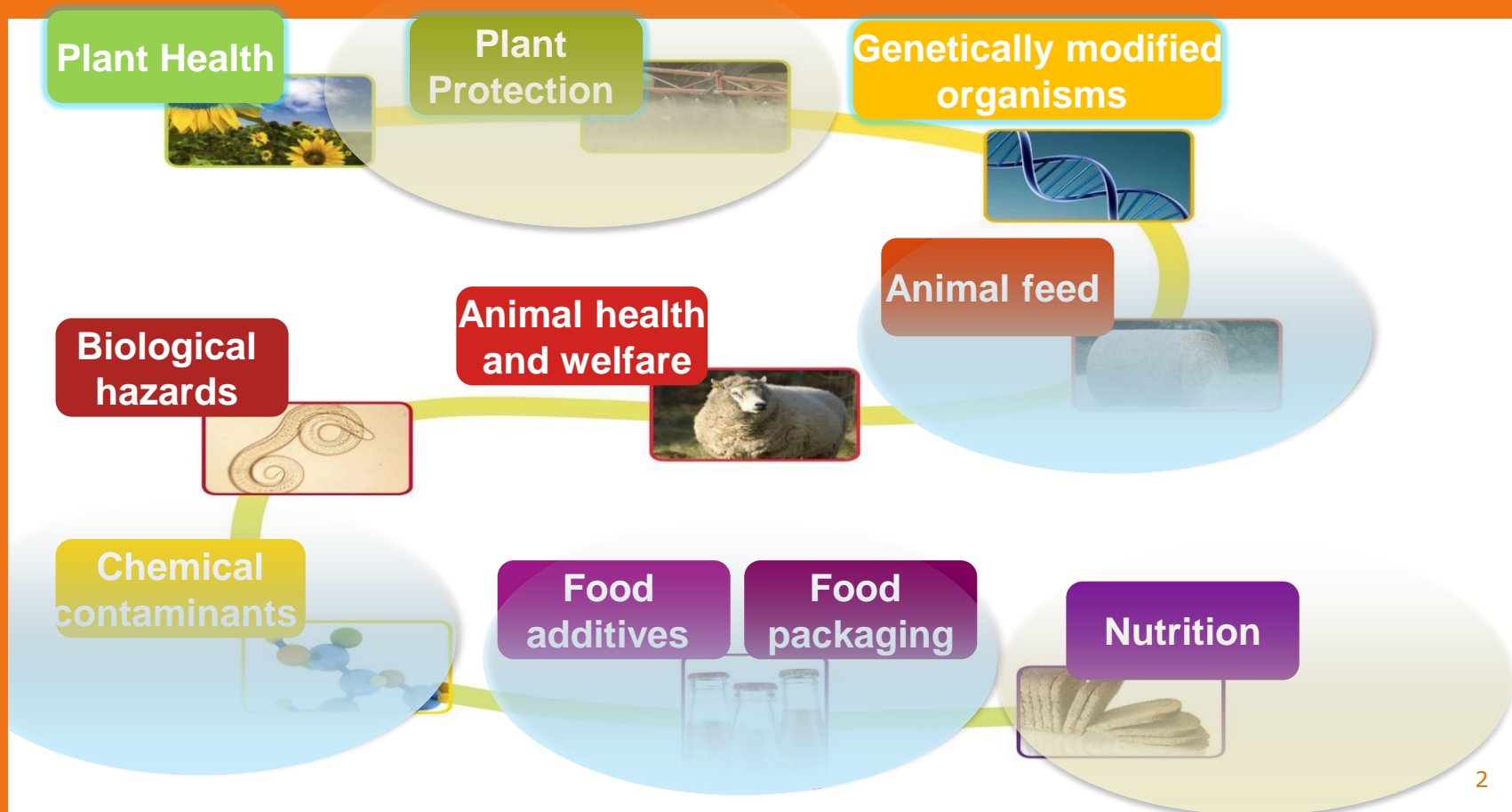




Guidance for risk assessment of nanomaterial in agri/food/feed

FCM Network, 10 July, Parma
Reinhilde Schoonjans

5/10 PANELS involved with nano



GUIDANCE DEVELOPMENT

- 2 tasks

- 2016-2018: Update of 2011 guidance for **human/animal** health risk assessment,
- Including physicochemical characterisation
- 2017 -2019: *de novo* development for **environmental risk assessment**



GUIDANCE DEVELOPMENT

- 2 principles



- Nano guidance is **to supplement** existing sector-specific guidance for risk assessment, linked to the **respective EU legislation** per sector



- No tick box for core studies, but **tiered approach**: not all studies are always required, ANS/NDA guidance used as basis for hazard characterisation



INFORMATION/EVIDENCE BASIS FOR UPDATE

Input needed
for updating
guidance on
human/animal
health



FOOD ADDITIVES

Re-evaluation programme (Reg (EU) no 257/2010)

- All materials permitted before January 2009
- Ag, Au, TiO_2 + other powders are bulk and are not in the nanoscale, but comprise a nanofraction
- SAS (to be evaluated) is nanomaterial
- Size distribution is always requested

FEED

FOOD CONTACT MATERIALS

Passed and ongoing applications

- Dossiers submitted on explicitly engineered nanomaterial
- Exposure scenario: no migration into the food

FOOD CONTACT MATERIALS

EFSA-Q-2014-00529	Additional data request	Request for the evaluation of Zinc oxide nano particles
EFSA-Q-2014-00308	Finished	Request for safety evaluation of zinc oxide, nano particles for use as an additive in plastics
EFSA-Q-2013-00641	Additional data request	Request for safety evaluation of Nano-Hexadecyltrimethylammonium Bromide modified Montmorillonite Organoclay for use as additive in plastics
EFSA-Q-2013-00100	Finished	Request for the evaluation of additive : copolymer in Nanoform of methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl acrylate, butadiene
EFSA-Q-2012-00706	Finished	Request for the evaluation of Additive : Copolymer in nanoform of ethyl acrylate, methyl methacrylate, butadiene, styrene and either not crosslinked or crosslinked with divinyl benzene or 1,3-butanediol dimethacrylate
EFSA-Q-2011-01079	Finished	Titanium nitride, nanoparticles
EFSA-Q-2006-323	Finished	Titanium nitride, nanoparticles

ISSUES COVERED

CEF

- The Panel and its previous work is represented in the working group
- Migration studies: detection limits in the methods used for determining nanomaterial (migration considering the number of particles and considering relevant particle distribution) should be state of the art

CONTAM

Presence of microplastics and nanoplastics in (sea) food



- Need for standardisation of analytical methods to assess their presence, identity and to quantify their amount in food
- Toxicokinetics and toxicity research needed

ISSUES COVERED

CONTAM

- Nanoplastics outside remit of the WG?
- Life-cycle discussion tbc



CONTRACT 2014

Systematic Literature Survey 2014

EFSA supporting publication 2014:EN-621

■ <http://www.efsa.europa.eu/en/supporting/pub/621e>

EXTERNAL SCIENTIFIC REPORT

Inventory of Nanotechnology applications in the agricultural, feed and food sector

CFT/EFSA/FEED/2012/01

Ruud Peters*, Puck Brandhoff, Stefan Weigel, Hans Marvin, Hans Bouwmeester

RIKILT: Wageningen UR, Wageningen, The Netherlands

*corresponding author; ruudj.peters@wur.nl

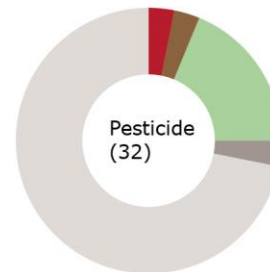
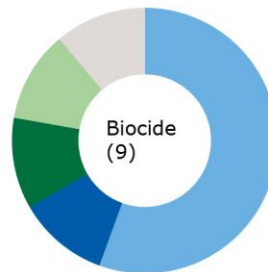
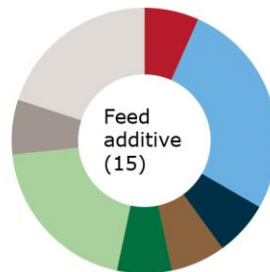
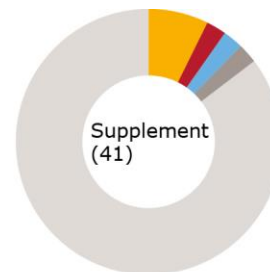
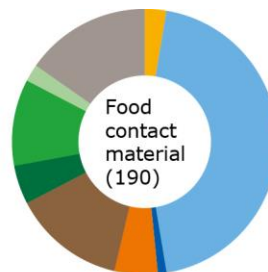
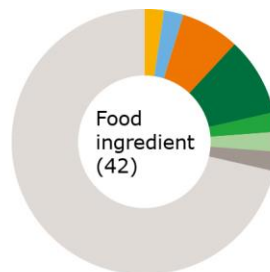
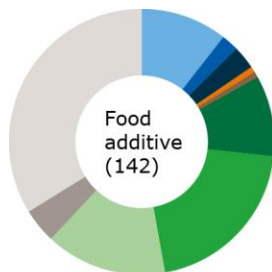
Karin Aschberger, Hubert Rauscher, Valeria Amenta, Maria Arena, Filipa Botelho Moniz, Stefania Gottardo, Agnieszka Mech

JRC: Nanobiosciences Unit, Institute for Health and Consumer Protection, Ispra, Italy

CONTRACT 2014

Systematic Literature Survey 2014

■ Peters et al, 2016



Gold
Iron
Silver

Chitosan
Nisin
Carbon nanotubes

Clay
Zinc oxide
Titanium dioxide

Silica
Nano-composite
Nano-encapsulate

COOPERATION

Input from:

- Risk assessment related:
 - ECHA, EMA, US-FDA, US-EPA, WHO, EC non-food Scientific Committees, EEA, DG ENV
- Standards related:
 - JRC, OECD, and institutes for metrology or standards development like ISO/CEN, ASTM, NCI/NCL, NIST, NMIs
- EU FP7 research projects:
 - NanoGenotox, NanoREg, NanoDefine, NanoLyse

COOPERATION

Input/alignment expected with

- Stakeholders:
 - Public consultations
- Member States:
 - EFSA Scientific Network for Nanomaterials

THANKS FOR YOUR ATTENTION

Acknowledgement

- Working group Experts:
 - Alicja Mortensen, David Gott, Francesco Cubadda, Stefan Weigel, Agnes Oomen, Qasim Chaudhry (Andrea Zijno, Jonathan Powell, Barbara Drasler)
 - Hearing:
- EFSA colleagues:
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 - Maria Vittoria Vettori, Emanuela Tiramani (feed)
 - Ana Rincon, Federica Lodi (food)
 - Alexandros Lioupis, Eric Barthelemy (FCM)
 - Wolfgang Gelbman, Reinhard Ackerl (NDA)
 - Andrea Terron, Dimitra Kardassi Marcella De Maglie (PPR)
- Contractors:
 - Ruud Peters (RIKILT); Karin Aschberger, Hubert Rauscher (JRC)



Reinhilde.Schoonjans@efsa.europa.eu