Organics Council ® Nanoparticle position statement

The Organics Council ® understand that nanoparticle safety is a complex issue and cannot be defined in a single unequivocal rule. Therefore we have created this position statement as a form of guidance:

1.1. The Organics Council ® consider any particle with all dimensions showing a mean distribution of 500 nanometers or less to be considered a nanoparticle.

Explanatory note: Mixed opinions exist on the size of nanoparticles. Even though the International Organization for Standardization defines nanoparticles as particles with all three dimensions in the range of 1 to 100 nanometers, some safety and health experts propose an upper limit of 450 nanometers to better encompass the full-size range of particles with potentially similar toxicologic properties [American College of Occupational and Environmental Medicine ACOEM].

1.2. Because of their small size, much greater surface area for any given mass, nanoparticles often have different physical and toxicological properties compared to larger particles of the same chemical composition. There is the potential for greater biological reactivity, a greater ability to penetrate through membranes and into tissues, as well as the potential for environmental spread and contamination throughout soils, water and the air we breathe.

1.3. The Organics Council are against the use of any synthetically engineered or manufactured nano-scale substances or materials, nor do we support products using nano-technology, where the precise control of the shape, size and structure of substances or materials, is used to create different or enhanced nanostructure-dependent product properties.

1.4. Engineered nanoscale substances will never be approved for use in the production of products such as FCM's, personal care or household cleaning products, due to the potential risk of migration and exposure to humans and environment. Due to uncertainties regarding potential human and environmental health effects from exposure to synthetic or engineered nanoparticles and potential adverse effects, exposure should be prevented. In addition, there is a concerning lack of knowledge regarding the chronic occupational exposures, making it difficult to ensure the effectiveness of current preventive and screening measures for synthetic or engineered nanoparticles or nanomaterials.

1.5. Naturally occurring nanoparticles are commonly occurring and many of these considered completely safe when used correctly, as they have been historically with no risk to health. The Organics Council support the use of substances that contain a natural nanoscale component, ensuring appropriate restrictions and controls are in place to control NPs and avoid all risk to health or environmental contamination. If a substance or material naturally exists with over 10% of particles in the nanoparticle scale, this will usually be considered a concerning nanoparticle content, that requires further investigation, restrictions, controls and limitations.

1.6. Manufacturers must ensure NPs generated during manufacturing and production, are strictly controlled and that the percentage of total waste, emissions or effluents are limited to:

- Atmospheric emission concentration:
  - No limits are available for ultrafine particles (PM_1 or below), therefore theoretically we should reduce the $PM_{2.5}$ recommended limit (as PM1 has greater toxicity per unit mass) which is 10 µg/m3 annual mean (WHO recommended for $PM_{2.5}$)
  - Adverse health effects have been demonstrated at not greatly above the ambient background atmospheric concentrations, which for ultra fine particles has been estimated to be 3–5 µg/m3 in both the United States and western Europe.
  - Therefore halving the PM2.5 limit (according to WHO) to 5 µg/m3 for PM_1 would be highly reasonable as a maximum occupational exposure for nanoparticles.
  - Complete avoidance of emissions should be in place, with an absolute minimum of 99% nanoparticle removal from emissions.
- Aquatic effluent concentration: Complete avoidance of contaminated wastewater should be in place, with an absolute minimum of 99% nanoparticle removal from wastewater effluents.
- Solid waste concentration: Complete avoidance of NP contaminated solid waste should be ensured, either by control of NP release to solid waste, or by waste management to ensure an absolute minimum of 99% nanoparticle removal from solid waste treatment emissions.

1.7. Inhalation should be avoided of any particle classified as ultra fine (1000 nm in diameter or smaller), this includes in occupational settings, via product use or disposal, or due to environmental release.

1.8. Manufacturers must be able to show that systems are in place to ensure no NP release occurs due to production operations that may cause human or environmental exposure to NPs.

Definitions:

Nanoparticle
A natural, incidental or engineered material containing particles, where 50% or more of the particles in the number size distribution, have one or more dimension of less than 100 nanometers.

Nanomaterial
A natural, incidental or engineered material containing particles, where 50% or more of the particles in the number size distribution, have one or more dimension of less than 100 nanometers.

Natural nanoparticle
A naturally formed particle where 50% or more of the particles in the number size distribution, naturally have one or more dimension of less than 100 nanometers. Natural nanoparticles occur commonly in the environment and may have irregular or regular shapes and distribution patterns.

Incidental nanoparticle
An unintentionally formed particle where 50% or more of the particles in the number size distribution, naturally have one or more dimension of less than 100 nanometers. Incidental nanoparticles, sometimes also called waste or anthropogenic particles, occur as the result of anthropogenic or industrial processes and may have irregular or regular shapes and distribution patterns.

Engineered nanoparticle
A deliberately engineered particle where 50% or more of the particles in the number size distribution, naturally have one or more dimension of less than 100 nanometers. Engineered nanoparticles most often have a controlled particle size with a narrow size distribution and are regular shapes, such as tubes, spheres, rings, etc.

Annex I. Examples of Particle diameter data for substances with NP contents, highlighting that a majority of substances are significantly above the NP scale unless specific engineering is performed:

Substance	Median particle diameter	D10	D50	D90	Notes
Titanium dioxide		>= 94000nm	>= 174000nm	>= 259000nm	
Aluminum calcium sodium silicate	2730nm				
Magnesium hydroxide					Reported between 6000–30000 nm
Kaolin		1200nm	8140nm	31000nm	
Talc		2340nm	5900nm	>20000nm	

Mica			10000nm		
Diatomaceous Earth		3000nm	10000nm		
Chromium oxide			500nm-3500nm		