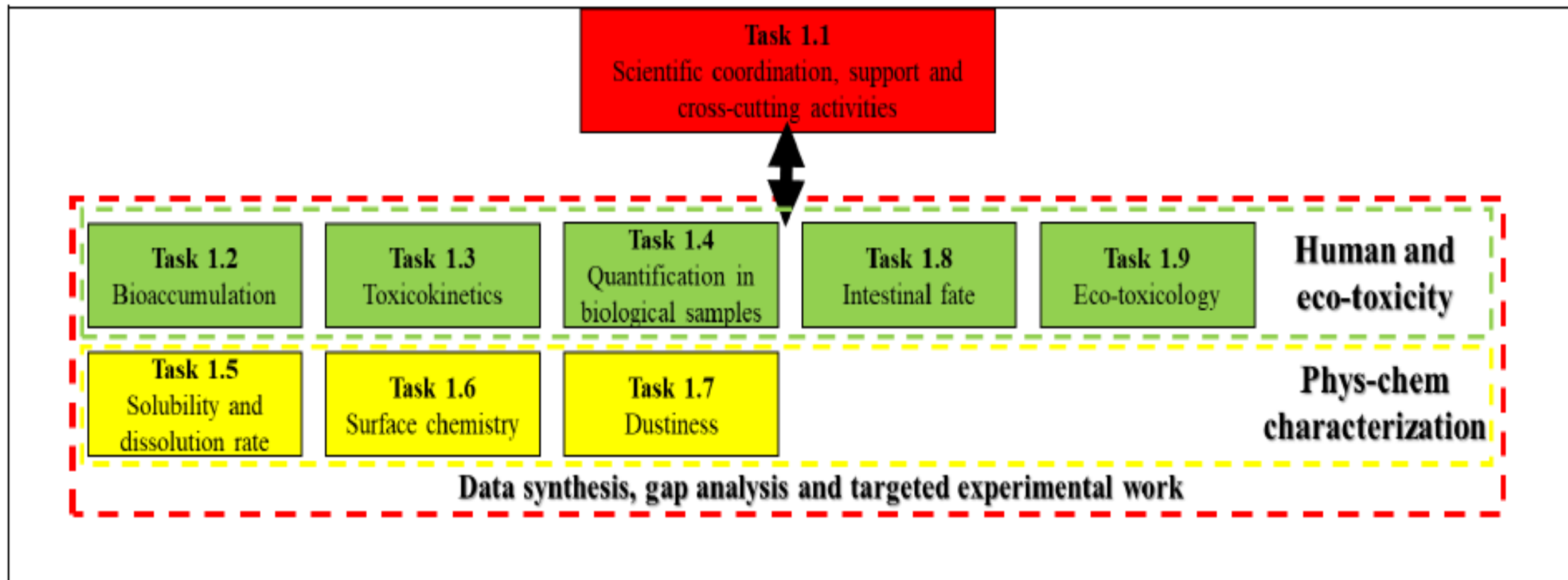


# Scientific base to support development of OECD Test Guidelines and Guidance Documents

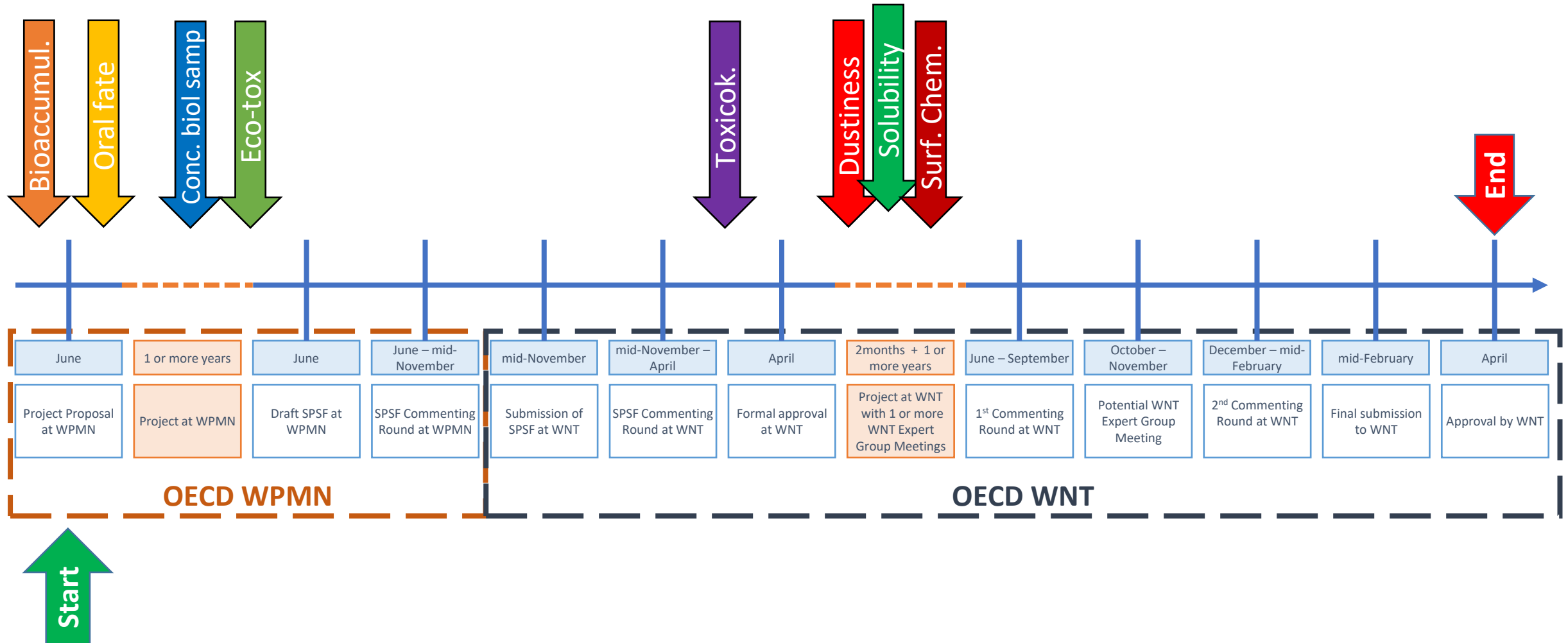
7<sup>th</sup> July 2020  
Rachel Smith (PHE)



# Work Package 1: Tasks



# Timelines of associated OECD projects



# Task 1.6

Identification and quantification of the surface chemistry and coatings on nano- and microscale materials

NanoHarmony



OECD Project: Identification and quantification of the surface chemistry and coatings on nano- and microscale materials. Denmark lead, Germany co-Lead

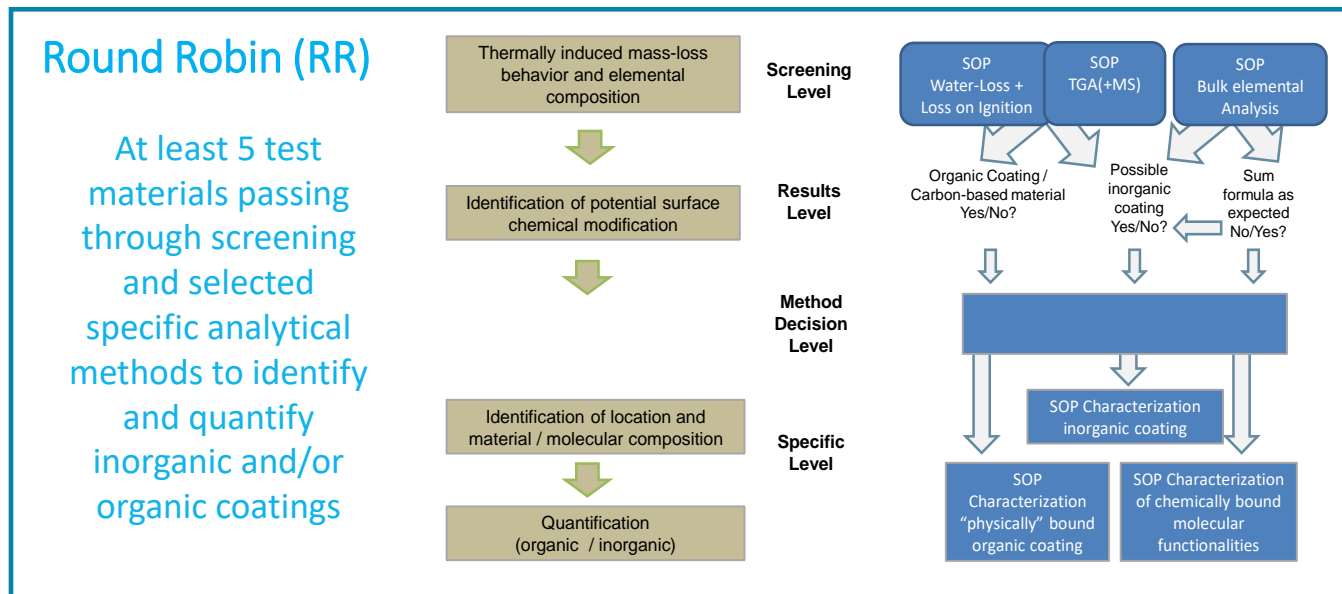
**Reason for inclusion in NanoHarmony** – The main objective of Task 1.6 is to expand the scientific basis and consolidate the knowledge from national and international projects in order to support the development of GD for the ongoing OECD project for the qualitative and quantitative characterization of the surface chemistry of ENMs. In particular NH also supports a RR study

## Activities

- A harmonized protocol will be developed starting from already existing SOPs, which will be collected from ongoing or completed national and international projects and input from relevant stakeholders
- A minimum of 5 different materials coated with organic or inorganic compounds will be analysed in an inter-laboratory comparison study to demonstrate practical feasibility and limitations of the analytical approaches.

**Outcome** The results will be collated in a report containing the consensus SOP and results from RR testing to support development of the OECD GD for characterization of the coating of ENMs.

**Partners** NRCWE (Denmark), BfR (Germany); BASF (Germany) **Associated partners** JRC (EU), KRISS (South Korea); NPL (UK); BAM (D); PTB (D), NRC/CNR (CAN)



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 885931

# Task 1.5

Scientific basis for a new GD on the determination of solubility and dissolution rate of ENMs

NanoHarmony



OECD Project: Determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biological media. Denmark lead, Germany co-Lead

**Reason for inclusion in NanoHarmony** – The OECD project has high interest from many different stakeholders and can provide key information to several parallel OECD GD and TG developments. While other projects, such as GOV4NANO, PATROLS, and GRACIOUS, provide excellent methodological background, there is a further need to expand RR comparisons of similar and different test set-ups.

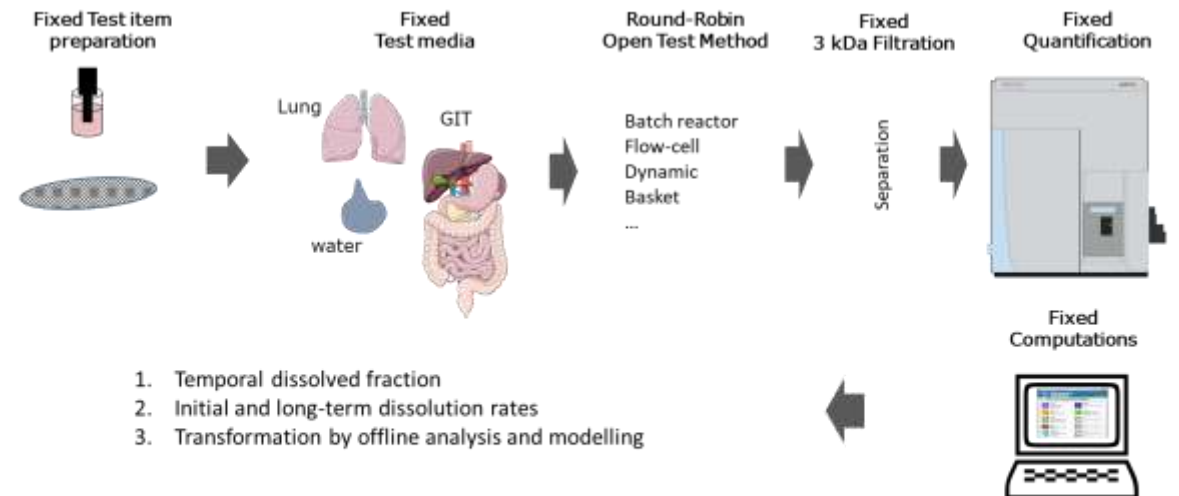
## Activities

- Workshop to map methods and data to define minimum criteria for testing solubility and dissolution in water and biologically relevant media and RR and documentation of phase transformations by characterization and modelling.
- Conduct interlaboratory comparison of tests using similar and different methods for dissolution testing (partners undertake all chemical analysis by ICP-MS and WDXRF)

**Outcome** Results of the task will be consolidated into a technical document to support development of a new OECD GD on solubility and dissolution rate measurement for ENMs in biologically relevant media.

**Partners** NRCWE (Denmark), BfR (Germany); BASF (Germany) **Associated partners** URMIC (USA), IIT (Italy); KRISS (South Korea); FORTH (Schweiz)

## Round Robin (RR) – Interlaboratory comparison of methods



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 885931

# Task 1.7

Scientific basis for Dustiness testing of ENMs (new TG), including high aspect ratio nanomaterials (HARN), for exposure and ATEX industrial risks (new GD)

NanoHarmony

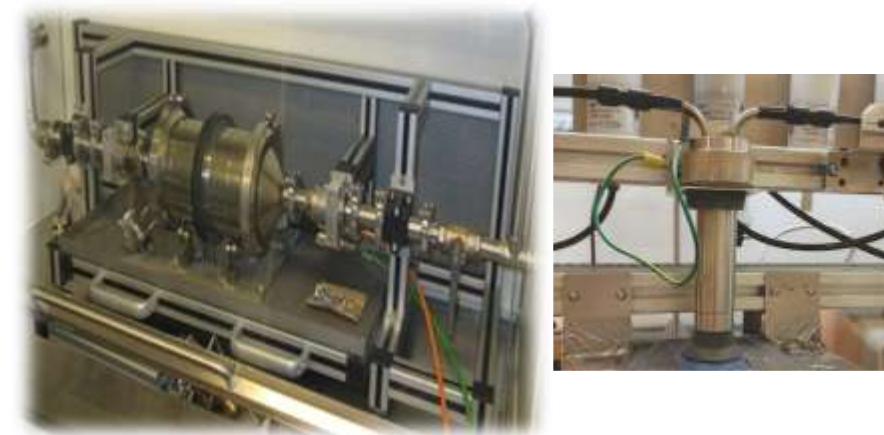


OECD Project: Determination of the Dustiness of Manufactured Nanomaterials. France lead

**Reason for inclusion in NanoHarmony** - expand the scientific basis for the dustiness testing of HARNs, including flammable materials, for operational use of dustiness parameter as a relevant input for ATEX safety assessment and exposure.

## Activities

- Decision on relevant dustiness indexes (number/mass based) for HARN
- Morphological analysis of aerosol samples
- Interlaboratory comparison of different dustiness methods
- Establishment of a method specific ranking scheme
- Establishment of safety recommendations for dustiness testing of flammable materials
- Operational methodology for the use of dustiness for ATEX safety assessment



**Outcome** internationally validated SOPs on testing of HARN and ranking schemes as support for the TG on Dustiness of Manufactured Nanomaterials and for the GD on ATEX safety.

**Partners** Institut National de l'Environnement Industriel et des Risques (INERIS, FR), Federal Institute of Occupation Safety and Health (BAuA, DE), National Research Centre for the Working Environment (NRCWE, DN)



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 885931

# Task 1.3

## Scientific basis for a new TG on toxicokinetics of nanoparticles

NanoHarmony



OECD Project: Development of new Test Guideline on toxicokinetics to accommodate testing of nanoparticles. NL lead

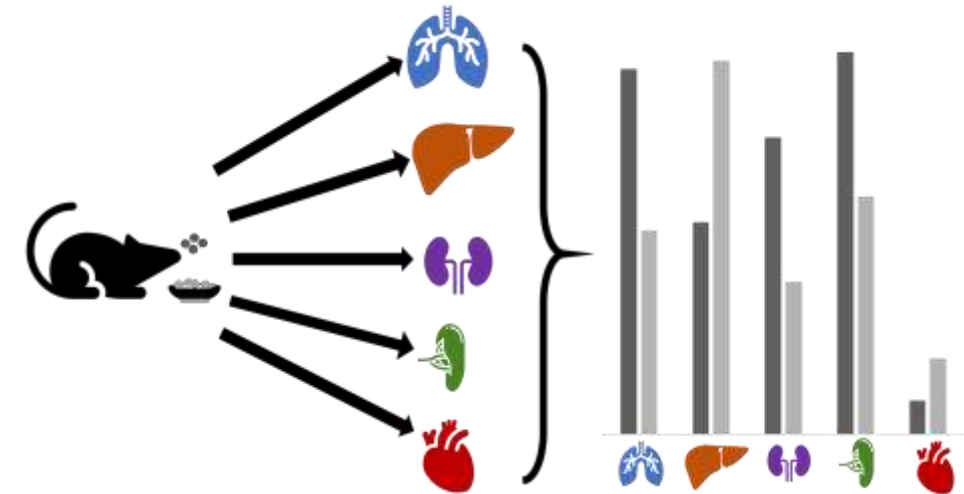
**Reason for inclusion in NanoHarmony** - this task aims to provide the scientific basis for a new OECD TG to harmonize the generation of *in vivo* toxicokinetic data on nanoparticles for regulatory purposes, as the current OECD TG on toxicokinetics is not applicable to nanomaterials.

### Activities

- Data gap analysis on study design requirements for *in vivo* toxicokinetic studies
- Experimental studies to complement existing toxicokinetic data
- Identify minimum study design requirements for *in vivo* toxicokinetic studies
- Workshops to identify additional data and to obtain input from experts

### Outcome

- Scientific document to support OECD activities on the development of TG on toxicokinetics of nanoparticles



**Partners** National Institute for Public Health and the Environment (RIVM), Public Health England (DH PHE), National Research Centre for the Working Environment (NFA), BASF



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 885931

# Task 1.8

Scientific basis for a new GD on an integrated *in vitro* approach for the intestinal fate of orally ingested nanomaterials

NanoHarmony



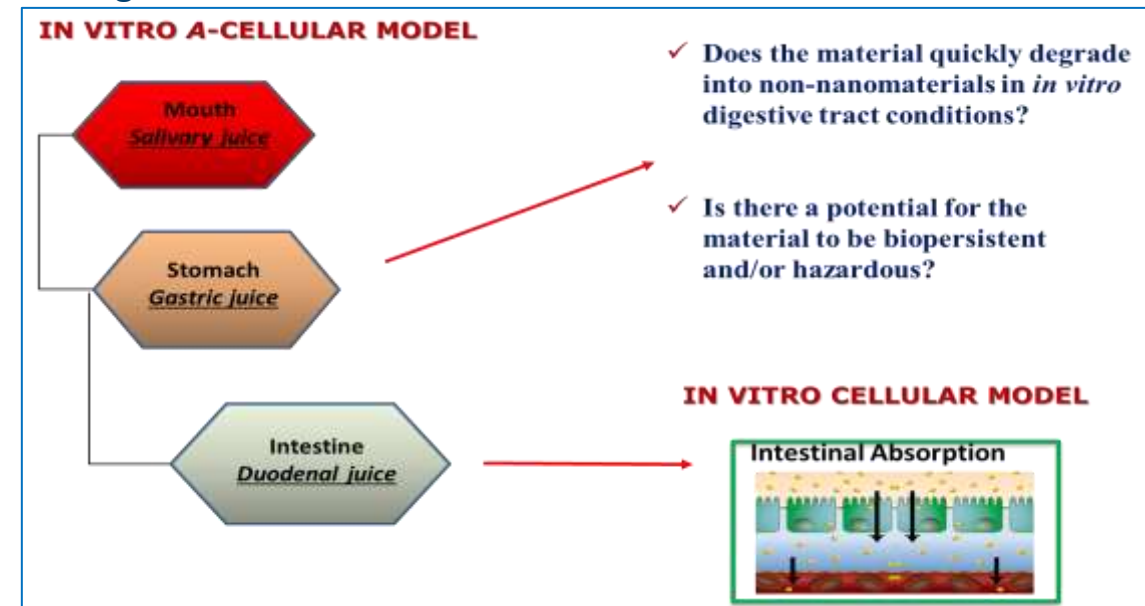
**OECD Project:** Development of a new Guidance Document (GD) on integrated *in vitro* approach for intestinal fate of orally ingested nanomaterials. Italy lead

**Reason for inclusion in NanoHarmony** – task aims to investigate the first steps of ENMs digestive process combining two *in vitro* approaches: 1) ENMs fate in different gastro-intestinal fluids, and 2) ENMs internalization and translocation through the intestinal barrier of the digested ENMs. These information are crucial for subsequent ENMs distribution within the organism.

## Activities

- State of the art analysis and review of available protocols for both steps
- Data gap analysis on intestinal digestion/absorption of selected ENMs
- Inter-laboratory comparison studies (Round Robins) for both steps to verify applicability and reproducibility of the selected protocols

**Outcome** Production of a consensus document supporting OECD activities on development of a new GD to determine ingested ENMs behaviour in intestinal environment.



**Partners:** Italian National Institute of Health (ISS), EcamRicert, EU-JRC, Luxembourg Institute of Science and Technology (LIST), Istituto Italiano di Tecnologia (IIT), Universitat Autònoma de Barcelona



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 885931



# Task 1.9

Scientific basis for the eco-toxicological testing of ENMs by generating technical recommendations on how to apply to ENMs the most commonly used aquatic ecotoxicity tests (TGs 201, 202, 203)

NanoHarmony



OECD Project: Adaptation of OECD Test Guidelines 201, 202 and 203 for the determination of the ecotoxicity of Manufactured Nanomaterials (MNs). Spain (co-lead) / France (co-lead)

**Reason for inclusion in NanoHarmony** – Identification of an enormous scarcity of data of acute toxicity to algae, daphnia and fish due to the use of different protocols for testing NMs. There is a need to address how to prepare the exposure concentrations, to avoid interferences and to justify the appropriateness of the limit test.

## Activities

- Identification of the state of the art and data gaps in existing protocols.
- Experimentation to optimize protocols for different types of MNs (metallic, organic, C-based) and different solubilities
- Assessment of transferability of the optimized test protocols among partners and associated partners

**Outcome:** Adaptations and/or specific technical recommendations about the use of TGs 201, 202 and 203 with MNs as annexes to the Guidance Document on aquatic and sediment toxicological testing of nanomaterials (Project 2.51).



OECD TG201

Several MNs  
≠ properties



OECD TG202

Adaptation of protocols



OECD TG203

Interlab comparison  
(transferability/repeatability)

Partners INIA, INERIS, UAVR Associated partners: UCO, UCM



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 885931

# Task 1.2 Scientific basis to support a possible tiered approach for bioaccumulation potential of ENMs



OECD Project: Development of a scoping review to consider when to trigger or waive the TG 305 bioaccumulation in fish test for manufactured nanomaterials. UK lead

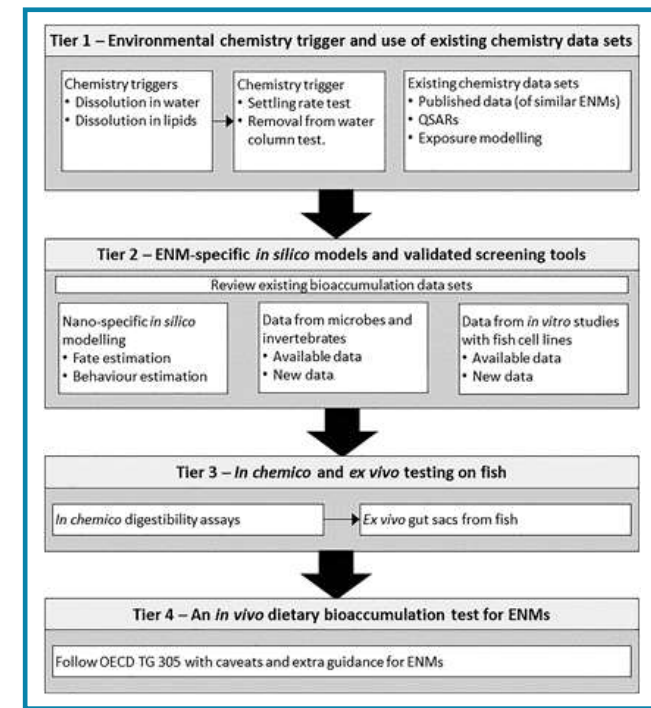
**Reason for inclusion in NanoHarmony** – There is a need for a credible and robust testing strategy to trigger or waive the TG 305 test for ENMs to ensure that its use is targeted to maintain high levels of chemical safety whilst minimizing vertebrate testing

## Activities

- Summarising existing data, test methods, and developing recommendations for a tiered approach. Continue the meta-analysis of data sets from existing EU projects (MARINA, SUN, Nanosolutions, Nanofase) held at Plymouth and obtain data from other EU projects and the scientific literature to add to the analysis.
- Publish data sets on different materials as papers to place some of the key information in the public domain and to support the OECD process.
- Workshops to identify key data and obtain input from experts.
- Undertake experimental studies for possible supporting assessment tiers (e.g. phys-chem, invertebrate, ex vivo gut sac approaches)

**Outcome** Scientific data and analysis document to support the development of a tiered approach at the OECD level.

**Partners** University of Plymouth, UK Centre for Ecology & Hydrology



# Task 1.4 Scientific basis for a GD on the determination of concentrations of ENMs in biological samples



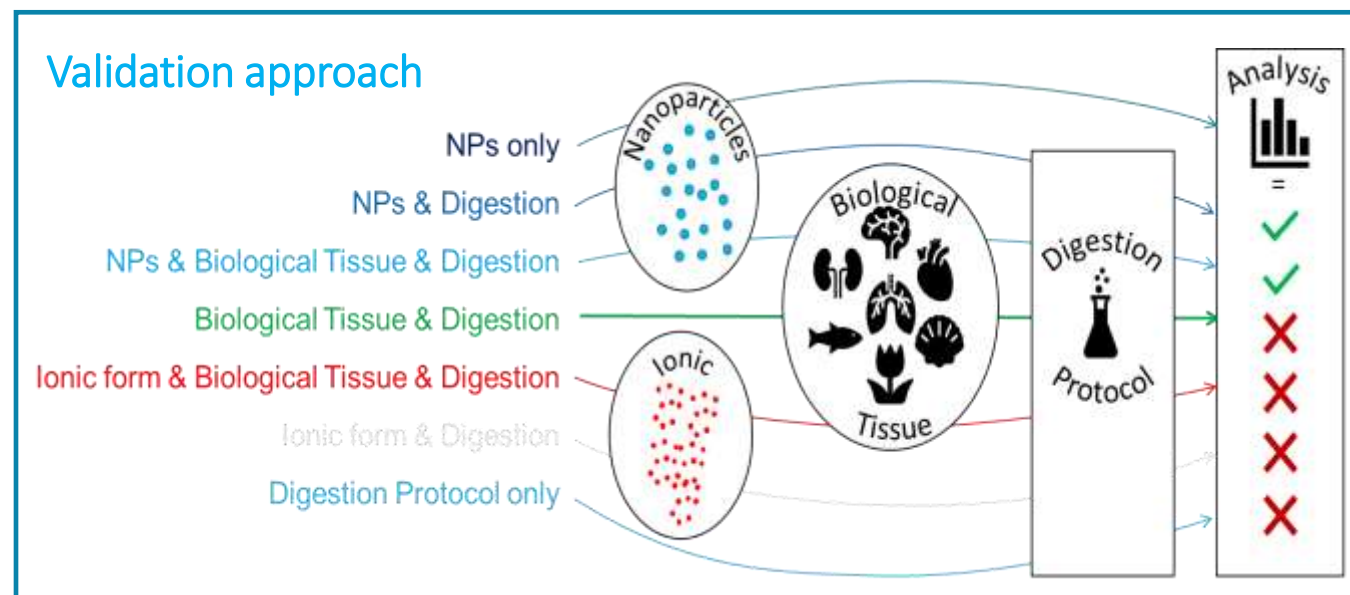
OECD Project: Development of a new Guidance Document on the determination of nanoparticles in biological samples for (eco)toxicity studies. UK lead

**Reason for inclusion in NanoHarmony** - a number of existing and proposed Test Guidelines (e.g. ecotoxicity and toxicokinetics) identify a requirement to determine concentrations of nanoparticles in biological samples, but do not provide detailed guidance on how this should be undertaken. This is a gap that needs to be addressed by reviewing available information and undertaking targeted experimental studies.

## Activities

- Identification of the state of the art and data gaps
- Experimental studies on spICP-MS and dark-field imaging
- Workshops to identify key data and obtain input from experts (focus spICP-MS and imaging approaches)

**Outcome** Scientific document with a broad consensus to support OECD Guidance Document development, addressing current state-of-the-art techniques and protocols. Reflecting new data generated and focussing on sample treatment (e.g. digestion protocols), detection limits, validation approaches.



**Partners** Public Health England, University of Plymouth, National Research Centre for the Working Environment (NFA), UK Centre for Ecology & Hydrology



# Want to be involved?

NanoHarmony



Do you have relevant data and/or expertise?  
Would you like to contribute experimental studies?  
Could you join laboratory intracomparison / round robin tests?

Email: [NanoHarmony@baua.bund.de](mailto:NanoHarmony@baua.bund.de)

**International Workshop 3-5 November 2020 (online)**  
Gap analysis and data requirements to support Test Guidelines and  
Guidance Document development

[www.NanoHarmony.eu](http://www.NanoHarmony.eu)



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 885931

# Thank you

NanoHarmony



Visit the NanoHarmony website [www.nanoharmony.eu](http://www.nanoharmony.eu)

Become a stakeholder by signing up for the newsletter [HERE](#)

Contact the NanoHarmony project office [NanoHarmony@buaa.bund.de](mailto:NanoHarmony@buaa.bund.de)

Sign up for the next NanoHarmony webinar

The graphic is a promotional banner for a webinar. It features a background of a green fractal pattern on a reddish-orange gradient. In the top left corner, there is the OECD logo (a globe with three green arrows) and the text 'OECD'. In the top right corner, there is the NanoHarmony logo (a globe with a blue arc) and the text 'NanoHarmony'. The main title is 'The pathway to Test Guidelines: from science to standards for nanomaterials' in large white font. Below the title, it says '16 September 2020, 14:00 CEST Webinar'. On the right side, there is a white box containing the date 'SEP 16', the title 'The pathway to Test Guidelines: from science to standards for nanomaterials', the author 'by Nanotechnology Industries Association', a 'Follow' button, and the word 'Free'.



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 885931