

Policy brief

REGULATORY RELEVANCE OF THE EUROPEAN RESEARCH CLUSTER TO UNDERSTAND THE HEALTH IMPACTS OF MICRO- AND NANOPLASTICS (CUSP)

Micro- and nanoplastics: substances of public health concern?

The presence of micro and nanoplastics (MNPs) is part of our everyday life and they find their way into our bodies through the air we breathe, the water we drink and the food we eat. It is not known how MNPs might be affecting

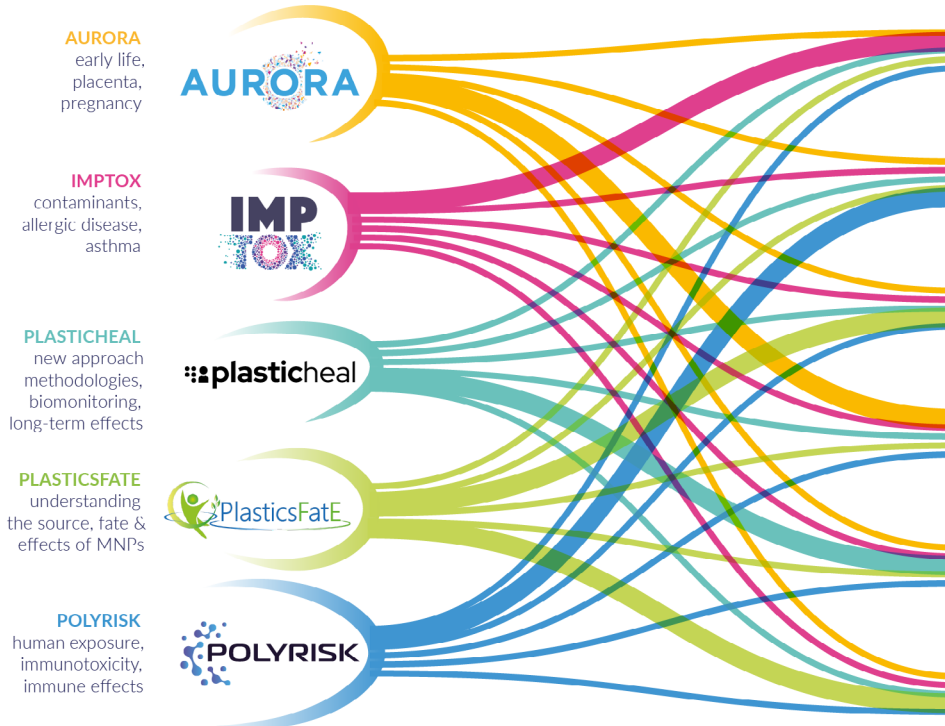
human health. Policymakers and regulatory authorities around the world are increasingly implementing regulatory measures to address this concern. For instance, policymakers in the EU have adopted the Single-use

Plastics Directive to reduce the environmental impact of certain forms of plastics used once or for a very limited period of time, such as straws, cutlery, plates, cotton swabs and balloon sticks¹.

¹ Directive (EU) 2019/904

projects

and their specific studies related to MNPs



working groups

a coordinated effort across the cluster

Figure 1: The five large-scale research projects united under CUSP and the CUSP working groups.

CUSP

Early in 2021, the European Commission funded five large-scale research projects under the European Union's Horizon 2020 research and innovation programme (see figure 1) and united them under the **European Research Cluster to Understand the Health Impacts of Micro- and Nanoplastics (CUSP)** (see <https://cusp-research.eu>). In total, CUSP unites a multidisciplinary

team of scientists, industries, and policymakers from 75 organisations across 21 countries.

The five projects collaborate in understanding exposure routes; in assessment of hazard and risk; in developing new analytical tools, in data-sharing, in inter-laboratory comparisons, and in communicating and disseminating research results.

By establishing six CUSP working groups, our synergies seek to amplify the efforts of individual projects. The close collaboration with the European Commission's Joint Research Centre (JRC) and a constant dialogue between scientists, stakeholders and policymakers will enhance the policy relevance and impact of the research.

From Science to Policy

There are several EU policy and legislative areas that can be informed by CUSP findings such as the chemicals, plastics, food, and water (see the summary below).

Chemicals

Zero pollution action plan	CUSP will establish whether there are any potential human health risks associated with MNPs and absorbed/desorbed/adsorbed contaminants. This will help in the identification and elimination of pollution sources and reduce consumer and occupational exposure to e.g., carcinogenic and endocrine disrupting substances.	Chemical Agents Directive (98/24/EC) EU Strategic Framework on Health and Safety at work 2021-2027	The data on occupational exposure and health effects of MNPs generated in CUSP may be utilised when considering occupational exposure control plan e.g., by setting occupational exposure limit values.
Chemicals Strategy for Sustainability	CUSP will develop methodologies for chemical risk assessment that consider the whole life cycle of substances, materials and products and develop risk evaluation frameworks that can facilitate the development of safe and sustainable alternatives.	Carcinogens and Mutagens Directive (2004/37/EC)	The data generated on potential genotoxicity and carcinogenicity of MNPs in CUSP may be utilised to conclude whether these materials should be considered as mutagens or carcinogens.
REACH Regulation (EC) No 1907/2006	CUSP will assist in the operationalization of a practical definition of a synthetic polymer and guidance on how to complete human risk assessment of MNPs. CUSP will furthermore assist regulators in specifying the information requirements that should apply to MNPs under REACH in the future. Analytical methods will be developed to determine the presence and risks of synthetic polymer microparticles (≤ 5 mm in size) intentionally added to products including cosmetic products, detergents and maintenance products, paints and coatings.	EU Plastic Strategy COM 2018/028	CUSP will help address the unknown impacts on human health of microplastic noted in the EU Plastic Strategy, as well as the effect of littering and leakage from plastic waste as possibly affecting human health through the food chain.
Classification labelling and packaging (CLP) Regulation (EC) No 1272/2008	Data and information on human health risks of MNPs generated in CUSP will be compared to current CLP criteria and Regulation	Single Use Plastics Directive (EU) No 2019/904	CUSP will help in assessing the risks stemming from environmental exposure of MNPs e.g., seafood, sea salt.
Horizon Europe Mission on Cancer	CUSP will help establish potential cancer risks associated with MNPs and absorbed/desorbed/adsorbed contaminants.	Bioeconomy Strategy	CUSP will assess applications where the use of eco-friendly, biodegradable or compostable plastics and nanocelluloses can be considered less harmful compared to HDPE, PP, PET and PA. Harmonised methods will be developed to measure unintentionally released MNPs and increase our capability to observe, measure and monitor progress made towards a sustainable plastics bioeconomy.

Plastics

Food

Food Contact Material (FCM) Regulation (EC) No 1935/2004	The CUSP monitoring of MNPs and associated contaminants in food and bottled drinking water will assist the safety assessment of plastics and plastics-enabled products in contact with food.
Plastic FCM and articles Commission Regulation (EU) No 10/2011	CUSP will help our understanding of how packaging and storage conditions contribute to the migration of MNPs and/or associated contaminants to foods and inform future revisions of the composition requirements and migration limits authorized.
Active and intelligent materials and articles FCM Commission Regulation (EC) No 450/2009	The data generated within CUSP will support the directive in the labelling and identification of substances to be avoided in packaging materials designed to lengthen the shelf-life of food.
EU-Sustainable food Farm to Fork Strategy	CUSP will monitor plastics contamination in food and obtain exposure data so that the potential health risks of MNPs -if any- can be identified, thereby addressing major concern of MNPs contamination in food.

Water

Drinking Water Directive Urban Waste Water Treatment Directive and Sewage Sludge Directive Marine Strategy Framework Directive	CUSP will contribute to developing and harmonizing methods for measuring MNPs. This effort will help meet the objectives of increasing observation, measurement, monitoring and reporting capabilities to track MNPs in drinking water, wastewater, sewage sludge and the marine environment.
Horizon Europe Mission on Ocean and Waters	CUSP will help establish whether there are any potential cancer risks associated with MNPs and absorbed/desorbed/adsorbed contaminants, which can be used to monitor, evaluate, forecast and value the health of the ocean and water system accurately and systematically. This will facilitate the reduction in levels of carcinogenic substances in the oceans/waters and substances that cause reprotoxic and immune effects and lower their intake.

CUSP activities that could contribute to EU regulation, initiatives and missions.

Across the many policy initiatives, CUSP's future contributions can be grouped across five overall areas: 1) Sampling, measuring, and monitoring; 2) Fate and exposure assessment; 3) Hazard assessment; 4) Risk assessment and evaluation and 5) Understanding and meeting stakeholder needs (see figure 2).

Sampling, measuring and monitoring

Across EU regulation, initiatives and missions, there is a need for harmonised definitions in accordance with different environmental matrices for sampling, measuring, and monitoring of MNPs. Standardised sampling, measuring, and monitoring of MNPs are also required by several policy initiatives. CUSP will develop and adapt existing analytical workflows for detection, identification, and quantification of MNPs in environmental and biological matrices, such as air, drinking water, food and human and animal tissues and cells.

Fate and exposure assessment

There is a need for the assessment of human exposure to MNPs via air, water, and food. CUSP will investigate the fate of fragments, spheres, fibres, and sizes of

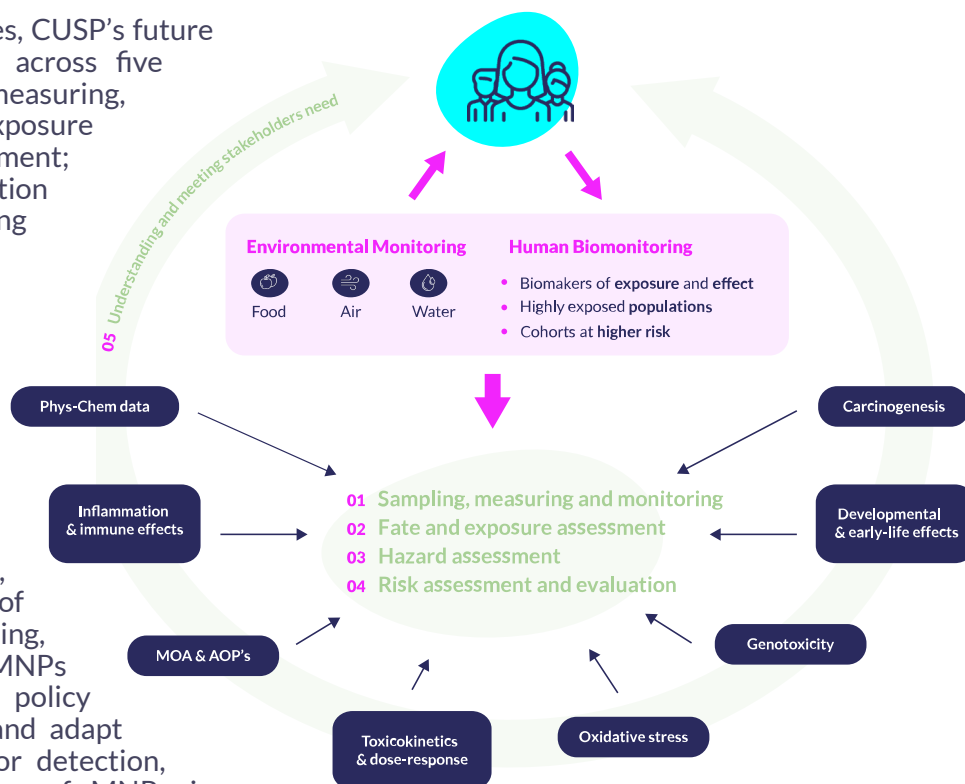


Figure 2: Overview of CUSP main areas of contribution.

polymers commonly found in occupational settings and in the environment (PE, PP, PA, PVC, PET and tyres). Existing environmental fate models will be adapted to model the fate and behaviour of MNPs. Human biomonitoring will be used to establish MNPs internal exposure estimates.

Hazard assessment

There is a lack of comprehensive health and safety information on all substances placed on the market and, in particular, on polymers. CUSP will provide information on the possible harmful impact of MNPs on pregnancy and early life; allergic diseases and asthma; the human intestinal tract; the immune system; and on the carcinogenicity of MNPs as well as other critical hazards (see figure 3). The areas where CUSP projects are most likely to contribute are: MNPs shape and surface area; non-human data for acute toxicity; testing data on repeated dose toxicity and non-animal data and methods (NAMs); (Q)SAR; as well as in vitro data and Adverse Outcome Pathways (AOPs).

Risk assessment and evaluation

Methodologies for chemical risk assessment that consider the whole life cycle of substances, materials, and products are needed to create non-toxic material cycles². CUSP will investigate the applicability of existing risk assessment frameworks when it comes to MNPs, including chemicals and nanomaterial risk assessment under REACH and Food Safety Regulations. Furthermore, CUSP will develop risk evaluation frameworks tailored to the different sources, fate, exposure route and scenarios, hazardous

effects and risk indicators of different types and shapes of MNPs. SciRAP (Science in Risk Assessment and Policy) evaluation criteria (www.Scirap.org) will be applied to ensure regulatory reliability and relevance of data produced by the projects.

Understanding and meeting stakeholder needs

Continuous dialogue with policy makers, regulators, and other stakeholders in the plastic value chain is vital to ensure that developed tests, methodologies, and frameworks are societally relevant. CUSP will establish a forum for researchers and stakeholders to discuss challenges that should be addressed.

Stakeholders include the European Commission, national environmental and health authorities, plastic-related industries, consumer associations, and non-governmental organizations.

CUSP will reach out to and interact with more than 500 different stakeholders to understand the most important knowledge gaps, the main research needs from a regulatory perspective, and the potential regulatory gaps. All this information will be fed into a public searchable online database on research projects and regulatory initiatives (www.plasticheal.dk).

² <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

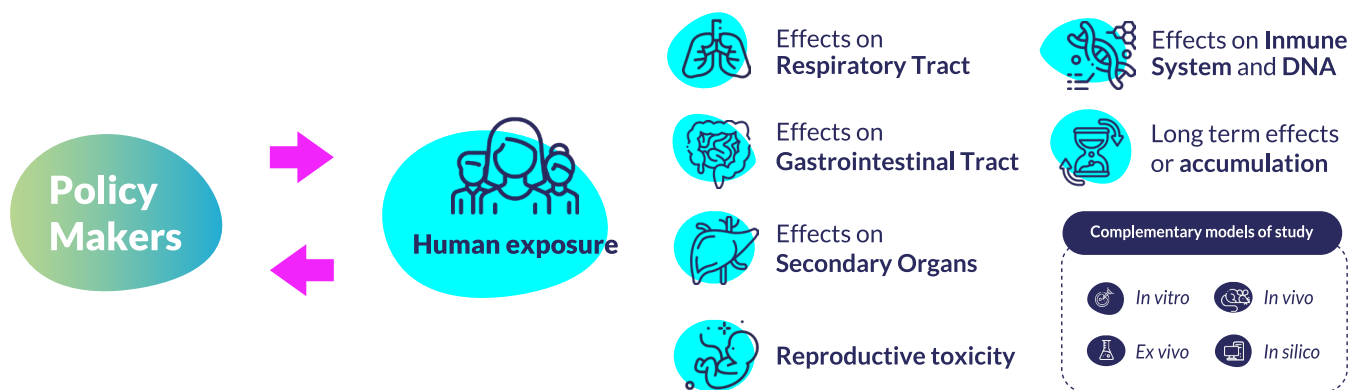


Figure 3. Visual summary of the data that will be generated in CUSP.

Contact us at
www.cusp-research.eu
hello@cusp-research.eu

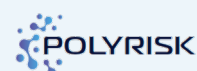
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