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## **UPDATE ON EFSA'S SCIENTIFIC COMMITTEE NANO GUIDANCE DOCUMENTS AND RELATED ACTIVITIES**

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# BACKGROUND: 2021 NANO GUIDANCE DOCUMENTS

**Aim:** assess and/or exclude possible risk from the presence of nanoparticles in food

**Guidance on Particle - Technical Requirements:**  
*Are 'nanoscale considerations' needed for the risk assessment?*

**Guidance on Nano – Risk Assessment:**  
*How to conduct a 'nanoscale' risk assessment?*

**!New**

GUIDANCE



ADOPTED: 30 June 2021  
doi: 10.2903/j.efsa.2021.6769

**Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles**

**Conventional materials** which do NOT meet the definition of engineered nanomaterial but **may contain small particles including particles at the nanoscale**

**!Update**

GUIDANCE



ADOPTED: 30 June 2021  
doi: 10.2903/j.efsa.2021.6768

**Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health**

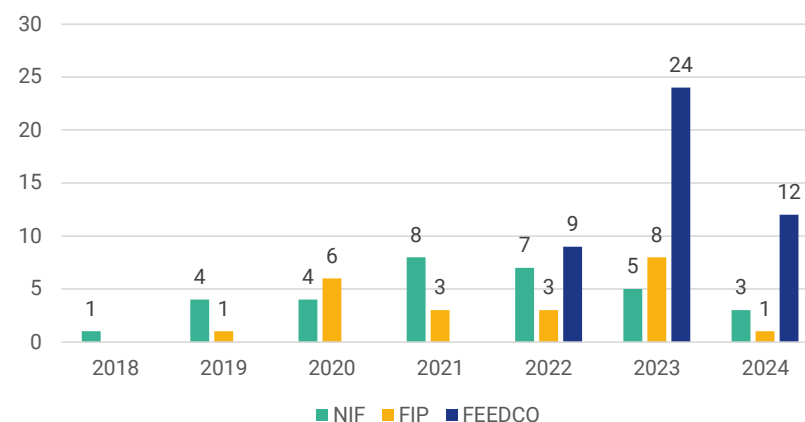
Materials that meet the definition of **engineered nanomaterial, nanoforms, nanostructured materials, and materials with a fraction of nanoparticles**

# RECENT ACTIVITIES (2021→ 2024)

## Activities ccWG Nanotechnologies:

- A. To provide support to EFSA Panels & Units in the correct and harmonised implementation of its Nano Guidance documents
- B. To monitor lesson learnt from the first implementation phase and brainstorm to plan next steps

Requests for assistance received by the ccWG Nano



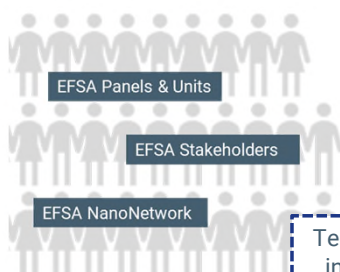
Elements for improvement identified from the experience with practical cases



Further elements collected from targeted surveys



Discuss the input received with the SC to define a roadmap for guidance update



# RECENT ACTIVITIES (2021→ 2024)

While major updates will be covered in the context of a new self-task mandate, work to provide **further guidance to applicants and risk assessors** has already started →

New Annex on Dissolution added in Nov 2022, as per request from the CEP Panel

Clarification on DLS published in Feb 2024, as per request from the FIP Unit

New Annex on 'Clarification on the use of a K<sub>ow</sub>-based threshold for lipid-soluble substances as a possible appraisal route' in July 2024 produced as per request from the NIF Unit/NDA Panel

New Annex to support the reporting of electron microscopy analysis results (*in preparation*)

Annex A – Guidance on Particle - Technical Requirements



## Annex A – Degradation/dissolution rate under acidic conditions

### 1. Introduction

Dissolution rate determination is one of the appraisal routes that can be used by applicants, and other interested parties, to demonstrate that a conventional material does not require specific nanoscale considerations and, consequently, a conventional assessment according to the sectoral guidance is sufficient.

This criterion is implemented in Section 2.3.2 of this Guidance, which states that "If, at a concentration corresponding to exposure at maximum use level (as detailed in Section 2.3.2.3), the (mass-based) dissolution rate of the material in water (or the dissolution rate of each constituent in case of a multi-constituent substance) shows a half-life of 10 min or less, no additional assessment for the fraction of small particles is needed. This dissolution rate corresponds to 12% or less of the material (mass-based) remaining present as particles after 30 min, a percentage and time point adequate for minimising

## Milestones

<https://www.efsa.europa.eu/en/topics/topic/nanotechnology>

2024 February  
Experts clarify 'the use of Dynamic Light Scattering (DLS) and other light scattering methods for characterisation of particle size distribution' at 50th meeting of the Working Group on Nanotechnologies (see Annex I).

Annex B – Guidance on Particle - Technical Requirements



## Annex B – Clarification on the use of a K<sub>ow</sub>-based threshold for lipid-soluble (lipophilic) substances as a possible appraisal route

### Scope of this document

The aim of this document is to clarify the use of K<sub>ow</sub> for organic lipid-soluble substances to be marketed in a lipid matrix or oily fluid/food, in the context of Section 2.3.4 "Solubility/dissolution in the marketed product or in food" of the Guidance on Particle - Technical Requirements (TR).

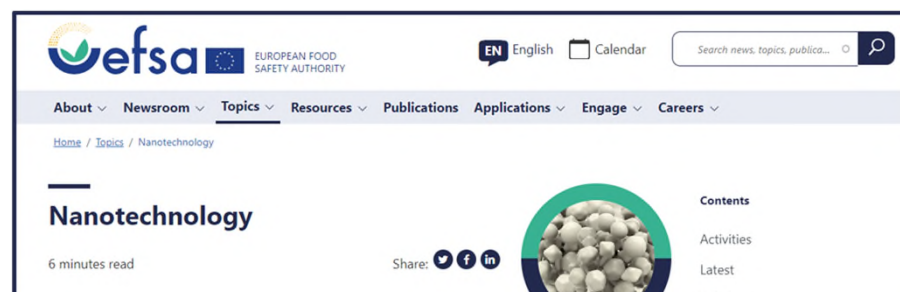




# RECENT ACTIVITIES (2021→ 2024)

## Other activities:

- **EFSA Webpage on Nanotechnologies updated** with recent developments and training material.
- **Call for experts launched** with the aim to increase expertise on the topic in EFSA Panels' WGs.
- Cooperation with the EC JRC to join forces to **work on capacity building** on the topic. Results from the survey will be used to identify training needs.
- Invest in experimental projects to **promote implementation of NAM-based methodologies** for possible integration in nano-specific risk assessment (EFSA's NAMs Nanocellulose Case Study and NAMs4NANO Project).
- Continue **monitoring the experiences from international activities and other agencies** to ensure alignment and integrate new relevant knowledge into EFSA guidance documents.

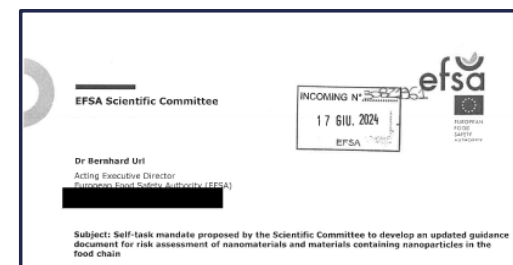


# NEXT STEPS: ROADMAP FOR GUIDANCE UPDATE

## New self-task mandate for updating 2021 EFSA's Nano Guidances

### Roadmap for guidance update, 3 phases:

- **Short term (18 months):** merge the existing guidance documents and include clarification on the structure and requirements. Start integrating further guidance on the use of NAMs in support of nanoparticles RA based on experience from other agencies and finalised EFSA-funded projects on NAMs.
- **Medium term (3 years):** integrate major scientific updates (e.g. indications for ERA, new knowledge on nanocarriers, advanced materials, and SSbD. Further work will be carried out to advance the implementation of NAMs for nano-specific RA. The development of further nano-specific guidance for feed additives will be addressed in parallel by the FEEDAP Panel.
- **Long term (5 years):** integrate with the results of the EFSA NAMs4NANO Project.



<https://open.efsa.europa.eu/questions/EFSA-Q-2024-00439>



# EFSA'S PROJECTS ON NAMS & NANO

☑ Q1 2021 - Q2 2023

## EFSA Pilot Project on NAMS for the hazard assessment of nanofibers

([GP/EFSA/SCER/2020/04](#))



- **Lot 1:** 'NANOCELLulose oral exposure: gastrointestinal digestion, nanofibers Uptake and local effects' Vincentini et al., 2013
- **Lot 2:** 'Exploring the use of gut-on-a-chip models for risk assessments of nanofibers' Italiani et al., 2013

⌚ Q1 2023 - Q2 2027

## EFSA NAMS4NANO Project ([GP/EFSA/MESE/2022/01](#))

*Integration of New Approach Methodologies results in chemical risk assessments: case studies addressing nanoscale considerations*



- **Lot 1:** Review of NAM-based tools for nano-specific risk assessment and developing a 'Qualification System for NAMS' using the experience from EMA & US FDA
- **Lot 2:** Designing and conducting a set of risk assessment case studies
- **Lot 3:** Designing and conducting a set of methodological case studies



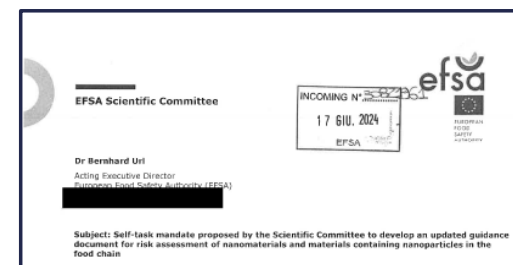
**Final goal:** Develop further recommendations on the use of NAMS for addressing nanoscale considerations and in parallel foster the general implementation of NAMS

# NEXT STEPS: ROADMAP FOR GUIDANCE UPDATE

## New self-task mandate for updating 2021 EFSA's Nano Guidances

### Key elements to be considered:

- Update according to the most recent state-of-the-art to provide best practices for building a **realistic and relevant RA**.
- Foresee an **increase in engagement activities to strengthen international cooperation**, promote alignment of methodologies and foster interaction with stakeholders through ad hoc consultations, (e.g. with targeted meetings and/or the public consultation).
- In support of this work, EFSA is asked to **set up a WG covering the expertise needed**. The WG should also ensure liaison with relevant external institutions (e.g. such as ECHA, EEA, EMA, US FDA, US EPA, WHO, EC's non-food Scientific Committees) or that develop standards in this area (e.g. JRC, OECD WPMN, ISO/CEN, EU-funded Projects).



<https://open.efsa.europa.eu/questions/EFSA-Q-2024-00439>



# NEW WG & ENGAGEMENT ACTIVITIES

## WG re-shaping:

- New WG established to address new mandate and tasks: [ccWG on Particle Risk Assessment](#)
  - **Name aligned with the extended scope of this WG** (i.e. assess risk of particulate materials, including nanomaterials but not exclusively)
  - **Two subgroups** are created to deal with Advice & Guidance update
  - **Composition refined** to add new experts covering relevant expertise

## Dissemination/engagement activities:

- 14<sup>th</sup> Annual meeting of the EFSA Network on Nanotechnologies in food and feed (NanoNetwork) – 26-27 Nov 2024
- Workshop with EU Agencies and international partners – Q1/2 2025
- Ad hoc meetings with targeted Stakeholders – TBD
- Stakeholder Event – TBD



# ACKNOWLEDGMENTS



EFSA's ccWG Particle Risk Assessment (former ccWG Nanotechnologies)

EFSA Panels & Units

EFSA NanoNetwork

EFSA Stakeholders

## WG Members

- WG Chair: Qasim Chaudhry
- Subgroup Guidance: Anthony Cadène, Jacqueline Castenmiller, Laurence Castle, Francesco Cellesi, Wim de Jong, Francesca Maranghi, Jan Mast, Agnes Oomen, Olimpia Vincentini, Ivana Vinković
- Subgroup Risk Assessment: Maria Bastos, Ulrike Bernauer, Francesco Cubadda, Roland Franz, Henriqueta Louro, Eveline Verleysen

## EC Representatives

- Hubert Rauscher and Susanne Bremer Hoffman (EC JRC), Ivona Babic and Aurélien Perez (DG SANTE), Camelia Constantin and Virginia Rodriguez Unamuno (ECHA), Anja Pfalzgraff and Garcia del Blanco (EMA)

## EFSA Taskforce

- MESE Unit: Maria Chiara Astuto, Irene Cattaneo, Claudia Cascio
- FIP Unit: Eric Barthélémy, Daniele Comandella, Agnieszka Mech, Ana Rincon
- FEEDCO Unit: Orsolya Holczknecht, Maria Vittoria Vettori
- NIF Unit: Reinhard Ackerl, Marcello Laganaro

**Thank you for  
your attention!**



**Any questions?  
Input?**

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