COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Overarching statement on the potential risks from exposure to microplastics

Background

1.   Plastic pollution has been widely recognised as a global environmental problem (Villarrubia-Gómez *et al*., 2018). The adverse effects of plastic litter have been widely documented for marine animals (*e.g.* entanglement, ingestion and lacerations); however, the potential risks from exposure to smaller plastic particles *i.e.* micro- and nanoplastics in humans are yet to be fully understood.

Scope and purpose

2.   As part of horizon scanning, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) identified the potential risks from microplastics as a topic it should consider. Upon review of the literature, it was decided that nanoplastics should also be included. An initial scoping paper was presented to the COT in October 2019 (TOX/2019/62)[1], since when the topic and additional information has been discussed several times by COT with the final substantive discussion in December 2020. A list of all discussion papers considered by the COT during the review is given in Annex A.

3.   The purpose of this overarching statement is to bring together these discussions, summarise the COT conclusions reached to date and provide a high-level overview of the current state of knowledge, data gaps and research needs with regards to this topic.

4.   Future sub-statements, which will consider in detail the potential toxicological risks of exposure from microplastics *via* the oral and inhalation routes, are intended to provide supplementary material for this overarching statement. The Committee has discussed a review of the potential risks from oral exposure of microplastics (resulting from their presence in food and bottled drinks). A review of the potential risks of microplastics *via* the inhalation route will be produced jointly with the Committee of

---

[1] TOX/2019/62 is available on the [COT website](#).

Medical Effects of Air Pollutants (COMEAP) Secretariat at Public Health England. The need for additional reviews of other significant routes of exposure will also be considered.

Definitions

5.   For the purposes of this overarching statement, microplastics and nanoplastics have been differentiated solely on the basis of size without consideration of other properties characteristic of the nanoscale.

Microplastics

6.   Currently there is no internationally agreed definition of a microplastic, however, publications by Verschoor (2015) and Hartmann *et al*., (2015) have proposed criteria and considerations to be included in the definition of microplastics. In Europe, the European Chemicals Agency (ECHA) has proposed a regulatory definition for a microplastic under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (ECHA, 2019). In the US, the California Water Boards also recently published a proposed definition of microplastics in drinking water in March 2020[2].

7.   Verschoor (2015) included 5 major properties to be considered including the chemical composition, physical state, particle size, solubility in water and degradability. On a similar note Hartmann *et al*., (2015) proposed seven criteria; chemical composition, solid state, solubility, size, shape and structure, colour and origin (*i.e.* primary or secondary, as discussed in the following paragraphs).

8.   In Europe, the definition proposed by ECHA for a microplastic is a "material consisting of solid polymer-containing particles, to which additives or other substance(s) may have been added, and where ≥ 1% w/w have (i) all dimensions 1 nm ≤ x ≤ 5 mm or (ii) for fibres, a length of 3 nm ≤ x ≤ 15 mm and length to diameter ratio of >3. Polymers that occur in nature that have not been chemically modified (other than by hydrolysis) are excluded, as are polymers that are (bio)degradable." (ECHA, 2019).

9.   The current adopted definition of microplastics in drinking water by the California Water Boards is: "Microplastics in drinking water are defined as solid polymeric materials to which chemical additives or other substances may have been added, which are particles which have at least two dimensions that are greater than 1 and less than 5,000 μm. Polymers that are derived in nature that have not been chemically modified (other than by hydrolysis) are excluded." (California Water Boards, 2020).

---

[2] Further information on the California Water Boards activity on this topic are available on the California Water Boards website.

10.   As evidenced above, definitions for microplastics are broad. Therefore, for the purposes of this document, the COT has adopted a working definition that microplastics are defined as synthetic particles or heavily modified natural particles with a high polymer content that are submicron-mm in size (0.1 to 5,000 µm or micrometres). Plastics that are below this size range are classed as nanoplastics (*i.e.* 1 nm to 0.1 µm).

11.   The Committee also noted that microplastic particles that are present in the environment are not stable in size; meaning that as the duration of the degradation process lengthens, the particle size continues to become smaller by fragmentation.

Nanoplastics

12.   Nanoplastics are plastic particles with a diameter from 1 nm to 0.1 µm. Nanoparticle is a general term based on the physical properties for a variety of chemical compositions. There is currently no further proposed definition.

13.   A number of documents have assessed the risks of nanomaterials and provided guidance on their assessment, which could also apply to nanoplastics. For example, the European Food Safety Authority (EFSA) Scientific Committee published an opinion on the potential risks arising from nanoscience and nanotechnologies on food and feed safety in 2009 (EFSA, 2009). This opinion did not intend to provide any definitions; however, the term nanoscale refers to a dimension of the order of 100 nm and below. Engineered nanomaterial was described as any material that is deliberately created such that it is composed of discrete functional and structural parts, either internally or at the surface, many of which will have one or more dimensions of the order of 100 nm or less.

14.   The EFSA Scientific Committee recommended that the addition of other metrics (*i.e.* specific surface area which is independent of the agglomeration status of particles) should be included into the current definition of nanoscale materials (EFSA, 2009).

15.   In 2011, EFSA published a guidance document on how EFSA's Panels should assess potential risks related to certain food-related uses of nanotechnology. New guidance on assessing the safety for humans and animals of nanoscience and nanotechnology applications in the food and feed chain was published in 2018 (EFSA, 2018).

16.   The EFSA 2018 guidance was said to be applicable for: a material that meets the criteria for an engineered nanomaterial, as outlined in Novel Food Regulation (EU) No 2015/2283[3] and Regulation (EU) No 1169/2011[4] (*i.e.* have particle sizes in the defined nanoscale; 1-100 nm), a material that contains particles having a size above 100 nm which could retain properties that are characteristic of the nanoscale (not further elaborated), a material that is not engineered as nanomaterial but contains a fraction of

---

[3] The Novel Food Regulation can be found in the EUR-Lex website.
[4] Regulation (EU) No. 1169/2011 can be found in the EUR-Lex website.

particles (<50% in the number-size distribution) with one or more external dimensions in the size range 1-100 nm, a nanomaterial having the same elemental composition but that occurs in different morphological shapes, sizes, crystalline forms and/or surface properties, and a nanoscale entity that is made or natural materials.

17.   In July 2020, EFSA held a public consultation on its draft Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles[5]. The draft guidance outlines appraisal criteria grouped in three sections, to confirm whether or not the conventional risk assessment should be complemented with nano-specific considerations.

18.   The first group addresses solubility and dissolution rate as key physicochemical properties to assess whether consumers will be exposed to particles. The second group establishes the information requirements for assessing whether the conventional material consists of small particles or contains a fraction thereof, and its characterisation. The third group describes the information to be presented for existing safety studies to demonstrate that the fraction of small particles, including those at the nanoscale, has been properly evaluated. Post-finalisation, this guidance was to completement the EFSA 2018 guidance (as described above) (EFSA, 2020).

19.   To make clear, the above nano- definitions (from paragraphs 13-16) are based on EFSA Guidance, but the applicability of their guidance for the risk assessment of nanomaterials could also apply to nanoplastics.

Types

20.   Microplastics can be divided into two major types. Firstly, those that are deliberately manufactured to be in the size range of 0.1 to 5,000 μm called primary microplastics, which are intentionally used in personal care products (*i.e.* microbeads) or for various industrial applications. Secondary microplastics can be formed in the environment due to fragmentation of larger pieces of plastic (*e.g.* toys, plastic bags, food contact materials, polymer coatings *e.g.* in fruit) caused by a culmination of physical, biological and photochemical degradation. Secondary microplastics have been termed microplastic particles (MPPs). MPPs can be further degraded to form nanoplastics, as defined above.

21.   Besides the types (and sources) mentioned above, within the scientific field there is some debate as to whether rubber tyre particles should be considered microplastics. Tyres were initially made of natural rubber from the Brazilian rubber tree (*Hevea brasiliensis*). Currently, tyres are synthesised from a mixture of natural and synthetic materials. Synthetic rubbers are made from petroleum products and are functionalised with the addition of sulfur (1-4%), zinc oxide (1%), carbon black/silica (22-40%) and oil (Kole *et al*., 2017).

---

[5] Further details on the public consultation are available on the EFSA website.

22.   Car tyres release wear particles through mechanical abrasion, resulting from contact between the road surface and the tyre. The amount and particle size are dependent on several factors such as climate (temperature), composition and structure of the tyre, tyre age, road surface, driving speed and style, and nature of the contact. As such, tyre wear particles could be described as another environmental source of microplastics, depending on the presence of synthetic materials in their composition (Baensch-Baltruschat *et al*., 2020) (Kole *et al*., 2017).

Characteristics

Chemical composition

23.   The chemical composition of microplastics can vary (Rochman *et al*., 2019). Some can be made from single monomer repeats (*i.e.* polymers) such as polyethylene (PE) and polypropylene (PP), which are common in food packaging applications, and some are made from two monomers (*i.e.* co-polymers), for example styrene-butadiene.

24.   The composition can also vary based on the addition of filler compounds or on the presence of incidental compounds (*e.g.* impurities stemming from manufacturing processes). Examples include additives that are required to preserve the stability of the polymer, impurities deriving from the manufacturing process, and the potential presence of unreacted monomers. Furthermore, other substance(s) may be added to improve the functionality of the polymer, for example, pigments, lubricants, thickeners, anti-static agents, anti-fogging agents, nucleating agents and flame retardants.

Sources

25.   Both nano- and microplastics (NMPs) are persistent environmental contaminants and have been detected in both the aquatic (*e.g.* oceans, freshwater rivers and lakes) and terrestrial (*e.g.* landfills, agricultural land from utilisation of plastic mulch, wastewater, sewage sludge, compost and anaerobic digestate) environments, often far removed from the point of manufacture or use of the original plastic materials. Due to their small size (*i.e.* low mass), they are present in both indoor and outdoor air (Schneider *et al*., 1996; Gasperi *et al*., 2018).

26.   Due to their widespread presence in the environment, microplastics also occur in food (*e.g.* seafoods, beer, salt and honey, tea, vegetables) and drinks (*e.g.* bottled water, milk, soft drinks) (Toussaint *et al*, 2019).

27.   Plastics for use in a medical setting can also degrade to form NMPs. This includes wear particles from joints (*e.g.* polyethylene for hip prostheses (Merola & Affatato, 2019)) and biodegradable sutures. Note that these sources do not result from environmental exposures, as they are produced *in situ* in the body and remain in the affected area (*e.g.* joints) and/or further degrade there. Further note that this

degradation is regulated under Regulation (EU) 2017/745 concerning the safety of medical devices[6].

Physicochemical properties

28.   There are currently only limited analytical methods available to detect and quantify the presence NMPs in various matrices. These include Fourier-transform infrared spectroscopy (FT-IR), Nile Red staining techniques, Micro-Raman spectroscopy, quantitative ^{1}H nuclear magnetic resonance spectroscopy (qNMR) (Peez *et al*., 2019) and mass-spectroscopy; however, each of these methods has its own associated limitations (Nguyen *et al*., 2019).

29.   Additionally, there are neither standardised testing protocols for different matrices (*i.e.* air, soil, food and water), nor standard refence materials for analysis, characterization and quantification of micro and nanoplastics. No single technique is suitable for all plastic types and for all particle sizes or shapes. Therefore, the utilization of either a suite of methods or generation of new techniques will be necessary.

30.   Comparison and replication of studies can be difficult due to differences in sampling, extraction, purification and analytical methods for enumerating and characterising microplastics. These methods are not yet standardized or subject to interlaboratory validation. Contamination with airborne microplastics or cross-contamination of samples also pose a concern, so suitable control samples may be difficult to obtain.

31.   Most studies have performed tests on pristine particles; however, this may not be representative of what is present in the environment (*i.e.* particles have not been subject to environmental degradative processes). Therefore, it is important to consider variability among samples and batches of pristine particles when comparing studies of the same polymer type.

Physical properties

32.   As mentioned in earlier paragraphs, NMPs can differ in their shape (*e.g.* spherical, granules, fragments, fibres, spheroids, pellets, flakes and beads) size (*e.g.* nano-, micro-, macro), density, surface charge, *etc.* The consideration of physical properties during hazard and/or risk assessment of plastic particles is important because their interactions with biological systems can vary with differences in their size and shape (Nel *et al*., 2009), even with the same chemical composition.

---

[6] Regulation (EU) 2017/745 is available on the [EUR-Lex website.](#) Note that hip, knee, and shoulder replacements have been reclassified as medical devices falling within class III.

33.   The physical properties and morphologies of tyre materials can also vary under different sampling conditions. Those collected from road runoff and shredded tyres have elongated shapes, whilst samples generated from road simulator systems in laboratories range from jagged, droplets, granules, warped, porous, irregular, and near spherical (Wagner *et al*., 2018). As for the size distribution range of tyre wear and tear particles, a review by Kole *et al*., (2017) revealed that this could be from 6-350,000 nm. This wide size distribution range was attributed to several factors including the use of difference size metrics (*e.g.* particle mass versus particle numbers), analytical difficulties to separate tyre from road particles, and the large variation in experimental conditions and analytical equipment.

Chemical properties

34.   A particle's chemical properties such as charge or zeta potential (when particles are immersed in a conducting liquid *e.g.* water) are dependent on its chemical composition.

35.   A particle's properties can also be influenced and changed by its surface chemistry. Each particle could have its own unique corona consisting of proteins adsorbed from plasma and/or intracellular fluid, adsorbed chemicals from the environment (*e.g.* persistent organic pollutants, pharmaceutical compounds, metals) or microbiological organisms.

36.   The physicochemical properties of micro and nanoplastics can change over their life cycle and can also affect each other. For example, physical degradation resulting in the formation of nano-sized plastic particles and/or plastic particles with different shapes can generate a higher number of particles and thus gives rise to a larger total surface area and higher particle number which in turn affects the concentration. The weathering process can change the surface chemistry and size of microplastics, and chemical migration from the MPPs into the surrounding medium results in altered stability which in turn changes the physical degradation processes.

Hazard identification

37.   There are four morphological and chemical characteristics of microplastics, *i.e.* physicochemical properties, which influence their potential hazards. These are:

  i).   Physical (*e.g.* bulk, which could lead to gut blockage, as observed in aquatic and avian species);
  ii).   Chemical composition (unbound monomers, additives, sorbed chemicals from the environment *e.g.* persistent organic pollutants and metals);
  iii).   Metabolism or degradation to form monomers or other derivatives, some of which could be chemically reactive (*e.g.* isocyanates from polyurethane) and;
  iv).   The presence of biofilms (attachment and colonisation of microorganisms on the plastics).

38.   Due to the small size of some NMPs, uptake across the gastrointestinal tract (GIT) and uptake into internal tissues is possible and thus they may have both local and systemic effects. Particles <50 μm can be absorbed from the gut *via* inter-cellular gaps and by phagocytic and endocytic pathways but only those of <1-2 μm in size are able to cross cell membranes of internal organs.

39.   In terms of microplastic fibres/airborne NMPs, the Committee previously reviewed the studies from Pimentel *et al*., (1975), Hillerdal *et al*., (1988) and Pauly *et al*., (1998) on the *in vivo* effects of occupational exposure to synthetic fibres. The Committee concluded that the morphology of such NMPs is critical, as long-term exposures could lead to chronic bronchitis and/or other respiratory diseases, depending on particle size, shape and rigidity.

40.   The UK Food Standards Agency (FSA) is currently performing a critical literature review on the microbiological colonisation of micro- and nanoplastics and their significance to the food chain (FS307021)[7]; the project is scheduled for completion in early 2021. The critical review is expected to present an overview of NMPs in the environment, the interaction of NMPs and micro-organisms, the identification of key pathways by which these microbiologically contaminated materials could enter the food chain from environmental sources (*e.g.* water, soil, and air), and the risk(s) that these might pose to the consumer (FSA, 2020).

Analytical detection methodologies

41.   From the literature, the detection methods described for microplastics include one or more of the following steps: sample collection and extraction (or degradation) of biogenic matter, detection and quantification (enumeration) and, the characterisation of the plastic (*i.e.* its chemical composition or polymer type) (Nguyen *et al*., 2019; Kwon, *et al*., 2020). It is important to note that during all these steps precautions to avoid contamination from particles in the air, or with fibres from clothing, equipment or the reagents used, should be optimised (see *Figure 1*.)

42.   As seen in *Figure 1*, the majority of biological samples have been taken from aquatic species. The pre-separation method is dissection which recovers MPPs >500 μm, then followed by separation methods including density separation (floatation, centrifugation and ultrasonic separation), digestion using enzymes and various compounds (*e.g.* hydrogen peroxide, hydrochloric acid, potassium hydroxide) and filtration techniques. The analytical method is split between three categories: visual microscopic analysis (coupled with or without staining), vibration spectroscopy (*e.g.* FT-IR and Raman spectroscopy) and mass spectroscopy, the last of which is suitable for the characterisation, quantification and identification of nanoplastics (*e.g.* thermodesorption gas chromatography with mass spectrometric detection (TDS-GC-

---

[7] Further details concerning this research project (FS307021) are available on the FSA website.

MS) and pyrolysis coupled with gas chromatography and mass spectroscopy (py-GC-MS)).

43.	Personal communications with National Reference Laboratories in the UK revealed that organic contaminant analysis usually applies only to the edible portions of food and that contaminants adsorbed to microplastics are generally not taken into account when measuring residues in foodstuff. Although it was noted that this would be method dependent rather than an intrinsic property (Gilbert, personal communication, 2020).

44.	For example, when analysing fish - the head, digestive tract, offal and bones are removed before analysis. It is expected that the majority of microplastics will be in the GIT; therefore, any contaminants associated with them would not directly contribute to measured contaminant levels. However, depending on the nature of the microplastic (*e.g.* size, type of plastic, age) contaminants may be desorbed in the stomach and may contribute to the measured concentration in the edible parts of the fish (depending on partition between MPP and extraction solvent).

Sources of exposure

45.	This section addresses two possible sources of exposure; exposure from food and drink (*e.g.* bottled water) and exposure from environmental sources (*e.g.* air, soil and drinking water).

Food and bottled water

46.	NMPs found in food are commonly attributed to environmental sources, rather than originating from the food itself. It is hypothesised that the concentration of NMPs in food and drinks could increase during processing, arising from manufacturing equipment, and workers clothing. Fadare *et al*., (2020), using FT-IR and SEM, have also identified and characterised microplastics in food and drinks stemming from consumer plastic food containers. There is also an increase in the number of studies reporting the presence of MPPs in food crops as a result of agricultural practices such as the use of sludge and plastic mulching. The effect of other processes (*e.g.* cooking and baking) on the content of plastics in food is not yet known.

47.	As highlighted in earlier sections, the methods for determining microplastics in foods have not been standardised and harmonised. This also includes the methods for sampling and the availability of reference materials.
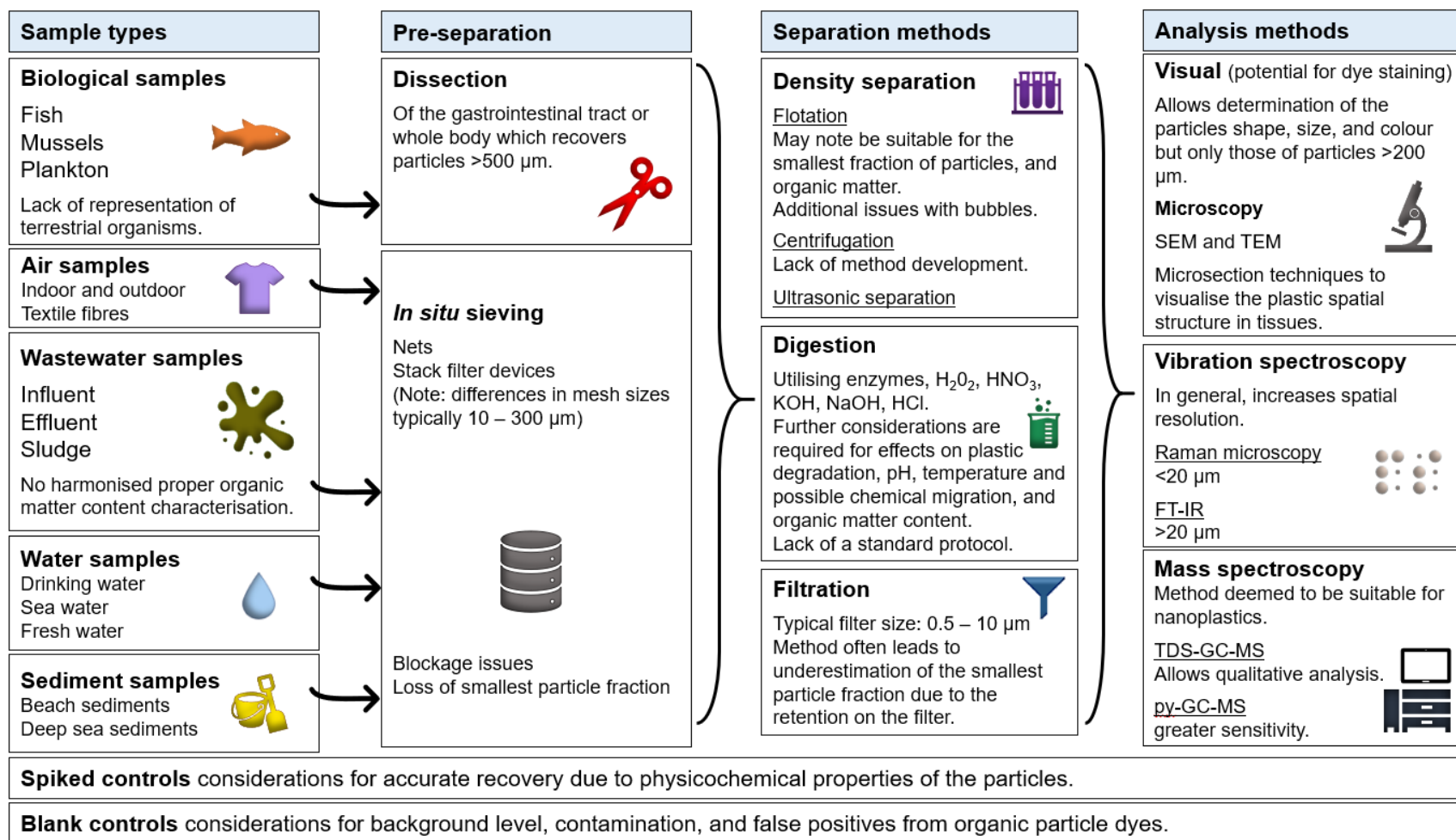
Sample types

Biological samples

Fish
Mussels
Plankton

Lack of representation of terrestrial organisms.

Air samples
Indoor and outdoor
Textile fibres

Wastewater samples

Influent
Effluent
Sludge

No harmonised proper organic matter content characterisation.

Water samples
Drinking water
Sea water
Fresh water

Sediment samples
Beach sediments
Deep sea sediments

Pre-separation

Dissection

Of the gastrointestinal tract or whole body which recovers particles >500 µm.

In situ **sieving**

Nets
Stack filter devices
(Note: differences in mesh sizes typically 10 – 300 µm)

Blockage issues
Loss of smallest particle fraction

Separation methods

Density separation

Flotation
May note be suitable for the smallest fraction of particles, and organic matter.
Additional issues with bubbles.

Centrifugation
Lack of method development.

Ultrasonic separation

Digestion

Utilising enzymes, H_2O_2, HNO_3, KOH, NaOH, HCl.
Further considerations are required for effects on plastic degradation, pH, temperature and possible chemical migration, and organic matter content.
Lack of a standard protocol.

Filtration

Typical filter size: 0.5 – 10 µm
Method often leads to underestimation of the smallest particle fraction due to the retention on the filter.

Analysis methods

Visual (potential for dye staining)

Allows determination of the particles shape, size, and colour but only those of particles >200 µm.

Microscopy

SEM and TEM

Microsection techniques to visualise the plastic spatial structure in tissues.

Vibration spectroscopy

In general, increases spatial resolution.

Raman microscopy
<20 µm

FT-IR
>20 µm

Mass spectroscopy
Method deemed to be suitable for nanoplastics.

TDS-GC-MS
Allows qualitative analysis.

py-GC-MS
greater sensitivity.

Spiked controls considerations for accurate recovery due to physicochemical properties of the particles.

Blank controls considerations for background level, contamination, and false positives from organic particle dyes.

Figure 1 provides an overview of the methodologies utilised in the separation and analysis of microplastics and nanoplastics in complex environmental samples including: biological samples (fish, mussels and plankton), air samples (indoor and outdoor, synthetic textile fibres), wastewater samples (influent, effluent and sludge), water samples (drinking water, sea water and fresh water) and sediment samples (adapted from Nguyen *et al*., 2019). Abbreviations: H_2O_2 = hydrogen peroxide; HNO_3 = nitric acid; KOH = potassium hydroxide; HCl = hydrochloric acid; SEM = Scanning electron microscope; TEM = Transmission electron microscopy; FT-IR = Fourier-transmission infrared; TDS-GC-MS = Thermodesorption gas chromatography-mass spectrometry; py-GC-MS = Pyrolysis gas chromatography-mass spectrometry

Seafood

48.   Evaluations by the EFSA Panel on Contaminants in the Food Chain (CONTAM) focused on the presence of NMPs in seafood (EFSA, 2016). The occurrence of microplastics has been reported in seafood (in fish, average of 1 - 7 particles per fish; in shrimp average of 0.75 particles/g; in bivalves, average of 0.2-4 (median value) particles/g), honey (0.166 fibres/g and 0.009 fragments/g), beer (0.025 fibres/mL, 0.033 fragments/mL and 0.017 granules/mL) and salt (0.007-0.68 particles/g), with most of the data being on seafood.

49.   It had been postulated that MPPs could act as a vehicle for metal (*e.g.* aluminium, chromium, cobalt, iron, manganese, nickel, zinc, cadmium and lead) transport, however, the EFSA CONTAM Panel could not identify a study that assessed the contribution of metals adsorbed to microplastics in food to human exposure.

50.   The EFSA CONTAM Panel also considered the microbial contamination of microplastics and its relevance to food and consequence(s) to human health; however, due to data limitations it was not possible to perform a more detailed risk assessment. In order to fill this data gap, as indicated in paragraph 40, the UK FSA is performing a critical literature review on the microbiological colonisation of micro- and nanoplastics and the significance to the food chain (FS307021)[8].

51.   In terms of filler materials, the EFSA CONTAM Panel reported that microplastics can contain ~4% of additives and that plastics can adsorb chemicals, and that both can be organic or inorganic. The trophic transfer of contaminants (like persistent organic pollutants) has been reported and biomagnification[9] has been shown. The most commonly reported plastic additives and adsorbed chemicals reported at the time of the EFSA review include phthalates, bisphenol A, polybrominated diphenyl ethers, polyaromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs).

52.   The EFSA CONTAM Panel used the highest concentrations of PAHs and PCBs that had been reported in microplastics deposited at beaches, 24,000 ng/g and 2,750 ng/g, respectively, as a conservative scenario and calculated that this would lead to an estimated additional exposure of 170 and 19 pg/person/day of PAHs and PCBs, respectively.

53.   EFSA had previously estimated the median dietary exposure to PAHs by the European population to be 3.8 µg/day and exposure to PCBs to be 0.3-1.8 µg/day. The increases in these dietary exposures from consuming a portion of mussels per day (225 g) would be 0.001-0.006% for the PAHs and 0.004% for the PCBs.

54.   For fish, data on microplastics only in the digestive tract were available and the digestive tract is usually discarded and not consumed. The EFSA CONTAM

---

[8] Further details concerning this research project (FS307021) are available on the [FSA website](#).
[9] Biomagnification describes the increasing build-up of a toxic substance(s) within organisms that happens at each stage of the food chain.

Panel considered that the quantity of microplastics in the edible tissue of fish was "likely to be negligible". A conservative estimate of exposure to microplastics after consumption of a portion of mussels (225 g) was made by EFSA; this was 7 μg of plastics (EFSA, 2016).

Bottled water

55.   In terms of bottled drinking-water, the major polymer type detected is polyethylene terephthalate (PET), which is the most commonly used polymer in bottle manufacturing. Varied quantities and morphology of microplastic particles have been reported, depending on material type. The source of microplastic is either the packaging itself (*e.g.* lid cracking or other mechanical stress) (Winkler *et al*., 2019) or through the manufacturing process.

NMPs in the diet

56.   From the food items described above, humans can be exposed to NMPs in the diet, though the quantitative estimation of this is difficult. Presently, the risks from this exposure route to humans have yet to be fully characterised (Lu *et al*., 2019; van Raamsdonk *et al*., 2020).

57.   From the available toxicokinetic data in animal studies, uptake and distribution of MPs in tissues is partially determined by particle size. Particles >150 μm usually do not translocate across the gut epithelium, whilst smaller particles especially those within the nanoscale (1 nm to 0.1 μm) have the potential for uptake by organs (as mentioned previously). Microplastics may be taken up into cells but there is a lack of information on possible metabolism.

58.   While studies in mice have reported that microplastics can perturb gut microbiota processes (Lu *et al*., 2018; Deng *et al*., 2017), the Committee concluded that these data could not be easily compared with each other and so it was difficult to draw any meaningful conclusions.

59.   Although the presence of microplastics in honey, beer and salt (Liebezeit and Liebezeit, 2013; 2014) has been reported, the studies have their limitations, including the small sample size and, most importantly, the methodology for identification and quantification of the microplastics involved a simple staining method (fuchsin and Rose Bengal). Particles were not further characterised with other methods such as FT-IR or Raman spectroscopy.

60.   In general, the associated uncertainties with the potential risks from exposure to NMPs in food are:

- The unavailability of harmonised methodologies to characterise, quantify and identify NMPs;
- The lack of toxicokinetic and toxicity data;
- The paucity of available data for microplastics in different food types and matrices and;
- The difficulty of performing an accurate exposure assessment and therefore a robust risk assessment.

Environmental sources

Air

61.   Environmental exposure to airborne microplastics is dependent on the wide distribution of their sources. Synthetic textiles and erosion of synthetic rubber tyres are the most reported sources of airborne microplastics within the literature. Resuspended city dust which contains a fraction of settled synthetic fibres/rubber tyres is a secondary source of airborne microplastics. Wind transfer is estimated to be responsible for 7% of the ocean's contamination (Boucher & Friot, 2017).

62.   There is still limited information regarding the concentrations of airborne microplastics, however, the Dris *et al*., (2016, 2017) studies carried out in Greater Paris found indoor concentrations of 1-60 fibres/m^3 and outdoor concentrations of 0.3-1.5 fibres/m^3. Data for Central London on deposition rates of microplastics have also been reported, and these range from 575-1,008 fibres/m^2/day (Wright *et al*., 2020). Although, these numbers are affected by climate conditions and seasonality. They are also affected by the sampling and analytical methodologies used.

63.   The fate and dispersion of microplastics in outdoor environments are dependent on several factors. These include vertical pollution concentration gradient (higher concentrations near the ground due to deposition and settling), wind speed and direction, land topography, precipitation and temperature. Concentrations of airborne microplastics in outdoor air are expected to be low, due to dilution.
64.   The indoor behaviour of airborne microplastics is dependent on factors including room partition, ventilation and airflow.

65.   Atmospheric deposition of MPPs onto food prior to consumption must also be considered as a potential source of exposure.

66.   Catarino *et al*., (2018) compared the potential exposure of humans to household dust fibres during a meal to compare with amounts of MPPs present in edible mussels from Scottish waters collected throughout 2015. The mean number of MPPs in *Modiolus modiolus* was 0.086/gram wet weight (n=6). In *Mytilus* spp. the mean number of MPPs/gram wet weight was 3.0 (n=36). Fibres were the most common shape morphology of MPPs detected, utilising FT-IR and Nile Red staining techniques. PET was estimated to be the most common plastic type. The authors estimated that microplastic ingestion by humans *via* consumption of mussels was 123 MPPs/y/capita in the UK, however, the risk of plastic ingestion *via* mussel consumption was minimal when compared to fibre exposure during an evening meal *via* dust fallout in a household at ~14,000-68,000 MPPs/y/person. These values were based on the following assumptions; deposition of 1 particle per 20 minutes for an area of 4.32 cm^2, extrapolate this value for a 12.5 cm radius plate, resulting in 114 particles (assuming constant exposure rate), equating to ~42,000 MPPs consumption/year/person, for 20 minutes during consumption of an evening meal. During a cooking period of 20 minutes, a constant fibre fallout of 5 MPPs per 4.32 cm^2 was assumed, the potential human ingestion increases to ~207,000 MPPs/year/person. These values were then corrected by 33% which was reported to be the proportion of petrochemical based fibres found in dust by Dris *et al*., (2017).

67.   An American study (Cox *et al.*, 2019) has proposed an estimated daily consumption and inhalation of 142 MPPs and 170 MPPs in male adults, respectively. For female adults, the estimated values are 126 MPPs and 132 MPPs, respectively for the same exposure routes. Based on these values, a total annual estimated exposure of ~120,00 and ~98,000 MPPs annually was calculated in male and female adults, respectively. These exposure estimates were based on reported microplastic concentrations in salt, alcohol (beer), seafood (fish, shellfish and crustaceans), added sugars (sugar and honey), water (bottled and tap), and in air. Note that the estimated annual exposure values did not take into account atmospheric deposition of microplastics during food preparation and consumption. The authors are of the view that "these estimates are subject to large amounts of variation; however, given methodological and data limitations, these values are likely underestimates."

68.   Occupational inhalation of microplastics can result in toxicity due either to the particles (*i.e.* physical effect) or their leachates (*i.e.* chemical effect). The response in humans depends on differences on individual metabolism and susceptibility (Amato-Lourenço *et al.*, 2020). It is not yet known how the toxicity of synthetic fibres compares with that of organic/natural fibres (Donaldson & Tran, 2002). It is known that fibres from synthetic textiles are quite flexible (Bunsell (ed), 2018) and hence do not possess the characteristic long thin morphology of asbestos fibres, responsible for their toxicity and carcinogenicity.

69.   The deposition of inhaled microplastics is dependent on the particle's physicochemical properties, as well as the subject's physiology and lung anatomy. Deposition in the upper airways occurs by impaction, while in the small airways it occurs by sedimentation. Fibres have higher potential than spherical particles for penetration due to their high aspect ratio (Donaldson & Tran, 2002). Clearance relies on mechanical processes (*e.g.* mucociliary clearance where the mucous progresses towards the pharynx caused by the beating of cilia), alveolar macrophage phagocytosis and migration, and by lymphatic transport.

70.   In general, the mechanisms of inhaled particle injury include dust overload (high surface area particles induce high chemotactic gradients that prevent macrophage migration), oxidative stress (production of reactive oxygen species, which induces cell injury and release of inflammatory mediators), cytotoxicity (free intracellular particles may damage cellular structures), and translocation (injury of secondary sites and vascular occlusion by particles or increased coagulability). Depending on the nature of the particle and the extent of exposure, such mechanisms might lead to adverse endpoints such as fibrosis, which can develop as a result of chronic cytotoxicity and inflammation.

Soil

71.   Plastic mulch films, greenhouse materials and soil conditioners are direct sources of micro and nanoplastics in agriculture. Indirect sources include general litter, aerial depositing of plastic particles, and the use of treated wastewater and biosolids (*i.e.* sludge). To a lesser extent, composts derived from residential or municipal solid waste and garden organic waste are additional sources of plastic pollution in agroecosystems.

72.   On the soil surface, plastics degrade *via* oxidative degradation which is influenced by various environmental conditions. Plastic particles can form eco-coronas with organic and inorganic soil constituents, which may affect their bioavailability and toxicity.

73.   Based on available information, the uptake of MPPs by plants is generally not expected due to their high molecular weight or their large size. This latter physicochemical property prevents their penetration through the plant cell wall (Teuten *et al*., 2009).

74.   Functionalised multi-wall carbon nanotube uptake has been shown in edible food crops (*e.g. Arabidopsis* leaves; Zhao *et al*., 2017). The proposed pathways for entry include endocytosis *via* the plasmodesmata, passage *via* ion transport channels, carrier proteins or aquaporins, and soil or carbon root exudate mediated entry (Ng *et al*., 2018). It is not known whether some MPPs can also be taken up by such mechanisms.

75.   Information regarding the bioavailability and bioaccumulation of microplastics in soil organisms is generally lacking. Results from studies in earthworms reveal that they either survive and disperse micro- and nanoplastics *via* defecation or cast shedding (Huerta Lwanga *et al*., 2016), or they die as a result of high exposures.

76.   Future research on the analytical and methodological aspects of sampling and quantification are required to perform an accurate assessment of the presence of micro and nanoplastics in soil. Baseline studies on soil exposure will establish the scale of contamination and can potentially enable the determination of sources (*e.g.* micro and/or nanoplastics fibres and microbeads as indicators of sludge application for agriculture or tyre dust as an indicator for road runoff). Additional studies are required to assess and better understand microplastic transfer from soil to humans through uptake in food webs and through leaching to groundwater (Hurley & Nizetto, 2018).

Water

77.   The COT reviewed numerous studies in relation to exposure to NMPs *via* ingestion of water including the World Health Organisation (WHO) report on microplastics in drinking-water (WHO, 2019), key literature articles (Zucarello *et al*., 2019; Pivonsky *et al*., 2018) and UK specific data from a Department for Environment, Food and Rural Affairs (Defra) funded study titled, "Sink to River – River to Tap: A review of potential risks from nanoparticles & microplastics." (research code: WT2219)[10].

78.   In this, the UK water industry has been found to be successful at removing microplastics (>25 μm in size) from raw water or crude sewage at >99.99% efficiency. Particles were detected in raw water with an average concentration of 4.9 MPPs/L, potable water had an average of 0.00011 MPPs/L, whilst the average was 5.1 MPPs/L for wastewater effluent samples (determined utilising FT-IR methodologies). Sludge samples were found to have levels of 2,000 – 4,000 MPPs/g

---

[10] Full report available at the UKWIR website.

dry weight due to the high removal rates of MPPs through both water and wastewater treatment processes.

79.   Smaller particles (*i.e.* <25 µm) were not analysed and as such the report could not comment on how effective water treatment processes are at filtering these materials. The presence of black particles (such as tyre fragments) was also considered, however, these were difficult to quantify utilising FT-IR, and so were not further addressed within the report.

80.   The most common polymer types found in raw water were PE, PET and PP. For potable water, the polymers detected above the limit of quantification were acrylonitrile butadiene styrene (ABS) and polystyrene. It was hypothesised that these polymers were generated within the water treatment works. Polymers that were detected in wastewater influent and effluent samples were PE, PET and PP (UKWIR, 2019).

81.   The WHO Panel concluded that based on the limited evidence available, chemicals and microbial pathogens associated with microplastics in drinking-water pose a low concern for human health, stating that "humans have ingested microplastics and other particles in the environment for decades with no related indication of adverse health effects". Furthermore, drinking-water treatment is effective at removing particles, especially with advanced membrane filtration techniques which is expected to achieve 100% removal of plastic particles: > 0.001 µm for nanofiltration, >0.01 µm for ultrafiltration and >1 µm for microfiltration (WHO, 2019).

82.   No epidemiological data or human studies on ingested microplastics were identified by the WHO Panel at the time of review, most toxicological studies having been focused on aquatic organisms or ecotoxicology. Data from studies in rats and mice were found to be inadequate to inform human health risk assessment of microplastic ingestion.

83.   One of the rat studies assessed by the WHO Panel attempted to establish a no observed adverse effect level (NOAEL) for PET powder (Merski *et al*., 2008). This was an OECD-compliant 90-day dietary study. PET powder was mixed into the diet of Sprague Dawley rats (n=10/sex) and they were dosed with 0, 0.5, 2.5 or 5% PET in the diet. The size and count of the PET particles were not determined/reported; however, the particles were deemed likely to be in the range of 1-50 µm. No treatment related adverse health effects on blood parameters, organ weights or histopathology, as well as mutagenicity, were observed. A NOAEL was not reported by the authors; however, the WHO Panel considered that the NOAEL can be considered as the highest dose tested, ~2,500 mg/kg bw/day (at the highest 5% inclusion in the diet).

84.   A conservative exposure estimate was calculated by the WHO Panel. Several parameters were assumed prior to the calculation. These were the shape (sphere), size in diameter (150 µm), density (2.3 g/cm^3) and the concentration of particles in water (10.4 particles/L). Considering the above assumptions on particle characteristics and a default consumption of drinking water of 2 L/day; an intake of 85 µg of microplastics/day was estimated, which corresponds to 1.4 µg of

microplastics/kg bw/day for a 60 kg adult, although, realistic estimates based on reported data ranged from 0.01 – 8.7 µg of microplastics/kg bw/day.

85.   No adverse health effects were expected from the following chemical contaminants present in microplastics for drinking-water: bisphenol A, cadmium, chlordane, di(2-ehtylhexyl)phthalate, dichlorodiphenyltrichloroethane, hexachlorobenzene, PAHs, polybrominated diphenyl ethers, and PCBs based on margin of exposure (MOE) calculations.

86.   For pathogens in microplastic associated biofilms, the risks were considered to be lower than the risk posed by the high concentrations and diversity of pathogens present in human and livestock waste resulting from inadequate water treatment. Drinking-water treatment processes are designed to remove particles present in the water and the use of disinfection will reduce the potential for any pathogens to be present in drinking-water.

87.   With regards to nanoplastics, there was insufficient information available at the time of review for the WHO Panel to be able to draw conclusions on their toxicity. However, there is no reliable information to suggest that nanoplastics in drinking water are of health concern to humans.

88.   Much like the scenario with food and bottled water, the associated uncertainties with the potential risks from exposure to NMPs in drinking water include:

- The unavailability of harmonised methodologies to characterise, quantify and identify NMPs;
- The lack of toxicokinetic and toxicity data;
- The limited amount of data available for microplastics in drinking water and;
- The difficulty of performing an accurate exposure assessment and subsequent risk assessment.

Other

89.   Other sources of NMPs can include the use of cosmetics containing microbeads, and exposure as a result of abrasion of everyday household objects such as cutlery, toothbrushes, and cups (Rodrigues *et al.,* 2019). It is possible that toddlers may have increased exposure given the number of plastic items they can be exposed to during oral exploration as part of a normal stage of development. Moreover, synthetic fibres present in deposited dust, carpets, soft furnishings *etc.,* may contribute to human exposure to NMPs particularly by young children due to their frequent hand-to-mouth contacts. However, at the time of the COT review, there were no data available for such exposures.

90.   The potential exposure of infants to micro and nanoplastics from breast milk was considered by the COT, specifically relating to its storage in plastic bottles. Available data suggest that the presence of MPPs in bottled water supplied in plastic containers is due to the manufacturing process; however, the quality of the plastic and lid cracking have also been found to contribute to the overall particle number. Thus, it could be hypothesised that breast milk stored by mothers for later personal

use or for donation to hospitals or milk banks in plastic containers may be a potential source of micro and nanoplastic exposure of infants.

91.   A study by Li *et al*., (2020) reported data on the release of microplastics from the degradation of PP feeding bottles during infant formula preparation. The highest release was recorded at 16,200,000 particles/L, and the release was shown to be dependent on water temperature. The majority of microplastics were <20 µm in size. The potential exposure of infants up to 12 months old was estimated to range from 14,600- 4,550,000 particles/infant/day. UK infants were estimated to be exposed to >3 million particles/day. Although the reliability of the methodological protocol was assessed using a recovery test, this was performed with polystyrene microplastic samples rather than PP. If confirmed, this would be a major source of exposure to NMPs.

92.   An ongoing study titled Mothers' Information on Lactation and Collection (MILC) study[11] by Bradman and his colleagues at UC Berkeley is assessing breastmilk collection and storage materials to determine whether inappropriate handling and storage increases chemical contamination in breastmilk; however, it is not clear whether the presence of micro and nanoplastics is within the scope of this research (MILC, 2016). The Secretariat has attempted to contact the researchers for clarification; however, no response had been received by the time of publication.

Tyre and road wear particles (TRWPs)

93.   In terms of TRWPs, tyres contain a wide range of chemicals. The bulk of tyre tread is composed of a variety of rubbers, including natural rubber co-polymers, poly-butadiene rubber, styrene-butadiene rubber, nitrile rubber, neoprene rubber, isoprene rubber, and polysulfide rubber. The interaction of tyres and road surface alters both the chemical composition and the characteristics of particles generated compared to the original tyre tread due to heat and friction, as well as incorporation of materials such as environmental "*dust*", brakes, fuels, the atmosphere, and roadway particles.

94.   Human exposure to chemicals leached from tyres, shredded tyres, and tyre wear material can occur by dermal exposure from environmental sources and ingestion of contaminated materials, as well as inhalation of airborne particulate matter derived from tyre wear material.

95.   The COT have previously reviewed risk assessments carried out by various groups such as the European Tyre and Road Wear Platform; Tyre Industry Project (Jekel, 2019), Joint Research Centre (Grigoratos & Martini, 2014), Defra (AQEG, 2019), Health and Safety Executive (RUBIAC, 2007; HSE, 2011), Committee on Medical Effects of Air Pollution (COMEAP, 2015; 2020), WHO (WHO, 2013), National Institute for Public Health and the Environment (Verschoor *et al*., 2016), and ECHA (ECHA, 2017).

96.   The COT concluded that the literature data on exposure to particles from tyre wear would need separate consideration from microplastic exposure from food, since

---

[11] Further information is available from the [MILC study website](#).

the particles are chemically quite different in their polymeric nature. The COT considered that inhalation was likely to be the most significant route of exposure to TRWPs. The COT was of the opinion that uptake by plants, with subsequent dietary exposure, was unlikely to be a major route. Risk assessments of such materials was potentially considered outside of the scope of the current exercise.

Summary of exposure sources

97.   The routes for which humans can be exposed to NMPs include the oral and inhalation routes. In terms of the oral route, this is a consequence of the consumption of contaminated food products. Foods that have been investigated to date, in which NMPs have been detected, include seafood (*e.g.* mussels), bottled water, and other food products such as beer, honey, salt, vegetables and tea (Toussaint *et al*., 2019). Potential exposure could also arise from consumption of food crops on which have been deposited airborne MPPs. Nanoplastic uptake into edible food crops has also been reported in the literature. Other sources of NMPs have also been discussed in paragraphs 89-92.

98.   The EFSA CONTAM Panel estimated a maximum total consumption of 7 µg of plastics from a serving of mussels (225 g) (EFSA, 2016). The WHO Panel calculated a conservative estimate of exposure from drinking water of 85 µg MPPs/day, which corresponds to 1.4 µg MPPs/kg bw/day for a 60 kg adult (range 0.01-8.7 µg of MPPs/kg bw/day).

99.   Airborne MPPs can also be inhaled. Indoor concentrations of MPPs are thought to be greater than outdoor concentrations due to greater dilution outdoors. Although there is a lack of data on these concentrations, studies from Greater Paris report indoor concentrations of 1-60 fibres/m^3 and outdoor concentrations of 0.3-1.5 fibres/m^3 (Dris *et al*., 2016, 2017). Data for Central London on deposition rates of microplastics range from 575-1,008 fibres/m^2/day (Wright *et al*., 2020). These numbers are affected by climate conditions, and seasonality, but also by the sampling and analytical methodologies.

100.   As mentioned previously, airborne microplastics can be deposited on food products during various processes (*e.g.* from manufacturing, equipment and textiles). Estimates of indoor dust fallout during evening meal preparations were ~14,000-68,000 MPPs/y/person (Catarino *et al*., 2018). Estimated daily consumption and inhalation of 142 and 170 MPPs, respectively were estimated for American adult males by Cox *et al*., (2019). This results in an estimated total annual exposure to ~120,000 and ~98,000 MPPs annually in male and female adults, respectively.

Evaluations by other authoritative bodies

101.   The EFSA 2016 statement (EFSA, 2016) and WHO drinking-water report (WHO, 2019) on NMPs have been summarised in paragraphs 48-54, and paragraphs 81-87, respectively.

102. The following section will provide executive summaries on other evaluations carried out by ECHA, the EU Group of Chief Scientific Advisors; Scientific Advice Mechanism (SAM)[12], EU Science Advice for Policy by European Academies (SAPEA)[13], and Environment and Climate Change Canada and Health Canada (ECCC and HC)[14].

European Chemicals Agency (ECHA)

103. In 2017, the European Commission (EC) requested ECHA to assess the scientific evidence for taking regulatory action at the EU level on microplastics that are intentionally added to products (*i.e.* substances and mixtures). It was identified that intentionally added microplastics have diverse technical functions in several fields[15].

104. In 2019, ECHA published a restriction report in response to the EC's request (ECHA, 2019). In this, ECHA identified four concerns stemming from the potential environmental and human health risks posed by the presence of microplastics in the environment. These were; their size "small (typically microscopic) making them readily available for ingestion and potentially liable to transfer within food chains, very resistant to environmental (bio)degradation, (bio)degrade in the environment progressively *via* fragmentation, and are practically impossible to remove from the environment after release."

105. The ECHA restriction report refers to the EFSA (2016) report on estimating a worst-case scenario for human intake of 7 µg of microplastics (from a 225 g portion of mussels), and based on the conclusions by Lusher *et al*., (2017) this would have a negligible effect on exposure to chemical contaminants and plasticisers in humans.

106. The report concluded that the environmental and health risks posed by microplastics are difficult to quantify and not yet well understood; however, the extent of the hazards and risks posed are of those described in paragraph 104.

107. The Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) provided their opinion on the ECHA restriction report in June 2020 (RAC, 2020; SEAC, 2020).

108. The RAC considered that, "the proposed restriction on polymers as microplastics is the most appropriate Union-wide measure to address the identified risks..." (RAC, 2020).

---

[12] The SAM report is available on the European Commission website.

[13] The SAPEA report is available on the SAPEA website.

[14] The ECCC and HC report is available on the Health Canada website.

[15] For example, in agriculture (in fertilisers and plant protection products), cosmetic products (both in rinse-off and leave-in products), detergents (capsules and maintenance products, paints, coatings and inks (in professional and consumer uses), chemicals used in the oil and gas sector, construction, medicinal products, medical devices, and food supplements and medical food.

109.   The SEAC considered that, "the proposed restriction on intentionally added microplastics is the most appropriate Union-wide measure to address the identified risks…" and that they consider "the definition of microplastics should not set a lower size limit. However, in order to ensure that proposed restriction is implementable, enforceable and monitorable SEAC acknowledges the necessity to set a lower size limit for the conditions of the restriction as 0.1 µm." (SEAC, 2020).

EU Group of Chief Scientific Advisors; Scientific Advice Mechanism (SAM)

110.   In brief, the SAM advisors agreed that most laboratory studies to date do not reflect real-world exposure; and a better understanding is required of the effects of different concentrations, compositions, sizes and shapes of microplastics in ecosystems and humans before robust conclusions can be drawn about real risks.

111.   The limited evidence currently available suggests that microplastic pollution at present does not pose a widespread risk to humans or to the environment. However, there are significant grounds for concern, including "the reported adverse effects of acute occupational exposure to microplastics, animal experiments and what is known about the potential hazards". Hence, it is recommended that precautionary and proportional measures should be taken. The measures should aim to: "a. limit the unnecessary use of plastic; b. restrict the intentional use of microplastics; c. prevent or attenuate microplastic formation over the life-cycle of plastics and plastic-containing products; d. avoid release to the environment as near to the source as possible; and e. mitigate and control at key points in pathways from source to sink."

112.   A clear evidence-based communication of the uncertainties related to the environment, food and human health was also deemed necessary by the SAM advisors.

113.   Three recommendations were made by the SAM advisors. Firstly, the broadening of policy cover to prevent and reduce microplastic pollution. Secondly, to address wider socio-economic and trade-off implications of microplastic pollution and policy actions. Lastly, to promote global cooperation, high-quality scientific exchange and policy coherence (SAM, 2019).

EU Science Advice for Policy by European Academies (SAPEA)

114.   The SAPEA concluded that there is a need for improved quality and international harmonisation of the methods used to assess exposure, fates and effects of micro- and nanoplastics on biota and humans (SAPEA, 2019).

115.   The conclusion of the working group was that there was only limited evidence available but there was no indication of widespread risk to human health from micro- and nanoplastics at present. However, the absence of sufficient evidence on microplastic risks did not allow the working group to conclude with any degree of certainty either that risk is present or that it is absent in nature.

116.   Adverse effects were observed (negative effect on food consumption, growth, reproduction and survival) in laboratory studies once effect thresholds are exceeded. The concentrations utilised were often higher than those reported in the

environment. Additionally, the use of virgin or spherical particles is not representative of NMPs that are present in the environment. Furthermore, short exposure times are often applied in laboratory studies. As such, there is no evidence that the adverse effects observed in laboratory studies reflect those that might occur in humans. Therefore, available data on animal studies limit the reliability of the risk assessments for micro- and nanoplastics.

117.   Chemicals associated with microplastics can have additional human health effect(s) (which was deemed difficult to assess by the SAPEA group), *e.g.* reproductive toxicity and carcinogenicity; however, the relative contribution to chemical exposure of micro- and nanoplastics among the mix of other chemicals probably represents a small proportion to the overall total exposure.

118.   The SAPEA working group recommendations are described in the following paragraphs. Firstly, it was recommended that there is a need to understand the potential modes of toxicity for different size-shape-type of micro and nanoplastics combinations in selected human models, before robust conclusions on actual risks to humans can be made.

119.   Secondly, communicating transparently about the uncertainties in the scientific evidence is a safer approach than assuming a lack of risk, especially in sensitive domains such as food and human health. The SAPEA working group conclude that there is consensus and momentum for action and no evidence of "plastic denial" phenomenon. Due to the lack of scientific understanding, the precautionary principle has been part of the foundation for current regulations.

120.   Close interdisciplinary collaboration between the natural, social and behavioural, and regulatory sciences was recommended as a way forward for addressing the complex issue of plastic waste and pollution.

121.   The SAPEA working group further concluded that it would be important to implement both agreements and legislation which focus on emission reduction and the use of less hazardous materials. Evidence suggests that focus should be on circular economy approaches, away from linear processes and end-of life clean-up.

Environment and Climate Change Canada and Health Canada (ECCC and HC)

122.   ECCC and HC published a report on their science assessment of plastic pollution (ECCC & HC, 2020). The intended purpose of the report is to act as a guide for future scientific and regulatory activities, not to quantify the risks of plastic pollution on the environment or on human health.

123.   The ECCC and HC summarised that humans may be exposed to microplastics *via* the ingestion of food, bottled water, and tap water, as well as through the inhalation of indoor and outdoor air. However, information on the human health effects of microplastics is limited, and further research is required to better inform target tissues, threshold doses, and mode of action.

124.   Although some associations between exposures to high levels of microplastics and adverse health effects in laboratory animals and in humans (from

occupational data) have been reported, the ECCC and HC deemed that "these health effects cannot be linked to exposure in the general population" and noted that conflicting observations have been made for cancers of the respiratory tract and digestive system.

125.   The reviewed scientific literature did not identify a concern for human health; however, the ECCC and HC stressed that there are insufficient data to allow for a robust evaluation of the potential human health risks of ingested microplastics. As for the available inhalation studies, no dose-response relationship has been observed in mortality, survival time, behaviour, clinical observations, or tumour incidence from inhalation exposures.

126.   In terms of the risks from sorbed and chemically bound (*e.g.* persistent organic pollutants) and unbound chemicals (*e.g.* monomers) on plastic particles, current available literature indicates that there is likely a low health concern for human exposure to chemicals from ingestion of microplastics from food or drinking water.

127.   As for the presence and formation of biofilms on the surface of MPPs, the ECCC and HC indicated that there is currently no indication that this would impact human health. Despite limited data, it is anticipated that drinking water treatment processes have the ability to inactivate biofilm-associated microorganisms.

128.   To conclude, the ECC and HC are of the view that due to the considerable uncertainty and the environmental persistence of MPPs, under the precautionary principle, further action is needed to reduce the presence of macro- and microplastics that end up in the environment.

129.   The following research needs were identified in order to carry out a human health risk assessment; development of standardised methods for sampling, quantifying, characterising, and evaluating the effects of macro and microplastics, studies to further understand the extent of human exposure to microplastics and its effect(s) to humans, and lastly, to expand and develop consistent monitoring efforts to include poorly characterised environmental compartments such as soil.

COT evaluation

130. Micro- and nanoplastics are widespread, they are either intentionally added to products or occur as a result of plastics being fragmented down into smaller sizes by natural processes such as wear, weathering and corrosion. There is no internationally agreed definition of what a microplastic is, however, the most widely used size range is from 0.1 to 5,000 µm. Plastic particles that are smaller than the lower range are considered nanoplastics (*i.e.* 1 nm to 0.1 µm).

131. MPPs >150 µm are unlikely to be absorbed. Particles <50 µm could be absorbed from the gut *via* tight junction gaps (paracellular persorption) and endocytic pathways (endocytosis by M cells) but only those of <1-2 µm in size are able to cross cell membranes in tissues.

132. The uptake of these smaller microplastics (*i.e.* <50 µm) is limited (≤0.3%). The absorption and distribution of nanoplastics (up to 7% for <0.1 µm particles) may be more significant than for microplastics (WHO, 2019).

133. Chemical leachates and adsorbed substances from microplastics are not expected to cause adverse health effects in humans as they make only a small contribution to overall exposure from other sources of the same chemical as evidenced by the EFSA, 2016 review and the WHO, 2019 MOE calculations. Other evaluations by ECHA, SAM, SAPEA, ECCC and HC (as summarised in earlier sections) further support this conclusion.

134. As highlighted throughout this document, microplastics can have a wide range of physicochemical properties, depending on the primary purpose of the plastic; however, these properties do not necessarily reflect those of secondary microplastics, where fragmentation has occurred as a result of natural processes (and as such the MPPs are not considered pristine). Additionally, analytical methodology is limited to FT-IR, Nile Red, qNMR, Micro-Raman spectroscopy and mass-spectroscopy. There are no standardised testing methods for different matrices (*i.e.* air, soil, food and water), the available methods have their own associated limitations, and suitable reference materials are not available (see *Figure 1*). Furthermore, no single technique is suitable for all plastic types and for all particle sizes or shapes. Using a suite or generation of new techniques will be necessary.

135. In terms of the toxicity of NMPs, there is no identified NOAEL for each polymer type (except possibly for PET powder at 2,500 mg/kg bw/day in rats as reported by Merski *et al*., 2008, which has several limitations). Available data on the ECHA REACH database relates to the starting materials *i.e.* the monomers. Furthermore, variability in exposure routes must also be considered.

136. Other challenges include the difficulties in the comparison of published studies due to differences in sampling, extraction, purification and because analytical methods for enumerating and characterising microplastics are not yet standardised. The COT noted that different types of plastic particles have been utilised, depending on the specific endpoint or target organ being investigated, which further adds to the challenges of comparing available data. Contamination with airborne microplastics or

cross-contamination of samples also pose a concern, so suitable control samples may be difficult to obtain.

137.   Most studies have been performed with pristine particles; however, these may not be representative of what is present in the environment (*i.e.* particles have not undergone degradative processes in the environment). Therefore, it is important to consider variability among samples and batches of pristine particles when comparing studies on the same polymer type.

138.   The lack of reliable data on exposure and effects of MPPs has been noted by Koelmans *et al*., (2019). They therefore proposed quality assessment criteria to rank the reliability of results published in the literature, with the aim to better understand the potential exposure and to inform human health risk assessments. There are nine criteria based on reproducibility, precision, accuracy and sensitivity; these are sampling method, sample size, sample processing and storage, laboratory preparation, clean air conditions, negative controls, positive controls, core sample treatment and polymer identification. For each criterion, a value of 2 (reliable), 1 (reliable to a limited extent) or 0 (unreliable) is assigned. The "Total Accumulated Score" is calculated by adding scores for individual criteria (maximum 18 points). For data to be considered reliable, a study should preferably have no 'zero' values for any of the individual scores.

139.   Presently, a full risk assessment on the potential toxic effect(s) of micro and/or nanoplastics could not be carried out due to several data gaps including:

- The unavailability of harmonised methodologies to characterise, quantify and identify NMPs;

- The lack of toxicokinetic and toxicity data in general. There is no identified NOAEL for the different polymer types except possibly for PET powder at 2,500 mg/kg bw/day in rats, (see paragraph 83), which had a number of limitations (e.g. particle size and count were not determined/reported);

- The paucity of currently available data for microplastics in different food types and matrices and;

- The difficulty of performing an accurate exposure assessment.

140.   For the reasons above, a case-by-case approach to risk assessments may need to be considered.

Research priorities for risk assessment

141.   Current research efforts from the UK FSA include a critical review of microbiological colonisation of nano-and microplastics (as described in paragraph 40). The National Institute for Health Research Health Protection Unit in Environmental Exposures and Health at Imperial College London are also carrying out research to determine if microplastics have detrimental human health effects[16]. The WHO is following up its report on MPPs in drinking water with a more comprehensive assessment of the potential implications for human health of dietary and inhalation exposure to nano- and microplastic particles[17]. International Life Sciences Institute (ILSI) Europe, in cooperation with a number of public and private organizations, in exploring the possibility of establishing a reference library for MPPs[18].

142.   The COT recommends the following research priorities for the risk assessment of NMPs.

- Comprehensive assessment of MPs and associated contaminant concentrations in different food types (*e.g.* seafood, edible meat tissue and offal, vegetables, fruit, drinks) and matrices (*i.e.* air, soil, food and water) and the impact of the effect of cooking on the desorption and subsequent bioavailability of contaminants/leachates.

- Assessment of the degradation of novel/emerging plastic-based materials on the market such as biobased plastics (*e.g.* bamboo ware, polylactic acid, chitin) and other advanced polymer matrix composite materials during their use and end-of-life for their possible contribution to NMPs. It is unclear whether and by how much they already contribute to the burden of NMPs.

- Studies (*in silico*, *in vitro* and/or *in vivo*) to explore the effect(s) of the same type of NMP on different tissues (*e.g.* heart, brain, liver, stomach, intestines), and of different types of NMP (*e.g.* polymer type, size, shape) on the same target tissue.

- Studies on the persistence and potential accumulation of NMPs in the human body, and on the extent to which NMPs are digestible.

- Investigation of the extent to which NMPs with a range of sizes and compositions are assimilated into human tissues and the development of techniques capable of identifying the presence of microplastics in the human body (*e.g.* in biopsies, samples from tissue banks, if possible, histopathology sections).

---

[16] Further information on other research themes is available on the EEH HPRU website.

[17] Details on the call for experts is available on the WHO website.

[18] Additional information regarding the ILSI Europe initiative on microplastics is available on the ILSI website.

143.   The most significant data gaps hindering a robust risk assessment for exposure *via* the oral route include the lack of:

- Appropriate and harmonised analytical methods for the detection of different NMPs in various food matrices;
- Understanding of human exposure and;
- Human-relevant information on the absorption, distribution, metabolism and excretion (*i.e.* the toxicokinetic profile) and on the toxicity profiles of NMPs.

144.   For the inhalation route the significant data gaps include the lack of:

- Harmonised analytical methods for detection of different NMPs during sample collection;
- Understanding the contribution and effects of different exposure scenarios (*e.g.* indoor and outdoor environments);
- Understanding how different lung disease states may be involved in the observed effects from microplastic exposure and;
- How available occupational data should be extrapolated to the general population.

145.   Microplastic concentrations are expected to increase in the future. Hence, there will be a need to regularly assess the levels of microplastics in relevant food stuffs, water and the air, such as by establishing a monitoring programme. This would best be achieved by collaboration among academia, researchers and government bodies at a national and international level.

COT Conclusions

146.   The COT noted that there are limited data regarding the toxicokinetic fate of orally ingested microplastics in mammalian species, and that MPPs can either remain confined in the GIT, translocate from the GIT into organs or tissues (*via* endocytosis by M cells and paracellular persorption), and/or be excreted (~>90%). No epidemiological or controlled dose studies that evaluated the effects of orally ingested microplastics in humans were identified. There is a similar lack of information on inhaled microplastics.

147.   As such, the COT concludes that based on the available data, it is not yet possible to perform a complete assessment for the potential risks from exposure to micro and nanoplastics *via* the oral and inhalation routes; however, they concur with the conclusions reached by other authoritative bodies (EFSA, WHO, ECCC and HC, SAPEA, SAM, as described in their relevant sections in this document).

148.   The COT concluded that the literature data on exposure to particles from tyre wear would need separate consideration from microplastic exposure from food, since the particles were chemically quite different in their polymeric nature. Risk assessment of such material was considered potentially outside the scope of the current exercise.

149.   The most significant data gaps are the lack of appropriate and harmonised analytical methods for the detection of micro- and nanoplastics (together with suitable reference standards), as well as information on their toxicokinetic and toxicity profiles in/relevant for humans.

150.   The COT highlighted that additional information will be needed from all exposure sources, which include indoor and outdoor air, dust and soil before a risk assessment can be completed. The presence of MPs in food and water needs to be put into perspective with other sources of MPs such as atmospheric fallout.

151.   Comprehensive assessment of microplastics and contaminant concentrations in different foods and the impact of cooking on the desorption and subsequent bioavailability of contaminants/leachates, need to be further investigated to better understand the implications for human health.

152.   Current studies typically focus on only one type of particle/tissue interaction, as such, further research is necessary to explore the effects of the range of particle types in different tissues *in silico, in vitro* and/or *in vivo*. These range of particle types should also take account of emerging/novel plastic-based materials such as bioplastics.

COT
February 2021
Statement Number 2021/02

Abbreviations

ABS	Acrylonitrile butadiene styrene
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
COMEAP	Committee on Medical Effects of Air Pollution
CONTAM	Contaminants in the Food Chain
Defra	Department for Environment, Food and Rural Affairs
EC	European Commission
ECC	Environment and Climate Change
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
FT-IR	Fourier-transform infrared spectroscopy
FSA	Food Standards Agency
GIT	Gastrointestinal tract
HC	Health Canada
ILSI	International Life Sciences Institute
MILC	Mothers' information on lactation and collection
MOE	Margin of exposure
MPPs	Microplastic particles
NEE	Non-exhaust emission
NMPs	Nano- and microplastics
NOAEL	No observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PAHs	Polyaromatic hydrocarbons
PCBs	Polychlorinated biphenyls
PE	Polyethylene
PET	Polyethylene terephthalate
PM_{10}	Particulate matter (10 μm)
PP	Polypropylene
py-GC-MS	Pyrolysis coupled with gas chromatography and mass spectroscopy
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RUBIAC	Rubber Industry Advisory Committee
SAM	EU Group of Chief Scientific Advisors; Scientific Advice Mechanism
SAPEA	EU Science Advice for Policy by European Academies
SEAC	Committee for Socio-economic Analysis
TDS-GC-MS	Thermodesorption gas chromatography with mass spectrometric detection
TWPs	Tyre wear particles
TRWPs	Tyre and road wear particles
UK	United Kingdom
UKWIR	United Kingdom Water Industry Research
US	United States
VOCs	Volatile organic compounds
WHO	World Health Organisation

References

Amato- Lourenço, L., dos Santos Galvão, L., de Weger, L. A., Hiemstra, P., S., Vijver, M. G. and Mauad, T. (2020) An emerging class of air pollutants: Potential effects of microplastics to respiratory human health? Science of the Total Environment 749, 141676.

AQEG. (2019) Non-exhaust emissions from road traffic. Available at: https://ukair.defra.gov.uk/assets/documents/reports/cat09/1907101151_20190709_Non_Exha ust_Emissions_typeset_Final.pdf. Accessed: 17/17/2020.

Baensch-Baltruschat, B., Kocher, B., Stock, F., Reifferschied. G. (2020) Tyre and road wear particles (TRWP) – A review of generation, properties, emissions, human health risks, ecotoxicity, and fate in the environment. Science of the Total Environment 733, 137823.

Barrero-Moreno, J., Senaldi, C., Bianchi, I., Geiss, O., Tirendi, S., Folgado de Lucena, A., Barahona, F., Mainardi, G., Leva, P. and Aguar-Fernandez, P. (2018) Migration of Polycyclic Aromatic Hydrocarbons (PAHs) from plastic and rubber articles - Final report on the development of a migration measurement method. JRC Technical Reports JRC111476. Available at: https://publications.jrc.ec.europa.eu/repository/bitstream/JRC111476/kjna29282enn.pdf. Accessed: 17/08/2020.

Boucher, J. and Friot, D. (2017) Primary microplastics in the Oceans: A global evaluation of sources. Gland, Switzerland: IUCN. Available at: https://portals.iucn.org/library/node/46622. Accessed: 15/12/2020.

Bunsell, A.R. (ed.) (2018) Handbook of Properties of Textile and Technical Fibres, 2nd Edition. Woodhead Publishing/Elsevier Ltd, Duxford.

California Water Boards. (2020) State Water Resources Control Board Resolution No. 2020-0021. Adoption of definition of 'Microplastics in Drinking Water'. Available at: https://www.waterboards.ca.gov/board_decisions/adopted_orders/resolutions/2020/rs2020_0021.pdf. Accessed: 01/09/2020.

COMEAP. (2015) Statement on the evident for differential health effects of particulate matter according to source or components. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/411762/COMEAP_The_evidence_for_differential_health_effects_of_particulate_matter_according_to_source_or_components.pdf. Accessed: 03/01/2020.

COMEAP. (2020) Statement on the evidence for health effects associated with exposure to non-exhaust particulate matter from road transport. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/917308/COMEAP_Statement__on_the__evidence__for__health__effects__associated__with__exposure_to_non_exhaust_particulate_

matter_from_road_transport_-COMEAP-Statement-non-exhaust-PM-health-effects.pdf. Accessed: 19/11/2020.

Cox, K. D., Covernton, G. A., Davies, H. L., Dower, J. F., Juanes, F., Dudas, S. E. (2019) Human consumption of microplastics. Environmental Science & Technology 53, pp. 7068-7074.

Culp, S. J., Gaylor, D. W., Sheldon, W. G., Golstein, L. S. and Beland, F. A. (1998) A comparison of the tumors induced by coal tar and benzo[a]pyrene in a 2-year bioassay. Carcinogenesis 19, pp 117–124.

Deng, Y., Zhang, Y. Lemos, B. and Ren, H. (2017) Tissue accumulation of microplastics in mice and biomarker responses suggest widespread health risks of exposure. Scientific Reports 7, 46687.

Donaldson, K., and Lang Tran, C. (2002) Inflammation caused by particles and fibres. Inhalation Toxicology 14, pp. 5-27.

Dris, R., Gasperi, J., Saad, M., Mirande, C. and Tassin, B. (2016) Synthetic fibres in atmospheric fallout: A source of microplastics in the environment? Marine Pollution Bulletin 104, pp. 290-293.

Dris, R., Gasperi, J., Mirande, C., Mandin, C., Guerrouache, M., Langlois, V. and Tassin, B. (2017) A first overview of textile fibres, including microplastics, in indoor and outdoor environments. Environmental Pollution 221, pp. 453-458.

ECCC & HC. (2020) Science assessment of plastic pollution. Available at: https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/science-assessment-plastic-pollution.html. Accessed: 23/12/2020.

ECHA. (2017) Annex XV Report. An evaluation of the possible health risks of recycled rubber granules used as infill in synthetic turf sports fields. Available at: https://echa.europa.eu/documents/10162/13563/annexxv_report_rubber_granules_en.pdf/dbcb4ee6-1c65-af35-7a18-f6ac1ac29fe4. Accessed: 14/01/2020.

ECHA. (2019) Annex XV Restriction Report Proposal for a Restriction for intentionally added microplastics. Available at: https://echa.europa.eu/documents/10162/05bd96e3-b969-0a7c-c6d0-441182893720. Accessed: 10/11/2020.

EFSA. (2009) The potential risks arising from nanoscience and nanotechnologies on food and feed safety. The EFSA Journal 958, pp. 1-39. Available at: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2009.958. Accessed: 01/09/2020.

EFSA. (2016) Presence of microplastics and nanoplastics in food, with particular focus on seafood. The EFSA Journal 14, 4501. Available at:

https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4501.
Accessed: 04/08/2020.

EFSA. (2018) Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health. The EFSA Journal 16, 5327. Available at: http://www.efsa.europa.eu/en/efsajournal/pub/5327. Accessed: 01/09/2020.

EFSA. (2020) EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. Available at: https://www.efsa.europa.eu/sites/default/files/consultation/consultation/Draft-Nano-Technical-Guidance-For-Public-Consultation.pdf. Accessed: 10/11/2020.

Fadare, O. O., Wan , B., Guo, L-H. and Zhao, L. (2020) Microplastics from consumer plastic food containers: Are we consuming it? Chemosphere 253, 126787.

FSA. (2020) A critical review of microbiological colonisation of nano-and microplastics (NMPs) and their significance to the food chain. Available at: https://www.food.gov.uk/research/research-projects/a-critical-review-of-microbiological-colonisation-of-nano-and-microplastics-nmps-and-their-significance-to-the-food-chain. Accessed: 24/08/2020.

Gasperi, J., Wright, S., L., Dris, R., Collard, F., Mandin, C., Guerrouache, M., Langlois, V., Kelly, F. J. and Tassin, B. (2018) Microplastics in air: Are we breathing it in? Current Opinion in Environmental Science & Health 1, pp. 1-5.

Gilbert, M. (2020) Personal communication.

Grigoratos, T., Martini, G. (2014) Non-exhaust traffic related emissions. Brake and tyre wear PM; Literature review. Available at: https://publications.jrc.ec.europa.eu/repository/bitstream/JRC89231/jrc89231-online%20final%20version%202.pdf. Accessed: 17/08/2020.

Hartmann, N. B., Hüffer, T., Thompson, R. C., Hassellöv, M., Verschoor, A., Daugaard, A. E., Rist, S., Karlsson, T., Brennholt, N., Cole, M., Herrling, M. P., Hess, M. C., Ivleva, N. P., Lusher, A. L. and Wagner, M. (2019) Are we speaking the same language? Recommendations for a definition and categorization framework for plastic debris. Environmental Science and Technology 53, pp. 1039-1047.

Hillerdal, G., Steinholtz, Rosenhall, L. and Lindgren, A. (1988) Pulmonary fibrosis caused by synthetic textile fibres? VIIth International Pneumoconioses Conference, pp. 1405-1407. Available at: https://www.cdc.gov/niosh/docs/90-108/pdfs/90-108- 2.pdf?id=10.26616/NIOSHPUB90108. Accessed: 15/08/2019.

HSE. (2011) Safe to Breathe: Dust and fume control in the rubber industry. Available at: https://www.hse.gov.uk/pubns/iacl95.htm. Accessed: 02/01/2019.

Huerta Lwanga, E., Gertsen, H., Gooren, H., Peters, P., Salánki, T., van der Ploeg, M., Besselingm E., Koelmans, A. A. and Geissen, V. (2016) Microplastics in the terrestrial ecosystem: Implications for *Lumbricus terrestris* (Oligochaeta, Lumbricidae). Environmental Science & Technology 50, pp. 2685-2691.

Hurley, R. R., Nizzetto, L. (2018) Fate and occurrence of micro(nano) plastics in soils: Knowledge gaps and possible risks. Current Opinion in Environmental Science and Health 1, pp. 6-11.

Jekel, M. (2019) Scientific report on tyre and road wear particles, TRWP, in the aquatic environment a European TRWP Platform publication. Available at: https://www.tyreandroadwear.com/wp-content/uploads/2019/10/FINAL-ScientificReport-on-Tyre-and-Road-Wear-Particles.pdf. Accessed: 19/12/2019.

Koelmans, A. A., Nor, N. H. M., Hermsen, E., Kooi, M., Mintenig, S. M., De France, J. (2019) Microplastics in freshwaters and drinking water: Critical review and assessment of data quality. Water Research 155, pp. 410-422.

Kole, P. J., Löhr, A. J., Van Belleghem, F. G. A. J. and Ragas, A. M. J. (2017) Wear and Tear of Tyres: A stealthy source of microplastics in the environment. International Journal of Environmental Research and Public Health 14, 1265.

Kwon, J-H., Kim, J-W., Pham, T. D., Tarafdar, A., Hong, S., Chun, S-H., Lee, S-H., Kang, D-Y., Kimn, J-Y., Kim, S-B. and Jung, J. (2020) Microplastics in Food: A review on analytical methods and challenges. International Journal of Environmental Research and Public Health 17, 6710.

Li, D., Shi, Y., Yang, L., Xiao, Kehoe, D. K., Gun'ko, Y. K., Boland, J. J. and Wang, J. J. (2020) Microplastic release from the degradation of polypropylene feeding bottles during infant formula preparation. Nature Food 1, pp. 746-754.

Liebezeit, G. and Liebezeit, E. (2013) Non-pollen particulates in honey and sugar. Food Additives and Contaminants. Part A, Chemistry, Analysis, Control, Exposure and Risk Assessment 30, pp. 2136–2140.

Liebezeit, G. and Liebezeit, E. (2014) Synthetic particles as contaminants in German beers. Food Additives and Contaminants. Part A, Chemistry, Analysis, Control, Exposure and Risk Assessment 31, pp. 1574–1578.

Lu, L., Wan, Z., Luo, T., Fu, Z. and Jin, Y. (2018) Polystyrene microplastics induce gut microbiota dysbiosis and hepatic lipid metabolism disorder in mice. Science of the Total Environment 631-632, pp. 449-458.

Lu, L., Lou, T., Zhao, Y., Cai, C., Fu, Z. and Jin, Y. (2019) Interaction between microplastics and microorganism as well as gut microbiota: A consideration on environmental animal and human health. Science of the Total Environment 667, pp. 94-100.

Lusher, A., Hollman, P. and Mendoza-Hill, J. (2017) Microplastics in fisheries and aquaculture. Status of knowledge on their occurrence and implications for aquatic organisms and food safety. FAO Fisheries and Aquaculture Technical

Paper No. 615. Available at: http://www.fao.org/3/a-i7677e.pdf. Accessed: 14/12/2020.

Merola, M. and Affatato, S. (2019) Materials for hip prostheses: A review of wear and loading considerations. Materials 12, 495.

Merski, J. A., Johnson, W. D., Muzzio, M., Lyang, N. L. and Gaworski, C. L. (2008) Oral toxicity and bacterial mutagenicity studies with a spun bound polyethylene and polyethylene terephthalate polymer fabric. International Journal of Toxicology 27, pp. 387-395.

MILC. (2016) Mothers' information on lactation and collection (MILC) study. Available at: http://www.milcstudy.com/. Accessed: 14/08/2020.

Nel, A. E., Mädler, L., Velegol, D., Xia, T., Hoek, E. M. V., Somasundaran, P., Klaessig, F., Castranova, V. and Thompson, M. (2009) Understanding biophysicochemical interactions at the nano-bio interface. Nature Materials 8, pp. 543–557.

Ng, E-L., Huerta Lwanga, E., Eldridge, S. M., Johnston, P., Hu, H-W., Geissen, V., Chen. D. (2018) An overview of microplastic and nanoplastic pollution in agroecosystems. Science of the Total Environment 627, pp. 1377- 1388.

Nguyen, B., Claveau-Mallet, D., Hernandez, L. M., Xu, E. G., Farner, J. M. and Tufenkji, N. (2019) Separation and analysis of microplastics and nanoplastics in complex environmental samples. Accounts of Chemical Research 52, pp. 858-866.

Pauly, J. L., Stegmeier, S. J., Allaart, H. A., Cheney, R. T., Zhang, P. J., Mayer, A. G. and Streck, R. J. (1998) Inhaled cellulosic and plastic fibres found in human lung tissue. Cancer Epidemiology, Biomarkers and Prevention 7, pp. 419-428.

Peez, N., Janiska, M-C. and Imhof, W. (2019) The first application of quantitative ^{1}H NMR spectroscopy as a simple and fast method of identification and quantification of microplastic particles (PE, PET, and PS). Analytical and Bioanalytical Chemistry 411, pp. 823-833.

Pimentel, J. C., Avila, R. and Lourenço, A. G. (1975) Respiratory disease caused by synthetic fibres: a new occupational disease. Thorax 30, pp. 204-219.

Pivonsky, M., Cermakova, L., Novotna, K., Peer, P., Cajthaml, T. and Janda, V. (2018) Occurrence of microplastics in raw and treated drinking-water. Science of the Total Environment 643, pp. 1644-1651.

RAC. (2020) Opinion on an Annex XV dossier proposing restrictions on intentionally added microplastics. Available at: https://echa.europa.eu/documents/10162/23665416/rest_microplastics_opinion_rac_16339_en.pdf/b4d383cd-24fc-82e9-cccf-6d9f66ee9089. Accessed: 14/12/2020.

Rochman, C., M., Brookson, C., Bikker, J., Djuric. N., Earn, A., Bucci, K., Athey, S., Huntington, A., McIlwraith, H., Munno, K., De Frond, H., Kolomijeca, A., Erdle, L., Grbic, J., Bayoumi, M., Borrelle, S. B., Wu, T., Santoro, S., Werbowski, L. M., Zhu, X., Giles, R. K., Hamilton, B. M., Thaysen, C., Kaura, A., Klasios, N., Ead, L, Kim, J., Sherlock, C., Ho, A. and Hung, C. (2019) Rethinking microplastics as a diverse contaminant suite. Environmental Toxicology and Chemistry 38, pp. 703-711.

RUBIAC. (2007) RUBIAC statement on occupational cancers. Available at: https://www.hse.gov.uk/rubber/cancerstatement.htm. Accessed: 17/07/2020.

SAM. (2019) Environmental and Health Risks of Microplastic Pollution. Available at: https://ec.europa.eu/info/sites/info/files/research_and_innovation/groups/sam/ec_rtd_sam-mnp-opinion_042019.pdf. Accessed: 17/08/2020.

SAPEA. (2019) A scientific perspective on microplastics in nature and society. Available at: https://www.sapea.info/wp-content/uploads/report.pdf. Accessed: 23/12/2020.

SEAC. (2020) Opinion on an Annex XV dossier proposing restrictions on intentionally added microplastics. Available at: https://echa.europa.eu/documents/10162/5a730193-cb17-2972-b595-93084c4f39c8. Accessed: 14/12/2020.

Schneider, T., Burdett, G., Martinon, L., Brochard, P., Guillemin, M., Teichert, U. and Draeger, U. (1996) Ubiquitous fiber exposure in selected sampling sites in Europe. Scandinavian Journal of Work, Environment and Health 22(4), pp. 274-284.

Teuten, E. L., Saquing, J. M., Knappe, D. R. U., Barlaz, M. A., Jonsson, S., Björn, A., Rowland, S. J., Thompson, R. C., Galloway, T. S., Yamashita, R., Ochi, D., Watanuki, Y., Moore, C., Viet, P. H., Tana, T. S., Prudente, M. P., Boonyatumanond, R., Zakaria, M. P., Akkhavong, K., Ogata, Y., Hirai, H., Iwasa, S., Mizukawa, K., Hagino, Y., Imamura, A., Saha, M. andTakada, H. (2009) Transport and release of chemicals from plastics to the environment and to wildlife. Philosophical Transactions of the Royal Society B 364. Article ID: 20080284.

Toussaint, B., Raffael, B., Angers-Loustau, A., Gilliland, D., Kestens, V., Petrillo, M., Rio-Echevarria, I.M. and Van den Eede, G. (2019) Review of micro-and nanoplastic contamination in the food chain. Food Additives & Contaminants: Part A, 36(5), pp. 639-673.

UKWIR. (2019) Sink to river – River to tap: A review of potential risks from nanoparticles and microplastics. Available at: https://ukwir.org/view/$NvDnwfm. Accessed: 10/09/2019.

van Raamsdonk, L. W. D., van der Zande, M., Koelmans, A. A., Hoogenboom, R. L. A. P., Peters, R. J. B., Groot, M. J., Peijnenburg, A. A. C. M. and Weesepoel, Y. J. A. (2020) Current insights into monitoring, bioaccumulation, and potential health effects of microplastics present in the food chain. Foods 9, 72.

Verschoor, A. J. (2015) Towards a definition of microplastics. Available at: https://www.rivm.nl/bibliotheek/rapporten/2015-0116.pdf. Accessed: 04/08/2020.

Verschoor, A., de Valk, E. (2016) Emission of microplastics and potential mitigation measures: Abrasive cleaning agents, paints and tyre wear RIVM Report 2016-0026. Available at: https://www.rivm.nl/bibliotheek/rapporten/2016-0026.pdf. Accessed: 17/08/2020.

Villarrubia-Gómez, P., Cornell, S.E. and Fabres, J. (2018). Marine plastic pollution as a planetary boundary threat–The drifting piece in the sustainability puzzle. Marine Policy, 96, pp. 213-220.

Wagner, S., Hüffer, T. Klöckner, P., Wehrhahn, M., Hofmann, T. and Reemtsma, T. (2018) Tire wear particles in the aquatic environment - A review on generation, analysis, occurrence, fate and effects. Water Research, 139, pp. 83-100.

Winkler, A., Santo, N., Ortenzi, M. A., Bolzoni, E., Bacchetta, R. and Tremolada, P. (2019) Does mechanical stress cause microplastic release from plastic water bottles? Water Research 116, 115082.

WHO. (2013) Review of evidence on health aspects of air pollution – REVIHAAP Project Technical Report. Available at: http://www.euro.who.int/__data/assets/pdf_file/0004/193108/REVIHAAP-Finaltechnical-report.pdf. Accessed: 03/01/2020.

WHO. (2019) Microplastics in drinking-water. Available at: https://www.who.int/water_sanitation_health/publications/microplastics-in-drinking-water/en/. Accessed: 17/08/2020.

Wright, S., L., Ulke, J., Font, A., Chan, K. L. A. and Kelly, F. J. (2020) Atmospheric microplastic deposition in an urban environment and an evaluation of transport. Environment International 136, 105411.

Zhao, Q., Ma, C., White, J. C., Dhankher, O. P., Zhang, X., Zhang, S. and Xing, B. (2017) Quantitative evaluation of multi-wall carbon nanotube uptake by terrestrial plants. Carbon 114, pp. 661-670.

Zucarello, P., Ferrante, M., Cristaldi, A., Copat, C., Grasso, A., Sangregorio, D., Fiore, M., and Oliveri Conti, G. (2019) Exposure to microplastics (<10 μm) associated to plastic bottles mineral water consumption: The first quantitative study. Water Research 157, pp. 365-371.

Discussion papers presented to the COT on the potential risks from exposure to microplastics

TOX/2019/62 (22/10/2019)   Paper 1: Scoping paper on the potential risks from exposure to microplastics

TOX/2020/15 (11/03/2020)   Paper 2: Potential risks from exposure to microplastics: First draft overarching statement (Cover page)

        Annex A   First draft overarching statement on the potential risks from exposure to microplastics

        Annex B   Paper for information: Background on tyre wear

        Annex C   Paper for information: Update on literature

TOX/2020/40 (15/09/2020)   Follow-up to Paper 2: Overarching statement on the potential risks from exposure to microplastics (Cover page)

        Annex A   Second draft overarching statement on the potential risks from exposure to microplastics

TOX/2020/58 (01/12/2020)   Follow-up to September 2020 meeting: Overarching statement on the potential risks from exposure to microplastics: Third draft (Cover page)

        Annex A   Third draft overarching statement on the potential risks to microplastics