



EU regulation on microplastics and nanoplastic: present action, plans and needs

CUSP workshop

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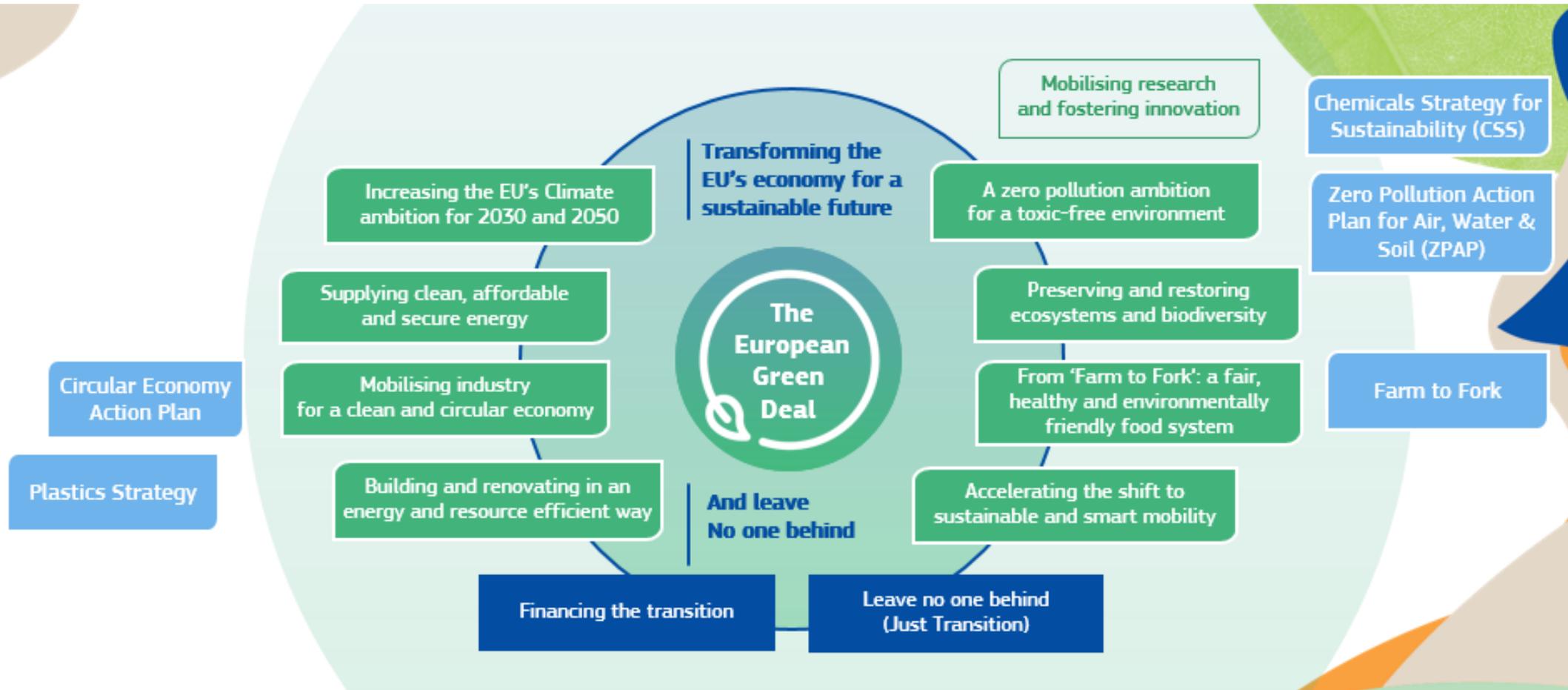
European Commission

DG ENV B2 – Safe and sustainable chemicals

Overview

- Policies and objectives to reduce (micro)plastics pollution
- On-going actions and status
- Gaps with regard to microplastics to support EU policy
- Policy needs regarding microplastics research

The European Green Deal



Policies and objectives

- **Prevention**

- *Circular Economy Action Plan and Plastics Strategy:*

- *Restricting the use of **intentionally added microplastics** in products (REACH restriction)*
 - *Reduce **unintentional release of microplastics***

- **Minimisation and control**

- *Zero Pollution Action Plan:*

- *Reduce plastic litter at sea by 50% by 2030*
 - *Reduce microplastics released into the environment by 30% by 2030*

- *Plastics Strategy & Circular Economy Action Plan*

- *Reduce littering, increase recycling (packaging)*
 - *Close the gaps in scientific knowledge related to the risk and presence of microplastics (environment, drinking water, food)*

Relevant regulatory frameworks

- Chemicals legislation (REACH)
- Several sector- and product-specific legislations (tyre labelling, detergents regulation, construction products, textiles labelling, ESPR)
- Water legislation (drinking water, water framework and EQS directives)
- Food contaminants regulation
- International dimension: 5th United Nations Environment Assembly adopted “End Plastic Pollution: towards an international legally binding instrument”
 - Preamble highlights that “plastic pollution includes microplastics”.

REACH restriction

- Covers intentionally used microplastics: bans, reporting, instructions
- COM proposal currently discussed in the Reach Committee
 - Adoption foreseen in 2023
- Key points:
 - Restriction based on ENV RA (not sufficient data for HH RA)
 - No lower size limit in the scope: covers all microplastics
 - Need for analytical methods for implementation and enforcement
 - Practical limit of 0.1 μm set for enforcement purpose, until analytical methods are available

Unintentional microplastics

- Originally determined as most important sources:
 - Pellets: small granules that are intermediate raw material to manufacture plastic items
 - Tyres
 - Textiles - clothes
- Three additional sources identified in the 'draft IA study' and by stakeholders:
 - Paints: marine paints, road markings, architectural paints, ...
 - Geotextiles: used in construction e.g. for building roads, coastal & flooding protection
 - Soluble films in detergent capsules for laundry and dishwashers

Possible legislative proposal in 2023

Water legislation

- COM proposal to review the list of pollutants for WFD, EQSD and GWD
 - Development of an harmonised method to measure MP in surface, coastal and groundwaters
 - When method available: inclusion of MP in the watchlists for surface water and groundwater
 - Monitoring of MP for 2 years before setting an EQS or a limit in GWD
- Drinking water directive
 - By January 2024, adopt a methodology for measuring MP for potential inclusion in watchlist, monitoring and reporting
 - Work on-going with JRC. Preliminary results: detection limit of 20 µm proposed

Food contaminants Regulation

- 2016 EFSA statement on the presence of microplastics and nanoplastics in food (<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4501>): list of data gaps,
 - Limited data availability for some foods and drinking water
 - Exposure assessment: more refined estimates are needed
 - Risks for human health ???
- Regulatory measures on MPs in food can only be considered when there is evidence of risks to human health → a human health risk assessment is needed
- EFSA colloquium, May 2021:
 - Some progress has been made, but scientific evidence on human health effects is still limited

Gaps with regard to M(N)P* to support EU policy

- (Harmonised) definitions
- M(N)P sources, breakdown mechanisms / pathways / fate
- Sampling / Identification / Quantification
- Environmental risks / Human health risks / effects
- Economic impact assessment / instruments
- Innovative technologies (tracking, recycling, removal) and digital solutions. Alternatives
- Recall: CUSP Annual meeting CUSP 2022 (June 2022), picked up also in [CUSP policy brief](#) in October 2022

Harmonisation & standardisation

- *Definitions*
 - Common understanding, data collection, modelling, interpretation, response
 - Link to methods/standards that have *adequate scope (e.g. particle size, types covered) and ensure supporting data is collected:*
- *Standard (analytical) methods for identification, quantification in accordance with environmental matrices, in food, biomonitoring,*
- *Methods supporting health & environmental assessment of MP (?)*
- *Performance standards e.g. on unintentional MP releases (tyres, textile, ...)*

Harmonisation & standardisation (2)

- *Analytical methods for products covered by the REACH restriction intentionally added MP*
- *Drinking Water Directive (DWD) (reviewed): establishment of a methodology for measuring MP in drinking water by January 2024*
- *Urban Waste Water Treatment Directive (UWWTD) (under revision): measuring/monitoring of MP*
- *Sewage Sludge Directive (SSD) (under evaluation): measuring MP content in secondary material (e.g. agriculture)*
- *Environmental Quality Standards Directive (EQSD) (under review): measuring MP will be considered*
- *Marine Strategy Framework Directive (MSFD): harmonisation measurement/monitoring methodologies + establishing baselines for quantities with a view to prepare legislative thresholds*
- *Regulatory Framework on contaminants in food: harmonisation of MP definitions and analytical methods*

Data collection and knowledge sharing

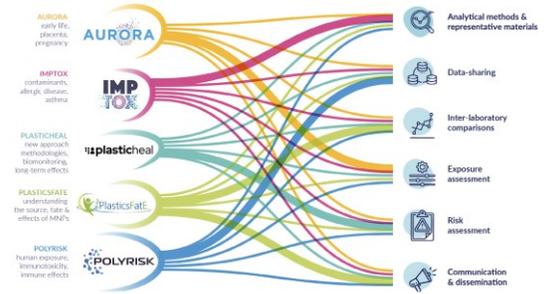
- *Sources (including sectoral impacts e.g. fisheries)*
- *Release mechanisms*
- *Occurrence, pathways & fate (including ultimate sink). Flow model(s)*
- **Environmental risks / Human health risks / effects**
 - **Dose/response; human/microbiota; own/as vectors for toxic chemicals**
- *Interactions with environment, effects on ecosystem functions*
- *ALL microplastics & differences between types of plastics, particles of different sizes (micro/nanoplastics)*

Areas that can be informed by CUSP findings

Chemicals		Plastics		Food		Water		
Zero pollution action plan CUSP will establish whether there are any potential human health risks associated with MNPs and adsorbed/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.	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.	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.	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.	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.	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.	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.	Horizon Europe Mission on Ocean and Waters CUSP will help establish whether there are any potential cancer risks associated with MNPs and adsorbed/desorbed/adsorbed contaminants, which can be used to monitor, evaluate, forecast and validate 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.
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	Garcinogens 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.	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 adsorbed/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.	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.	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.		

CUSP coverage of policy needs

- *Not surprisingly, largest coverage of health impacts and standardisations*
 - **Not all endpoints covered?**
 - **Harmonization/standardisation outputs – delivery in 24/25. Timely?**
- *Use of (and support to agreement on) definitions*
- *(FAIR) data*
- *Assessments with translation for policy*



Conclusions

- **EU policies covering M(N)P are very recent**
- **Concern on M(N)P release across many EU policy strategies (precautionary principle). A number of policy actions are taken whilst knowledge gaps still being filled**

Prevention → Minimisation & Control → Elimination and Remediate

- Immediate needs for policy interventions to ensure data gathering (standard methods for monitoring) and no-regret interventions
- *Quick closing of remaining knowledge gaps (fate, impacts) to ensure policy effectiveness. Comprehensive coverage of all M(N)P >> informed decisions*

Thank you !

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