Microplastics - Inhalation route - Scope and purpose

In this guide

13. As there is evidence for the presence of plastic particles in both indoor and outdoor air, inhalation is a possible route of exposure (Gasperi et al., 2018; Domenech & Marcos, 2021).

14. The purpose of this sub-statement is to provide supplementary material to the overarching statement (COT Statement 2021/02) and to consider in detail the potential toxicological risks of exposure from microplastics *via* the inhalation route. It is based on the currently available literature and data from internal tools at the FSA (these include: a literature search application and signal prioritising dashboards).

Microplastics

15. Currently there is no internationally agreed definition of a microplastic, however, publications by Verschoor (2015) and Hartmann et al., (2015) have proposed criteria that could 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.

16. Verschoor (2015) included 5 major properties that could be considered including chemical composition, physical state, particle size, solubility in water and degradability. Similarly, Hartmann et al., (2015) proposed seven criteria; chemical composition, solid state, solubility, size, shape and structure, colour and origin (i.e. primary or secondary particles; also known as pristine and aged), as discussed in the following paragraphs.

17. In Europe, the definition of a microplastic (which includes nano size) proposed by ECHA 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).

18. The current definition of microplastics (which excludes nano size) in drinking water adopted 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).

19. As noted above, the definitions of 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 in size (0.1µm to 5 mm). Plastics that are below this size range are classed as nanoplastics (i.e. 1 nm to 0.1 µm) (COT, 2021; Bermúdez and Swarzenski, 2021; Frias and Nash, 2019). However, consensus on the size range is challenging.

20. 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 and agglomeration processes lengthen, the particle size continues to change due to fragmentation and erosion/weathering.

Nanoplastics

21. Nanoplastics have been defined as a material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale (1 nm to 0.1 µm) (EFSA, 2016, European Commission, 2011). Nanoparticle is a general term based on the physical properties for a variety of chemical compositions. There is currently no further proposed definition.

22. A number of authoritative bodies 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 provide any definitions; however, it was stated that 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.

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

24. 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).

25. The EFSA 2018 guidance is applicable to:

- A material that meets the criteria for an engineered nanomaterial, as outlined in Novel Food Regulation (EU) No 2015/2283 and Regulation (EU) No 1169/2011 (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 particles (<50% in the number-size distribution. Elsewhere (EFSA Tech Req, 2021), less than 10% particles (number-based) with at least one dimension smaller than 250 nm no nano RA required) with one or more external dimensions in the size range 1-100 nm or less.
- A nanomaterial having the same elemental composition but that occurs in different morphological shapes, sizes, crystalline forms and/or surface properties.
- A nanoscale entity that is made of natural materials.

26. 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". 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.

27. The first group of criteria 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).

28. The definitions of nanomaterials above (paragraphs 25-28) are based on EFSA Guidance, but their guidance for the risk assessment of nanomaterials could also apply to nanoplastics.

Types of microplastics

29. 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 which are known as primary microplastics (generally spherical) and are intentionally used in personal care products (for example, microbeads) or for various industrial applications. Secondary microplastics can be formed in the environment due to

fragmentation of larger pieces of plastic 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.

30. Besides the types of microplastics mentioned above, there is some debate within the scientific field 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 produced 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).

31. 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, vehicle characteristics 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).