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## Status of current work on OECD TGs/GDs in Gov4Nano

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NanoHarmony 2<sup>nd</sup> Project Workshop, 25 November 2021

# Ongoing OECD activities

Section 1 Physical Chemical Properties	Section 2 Effects on Biotic Systems	Section 3 Env. Fate and Behaviour	Section 4 Health Effects
<p>TG on determination of the (volume) specific manufactured nanomaterials (EU) <b>WNT 1.3</b></p> 	<p>Adaptation of OECD TGs 201, 202 and 203 for the ecotoxicity of MNs (FR/IT) <b>NanoHarmony WPMN</b></p> 	<p>TG on dissolution rate of nanomaterials in aquatic environment (DE) <b>WNT 3.10</b></p>	<p>GD on the adaptation of <i>in vitro</i> mammalian cell based genotoxicity TGs for testing of manufactured nanomaterials (EU)</p>
<p>TG on particle size and size distribution of manufactured nanomaterials (DE) <b>WNT 1.4</b></p>		<p>GD on assessment of accumulation of nanomaterials (EU) <b>Gov4Nano</b></p> 	<p>Applicability of the key event based TG 442E for testing of sensitisation of manufactured nanomaterials (CH) <b>WNT 4.133</b></p> 
<p>GD on determination of solubility and dissolution rate of nanomaterials and relevant synthetic biological systems (EU) <b>WNT 1.5</b></p>  		<p>GD on environmental transformation of nanomaterials (AT) <b>WNT 3.11</b></p> 	<p>TG on toxicokinetics to accommodate testing of nanoparticles (NL/UK) <b>WNT 4.146</b></p> 
<p>GD on identification and quantification of the surface chemistry of nanomaterials and microspheres (EU) <b>WNT 1.6</b></p>  		<p>Scoping review for a tiered approach for reliable bioaccumulation assessment of MNs in aquatic systems including use of higher tier vertebrate models (UK) <b>WPMN</b></p> 	<p>Integrated <i>in vitro</i> approach for intestinal fate or orally ingested nanomaterials (IT) <b>WPMN</b></p> 
<p>TG on determination of surface hydrophobicity of manufactured nanomaterials (EU) <b>WNT 1.7</b></p>		<p>Assessment of the durability of NMs and their surface ligands in env. surroundings (biodurable/biodegradable) (SA/Korea) <b>WPMN</b></p>	<p>GD on the determination of concentrations of nanoparticles in biological samples for (eco)toxicity studies (UK) <b>WNT 4.147</b></p> 
<p>TG on determination of the dustiness of manufactured nanomaterials (DK/FR) <b>WNT 1.8</b></p>  			

# Work in Gov4nano

TG on determination of the (volume) specific surface area of manufactured nanomaterial



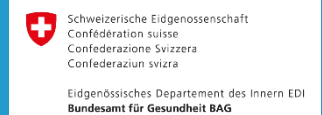
GD on assessing the apparent accumulation potential for nanomaterials



GD on environmental abiotic transformation of nanomaterials



Applicability of the key event based TG 442D for *in vitro* skin sensitization testing of nanomaterials



Guidance on release tests for manufactured nanomaterials



# TG on determination of the (volume) specific surface area of manufactured nanomaterials

## Background

- Specific surface area is an important parameter to characterise nanomaterials
- BET analysis technique: ISO 9277 (2010)
- Measurement of density: TG 109 Density of Liquids and Solids (2012); ISO 12154:2014

## Objectives

- Recommend testing protocol with clear scope and specifications
- Execution and evaluation of inter-laboratory comparison

## Expected Outcomes

- Creation of a protocol to underpin the development of a OECD Test Guideline for the determination of the (V)SSA of Manufactured Nanomaterials based on the Brunauer Emmett and Teller (BET) method

# TG on determination of the (volume) specific surface area of manufactured nanomaterials

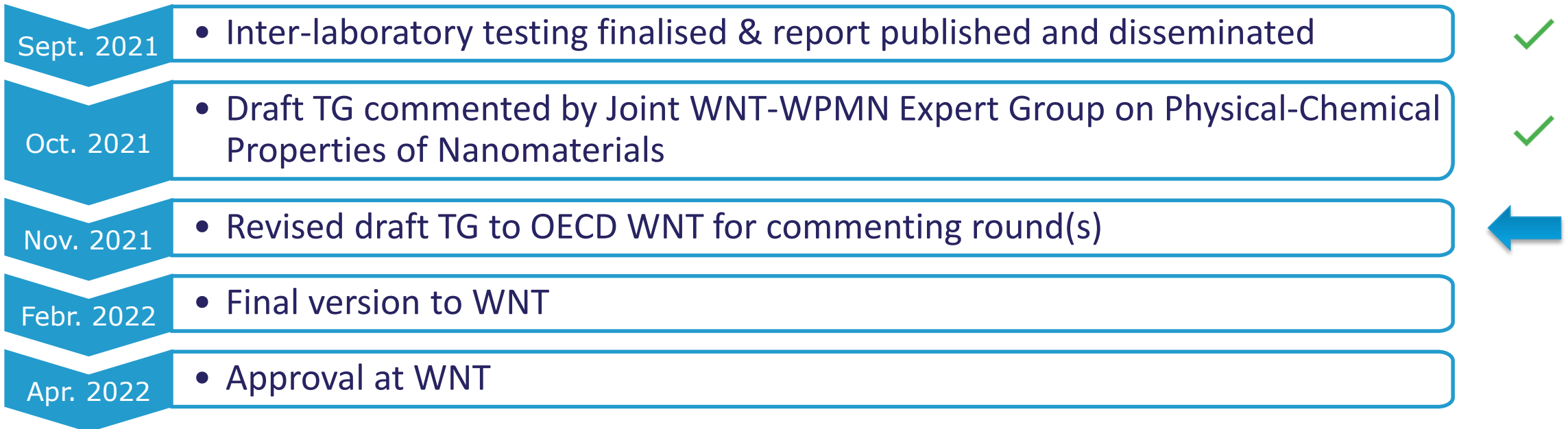
## Current and upcoming scientific work

- Interlaboratory comparison on the determination of the Volume Specific Surface Area (VSSA) of Manufactured Nanomaterials (doi: [10.2760/41115](https://doi.org/10.2760/41115))
- Recommended testing protocol with clear specifications, scope and acceptance criteria
- Draft OECD TG produced
- Finalisation of TG (April 2022)

## Parallel process

- ISO 9277:2010 (Determination of the specific surface area of solids by gas adsorption — BET method) is currently in revision
  - JRC follows the process to avoid discrepancies

# TG on determination of the (volume) specific surface area of manufactured nanomaterials



# GD on assessing the apparent accumulation potential for nanomaterials

## Background

- Difficulties in applying TG305 to nanomaterials
  - Nanomaterials show limited solubility and limited stability in water
  - Preferred route for nanomaterials would be dietary exposure → a BMF will be derived instead of a BCF
  - Problems to determine nanomaterials in tissues

## Objectives

- Further development of bioaccumulation testing for nanomaterials
- Provide further guidance on the application of OECD TG 305

## Expected Outcomes

- New Guidance Document on assessing the apparent accumulation potential for nanomaterials

# GD on assessing the apparent accumulation potential for nanomaterials

## Finalised scientific work

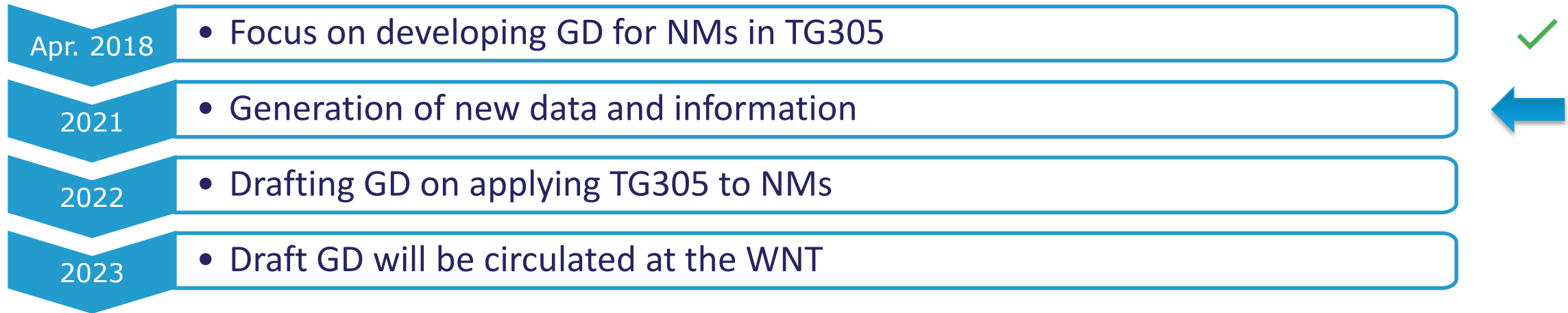
- Report on all the available information on bioaccumulation studies in fish and on analytical techniques to determine MNs in solid matrices
- Report on the experimental data on spiked fish feed with NM
- Report on the analytical techniques to determine nanomaterials and its transformation products in fish tissues

## Current and upcoming scientific work

- Bioaccumulation assays (report in June 2022):
  - Dietary & aqueous exposures
  - *CuO spherical*, CuO nanorods, COOH-coated CdTe QDs, PEG-coated CdTe QDs
- Determination of CuO NPs and Cu ions in fish tissues by ICP-MS
- Analytical capabilities to determine difficult to determine MNs in fish and tissues such as Al<sub>2</sub>O<sub>3</sub>-SiO<sub>2</sub> NMs or CNTs



# GD on assessing the apparent accumulation potential for nanomaterials



# GD on environmental abiotic transformation of nanomaterials

## Background

- Need to predict the fate of NMs in natural environments
- NMs transformations play a crucial role in risk assessment
- NMs transformations depend strongly on composition of the media: environmentally relevant conditions crucial to predict the fate of NMs

## Objectives

- Framing the concept of NM transformation pathways in aquatic environments
- Determine the important and relevant parameters to consider
- Develop suitable experimental approaches for testing transformation

## Expected Outcomes

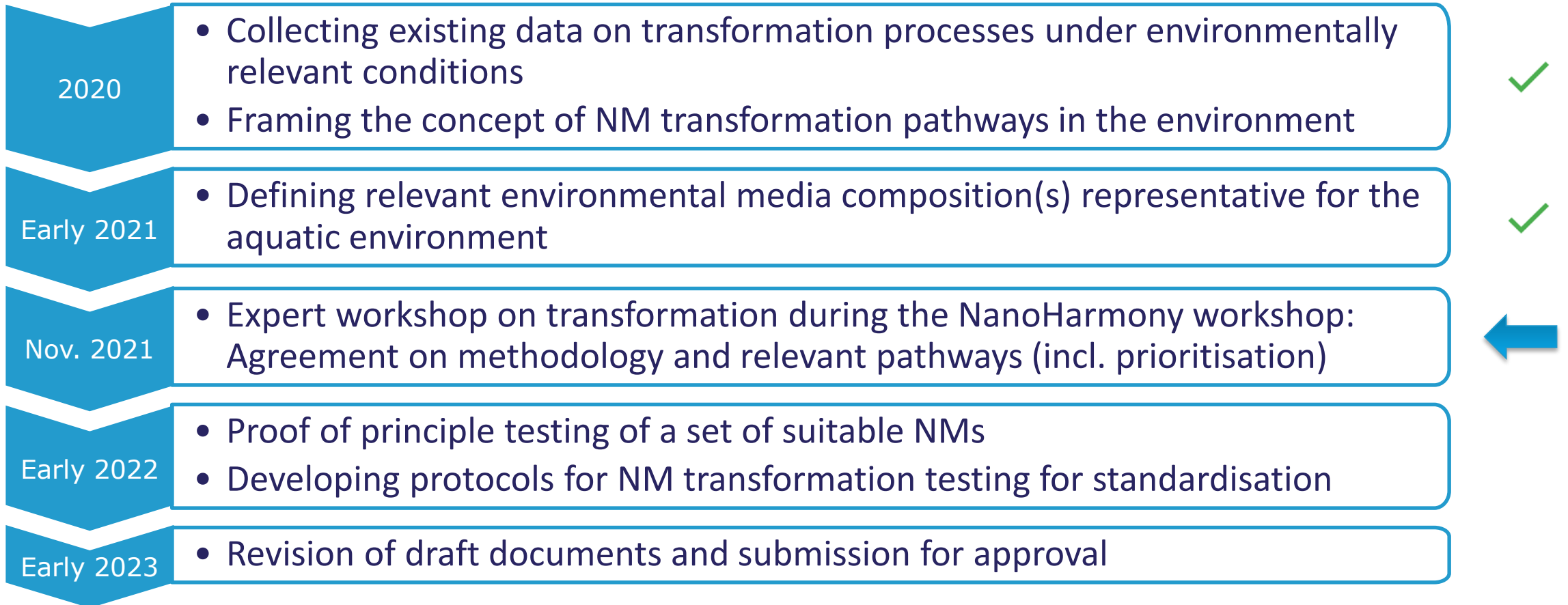
- Proof of principle testing of NMs for relevant transformation paths
- Draft GD on environmental transformations of NMs

# GD on environmental abiotic transformation of nanomaterials

## Current and upcoming scientific work

- Batch experiments on ZnO NPs transformation in sediments under define redox conditions  
L. Stetten, F. von der Kammer, O. Proux, G. Landrot, R. Kaegi, T. Hofmann *Transformation of zinc oxide nanoparticles in freshwater sediments under oxic and anoxic conditions.* (submitted to ES&T)
- Experiment on Ag NPs dissolution in aqueous media using a flow-through system  
L. Stetten, A. Mackevica, N. Tepe, T. Hofmann, F. von der Kammer *Towards a standardization for determining dissolution kinetics of nanomaterials in natural aquatic environments: continuous flow dissolution testing on Ag nanoparticles* (in preparation)
- Experiment on NMs transformation in several media relevant of surface and pore waters  
*In progress*

# GD on environmental abiotic transformation of nanomaterials



# Applicability of the key event based TG 442D for *in vitro* skin sensitization testing of nanomaterials

## Background

- Investigate the applicability of the ARE-Nrf2 luciferase method (TG 442D) for nanomaterials with an experimental focus on the KeratinoSens<sup>®</sup> assay.
- To evaluate whether it is fit for purpose, or whether some adaptations are needed, e.g. in the TG itself, in the SOP or in some additional guidance.

## Objectives

- Recommendations for adaptation of TG 442D
- Recommendations for validation of future adaptations

## Expected Outcomes

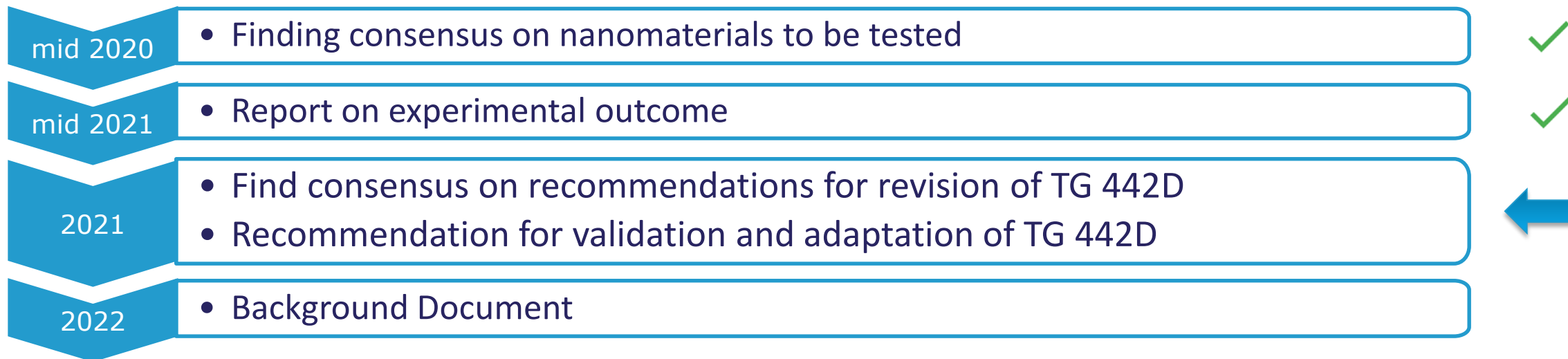
- Background Document

# Applicability of the key event based TG 442D for *in vitro* skin sensitization testing of nanomaterials

## Current and upcoming scientific work

- Ongoing work on *in vivo* / *in vitro* correlation of the results from nanomaterial testing in KeratinoSens®

# Applicability of the key event based TG 442D for *in vitro* skin sensitization testing of nanomaterials



# Guidance on Release Tests for Manufactured Nanomaterials

## Background

- Release of NMs is the first step towards exposure workers, consumers and the environment
- Release tests provide information on amount and state of NMs released during a specific process
- Lack of detailed guidance on standardised release tests for NMs

## Objectives

- Development of a new guidance on release tests for NMs
- Link (standardised) release test methods and release processes

## Expected Outcomes

- Guidance on standardised release tests for NMs
- Including a decision framework to facilitate the choice of appropriate release tests

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# Guidance on Release Tests for Manufactured Nanomaterials

## Finalised scientific work

- Overview on release tests was compiled recently in the project Gov4Nano

## Current and upcoming scientific work

- Review available (non-)standardised release tests
- Discuss applicability of the release tests for NMs and NM-products
- Develop a framework for a justified choice to use an appropriate test method for a specific release process
- Write detailed guidance

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# Guidance on Release Tests for Manufactured Nanomaterials

