

Stakeholder Workshop 2022 Wrap up of Session 1 and introduction to Session 2

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 Guidance on Technical Requirements for conventional materials

 Technical requirements for conventional materials

- Not connected to definitions or the EC recommendation for nanomaterials/nanoforms.
- Includes thresholds based on risk assessment principles
 - Consumers safety is sufficiently covered by sectoral guidance

 The fraction of nanoparticles may have different hazard properties than the bulk material.





 Guidance on Technical Requirements for conventional materials

- New considerations also for previously assessed materials
 - Triggering new information requirements

- Scientific knowledge evolves, and guidance evolve accordingly for ensuring consumers protection.
- Nano-scale considerations not or only partially addressed in previous EFSA assessments
- Previous dossiers did not include information for assessing the possible presence of a fraction of nanoparticleş





 Guidance on Technical Requirements for conventional materials

- Applicable to
 - all chemical substances and materials requiring EFSA assessment

 Specific information to be included in dossiers and submissions to EFSA

 Different options for demonstrating that a conventional assessment is sufficient

 If cannot be demonstrated, the dossier/application should follow the Nano RA Guidance





 Guidance on Technical Requirements for conventional materials

 Provides flexibility, but also requires consistency Select the appraisal route and method that better suits your material

- If your material has properties at the nanoscale (e.g. large specific surface area), the risk assessment should address these properties:
 - E.g. nanostructured materials and nanocarriers must follow the Nano RA Guidance (Section 1.3 point e)





 Guidance on Nanoscale considerations in risk assessment

- Applicable to:
- engineered nanomaterials and nanoforms,
- conventional materials with a fraction of nanoparticles,
- Nanostructured materials and nanocarriers

Practical arrangements



- The meeting will be recorded and the recordings will made publicly available on the EFSA website
 - Participation represents implicit agreement for recording the meeting (see invitation letter)
- Presentations will be disseminated through the EFSA website
- All participants can use the "chat function"



- Video and audio connection is provided only to speakers
 - Please keep the video and audio off while not presenting or talking

Q&A Sessions during the meeting



- Send your questions using the chat during the presentations or breaks
 - Use the like function to indicate interest on a question formulated by another participant
- Start with YOUR Name, SURNAME and ORGANISATION
 - If your question is for a specific speaker after your name add
 @Speaker's Name, e.g. @Tarazona
- EFSA will select and group the questions considering generic interest
- Questions will be answered orally during the dedicated Q&A Sessions

Q&A Sessions after the meeting



- EFSA will prepare and publish a Frequently Asked Questions (FAQs) document
 - No written response will be provided to specific questions



 If your question has not been covered during the meeting or by the FAQs, and in case you have a follow-up question, please submit it through ask EFSA



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