Programme

Stakeholder workshop on nanoscience and nanotechnology | Parma, 1-2 April 2019

The European Food Safety Authority published in July 2018 its Guidance on human and animal health aspects (Part 1) of the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain.

The document takes account of scientific developments related to human and animal health since publication of the previous guidance in 2011, particularly regarding physico-chemical characterisation, exposure assessment and hazard characterisation of nanomaterials. The guidance also details nano-specific considerations when performing in vivo/in vitro studies and outlines a tiered framework for toxicological assessment.

The guidance is applicable to novel foods, food contact materials (FCMs), food/feed additives and pesticides. Its correct implementation is important for the applicants who seek market approval/renewal of a product under the various food laws, as well as for regulatory risk assessors from EFSA, Member States, and other stakeholders. Since the new novel food legislation came into force in January 2018, it has been mandatory for the most up-to-date test methods to be used in risk assessments.

Objectives and expected outcome

EFSA invites applicants to share their experiences of implementing the Guidance. The workshop gives the floor to the applicants who want to raise specific issues of implementing the guidance and discuss them with EFSA scientists.

After each presentation, the discussion between the speakers, participants and EFSA experts, will address the questions in a targeted and efficient way linked to the guidance. The main outcome of this workshop will be constructive suggestions for making amendments to the EFSA Guidance at the end of the pilot-phase.

Active participation by the stakeholders who are using nanosciences and nanotechnologies and intend to submit dossiers to EFSA is particularly expected for a successful exchange of information and discussion. Please prepare for such exchange by reading the EFSA Guidance on risk assessment of nanoscience and nanotechnologies applications in the food and feed chain: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5327.

Detailed Programme

Overall Chair: Reinhilde Schoonjans, SCER Unit, EFSA
Overall Co-Chair: Qasim Chaudhry, University of Chester

1 April 2019

13.00-13.30	**Registration** **Health and Safety video**	
13.30-13.45	**Welcome and introduction to the event**	Reinhilde SCHOONJANS, Chair, SCER Unit, EFSA
13.45-14.15	**EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products** The EFSA Catalogue of services	Remigio MARANO, APDESK, EFSA
14.15-14.30 +15 min discussion	**Overview of the EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain**	Francesco CUBADDA, ISS (Italy), WG Member
SESSION Chapter 4.1 – 4.2 Physicochemical Characterisation **Chair: Hubert RAUSCHER, Joint Research Centre (JRC)** **Co-Chair: Jan MAST, Sciensano**		
14.45-14.55	**Welcome and introduction to the session** **Focus on chapters 4.1 – 4.2.2, including techniques and methods (EM)**	Hubert RAUSCHER, JRC, EC
14.55-15.15 +15 min discussion	**Characterization of the nano-sized particles in E171 and E174 and in food containing these additives**	Jan MAST , Sciensano *(Belgium)*
15.30-15.45 +15 min discussion	**TDMA report on E171 (titanium dioxide) and E172 (iron dioxide) - analytical perspectives from research**	David BRIZZOLARA, Titanium Dioxide Manufacturers Association (TDMA) *(Germany)*
16.00-16.30	*Coffee/Tea break*	
16.30-17.30	**General discussion** **Implementation issues related to the EFSA GD Questions received from stakeholders**	Hubert RAUSCHER, JRC, EC
17.30	**Closure** of the first meeting day	

2 April 2019

SESSION Chapter 4.3 – 4.4 Physicochemical Characterisation **Chair: Francesco CUBADDA, Istituto Superiore di Sanità - Italian National Institute of Health (ISS), WG Member** **Co-Chair: Stefan WEIGEL, Bundesinstitut für Risikobewertung (BfR), WG Member**		
08.30-08.40	**Welcome and introduction to the session** **Focus on Chapters 4.3-4.4.3, including solubility and degradation/dissolution rate**	Francesco CUBADDA, *ISS (Italy), WG Member*
08.40-08.55 +15 min discussion	**Physical Chemical Characterization of Nanomaterials**	Bjoern BRAUN, *Evonik Resource Efficiency GmbH, (Germany)*
09.10-09.25 +15 min discussion	**Food and Feed Ingredient Submissions – The Importance of Particle Size - Understanding and Interpreting EFSA's Guidance on Nanotechnologies**	Nigel BALDWIN, *INTERTEK (United Kingdom)*
09.40-10.40	**General discussion** **Implementation issues related to the EFSA GD**	
10.40-11.10	*Coffee/Tea break*	
SESSION Chapters 5 and 6 – Hazard Identification and Hazard Characterisation **Chair: Alicja MORTENSEN, National Research Centre for Working Environment (NRCWE), Denmark** **Co-Chair: Agnes Oomen, RIVM**		
11.10-11.20	**Welcome and introduction to the session** **Focus on Chapters 5 & 6 covering Oral Exposure Assessment and Hazard identification/characterisation**	Alicja MORTENSEN, *NRCWE (Denmark)*
11.20-11.35 +15 min discussion	**Intestinal uptake of particles**	Nils KRUEGER, *Evonik Resource Efficiency GmbH, (Germany)* And Klaus WEBER *AnaPath GmbH, (Switzerland)*
11.50-12.50	**General discussion**	

	Implementation issues related to the EFSA GD	
12.50-14.30	**Lunch break**	
SESSION Chapter 3 Scope of the Guidance **Chair: Reinhilde Schoonjans, SCER Unit, EFSA** **Co-Chair: Qasim Chaudhry, University of Chester**		
14.30-14.40	**Welcome and introduction to the session**	Reinhilde SCHOONJANS, Chair, SCER Unit, EFSA
14.40-14.55 +15 min discussion	**Nanomaterials in the EU Food Regulations** • EU Food and Food Contact Material Legislation (Panagiotis Daskaleros)	Reinhilde SCHOONJANS, Chair, SCER Unit, EFSA
15.10-15.25 +15 min discussion	**Bottlenecks faced in the industry and multi-disciplinary approach in risk assessment of nanomaterials: A Regulatory perspective**	David CARLANDER, *Nanotechnology Industries Association (NIA), (Belgium)*
15.45-16.00	*Coffee/Tea break*	
16.00-17.00	**General discussion** **Possible scope issues related to the EFSA GD** - The use of a representative formulation to derive conclusion of safety of nano-formulations (e.g. for nano-pesticide) - Any other topics	
17.00	**Closure of the workshop**	