COMMITTEE ON THE MEDICAL EFFECTS OF AIR POLLUTANTS

Working paper for COMEAP 'Statement on airborne nano- and microplastic particles and fibres'

Interim assessment for the Synthesis and Integration of Epidemiological and Toxicological Evidence (SETE) for the population health effects from the inhalation of environmental airborne nano- and microplastic particles and fibres (NMPs).

Approach

1. This paper presents a provisional assessment of the strength of evidence for a risk to human health from inhalation exposure to current environmental levels of nano-microplastics (NMPs).

2. This assessment has used the framework described in a report of the Joint COT and COC Synthesis and Integration of Epidemiological and Toxicological Evidence subgroup (SETE), which reviewed approaches for synthesising and integrating epidemiological and toxicological evidence[1]. COMEAP discussed the application of this framework to its work at the May and November 2022 COMEAP meetings, details of which can be found in the meeting minutes[2]. Discussion points included that it may be more difficult to apply the approach to a complex mixture, such as particulate air pollution, than a well-defined chemical entity. Additionally, COMEAP's approach to integrating epidemiological and toxicological evidence may be different to that used in other chemical risk assessment settings: it was suggested that COMEAP interpreted the axis "epidemiological evidence for causation" as the strength of epidemiological evidence for a risk to health and the axis "experimental evidence for causation" as the strength of experimental evidence for a risk to health. Following discussion at the COMEAP meeting held in March 2025, the labelling of the axes has been amended to make it clear that the evaluation is of a risk to population health from current environmental exposures.

[1] SETE | Committee on Toxicity (food.gov.uk)
[2] Minutes of COMEAP meetings are available at: Committee on the Medical Effects of Air Pollutants.

3. The SETE approach requires that the integration of evidence, and visualisation, reflect the considered views of all of those evaluating the evidence, as discussed at each stage of the review process. This SETE assessment has been developed following an evaluation of the evidence as discussed in the Statement. The epidemiological and mechanistic evidence reviewed is not comprehensive and, therefore, the assessment of health risk should be considered provisional.

4. The diagram shown provides a means of visually indicating the consensus view of the Committee on the overall strength of the epidemiological and experimental (mechanistic) evidence that the inhalation of current levels of environmental NMPs poses a risk to human health. The diagram is not intended to reflect a probabilistic or numerical approach but rather, provides a representation of the influence of the different lines of evidence assessed in the statement on risk on the strength of the overall conclusion. To provide context, the assessment and diagram could be compared to other SETE assessments. For example, assessments of the health risks from current environmental, inhalation exposure to traffic related air pollution (TRAP).

Lines of evidence

5. Detecting and quantifying airborne NMPs is difficult due to limitations in current analytical methods. There is, therefore, limited data on the concentrations, and characteristics, of NMPs in the size fractions that are relevant for inhalation exposure and deposition in the lung. As a result, there is a lack of epidemiological studies on the effects of short- and long-term inhalation of environmental levels of NMPs on human health.

6. There is some evidence from occupational studies that exposure to high concentrations of NMPs, much greater than levels experienced by the general population, can increase the risk of restrictive (fibrotic) lung disease.

7. Currently, there is a lack of good quality toxicological studies in the literature using well characterised NMP particles, validated reproducible methods, and using other particles with similar physicochemical properties for comparison. Most toxicity studies have been performed using pristine particles, mainly polystyrene, which do not represent plastic particles in the environment. These pristine polystyrene spheres may not represent suitable model particles and would be unsuitable for assessing the health risks associated with exposure to polystyrene NMPs in the environment. Most studies used inappropriately high exposure concentrations of NMPs with inadequate characterisation, meaning that their relevance to real-world exposures is limited, preventing a meaningful consideration of relevant toxicological pathways and the potential human health impact. In addition, most studies do not report the

toxicological effects of NMPs in comparison with other PM components, at an equivalent dose.

8. There is a lack of research on the uptake, distribution, persistence and elimination of NMPs and their dosimetry within the human body. There are a limited number of studies reporting the presence of NMPs in human lung tissue. Studies reporting large NMPs in tissues and biological samples of a size significantly greater than 1 µm are contrary to the current understanding of how particles are transported within the body. In addition, for the majority of these studies, it is unclear whether translocation of the NMPs detected would have occurred in the lung following inhalation or the gastrointestinal tract following ingestion, which is more likely.

9. Overall, there is currently insufficient epidemiological and toxicological evidence to provide an informative assessment of the risk to health from inhalation exposure to NMPs in the environment. Further research is needed to understand exposure and the potential health effects associated with inhaled NMPs to better inform risk assessment.

Table 1: Summary of the strengths and weaknesses of the data examined for health effects from the inhalation of airborne nano- and microplastics (NMPs) and the influence of the lines of evidence on the overall conclusion.

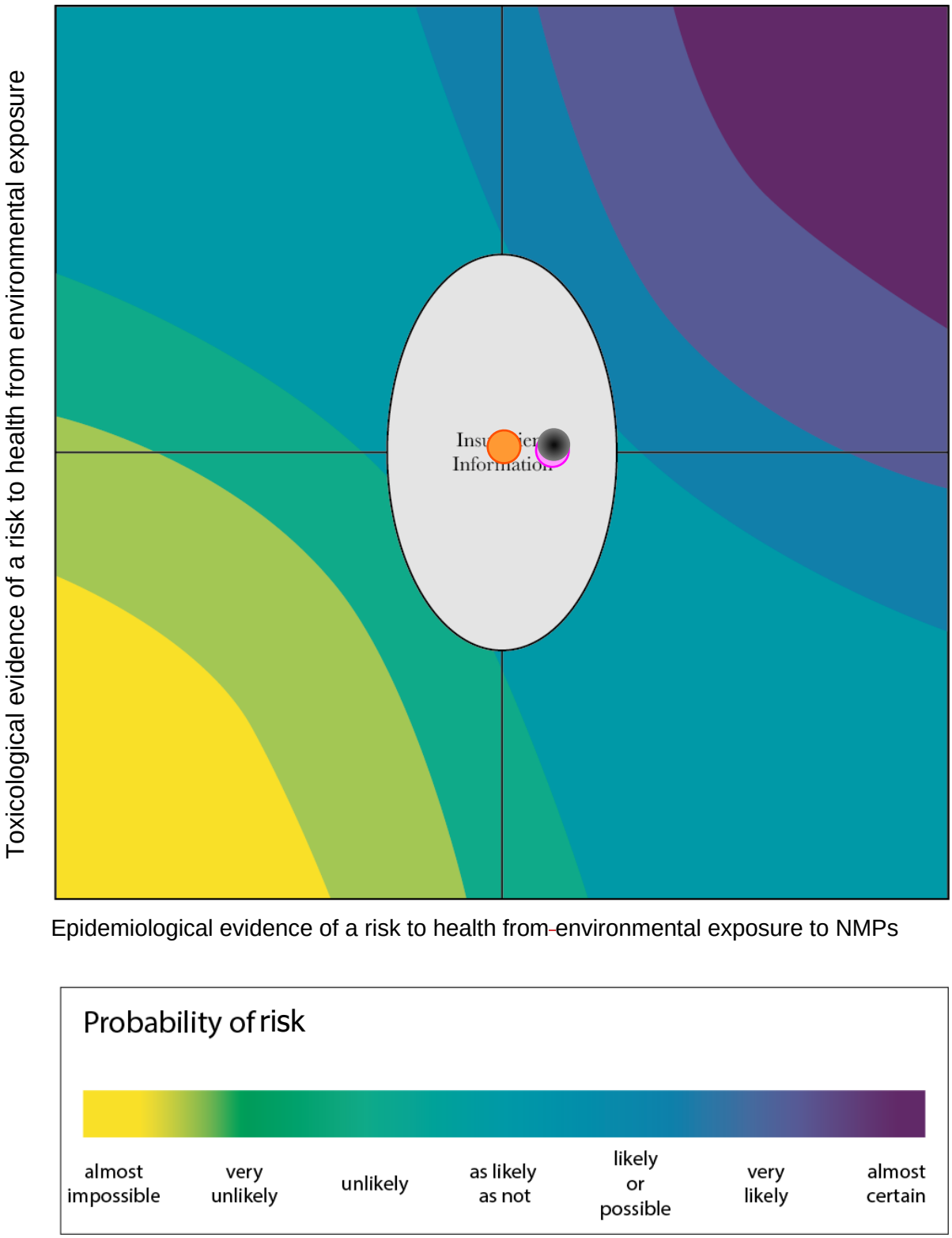
Lines of evidence and their main strengths (S) and weaknesses (W)	**Influence on Conclusion**
<u>Epidemiological data</u> S – There are numerous epidemiological studies of workers exposed to NMPs in the plastics and textile industries. There is some evidence of reduced pulmonary function and specific lung pathology, such as interstitial lung disease, from these occupational studies. W – Studies of occupational exposure are based on workers exposed to extremely high concentrations, much greater than ambient levels to which the general population might be exposed. W – There is currently a lack of data on the concentrations and characteristics of airborne NMPs, in the size fractions that are relevant for inhalation exposure, to accurately measure and assess exposure. Without better exposure data epidemiologuical studies describing the association between the inhalation of airborne	There is evidence of hazard following prolonged high inhalation exposure to certain types of microplastics. However, there is currently a lack of data on the concentrations and characteristics of airborne NMPs, in the size fractions that are relevant for inhalation exposure, to accurately measure and assess exposure. Without this data, meaningful epidemiological studies of the relationship between environmental exposure and potential health effects are not possible.

NMPs and health effects are not possible to interpret.	
<u>Mechanistic data</u> W – There is a lack of data on the effects of inhaled microplastics in mammalian species and their retention in the lung is unclear. W - Most studies investigating NMP toxicity to date have used pristine, polystyrene spheres. However, there are significant physiochemical differences between polystyrene nano and microspheres made for biological and analytical studies and environmentally generated NMPs. Therefore, these may not represent suitable model particles and would be unsuitable for assessing the health risks associated with inhalation exposure to NMPs in the environment. W/S - Some limited evidence from toxicity studies to suggest that NMPs deposited in the lung induce oxidative stress, inflammation and cytotoxicity. These toxic effects resemble those induced by other solid and insoluble particles, however, none of the reported studies directly compared NMP particles with known particulate matter pollutants. W – Most studies used inappropriately high exposure concentrations of NMPs with inadequate characterisation of both the particles and of the adverse outcome pathway, meaning that their relevance to real-world inhalation exposures is limited W – There are a limited number of studies reporting NMP particles and fibres in human lung tissue. Studies reporting large MPs in tissues and biological samples of a size significantly greater than 1 µm are contrary to the current understanding of how particles are transported within the body. In addition, for the majority of these studies it is unclear whether translocation of the MPs detected would have occurred in the lung following inhalation or the gastrointestinal tract following ingestion, which is more likely. W/S – it may be possible to read across toxicological effects of NMPs based on	Due to limitations in current analytical methods, there are limited data on the concentrations, and characteristics, of NMPs in the size fractions that are relevant for inhalation exposure and deposition in the lung. Most studies investigating the inhalation toxicity of NMPs use pristine, polystyrene spheres, and many use inappropriately high exposure concentrations with inadequate characterisation. More data is needed on the effects of size, shape, chemical composition and other factors from exposure to real-world NMPs, at environmentally relevant concentrations, and in comparison, with other types of particles and fibres with similar properties. There is insufficient data on the fate of inhaled NMPs within the human body including their potential to accumulate in organs and tissues.

knowledge of other airborne particles with similar physicochemimical properties, such as, ultrafine particles (UFP), diesel exhaust particles (DEPs), silica and asbestos. However, there is a lack of clarity and understanding of the actual physical (and chemical) characteristics of NMPs to which humans could become exposed.	
Conclusions on risk to health	Currently, there is a lack of evidence for the level of association between inhalation exposure to NMPs in the environment and the risk of adverse health effects. There is insuffient data quantifying and characterising NMP exposure in air to carry out meaningful environmental epidemiological studies. There is a lack of good quality toxicological studies in the literature using well characterised, represenative NMPs, validated reproducible methods, and using other particles with similar physicochemical properties for comparison.

10. The diagram is a visual representation of the consensus view of the Committee on the overall strength of the epidemiological and experimental (mechanistic) evidence that inhalation of current levels of environmental NMPs pose a risk to human health. The axes do not portray probabilistic or numerical estimates, but rather reflect the views of the Committee on the relative influence of the different lines of evidence assessed in the statement on risk on the overall conclusion. To provide context, the assessment and diagram could be compared to other SETE assessments. For example, assessments of the health risks from current environmental, inhalation exposure to traffic related air pollution (TRAP).

Figure 1: Interim assessment and visualisation of the risk to population health from environmental, inhalation exposure to NMPs.



The pink circle is representative of all of the epidemiological evidence assessed (both the environmental and occupational evidence); the orange circle of all of the toxicological evidence assessed. The black circle represents the conclusion of the risk to health from integrating the evidence. The circles are in the grey area in the centre of the figure indicating that there is currently insufficient information on the epidemiology and toxicological

mechanisms to inform a conclusion. However, the position of the circles will change as more evidence becomes available. For comparison, the assessment and diagram should be compared to an assessment of a risk to health from environmental, inhalation exposure to traffic related air pollution (TRAP).

COMEAP Microplastics Sub-group
September 2025