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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?**

!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**

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

!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

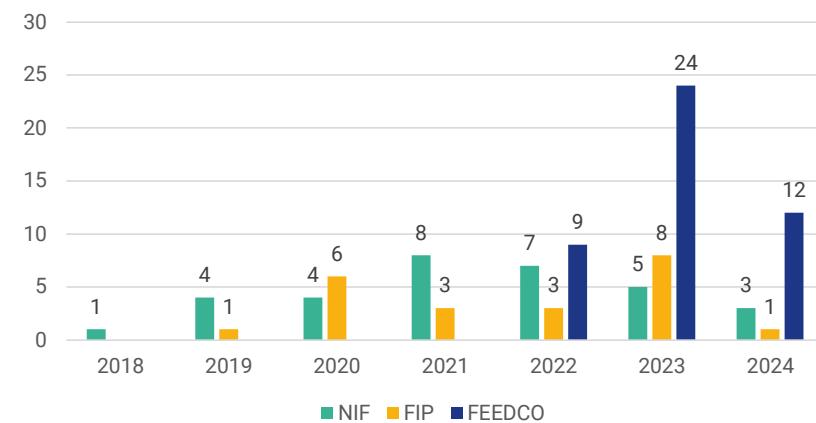
Materials that meet the definition of **engineered nanomaterial, nanoforms, nanostructured materials, and materials with a fraction of nanoparticles**

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

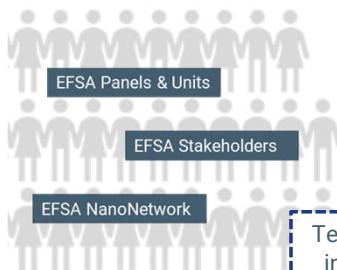
Requests for assistance received by the ccWG Nano



Elements for improvement identified from the experience with practical cases



Further elements collected from targeted surveys



Technical report in preparation



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 'Clarification on the use of a K_{ow}-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*)

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

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

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).

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

Annex B – Guidance on Particle - Technical Requirements

efsa JOURNAL

Annex B – Clarification on the use of a K_{ow}-based threshold for lipid-soluble (lipophilic) substances as a possible appraisal route

Scope of this document

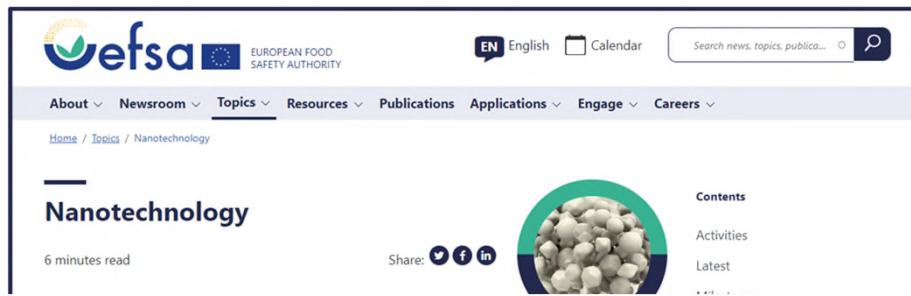
The aim of this document is to clarify the use of K_{ow} for **organic lipid-soluble substances** to be marketed in a lipid matrix or oily food/feed, in the context of Section 2.3.4 "Solubility/dissolution in the marketed product or in food" of the Guidance on Particle - Technical Requirements (TR).



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.

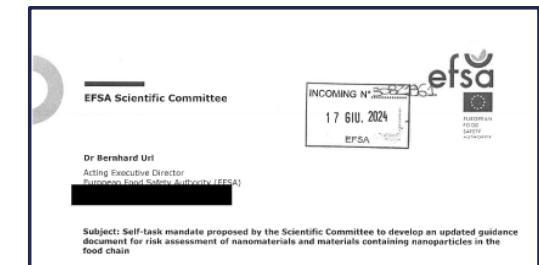


NEXT STEPS: ROADMAP FOR GUIDANCE UPDATE

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'
- **Lot 2:** 'Exploring the use of gut-on-a-chip models for risk assessments of nanofibers'



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

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

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:

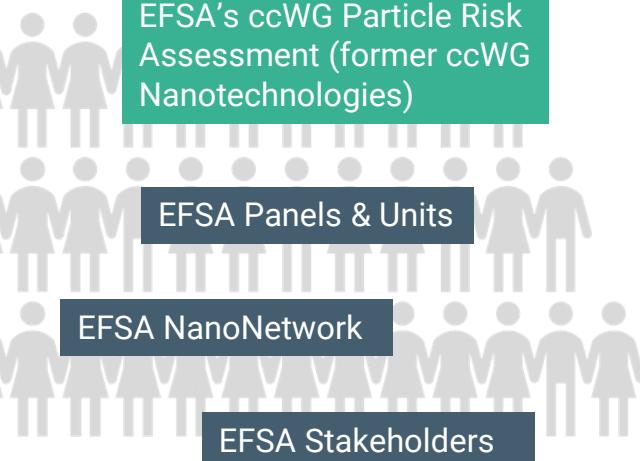
- New WG established to address new mandate and tasks: [**ccWG on Particle Risk Assessment**](#)
 - **Name aligned with the extended scope of this WG** (i.e. assess risk of particulate materials, including nanomaterials but not exclusively)
 - **Two subgroups** are created to deal with Advice & Guidance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

Dissemination/engagement activities:

- 14th 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



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, Henrique 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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