
**EFSA Scientific Colloquium on micro- and nanoplastics in food and feed – 6-7 May 2021**

# Regulatory needs and challenges to inform fit-forpurpose research activities on micro- and nanoplastics, including outcomes of the SAM report.

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# Overview

- 2019 SAM report on environmental and health risks of microplastics pollution.
- Directive (EU) 2020/2184 on drinking water.
- Regulatory framework on contaminants in food.
- 2016 EFSA Statement on the presence of micro- and nanoplastics (MNPs) in food.
- Information needs for a possible Regulation on microplastics in food.

# 2019 SAM report on environmental and health risks of microplastics pollution

**SAM**: Scientific Advice Mechanism of the European Commission

- Group of Chief Scientific Advisors
  - Gives independent scientific advice to the Commission to inform policy making.
  - Makes recommendations to improve the interaction between policy making and scientific advice.
- SAPEA:
  - The advisors work closely with the Scientific Advice for Policy by European Academies (SAPEA) consortium, which gathers expertise in engineering, humanities, medicine, natural and social sciences from over 100 academies and societies across Europe.
- Secretariat in the EC research and innovation department

# 2019 SAM report on environmental and health risks of microplastics pollution

- SAPEA 2019 report: A scientific perspective on micro-plastics in nature and society

  Review of evidence available on MNPs regarding
  - Natural science perspectives
  - Social and behavioral sciences perspectives
  - Regulatory and legislative aspects

https://www.sapea.info/topics/microplastics/

# 2019 SAM report on environmental and health risks of microplastics pollution

Paper with recommendations for policy regarding MNPs and their rationale:

https://ec.europa.eu/info/sites/info/files/research_and_innovation/groups/sam/ec_rtd_sam-mnp-opinion_042019.pdf

# 2019 SAM report on environmental and health risks of microplastics pollution

- **Occurrence in eco-systems and in humans:**
  - Few studies on the occurrence in nature of microplastics with a size< 10-50 µm.
  - Smaller MNPs remain often below LOD of the analytical methods.
  - Some studies show increasing concentrations with decreasing size.
  - Actually occurring concentrations might be higher than those reported to date.

# 2019 SAM report on environmental and health risks of microplastics pollution

- **Ecological risks:**
  - Evidence is available on irreversible long-term ecological risks for some coastal waters and sediments.
  - If emissions to the environment continue at the current rate or increase, ecological risks could be widespread within a century.
- **Health risks**:
  - Toxicity and ease with which microplastics cross biological barriers is expected to increase with decreasing size.
  - At present there is no evidence of a widespread risk to humans.
  - There are significant grounds for concern.

→ **Better understanding is needed on the effects of different concentrations, compositions, sizes and shapes of MNP on ecosystems and humans.**

# 2019 SAM report on environmental and health risks of microplastics pollution

- **Precautionary measures**
  - The precautionary principle may be invoked when there is uncertainty on risk to human health or the environment of a product or substance.
  - The growing evidence of hazards of MNPs and their long-term persistence justify measures to prevent the release and formation of MNPs in the environment:
    - Limit unnecessary use of plastics
    - Restrict intentional use of microplastics
    - Prevent formation MNPs in life cycle of plastics
    - Avoid release of MNPs in the environment
    - Mitigate and control MNPs from source to sink
  - Experts and society must come to a mutual agreement on risk level and appropriate responses.
  - As plastics play a crucial role in modern life, changing human behavior is essential→ values, motivations, incentives and supportive measures can help to facilitate pro-environmental behavioral changes.

# The EU Strategy for Plastics in a circular Economy

→ protect the environment from plastics pollution

- Make recycling profitable for business
  - By 3030 all plastics on the EU market should be recyclable
- Curb plastic waste
  - Reduction of single-use plastics and plastic fishing gear
  - Restriction of the intentional use of microplastics under REACH
- Stop littering at sea
- Drive investment and innovation to minimize plastic waste at the source
- Spur change across the world

https://ec.europa.eu/environment/waste/plastic_waste.htm

European Commission

# 2019 SAM report on environmental and health risks of microplastics pollution

- Recommendation 1: Broaden policy cover to prevent and reduce microplastics pollution
  - Exploit existing legal instruments to prevent and reduce microplastics in water, air and soil.
    - E.g. Water Framework Directive, air quality legislation, the use of sewage sludge as fertilisers
  - Supplement these policies with measures, which are substance- and context-specific.
    - Science and evidence based
    - Target high-emission and/ or intrinsically hazardous sources of microplastics e.g. tighter licencing conditions for plastic pellet producers under the Industrial Emissions Directive, performance standards for washing machines,...
  - Fill knowledge gaps regarding the presence, concentration and behaviour of nanoplastics pollution.
    - Equip policy makers with the necessary knowledge to take preventive or risk-mitigating measures in case of scientific evidence of human and/or ecological health risks.

# 2019 SAM report on environmental and health risks of microplastics pollution

- Recommendation 2: Address wider socio-economic and trade-off implications of microplastics pollution policy actions
  - Preventive measures should be politically and economically feasible.
  - Impact assessments of the measures should help to ensure a net positive and sustainable benefit to society.
  - The measures should be embedded in the circular economy logic, in order to ensure a better environmental, economic and social outcome of the plastics system as a whole.
  - The public concerns can help to implement difficult environmental and health protection actions.

# 2019 SAM report on environmental and health risks of microplastics pollution

- Recommendation 3: Promote global cooperation, high quality scientific exchange and policy coherence
  - Promote a global treaty to reduce plastics and microplastics pollution.
  - Facilitate international and cross-disciplinary collaboration and knowledge sharing.
  - Promote advances in detection, measurement and analysis and risk assessment methodologies.
  - Encourage comprehensive dose/response and no-effect studies.
  - Initiate the development of consensual international definitions and standards for measurement and monitoring.

# Regulatory measures to protect human health

- EU Drinking Water Directive
- EU Regulatory Framework on Contaminants in Food

# EU Drinking Water Directive

- Directive (Dir. (EU) 2020/2184)
  - The Directive introduces a **watch list mechanism** to add substances of growing concern in a flexible way and to monitor them. The first watch list shall be established by 12 January 2022.
  - By 12 January 2024, the Commission shall adopt delegated acts in order to supplement this Directive by **adopting a methodology to measure microplastics** with a view to including them on the watch list with substances of concern to the public or the scientific community on health ground.
  - The watch list mechanism will enable **follow-up on new knowledge** about the relevance for human health of emerging compounds and on new knowledge about the most appropriate monitoring approaches and methodologies.
  - No later than 12 January 2029, the Commission shall submit a **report** to the European Parliament and to the Council on the potential threat from microplastics to sources of water intended for human consumption.

# Regulatory framework contaminants in food

- Council Regulation (EEC) No 315/93
  - Food containing a contaminant in an amount which is unacceptable from the public health viewpoint shall not be placed on the market.
  - Contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all the stages.
  - In order to protect public health the Commission may where necessary establish the maximum tolerances for specific contaminants.
- Commission Regulation (EC) 1881/2006
  - Establishes maximum levels for certain contaminants in food.

➔ MLs can be established when evidence becomes available, which indicates a **risk to human health**

➔ MLs are established on the basis of **occurrence data** according to the ALARA principle

# Regulatory framework contaminants in food

- Commission Recommendations
  - To gather occurence data
  - To develop mitigation measures (‘prevention is better than cure’)
  - To describe/encourage/oblige good agricultural/ manufacturing/ storage practices
  - To set Guideline Levels/ Target Levels/ Action Levels

# 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

- Based on a conservative estimate the presence of microplastics in seafood would have a small effect on the overall exposure to additives or contaminants.
- Toxicity and toxicokinetic data are lacking for both microplastics and nanoplastics for a human risk assessment.
- List of data gaps, which need to be filled to allow a consumer risk assessment

# Regulatory needs

- Regulatory measures for micro- and nano-plastics in food can only be considered when there is evidence that MNPs in food could cause risks to human health→ a human health risk assessment is needed.
  - Occurence data
    - Limited availability for some foods and drinking water, more data are needed
  - Exposure assessment
    - Rough estimates, suggest an intake up to the weight of 1 credit card in microplastics each week.
    - More refined estimates are needed
  - Risks for human health ???
    - Microbiological risks
    - Chemical risks due to absorbed chemicals
    - Risks caused by the particles themselves?
- Despite of the public concerns, it would be preliminary to regulate micro- and nano-plastics in food.

# Regulatory needs

- Top priority should be:
  - To harmonise the definition of micro- and nano-plastics
  - To develop validated analytical and sampling methods
  - To harmonise method requirements

- Once the methods are available work can be started on
  - Toxicological and toxico-kinetic studies
  - Gathering occurence data
  - Identifying sources of microplastics in food
  - Development of good practices to mitigate microplastics in food.

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# Questions?

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