brigid

bridging the gap
between microplastics
and human health

Brigid Executive Summary

With an annual global production of 359 million tonnes in 2018, plastic is the third most abundant man-made material after steel and concrete. Plastic has a range of useful characteristics: durability, resistance to degradation, low production cost. These properties have solidified the position of plastics as first-choice material in a variety of applications: food storage and preservation, medical equipment, construction, mobility, electronics, sports, et cetera. Increasing use of plastics in our daily lives, whilst affording us the comforts and technological advances of the modern era, has created the unwanted side effect of global plastic pollution, stemming from improper or inadequate waste management and/or accidental releases. Degradation processes can fragment larger plastics into smaller particles measuring <5mm, so-called microplastics (MPs). The large volumes of plastics present in the environment have been associated with measurable MP presence across the globe, leading to unintentional biota and human exposure.

Currently, there is no clear indication of any adverse health effects of MP exposure; however, large knowledge gaps still exist within this research topic. MP pollution has been extensively present in the media and in the policymaking discourse, which has resulted in calls for additional investigations and precautionary measures to be taken.

Research on MP exposure and potential risk for humans is complex, presenting a myriad of gaps in our scientific understanding. For example:

- external exposure levels for the average person,
- potential for uptake and distribution in the body,
- possible human health effects of real-world relevant particle sizes, shape, and polymer compositions.

There is an urgent need to systematically fill these gaps with high quality and reliable scientific data, to both allow legislators to make informed decisions based on a sound risk assessment, and to predict potential human health implications of MP exposure. Another important component in this analysis is the comparison of MPs in terms of exposure, uptake, and potential effects to other particles to which humans are exposed daily. Presently, publications on the potential human hazards of MPs are emerging at an exponential rate: MPs have been purported to be associated with different biological responses - such as oxidative stress, inflammation, and even cell death. However, these studies were conducted under experimental conditions that do not align with the current understanding of potential MP exposure in humans from the environment. In fact, these studies often employ unrealistic scenarios of exposure, such as high concentrations of perfectly spherical, even-sized polystyrene beads, which do not reflect real-life exposure levels nor particle characteristics (polymer types, shapes, and sizes) that the average human may encounter during their daily life. Prioritising and investing in MP research will

allow for a pragmatic, coordinated approach to address data gaps in the human health space; moreover, it is a step forward in industry's commitment to be an active part of the solution.

For these reasons, Plastics Europe is launching a multimillion-euro, five-year scientific research project: **Brigid**. This project aims to assess the potential risks to human health from MP exposure **via ingestion** (one of the major hypothesized routes of exposure, together with inhalation). To deliver results that reflect a realistic exposure scenario, Brigid will focus on secondary MPs of seven different polymer types: polyethylene (both linear low density & low/high density), polypropylene, polystyrene, (rigid) poly(vinyl chloride), polycarbonate, and polyamide-6. In the absence of robust real-world exposure data, these polymer types - amongst those in our members' portfolios - are assumed to be representative of what the average human potentially encounters most often during their daily life.

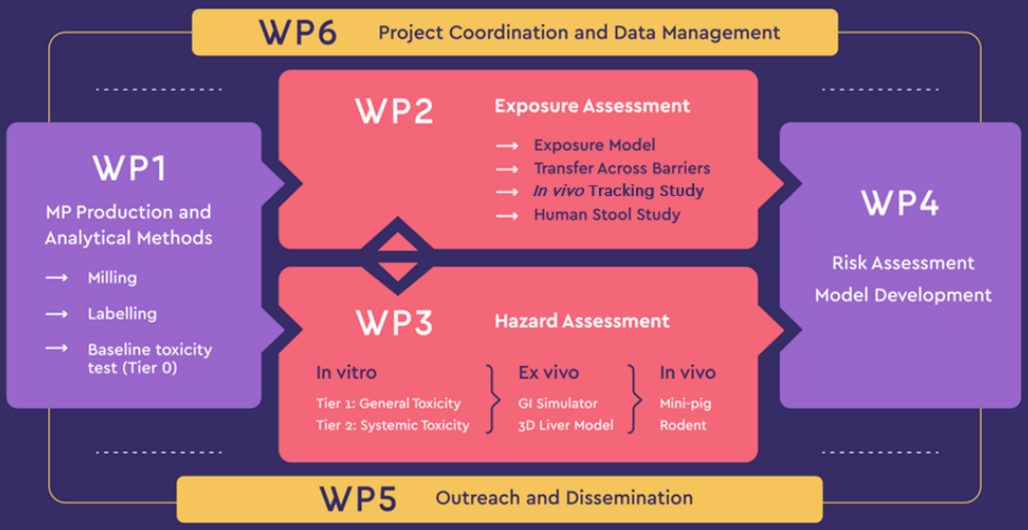

Figure 1. Brigid project structure divided in Working Packages (WPs).

The five objectives of the project, integrated in six working packages (WPs; see Figure 1), are:

1. Creation and characterisation of secondary MPs through milling and other techniques in relevant size ranges. Some of the MPs will also be labelled (radiolabelled & fluorescence probe) to help with exposure studies;
2. Quantification of MP potential human internal exposure through ingestion, via a set of *in vitro* biokinetic studies and innovative in vivo studies. These data, together with information gathered from scientific literature, will contribute to the development of the most detailed *in silico* exposure model to date;
3. In-depth MP effect characterisation using a tiered approach, starting with basic *in vitro* human cell models, progressing through highly advanced *ex vivo* models, to benchmark results derived from *in vivo* animal models;

4. Development of a hybrid Risk Assessment framework informed by the comprehensive and robust data produced during the project. The hybrid characteristics of this framework fit in the European regulatory environment, by blending solid *in vivo*-based assessment and elements from the next-generation *in vitro* approach;
5. Active stakeholder dialogues with different interest groups from the beginning of the project. The outcome of the risk assessment framework will be translated into recommendations and information understandable by a non-specialised public.

It should be clear that this effort stands as an initial steppingstone toward understanding potential risk, rather than a self-contained exercise. **Brigid** demonstrates that European plastic manufacturers are committed to the EU's Safety, Sustainability, and Circularity goals. Moreover, Brigid is seeking to address identified data gaps on the potential effects of MP exposure in humans - in turn, enabling informed and robust science-based policymaking for the benefit of all EU citizens.