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

First Draft Overarching statement on the potential risks from exposure to microplastics

Background and introduction

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 elucidated.

2. As part of horizon scanning, the 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.

3. This overarching statement bring together the discussions that took place at the COT meetings from October 2019 – March 2020, and summarises the conclusions reached to date and explains the current state of knowledge, data gaps, and research needs with regards to this topic.

Definitions

4. For the purposes of this paper microplastics and nanoplastics have been differentiated solely on the basis of size without consideration of properties characteristic of the nanoscale.

Microplastics

5. Microplastics are defined as synthetic particles or heavily modified natural particles with a high polymer content that are submicron in size (0.1 to 5,000 µm or micrometres).

6. It should be noted that currently there is no internationally agreed definition of what a microplastic is, however, publications by Verschoor (2015) and Hartmann *et al*., (2015) have proposed criteria and considerations to be included in the definition of

microplastics. The California Water Boards also recently published a proposed definition of microplastics in drinking water in March 2020[1].

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. 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).

Nanoplastics

9. Nanoplastics measure from 1 nm to 0.1 µm. It is a general term based on the physical properties for a variety of chemical compositions.

10. 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.

11. 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).

12. In 2011, the 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).

13. 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

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

2015/2283[2] and Regulation (EU) No 1169/2011[3] (*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, a material that is not engineered as nanomaterial but contains a fraction of 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.

Types

14. There are two major types of microplastics. Firstly, those that are deliberately manufactured to be in the size range of (0.1 to 5,000 µm) are called primary microplastics, which are intentionally added for use in personal care products (*i.e.* microbeads) or for various industrial applications or they can either be formed in the environment due to fragmentation of larger pieces of plastic (*e.g.* toys, plastic bags, food contact materials, polymer coatings for example in fruit) caused by a culmination of physical, biological and photochemical degradation termed; secondary microplastics. Microplastic particles (MPPs) can be further degraded to form nanoplastics which are less than 0.1 µm in length.

15. Within the scientific field there is also some debate as to whether rubber tyre particles are considered microplastics. Tyres were initially made of natural rubber from; the Brazilian rubber tree (*Hevea brasiliensis*), however, currently tyres are synthesised from a mixture of natural and synthetic materials. Synthetic rubbers are made from petroleum and are functionalised with the addition of; sulphur (1-4%), zinc oxide (1%), carbon black/silica (22-40%) and oil (Kole *et al*., 2017).

16. Car tyres release wear particles through mechanical abrasion, resulting from the 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. Experimental set-up is also an important factor to consider. In general, most tyre wear and tear are conglomerates with road wear (Baensch-Baltruschat *et al*., 2020) (Kole *et al*., 2017).

Characteristics

Chemical composition

17. The chemical composition of microplastics can vary. Some can be made from single monomer repeats (*i.e.* polymers) such as polyethylene and polypropylene which

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

are common in food packaging applications, and some are made from two monomers (*i.e.* co-polymers) for example styrene-butadiene.

18. The composition can also vary based on the addition of other filler compounds, for example, 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, substances may also be added to improve the functionality of the polymer including: pigment, lubricants, thickeners, anti-static agents, anti-fogging agents, nucleating agents and flame retardants.

Sources

19. 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 minute size (*i.e.* lighter mass), their presence in the air has also been detected (Gasperi *et al*., 2018).

20. Due to their omnipresent status in the environment, microplastics have been also detected in food (*e.g.* seafoods, beer, salt and honey, tea, vegetables) and drinks (*e.g.* bottled water, milk, soft drinks) (Touissant *et al*, 2019).

21. 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.

Physicochemical properties

22. Due to the varying chemical composition and physicochemical properties of NMPs, there is currently limited analytical methodology processes that have been utilised to detect their presence in various matrices. Currently, these include Fourier-transform infrared spectroscopy (FT-IR), Nile Red staining techniques, Micro-Raman spectroscopy and mass-spectroscopy, however, these methods have their own associated limitations (Nguyen *et al*., 2019).

23. Additionally, there are neither standardised testing methods for different matrices (*i.e*. air, soil, food and water), nor standard refence materials. No single technique is suitable for all plastic types and for all particle sizes or shapes, and so the utilization of a suite or generation of new techniques may be necessary.

24. Comparison and replication of studies can be difficult due to differences in sampling, extraction, purification and analytical methods for enumerating and

characterising microplastics are not yet standardized or subject to interlaboratory validation. Contamination with airborne microplastics or cross-contamination of samples pose as an issue, control samples may be difficult to ascertain.

25. Most studies have performed tests on pristine particles; therefore, it is important to consider inter-variability of samples and batches and how this may not be representative of what is present in the environment (*i.e*. particles have not undergone degradative processes in the environment).

Physical properties

26. As eluded to 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, colour *etc.*

27. Differences in physical properties for morphologies of tyre materials can also vary under various 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, the wide range which was attributed to the use of different size metrics.

Chemical properties

28. A particle's chemical property is dependent on its chemical composition. The particle's charge or zeta potential (when particles are immersed in a conduction liquid *e.g*. water) is described as a chemical property.

29. A particle's chemical 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.* other persistent organic pollutants, pharmaceutical compounds, metals) or microbiological organisms.

30. It should be noted that the physicochemical properties of microplastics can change over their life cycle which 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 generates a higher number of particles and as such gives rise to a larger total surface area and higher particle 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

31. There are three potential hazards with microplastics which are dependent on the particles' chemical composition and therefore their physicochemical properties) these are: physical (*e.g.* gut blockage, as observed in aquatic and aviary species), chemical (unbound monomers, additives, sorbed chemicals from the environment) and the presence of biofilms (attachment and colonisation of microorganisms on the plastics).

32. Due to the small size of NMPs, uptake across the gastrointestinal tract and uptake into internal tissues is possible. Particles <50 µm can be absorbed from the gut *via* 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.

33. In terms of microplastic fibres/airborne MPPs – their particulate properties must be characterised as long-term exposures could lead to chronic bronchitis and/or other respiratory diseases. The Committee previously reviewed the studies from Pimentel *et al*., (1975), Hillerdal *et al*., (1988) and Pauly *et al*., (1998), whom studied the *in vivo* effects of occupational exposure to synthetic fibres.

34. The Food Standards Agency is currently performing a critical literature review on the microbiological colonisation of micro- and nanoplastics and their significance to the food chain (FS307021)[4], the project completion date is scheduled for early 2021. The critical review is expected to present an overview of NMPs in the environment, the interaction of NMP and micro-organisms, the identification of key pathways 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).

Sources of exposure

35. This section will be divided into two scenarios; exposures from food and drinks (*i.e.* bottled water) and exposure from environmental sources.

Food and bottled water

36. The sources of NMPs in food are commonly attributed to those found in the environment, that it, likely to originate from other sources than the food itself. It is hypothesised that the concentration of NMPs in food and drinks will increase during processing arising from manufacturing, equipment, and workers clothing. There is also an increase in the number of studies on reporting the presence of MPPs in food crops as a result of agricultural practices *s*uch as the use of sludge and plastic mulching. The effect of other processes (*e.g.* cooking and baking) on the content of plastics is not yet known.

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

37. 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.

Analytical detection methodologies

38. From the literature, the 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). 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*.)

39. As seen in *Figure 1*, the majority of biological samples are taken from aquatic species, the pre-separation includes 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 *etc*) 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 Rama spectroscopy) and mass spectroscopy which have been suitable for the characterisation, quantification and identification of nanoplastics (*e.g.* thermodesorption gas chromatography with mass spectrometric detection (TDS-GC-MS) and pyrolysis coupled with gas chromatography and mass spectroscopy (py-GC-MS)).

40. Personal communications with National Reference Laboratories in the United Kingdom (UK) revealed that organic contaminant analysis only usually analyses 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.

41. For example, when analysing fish - the head, digestive tract, offal and bones are removed before analysis. It is expected that majority of microplastics are in the stomach contents; 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).

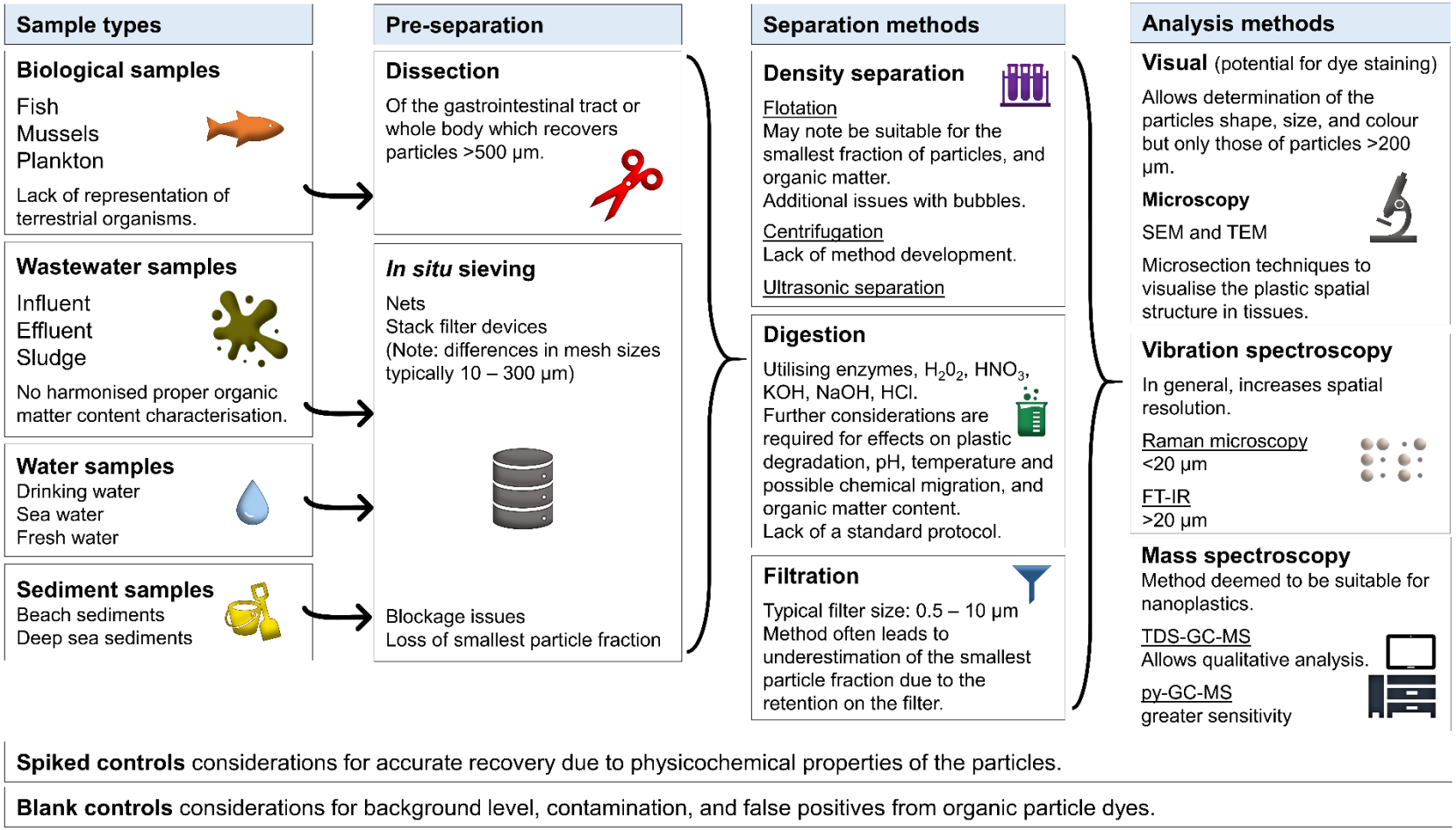

Figure 1 provides an overview of the methodologies utilized in the separation and analysis of microplastics and nanoplastics in complex environmental samples including: biological samples (fish, mussels and plankton), wastewater samples (influent, effluent and sludge), water samples (drinking water, 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

42. Evaluations by the EFSA Contaminants in the Food Chain (CONTAM) Panel focused their efforts on the presence of NMPs in seafood (EFSA, 2016). The occurrence of microplastics has been reported in seafood (between 1 and 7 particles), 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 occurrence in seafood.

43. It was 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.

44. 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 risk assessments.

45. 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) have been reported and biomagnification has been shown. The main plastic additives and adsorbed chemicals include phthalates, bisphenol A, polybrominated diphenyl ethers, polyaromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs).

46. The EFSA CONTAM Panel made use of 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 and calculated an estimated exposure of 170 pg of PAHs and 19 pg of PCBs.

47. 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 would be 0.001-0.006% for the PAHs and 0.004% for the PCBs.

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

49. In terms of bottled drinking-water; the major polymer type detected is polyethylene terephthalate (PET), which is the most common polymer utilised in bottle manufacturing. Varied quantities and morphology of microplastic particles are reported, depending on material type. The source of microplastic either stems from the packaging itself or through manufacturing processes.

50. From the food items described above, it would seem that humans can be exposed to NMPs in the diet, though the estimation of this is difficult. Presently, the risks from this exposure route to humans are to be fully characterised.

51. From the available toxicokinetic data in animal studies, distribution of MPs in tissues is partially determined by particle size. Particles >150 µm are not absorbed, smaller particles especially those within the nanoscale (1-100 nm) are able to absorb into all organs (as mentioned previously). The metabolism of microplastics is not expected due to their persistent nature.

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

53. 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 currently available data for microplastics in different food types being limited, the difficulty of performing an accurate and reflective risk assessment and, the lack of toxicokinetic and toxicity data.

Environmental sources

Air

54. Environmental exposure to airborne microplastics is dependent on the wide distribution of their sources. Synthetic textiles, erosion of synthetic rubber tyres, and city dust are the most reported sources of airborne microplastics within the literature. Wind transfer is estimated to be responsible for 7% of the ocean's contamination.

55. There is still little information regarding the concentrations of airborne microplastics, however, the Dris *et al*., (2016, 2017) studies carried out in Greater Paris provides indoor concentrations of 1-60 fibres/m^3 and outdoor concentrations of 0.3-1.5 fibres/m^3. Although, these numbers are affected by climate conditions, and seasonality, but also of the sampling methodology.

56. The fate and dispersion of microplastics in indoor and outdoor environments are dependent on several factors, that ultimately influences human exposure. These factors include; vertical pollution concentration gradient (higher concentrations near the ground), wind speed, land topography, wind speed and direction, precipitation and temperature. Exposure to low concentrations of airborne microplastics is expected in outdoor air due to dilution. The indoor behaviour of airborne microplastics is dependent on factors including room partition, ventilation and airflow, resulting in higher concentrations in rooms downwind.

57. Atmospheric deposition of MPPs onto food prior to consumption must also be considered.

58. Catarino *et al*., (2018) compared the potential exposure to humans to household dust fibres during a meal to compare with amounts of microplastics particles present in edible mussels from Scottish waters collected throughout 2015. The mean number of MPPs in *M. modiolus* was 0.086/g ww (n=6). In *Mytilus* spp. the mean number of MPPs/g ww was 3.0 (n=36). Fibres were the most common shape morphology of detected fibres 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 is 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. This range value was based on the following assumptions; 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, equating to ~42,000 MPPs consumption/year/person, for 20 minutes during consumption of an evening meal. During a cooking period of 20 minutes, 5 MPPs per 4.32 cm^2 was estimated, leading to the potential of ingesting a further ~207,000 MPPs/year/person. These values were then corrected by 33% which was reported to be the amount of petrochemical based fibres found in dust by Dris *et al*., (2017).

59. An American study (Cox *et al*., 2019) has proposed an estimated daily consumption and inhalation of 142 MPPs and 170 MPPs, respectively; this results in a total annual exposure to ~120,00 MPPs annually in males, and for female adults the value was ~98,000 MPPs. Although, this calculation did not include values for the atmospheric deposition of microplastics during food preparation and consumption. Should this factor be considered, an estimated additional microplastic fibre exposure of ~14,000-68,000 MPPs/y/person has been calculated during an evening meal via dust fallout in a household.

60. Occupationally inhaled microplastics result in toxicity after inhalation of plastic particles or their leachates. The response in humans depends on differences on individual metabolism and susceptibility. It is not yet known whether synthetic fibres may have similar or lower toxicities when compared to organic/natural fibres.

61. The deposition of inhaled microplastics is dependent on particle properties, and the patient'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 for penetration due to its high aspect ratio (Donaldson & Tran, 2002). Clearance relies on mechanical methods (mucous progression towards the pharynx caused by the beating of cilia), alveolar macrophage phagocytosis and latter migration and by lymphatic transport.

62. In general, the mechanisms of inhaled particle injury include dust overload (high surface 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). Such mechanisms can lead to endpoints such as cancer, which can develop as a result of chronic inflammation or from gene mutation cause by oxidative stress.

Soil

63. 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. To a lesser extent, composts derived from residential or municipal solid waste and garden organic waste are additional sources of plastic pollution in agroecosystems.

64. On the soil surface, plastics degrade *via* the oxidative degradation process which is influenced by various environmental conditions. Plastic particles are reported to form eco-coronas with organic and in-organic soil biota, which may affect its bioavailability and toxicity.

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

66. Information about 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 with them *via* defecation or cast shedding or they die from high exposures.

67. 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). Zhao *et al*., (2017) postulated that plant metabolic processes may produce novel compounds within the food chain, as a result of nanoplastic uptake.

68. Future research in 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 provide an establishment of the scale of contamination and can potentially allow 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 the groundwater (Hurley & Nizetto, 2018).

Water

69. The COT reviewed numerous studies in relation to exposure to NMPs *via* 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)[5].

70. 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, >99.99%. Particles were detected in raw water with an average concentration of 4.9 mpp/L and with potable water having an average of 0.00011 mpp/L, whilst the average was 5.1 mpp/L for wastewater effluent samples (determined utilising FT-IR methodologies). Sludge samples were found to have levels of 2,000 – 4,000 mpp/g_{dw}, due to the high removal rates of MPPs through both water and wastewater treatment processes.

71. 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) were also considered, however, these were difficult to quantify utilising FT-IR, and so were not accounted for within the report.

72. The most common polymer type found in raw water were polyethylene (PE), PET and polypropylene (PP). For potable water, the polymers detected above the limit of quantification were acrylonitrile butadiene styrene 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).

[5] Full report available at the UKWIR website.

73. 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).

74. No epidemiological data or human studies on ingested microplastics were identified by the WHO Panel, most toxicological studies have focused on aquatic organisms or ecotoxicology. Data from rat and mice studies were found to be inadequate to inform human health risk assessment of microplastic ingestion.

75. One of the rat studies assessed by the WHO, 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 was dosed at 0, 0.5, 2.5 or 5% PET in the diet. The size and count of the PET particles was not determined/reported; however, it was 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 no observed adverse effect level was not reported by the authors; however, the NOAEL can be considered the highest dose ~2,500 mg/kg bw/day (at the highest 5% inclusion in the diet).

76. A conservative exposure scenario was carried out 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/cm3) and the number 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.

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

78. 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.

79. 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, although, no reliable information suggests it is of concern to humans.

80. Much like the scenario with food and bottled water, the associated uncertainties with the potential risks from exposure to NMPs in water is the unavailability of harmonised methodologies to characterise, quantify and identify NMPs, the current available data for microplastics in different food and drink matrices is limited, the difficulty of performing an accurate and reflective risk assessment, and the lack of toxicokinetic and toxicity data.

Other

81. Other sources of NMPs can include the use of cosmetics utilising microbeads, exposure as a result of abrasion for everyday household objects such as cutlery, toothbrush, and cups (Rodrigues *et al*, 2019). It is possible the toddlers may have increased exposure given the number of plastic items can be exposed to during oral exploration as part of a normal stage of development. Moreover, synthetic fibres present in deposited dust, carpets *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 review the are no data based on such exposures.

82. The potential exposure of microplastics from breast milk to infants were considered, specifically relating to its storage in plastic bottles. The potential risks of ingesting microplastics from bottled water as a source has been discussed. Available data suggest that the presence of MPPs in bottled water are due to the manufacturing process, however, the quality of the plastic and lid cracking have also been found to contribute to the overall number. Thus, it could be hypothesised that mothers storing breast milk for later personal use or for donation to hospitals or milk banks in plastic containers; may be a potential source of microplastic exposure to infants.

83. No data has yet been reported to prove this hypothesis, however, an ongoing study; titled Mothers' information on lactation and collection (MILC) study carried out by Bradman and his colleagues at UC Berkeley are 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 microplastics is within the scope of this research (MILC, 2016).

Tyre and road wear particles (TWRPs)

84. 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, nitride rubber, neoprene rubber, isoprene rubber, and polysulphide rubber. The interaction of tyres and pavement alters both the chemical composition and 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 and the atmosphere, as well as roadway particles.

85. 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.

86. The initial risk assessments carried out by various assessment groups (European Tyre and Road Wear Platform; Tyre Industry Project (ETRWP TIP), Joint Research Centre (JRC), Defra, Health and Safety Executive (HSE), Committee on Medical Effects of Air Pollution (COMEAP), WHO, National Institute for Public Health and the Environment (RIVM), and European Chemicals Agency (EHCA)), showed variation as set out below.

87. The ETRWP TIP subgroup concluded that tyre wear has a significant share in general microplastics emissions (20-60%), however, the current data available does not allow for direct comparison due to differences in assumptions and target points in the environment (Jekel, 2019).

88. A JRC non-exhaust emission (NEE) 2014 report (Grigoratos & Martini, 2014) concluded that exhaust and non-exhaust sources approximately contribute to total traffic related PM_{10} emissions. In terms of human adverse health effects, TRWP contains particles from all fractions involved in respiratory function. It was acknowledged that some constituents of tyre wear particles (TWPs) have been recognised as hazardous (*e.g.* PAHs) or potentially dangerous for humans (*e.g.* presence of zinc and natural rubber latex), however, there were no comprehensive studies linking TWPs with adverse effects on human health, and the available *in vitro* studies were contradictory.

89. In addition to the report summarised above, the JRC further published a technical report on the migration of PAHs from plastic and rubber particles in 2018 (Barrero-Moreno *et al*., 2018), none of the plastic polymeric materials led to detectable levels of the 8 target PAHs listed under Regulation (EU) No. 1272/2013[6].

[6] The eight PAHs are: benzo[a]pyrene, benzo[e]pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene and dibenzo[a,h]anthracene.

90. Defra called for evidence on brake, tyre wear and road surface wear in July. 2018, in response to this the Air Quality Expert Group (AQEG) published a NEE report in 2019. AQEG identified that particles from brake wear, tyre wear and road surface wear currently constitute 60% and 73% (by mass), respectively, of primary $PM_{2.5}$ and PM_{10} emissions from road transport. It was stated that these emissions contribute to the total ambient particulate matter burden associated with human ill-health and premature mortality (AQEG, 2019).

91. The HSE and the Rubber Industry Advisory Committee (RUBIAC) reviewed the recent epidemiological data concerning the exposure to beta-naphthylamine in the tyre manufacturing, as it has been historically associated with the increased risk of bladder cancer. The review concluded that these increased risks are no longer present in the tyre industry, however, observations of multiple myeloma cases were present in the general rubber goods sector only (currently under investigation) (RUBIAC, 2007).

92. The current work exposure limit is 6 mg/m^3 for rubber process dust and 0.6 mg/m^3 for rubber fume in an 8-hour time weighted average, however, it must be noted that these limits apply to the dust produced from rubber manufacturing and does not include dusts arising from the abrasion of cured rubber (HSE, 2011).

93. In 2015, the COMEAP highlighted that it is unlikely that all components of particulate matter have the same potency in causing adverse human health effects, and that the available evidence during their review in 2015 were insufficient to draw reliable conclusions regarding the most health-damaging components and/or sources of ambient particulate matter. Furthermore, the COMEAP were not able to recommend differential coefficients for quantification.

94. It was therefore concluded that, since there was evidence to suggest that both primary and secondary (particularly sulphate) particulate matter were detrimental to health, its reduction as a source in the environment was likely to be beneficial to health (COMEAP, 2015).

95. THE WHO Review of the Evidence on Health Aspects of Air Pollution project (WHO, 2013) highlighted that there was a limited number of studies to suggest that traffic-generated dust, including road, brake and tyre wear, also contribute to human adverse health effects, however, they may become relatively more important with progressive reductions in exhaust emissions. Therefore, toxicological research increasingly indicates that such non-exhaust pollutants could be responsible for some of the observed effects on health.

96. RIVM (Verschoor *et al*., 2016) estimated that the contribution of traffic-related NEE wear to total particulate matter within the 10 µm fraction (PM_{10}) emissions in the Netherlands to be ~10%, an estimated 35 of which is caused by tyre wear, 20% by brake wear and the remaining 45% by road wear.

TRWP were described to have a size range of 10-400 µm. The estimated distribution of car tyre wear amongst environmental compartments were; road residue (43%), soil (36%), surface water *via* sewerage (8%), surface water direct (3%), air (5%), sludge (6%).

97. The dermal, accidental swallowing and inhalation of fumes from rubber crumb material from synthetic turfs sports field were reviewed by ECHA (ECHA, 2017). The substances that were identified to be commonly present in recycled rubber granules identified through a literature review included; PAHs, metals, phthalates, volatile organic compounds (VOCs) and semi volatile organic compounds.

98. In terms of dermal contact, the migration factors of PAHs to artificial sweat have been detected from 0.007-0.02%, absorption of 100% was used in the risk characterisation, which takes into account the effects of any abrasion of the skin.

99. For oral exposure, ECHA estimated the accidental swallowing of rubber granulate by children and adults to be 0.05 and 0.01 g, in one event respectively.

100. The highest measured value for inhalable dust has been 3.1 mg/m^3, whilst for respirable dust it was 1.4 mg/m^3. The maximum concentration for PM_{10} was 40 mg/m^3.

101. The excess lifetime cancer risk, for EU-8 PAHs was calculated and was below one in a million for players, goalkeepers and workers. The $BMDL_{10}$ was derived from a 2-year carcinogenicity study in female mice (Culp *et al*., 1998).

102. ECHA concluded that there was a very low level of concern from exposure to PAHs from recycled rubber granules since the concentrations of PAHs in recycled rubber granules have normally been below the limit values in the REACH[7] restriction.

103. Furthermore, the data regarding migration of metals, showed negligible concern to those typically exposed (players and workers), since the levels are below the limits in accordance with the EU toys legislation (Directive 2009/48/EC), when compared with limit values for dry powder or pliable toy materials.

104. The concentrations of phthalates, benzothiazole, and methyl isobutyl ketone in rubber granules were found to be of no concern to players and

[7] REACH: Registration, Evaluation, Authorisation and Restriction of chemicals of Chemicals is a European Union regulation dating from 18 December 2006. REACH addresses the production and use of chemical substances, and their potential impacts on both human health and the environment.

workers, since these were below the concentrations that would lead to adverse health effects.

105. Lastly, ECHA acknowledged that reports that VOCs emitted from rubber granules in indoor halls may cause irritation to the respiratory tract, eyes and skin.

106. Challenges associated with evaluating risk from exposure becomes complex when considering other factors such as the effects of weathering and ageing of tyre materials, the effects of temperature, pavement types and driving style. All in all, this will result in the generation of various chemicals with significantly different biological and toxicological effects and potencies (ECHA, 2017).

Summary of exposure sources

107. The routes for which humans can be exposed to microplastics include the oral and inhalation routes. In terms of the oral route, this is achieved from the consumption of contaminated food products such as seafood (*e.g.* mussels), bottled water, and other food products such as beer, honey, salt and tea. Potential exposure could also arise from consumption of food crops that have deposited airborne MPPs. Nanoplastic uptake into edible food crops have also been reported within the literature.

108. The EFSA CONTAM Panel estimated a 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 to drinking water at 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).

109. 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. These numbers are affected by climate conditions, and seasonality, but also by the sampling methodology (Dris *et al*., 2016, 2017).

110. 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 estimated to be ~14,000-68,000 MPPs/y/person (Catarino *et al*., 2018). Estimated daily consumption and inhalation of 142 MPPs and 170 MPPs, respectively was estimated by Cox *et al*., (2019) for an American individual; resulting in a total annual exposure to ~120,00 MPPs annually in males, and for female adults the value was ~98,000 MPPs (± ~14,000-68,000 MPPs/y/person for indoor dust fallout).

Evaluations by other authoritative bodies

111. The EFSA 2016 statement (EFSA, 2016) and WHO drinking-water report (WHO, 2019) on NMPs have been summarised in paragraphs 34-40, and paragraphs 67-73, respectively.

112. The following section will provide executive summaries on other evaluations carried out by the EU Group of Chief Scientific Advisors; Scientific Advice Mechanism (SAM)[8], EU Science Advice for Policy by European Academies (SAPEA)[9], and Environment and Climate Change and Health Canada (ECC and HC)[10].

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

113. In brief, the SAM advisors agreed that most laboratory studies to date does 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.

114. Currently, the available evidence suggests that microplastic pollution at present does not pose widespread risk to humans or the environment, however, there are significant grounds for concern and for precautionary measures to be taken.

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

116. The SAM advisors provided three recommendations. 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)

117. 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 nano- and microplastics on biota and humans (SAPEA, 2019).

118. The conclusion of the working group is that there was no evidence of widespread risk to human health from micro and nanoplastics at present, and that the absence of concrete evidence of microplastic risks at present did not

[8] The SAM report is available on the European Commission website.
[9] The SAPEA report is available on the SAPEA website.
[10] The ECCC and HC report is available on the Health Canada website.

allow us the working group to conclude with sufficient certainty either that risk is present or that it is absent in nature.

119. Adverse effects were observed (negative effect on food consumption, growth, reproduction and survival) once effect thresholds are exceeded. The concentrations utilised are higher than those reported in the environment. Furthermore, the utilisation of virgin or spherical particles are not representative of the environment, and often short exposure times are applied in laboratory studies in the aquatic organisms investigated. As such, there is no evidence that these effects occur in nature. Therefore, these limit the reliability of the risk assessments for micro and nanoplastics.

120. Chemicals associated with microplastics can have additional human health effect(s) (which is deemed difficult to assess), 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.

121. The SAPEA working group recommendations are listed 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 real human risks can be made.

122. 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 authors conclude that there is consensus and momentum for action and no evidence of “plastic denial” phenomenon. Due to the lack of scientific understating, the precautionary principle has been part of the foundation for current regulations.

123. 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.

124. The 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 (ECC and HC)

125. ECC and HC concluded that in the available animal studies, there were no dose-response relationship 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 indicate 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 ECC 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 in the view that 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 recommended 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 nanoplastics, studies to further understand the effects of microplastics exposure in human and the environment, and lastly, expanding and development consistent monitoring efforts to include poorly characterised compartments such as soil.

COT evaluation

130. Microplastics are omnipresent, 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 weathering and corrosion. There is no internationally agreed definition of what a microplastic is, however, there is a general acceptance that the size range is from 0.1-5,000 µm.

131. MPPs >150 µm are unlikely to be absorbed. Particles <50 µm could be adsorbed from the gut *via* tight junction gaps and endocytic pathways but only those of <1-2 µm in size were able to cross cell membrane organs.

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

133. The risk of chemical leachates and adsorbed substances from microplastics is not expected to cause adverse health effects in humans due to their small contribution to the overall exposure from other sources of the same chemical as evidenced by the EFSA 2016 review and the WHO 2019 MOE calculations.

134. Other evaluations by the SAM, SAPEA, ECCC and HC further support the above conclusion.

135. At the present time, a full risk assessment on the potential toxic effects of micro and/or nanoplastics could not be carried out due to the lack of comparative data available for baseline levels of both materials. Furthermore, there is no established NOAEL for the different polymer types except for PET powder at 2,500 mg/kg bw/day in rats, (see paragraph 65), which had a number of limitations (size and count were not determined/reported, and the small sample size); this material type may also not be representative of NMPs found in the environment.

136. The lack of reliable data has been noted; Koelmans *et al*., (2019) proposed a quality assessment criterion to rank the reliability of published results in 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. Therefore, 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.

137. As highlighted throughout the document, microplastics have many varying physicochemical properties to suit its primary purpose, however, these properties do not correlate to secondary microplastics where they are fragmented down as a result of natural processes and NMPs that are not considered pristine. Additionally, analytical methodology processes are limited to FT-IR, Nile Red, Micro-Raman spectroscopy and mass-spectroscopy. There are no standardised testing methods for different matrices (*i.e.* air, soil, food and water), and the available methods have their own associated limitations (see *Figure 1*). Furthermore, no single technique is suitable for all plastic types and for all particle sizes or shapes. Using a library or generation of techniques may be necessary.

138. In terms of the toxicity of NMPs, there is no established NOAEL for each polymer type (except PET powder at 2,500 mg/kg bw/day in rats as reported by Merski *et al*., 2008). 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.

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

140. Other challenges include the difficulties in the comparison of published studies due to differences in sampling, extraction, purification and analytical

methods for enumerating and characterising microplastics are not yet standardised, and therefore suitable reference materials are also required. Contamination with airborne microplastics or cross-contamination of samples pose as an issue, control samples may be difficult to ascertain.

141. Most studies have performed tests on pristine particles; therefore, it is important to consider inter-variability of samples and batches and how this may not be representative of what is present in the environment (*i.e.* particles have not undergone degradative processes in the environment).

Research priorities for risk assessment

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

143. Comprehensive assessment of NMPs and contaminant concentrations in seafood species and the impact of what cooking may have on the desorption and subsequent bioavailability of contaminants/leachants, needs to be further investigated to better understand the implications for human health.

144. Current studies typically only deal with one type of particle/tissue interaction, as such, further research is necessary to explore the effects of the combination of particle types *in vitro* (*e.g. in silico* assessments, organ on a chip, organoids *etc*) and/or *in vivo*.

145. Since microplastic concentrations are expected to increase in the future, it will be important to establish a monitoring program to regularly assess the levels of microplastics in food, water and the air. This would need collaborations between academia, researchers and government bodies at a national and international level.

146. There is also a need to study the assimilation of a range of microplastic sizes and compositions into human tissues and in the development of techniques capable of identifying the presence of microplastics in the human body (*e.g.* biopsies and tissue banks).

147. The most significant data gaps appear to be the lack of appropriate and harmonised analytical methods for the detection of micro and nanoplastics.

148. There is also a lack of data with regards to the absorption, metabolism, distribution and excretion (*i.e.* the toxicokinetic profile) and toxic profiles on NMPs in human.

COT Conclusions

149. The COT concludes that based on the available data, it is not yet possible to perform a complete risk assessment for the potential, however, they concur with the conclusions reached by other authoritative bodies (EFSA, WHO, ECCC and HC, SAPEA, SAM)

150. The Committee 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.

151. The most significant data gaps appear to be the lack of appropriate and harmonised analytical methods for the detection of micro and nanoplastics (together with suitable reference standards), as well as their toxicokinetic and toxicity profiles.

152. The Committee highlighted that additional information will be needed from all exposure sources, which include indoor and outdoor air, dust and soil. The presence of MPs in seafood and water may need to be put into perspective with other sources of MPs such as atmospheric fallout.

153. Comprehensive assessment of microplastics and contaminant concentrations in seafood species and the impact of what cooking may have on the desorption and subsequent bioavailability of contaminants/leachants, needs to be further investigated to better understand the implications for human health.

154. Current studies typically only deal with one type of particle/tissue interaction, as such, further research is necessary to explore the effects of the range of particle types *in vitro* and/or *in vivo*.

September 2020

Abbreviations

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
ECC	Environment and Climate Change
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
ETRWP TIP	European Tyre and Road Wear Platform; Tyre Industry Project
FT-IR	Fourier-transform infrared spectroscopy
HC	Health Canada
HSE	Health and Safety Executive
JRC	Joint Research Centre
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
RIVM	National Institute for Public Health and the Environment
RUBIAC	Rubber Industry Advisory Committee
SAM	EU Group of Chief Scientific Advisors; Scientific Advice Mechanism
SAPEA	EU Science Advice for Policy by European Academies
TDS-GC-MS	Thermodesorption gas chromatography with mass spectrometric detection
TWPs	Tyre wear particles
TWRPs	Tyre and road wear particles
UK	United Kingdom
VOCs	Volatile organic compounds
WHO	World Health Organisation

References

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.

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) Committee on the Medical Effects of Air Pollutants. 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.