environment, and in the outdoor environment, along with the duration of exposure, as well as concentrations in food and liquids ingested or inhaled and absorption of materials in contact with skin. The major objective of a toxicological study is to quantify the effects of a suspected toxicant on the body (Crowl & Louvar, 2019). Unfortunately, the mechanism of exposure directly into tissue by diffusion through a particle is not considered. Most toxicological studies focus on Threshold Limit Values (TLV). Threshold limit values are based on the concentrations of substances that a healthy adult could be exposed to for different time periods without any negative health impacts. Definitions of the different TLV metrics used are given in Table 5.

Table 5: *Definitions of TLV doses*

TVL Type	Definition
TLV-TWA	Threshold limit value-time weighted average
TLV-STEL	Threshold limit value short-term exposure limit
TLV-C	Threshold limit value-ceiling

Other metrics include the Permissible Exposure Limit (PEL) and the Lethal Dose at which 50% of the organisms exposed die (LD50). These metrics are insufficient for exposure due to the uniqueness of MNP delivery and the diffusion of their chemicals. Research reports that MNP may become directly lodged in soft tissue and release potentially hazardous or toxic chemical additives directly via diffusion (Kopatz et al., 2023; Roslan et al., 2024). The TLV PEL and LD50, as currently determined, do not account for this mechanism of exposure.

3.5.2 Gaps in Traditional Approaches to Toxicology Relevant to MNP and Plastic Redesign

Traditional toxicology focuses on dose-response to exposure, taking into account the body's natural defenses. MNP pose a potential threat because of their unique properties and diffusion capabilities that these types of studies do not take into consideration. Published evidence from animal studies suggests that MNP can cross the BBB, directly delivering microorganisms, potentially including pathogens, and plastic chemicals to brain tissue (Kopatz et al., 2023). Toxic dose-response based on surface contamination from microorganisms attached to the surface of MNP, bypassing macrophages in the body that attack and eliminate threats, and diffusion of potential plastic chemicals of concern are not currently included in existing toxicological studies. Leaching profiles of chemical additives show different rates in their molecular transport within plastic, referred to as kinetic profiles, depending upon the plastic type. Based on studies of PET, LDPE, Nylon6, and PVC (Bridson et al., 2023), it is clear that understanding the behaviour of a chemical within an MNP is critical. Once MNP have been shed from the plastic product and become, through exposure, lodged in the brain or other soft tissue, they will continue to leach out chemical species, including potentially hazardous or toxic species (Kopatz et al., 2023; Roslan et al., 2024). New toxicology data is needed based on the delivery of potentially hazardous or toxic species via such transport mechanisms, where currently MNP studies appear to focus only on the presence of MNP in the body and not their effect. More studies are needed reflecting behaviour of MNP in cellular processes (Stock et al., 2022). In addition, uncertainty in analytical approaches, such as the approach quantifying MNP loading in human tissue using pyrolysis - gas chromatography mass spectrometry (Py-GCMS) analysis referenced in Chapter 2 and discussed in Chapter 4 must be considered (Campen et al., 2024) (Preprint).

3.6 Plastic Design Strategies to Minimize Risk Associated with MNP

With this section, potential approaches to mitigate and minimize the potential for MNP exposure through design of plastic and engineering processes are discussed. Approaches to mitigate the toxicity of MNP should exposure occur are also addressed.

3.6.1 Foundation

It is critical to recognize that all plastic either in use or in the environment is a potential source of MNP, regardless of source or design. MNP are shed from everyday items, including textiles, tyres, personal care products, baby bottles, cigarette filters, fishing gear, packaging, and paints, among others. Textile fibers (Zhang Y. et al., 2022) and tyre shred (An et al., 2020) are major sources of environmental microplastic pollution. Approximately 10% of the plastic particles shed by tyres enter surface waters, 40% accumulate in the surrounding soil, 5% enter the atmosphere, and 45% come into direct contact with road surfaces upon initial ejection from the tyres (Matavos-Aramyan, 2024). Recent studies indicate that even tooth brushing releases MPs directly into the mouth with every brush (Dipankara et al., 2021; Fang et al., 2023; Protyusha et al., 2023) where they can get stuck in gums before being ingested. Another study indicates that food-grade nylon bags and hot beveragecups made of plastic or lined with plastic release NPs at densities greater than 1012 per litre when exposed to hot water (Zangmeister et al., 2022). These particles are too small to be effectively removed in wastewater treatment plants (Kay et al., 2018), meaning these sources, as well as particles shed from cookware and textiles, are directly introduced into the environment via household wastewater. These studies indicate that MNP are now an inescapable fact of life for all people on Earth. Weathering, wear and tear, and environmental degradation are all mechanisms that lead to MNP formation and release into the environment. Therefore, strategies to end plastic pollution in the natural environment must include six essential broad approaches:

1. Eliminate production of plastic products known to commonly leak into the environment
2. Effective recovery of post-use plastic in closed system, while preventing releases and emissions of plastic into the environment (macro, micro and nano),
3. Simplification of polymer formulations to eliminate plastic chemicals of concern
4. Transparency along the supply chain to enable comprehensive risk assessment and tracking of additives, including migration and leaching profiles,
5. Development and adherence to design principles that reduce exposure to MNP and risk of harm when exposure occurs, and
6. Cleanup of legacy plastic in the environment, especially in low-GDP countries where effective waste management infrastructure is limited.

3.6.2 Design Approaches

Currently, design strategies for eliminating MNP in manufacture, use, and end-of-life do not exist. Given the known adverse environmental and public health impacts of MNP, design of polymer formulations and plastic products should incorporate a systems-oriented approach to address the six broad approaches previously described. The earth is a closed system with regard to waste. It is now understood that while plastic does not meaningfully biodegrade, all plastic degrades by fragmentation into MN in the environment and through use as intended. Current waste management practices are insufficient to capture MNP. Therefore, the design of plastic use and manufacturing practices must capture all plastic waste to prevent release of MNP in a closed-loop system. This concept is illustrated in Figure 4.

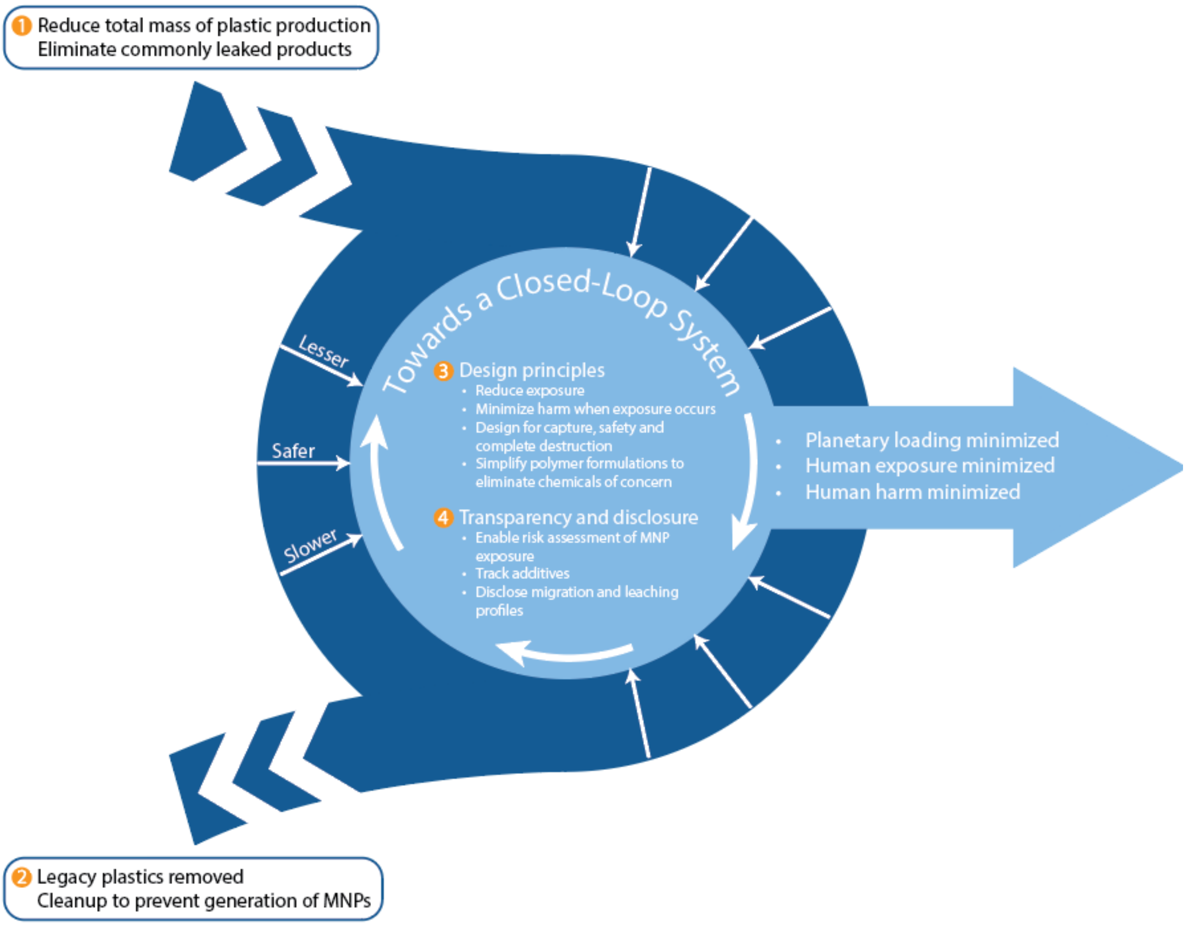


Figure 4: *Closed loop concept for plastic use and disposal*

Eliminate Production of Problematic Plastic Products Including Those Known to Leak into Environment

Because all plastic generates MNP, it should only be produced where necessary, and only as long as it is tracked and managed within a closed system to ensure recovery, is completely destroyed following its useful life, and presents no risk of MNP shedding and plastic chemical exposure throughout its existence. At this time, most of the plastic produced to date is in the environment. Thus, most plastic production, especially single use plastic, should be minimized. How to eliminate unnecessary and harmful plastic production requires understanding plastic and why it leaks into the environment.

As defined initially, but discussed in more detail here, plastics are generally grouped into two categories: thermoset and thermoplastic polymers (including the subset of elastomers). Thermoset plastics are polymer formations made rigid by exposure to heat. This makes thermoset plastics difficult to recycle in the same way as thermoplastic, and thus may be recovered separately for pelletizing, potentially emitting and releasing MNP in the process, as discussed in the section on Waste Management. However, at the same time, thermoset plastics are stronger and more durable than thermoplastics. They are able to withstand higher temperatures and have a higher chemical resistance than thermoplastics. Thermoset plastics have a crosslinked structure which gives added strength. However, if exposed to degrading conditions like UV light exposure, thermoset plastics are prone to chipping and fracturing under stress, emitting and releasing MNP.

In designing plastic products, many thermoplastics, particularly PET, HDPE, LDPE, PP, and PS, are used to produce single-use items. The packaging industry is the largest consumer of plastics, accounting for approximately 36% of global plastic demand (WEF, 2022). Single-use plastics are a major source of MNP due to casual use and mismanagement, especially when used with heat sources or while in food or beverage contact, leading to increased shedding. Because of the inherent nature of their application and the challenges faced around the world in their management, the use of single-use items should be restricted to globally agreed upon essential uses and production of avoidable single-use items banned. Essential single-use items, such as healthcare items, must be redesigned to eliminate chemicals of concern and shedding potential. Additionally, use restrictions should be enacted where items may be exposed to heat, abrasion, or UV light. Human exposure to MNP comes from environmental sources and the everyday use of plastic items, particularly high-contact items such as clothing and toothbrushes.

Because all plastics shed MNP, even during their intended use cycle, reusing plastic items is not an effective strategy to eliminate MNP exposure. As discussed in the Section on Waste Management, any handling of plastic can produce MNP. Thus, high intensity processing such as waste collection, sorting, recycling and incineration can produce MNP. The longer a plastic is used and the more physical stress and degrading conditions a product experiences during its use, the more the shedding rate is likely to increase. Even if a plastic product is designed for durability, it can still shed MNP under the right conditions. But formal reuse-refill systems accepting plastic containers may reduce overall MNP planetary loading as compared with continued single-use, despite reuse-refill often requiring washing before refilling. If implemented, such formal reuse-refill programs accepting plastic should ensure cleaning does not utilize chemicals that will cause the plastic to release MNP.

Within design considerations is the recognition that some particularly problematic polymers, including PS and PVC, should simply not be chosen as the material for use. These two particularly polymers are quite problematic, due to their hazardous monomers (styrene and vinyl chloride respectively), and relatively more hazardous combustion byproducts (from styrene and chlorine in vinyl chloride. Eliminating, or at least reducing PVC will also dramatically reduce phthalate chemical additive burden, where 70% of phthalate is used for the production of PVC. Options to replace PVC include HDPE, stainless steel, and ductile iron for piping, crosslinked PE (PEX) for wire insulation, wood, bamboo, or linoleum for vinyl flooring, and aluminium for window cladding. Options to replace PS include sugarcane for drinking straws, bamboo for disposable cutlery, cellulose, moulded paperboard, and mycelium (mushroom) for packaging delicate items, and beeswax-coated fabric for plastic food wrap. Although each of these substitutions has specific concerns, they do not carry the potential environmental and human health impacts of the plastics they are intended to replace.

Effective recovery of post-use plastic in closed system, while preventing releases and emissions of plastic into the environment (macro, micro and nano)

To effectively capture post-use plastic within a closed system, plastic uses known to defeat attempts to capture it post-use, such as single-use items and similar consumer products, should be eliminated. Alternatives to such plastic products should replace these uses. Where such substitutions are unlikely, mitigating measures should be considered. Substitutions are unlikely with health care products, but these may be efficiently tracked with medical waste tracking programs and diverted to properly designed destruction processes that eliminate MNP emissions and releases. Substitutions are also unlikely with synthetic fibres in consumer textiles.

However synthetic fibres can be redesigned to shed fewer MNP, where very loose weave products like fleece can simply be banned. Additionally, maintenance of these products through their use can be improved, including designing to mitigate MNP release from these products in the design specifications of consumer goods impacting the release of MNP from these products. For consumer textiles, common products such as sinks, washing machines, can be fitted with filters to capture MNP and clothing can be designed to minimize discharge of MNP into the environment.

Simplification of polymer formulations to eliminate hazardous and toxic additives

Another pressing issue is the need to simplify plastic formulations. As previously stated, there are currently 70,000 plastic formulations available for use, with over 16,000 plastic chemicals present (Wagner et al., 2024). However, the sheer number of plastic chemicals on the marketplace does not represent the actual variability within the plastic chemical category, given that many of the marketed chemicals are very similar and created from similar products for artificially driven business purposes and not their unique chemical role as a plastic chemical. This reality can be exploited to greatly simplify the list of recognized plastic chemicals into categories of similar molecular structures. But in any case, this array of chemicals poses significant challenges in managing post-consumer plastics and raises serious human and environmental exposure concerns.

Simplification of the unnecessary complexity among plastic additives and redesign of the manufacturing process, coupled with regulation based not only on hazard and toxicity but also on the delivery mechanism of the chemical additive into biological organisms, including humans, is needed to prevent long-term exposure to plastic chemicals, including endocrine disruptors, carcinogens, heavy metals, and other toxic substances. Eliminating chemicals of concern in plastic formulations, such as phthalates, heavy metals, and carcinogens, among others, would reduce the risks associated with new plastics. Additionally, problematic polymers like polystyrene (PS) and polyvinyl chloride (PVC), which are based on inherently hazardous molecules, should be phased out of production in favor of existing safer alternatives.

Of the more than 16,000 chemicals used in the production of plastic formulations, 4,200 are chemicals of concern due to being persistent, bioaccumulative, mobile, or toxic (PBMT) (Wagner et al., 2024). Currently, the production and use of only 2.7% of all plastic chemicals are regulated at the global level (Wagner et al., 2024). Reducing the use of plastic chemicals of concern must be a priority. Eliminating the use of plastic chemicals of concern will reduce the potential environmental and public health impacts of the MNP. It is important to consider that some plastic chemicals may delay the release of MNP due to their protective properties. Examples include antioxidants and UV light stabilizers, as long as those additives are not themselves PBMT. Reducing toxicity requires eliminating harmful additives, simplifying the number of additives used, and transparency throughout the supply chain.

Transparency along the supply chain to enable comprehensive risk assessment and tracking of additives, including migration and leaching profiles

To effectuate real change in the plastic industry, both transparency and simplification must be implemented, where simplification greatly enhances the ability to enforce transparency. Undertaking a redesign of the manufacture and use of plastics requires an understanding of the value judgments and worldviews that shape how producers, policymakers, and the public perceive and respond to the problem of plastic pollution (Matavos-Aramyan, 2024). Understanding these value judgments is critical due to their crucial role in shaping preferences and driving the framing of the problem (Matavos-Aramyan, 2024).

Redesigning plastic manufacturing will require a coordinated effort among producers, policymakers, and the public, including continuing testing for environmental loading to limit potential harm. The plastic industry must adopt several strategies to address the concerns highlighted in this chapter. The first step is transparency. Currently, for any particular plastic product, it is not readily known exactly what formulations of polymers and chemicals were used in its production, how much of each, or, as a result, the hazards it might present. There must be a higher level of transparency to understand better what is being put into the world.

3.6.3 Development and adherence to design principles that reduce exposure to MNP and risk of harm when exposure occurs

Material Selection

In plastic design, the first step is material selection. Based upon the discussion above, plastic may not be the most suitable material for the intended use. First, all plastic can potentially release MNP given the conditions experienced by the plastic. Thus, all plastic can release MNP during industrial use, plastic production and waste management operations, as well as consumer use, reuse and disposal. Workers, consumers, and members of the public, should be protected from MNP through careful material selection based upon the intended use of the product, considering characteristics of the proposed plastic polymer, and plastic chemicals required to support such use discussed above. Where plastic is not the best material due to direct human exposure and potential deteriorating conditions, then plastic might be avoided, thereby allowing reduction of plastic reliance and more appropriate plastic usage. These measures would help mitigate or eliminate the risk from MNP and chemical exposure from releases of MNP and potentially hazardous and toxic additives during production, use, processing and end of life.

As discussed herein, leading the lists of problematic and avoidable plastic uses are single use plastics (due to leakage); degrading uses such as containers used for heating of food, plastic surfaces for food preparation through cutting, abrasive uses (due to MNP and plastic chemical shedding); highly MNP shedding uses (tyres, loosely woven synthetic fabrics); and intentionally released MNP (agriculture, microbeads). Where plastic use cannot be avoided, design can be undertaken to minimize risk from use including risk from MNP shedding and chemical exposure throughout the plastic's existence.

Biobased plastics are often discussed as alternatives to traditional, crude-oil derived plastics. However, several important distinctions must be drawn. First, the carbon source used to create the plastic does not matter with regard to the final material properties. Using a biobased resource, does not ensure that the final product is biodegradable or compostable. In this regard, biobased plastics must be designed and managed to the same closed-loop standards applied to crude-oil derived plastics. Second, with respect to biodegradable and compostable plastics, the time scale for decomposition is critical. The decomposition time must be fast enough to allow complete decomposition before the material can break down into MNP. Many compostable bioplastics are only compostable in industrial facilities, which operate at a higher temperature than home composting. These facilities are not available in all areas. Thirdly, simplification of the plastic chemicals used and transparency throughout the supply chain are still critical to ensure that potentially hazardous plastic chemicals are not left behind after the polymer is decomposed. Finally, biodegradable plastics are not generally recyclable and may confound traditional recycling efforts. When used, biobased and biodegradable materials must still be maintained in a closed-loop system to prevent improper introduction into the environment.

Textiles

Approximately 9 percent of ocean microplastic pollution comes from the textile industry (UNEP, 2024). Common thermoset plastics used in textile manufacture include nylon and viscose (Rayon). Common thermoplastics used in textile manufacture include polyester, acrylic, and PET. Polyester alone constitutes about 60% of the material used in garments globally (Ellen MacArthur Foundation, 2017). The material shed from fabrics are referred to as micro- and nanofibers (MNF), i.e., actual fibres quite distinct from other MNP which consist of particles and tyre shred MNP as MNFs are released both when garments are worn and when they are laundered. The type of fabric and the weave contribute significantly to the amount of MNFs released. Knitted fabrics shed more MNF than woven fabrics, and satin texture fabrics release more MNF than fabrics woven with a non-satin texture (Cui & Xu, 2022). The design and production of textiles made from plastic materials should be optimized and employ fabrics specifically woven to minimize MNF shedding (e.g., tighter weave). Additionally, as long as synthetic thermoset textiles are used, washers should be designed with filters for MNP to help reduce the direct disposal of MNP into the environment through washer discharge water. Filters are already in use and have been proven effective in mitigating some of the MNP release (Brodin et al., 2018).

Plastic Manufacturing

Because all plastic is a source of MNP, alternatives to plastic and reduce overall plastic production must be found. Reductions in plastic production can be achieved through banning avoidable plastic products, problematic products including composite materials, polymers and chemicals of concern, thus both lowering overall planetary plastic MNP precursor loading and reducing their potential hazards. Reduction in plastic production also reduces the need for transport of pre-production pellets, which are prone to leakage, transport of products using plastic pallets, and the use of primary, secondary and tertiary packaging.

All Industry

Industry has adopted prolific use of plastic in all aspects of its operations. It is light, cheap, and currently mostly unregulated. Thus, plastic is used for industry process components and packaging to the degree that all industry emissions should be regulated for MNP emissions. Where conveyor belts, buildings, process components, and piping may have been made of canvas, glass, aluminium, stainless steel and cast iron in the past, processes now largely incorporate plastic and will generate MNP during operation. Packaging and vehicular traffic also generate MNP from handling and tyre shred. Combustion processes used by industry may be used to dispose of solid waste but are currently not designed or operated to completely destroy plastic waste. MNP emissions from these industry sources are from both point sources, such as a vent pipe directing particulate process emissions containing MNP from industry operations and processes to the atmosphere, and ground level fugitive emissions, defined as uncaptured particulate containing MNP created incidentally from industrial facility use of plastic materials and equipment, including tyres. Onsite workers should be protected from microplastic released in the workplace from industrial operations while point source and fugitive particulate air emissions, storm water discharges and plastic waste management, should all be regulated to prevent microplastic releases to the environment. Programs mandating industry best practices to protect worker exposure and prevent plastic waste and pollution, including elements of voluntary programs such as Clean Sweep, and others may encourage minimization of plastic reliance.

Health Care

While there may be some uses of plastic in the healthcare industry that are not really necessary, society will likely be reluctant to prioritize mitigation of MNP risks over hygienic protection provided by new single use products for patient care. Thus, proper management of products post-use may be the most effective means of minimizing MNP from the health care sector. Certain products that cannot be managed in this manner should be reviewed for possible alternative products, along with alternative management approaches to minimize MNP.

Used medical single use and other waste may be tracked for disposal as Medical Waste to mitigate pathogenic risks and other hazards. This waste may be tracked for destruction in medical incinerators. Medical waste incinerators, like other government permitted industrial incinerators, are usually permitted to limit particulate and other hazardous emissions. However, due to the historic failure to recognize MNP risks, and lack of sampling and analytical methods for MNP to characterize MNP risks from medical waste incineration, these processes are not designed to prevent MNP emissions through proper incinerator design to ensure complete destruction of the plastic matrix.

To ensure that all medical waste is properly tracked for complete destruction, medical waste regulation should be developed to ensure complete capture of medical waste following use within regulatory tracking systems. The medical waste should be tracked to an approved medical waste incineration facility, as it is often currently tracked, but with additional requirements mandating capture of MNP generated during medical waste management prior to incineration, complete destruction of the plastic matrix and permits mandating best available technology and practices for such processes to ensure complete destruction of the plastic matrix with demonstration through MNP testing of air emissions, wastewater discharge and ash.

Waste Management

Plastic waste management contributes significantly to planetary MNP loading. When plastic waste management infrastructure fails, plastic is leaked into the environment. Given the challenges in recovering leaked plastic pollution for purposes of remediation, eliminating plastic leakage should be a primary goal of plastic regulation. But, next, all recovered plastic must be properly managed. Waste management itself is not currently regulated to mitigate MNP releases and emissions. All plastic waste management should be designed to ensure mitigation of MNP releases, including capture and control fugitive MNP emissions from collecting, loading, sorting, and other recycling activities.

Usage of plastic should be restricted to only globally agreed upon essential uses, (with exceptions for need as demonstrated) such as health care, automotive, aerospace, insulation and other critical uses where there is no effective substitute. Certain uses should be eliminated, including Intentional Release, Degrading Use (DU), Direct Exposure (DE), Vulnerable Population Use (VPU), and Use Constituting Disposal (UCD). These uses are known to release MNP and should be avoided. Intentional release includes uses of MNP as abrasives or direct intentional application. Abrasive uses include toothbrushes, kitchen scrubbers, etc. Direct intentional application included land application, tyres, etc. Degrading use includes outdoor uses like architectural, coatings, heated food containers (baby bottles, food), and artificial turf, etc. Direct exposure use, including exposure to plastic chemicals, include food contact, clothing, coatings from indoor paint, etc. Use constituting exposure includes single use items, packaging, and microbeads. Vulnerable population use includes items such as baby bottles, baby clothing and fabrics, plastic diapers, highly processed food production for baby food, pacifiers and teething rings. These uses are illustrated in Figure 5.

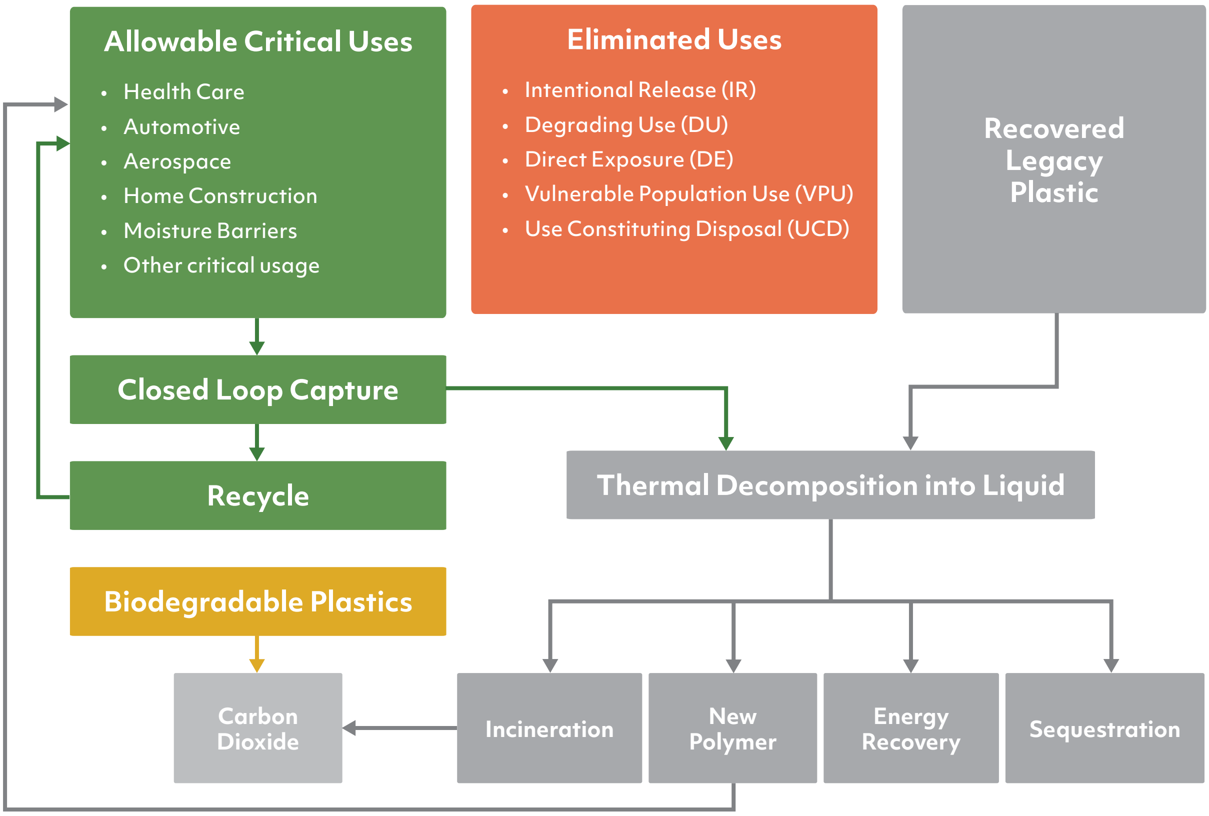
Incineration, as currently utilized, is a flawed technique for destroying plastic waste. Incineration processes are not currently designed specifically to ensure 100% destruction of plastic waste, or even 99.9999% direct removal efficiency (DRE) as may be required for other hazardous materials such as dioxin waste. Plastic waste may be fed with other solid waste to solid waste incinerators, which, based on detection of MNP in on air, water and waste streams from incineration, do not reach sufficient time, temperature, and turbulence process parameters to ensure complete destruction and removal of MNP (Tsunematsu et al., 2023; Yang et al., 2021). Thus, these processes are allowed to release tons of particles through air emissions, wastewater discharges and ash disposal, which may be MNP. A recent report reviewing environmental impacts of incineration, while comprehensive, did not recognize the fact that incinerators are not specifically designed to completely destroy, and demonstrate complete destruction, of the plastic matrix. While identifying complex organic molecules detected incinerator stack, ash and wastewater discharge, the fact that the enduring matter of MNP is also present is not fully addressed. The report discusses dust emissions but does not consider that the dust itself is not just benign carbonaceous aggregate or metal oxides, but also will include MNP. Where MNP is found in ash and wastewater, plastic is not completely combusted. Smaller MNP will be captured along with dust in the dust collectors, while even smaller MNP is likely emitted and released as stack emissions, again counted and considered merely as dust. While this same report does discuss pyrolysis, it does not recognize that plastic waste feed for incineration should be liquified through heating with low oxygen conditions (essentially pyrolysis) as an initial step in plastic waste feed preparation, preceded by proper sorting, that could enable complete oxidation, as complete as liquid hydrocarbon fuel (Jelinek et al., 2024). The general failure to consider MNP in incinerator particulate emissions, or any regulated particulate emissions, is consistent throughout current air pollution regulatory approaches given the fairly recent recognition of this aspect of plastic pollution. It is time to redesign conventional processes to prevent emission and releases of MNP.

Complete plastic waste destruction should be ensured through fundamental reconsideration of plastic waste incineration design. Liquification of sorted plastic is a potential option as a preliminary step to incineration. Polyolefin plastic waste particularly can be thermally decomposed in the absence of oxygen to create a primarily alkane liquid in the range of kerosene or diesel fuel. These alkanes can be incinerated and used for energy recovery (ensuring complete destruction of both alkane and plastic chemical additives), disposed through reinjection back into petroleum producing geological formations as a form of carbon sequestration through environmental permits such as the U.S. Environmental Protection Agency (EPA) Safe Drinking Water Act (SDWA) Underground Injection Control (UIC) Program, or used as a first step in advanced recycling to manufacture more polymer products. Sorting to separate plastic waste from solid waste would allow a significant percentage of the waste to be directed liquified through oxygen limited thermal degradation, which could be atomized in the combustion zone, and treated with sufficient time, temperature and turbulence, to demonstrate through testing elimination of MNP from air emission, wastewater discharges and ash streams. Thermoset plastic could be directed for sequestration or crushed into powder and atomized in the combustion zone for its separate sufficiently designed destruction by incineration.

As discussed, incineration processes for plastic destruction should specifically be designed for that purpose, considering the potential for solid plastic particles, as MNP, to be formed and released through air (as PM2.5), wastewater (as total suspended solids) and ash (as solid waste) emissions, discharges and waste. Such best available technology and best practices should include:

- Sorting solid waste to isolate the plastic waste stream.
- Liquification of the waste plastic through oxygen limited thermal degradation
- Introduction of atomized liquid in the combustion zone of a properly designed incinerator
- Air pollution mitigation through multistage air pollution control equipment, coupled with energy recovery.
- Demonstration of complete combustion and removal efficiency with testing and ongoing compliance with operating permit provisions drafted for this purpose.

MNP should be captured and mitigated and all steps in the process with appropriate measures enforced through operating permit provisions. This approach to design is illustrated in Figure 5. Biodegradable plastics are not suitable for recycling. Biodegradable plastics that biodegrade in the environment can be landfilled, where they eventually decompose into carbon dioxide.



IR:	Intentional release of MNP through use as abrasives of direct intentional application. Abrasive uses include tooth brushes, kitchen scrubbers, etc. Direct intentional application included land application, tires, etc.
DU:	Includes outdoor uses like architectural, coatings, heated food containers (baby bottles, food), and artificial turf, etc.
DE:	Direct use, including exposure to plastic chemicals, including food contact, clothing, coatings from indoor paint, toothbrushes, etc.
UCD:	Includes single use items, packaging, and microbeads.
VPU:	Includes items such as baby bottles, baby clothing and fabrics, plastic diapers, highly processed food production for baby food, pacifiers and teething rings.

Figure 5: *Plastic use and disposal flowchart*

Agriculture

Agricultural operations utilize significant quantities of polymers, including polymer-based systems (PBS) to control release of herbicides and pesticides over time; plastic sheeting used for weed control; plastic piping for irrigation; land applied biosolids with significant microplastic content from synthetic fibres and other microplastic found in wastewater treatment plant sludge. While it is critical to maintain a robust agriculture industry to feed populations, all these uses contribute significantly to human exposure to MNP through ingestion of MNP contaminated food products. Thus, mitigation is warranted, including natural degradable alternatives to PBS; regulation of other uses like plastic sheeting and piping to mitigate abandonment of this plastic in the environment and prevent related contamination of the soil column; and banning high MNP content biosludge application for agricultural purposes.

Legacy Plastic

Legacy plastic, herein meaning that unmanaged or undermanaged plastic waste currently in the environment, presents a significant environmental challenge, especially in low-GDP countries lacking effective waste management infrastructure. Corruption, lack of strong governmental institutions, and an emphasis on economic growth above environmental protection and public health have all contributed to the current crisis. Cleanup operations to remediate legacy plastic should be funded by the plastic producer, likely through international cooperation as many low-GDP countries do not produce plastic yet are overwhelmingly burdened by plastic pollution that must be remediated. Legacy plastic remediation, while necessary, must be well managed to prevent further environmental degradation. However, any potential environmental harm from cleanup operations must be considered against the immediate environmental and public health harm from MNP and chemical additive leaching if plastics are allowed to remain in the environment.

3.7 Summary of Design Approaches for MNP Release by Design and MNP Incidental Release

Chapter 3 focuses on design, beginning with preventing avoidable loading of plastic into the environment by reducing production overall, and restricting unnecessary, avoidable and problematic plastic products, polymers and chemicals of concern to minimize leakage and risk to human health and the environment from that leakage.

But even after these initial steps, all plastic products must be designed to mitigate human exposure to MNP. Thus, further design elements include mitigating intentional release of MNP from products and processes, and also incidental release of MNP from all sources including consumer and industrial sources. From a design perspective, these are the primary distinctions in MNP release: whether release of MNP is part of the design, or instead simply an unfortunate, unknown or ignored fact incident to that product. If MNP release is critical to the design, then designing to avoid MNP is a greater challenge. Where MNP is released through design, and such design is critical to achieve the product's purpose, then redesigning the product will present challenges. Perhaps in these cases, focus should be prioritized to mitigate the risk of the MNP upon its release.

For example, comparing tyres and synthetic fleece: one may be very difficult to replace but could be improved through design, and the other is not critical and can simply be banned. Tyres fill a critical transportation need around the world. Tyres actually function by relying on MNP shedding. Tyre material is abraded by friction to overcome momentum during changes in acceleration, thereby emitting and releasing MNP. Tyres are currently made with a large percentage of synthetic rubber, i.e., plastic. Some tyre formulations include an anti-oxidant called compound N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD). While tyres currently shred microplastic as a necessary aspect of their function, tyres do not need to include this particular plastic antioxidant, 6PPD, which transforms in the environment into 6PPD-quinone, a particularly toxic compound for salmon (Tian, et al., 2021). Thus, MNP release may be a necessary aspect of tyre function, but 6PPD toxicity may be mitigated. However, while synthetic fibre fleece may be warm, the MNP release from synthetic fibre fleece serves no purpose. While we cannot yet simply replace tyres, we might replace synthetic fibre fleece or at least restrict it. Redesign to encapsulate the fleece insulating material or simply mandate tighter weave that does not shed MNP would not harm the functionality of the product. And where synthetic fibre MNP release is minimized, there are benefits throughout the product's life, with minimized human exposure during use, and throughout product maintenance including laundry/cleaning. Reduction of synthetic fibre MNP release alone would significantly benefit operation of wastewater treatment plants.

Aspects of microplastics relevant to design for mitigating human exposure are listed in Tables 6 and 7, including those mitigating MNP Release by Design, as well as MNP Incidental Release, respectively

Table 6: *MNP Release by Design of Product or Process*

Product	Risk of Human Exposure	Primary Route of Exposure	Shape	Size	Anticipated Effects	Necessity	Mass Loading	Preventative Mitigative Options
Microbead	High	Ingestion	sphere	10 um to 1 mm	Not significantly retained as spheres; higher risk following environmental fracture and adsorption of chemicals and pathogens	Low	tbd	Ban
AGRO polymers	High, but secondary, following accumulation in farmed soil column	Ingestion, impacted crops	particles	<5mm	Through food chain, anticipated to be accumulating in organs	Low	tbd	Ban
Industrial abrasives	High	Ingestion, Inhalation	particles	<5 mm	Through worker exposure, anticipated to be accumulating in organs	High	tbd	Redesign product to reduce toxicity; replace with natural materials, e.g., ,silica or other mineral, or cellulosic media
Tire shred	High	Inhalation	shred	1-2 um	Through air pollution, anticipated to be accumulating in pulmonary tissues	High	tbd	Reduce chemical toxicity (6PPD); minimize use, road miles, vehicle weight
Waste Incineration, Permitted Particulate Emissions	High	Inhalation	particles	<15um	Through environmental pollution, anticipated to be accumulating in organs	High	tbd	Redesign incineration for plastic; sort solid waste to isolate plastic waste stream; liquify amenable waste plastic through thermal degradation in low oxygen; atomize liquid in combustion zone; follow with secondary combustor and air pollution control equipment; demonstrate complete combustion and removal efficiency
Biosolid Application	High, but secondary, following accumulation in farmed soil column	Ingestion, impacted crops	Fibers and particles	<10 um to <5000 um	Through food chain, anticipated to be accumulating in digestive tract	Low	tbd	Redesign process to eliminate microplastic prior to application for fertilization

Table 7: *MNP Release Incidental to Product or Process*

Product	Risk of Direct Exposure	Primary Route of Exposure	Shape	Size	Key Pathways and Anticipated Effects	Necessity	Mass Loading	Preventative Mitigative Options
Synthetic Fibers	High	Inhalation, Ingestion, Absorption	Fiber	<10 um to <5000 um	Anticipated to be ccumulating in pulmonary and digestive tissue	Low, re high risk uses	tbd	Clothing: Ban loose weave synthetic fiber products; mandate fiber capture in laundry devices; impose design standards to limit MNP shedding, reduce chemical toxicity of particles shed by eliminating toxic additives; prohibit high MNP content biosolid land application; Indoor Use: Mandate synthetic fabric design to limit MNP shedding for indoor use; reduce chemical toxicity. Outdoor Use: Ban artificial turf; regulate architectural fibers to minimize MNP shedding.
Single use Consumer Products	High	Inhalation, ingestion	Particles, Fibers	All sizes	Anticipated to be accumulating in target organs	Low, re high risk uses	tbd	Ban where possible, especially high risk uses such as "heat in container" food items. Where unavoidable, ban uses of polymers and chemicals of concern, and mandate closed system recovery.
Single use Medical Products	High	Inhalation, ingestion, dermal absorption	Particles, fibers	All sizes	nticipated to be accumulating in target organs	High	tbd	Used Medical Single Use Products may be regulated as Medical Waste to mitigate pathogenic risks and tracked for destruction in medical incinerators; redesign medical incinerators to ensure complete combustion of plastic; separate plastic suitable for liquification by thermal degradation in low oxygen at source and atomize for complete combustion followed by secondary combustion and pollution control equipment; reconsider single use medical plastic that cannot be completely destroyed with sorting and pyrolysis prior to combustion.
Industrial Processes	High for Worker Exposure, lower for impacted populations	Inhalation	Particles, fibers, shred, Fumes	All sizes	Anticipated to be accumulating in target organs	Significant percentage is avoidable		All Industry Generally including Plastic: Regulate MNP releases in work environment to protect workers; regulate MNP emissions and discharges to the environment from fugitive, ground level sources and stormwater runoff; encourage clean sweep programs and minimization of plastic reliance. Additional Mitigation for Plastic Manufacturing: In addition to the above, reduce overall plastic production, ban avoidable plastic products, problematic products including composite materials, polymers and chemicals of concern to lower overall planetary loading of MNP and reduce its toxicity.

Note that certain use applications increase exposure, such as heating, or using a plastic item in a microwave oven.

3.8 Conclusion

In conclusion, manufactured plastic goods have led to increased convenience and economic growth. Unfortunately, due to its design, plastic is persistent, but not permanent. All plastic sheds MNP, through both intended use and environmental degradation. MNP present a clear threat to the environment and public health. The potential pushback from the redesign of plastic manufacturing must be weighed against the increase in public health burden and cost from plastic pollution. Finding alternative materials that provide the convenience consumers want without the public health impacts of plastic will be critical. The routes of potential toxic exposure from MNP are complex and governed by material properties and mass transport phenomena. To achieve a closed-loop system for plastic, systematic redesign of the plastics industry is needed. Plastics known to leak into the environment, especially single use items, must be eliminated, post-use plastic must be recovered and properly disposed of, polymer formulations must be simplified and harmful plastic chemicals eliminated. Transparency along the entire supply chain must be achieved, products must be designed to eliminate MNP shedding during use, and legacy plastic must be addressed to prevent further breakdown into MNP. Achieving these goals will also require a rethinking of the consumer relationship with plastic. Plastic provides convenience and low cost, but it comes with significant public health and environmental consequences. The Precautionary Principle, discussed in Chapter 4, compels that this potential harm be considered in the case of MNP exposure and weighed against the economic cost and loss of consumer convenience. As the full extent of their impact continues to be studied, it is imperative to prioritize prevention and safeguard both human health and the environment.

4. National and regional legal authorities supporting Closed-Loop Design to prevent human exposure to MNP

Key points

- Current peer reviewed and published studies reporting MNP in human tissue supports adoption of Closed-Loop Design to prevent human exposure to MNP through existing legal principles and authorities.

- The Precautionary Principle, Rio Declaration Principle 15 (provided for convenience below) should be utilized to prevent MNP emissions and releases, while mitigating human exposure to MNP, due to the inherent uncertainties in strict quantitative risk assessment for such a ubiquitous, variable and changing particle and chemical pollutant, the inevitable continued planetary loading with plastic and MNP sources, and the sobering associations with human disease processes described in recent research discussed in Chapter 2.

- Where the Precautionary Principle has not been formally adopted, litigation pathways may compel a remedy to harm from MNP based upon similar exposure, tissue accumulation and disease rate associations which have supported past regulation of other persistent and ubiquitous pollutants such as asbestos and PFAS.

- The Precautionary Principle is applied specifically to situations where evidence is less clear, such as the case of MNP, where conventional risk assessment "dose-response" approaches are challenged due to the inherent variability of MNP. But, pursuant to the Precautionary Principle, current evidence is sufficient to both act as well as shift the burden of proof: associations between human MNP-containing tissue samples and plastic usage reflecting exposure rates, to disease rates and other health data can provide sufficient evidence to support action. Thus, the combined recognition of MNP as hazardous substances in the ongoing treaty negotiations (see the Chair's Non-Paper 3 discussed in Chapter 5), potential risk from reported detections of MNP in human tissue, accumulating reports of associated diseases, and inevitable MNP exposure from planetary overload, compels adoption of legal authority to mitigate, where possible, direct MNP exposure even in the absence of specific dose-response causal relationships.

- With this basis, regional and national legal authority and mechanisms can be better adapted, and new authority adopted, to more fully mitigate human exposure to MNP emissions and releases, including varying applications of the Precautionary Principle to prevent such exposure while recognizing the potential for significant litigation to remedy harms resulting from such exposure.

- Such MNP mitigation should be implemented throughout the existence of plastic, from design and production of consumer and other products, through all kinds of industrial activities including waste management, and management of plastic pollution including strategies to mitigate plastic waste.

- While these regional and national strategies can be improved, because plastic is a long-range air pollutant, present in all oceans and land masses, most industrial pollution and most consumer products - including food and water - global action is required to successfully mitigate human exposures with specific provisions in the Internationally Legally Binding Instrument to End Plastic Pollution. This is in line with UNEA Resolution 5/14 that recognizes that plastic pollution includes microplastics.

4.1 Overview

The following chapter reviews legal strategies that may be used to mitigate human exposure to MNP at regional and national levels in the context of the Precautionary Principle, as well as the potential for litigation and evidentiary issues in the context of the limitations of conventional dose-response human health risk assessments. After a summary of the Precautionary Principle as it may apply to policy mitigating MNP exposure, and evidentiary issues arising therewith, this chapter will then compare and contrast different legal strategies for adopting such policy. Specifically, the chapter compares three separate governmental bodies representing a range of approaches including: the EU, US and Tuvalu. The legal opportunities and strategies of these quite different governmental bodies will allow examination of the overall potential authority that may be relied upon to govern plastic and plastic product design, for consumer products, industrial activities of all kinds, and plastic pollution remediation in the context of the application of the Precautionary Principle and potential for litigation to remedy harm. Provided below for the readers' convenience is Rio Declaration Principle 15, known as the Precautionary Principle.

Precautionary principle, Rio Declaration Principle 15:[1]

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

4.2 Summary

Governments are limited in their powers and adopt legislation within the scope of power embodied in the documents evidencing their formation, for example, constitutions. Government authority is exercised in a number of ways depending on the structure of government, and the interaction of branches of government within their own powers, such as legislative, executive and judicial. Some national governments are subject to overarching powers, such as the European Union. In this way, governmental power to adopt and implement legislation and regulation to address environmental pollutants will vary among governments, and some are more limited than others. For example, some nations may have incorporated the Precautionary Principle into their laws, as well as provide access to and relief within available paths to justice. National authorities are also limited by each nation's commitments pursuant to international agreements as discussed herein.

Regarding plastic and microplastic, including the MNP risk discussed in Chapter 2 and MNP mitigating design discussed in Chapter 3, each nation's laws governing manufacturing and trade, environmental pollution and protection, worker and consumer protection are most relevant (Nicholas Institute). Also relevant are those actions a nation's government may choose to adopt to control its own actions, such as when the executive branch decides to, pursuant to its existing legislative authority, assess and reduce pollution from plastic production, promote innovation of materials and product design, decrease plastic waste generation by reducing federal procurement of single-use and other plastic products, improve environmentally sound waste management, and inform and conduct plastic pollution capture and removal (U.S. White House CEQ 2024). Where the government fails to protect human health and the environment from MNP, as with historical failures in environmental policy, litigation has been utilized to hold those responsible for harm accountable. While plastic litigation is still in its early days, and the science is evolving, plastic products have already been the basis for litigation filed against producers of consumer goods such as baby bottles and drinking water bottles shedding MNP (PlasticLitigationTracker.org)). Plastic litigation may follow the similar paths of historical asbestos litigation and current PFAS litigation. Ongoing PFAS litigation mirrors historical litigation regarding asbestos, both of which have driven adoption of legal authority based upon, in part, evidence found sufficient by the courts in litigation.

1 For further discussion on the Precautionary Principle, see Pinto-Bazurco, J. F., 2022.

Within each nation, state, local and other jurisdictions have also taken action regarding MNP, to the extent not pre-empted by national law. These specific state and local actions are beyond the scope of this paper, except to note that in many cases, historically these state and local efforts have often illustrated a path for developing national authority, while litigation has forced action toward adoption of national authority.

Three examples of MNP legal strategies to mitigate the risk from MNP exposure discussed in Chapter 2, with design approaches discussed in Chapter 3, are discussed below including, comparing and contrasting the MNP relevant legal authority of three very different authoritative bodies: the EU, the US and Tuvalu.

4.3 Precautionary Principle

The 1992 Rio Declaration on Environment and Development provides twenty-seven principles defining the rights and responsibilities of nations in relation to the environment, stating that humans are at the core of sustainable development and are entitled to live in harmony with nature. The Declaration recognizes that nations have a responsibility to ensure their activities do not harm the environment or other nations. In implementing these twenty-seven principles, along with the polluter pays principle, recognizing the need for effective cooperation between public and private sectors, and goal of forming global partnership with international agreements, the Declaration also recommends use of the Precautionary principle.

The Precautionary Principle (PP) has been a source of contention at worst, and a reasonable approach to evaluating costs and benefits at best (Peterson et al., 2006). Peterson, Section 3.1 states, "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation (Principle 15, Rio Declaration on Environment and Development, 1992)". The PP, and its underlying concepts, is implemented to some extent, formally or not, at all levels of government when considering evidentiary support for authority to mitigate risk versus the cost of mitigating that risk. Where the cost is high and evidentiary support is less than compelling, often that evidence will not be considered adequate to support the adoption of that authority. Where the PP is implemented in a manner that is considered weak, then more compelling causal evidence will be required. Where the PP is implemented in a manner that is considered strong, then less compelling causal evidence will be required.

Reviews of various PP implementation approaches identify differences arising from: whether the level of threat or potential for harm is sufficient to trigger application of the principle (the threshold of harm); whether the potential threats are balanced against other considerations, such as costs or non-economic factors, in deciding what precautionary measures to implement; whether the principle imposes a positive obligation to act or simply permit action; where the burden of proof rests to show the existence or absence of risk of harm; whether liability for environmental harm assigned and, if so, who bears liability.

In the case of MNP:

- **Threshold of Harm**: The current data regarding MNP hazard, as well as developing data regarding risk to human health from MNP exposure, as discussed in Chapter 2, presents a future of escalating concern regarding human exposure to MNP over a broad range of issues This risk appears to be significant, is anticipated to grow, and thus appears to meet the threshold of harm for triggering application of the PP.

- **Balancing**: The human health risks from human exposure to MNP and potential responses to mitigate such exposure should be balanced against other considerations, such as the non-economic factor of necessity or essentiality. Where plastic is considered necessary, careful balancing is required. For example, in health care, disciplined and spare reliance on single use plastic products as required for hygienic purposes should be acceptable as long as these products are designed safely without hazardous chemicals (such Di(2-ethylhexyl)phthalate or DEHP banned by the California AB 2300, Toxic-Free Medical Device Act), and plastic waste is properly managed to minimize MNP. Certainly, unnecessary use of plastic is recognized by the medical community (GlobalNoHarm, 2024). But given the artificially low cost of plastic goods that fail to internalize the costs of harm to human health and the environment, costs to mitigate MNP exposure are generally justified. These costs of mitigation can be considered in the context of deciding which specific MNP mitigation measures should be adopted.

- **Obligation**: Given the risks to human health from MNP discussed in Chapter 2, the **design approaches** to mitigate human exposure to MNP discussed in Chapter 3, and the **regulatory approaches** discussed below in Chapter 4 allowing mitigation of these risks, the PP appears to justify imposing both a positive obligation to act as well as more restrictive measures in permitting/restricting action.

- **Burden of Proof**: With the developing evidence of both hazard and risk presented in Chapter 2, and the many reasonable approaches to mitigate this risk through design, environmental regulation and plastic pollution mitigation and remediation, the burden of proof should be shifted to those actors chiefly responsible for the sources of human exposure to MNP to prove the absence of risk of harm where continuing to defend sources of MNP known to result in such exposure.

- **Assignment of Liability**: Those responsible for plastic sources resulting in MNP exposure share liability for harm with all contributors to that MNP exposure.

Both the EU and the US implement some form of the PP. For the EU, the Treaty on the Functioning of the European Union (TFEU) article 191 provides authority to preserve, protect and improve the environment, protect human health and prudent and rational utilization of natural resources, aiming at a high level of protection, while incorporating: the Precautionary Principle; Prevention and Correction of Pollution at its Source; Polluter-Pays. The European Commission 2000 Communication provides guidelines for implementing the PP to avoid abuse as a "disguised form of protectionism" (Bourguignon, 2015). EU decisions must be based upon scientific evidence of risk, requiring evaluation of scientific data relevant to the risk, but recognizing that it is not possible to complete a comprehensive risk assessment in all cases. Further, use of the PP to those instances where the scientific data remains inadequate should be limited in any case, as long as the risk is considered too high to be imposed on society. EU decisions should also consider proportionality, consistency, balancing costs and benefits, while recognizing the shifting of burden of proof to the proponent to provide reasonable evidence of safety.

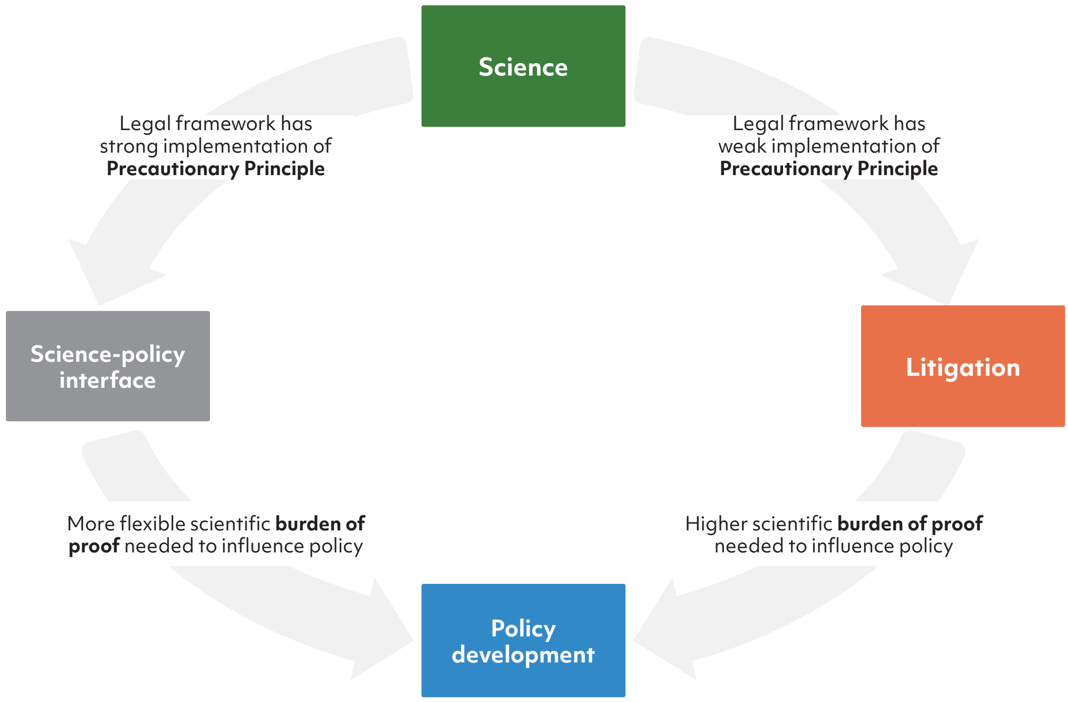


Figure 6: *The role of the Precautionary Principle in policy development*

In contrast, the US has not adopted the PP. Instead, as implemented by the U.S. Office of Information and Regulatory Affairs through Circular No. A-4 (U.S. OIRA, 2003; U.S. Circular No. A-4, 2003), the US exercises precautions when rendering decisions about potential hazards. As articulated in the U.S. National Research Council's Risk Assessment in the Federal Government, the US regulatory process requires that decisions about how to respond to a potential hazard are intended to be made considering "scientific risk assessment that is grounded in the weight of the scientific evidence" (U.S. National Research Council, 1983). However, OIRA's 2003 guidance allows for improved scientific information that reduces uncertainty in risk assessment and risk management. In 2023, the U.S. National Science and Technology Council established a new Subcommittee on Frontiers of Benefit-Cost Analysis which issued the U.S. National Science and Technology Council 2023 report for the US regulatory progress. This new report expressly recognizes the need to develop regulations for non-fatal health effects even when "agencies may lack dose-response functions to describe the relationship between exposures and health outcomes, especially for non-cancer effects or when low-dose human data is not available." (U.S. NSTC 2023). Circular A-4 has also been revised (U.S. Circular A-4, 2023). While the US efforts to move forward with regulation in the face of scientific uncertainty is evolving, these efforts by the US Executive Branch are highly subject to changes in political administrations. The efforts of one administration may be undone by the following administration (Brookings, Tracking Regulatory Changes). There remain many examples where the United States has failed to incorporate relatively more protective regulatory thresholds to protect human health and environment as adopted by the EU or other nations. Thus, in the United States, litigation has driven support for more protective regulation.

4.4 Burden of Proof

4.4.1 Burden of Proof with Precautionary Principle

Based on the current body of data representing the risk of MNP to human health discussed herein, the PP should support adoption of policy to mitigate human exposure to MNP. At the very least, the burden of proof should be shifted to industry to prove that MNP exposure does not present a risk to human health.

Where there is sufficient evidence of harm, the burden of proof should be shifted to the entity that may be responsible for the harm to prove there is no harm from their activities. Thus, the question becomes: what evidence is sufficient to prove harm from MNP, or at least shift the burden of proof to the plastic industry? As discussed in Chapter 2, for MNP, conventional risk assessments relying on dose-response evidence create a challenge, given the variability of MNP representative of expected exposure scenarios and human subjects. Additionally, detection of MNP poses challenges due to contamination of samples and human tissue interference in the analysis of the samples.

Approaches to demonstrating sufficient evidence of harm from MNP may include broad associations between human tissue concentration of MNP and diseases as discussed in Chapter 2. Such an approach was used to show disease association with regional exposures to polyfluorinated compounds through class action that compelled medical monitoring conducted during the DuPont PFAS litigation from 2005-2013 (C8 Science Panel). With global ubiquitous exposures to MNP, there would likely be no control group available. However, as discussed in Chapter 2, a strict control group is not necessary to draw positive associations provided there are other association trends available, such as plastic use, exposure, tissue accumulation and population disease trends.

Approaches to MNP analysis in animal studies, where animal biological mechanisms are similar to human biological mechanisms, as well as studies of human tissue, appear to be sufficiently reliable to constitute competent evidence that may satisfy the burden of proof, assuming assurance that sources of data error are resolved.

Pyrolysis - gas chromatography mass spectrometry (Py-GCMS) analytical techniques have been used frequently for analysis of polymer and plastic materials. Py-GCMS has been applied recently to the detection of MNP in human tissue. The process works by decomposing the macromolecules in the MNP under high temperatures, in a highly controlled manner including an inert atmosphere, to liberate, while preserving, fragments of the chemical species from the solid matrix as pyrolysis products (or pyrolyzates). These pyrolyzates are then characterised by separating them in a gas chromatography (GC) column based on size and chemical properties, and then identifying them in the mass spectrometry (MS) based on their mass-to-charge ratio, allowing determination of the composition of the fragments and the original sample. The identification of MNP is then based on detection of a set of known pyrolyzates of that polymer. A review of recent research using this Py-GCMS technique has reported detection of MNP in eight out of twelve human organ systems including cardiovascular, digestive, endocrine, integumentary, lymphatic, respiratory, reproductive and urinary (Roslan et al., 2024). While comparing and contrasting a range of analytical procedures utilized for detecting polymer composition of microplastics in different matrices, including Raman/(μRaman) spectroscopy, fourier transform infrared spectroscopy (FTIR)/micro-FTIR (μFTIR), Py-GC/MS, and laser-induced laser direct infrared spectroscopy (LDIR), this same review reported that MNP were also observed in other human biological samples including breastmilk, meconium, semen, stool, sputum and urine (Roslan et al., 2024). Concerningly, through Py-GCMS, high concentrations of microplastics (MNP) have now also been preliminarily reported in human brain tissue, with levels reaching up to 8,861 ppm in a study currently under peer review but available as a pre-print (Campen et al., 2024). Sources of error in Py-GCMS can include potential sample contamination by MNP in the sample collection or laboratory process, as well as interference from the human tissue matrix, which can occur where the pyrolysis products selected to identify polymers are insufficiently unique to distinguish polymer from naturally occurring components of the human tissue, particularly polyethylene (Roslan et al., 2024; Rauert et al., 2022). For example, the Py-GCMS pyrolyzates used to identify polyethylene may also be produced from pyrolysis of lipids found in human tissue samples. Thus, erroneous "false positive" results would occur without appropriate sample preparation to remove all such lipids from human tissue before introducing the sample into the Py-GCMS.

The developing nature of these analytical methods, including removal of human lipid and protein tissue prior to analysis, illustrate the complicated nature of ensuring representativeness and data integrity. For regulatory and litigation purposes, where proper procedures are followed, while the data may include an anticipated range of error, data may be considered generally reliable, as far as it goes, though not indisputable and subject to challenge by an expert witness.

To understand considerations in developing reliable MNP analysis for regulatory and litigation purposes, it is helpful to understand the context of analysis for other pollutants. For regulatory purposes, such as demonstrating compliance with environmental permit emission limits, and litigation purposes, such as proving the extent of contamination in environmental media, environmental data produced from sampling and analytical methods complying with standard quality assurance and quality control (QA/QC) measures are presumed to be reliable, though not indisputable. Environmental regulatory agencies such as the U.S. EPA (U.S. EPA SW-846) have strict guidance to ensure data quality, preventing contamination of samples and ensuring proper QA/QC with recommended sampling and analytical procedures, including sample preparation to eliminate interference that could render the data unreliable. While environmental samples can require a range of methods for complex biological tissue matrices, the U.S. EPA's specific procedures for PFAS sampling, for example, adapted sampling and analytical procedures to ensure data quality in the presence of the ubiquitous PFAS pollutant, present in clothing and other sources that could contaminate samples (U.S. EPA PFAS Analytical Methods Developing and Sampling Research). When such data quality procedures are utilized, there is a presumption of data reliability. Preliminary evidence could also be sufficient to justify precautionary actions.

4.4.2 Burden of Proof in Litigation

Where nations have not adopted the Precautionary Principle, as in the United States, litigation can drive development of legislation and regulation. Reviewing the United States as an example, civil claims to recover damages, as opposed to intentional criminal claims, arising from harm alleged to be caused by plastic pollution, including MNP, can arise in various forms: negligence, trespass, nuisance, toxic tort, strict product liability (PlasticLitigationTracker.org). To survive dismissal, each type of claim must satisfy threshold issues of legal standing requiring demonstration of harm to the plaintiff that was foreseeable, traceable to, and caused by, actions of the defendant that can be redressed by the court. Most civil claims have in common the evidentiary threshold of "preponderance of the evidence," i.e., evidence proving the plaintiff's claims are true, "more likely than not" (Leubsdorf, 2016; U.S. EPA Basic Information on Enforcement; Black's Law Dictionary, 12th ed.). Thus, litigation requiring proof of actual harm to human health from MNP to prevail will require a demonstration that actual harm is "more likely than not" based on the weight of all the evidence. While each case, its facts and state law will differ, as discussed more fully below, legal precedent in the United States has not strictly required human epidemiological studies to support such a burden and has accepted animal studies and other evidence.

Plastic litigation has increased drastically in the United States over the past five years (PlasticLitigationtracker.org). For purposes of illustration, three significant lawsuits, one of which was dismissed on October 31, 2024,, include those filed recently by the State of New York, the City of Baltimore and the State of California (State of New York, by its Attorney General, Letitia James, v. Pepsico, Inc., et al., (2023); Mayor and City Council of Baltimore v. Pepsico, Inc., et al. (2024); The People of the State California by its Attorney General Rob Bonta, v. Exxon Mobil Corporation, et al. (2024)). These cases are developing separately, and must be considered within their own context, facts, applicable law, legal theories and eventual implications. With any new area of law, novel legal theories may be pursued in an effort to seek relief from the alleged harm. And courts will need to be educated about new facts that may support new legal theories, including developing science, as they arise with this new wave of plastic litigation.

The State of New York filed suit on November 15, 2003 against: Pepsico, Inc.; Frito-Lay, Inc.; Frito-Lay North America, Inc. New York is seeking relief including recovery of civil penalties as well as remedies for damages to the Buffalo River and its shoreline, and disgorgement of all revenues, profits and gains wrongfully derived from unlawful acts, while enjoining further violations. New York's claims include: (1) public nuisance; (2) strict products liability failure to warn; (3) and violations of New York General Business Law and (4) Executive Law. New York alleges the harm arises from Pepsico's packaging, which is made of plastic that "does not biodegrade in the environment, but rather fragments into smaller and smaller pieces known as microplastic or nanoplastic." Allegations include knowingly producing and selling this material for this use despite knowledge that plastic does not biodegrade but fragments into MNP, in light of recent studies showing MNP are found in the human body and are associated with negative effects on human health, other species and the environment. This case was dismissed on November 1, 2024, leaving the State of New York considering its options. However, in dismissing the case, the Judge summarized his opinion that the State of New York failed to demonstrate that Pepsico's plastic packaging was defective or unlawful. "While no one doubts the harm litter and waste cause in our ecosystem, this does not create a civil cause of action from which to punish Pepsi/Frito Lay." Further, the Judge stated that plastic packaging is used by more than these companies, yet the State of New York only pursued these Defendants, which is nothing more than "selective prosecution based on a naive theory."

The City of Baltimore filed suit on June 20, 2024 against: Pepsico, Inc.; Frito-Lay, Inc.; Frito-Lay North America, Inc.; Coca-Cola, Inc.; W.R. Grace and Company; Mercury Plastics MD; Adell Plastics, Inc; and Polymershapes Baltimore. Baltimore seeks recovery for harm to its infrastructure, land and natural resources, overall economic impact including loss of value in the City's properties, and revenues and costs of remediating Defendant's litter. To remedy this harm, Baltimore specifically seeks compensatory damages, equitable relief, criminal penalties, punitive damages, injunctive relief and disgorgement of profits based on the following claims: (1) trespass; (2) strict liability for design defect; (3) negligent design defect; (4) public nuisance; (5) strict liability failure to warn; (6) negligent failure to warn; (7) negligence and (8) several specific violations, including knowing violations, of Maryland law (illegal dumping and litter control; consumer protection) and Baltimore City Code. Central to Baltimore's allegations is also the knowing and intentional production and distribution of plastic products in Maryland in forms that are not recyclable, cannot be recycled and that are unrecyclable, whereby plastic fragments into microplastic and nanoplastic can enter the body, cross cellular barriers including the blood-brain barrier, and cause harm. Baltimore also demands a trial by jury for triable claims.

The State of California filed suit on September 23, 2024 against: Exxon Mobil Corporation; and Does 1 through 100, inclusive (to be named later but described as those engaging in a "conspiracy, common enterprise and common course of conduct, as agent, servant, employee, alter ego, co-conspirator, aider and/or abettor of named defendants" and "acting individually and/or within the scope if its agency, servitude, employment, and conspiracy"). California seeks recovery for harm from the plastic and MNP pollution crisis to its natural and public trust resources and recreation, from disproportionate effects in communities of colour and low-income populations, harm to local coastal economies and economic harm to California taxpayers and public entities including costs of plastic contamination in recycling, worker injuries, disproportionate impacts, plastic litter cleanup and burden to governance. To remedy this harm, California specifically seeks civil penalties, abatement, preliminary and permanent injunctive and equitable relief including disgorgement according to proof, based on the following claims: (1) public nuisance; (2) equitable relief for pollution, impairment, and destruction of natural resources; (3) water pollution; (4) untrue or misleading advertising; (5) misleading environmental marketing; (6) unfair competition. Central to California's claims is the Defendants' knowingly marketing plastic for disposable purposes: where plastic, once in the environment as pollution, "is long-lived, cumulative friable, and mobile"(Complaint, ¶paragraph () 69) ; because it does not biodegrade but "inevitably disintegrates into smaller and smaller pieces until they eventually become 'microplastics,' … that are readily transported by air, wind, water, and the faecal matter of organisms that ingest them." (¶ 70) Further, Defendants are alleged to have continued these actions where emerging studies point to "potentially dire consequences" (¶ 75) for human health "once inhaled or ingested by humans" (¶ 76) given their accumulation in human tissue, role as vector for toxic transmission, and association with a wide range of toxic effects (¶¶ 76-78). "While the full health effects of human exposure to microplastics and the potential for accumulation of microplastics in human tissues remain unknown, the existing research indicates potentially severe, and even deadly, impacts."(¶ 79). California also requests a jury trial for all such triable issues.

All these matters seek relief, injunction and penalties, based on alleged, discoverable and verifiable costs to the plaintiffs arising from defendants' actions. Each filing alleges the fact of plastic pollution's harm to human health. Notably, each complaint filed - New York, Baltimore and California - is longer than the one prior (39, 71 and 147 pages respectively) with more detailed allegations of harm specifically from microplastic including human health (see complaints filed respectively, New York, ¶¶ 61-67; Baltimore, ¶¶ 31-38 (citing 13 health studies; California, ¶¶ 70-84). While proof of actual harm to human health from MNP may not be required to prevail on all the alleged claims given the broad scope of relief requested to recover from the harm and costs of plastic pollution, such harm has been alleged for purposes of litigation.

These early plastic lawsuits will evolve over time as they have for other historical pollutants. While they may be dismissed to be refiled again, or new lawsuits are filed with new legal theories, seeking always to remedy harm, the continuing drumbeat of litigation against the plastic industry will likely continue. In the US, litigation has often preceded national legislation for other historical pollutants and will likely precede legislation for plastic as well. Litigation will likely continue until the source of the harm from plastic is addressed with national legislation, mitigating the harm while providing a safe harbour and greater certainty for industry.

Sustaining legal claims in court require many elements including: standing (or properly maintained right to sue); demonstration of harm; causation fairly traceable to the defendant's actions; and redressability. In this formula, regarding causation, as with climate change litigation, plastic producers will echo petroleum producers' defence in arguing that plastic producers did not cause plastic pollution any more than petroleum producers caused climate change (i.e., plastic producers did not litter; petroleum producers did not burn the petroleum to produce greenhouse gas) (Climatecasechart.com). But beyond this inevitable legal battle regarding causation in these new plastic lawsuits, new to this litigation is the claim of harm to human health. Given plastic's historical approved use for consumer goods and containers for food and water, demonstrating harm from plastic, its chemicals and inevitable MNP, is the initial challenge. And in seeking recovery for harm from plastic, its chemicals and MNP exposure, demonstration of harm to human health must meet the required burden of proof.

The burden of proof for civil claims alleging harm to human health, including those arising in environmental, worker safety and consumer product law, requires evidence of harm from exposure to harmful materials deemed sufficient by the court. Historically in the US, evidence of harm to human health has been recognized when supported by both animal and human studies, even where there is an absence of clear human epidemiological studies. In re Paoli R.R. Yard PCB Litigation, 36 F.3d 717, 781 (3d Cir. 1994), found that, "Here, where EPA relied on animal studies to conclude that PCBs are a probable human carcinogen, where there is reason to think that animal studies are particularly valuable because animals react similarly to humans with respect to the chemical in question, and where the epidemiological data is inconclusive and some of it supports a finding of causation, we think that the district court abused its discretion in excluding the animal studies. Certainly, the evidence meets the relevance requirements of Rule 402 [of the Federal Rules of Evidence] and we think, after taking a hard look, that it also meets the reliability requirement of Rules 702, 703 and 403 [of the FRE]." Thus, the lack of specific human epidemiological data does not categorically render the current body of MNP human health research inadequate as evidence in civil litigation.

In any case, there is a unique aspect of MNP that may support both adoption of prospective authority and litigation to remedy past damages and compel future relief. As MNP fragments, each fragment remains largely chemically preserved as it was manufactured, as discussed in Chapter 3. When humans are exposed, it appears to accumulate in human tissues, where MNP, a synthetic material, has been reported in human tissues. Furthermore, due to the chemical manufacturing industry's preference for maintaining highly unique and proprietary polymer and chemical formulas, MNP may be sufficiently unique so as to be fingerprinted in some situations, where analytical procedures are available to identify the specific chemical molecules present in the MNP sample. Fingerprinting, i.e., identifying unique chemical characteristics of a mixture of contaminants for petroleum and other mixed groundwater contaminant plumes, has been a critical analytical tool for developing evidence in Superfund litigation. Fingerprinting allows identification and allocation of responsibility for remediation among potential responsible parties (Plumb, 2004; Gutierrez, 1997). In addition to the U.S. EPA's environmental sampling procedures compiled as SW-846 discussed herein used for fingerprinting groundwater contamination in U.S. Superfund litigation, new analytical techniques and resources are being developed specifically to identify plastic related compounds. The National Institute of Standards and Technology (NIST) is developing such methods, particularly to analyse human biofluids, biomedical applications and drinking water, including methods to analyse extractables and leachables. In this process, NIST is extending its existing NIST Mass Spectral Library for plastic related compounds and extractables and leachables from standard commercial polymers (Zuber et al., 2024). These procedures may be sufficient to support fingerprinting of MNP samples. Thus, fingerprinting MNP might be used to identify MNP sources in the home, in food, or MNP representative of regional environmental sources.

MNP in human tissue samples could also possibly be analysed to identify the original plastic manufacturers and support allocation of liability as responsible parties utilizing known unique chemical additives in the plastic chemical inventories. Data from MNP human tissue analysis may be the best evidence of damages compelling action. Like PFAS, MNP concentrations in human tissue, over time, associated with plastic use in any particular region, should allow association with human disease rates (DuPont PFAS litigation from 2005-2013, C8 Science Panel; Frank, 2024). These associations, sufficient to satisfy the United States' "preponderance of the evidence" (51%) threshold and compel payment of damages from the responsible parties, should be sufficient to compel action pursuant to the Precautionary Principle which may allow action based on less compelling evidence to mitigate great potential for harm. Such action would particularly be justified under the PP where plastic use is unnecessary or plastic process or design can easily be improved to avoid significant harm. Should responsible parties be identified with MNP polymer and chemical fingerprint analysis, this strategy should also be sufficient to develop legal theories that could compel remedies through United States civil litigation as well, which litigation is developing rapidly (PlasticLitigationTracker.org).

4.5 Regional and National Strategies Supporting Closed-Loop Plastic Design to Mitigate MNP Human Exposure

In the context of the Precautionary Principle and evidentiary burden, each government adopts its own plastic legal authority. Legal authority to regulate plastic and MNP varies greatly around the world. There are many resources summarizing plastic legal authorities, such as the UN 2018 report, Duke University's Nicholas Institute Plastic Policy Database and the Plastic Litigation Tracker website. There are several resources reviewing micro- and nanoplastics authority (see e.g., Osuna-Laveaga, D. R., et al., 2023). However, for purposes of illustration, examples discussed below illustrate the range of legal authority to support measures to mitigate human exposure to MNP, including the EU (RPa, 2022; GCSE, 2022), the US (ELI, 2024) and Tuvalu, from product regulation to industrial process regulation, to remediation of legacy plastic considering design principles discussed in Chapter 3.

4.5.1 Foundation: Comparing EU, the United States and Tuvalu

Regional authorities, such as the EU, have adopted legislation to regulate plastic pollution and waste, including product bans (GCSE 2022; EC Types of Law). Members to the EU consist of 27 primarily democratic nations sharing, among other values, desire to protect human health and environment, trade beneficially and avoid conflict. The EU can adopt legislation, which governs the member nations in the form of directives, that require the member nations to transpose them and adopt their own specific legislation to achieve a certain goal, or in the form of regulations that apply automatically. However, where the EU authority does not have exclusive jurisdiction, such as on environmental policies, individual member states, or their regional or local authorities can impose more stringent control. In a manner somewhat similar to the US, EU legal authority is developed, implemented and enforced through the EU's three branches of government: legislative (European Parliament and Council of the European Union), executive (European Commission) and judicial (Court of Justice of the European Union, CJEU).

Authority in the EU is exercised to protect human health and the environment through specific authority governing products, waste and pollution, to protect the health of consumers, as well as all human health and the environment from pollution including waste management. Consistent with its own authority, as well as recognized human rights to a clean, healthy and sustainable environment (RPa 2022, fn 17, the EU's jurisdiction extends to all environmental policy, from pollution to waste management and climate change through its Treaty on the Functioning of the European Union (TFEU). TFEU article 11 states, "Environmental protection requirements must be integrated into the definition and implementation of the Union's policies and activities, in particular with a view to promoting sustainable development." TFEU article 191 provides authority to preserve, protect and improve the environment, protect human health and prudent and rational utilization of natural resources, aiming at a high level of protection, while incorporating: the precautionary principle; prevention and correction of pollution at its source; polluter-pays. TFEU article 193 states, "The protective measures adopted pursuant to Article 192 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with the Treaties. They shall be notified to the Commission."

The authority for regulating chemical products, including plastic products and associated MNP, is recognized through market authority within TFEU article 114, which provides authority for internal markets and health, safety, environmental and consumer protections based on a high level of protection taking account in particular of any new development on scientific facts. Pursuant to TFEU article 14, the European Chemicals Agency (ECHA) is mandated to propose the restriction on intentionally added MP with Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH, CR 2023/2055). The EU has also proposed additional MP restrictions (as pellet losses) beyond REACH (EC Proposal, 2023) and plans to propose to extend the duty of registration under REACH to certain polymers of concern pursuant to the EU's Chemicals Strategy for Sustainability (CSS)(October 14, 2020). Of course, while eliminating intentionally added MP, preventing releases of manufactured MP, and restricting problematic polymers, should result in lower overall MNP loading released to the environment, this authority is not comprehensive environmental MNP emission and release regulation. However, TFEU article 192 providing authority for deciding what action is to be taken by the Union to achieve the objectives of TFEU article 191 has been put forth as the strongest basis for regulating microplastic (RPa, 2022), based upon a proposed revised Directive on Industrial Emissions based on authority specifically focused on environmental protection (RPa, 2022, fn 15). In any case, because microplastic poses unique consumer product risks, which may outweigh exposures accumulated through environmental exposure, while MP and MP containing product sale and use contributes significantly to MNP emissions and releases, all the above TFEA articles should be considered together as providing the authority to mitigate MNP risk to human health and the environment from products, industrial activities, waste management and environmental pollution

In contrast, some large nations such as the US have not adopted specific or comprehensive MNP legislation or regulation. The US has just adopted the rather narrow US MicroBead Free Waters Act. Similar to the EU, the US government, a democratic nation, consists of three branches, the legislative, executive and judicial branches, a construct mirrored by the individual states. The US, adopts national legislation through its legislative breach. The legislative branch delegates implementation of the legislation to specific agencies within the US executive branch. These federal agencies then adopt national regulation supported by their enabling legislation. Individual states within the US are governed by this national regulation and may also implement this national regulation at the state level through separate authority delegated to it by the delegated federal administrative agency. States can adopt more stringent regulation where not pre-empted by federal statute, and municipalities within each state might adopt more stringent requirements if not pre-empted by state and federal authority.

As mentioned above, the EU governs products and consumer safety protection from 1) MNP released by design, as well as 2) MNP released incidental to product use, with TFEA 114, e.g., REACH. The US, in contrast, relies on the Toxic Substances Control Act (TSCA), the U.S. Consumer Product Safety Commission (CPSC), and the Food and Drug Administration (FDA). Where the EU relies on TFEA 191 and 192 to govern pollutant emissions from industrial activities, and TFEA 191 and 193 to more broadly protect environmental quality, the US relies on media specific environmental statutes imposing pollutant limits on industrial activities based upon environmental quality goals, as well as operating and technical design standards derived from environmental quality goals, and the Occupational Safety and Health Act (OSHA) requirements to protect worker health. The EU has joined the Basel Convention and complies with its plastic waste export requirements while the US has not, but nonetheless complies with its terms as a member of the Organization for Economic Co-operation and Development (OECD). At this point, the US has not relied upon its delegated authority to regulate microplastic or nanoplastic releases, or MNP contamination in consumer products or food. However, individual states have moved forward with MNP specific strategies (ITRC microplastic project website), and at some point, US attorneys litigating claims arising under common law (such as public nuisance, tort), defective product and consumer protection laws to protect the environment and to correct harm to human health from actions or omissions causing toxic chemical exposure (toxic tort) will intervene as they did with asbestos and PFAS.

In contrast to the EU and the US, the very small South Pacific Nation of Tuvalu (population 11,204) is a constitutional monarchy, with a cabinet consisting of the Prime Minister and 16-member unicameral parliament. Tuvalu is without infrastructure or industry supporting such broad authority. Tuvalu is like many smaller nations that are most impacted by the authority exercised globally, regionally and by their neighbours. Tuvalu implements general environmental protection regulations including waste management, it remains at the mercy of international agreements and the decisions of other nations regarding imported plastic consumer products and exported plastic waste pursuant to the Basel Convention (Peel et al., 2020) However, Tuvalu can mitigate MNP releases through its Regional Marine Litter Disaster Action Plan.

Where plastic governance is exercised, MNP release is mitigated. Whether plastic production restrictions and design requirements, consumer protection measures, industrial regulation, worker safety, waste management or legacy plastic remediation, exercise of authority at each step reinforces the success of further mitigation with cumulative mitigation effect, especially for this pollutant that persists and accumulates in human tissue.

4.5.2 Closed-Loop Plastic Design

To review Chapter 4 in harmony with Chapter 3, first recall that Chapter 3 focuses on engineering design, addressing intentional release of MNP from products and processes, and then incidental release of MNP from all sources including consumer and industrial uses. From a design perspective, these are important MNP design distinctions, whether release of MNP is a critical part of a product's or process' design, or instead simply an unfortunate, unappreciated or ignored result of use incident to the design of that product or process. If MNP release is critical to the design or a critical product or process, mitigating the release of MNP with design poses greater challenges. Again, as discussed in Chapter 3, tyres actually function in reliance of MNP shedding, as tyre material is abraded by friction to overcome momentum in changes in acceleration. However, MNP release from synthetic fibre fleece is incidental and serves no purpose. Synthetic fibre fleece product is not enabled nor improved by shedding MNP; shedding MNP is simply wasteful and poor design. Thus, as discussed in Chapter 3 and Table 6, tyres that release MNP as a critical part of their function, may need to continue to release MNP, but the tyre material can be redesigned to mitigate the risk posed by MNP release such as eliminating 6PPD to start. In Table 7, synthetic fibre fleece that releases MNP only incidentally can simply be redesigned to eliminate that flaw by, for example, replacing loose weave with a tighter weave fabric as discussed in Chapter 3.

However, regulatory authority is not generally based upon intentional or incidental MNP release, it instead distinguishes between product regulation and industrial process regulation. For products, consumer safety is the focus. For industrial processes, worker and environmental protection is the focus. Thus, where in Chapter 3, tyres are listed in Table 6, covering MNP release by design, and synthetic fibres are listed in Chapter 3, Table 7, covering incidental MNP release, both tyres and synthetic fibres are products. And as products, both tyres and synthetic fibres are discussed together in the legal authorities reviewed in Table 8. MNP released from industrial processes are discussed together in legal authorities reviewed in Table 9.

Through these regulations, both MNP release by design and MNP release incidental to design, for both products and industrial processes, must be addressed. In the regulatory, though it is important to recognize where design impacts multiple areas of regulation and perhaps results in multiple benefits, or perhaps unintended consequences without further regulation. Also, it is important to recognize where design may create challenges which increases resistance to regulation.

An example of multiple benefits of a single regulation is mitigating MNP release from synthetic fabric fleece described in Table 8. Mitigating just this source would greatly reduce loading of MNP in industrial wastewater treatment plant operations described in Table 9, as well as microplastic content of biosolids applied to land in agricultural operations per Table 9. An example of unintended consequences may be requiring laundry filters to capture synthetic fibre MNP, which would shift the fibres to a solid waste stream that may still leak into the environment without specific measures to mitigate MNP releases during solid waste management operations.

Past history regulating other pollutants has shown that approaches to mitigating MNP release from both products and industrial processes are more challenging when MNP release is by design rather than merely incidental. For a critical product, where MNP release is by design and unavoidable, then there will be challenges in adopting authority to mitigate that release from a product given the impact to the product's utility. For an avoidable product, or where MNP release is merely incidental to the use of a product, adopting regulation to mitigate that MNP release should not be burdensome. For industrial processes, where MNP release is by design, or a function of conventional under-design when considering MNP, there may be vigorous challenges to proposed authority to mitigate MNP emissions and releases due to increases in cost. But for industrial processes where MNP release is merely incidental and avoidable, then adopting mitigating authority should be a matter of course.

Authority to Regulate Products

Following Chapter 3, including Table 6 regarding the release of MNP by design of product or process, and Table 7 regarding incidental release of MNP in products or processes, note that the principles of closed-loop plastic design discussed herein are intended to eliminate the risk to human health from MNP exposure at all stages of its existence beginning from the point it becomes plastic (upon its initial production), to the point it no longer exists (upon its destruction). Reduction of unnecessary plastic production generally, along with elimination of unnecessary, problematic and avoidable plastic polymers, chemicals and products are all the initial steps in closed-loop design for plastic production.

First, plastic production should generally be reduced overall to reduce planetary loading, and specifically to eliminate unnecessary uses which encourage plastic leakage and unmitigated MNP releases. As discussed in Chapter 3, plastic products with a high risk of leakage (e.g., single use) as well as unnecessary and avoidable plastic products (e.g., microbeads) should simply be banned. Such action will greatly reduce the planetary mass loading of plastic waste and pollution, all sources of MNP. Second, the remaining defensible and prioritized plastic products should be designed to minimize the potential for MNP release, the potential for MNP exposure should MNP be released, and the risk to human health from such potential MNP exposure given its polymer type, size, shape and chemical content.

These closed-loop plastic design elements for products focus on the chemical engineering of the polymer itself, its plastic chemicals (intentionally or unintentionally added) and design of specific products. With more responsible and safer plastic and plastic product design, all plastic manufacturing and uses of plastic, including consumer and industrial, will be safer. These same principles will significantly mitigate the potential for MNP formation from plastic, release of MNP and the risk posed by MNP through the different routes of human exposure to plastic. These MNP mitigation benefits are cumulative and will ensure mitigation of MNP exposure and toxicity throughout plastic's existence, including its use, and incidental to its use by consumers as well as from industrial activities, discussed in the next section. Specific authorities addressing design elements for plastic products are presented in Table 8.

Together with the EU's restrictions on intentionally added MP through REACH, proposed additional MP pellet restrictions and potential registration requirements for problematic polymers pursuant to the EU's CSS potentially requiring registration of problematic polymers discussed above, the EU's Circular Economy Action Plan (March 11, 2020), may significantly assist in reducing overall plastic loading, and resulting MNP, in the environment. The Circular Economy Action Plan extends to products, including electronics, batteries and vehicles, packaging, plastics, textiles, construction and buildings, food, water, and nutrients. It aims to reduce waste and enhance value through supporting circularity, creating secondary raw materials markets, and addressing waste exports. The Action Plan targets microplastics, particularly unintentionally released microplastics from tyres and textiles. Its goals include risk assessment regarding microplastics in the environment, drinking water, and foods; sourcing, labelling, and using bio-based plastics to ensure genuine environmental benefits beyond mere reduction of fossil fuel; and ensuring biodegradable and compostable labelling does not mislead consumers "to dispose of it in a way that causes littering or pollution due to unsuitable environmental conditions or insufficient time for degradation" (EU, 2020).

The new Action Plan builds on EU actions in 2018 and 2019 that mandated reductions in single-use plastics, set consumption reduction targets, and promoted waste regeneration systems and efficiency optimization. These actions also called for development of industrial parks to provide common services, such as energy and waste management, where least waste-producing practices may be implemented. The Action Plan seeks to impose "extended producer responsibility" on plastics producers to "bear financial or financial and organizational responsibility for the management of the waste stage of a product's life cycle including separate collection, sorting and treatment operations...," including "a responsibility to contribute to waste prevention and to the reusability and recyclability of products" (RPa, 2022).

In comparison, the US, other than the Microbead-Free Waters Act of 2015, has not exercised its existing authority to specifically regulate plastic or microplastic (GCSE, 2022; ELI, 2024). Plastic manufacturing is regulated pursuant to environmental and worker safety authority. Meanwhile, plastic products and consumer products that may contain plastic and plastic chemicals are governed by consumer safety and food and drug authority. Plastic waste is regulated by authority delegated to individual states within the United States as solid waste.

However, in response to research demonstrating the "growing presence of microplastics in the human body" and concerns that "the ingestion of microplastics and exposure to plastics-related pollution are posing a growing risk to public health," the United States Government has taken action to minimize plastic pollution. On July 24, 2024, the Biden Harris Administration released "Mobilizing Federal Action on Plastic Pollution, Progress, Principles and Priorities" (U.S. White House CEQ, 2024).

With this report, the Administration reviews all actions, from federal procurement restricting single use and other plastics in federal operations, to specific microplastic efforts, supported by existing legislative authority. As discussed above, with these priorities, the federal government expressed its intent to assess and reduce pollution from plastic production, promote innovation of materials and product design, decrease plastic waste generation by reducing its federal procurement of single-use and other plastic products, improve environmentally sound waste management, and inform and conduct plastic pollution capture and removal (U.S. White House CEQ 2024). While "microplastic," which is undefined in the referenced document, is a specific focus of the U.S. EPA and the Centers for Disease Control and Prevention (CDC) studies on human health, the expressed intent extends to taking stock of all federal agency engagement to assess and mitigate risks to human health and the environment from microplastic. The EPA is developing sampling and analytical methods to measure microplastic, however it may be defined regarding MNP for use in implementing its existing environmental authority.

The FDA and EPA's agency efforts to encourage companies to voluntarily end sales of PFAS for some food-contact applications may point to a similar strategy for the similar contaminant that is MNP. Of course, individual states have adopted bans of single use products and microplastics, where not pre-empted by state law (ITRC Microplastic Project). Additionally, apart from regulation, litigation is developing raising claims of inherently dangerous consumer products, as well as common law tort claims to remediate plastic and microplastic in the environment (PlasticLitigationTracker.org).

In Tuvalu, as Tuvalu does not manufacture any goods, the only authority it has for product and engineering design is to refuse imports, stressing Tuvalu's reliance on the efforts of other states and the effectiveness in this regard of the future global plastics instrument.

Consistent with the discussion above, including Chapters 2 and 3, the EU would be in a better position to adopt specific authority mitigating human exposure to microplastic relying on its existing microplastic authority and the Precautionary Principle as applied to the burden of the specific action in the context of the current scientific studies including human tissue MNP accumulation. Other than the Microbead-Free Waters Act, the US has failed to exercise its authority delegated to OSHA protecting worker safety, to EPA governing industrial activities and environmental quality, and CSPC governing consumer safety to mitigate MNP releases and exposure. However, the Biden Harris Administration is recognizing hazards from microplastic and may support action to address, while the states and litigators continue to lead plastic pollution mitigation efforts.

Where the EU and the US decide to address MNP, they could potentially impose authority like the following, where Basel limits recycling through conditional trade restrictions and mandates for environmentally sound management of wastes while limiting the re-introduction of chemicals of concern.

Table 8: *Comparisons of Potential Authority: MNP Release by Design of Products*

<table>
<tr><th></th><th>EU</th><th>US</th><th>Tuvalu</th></tr>
<tr><td>Restricting production of products:

Primary Plastic Production, polymer and chemicals including caps and bans, chemical simplification, transparency and disclosure</td><td>REACH restricts chemicals of concern. Other than intentionally added microplastic restrictions (C(2023) 6419, polymers are not currently subject to registration (but see CSS, 2020), but the monomers used to create them may need to be registered (EC Regulation 1907/2006)

Article 114 TFEU

Microplastic is defined as organic, insoluble and resists degradation</td><td>TSCA (EPA) regulates industrial chemical substances. Polymers, including plastics, are exempt; chemical additives are excluded because they are simply mixed with plastic and do not react. TSCA § 2(b), 15 U.S.C. § 2601(b).</td><td rowspan="3">Customs Revenue and Border Protection Act 2014, can prohibit import of banned plastic goods.

Customs Revenue and Border Protection Act 2014, can prohibit import of banned plastic goods.</td></tr>
<tr><td>Primary MP: Microbeads

Agricultural Time Release Polymers</td><td>REACH regulates intentionally-added MPNs from 10 different product categories: cosmetics, detergents, paints and coatings, agricultural products, medical products, cleaning products, polymer-based products like inks and adhesives, oil and gas extraction applications, construction materials, and fertilizers (Commission regulation 2023/2055)</td><td>Microbead Free Waters Act of 2015, 21 U.S.C. 301.</td></tr>
<tr><td>MNP contamination: Food and bottled beverages</td><td>TFEU articles 192, 193*

The EU Ecodesign for Sustainable Products Regulation (2024/1781) addresses 16 key ‘product aspects’ relevant to improving environmental sustainability, and for plastics, the most applicable aspects include recyclability, durability, material efficiency, and environmental impact.

EU sets thresholds for tyre and brake dust from 2025 (Euro 7 standards). EU Food contact material (1935/2004) and manufacturing practices (Reg. EC No. 2023-2006)

EU Fertilizing Products Regulation (2019/1009) bans polymer coated fertilizers unless they comply with the EU’s biodegradability criteria.

EU Directive on Water Quality (16/12/2006)</td><td>FDA delegated statutes*</td></tr>
</table>

<table>
<tr><th></th><th>EU</th><th>US</th><th>Tuvalu</th></tr>
<tr><td>High-leakage products: Single use and other problematic uses, products and containers</td><td></td><td>Consumer Safety Product Act*</td><td>Waste Management Act, Reg. 4 prohibits single use plastics.</td></tr>
<tr><td>Synthetic fibres: including fleece, home furnishings, laundry discharge, artificial turf</td><td></td><td>Consumer Product Safety Act*

Clean Water Act* Clean Air Act*</td><td></td></tr>
<tr><td>Products deployed directly into the environment: AGRO polymers (Agricultural Products, time release polymer)</td><td></td><td>Clean Water Act*</td><td rowspan="3">Environmental Protection Act of 2008

(Cap. 30.25)

Environmental Protection Act of 2008

(Cap. 30.25)</td></tr>
<tr><td>High abrasion products: Tyres</td><td></td><td>Clean Air Act, Clean Water Act*</td></tr>
<tr><td>MNP Contamination: Protection of public water supply ground and surface water sources</td><td></td><td>Safe Drinking Water Act,* California and other state approaches to MP drinking water source monitoring</td></tr>
</table>

**Not currently relied upon but could potentially support.*

MNP Release Incidental to Product or Process Including Industrial Regulation

Building on the cumulative benefits of closed-loop design principles for design of plastic products and plastic processes, the principles of closed-loop design further extend to secondary microplastic resulting incidentally from products or processes, including industrial processes, as listed in Table 8. Closed-loop design for plastic processes further mitigates risk to human health from incidental MNP exposure at all stages of its existence, including as plastic is used in consumer products, medical uses, and industrial processes including manufacturing, infrastructure, agriculture and through to waste management, recycling and complete plastic destruction. Closed-loop plastic product and process design has achieved lower potential MNP release rates, and lower risk from MNP exposure through safer polymer and chemical use, but while the risk from incidental MNP release will be lower, it will not be completely mitigated. Closed-loop design to mitigate incidental release of MNP will protect everyone from consumers in the home and outdoors, to workers in occupational MNP exposure, and impacted communities. These closed-loop plastic design elements to mitigate incidental MNP release, similar to current "best available technology" requirements imposed through environmental regulations, focus on process design improvements to mitigate MNP releases, human exposure and impacts to human health and the environment.

First, significant sources of MNP include synthetic fibres. As discussed in Chapter 3, synthetic fibres are not designed to intentionally release MNP. There is no benefit from such release, but there is no restriction either. Thus, given the studies demonstrating accumulation of nanoplastic fibres in the human body, authority to mitigate human exposure to this MNP once shed should be adopted.

All industry, including plastic manufacturing facilities, is governed by existing environmental permitting requirements limiting hazardous air pollutant emissions, toxic chemical and other pollutant wastewater discharges, and solid and hazardous waste management requirements. However, MNP releases are not generally regulated beyond fine particulate emission regulations (particulate matter less than 2.5 um), which generally do not account for the specific risk from plastic particles. Thus, all industry, including plastic manufacturing, must mitigate, and eliminate where possible, all MNP releases pursuant to newly defined environmental permitting considering MNP and its unique hazardous characteristics resulting from its size, shape and chemical burden.

To support elimination of MNP releases, industrial reliance on plastic (including agriculture) should be minimized where feasible, avoiding unnecessary plastic uses while mitigating MNP releases where plastic is considered necessary. Industrial plastic uses that should be reviewed for replacement with non-plastic alternatives, or MNP mitigation if there are no non-plastic alternatives, include: packaging such as shrink wrap, sheeting, crates, trays, and pallets; equipment, such as trays, conveyor belts, and piping; construction materials such as roofing, siding, coatings and fabrics; and heavy vehicular traffic with tyre shred emissions.

Second, where MNP releases are minimized by industry, occupational exposure should be mitigated. However, where worker exposure to MNP cannot be eliminated, worker protection standards should be implemented to ensure worker safety. Such standards should include occupational MNP threshold limit values, monitoring requirements and personal protective gear, such as tightly woven, washable, protective clothing, as opposed to plastic Tyvek, and face masks with air filters.

Third, the plastic waste management industry, including waste management infrastructure such as solid waste disposal, wastewater treatment facilities, plastic waste recycling and plastic waste to fuel energy recovery, must be designed to mitigate MNP releases. As discussed in Chapters 2 and 3, MNP is generated at high rates in waste management operations. Plastic collection, loading, unloading, and processing generates significant amounts of MNP that is not currently regulated as MNP, particularly if released as ground-level fugitive emissions. Wastewater treatment facilities are not designed to eliminate MNP and instead concentrate MNP in wastewater treatment plant sludge, which is later land applied in agricultural operations. Plastic incineration is not undertaken in facilities designed to completely destroy the plastic matrix. Such design for plastic destruction would ensure liquification first then atomization for complete oxidation(or an equivalent approach, with demonstration testing to ensure there is no MNP in air, water or solid waste streams. MNP from all industry sources must be mitigated to protect workers in occupational settings, and the public from industrial pollution.

Fourth, known industry high-risk MNP sources, such as use of plastic as abrasive material, or plastic uses constituting disposal, such as land application of wastewater treatment plant sludge, plastic sheeting, and time release polymer encased fertilizers should be eliminated where possible. Where elimination is not possible, monitoring of MNP in the environment where use continues should be mandated, along with responsibilities for remediation.

With regard to the EU/US/Tuvalu comparison, both the EU and the US implement regulations governing industrial activities to protect human health and the environment. While not currently implemented to mitigate MNP releases, where particles are regulated as "dust" or "fine particulate," this same authority can be more specifically interpreted to include the risk presented by MNP and implemented to mitigate release and exposure to MNP from industrial activities of all kinds, including plastic manufacturing and waste management especially incineration and recycling. Given high intensity use of plastic in all facets of and nearly all kinds of industrial activity, this regulation should be implemented to mitigate MNP releases and exposure from all industrial activities throughout the existence of plastic before it is destroyed, including authority to ensure plastic is carefully tracked and completely destroyed with destruction technologies specifically designed to completely destroy the plastic matrix. For example, as discussed in Chapter 3, disposal through incineration must be redesigned to ensure complete plastic destruction with: for amenable thermoplastic, an initial liquification stage, with heat and reduced oxygen, to reduce the plastic matrix into hydrocarbon liquid similar to kerosene; then atomization of the liquid into the combustion chamber with sufficient excess oxygen, time, temperature and turbulence to completely oxidize the liquid; followed by a secondary combustion chamber and multistage air pollution control equipment; while mitigating MNP releases during plastic waste feed management; continuous monitoring of operations and emissions; testing of all air emissions, wastewater discharge and combustion ash solid waste for MNP. By expanding the scope of fine particulate regulation to include MNP, governments could protect workers as well as human health and the environment from all sources of MNP, especially from highly polluting and indefensible practices such as land application of biosolids containing MNP.

Table 9: *Comparisons of Potential Authority: Industrial Process Regulation to Mitigate Incidental Release of MNP*

	EU	US	Tuvalu
Minimize Industry Reliance on Plastic: Industrial reliance on plastic components and goods to minimize MNP releases	Circular Economy Action Plan (March 11, 2020).	Litigation risk.	Customs Revenue and Border Protection Act 2014, can prohibit import of banned plastic goods.
Worker Safety: Mitigate worker exposure to MNP	Article 153 TFEU Single European Act European Pillar of Social Rights (2017) Directive 89/654/EEC	OSHA,* except for specific polymer manufacturing	
Minimize Industrial Releases of MNP: Industrial air emissions, water discharges and solid waste sources of microplastic including Plastic Production	EU Action Plan: Towards Zero Pollution for Air, Water and Soil (SWD(2021) (to reduce plastic litter at sea by 50%, and microplastic into the environment by 30% by 2030) (May 12, 2021). EU Clean Air Policy Water Framework Directive (2000/60/EC) Groundwater Directive (2006/118/EC) Drinking Water Directive (2020/2184) Environmental Quality Standards Directive (2008/105/EC) Urban Waste Water Treatment Directive (91/271/EEC)	Resource Conservation Recovery Act, Basel Convention requirements adopted as OECD member for plastic waste exports (relied upon currently); Environmental Statutes including Clean Air Act, Clean Water Act, Solid Waste Disposal Act, Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)*	Environment Protection (Litter and Waste Control), Regulations 2013, Reg. 7, prohibits burning of plastic. Waste Operations and Services Act 2009 Marine Pollution Act 1992 and 2017 Amendments Environmental Protection Act of 2008 (Cap. 30.25)
Waste Management: Waste plastic, recycling and complete destruction	European Green Deal Waste Framework Directive (2008/98/EC) imposing waste hierarchy Waste Incineration Directive (2000/76/EC)* Packaging Directive (94/62/EC)		Tuvalu Integrated Waste Policy and Action Plan 2017-2026 Waste Operations and Services Act 2009 Basel Convention Disaster Waste Management Action Plan (if adopted) (action 33, p. 61)
High Risk Products and Use Constituting Disposal: Agricultural use of plastic sheeting, piping and biosolid applications	Council Directive 86/278/EEC re sewage sludge application in agriculture*	Food Safety; For Biosolids, Clean Water Act,* and state programs focusing on MP	

**Not currently relied upon to regulate microplastic or nanoplastic as a specific pollutant other than particulate emissions, turbidity, total suspended solids and solid waste; but could potentially support.*

4.5.3 Closed-Loop Design: Plastic Pollution Remediation and Complete Destruction Including Financing Strategies

Because MNP continues to present risks from exposure to human health throughout its existence, authority currently relied upon to remediate legacy plastic, such as un or undermanaged plastic abandoned or remaining in the environment as pollutants or contaminants, and sources of hazardous substances adopted to protect human health and the environment. These existing authorities currently extend to listed hazardous substances not contemplated as plastic chemicals bound in a plastic matrix, but they could be interpreted to recognize the risks of MNP as pollutants, contaminants and contributors of already regulated toxic and hazardous substances. These same authorities could then be used to ensure the Polluter Pays, whether from specific assignment of liability to producers found to have contributed to the harm, or an industry wide plastic production tax.

To support the goal of removing plastic from the environment, this authority could be leveraged into industry supported caps and bans on problematic plastic products, and polymers and chemicals of concern as well as Financial Incentives, or Manufacturing Taxes. Compare, for example, the proposed Polymer Premium, Minderoo Foundation (2024), the reinstated U.S. Superfund Excise Tax, 5 U.S.C. 4661 and 4671. The U.S. Superfund tax funds remediation of hazardous substances but, while it applies to some plastic chemical additives listed in the covered 42 chemicals and 151 hazardous substances, Superfund has not been relied upon to remediate plastic waste. However, funding mechanisms such as this could support Extended Producer Responsibility which may include remediation obligations, as in Table 10.

Table 10: *Comparisons of Potential Authority: Remediation*

	EU	US	Tuvalu
Polluter pays	EU policy of Polluter Pays implemented through: Taxes, charges and fees; Tradable permits; Deposit refund schemes; Offsetting schemes. Payments for ecosystem services	Common law CERCLA,* SWDA,* CWA*	Environment Protection (Litter and Waste Control), Regulations 2013, Reg. 7, prohibits burning of plastic. Waste Operations and Services Act 2009 Marine Pollution Act 1992 and 2017 Amendments Environmental Protection Act of 2008 (Cap. 30.25)
Remediating Legacy Plastic at Source	EU policy to Rectify Pollution at Source.	Common law, CERCLA,* SWDA,* CWA*	Tuvalu Integrated Waste Policy and Action Plan 2017-2026 Waste Operations and Services Act 2009 Basel Convention Disaster Waste Management Action Plan (if adopted) (action 33, p. 61)

**Not currently relied upon but could potentially support.*

4.6 Conclusion: Human MNP Exposure is Preventable

The global regulatory history of other ubiquitous and persistent pollutants makes it clear that we can successfully mitigate human exposure to MNP. For example, asbestos was used prolifically in all manner of defence, construction, infrastructure and consumer products. When the harm to human health was associated with cancer from exposure to friable asbestos (Selikoff, 1964), litigation drove regulation which quickly resulted in protecting workers, banning asbestos consumer products and other unsafe asbestos uses. These restrictions were intended to mitigate exposure to "friable" asbestos and ensure asbestos fibres were not released during use by sealing the material, abating asbestos exposure in construction, and remediating asbestos in the environment. With its inherent chemical harm, legal authority regulating PFAS has been developing along a similar path. Upon recognition of the harm from PFAS exposure, demonstrated through medical monitoring compelled through litigation, and cumulative evidence demonstrating the ubiquitous presence of PFAS in the environment from years of regulatory failure, new regulation has evolved, including some EU member state proposals to ECHA to restrict PFAS as a class in the EU, resulting in cessation of production of certain types of PFAS, and now integration of PFAS into the U.S. EPA's full suite of environmental authority with the U.S. EPA PFAS Strategic Roadmap.

Like plastic, asbestos was once considered a miracle material and used prolifically, for an astonishing range of uses, including cigarette filters to the "snow" in the movie "Wizard of Oz." But there is no magic, nor any free lunch. The same properties that offered such utility also rendered it dangerous (Gee & Greenberg, 2008). PFAS followed a similar path, from miracle to malevolent. MNP poses risks similar to both asbestos and PFAS, where MNP has both friable particles like asbestos, and is a source of chemicals like PFAS (including PFAS itself). Like asbestos and PFAS, exposure to MNP is a preventable scenario. But due to its variability and other characteristics challenging conventional epidemiological approaches, regulation will likely rely on the use of the Precautionary Principle or be compelled through litigation.

An approach to mitigating human MNP exposure, for the reasons discussed in Chapter 2, and following design measures described in Chapter 3, is illustrated in Table 11. With this approach, we consider plastic to MNP mass flux (the rate at which plastic products shed or fragment into MNP), potential risk of exposure to MNP, potential risk posed by the MNP itself in terms of size, shape and chemical/pathogen burden, remediability/avoidability, product or process design mandates and legacy remediation projects. Products and activities that result in maximum MNP mass flux potential, acute human exposure potential, and high risk from exposure that is easily mitigated should be considered problematic and avoidable. A similar approach can be useful in prioritizing products, polymers and chemicals, for listing as problematic and avoidable, as well as prioritizing to mitigate MNP mass flux as releases and emissions of MNP.

Table 10: *Mitigating Human MNP Exposure: Examples for Comparison*

Product or Activity	MNP mass flux potential	Human exposure potential	Risk from Exposure	Practicability of Mitigation
Single use plastic items	Maximum for consumer products, Medium for single uses in health care given relatively rare exposure and likely regulation and destruction/disposal as biohazard/medical waste.	Acute during use Chronic in environment – delayed chronic toxicity	Depending on chemical additives and release rate of MNP from design and stress on solid plastic matrix, high to low	Mostly avoidable for consumer use, while some fraction of health care industry plastic may also be avoidable, or at least better designed for more complete medical waste incineration
Biosolid land and time release polymer coated herbicides application	Maximum through ingestion of contaminated of crops and meat	Acute through ingestion of contaminated crops and meat	High where MNP incorporated into crops and livestock will carry MNP along with pathogens and environmental chemicals	Avoidable, through regulation of MNP in biosolids and bans prohibiting use of time release polymer coated herbicides.

5. The international legal landscape of relevance to micro- and nanoplastics

Key points:

- **Recognizing the precautionary principle** provides grounds for more robust measures, including for establishing monitoring programs that establish regional baseline concentrations in human tissues and track accumulation over time. By combining this data with regional plastic usage and health outcomes, it is possible to assess relationships between exposure levels and disease rates. This information is crucial for identifying key sources of MNP in each region, allowing for the development of targeted mitigation strategies to reduce or eliminate exposure pathways. Moreover, recognizing the polluter pays principle can help to internalize the external costs of MNP, such as through EPR schemes, helping to cover costs of mitigation efforts.

- **Risk assessment:** Review through a possible subsidiary scientific and technical body can help to inform the Conference of Parties of need to ban and restrict MNP and associated chemicals of concern. Following the example set by other MEAs, the technical body of the plastics instrument is likely to rely on risk assessments prepared by national authorities and other sources when developing a possible risk profile and risk management evaluation, rather than conducting a full risk profile itself. The review should acknowledge that conventional dose-response epidemiological approaches are inadequate for addressing this type of pollution, as MNP are both extremely variable regarding particle characteristics and chemical burden, and also amplify the effects of chemicals of concern.

- **Product-specific regulation.** Restriction of primary plastic production, including polymers and chemicals, could be achieved by adopting a global target to reduce plastic production. Moreover, the adoption of global criteria for listing chemicals of concern for bans and restrictions is necessary to reduce the effect of MNP. To this end, adopting a chemical simplification, supported by the grouping of chemicals approach, will be crucial for the plastics instrument to effectively address regulatory gaps and prevent regrettable substitutions

- **Eliminate products of high risk of MNP release into environment:** The plastic instrument must include binding provisions mandating mitigation of releases and emissions of sources of MNP, through identification of both primary product groups with primary microplastics intended for phase out and primary product group emitting and releasing secondary microplastics, based on determined thresholds.

- **Recovery in closed loop:** The plastics instrument must go beyond the elimination approach employed by existing MEAs and lay strong foundations for the design of plastic products that minimize harm to humans and the environment. The following design principles are critical for reducing MNP and their impacts: non-toxicity, safe material composition, polymer integrity, longevity, and transparency.

- **Transparency and disclosure:** Transparency and disclosure are essential for consumer protection and promoting safer alternatives, focusing on MNP and chemical content, and potential secondary MNP releases. Transparency and disclosure are also important tools in enabling comprehensive risk assessment, as well as the tracking of plastic chemicals, including preparation of migration and leaching profiles. Trade controls could further enhance transparency by requiring a PIC procedure for hazardous plastic products, including those with MNP content or potential to release and emit MNP. The plastics instrument could mandate PRTRs for plastic pollution, requiring facilities to monitor, report, and increase access to data regarding MNP emissions and releases.

- **Minimizing industry reliance on plastic:** Non-plastic substitutes can play an important role for substituting certain uses of plastics. Assessing effects of substitutes will be important in order to avoid regrettable substitutions and to comprehensively consider other socio-economic considerations.

- **Waste Management:** Waste plastic, recycling and complete destruction: Recognition of the releases and emissions of MNP from industrial waste management processes must be addressed in the plastics instrument (fugitive and other). To minimize MNP exposure and promote a closed-loop approach for plastics, complete destruction must be considered as the preferred endpoint for plastics that do not meet, or no longer meet, the requirements of a closed-loop system. To prevent non-plastic related impacts to the environment and human health, all supporting closed-loop approaches must be given priority to minimize the need for complete destruction

- **Enhancing worker safety:** The plastics instrument should minimize microplastic exposure during both production and recycling, requiring protective equipment, ventilation systems, emission controls, and worker training. Companies must disclose potential MNP emissions to ensure workers are informed of the risks and safety measures. Special attention should be given to protecting informal sector workers.

- **Minimizing Industrial Releases of MNP -** Industrial air emissions, water discharges and solid waste sources of microplastic including Plastic Production: Emissions and releases should not be limited to sources listed in an Annex of the plastics instrument. Provisions must address all sources of emissions and releases from all types of industries, including sources not yet recognized.

- **High Risk Products and Use Constituting Disposal:** A sectoral approach for products that are applied directly into the environment and in high-degradation processes, can be supported through the development of annexes specific to the application, where appropriate, or guidelines to minimize their release of MNP through improved design and alternate practices.

- **Closed Loop Design:** Plastic Pollution Remediation Including Complete Destruction: Environmental and landfill remediation of existing plastic pollution will need to be featured in the plastics instrument to help prevent MNP releases.

- **Plastic pollution mitigation:** Financial mechanisms and institutions may also be alerted to the significance of plastics in the environment as an ongoing source of MNP and invest in necessary technology and activities. The instrument could also include remediation of plastic products and MNP in technology transfer and capacity building to stimulate research and development in this regard. Guidelines can be developed to ensure such activities are environmentally sound.

5.1 Current text of the plastics instrument

A Zero draft of the international legally binding instrument on plastic pollution, including in the marine environment (UNEP/PP/INC.3/4) (hereafter referred to as 'zero draft') was provided by the INC Secretariat in preparation for INC-3. This draft has been superseded by the Non-Paper 3 of the Chair of the Committee (hereafter referred to as "Chair's non-paper"), which has weakened some useful principles included in the zero draft, which addressed microplastics specifically in Part II.3 on problematic and avoidable plastic products, although for intentionally added microplastics only. Part IV.4.b also importantly included microplastics in the review of the instrument, while the proposed Annex B provided a placeholder for the listing of problematic and avoidable plastic products, including microplastics.

Part II.3. on problematic and avoidable plastic products, in particular paragraph b on intentionally added microplastics, as per option 1 of the zero draft, prohibited the "production, use in manufacturing, sale, distribution, import or export of plastics and products containing intentionally added microplastics, except where an exception is specified in part IV of annex B." Option 2 of the zero draft provided a national approach in which each Party "shall identify plastics and products containing intentionally added microplastics in accordance with the criteria contained in part V of annex B, and take the necessary measures to manage, restrict and, where appropriate, not allow, their production, use in manufacturing, sale, distribution, import or export." An online registry was also to be established for the listing of national measures taken to promote transparency and potentially incentivise similar action by other Parties.

Part II.5 on product design, composition and performance required each Party to "take measures, including those referred to in paragraphs 2 and 3, to enhance the design of plastic products, including packaging, and improve the composition of plastics and plastic products, with a view to" "minimizing releases and emissions from plastics and plastic products, including microplastics."

Part II.8 on emissions and releases required each Party to "prevent and eliminate the emissions and releases of plastic polymers, plastics, including microplastics, and plastic products across their life cycle, to the environment from the sources identified in annex E by the dates identified therein." This recognizes microplastics as a potentially hazardous substance, while specifically including microplastic releases of microplastics, to air, soil and water. Guidelines were to be developed, as well as scientific and technical innovation to be promoted, to prevent such releases.

Part II.10 on trade prohibited the export by Parties of a microplastic addressed in Part II.3, and if such export was to occur, an export permit was to be obtained together with prior informed consent from the importing country prior to trade. Import was also prohibited unless an exemption was provided for in the instrument. For any trade of microplastics addressed in Part II.3, the importing state was to be provided by the exporting state complete harmonized information, based on disclosure requirements to be outlined in Annex A. Where HS codes were available, these were to be mandated for inclusion in shipping documents.

The "Chair's non-paper", released late October 2024 in preparation for INC-5, suggested options for streamlining the plastics instrument with the aim of meeting the deadline for concluding negotiations at INC-5. Microplastics are specifically included in the proposed Article 2 on definitions, and proposed Article 7 on emissions and releases, listing releases of microplastics during production of plastics, but also including microplastic and nanoplastic releases during use of products.

A new Article 19 of the Chair's non-paper provides an improvement in the recognition of the health impacts of human exposure to microplastics, including occupational exposure and the need for ongoing monitoring of health risks related to exposure. More specifically, the article encourages

Parties to:

a) Promote the development and implementation of strategies and programmes to identify and protect populations at risk, particularly vulnerable populations, and which may include adopting science-based health guidelines relating to the exposure to plastic pollution, in particular microplastics and related issues, setting targets for their exposure reduction, where appropriate, and public education, with the participation of public health and other involved sectors;

b) Promote the development and implementation of science-based educational and preventive programmes on occupational exposure to plastic pollution, in particular microplastics and related issues;

c) Promote appropriate health-care services for prevention, treatment and care for populations affected by the exposure to plastic pollution, in particular microplastics and related issues; and

d) Establish and strengthen, as appropriate, the institutional and health professional capacities for the prevention, diagnosis, treatment and monitoring of health risks related to the exposure to plastic pollution, in particular microplastics and related issues.

However, the specific regulation of microplastics has been weakened, including for consumer protection. Also, several important provisions for MNPs have been omitted, or potentially merged within other provisions, such as the provision II.13 of the zero-daft on transparency, tracking, monitoring and labelling. Furthermore, while the Chair's non-paper reaffirms the principles of the Rio Declaration on Environment and Development, it does not specifically reference the precautionary principle of other relevant principles for MNP regulation.

5.2 Principles

5.2.1 Precautionary principle

<u>Examples from existing MEAs</u>

The following MEAs refer explicitly to the precautionary principle:

- **The Stockholm Convention** explicitly refers to the precautionary approach, as outlined in Principle 15 of the Rio Declaration on Environment and Development (Art. 1). This principle states that: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The objective of the Stockholm Convention, as stated in Art. 1, is to protect human health and the environment from POPs, and the precautionary approach is central to the convention's operationalization.
- **The London Protocol** explicitly incorporates the precautionary approach in its preamble and Article 3, which states that the precautionary approach should apply.
- The **BBNJ Agreement** requires Parties to be guided by the precautionary principle and the precautionary approach, as appropriate (Art. 7.e).

While the Stockholm Convention and the London Protocol are the only MEAs among those analysed that explicitly refer to the precautionary principle, this principle underpins many obligations in other chemicals and waste-related treaties. These obligations focus on minimizing harm from hazardous substances and preventing environmental and health risks, which is typical for chemicals and waste-related MEAs.

In addition, the UN Law of the Sea Convention mandates States to protect and preserve the marine environment (Art. 192), embodying the precautionary principle.

Considerations for the plastics instrument

The precautionary principle is not explicitly mentioned in the **Chair's non-paper**, although the preamble reaffirms the Rio Declaration on Environment and Development.

UNEA Resolution 5/14 decided the development of the plastics instrument must take into account the principles of the Rio Declaration (para. 3).

The precautionary approach is included in the list of principles of the **draft text** of the plastics instrument UNEP/PP/INC.4/3:

- Provision I.4(d): Precautionary approach

MNP represent a significant emerging threat, with uncertain but potentially severe consequences for human health and the environment. Current scientific knowledge does not yet fully capture the extent of MNP long-term effects, making the precautionary principle a crucial tool in establishing an enabling environment for the development of measures to prevent and manage MNP effectively.

The precautionary principle can help future-proof the plastics instrument against emerging scientific evidence on MNP, allowing it to evolve as knowledge about the issue grows. By embedding this principle, the instrument paves the way for ongoing incorporation of best available scientific information, including early indication of risk. This can be facilitated through a possible dedicated subsidiary scientific and technical body, which could provide continuous input, guidance and horizon scanning. Furthermore, the precautionary principle can also lead to the adoption of cost-effective preventative measures, allowing parties to act proactively rather than reactively.

To maximize this opportunity, the precautionary principle should be included in the text of the plastics instrument, preferably in a section that outlines the guiding principles (Part I.4 in the draft instrument, but now excluded from the Chair's non-paper) with an obligation to be applied broadly. This will ensure all operative measures fall under this principle. The preamble of an MEA is typically a short form of the instrument and is not an operative part of the instrument. It communicates the intention and purpose of the instrument and can be used for interpretation of operative measures. Should the instrument not include a section specific to guiding principles, the precautionary principle may be included as part of the objective should this be described in general terms.

5.2.2 *Polluter pays principle*

Examples from existing MEAs

The Polluter Pays Principle is not directly featured in MEAs, except the BBNJ Agreement[2] adopted more recently. The principle can, however, be given effect through fines, taxes, deposits schemes and extended producer responsibility schemes developed at the national level, aiming to implement obligations of MEAs.

- The **BBNJ Agreement** requires Parties to be guided by the polluter pays principle (Art. 7.a).
- The **Basel Convention** has developed guidelines that encourage the use of EPR as a policy tool for the environmentally sound management of hazardous wastes, including e-waste.

Considerations for the plastics instrument

The polluter pays principle is not explicitly mentioned the **Chair's non-paper**, although the preamble reaffirms the Rio Declaration on Environment and Development. Additionally, the following articles are of relevance:

- Art. 8: (waste management) suggests text for encouraging to adopt and implement extended producer responsibility schemes (para 2d).
- Art. 11: (finance) proposes including provisions for catalysing and align public and private financial flows for meeting the objective and provisions of the Convention.

The polluter pays principle is included in the following provisions of the **revised draft text** of the plastics instrument UNEP/PP/INC.4/3:

- Provision I.4: Principles and approaches (para c).
- Provision III.1: Financing mechanism, suggests private sector financing can assist in the broader implementation of the instrument, including application of the Polluter Pays Principle.
- Provision II.7: Extended producer responsibility

This approach is promoted to stimulate design improvements and require producers to take physical and/or financial responsibility for products at the end of intended use.

2 Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction.

The Polluter Pays Principle was included in Part I.4 of the draft instrument but is now excluded from the Chair's non-paper. The principle should be operationalized in the plastic instrument to help internalize the external costs of plastic products, such as through EPR schemes. In addition to financing waste management, EPR incentivises producers to reduce waste generation and to improve product design in order to facilitate recycling and resource recovery (Slunge and Alpizar, 2019). The plastics instrument can support EPR implementation by providing clear guidance on the following:

- Identification of products suitable for EPR and clear definition of the product concerned.
- Definition of the objectives, including setting measurable and achievable targets.
- Definition of the financial and operational responsibilities for of all stakeholders
- Establishment of a robust and transparent reporting, monitoring and enforcement mechanism

5.3 Burden of proof

Examples from existing MEAs

Risk assessment is commonly used to provide evidence of harm to human health and/or the environment. It is also used to assess implications of adopting new control measures, commonly with a focus on socio-economic factors.

Risk assessment is featured in the following chemicals MEAs, underpinned by efforts of specialized subsidiary scientific bodies:

- **The Stockholm Convention** considers risk assessments when evaluating whether a chemical should be listed for elimination (Annex A), restriction (Annex B) for measures to reduce unintentional releases (Annex C). The Persistent Organic Pollutants Review Committee (POPRC) conducts risk profiles and risk management evaluations before recommending listing (Articles 8 and 9). However, this process is not a full risk assessment in the conventional sense. Instead, it relies on existing scientific studies, monitoring data, and national assessments, to make informed decisions. The POPRC integrates this available data to assess the potential adverse effects of chemicals, even in cases where comprehensive risk assessments may not be conclusive. No guidance is provided on methods for conducting risk assessments at the national level, only the type of information to be provided by Parties submitting a nomination for listing (Annexes D, E and F).

- **The Rotterdam Convention** includes information requirements (Annex I) and global criteria (Annex II), including evidence of a risk evaluation conducted according to national or regional regulatory frameworks, for listing chemicals under the Prior Informed Consent (PIC) procedure in Annex III. The Chemicals Review Committee (CRC) is responsible for verifying that regulatory actions have been taken and these actions are based on a risk evaluation, which assesses the chemical's potential adverse effects on health or the environment. The CRC uses this information to recommend whether the chemical should be subject to the PIC procedure (Art. 7). Similar to the Stockholm Convention, no prescriptive guidance is provided for conducting risk assessments.
- The **BBNJ Agreement** requires Parties to conduct a screening of new activities conducted in the high seas where the effects of the activity are unknown or poorly understood to assess whether it has reasonable grounds for believing that the planned activity may cause substantial pollution. A threshold of harm is outlined in which Parties must consider, amongst others, the type of and technology used, the duration of the activity, the characteristics and ecosystem of the location, the potential impacts of the activity, including the potential cumulative impacts, and the extent to which the effects of the activity are unknown or poorly understood (Art. 30). Should the threshold be met, and environmental impact assessment must be conducted by the Party authorising the activity (Art. 30).

Note that under the Stockholm Convention and the Rotterdam Convention, it is the responsibility of the nominating Party to provide the risk assessment relating to human health and/or the environment.

Moreover, the following MEAs address risk assessment from a waste management perspective:

- **The London Protocol** mandates risk assessments for the disposal of wastes at sea, as per Annex II. A comprehensive risk assessment must confirm that the material in question will not adversely affect the marine environment before it is permitted for dumping.
- **The Basel Convention** indirectly involves risk assessment through consideration of Annex III, which lists hazardous characteristics used at the national level to classify wastes as hazardous, although it does not explicitly refer to risk assessment. Included in Annex III are toxic "substances or wastes which, if they are inhaled or ingested or if they penetrate the skin, may involve delayed or chronic effects," (H11), exotoxic "substances or wastes which if released present or may present immediate or delayed adverse impacts to the environment by means of bioaccumulation and/or toxic effects upon biotic systems," (H12), and those wastes "Capable, by any means, after disposal, of yielding another material, e.g., leachate, which possesses any of the

> characteristics listed above” (H13).[3] Exporting Parties must provide information to the importing country prior to trade on the potential for the wastes to demonstrate these characteristics, allowing the importing Party to make an informed decision to allow import.

While risk assessment functions as a basis for global chemicals control, a significant shortcoming of existing chemicals MEAs is that they primarily address conventional chemical exposure pathways. This is because they provide no prescriptive guidance on risk assessment, leaving a gap in addressing the complex interactions between plastics and chemicals. They overlook how harmful plastic chemicals become more acutely toxic when delivered directly into human tissue through incorporation to micro and nanoplastic particles. These particles originate from plastic pollution and plastic products in use that shed these particles.

In the example of the Basel Convention, it is limited in scope to wastes and does not control wastes shipped under the pretext of environmentally sound recycling. Given our current state of knowledge regarding the failures of recycling, the Basel Convention fails to address the hazards of micro- and nanoplastic particles released or emitted from post use plastics, or any plastic products upstream, and thus does not reach micro- and nanoplastic releases and emissions that could harm human health and the environment through inhalation, ingestion and dermal absorption of micro and nanoplastic particles generated from management of the plastic waste addressed therein, much less plastic manufacturing, plastic use, and plastic consumer products.

Similar to risk assessment, the provision of adequate data for safety of workers should also be a requirement for businesses to provide proactively. The ILO Chemicals Convention (No. 170) provides an example at the international level. The Convention provides for the establishment of a chemicals classification system based on specific criteria for determining the type and degree of health and physical hazards, including how such information can be used to assess if a chemical is hazardous (Art. 6.1). Suppliers of chemicals (manufacturers, importers and distributors) are required to assess the hazard potential of their chemicals, according to the national classification system or conduct their own assessments (Art. 9.1.a). All chemicals must be marked for identification, and hazardous chemicals must be labelled to provide workers with essential information on classification, the hazards they present and safety precautions (Art. 7). Suppliers must mark chemicals to allow for their identification (Art. 7.1) and hazardous chemicals must carry additional labelling that is easily understandable by workers (Art. 7.2). Employers are required to assess workers’ exposure to hazardous chemicals and ensure it does not exceed established exposure limits or other established criteria (Art. 12). Employers are required to assess risks arising from chemical use at work, including selecting chemicals that eliminate or minimize risk, and limit exposure to protect workers’ safety and health (Art. 13).

3 Basel Convention, Annex III.

Considerations for the plastics instrument

Risk assessment is indirectly addressed in the following article of the **Chair's non-paper**

- Art. 19 (health) suggests text for encouraging the adoption of science-based health guidelines relating to the exposure to plastic pollution, in particular microplastics and related issues (para 1a).

Risk assessment in indirectly addressed in the following provisions of the revised draft text of the plastics instrument UNEP/PP/INC.4/3:

- Provision II.3: Chemicals and polymers of concern
- Provision II.8: Emissions and releases of plastic throughout its life cycle

The scope of risk assessment must consider all potential intentional and unintentional releases of microplastics, whether from manufacturing, use, reuse and recycling activities or leakage into the environment.

Following the example set by other MEAs, the technical body of the plastics instrument is likely to rely on risk assessments prepared by national authorities and other sources when developing a possible risk profile and risk management evaluation for specific products when nominated for listing, rather than conducting a full risk profile itself. By relying on pre-existing assessments, this approach can help to identify possible thresholds for acceptable or unacceptable levels of unintentional releases from scrutinized products. Also, by using existing risk assessment, the plastic instrument can assess the availability of alternatives, including safer materials or processes that reduce MNP emissions. However, in practice the process may prove to be more reactive than proactive in addressing MNP releases, as it relies on existing information that is usually established once the product is already in widespread use or after harmful effects have been detected.

A review of risk assessment data could be conducted by a subsidiary scientific and technical body or review committee. The treaty must also define the information requirements as well as possible hazard criteria for countries nominating products for listing due to unintentional or intentional releases of microplastics. Hazard criteria must therefore include potential for releases of MNP. Guidelines for assessing the risk of products related to MNP releases and their effect on humans and the environment could assist countries in providing evidence based on associations and correlations between geographic MNP exposures, concentrations in human tissue and trends in human health disease within those populations exposed to MNP.

5.4 Global Measures Supporting Closed Loop Plastic Design to Mitigate MNP Human Exposure

Global MEAs do not directly regulate industrial activities. Instead, governments who ratify MEAs take on the obligations as set out in those MEAs that may translate into domestic industrial regulation. These may include national caps or reduction targets on production, use and trade of regulated substances. Types of regulation of industry may be promoted within the MEA, and guidelines may be developed for such purposes. In some cases, the use of technologies for specific processes may require approval by the Parties, and the export of technologies, equipment and facilities that facilitate their use may be regulated.

5.4.1 Closed Loop Design: Product-specific regulation

Product design is not typically featured in MEAs. However, measures targeting **elimination and restriction** of chemicals of concern can be considered an element of design. Such measures can also target a reduction in production and use of regulated substances.

Restricting production of products

Restricting production of products may include the following measures:

- Restriction of primary plastic production, polymers and chemicals, including caps and bans.
- Chemical simplification.
-

Examples from existing MEAs

The restriction of primary plastic production, polymers and chemicals, including caps and bans is featured in the following MEAs.

- **The Minamata Convention** includes product-level restrictions. It targets the phasing out of the manufacture of mercury-added products (Art. 4) listed in Part I of Annex A, such as, thermometers, batteries, and fluorescent lamps. Moreover, Art. 5 provides provision for phasing out mercury in manufacturing processes listed in Part I of Annex B, such as production of polyurethane using mercury-containing catalysts. Additionally, it restricts mercury-using processes listed in Part II of Annex B, such as the production of vinyl chloride monomer (VCM) and acetaldehyde, where mercury is used as a catalyst.

- **The Stockholm Convention** Restrictions on chemicals of concern throughout the product life cycle. It aims to eliminate chemicals classified as POPs under the Convention. It mandates the elimination of production and use of chemicals listed in Annex A. For chemicals listed in Annex B, elimination of production is not mandated, but their production and use are restricted to acceptable purposes provided for each chemical listed in Annex B (Art 3).
- **The Montreal Protocol** restricts production of chemicals of concern without direct application at the product level. It prohibits the manufacture and use of ozone depleting substances and restricts hydrofluorocarbons that have global warming potential. It provides for caps of regulated substances that Parties must achieve, mostly in a phased approach towards elimination. While it does not prescribe specific national regulations, it requires Parties to implement domestic measures to ensure compliance, including regulation at the industrial level to hold producers responsible for levels of production or emissions (Art. 2).

Chemical simplification is not directly featured in MEAs, as they have been slow in restricting the rapid proliferation in the number of plastic chemicals in commerce, now exceeding 16,000. However, the “essential use” concept can help deliver on the approach, which is highlighted by the following MEAs:

- **The Montreal Protocol** limits the use of controlled substances for essential use only. The following criteria have been defined for a substance to qualify as “essential”: 1) it is necessary for the health, safety or is critical for the functioning of society; and 2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health (Decision IV/25).

Moreover, a **grouping of chemicals approach** has been adopted in several MEAs, supporting chemical simplification as follows:

- **The Stockholm Convention** groups chemicals, such as PBDEs (Polybrominated diphenyl ethers), PCBs (Polychlorinated biphenyls), SCCPs (Short-chain chlorinated paraffins), PCNs (Polychlorinated naphthalenes), and several PFAS (Per- and polyfluoroalkyl substances) subgroups, based on structural similarities, such as congeners and isomers, ensuring that chemicals with comparable biological activity or environmental impact are managed together.
- **The Montreal Protocol** groups chemicals, such as CFCs (Chlorofluorocarbons), HCFCs (Hydrochlorofluorocarbons), and HFCs (Hydrofluorocarbons), based on their ozone-depleting potential and their contribution to global warming in the case of HFCs.

Considerations for the plastics instrument

A reduction of total production of plastics is included in the following article of the **Chair's non-paper**:

- Art. 6 (supply) proposes acknowledging the need to manage the supply of primary polymers, including requiring Parties to cooperate to achieve a global objective of sustainable production levels.

A reduction in total production of plastics is addressed in the following provisions of the **revised draft text** of the instrument (UNEP/PP/INC.4/3):

- Provision II.1: Primary plastic polymers
  Parties must protect the environment and human health through the reduction of primary plastic polymers.

Restriction of primary plastic production, including polymers and chemicals, could be achieved by adopting a global target to reduce plastic production, providing an efficient way to mitigate microplastic pollution. The Bridge to Busan Declaration has 40 government signatories committing to achieve levels of production of primary plastic polymers, which may include production freezes at specified levels, production reductions against agreed baselines, or other agreed constraints to prevent the unsustainable production of primary plastic polymers.4

The adoption of global criteria for listing chemicals of concern for bans and restrictions is necessary for achieving targeted efforts for minimizing human health hazards from microplastics. This will also support the reduction of primary plastics production

Adopting a chemical simplification supported by the grouping of chemicals approach will be crucial for the plastics instrument to effectively address regulatory gaps and prevent regrettable substitutions. This approach aligns with the precedent set by the Montreal Protocol, which allows essential uses only for chemicals crucial for health, safety, or societal functioning and there are no safer alternatives available yet. It also aligns with the Stockholm Convention, which uses structural grouping to regulate chemicals with similar properties.

4 https://www.bridgetobusan.com/

Eliminate products of high risk of MNP release into environment

Elimination of products not designed for a closed loop will reduce products of high risk of MNP release into the environment, thus decreasing the risk of human exposure to MNP. This approach focuses on two key areas:

- Intentionally added microplastics
- Non-intentionally added microplastics

Examples from existing MEAs

Existing MEAs do not address MNP releases into the environment, nor intentionally added microplastics nor non-intentionally added microplastics, as most MEAs were drafted before the uses gained prominence.

Considerations for the plastics instrument

The **Chair's non-paper** addresses products that are not designed for a closed loop in the following articles:

- Art. 3 (plastic products and chemicals of concern as used in plastic products) proposes including measures in the article to control plastic products and chemicals of concern, including establish necessary criteria and lists in Annexes to the convention.
- Art. 7 (emissions and releases) suggests text requiring Parties to take measures to manage, reduce, and, where possible, eliminate emissions and releases to the atmosphere, soil, water and the marine environment from the production, storage, transportation, use and end of life management of: (a) chemicals of concern as used in plastic products listed in Annex [A], and plastic products listed in Annex [B]; (b) plastic pellets, flakes and powder from the supply chain; (c) microplastics during production of plastics, and (d) microplastics and nano-plastics during use of products (para 1).

Products that are not designed for a closed loop are addressed in the following provisions of the **revised draft text** of the instrument (UNEP/PP/INC.4/3):

- Provision II.3: Problematic and avoidable plastic products

  Problematic product, such as single-use products or with a high risk of environmental leakage, are targeted for reduction, including those that have properties that may hinder their safe and environmentally sound management including their reusability, repairability, recyclability and disposability.

  Paragraph 3 aims to eliminate the production, use, distribution and trade of Intentionally added microplastics.

- Provision II.8: Emissions and releases of plastic throughout its life cycle

  Parties must take the necessary measures to prevent the unintentional releases and emissions of microplastics.

The plastics instrument must explicitly recognize the need to limit both intentionally added and non-intentionally added microplastics. This could involve adoption of specific annexes outlining both priority products groups for phasing out primary MNP and product-specific thresholds for minimizing secondary MNP releases. Listing of products can be driven by Party proposals, as envisaged for chemicals of concern. In his way, existing risk assessment data can be sued to help to identify priority product groups and thresholds, as well as possible alternatives. Moreover, plastic instruments may decide to develop guidelines for minimizing releases, including BET and BAP. This may require the support of a subsidiary scientific and technical body tasked with providing guidance for the Conference of Parties on:

- **Identification of primary product groups with primary microplastics intended for phase out**, with recommendations for phase-out targets. This may include cosmetics, detergents, paints and coatings, agricultural products, medical products, cleaning products, polymer-based products like inks and adhesives, oil and gas extraction applications, construction materials, and fertilizers.
- **Identification of primary product groups emitting and releasing secondary microplastics**, with recommendations for threshold for such releases. This may include MNP releases, inter alia, from polymer-coated fertilizers, tyre and brake wear and artificial turfs.

Recovery in closed loop

Recovery in a closed loop is an element of product design that is also indirectly influenced by provisions, often targeting plastic products downstream. Recovery in closed loop focuses on:

- Recycling, reuse and circularity of plastic materials
- Banning problematic and avoidable plastic products

MEAs do not include bans on problematic and avoidable plastic products. Instead, they promote provisions focused on recycling, reuse, and the circular economy. Both the Basel Convention and Stockholm Convention incorporate these elements to varying degrees.

Examples from existing MEAs

- The **Basel Convention** promotes the environmentally sound management of hazardous wastes, influencing the design of products to be less wasteful and more recyclable. Parties must ensure that the generation of hazardous wastes and other wastes are reduced to a minimum (Art. 4.2.b).
- The **Stockholm Convention** lists sources of emissions of unintentional POPs in Annex C. Article 5 provides measures to reduce or eliminate releases of POPs from these sources. Parties must promote the development and, where appropriate, mandate the use of substitute or modified **materials, products and processes** that prevent the formation of the POPs listed in Annex C, as well as their release (Art. 5c).
- The **Stockholm Convention** requires to take appropriate measures so that wastes, including products and articles upon becoming wastes, are disposed in an environmentally sound manner (Art. 61d).

Considerations for the plastics instrument

The **Chair's non-paper** addresses product design in the following article:

- Art. 5 (plastic product design) suggests text encouraging parties to take measures to promote enhanced design and performance of plastic products (para 1a).

Product design is addressed in the following provisions of the **revised draft text** of the instrument (UNEP/PP/INC.4/3):

- Provision II.5: Product design, composition and performance

  Products should be designed for circularity, including repair, reuse and recyclability

Plastic waste circularity is addressed in the following provisions of the revised draft text of the instrument (UNEP/PP/INC.4/3):

- Provision II.9: Waste management
- Provision IV.7: Awareness raising, education and research

The plastics instrument must go beyond the elimination approach of existing MEAs and lay strong foundations for design of plastic products that minimize harm to humans and the environment. The following **design principles** are critical for reducing microplastics and their impacts:

- **Non-toxicity:** Eliminate harmful chemicals and polymers not covered by existing global chemical regulations, as microplastics can act as vectors, delivering these chemicals deep into the human body.
- **Safe material composition:** Ensure product design considers material composition, including the presence of non-intentionally added microplastics.
- **Polymer integrity:** Improve polymer integrity through molecular design to make plastics more resistant to fragmentation and microplastic release.
- **Longevity:** Design plastic products for durability, ensuring they can be easily disassembled, repaired, and upgraded to extend their lifespan and reduce the need or premature disposal.
- **Transparency:** Ensure that products are properly labelled to provide information on safe use, potential microplastic or chemical content and releases.

Additionally, the plastics instrument needs to ensure that waste management adheres to the **waste management hierarchy**, focusing on design perspectives:

- **Prevention:** Limit production of plastics only for essential uses (guided by essentiality principles) to mitigate MNP releases.
- **Reuse:** Design products for safe reuse and refill, without compromising recyclability, and minimizing extended and increasing MNP exposure from incremental reuse.
- **Recycling:** Design products to be recyclable at the end of their life, considering factors that affect recyclability, such as the presence of colorants, additives, mixed materials, and contamination from use or disposal processes, and maximizing containment of MNP releases from recycling processes.
- **Energy recovery:** Contaminated plastics, including legacy plastics, and non-recyclable plastics (e.g., thermosets), promoting research into methodologies to measure and contain MNP release from incineration processes.[5]
- **Disposal:** Avoid disposal of plastics in landfills to prevent MNP releases from slow degradation.

5 Promotion of energy recovery processes must consider other related impacts, such as climate change and water usage.

Transparency and disclosure

Examples from existing MEAs

Transparency and disclosure are highlighted by the following MEA:

- The **Stockholm Convention** includes labelling requirements for certain POPs under specific exemptions that have uses in plastics. For instance, Parties must ensure that hexabromocyclododecane (HBCD) used in building materials like polystyrene foam is labelled or otherwise identified throughout its life cycle (Annex A, Part VII).
- The **Rotterdam Convention** requires chemicals listed in Annex III to be exported only with prior informed consent (PIC), enabling importing states to refuse or set conditions on imports. If a chemical is not listed in Annex III but banned or restricted by the exporting Party, the Party must notify the importing state before the first shipment and annually thereafter (Art. 10-12). Each Party must inform the Secretariat of banned or severely restricted chemicals, which is then compiled and shared with all Parties (Art. 12.1).
- The **UN Watercourses Convention** requires states sharing international watercourses to notify other states in the event of pollution or activities that could cause significant harm. The Convention does not explicitly mention plastics, but its broad scope would likely encompass plastic pollution, such as nurdle spills accidents, requiring Parties to notify others of such events.
- **The Kyiv Protocol on Pollutant Release and Transfer Registers (PRTRs)** requires facilities to report on pollutant releases and transfers, including those related to plastic and chemical production. Reporting is also required for final disposal and recovery operations, such as wastewater treatment plants, waste incineration, and landfills, which are significant sources of MNP. However, MNP are not currently reported separately in PRTR systems; instead, they may be included under broader categories such as particulate matter (PM10) or diffuse sources like tyre wear (UNECE, 2022).[6]
- **Long-Range Transboundary Air Pollution (LRTAP)** Convention emphasizes transparency in monitoring and reporting the emissions of pollutants that can travel across national borders. While microplastics are not yet a focus, the convention could potentially evolve to include them if research demonstrates their capacity for long-range air transport.

6 UNECE (2022). Note on possible linkages between pollutant release and transfer registers and plastic pollution. UN Doc. ECE/MP.PRTR/WG.1/2022/6. Available online: https://bit.ly/3nanHdb

Considerations for the plastics instrument

The **Chair's non-paper** addresses transparency in the following articles:

- Art. 3 (plastic products and chemicals of concern in plastic products) proposes referring to transparency and traceability.
- Art. 5 (plastic product design) suggests text for encouraging product transparency (para 1a).

Transparency and disclosure are addressed in the following provisions of the **revised draft text** of the instrument (UNEP/PP/INC.4/3):

- Provision II.10: Trade

  Parties exporting a product containing a listed chemical, a listed polymer or product shall require the exporter to provide the importing state with information based on harmonized disclosure requirements, and mark and label the product in accordance with harmonized labelling requirements.
- Provision II.13: Transparency, tracking, monitoring and labelling

  Parties shall require producers and importers to disclose harmonized information on chemical composition and type of polymer and ensure traceability of plastic products as well as plastic contents of products.
- Provision IV.7: Awareness raising, education and research

Transparency and disclosure will be necessary for ensuring consumer protection and for driving markets towards safer alternatives. At a minimum, product transparency is necessary to identify products with exceptions to inform about their potential human health and environmental hazards, and to ensure their safe disposal. Transparency and disclosure should focus on:

- **Microplastics content:** Clear information on the presence of microplastics in products, including their quantity and type
- **Potential for secondary microplastic releases:** Disclosure of how products may contribute to microplastic pollution over time, especially through wear and tear or degradation.
- **Chemical content:** Full transparency on the chemicals of potential chemicals of concern used in products and hazards caused

Transparency and disclosure are also important tools in enabling comprehensive risk assessment, as well as the tracking of plastic chemicals. This includes the preparation of migration and leaching profiles, which detail how chemicals move or are release from plastics over time. In order to ensure comprehensive risk assessment, the plastics instrument will need to ensure that available, information on chemicals relating to the health and safety of humans and the environment is made publicly available is not regarded as confidential.

Transparency could be further increased with trade controls, requiring a PIC procedure if plastic products fulfil certain characteristics that render them hazardous. Such characteristics could include contains intentionally-added microplastics or has potential for significant secondary microplastics releases, exceeding certain limit defined by the plastics instrument.

The plastic instrument could mandate the development PRTRs for plastic pollution, making it mandatory for facilities, including plastic producers and waste management and recovery operators, to monitor, report and increase access to data on MNP releases. It could present data in a more detailed and easily accessible manner, complementing PRTRs under the Kyiv Protocol.

5.4.2 Closed Loop Design: Broader industrial regulation

Necessary broader industrial regulation in context of achieving closed loop design includes:

- Minimizing industry reliance on plastic.
- Waste Management: waste plastic, recycling and complete destruction.
- Enhancing worker safety.
- Minimizing industrial releases of MNP: Industrial air emissions, water discharges and solid waste sources of microplastic including plastic production.
- High risk products and use constituting disposal.

Minimizing Industry Reliance on Plastic

Examples from existing MEAs

MEAs do not directly aim to directly minimize industry reliance on plastics. The following indirect references may lead to a reduction:

- **The Basel Convention:** Through its provisions on the environmentally sound management of hazardous wastes, including plastic waste, the Convention indirectly encourages industries to rethink their reliance on plastics that lead to waste generation and opt for more sustainable materials.

Considerations for the plastics instrument

The **Chair's non-paper** addresses the need for minimizing industry reliance on plastic in the following articles:

- Art. 3 (plastic products and chemicals of concern as used in plastic products) proposes including measures on alternatives and non-plastic substitutes.
- Art. 5 (plastic product design) suggests text to foster research, innovation, development, and use of sustainable alternatives and non-plastic substitutes, including products, technologies and services (para 1b).

Minimizing industry reliance on plastic is addressed in the following provisions of the **revised draft text** of the instrument (UNEP/PP/INC.4/3):

- Provision II.9: Non-plastic substitutes

Non-plastic substitutes include materials derived from natural, non-fossil sources including plants or minerals that are not considered plastic. They can play an important role for substituting certain uses of plastics. Assessing substitutes will be important in order to avoid regrettable substitutions and to comprehensively consider other socio-economic considerations, such as technical feasibility, costs, efficacy, risk, availability and accessibility.

Waste Management: Waste plastic, recycling and complete destruction

Examples from existing MEAs

- **The Basel Convention** includes provisions related to reducing hazardous wastes and other wastes to a minimum. By promoting proper waste management, recycling, and disposal practices, the convention indirectly helps to minimize MNP releases from mismanaged plastic waste. It distinguishes between preferred disposal operations and those that are not considered environmentally sound.
- **MARPOL Annex V** contains regulations aimed at preventing and minimizing pollution from vessels from operational wastes, including fishing gear.
- **The London Convention prohibits the dumping** of wastes or other matter listed in Annex I (Art. IV). This includes persistent plastics and other persistent synthetic materials (e.g., netting and ropes) which may float or may remain in suspension in the sea in such a manner as to interfere materially with legitimate uses of the sea (Annex I, para 4). For wastes not prohibited from dumping and incineration at sea or those listed under Annex II to the Convention, a prior permit is required (Art. IV, para 1b-c, Annex I, para 10b). This includes dredged material and sewage sludge (Annex I). These wastes are known to contain microplastics (Khan et al., 2022) and can lead to the unintentional application of microplastics to agricultural lands when sewage sludge is used as a soil improver (FAO, 2021). The incineration of sewage sludge and dredged material at sea is prohibited.
- **UN Law of the Sea Convention (UNCLOS)** primarily addressed the fishing industry within its text concerning specific industrial activities, but measures relate to preservation of fish stocks. Art. 194 establishes an obligation for States to take measures necessary to prevent, reduce and control pollution of the marine environment from any source (para. 1), while also ensuring that activities under their jurisdiction or control do not cause damage by pollution to other States and their environment (para. 2). This includes all sources of pollution from land, air or from dumping that are toxic, harmful or noxious, particularly those which are persistent (para 3).

Considerations for the plastics instrument

The **Chair's non-paper** addresses waste management in the following article:

- Art. 8 (waste management) suggests text for mandatory measures to ensure that plastic waste is managed in an environmentally sound manner, taking into account the waste hierarchy and relevant guidelines developed under the Basel Convention (para 1).

Waste management is addressed in the following in the following provisions of the revised draft text of the instrument (UNEP/PP/INC.4/3):

- Provision II.9: Waste Management: Best practices for environmentally sound waste management are to be developed that are complementary to the Basel Convention, with possible listing of preferred waste management practices in an Annex.

The plastics instrument currently contains provisions for waste management, but recognition of the releases and emissions of MNP from industrial processes are not addressed. Existing MEAs refer to the endpoint of waste management practices within different sectors (dumping, discharge, etc) but do not regulate releases from facilities that manage the waste (fugitive and other). To minimise MNP exposure and promote a closed-loop approach for plastics, complete destruction must be considered as the preferred endpoint for plastics that do not meet, or no longer meet, the requirements of a closed-loop system. To prevent non-plastic related impacts to the environment and human health, all supporting closed-loop approaches must be given priority to minimize the need for complete destruction.

Enhancing worker safety

Examples from existing MEAs

The International Labour Organization (ILO) provides for the safe use of chemicals at work, including production, handling, storage, and disposal processes within industrial settings, with the following convention articulating obligations for Parties:

- **ILO Chemicals Convention (C170)** aims to prevent or reduce the incidence of chemically induced illnesses and injuries at work (preamble). The Convention sets obligations for employers to ensure occupational safety. This includes assessing chemical hazards and taking preventive measures (Art. 7), providing information to workers through labelling and safety data sheets (Art. 8), controlling worker exposure through safe handling, storage, and disposal (Articles 10 and 11) and offering training on the safe use of chemicals and emergency procedures (Art. 12).

Considerations for the plastics instrument

The **Chair's non-paper** addresses worker safety in the following article:

- Art. 10 (just transition) suggests text for enhancing cooperation to promote and facilitate a transition towards sustainable production and consumption of plastic, taking account of the situation of workers in the informal sector (para 1).

Worker safety is addressed in the following in the following provisions of the revised draft text of the instrument (UNEP/PP/INC.4/3):

- Provision II.12: Just transition: An equitable and inclusive transition for affected population is to be promoted with particular consideration for workers and other relevant groups

The plastics instrument needs to minimize exposure of microplastics in production as well as recycling. In production, microplastics can be released from handling raw plastic materials, dust, and plastic manufacturing processes. Similarly, shredding of plastics for mechanical recycling produces microplastics releases that may jeopardize the health of workers, particularly for informal workers that often do not wear any protective gear. To address these risks the instrument should mandate:

- The use of protective equipment for all workers.
- The use of ventilation systems and dust control.
- Monitoring and controlling microplastic emissions in both production and recycling facilities.
- Provision of training on safe handling of plastics to minimize releases and exposure.

Moreover, companies should disclose the potential MNP emissions generated during the production process, so workers are aware of the risks and proper safety measures can be implemented. This could include the development of emission profile for MNP for products to enhance worker safety.

The Informal sector, including those collecting waste from households, commercial centres, and landfill, are particularly at risk. Parties should be required to assess national worker safety regulations for authority to protect informal sector and, if no authority is present, amend legislation for this purpose.

Exposure can be further minimized by recognizing many waste management processes that generate MNP. The definition of environmentally sound waste management should include emissions and releases of MNP and provide for processes that lead to complete destruction when required.

Minimizing Industrial Releases of MNP: Industrial air emissions, water discharges and solid waste sources of microplastic including Plastic Production

Examples from existing MEAs

Engineering design is reflected to a lesser degree in MEAs:

- The **Stockholm Convention** requires Parties to promote the use of best available techniques and best environmental practices towards limiting and reducing unintentional releases of chemicals listed in Annex C, both for existing sources and new sources.

Article 5(f) of the Stockholm Convention on engineering design to reduce or eliminate releases

i. "Best available techniques" means the most effective and advanced stage in the development of activities and their methods of operation which indicate the practical suitability of particular techniques for providing in principle the basis for release limitations designed to prevent and, where that is not practicable, generally to reduce releases of chemicals listed in Part I of Annex C and their impact on the environment as a whole. In this regard:

ii. "Techniques" includes both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned;

iii. "Available" techniques means those techniques that are accessible to the operator and that are developed on a scale that allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the costs and advantages; and

iv. "Best" means most effective in achieving a high general level of protection of the environment as a whole;

v. "Best environmental practices" means the application of the most appropriate combination of environmental control measures and strategies

Annex C of the Stockholm Convention provides General guidance on best available techniques and best environmental practices in Part V, which include engineering design considerations for facilities to avoid the formation and release of chemicals listed in Annex C.

Part V of Annex C, Stockholm Convention, related to design of facilities to avoid the formation and release of unintentional POPs

(b) General release reduction measures: When considering proposals to construct new facilities or significantly modify existing facilities using processes that release chemicals listed in this Annex, priority consideration should be given to alternative processes, techniques or practices that have similar usefulness but which avoid the formation and release of such chemicals. In cases where such facilities will be constructed or significantly modified, in addition to the prevention measures outlined in section A of Part V the following reduction measures could also be considered in determining best available techniques:

- **i.** Use of improved methods for flue-gas cleaning such as thermal or catalytic oxidation, dust precipitation, or adsorption;
- **ii.** Treatment of residuals, wastewater, wastes and sewage sludge by, for example, thermal treatment or rendering them inert or chemical processes that detoxify them;
- **iii.** Process changes that lead to the reduction or elimination of releases, such as moving to closed systems;
- **iv.** Modification of process designs to improve combustion and prevent formation of the chemicals listed in this Annex, through the control of parameters such as initial waste feed processing, incineration temperature or residence time.

- **The Montreal Protocol** requires Parties to discourage the export to non-Parties of technology for producing and for utilizing controlled substances (Art. 4.5). Parties must also refrain from providing new subsidies, aid, credits, guarantees or insurance programmes to non-Parties for the export of equipment, plants or technology that would facilitate the production of controlled substances (Art. 4.6). These measures do not apply where equipment, plants or technology improve the containment, recovery, recycling or destruction of controlled substances, or if they promote the development of alternative substances, or if they otherwise contribute to the reduction of emissions of controlled substances (Art. 4.7).
- **The Stockholm Convention** encourages Parties to set release limit values or performance standards to fulfil its commitments for best available techniques for eliminating releases from unintentional POPs (Art. 5g).

Considerations for the plastics instrument

The **Chair's non-paper** addresses industrial releases of MNP in the following article:

- Art. 7 (emissions and releases) suggests text on mandatory measures to manage, reduce, and, where possible, eliminate emissions and releases of plastic pellets, flakes and powder from the supply chain; microplastics during the production of plastics (para 1b-c).

Industrial releases on MNP are addressed in the following provisions of the **revised draft text** of the instrument (UNEP/PP/INC.4/3):

- Provision II.8: Emissions and releases of plastic throughout its life cycle

  This includes all potential intentional and unintentional releases, whether from manufacturing, use, reuse, recycling activities or leakage into the environment

Worker and consumer safety must be strengthened within the plastics instrument to mitigate:

1. exposure to MNP, and
2. health risks when exposure does occur.

Exposure can be mitigated through measures addressing emissions and releases of macroplastics and MNP. Measures must aim to minimise emissions to air of MNP and releases to soil and water during manufacture and during use by all industries, including waste management, and by consumers. Releases of macroplastics must be prevented to eliminate the risk of degradation into MNP. Emissions and releases should not be limited to sources listed in an Annex, but all emissions must be provided for to capture sources not yet recognized.

High Risk Products and Use Constituting Disposal

Specific high-risk products and those for which their intended use creates high disposal rates can be targeted for reduction and, at a minimum, ongoing monitoring that is made publicly available.

Examples from existing MEAs

- The **UN Fish Stocks Agreement**[7] requires coastal States and States fishing on the high seas to assess the impacts of fishing, other human activities and environmental factors on target stocks and species belonging to the same ecosystem or associated with or dependent upon the target stocks (Art. 5.d). In addition, pollution, waste and discards must be minimized as well as impacts on associated or dependent species, including through the development and use of environmentally safe fishing gear and techniques (Art. 5.f).
- The **BBNJ Agreement**[8] requires new activities taking place in the high seas, such as aquaculture, to be subject to environmental impact assessment (EIA). Parties to the agreement may register any concerns about unforeseen and significant adverse impacts that may occur as a result of these activities. The EIA must be made publicly available and the activity should only be authorised if it can be appropriately managed to prevent such impacts. The activity must also be monitored in a manner consistent with national processes (Art. 28).

Considerations for the plastics instrument

The **Chair's non-paper** addresses products that are not designed for a closed loop in the following articles:

- Art. 3 (plastic products and chemicals of concern as used in plastic products)
- Art. 7 (emissions and releases)

Products that are not designed for a closed loop are addressed in the following provisions of the revised draft text of the instrument (UNEP/PP/INC.4/3):

- Provision II.3: Problematic and avoidable plastic products
- Provision II.8: Emissions and releases of plastic throughout its life cycle

7 Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 Relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks.

8 Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction.

The plastics instrument currently targets problematic product, such as single-use products or with a high risk of environmental leakage, for reduction. A sectoral approach for products that are applied directly into the environment and in high-degradation processes, can be supported through the development of annexes specific to the application, where appropriate, or guidelines to minimize their release of MNP through improved design and alternate practices. Annexes and/or guidelines must aim to achieve provisions adopted for preventing the 'intentional by design' and the unintentional releases and emissions of microplastics.

5.4.3 Closed Loop Design: Plastic Pollution Remediation Including Complete Destruction

Examples from existing MEAs

- **The Stockholm Convention** requests Parties to manage stockpiles in a safe, efficient and environmentally sound manner (Art. 6, para 1c) and endeavour to develop strategies for identifying sites contaminated by chemicals listed in Annex A, B or C— if remediation of contaminated sites is undertaken it is to be performed in an environmentally sound manner (Art. 6, para 1e)
- The **Montreal Protocol** provides for the destruction of listed substances, mandating that only technologies approved by the Parties may be used for such purposes.
- The **Montreal Protocol** does not apply the measures relating to the export of technology for producing and using controlled substances, or the provision of new subsidies, aid, credits, guarantees or insurance programmes to non-Parties for the export of products, equipment, plants or technology that would facilitate the production of controlled substances, if these products, equipment, plants or technology improve the recovery or destruction of controlled substances (Art. 4.7).

Considerations for the plastics instrument

The **Chair's non-paper** addresses plastic pollution remediation in the following article:

- Art. 9 (existing plastic pollution) suggests text for enhancing cooperation to identify, evaluate and prioritize locations or accumulation zones most affected by existing plastic pollution; and to take mitigation and remediation measures, including clean-up activities in such identified affected locations or accumulation zones (para 1a-b).

Plastic pollution remediation is addressed in the following provisions of the **revised draft text** of the instrument (UNEP/PP/INC.4/3):

- Provisions II:9: Existing plastic pollution, including in the marine environment

Environmental and landfill remediation of existing plastic pollution will need to be featured in the plastics instrument to help prevent MNP releases. Landfill mining, which involves segregation of organic matter, can help to recover useful materials and optimising waste disposal. However, the process of collecting waste plastic from landfills, dumpsites and the environment, and processing it into a suitable alternative fuel, often involves considerable investments and operational costs, as well as generation of MNP. Addressing existing oceanic plastic pollution is daunting, as research indicates that a staggering 94% of plastics entering the oceans eventually settle on the sea floor, while a mere 1% remains at or near the surface (Sherrington et al. 2016). However, ongoing releases of MNP from plastics in the environment necessitate research and investment in this important approach to a high source of MNP exposure.

EPR is promoted in the plastics instrument, which may allow for some direction of funds towards remediation. Financial mechanisms and institutions may also be alerted to the significance of plastics in the environment as an ongoing source of MNP and invest in necessary technology and activities. The instrument could also include remediation of plastic products and MNP in technology transfer and capacity building to stimulate research and development in this regard. Guidelines can be developed to ensure such activities are environmentally sound.

5.5 Liability and compensation for damage

According to Principle 13 of the 1992 Rio Declaration on Environment and Development, States must develop international and national legal instruments regarding liability and compensation for the victims of pollution and other environmental damage. Giving effect to this and to Article 12 of the Basel Convention, a protocol to the Basel Convention was adopted in this regard. The Protocol is not yet in force but provides an interesting perspective on the polluter pays principle in international law. It may also be considered as the international mechanism similar to the US CERCLA and common law litigation discussion of Chapter 4.

The Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and Their Disposal provides for liability for damage resulting from the transboundary movement of hazardous wastes and other wastes and their disposal including illegal traffic in those wastes, and for 'adequate and prompt' compensation for such damage.

The Protocol sets out who is liable for damage and under which circumstances, applying financial (Art. 12) and time limits (Art. 13) to the liability. Liability may be assigned to a State or a person under the jurisdiction of a State who arranges for the export or import of the waste or disposes of such waste. Persons to whom strict liability may apply as per Article 4 of the Protocol must maintain financial guarantees that are sufficient to cover their liability and not less than the minimum limits specified in Annex B of the Protocol for the period of the liability time limit (Art. 14.2).

In recognition of the irreparable harm to the environment from MNP and mounting evidence of harm to human health, the plastics instrument could consider a liability and compensation measure for producers of products that do not meet the closed loop design criteria, particularly where MNP release profiles are above an agreed threshold. Such an approach would drive innovation towards minimisation of MNP exposure and associated chemicals of concern.

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