

Guidance on technical requirements of regulated food and feed product applications to establish the presence of particles at the nanoscale

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1. Background: regulatory context



- The risk assessment of substances is usually based on the chemical composition, not the physical form
- However materials with particles at the nanoscale have specific capacities for interacting with biological systems



 The risk assessment of nanomaterials is described in the EFSA 2018 Guidance on risk assessment of nanoscience and nanotechnologies in the food and feed chain (in finalisation after the pilot phase)

1. Regulatory clarifications



- According to the legal definitions, nanomaterials requiring assessment in line with the 2018 Guidance on Nano-RA include:
 - engineered nanomaterials (Novel Food Regulation) also applies to other regulated food products (e.g. food flavourings, food additives, feed additives, vitamins, minerals, food supplements)
 - nanoforms (REACH Regulation update) requiring EFSA assessment, this applies to food contact materials and pesticides
- A material not fulfilling the legal definition as engineered nanomaterial <u>may contain fraction of particles at a nanoscale</u>, requiring specific risk assessment considerations
- This has triggered a mandate from the European Commission

2. ToRs from the European Commission



- To develop **technical guidance** setting out the *information* requirements for applications in the regulated food and feed product areas of conventional materials which do not meet the definition of engineered nanomaterial set out in the Novel Food Regulation (EU) 2015/2283, in order to demonstrate whether a portion or the whole of the material is in the nanoscale.
- For those *materials* which have been determined to *contain a fraction of small particles*, including particles at the nanoscale, the European Commission asks the European Food Safety Authority to include in the guidance the *information requirements* demonstrating that the *nanoscale fraction of the material was properly evaluated in the safety studies* of the material.

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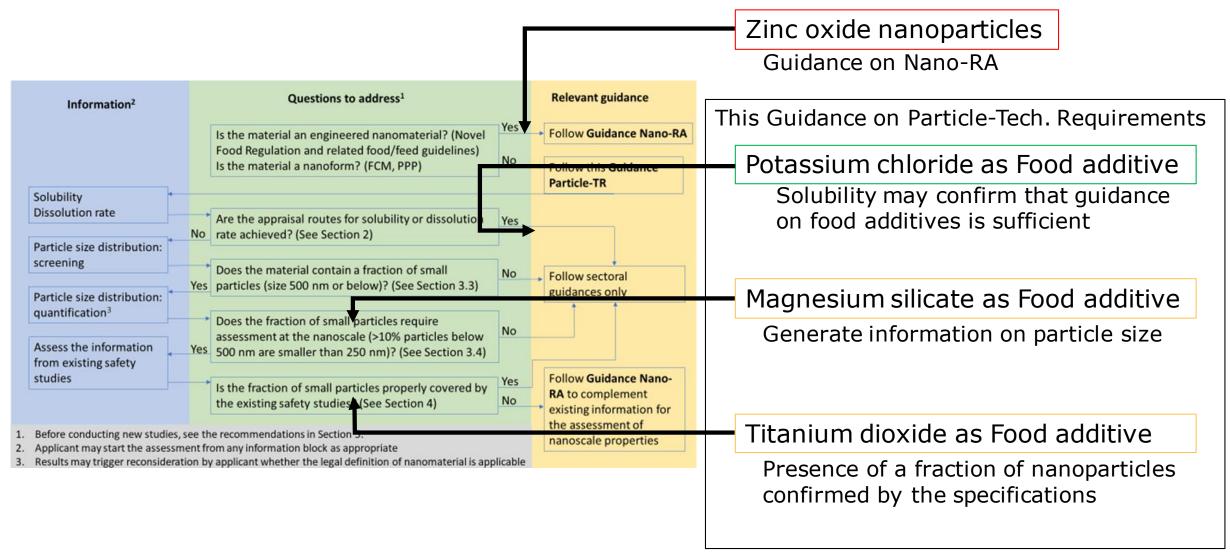
3. Implementation of the Guidance



- To be used by all applicants/interested parties to demonstrate that the material, or a fraction of it, does not require specific assessment of properties at the nanoscale.
- Several appraisal routes are offered:
 - Solubility dissolution rate
 - Particle size distribution
 - Proper coverage by existing safety studies
- If at least <u>one criterion is met, the sectoral guidance</u> (e.g. food/feed additives) <u>is sufficient</u>
- If the <u>presence of particles at the nanoscale is confirmed</u> and they are not properly covered by the safety studies, an assessment with the Guidance on Nano-Risk Assessment is needed

3. Information requirements





3. Document's overview: particle size



- Screening methods:
 - ✓ Centrifugal Liquid Sedimentation (CLS)
 - ✓ Particle tracking analysis
 - ✓ Descriptive Electron Microscopy
 - ✓ Filtration/centrifugation complemented with chemical analysis





- Quantitative information on the size distribution of the fraction of small particles (particle size below 500 nm)
 - ✓ Quantitative Electron Microscopy
 - No nanoscale assessment needed when less than 10% particles (number-based) are smaller than 250 nm,
 - If 10% or more, the presence of fraction requiring assessment at the nanoscale is confirmed



4. Next steps



- Public consultation held between 9 July and 9 September 2020
- All comments will be addressed
- Additional discussion with MSs and other relevant organisations at EFSA Nanonetwork meeting in October 2020
- Publication expected for the first semester of 2021
- EFSA is discussing with DG SANTE the implementation plan

 In parallel EFSA is updating the 2018 Guidance on Nano risk assessment

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