



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



Original Guidance
published

The Journey

2011



Start update



2016



Public consultation: guidance on nanomaterials



2018



Cross-Cutting
working
Group

GUIDANCE

ENDORSED: 29 May 2018

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Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health

EFSA Scientific Committee,
Anthony Hardy, Diane Benford, Thorhallur Halldorsson, Michael John Jeger,
Helle Katrine Knutsen, Simon More, Hanspeter Naegeli, Hubert Noteborn, Colin Ockleford,
Antonia Ricci, Guido Rychen, Josef R. Schlatter, Vittorio Silano, Roland Solecki,
Dominique Turck, Maged Younes, Qasim Chaudhry, Francesco Cubadda, David Gott,
Agnes Oomen, Stefan Weigel, Melpo Karamitrou, Reinhilde Schoonjans and Alicja Mortensen

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

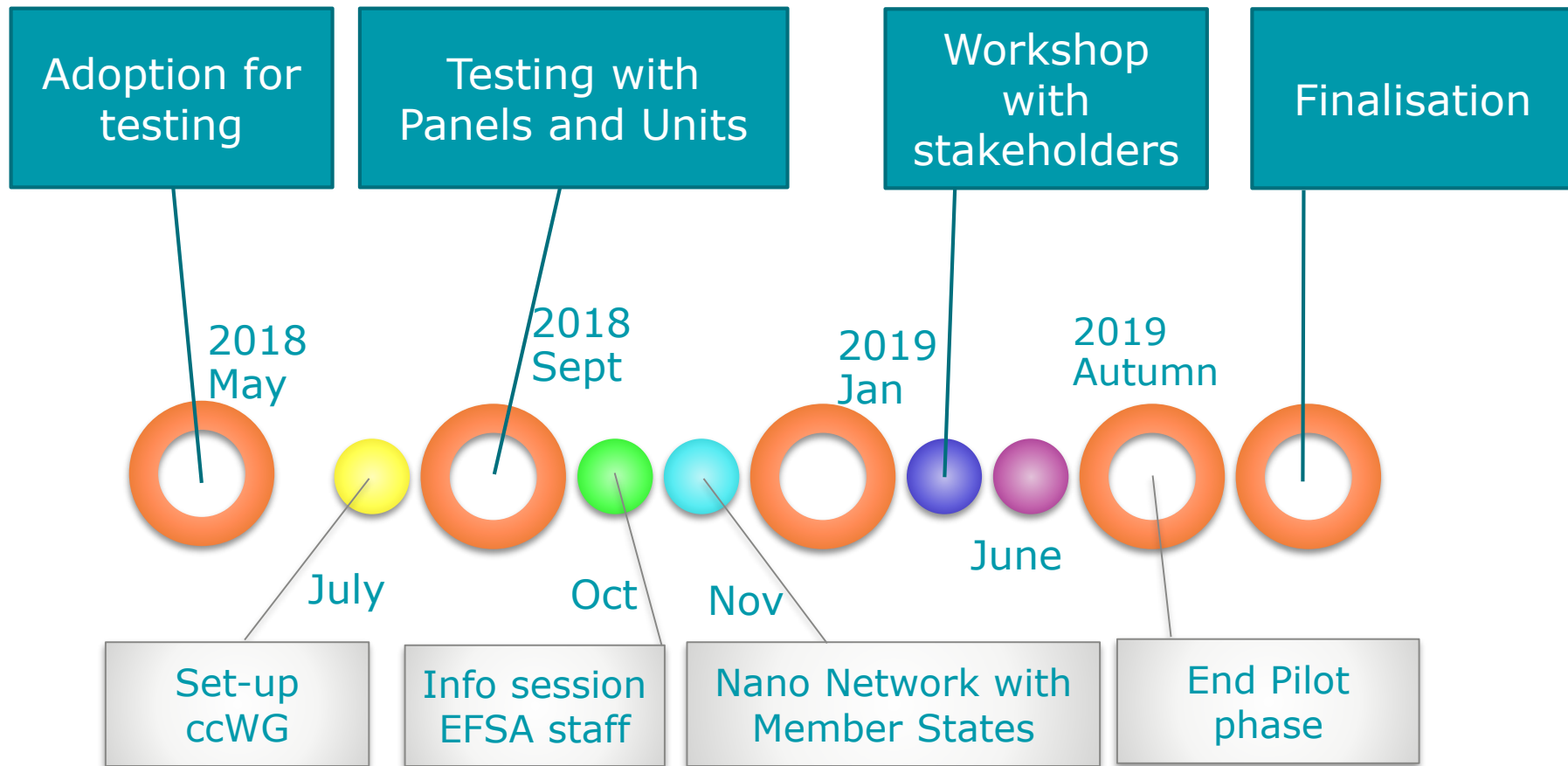
Public consultation: approximately 400 comments
received by the online tool and in letters,
submitted by 30 different parties

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



GUIDANCE DEVELOPMENT



Two tasks for the working group

2016-2018: Update of 2011 guidance for **human/animal health** risk assessment.

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.....

■ Buon Lavoro!



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