2 April 2019

Characterisation and quantification in matrix:

Focus on Chapters 4.3-4.4, including solubility and degradation/dissolution rate

Introduction to the session

Trusted science for safe food

efsa
European Food Safety Authority

Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health

Characterisation and quantification in matrix

❑ For the toxicological assessment of the nanomaterial: essential to know in which form the nanomaterial **is presented to the test systems**. Proper dispersion of the nanomaterial in the **test media** used in toxicokinetic and toxicological studies has to be checked

❑ **ADME studies** require the measurement of the nanomaterial in **body fluids, tissues and excreta** (quantify the amount present and specify in which form the nanomaterial is present)

❑ Quantification of the nanomaterial in **food/feed and migration from FCM** are needed for exposure assessment: the relevant matrices may be feed, food, food supplements, FCMs, food simulants

❑ In cases of technical limitations in the analysis of nanomaterials in food/feed matrices, characterisation and study of matrix interactions may be carried out using **food simulants**

❑ **Solubility** is the proportion of solute in solvent under equilibrium conditions. *Dissolution* (materials are solubilised into their individual ionic or molecular species) has not to be confused with *dispersion* (colloidal suspension of particles). Solubility is determined as the concentration of the dissolved material in a saturated solution (i.e. undissolved material present as solid phase) and is dependent on external parameters such as solvent, temperature, pressure and pH. High solubility is commonly understood as more than 1 mol/L solvent is dissolved

❑ **Degradation/dissolution rate** refers to the kinetics of dissolution. The dissolution rate is influenced by various factors, including solvent, temperature, pH, concentration, and presence of substances interacting with the particle's surface. It can be determined by kinetic measurements such as time- dependent concentration changes (of either the nanoparticles or the dissolved species) or changes in the particle size distribution (to smaller sizes)