

Amazentis

# EFSA Presentation → 31<sup>st</sup> March 2022

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## Description of the content to be presented

- 1. Review of the Guidance as seen through the eyes of the industry**
- 2. Practical application of the guidance**
- 3. Key learnings from following the EFSA guidance**



**Review of the  
Guidance as  
seen through  
the eyes of the  
industry**







# Size as a key driver for nanomaterial behaviour

## 1<sup>st</sup> challenge: Definition

### ❑ **European EC (2001)** - (2011/696/EU)

*A natural, incidental or manufactured material containing particles, ..., for 50 % or more ... is in the size range 1 nm - 100 nm.*

### ❑ **ISO & EUR 26567 EN:** Definitions by international organizations and committees

### ❑ **EFSA DEF:** Inclusion of small particles

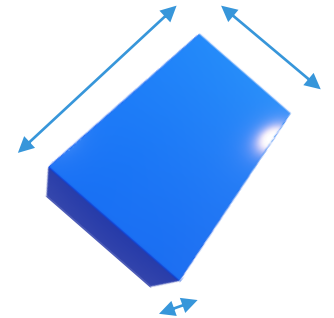
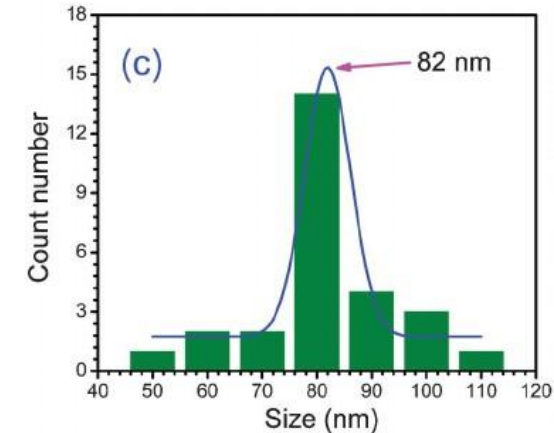
■ D10 < 500 nm

■ Characterization of small particles (< 500 nm)

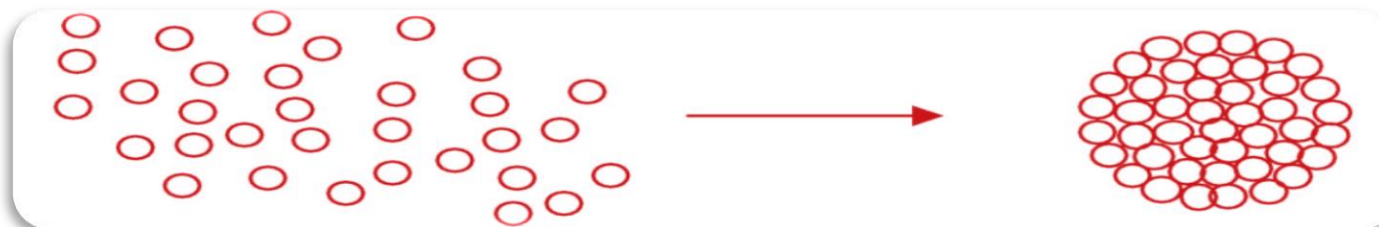
■ D10 < 250 nm

## 2<sup>nd</sup> challenge: Particle size distribution

Measuring 3 dimensions can be difficult



## 3<sup>rd</sup> challenge: **Agglomeration and aggregation** increase particle size



Natural tendency of small molecules to stick together

Agglomerate?, Aggregate?, Environment difference: pH, body fluid type, hydrodynamic size (simulate physiological body conditions).

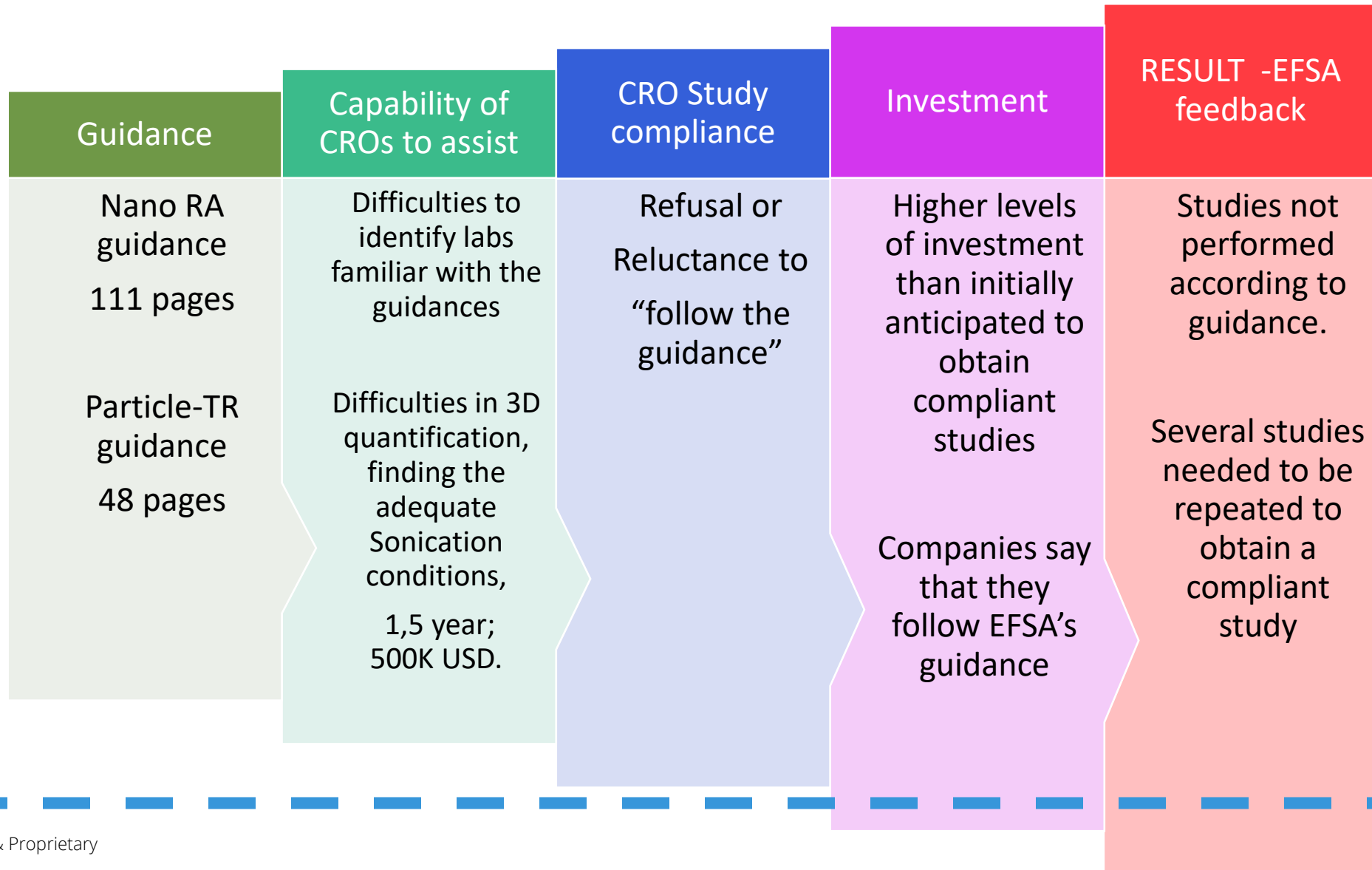


# Practical application of the guidance





# Applying the guidance





**Key learnings from  
following the EFSA  
guidance**





## Helpful insights & Proposals to consider:

Possibility to have a pre-submission consultation, determining acceptability of data

EFSA Webinars/Workshops that support both Applicants and CROs

Establishing a list of qualified/accredited CRO providers around Europe

Creation of FAQs to assist both providers and applicants

Beneficial to have smaller but more targeted guidances e.g.: sonication





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