The EFSA guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain

Welcome

History

Goals of the workshop

Reinhilde Schoonjans
European Food Safety Authority

Workshop with Stakeholders • 1-2 April 2019
Previously in EFSA

The Journey

Original Guidance published

2011

Start update

Public consultation: guidance on nanomaterials

2016

Cross-Cutting working Group

2018
PEOPLE INVOLVED

WG Member Experts:
- Qasim Chaudhry
- Francesco Cubadda
- David Gott
- Alicja Mortensen
- Agnes Oomen
- Stefan Weigel

Ad Hoc Experts:
- Roland Franz
- Barbara Drasler

Observers:
- Hubert Rauscher

EFSA Staff:
- Dimitra Kardassi (Pesticides)
- Maria Vittoria Vettori (Feed)
- Eric Barthélemy (FCM)
- Federica Lodi and Ana Rincon (Food additives)
- Reinhard Acherl (Novel food)
- Reinhilde Schoonjans (Scientific Committee)

EFSA Nano Network: 24 Experts, 21 alternates from 26 EU countries

Public consultation: approximately 400 comments received by the online tool and in letters, submitted by 30 different parties
Nano-applications covered

- Nanoscience and nanotechnology applications in the areas within EFSA’s remit:
  - Novel foods
  - Food contact materials
  - Food additives
  - Feed additives
  - Pesticides

- Appendix E – Sector Specific Information: Feed Additives, Nanopesticides, Food Contact Materials, Novel Foods, Nanocarriers – and, as contaminants, Nanoplastics
Timeline Pilot Phase

Adoption for testing

- 2018 May

Testing with Panels and Units

- 2018 Sept

Workshop with stakeholders

- 2019 Jan

Finalisation

- 2019 Autumn

- July
- Oct
- Nov

- Set-up ccWG
- Info session EFSA staff
- Nano Network with Member States
- End Pilot phase
Two tasks for the working group


2019-: de novo development for environmental risk assessment.

Two principles

To supplement existing sector-specific guidances: there are entry points and exit points for applying the nanoguidance.

No tick box for core studies: there is a tiered approach in which not all studies are always required.
Your feedback

- During the discussions
- On Sli.do
- With references to the guidance if possible

4. Physicochemical characterisation of nanomaterial .................................................................................................
4.1. Framework for distinguishing nanomaterials and non-nanomaterials .............................................................
4.2. Pristine material characterisation .....................................................................................................................
4.2.1. Parameters .....................................................................................................................................................
4.2.2. Specifications and representativeness of the test material ..............................................................................
4.2.3. Techniques and methods ................................................................................................................................
4.3. Characterisation and quantification in matrix .....................................................................................................
4.3.1. Characterisation in agri/food/feed products .................................................................................................
4.3.2. Characterisation in test media for in vitro and in vivo testing and in biological matrices ............................
4.3.3. Solubility and degradation/dissolution rate ....................................................................................................
4.3.4. Characterisation and quantification of nanomaterial in FCM and after transfer from FCM ......................
4.4. Quality assurance ................................................................................................................................................
4.4.1. Standardised methods ....................................................................................................................................
4.4.2. Method validation, performance criteria ........................................................................................................
4.4.3. Reference materials .......................................................................................................................................
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