OECD WORKING PARTY ON MANUFACTURED NANOMATERIALS (WPMN)

Update of the OECD's work on Advanced Materials

ANSI-NSP Workshop on Advanced Materials
3-4 May 2022

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EHS Division
OECD, Environment Directorate

OECD
BETTER POLICIES FOR BETTER LIVES

OECD WORK ON CHEMICAL SAFETY

Objectives	Protect human health and the environment	Share burden and increase efficiency in developing standard methods
Type of outputs	**Harmonised instruments** for the risk assessment of chemicals and GMOs	
Examples of outputs	• Test Guidelines, Principles of Good Laboratory Practice => Mutual Acceptance of Data • Tools for predicting the effects of chemicals (non-animal methods) • Guidance for Hazard and Exposure Assessment • Standards for exchange of information • Global Portal to Information on Chemical Substances	
Scope	Chemicals (incl. NM and AdMa, pesticides, biocides, chem. accidents, PRTRs, GMOs	
Practical implications	Safe use of chemicals	Work sharing; avoid duplication; avoid non-tariff trade barriers; shorten time to market; savings of 309 MEUR/y for industry and governments

Working Party on Manufactured Nanomaterials (& Advanced Materials)

Safer Innovation Approach (for more Sustainable Nanomaterials and Nano-enabled Products

RISK MANAGEMENT
RISK ASSESSMENT

Risk Assessment and Regulatory Programme

- To identify regulatory needs aiming at convergence of risk management decisions in the longer term.

HAZARD ASSESSMENT

Testing and Assessment

- To review and propose amendments and/or development of OECD Test Guidelines and Guidance Documents applicable;
- To consider the applicability of existing methodologies and supporting tools; and
- To explore the application of novel and alternative testing, as well as assessment approaches.

EXPOSURE ASSESSMENT

Exposure Measurements and Exposure Mitigation

- To exchange information on (or develop) guidance for exposure measurement and mitigation of manufactured nanomaterials risk.

Phys-Chem Properties

NEW_TG on Determination of the (Volume) Specific Surface Area of MNs (EU)

NEW_Test Guideline on particle size and size distribution of MNs (GER)

WNT 1.5_GD on Determination of solubility and dissolution rate of NMs in water and relevant synthetic biological media (**DNK/GER**)

WNT 1.6_ GD on Identification and quantification of the surface chemistry and coatings on nano- and microscale materials (**DNK/GER**)

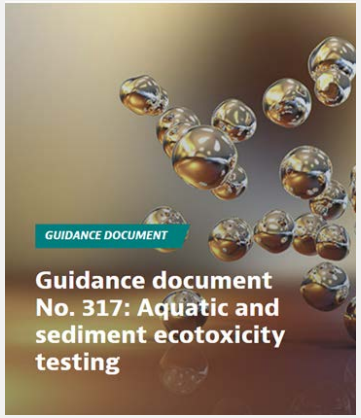
WNT 1.8_TG on Determination of Surface Hydrophobicity of MNs (**EU**)

WNT 1.9_TG on Determination of the Dustiness of MNs (**DNK/ FRA**)

WNT 1.10_GD on the determination of concentrations of nanoparticles in biological samples for (eco)toxicity studies (**UK**)

Effects on Biotic Systems

NEW project_Adaptation of OECD Test Guidelines 201, 202 and 203 for the determination of the ecotoxicity of MNs (**France/Spain**)



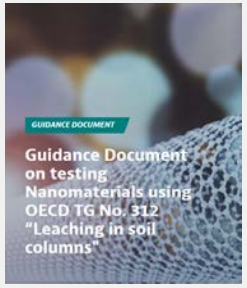
Env. Fate & Behaviour

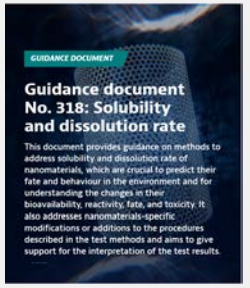
WNT 3.10_TG on dissolution rate of NMs in aquatic environment (**GER**)

WNT 3.12_GD on assessing the apparent accumulation potential for NMs (**Spain**)

WNT 3.16_GD Environmental abiotic transformation of NMs (**Austria**)

WPMN_Scoping review for a tiered approach for reliable bioaccumulation assessment of MNs in environmental organisms minimising use of higher tier vertebrate tests (**UK**)





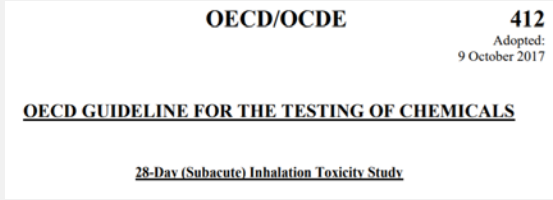
Health Effects

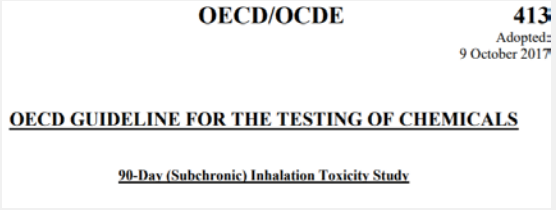
NEW_Study Report and Lessons learned on the Adaptation of *In Vitro* Mammalian Cell Based Genotoxicity TGs for Testing of MNs (**EU**)

WNT 4.133_Applicability of the key event based Test Guideline 442D for in vitro skin sensitisation testing of NMs (**Switzerland**)

WNT 4.146_TG on toxicokinetics to accommodate testing of nano-particles (**NED/ UK**)

NEW project_Integrated *in vitro* Approach for Intestinal Fate or Orally Ingested NMs (**Italy**)


OECD/OCDE 412
Adopted: 9 October 2017
OECD GUIDELINE FOR THE TESTING OF CHEMICALS
28-Day (Subacute) Inhalation Toxicity Study


OECD/OCDE 413
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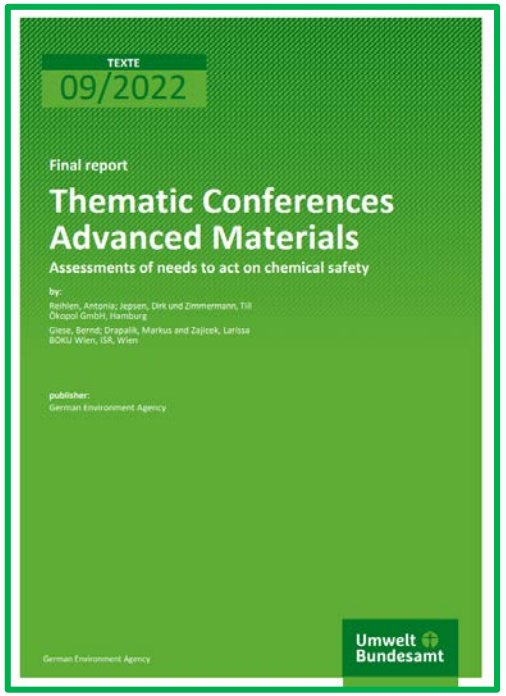
90-Day (Subchronic) Inhalation Toxicity Study

CBC Decision

- No definition of Advanced Materials to be developed
- No need for a new Programme of Work
- Knowledge on Advanced Materials / New Approaches
- Monitoring activities

- ✓ Identify delegations interest
- ✓ Scoping work in this area
- ✓ Get the mandate from the CBC to expand the scope of the WPMN



- Regulatory preparedness while coping with the pace of innovation
- Nanomaterials as a starting point for addressing advanced materials.
- Start to focus on AdMa with a nano-component (e.g. containing NMs or having a nanostructure). Need to clarify the playing field of AdMa relevant to the WPMN.
- Development of a strategy to address AdMa (within the scope of WPMN and CBC)

<u>June 2021</u>

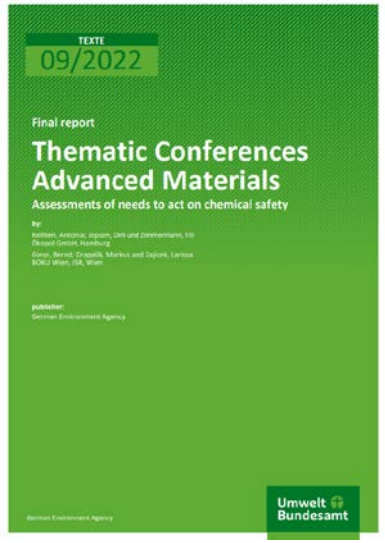
NEW WPMN Steering Group on Advanced Materials

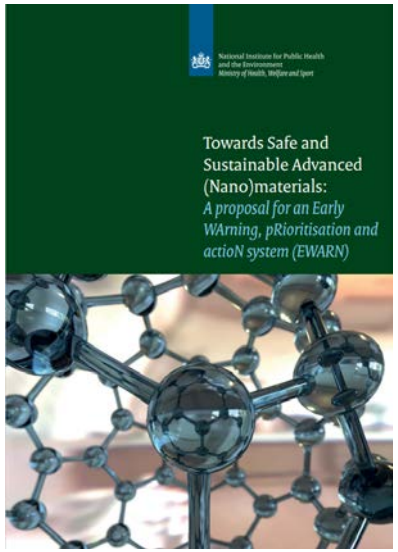
Advanced Materials Strategy: Scope

The strategy should outline the focus, goals/activities and purpose of the WPMN work on AdMa. Accordingly, it should consider:

- ✓ Enhance Regulatory Preparedness and Safe(r) and Sustainable by Design (SSbD) by building on existing knowledge on safety aspects form (e.g. include safe & sustainable by design for AdMa).
- ✓ Identify the relevant stakeholders, their roles, and how they can be engaged.
- ✓ Identify learnings relevant to AdMa from various policy areas (e.g. chemicals, product safety management, food & pharmaceuticals).
- ✓ Explore possible gaps for assessing safety and sustainability and the extent to which some or any AdMa pose a concern.
  - ✓ Identify those AdMa which may be of concern and for which existing assessment tools are not adequate, and prioritise those that are most relevant to the WPMN
- ✓ Identify options for actions for policymaking, e.g. risk management; define research needs; develop or improve assessment methods (including Test Guidelines), and information requirements.

WPMN progress since June 2021





1. Developed a draft WD outlining the **playing field** of advanced materials for the WPMN
2. Developing a draft strategic approach for addressing advanced materials' safety and sustainability (based on **Early4Nano**)

Scoping existing work on a number of AdMa (e.g.):

- NanoCarriers
- 3D Printing
- Graphene
- Case studies from EU Projects (ANSINA, HARMLESS,SUNSHINE)

Early4Nano: Early awareness and action system for AdMa

AdMa Playing Field: explain the scope

- AdMa are understood as materials that are rationally designed to have new or enhanced properties, and/or targeted or enhanced structural features (incl. emerging manufactured materials, and materials that are manufactured from traditional materials). This also includes materials from innovative manufacturing processes that enable the creation of targeted structures from starting materials, such as bottom-up approaches.
- WPMN to lead this activity and build on the knowledge gained on MNs (and include other AdMa with relevance to safety, sustainability and regulatory issues considering their whole life cycle).
- AdMa to be assessed to:

1. **learn** (and improve) their safety, sustainability and regulatory coverage within the strategic approach
2. **Identify** knowledge gaps and recommendations for action.

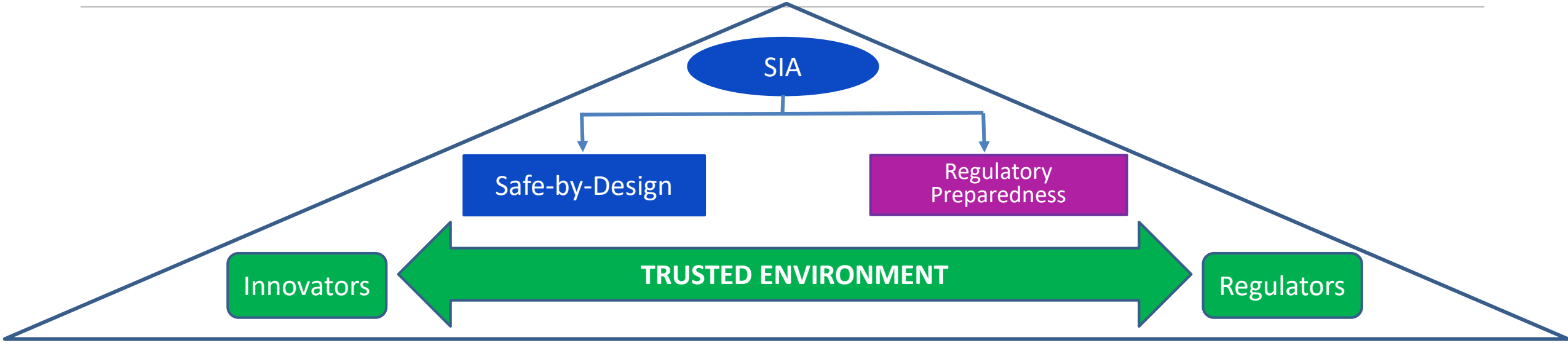
Recognition that AdMa in focus will evolve as additional knowledge is gained and appropriate strategies are developed.

Advanced Materials and Regulatory Preparedness

- Advanced Materials and suitability of existing methodologies and approaches (to which extend we can incorporate them in the regular work?)
- How to cop with the increasing speed of innovation and number of products brought to the market
- Should we anticipate the need for new approaches?

NEW WPMN Steering Group on the **Safer Innovation Approach (SIA)**

Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable NMs and Nano-enabled Products



Working Descriptions

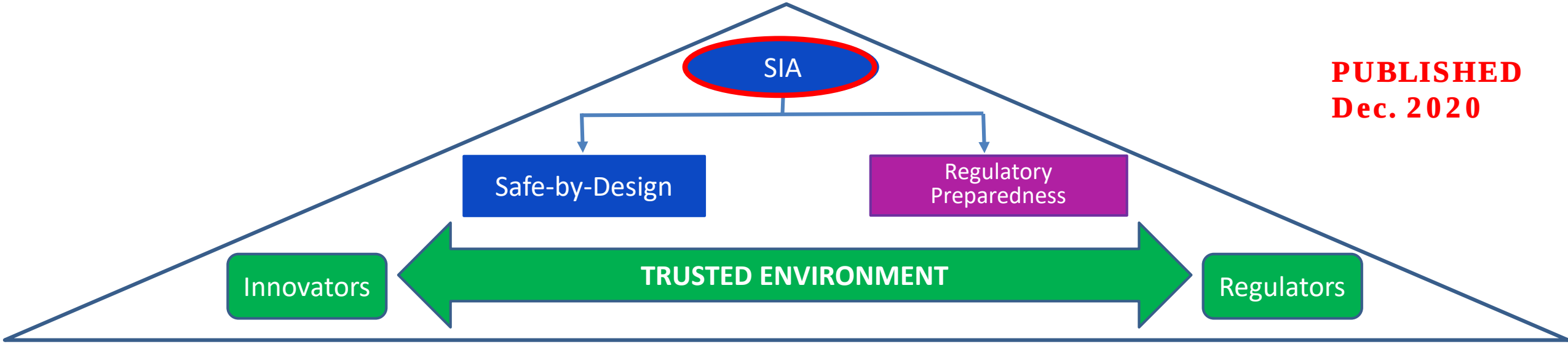
- Safe(r)-by-Design
- Regulatory Preparedness
- Safe(r) Innovation Approach (SIA)
- Trusted Environment

Safe(r) Innovation Approach: Risk Assessment Tools, Frameworks and Initiatives related to Safe(r)-by-Design

Anticipatory Governance/Regulatory Preparedness: Inventory of Strategies for Awareness and Decision-Making

PUBLISHED in December 2020: LINK

Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable NMs and Nano-enabled Products



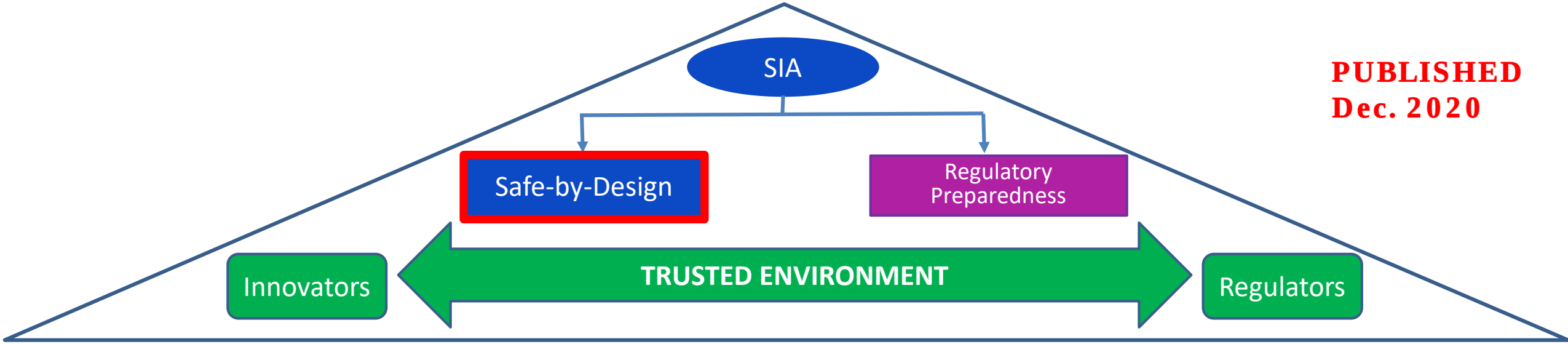
PUBLISHED Dec. 2020

OECD WPMN SIA project working description:

- The **Safe(r) Innovation Approach (SIA)** combines the **Safe-by-Design** and **Regulatory Preparedness** concepts in order to identify and minimize the possible health and environmental risks of innovative materials, products, applications, and processes in a timely manner during the innovation process.

- SIA addresses regulatory requirements for safety, including any necessary adaptations to cover the specific properties of materials or technologies. SIA thus relies on **dialogue between industry and regulators** and**, as appropriate, other stakeholders**. This dialogue ideally starts at **an early stage of the innovation process** and is facilitated by a Trusted Environment.

Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable NMs and Nano-enabled Products



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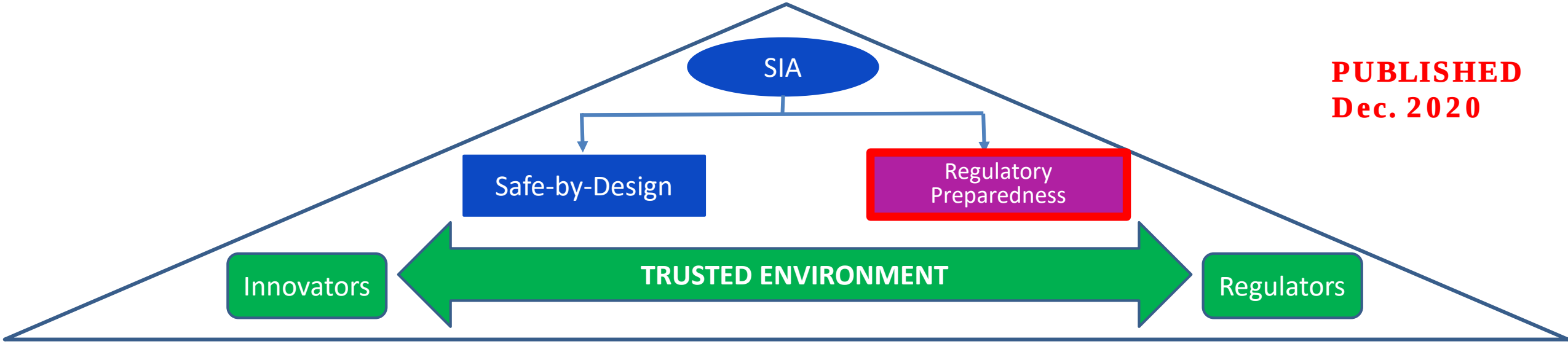
Why SbD?

SbD *was developed as a response to observations that NM safety would be more effective and less costly for companies if it was incorporated earlier into the innovation process and throughout.*

Safe(r)-by-design

- identifies the risks and uncertainties to humans and the environment at an early phase of the innovation process so as to minimize uncertainties, potential hazard(s) and/or exposure.
- addresses the safety of the material/product and associated processes through the whole life cycle
- in nanotechnology, three pillars of design can be specified:
  - safer material/product
  - safer production, and
  - safer use and end-of-life

Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable NMs and Nano-enabled Products



PUBLISHED Dec. 2020

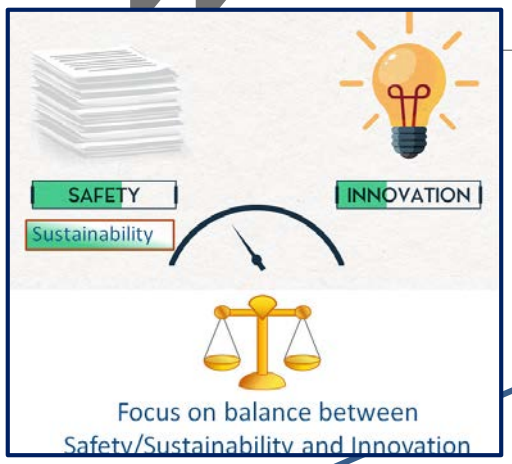
Why RP?

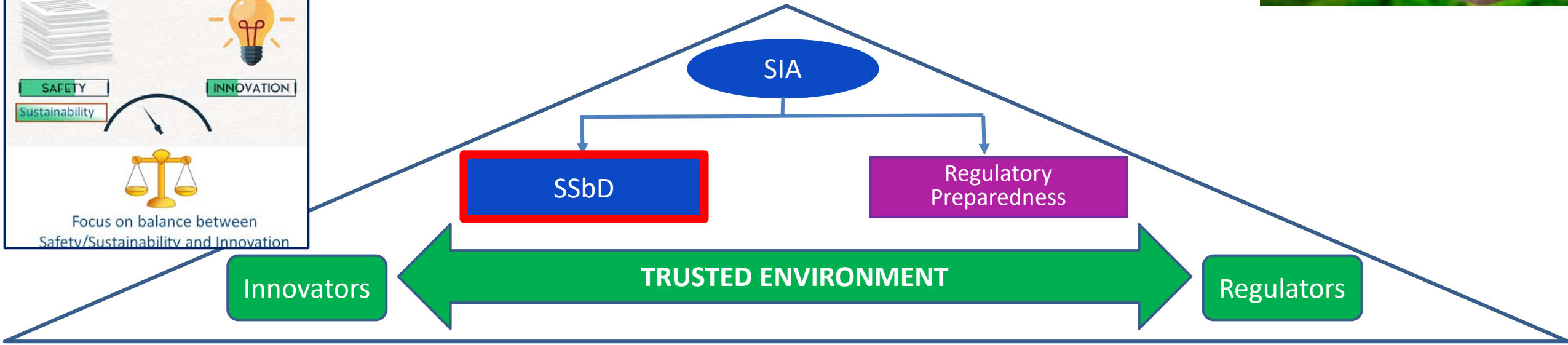
RP *was developed as a response to observations that regulators need to better anticipate and adapt governance to keep up with the pace of knowledge generation and innovation of nanomaterials and nano-enabled products.*

Regulatory Preparedness

- the capacity of regulators, including policymakers, to anticipate the regulatory challenges posed by emerging technologies such as nanotechnology, particularly those human and environmental health and safety challenges.
- This requires that regulators become aware of innovations sufficiently early to take appropriate action to modify or develop regulatory tools applicable to them, as needed.

SIA Steering Group Activities since June 2021





From Safe-by-design to Safe-and-**sustainable**-by-design (SSbD)

- Activity 1: Working Descriptions SSbD; Sustainability, integrating SSbD to SIA
- Activity 2: Develop an inventory of frameworks, methods, aspects/parameters, and tools/toolboxes for SSbD and RP

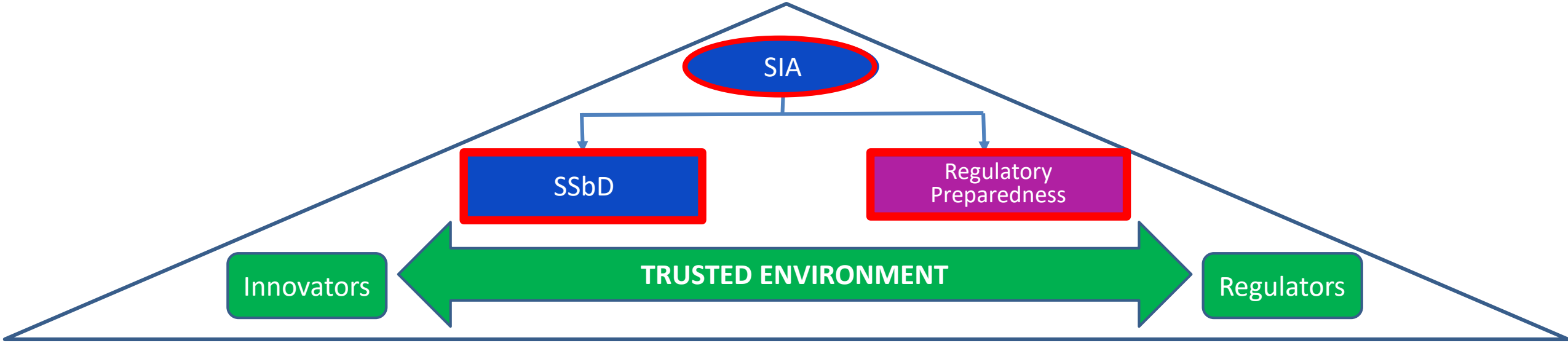
Safe (and Sustainable) Innovation Approach

- Activity 3: Bring SIA Closer to practical applicability (TE, dealing with Barriers and Constraints)

Safe (and Sustainable) Innovation Approach/Regulatory Preparedness

- Activity 4: Platform for Sharing Knowledge, learning from industry and regulator's experiences

Linking SIA to AdMa activities



RP, Playing field on AdMa:
Identify those AdMa which may be of concern and for which existing assessment tools are not adequate

Strategic Approach to Advanced Materials:

- Enhance ***RP and SSbD*** (linking to SIA work)
- Identify the ***relevant stakeholders, their roles, and how they can be engaged (TEs)***.
- Address possible ***gaps in regulatory approaches*** and in the assessment of safety and sustainability, learn from various policy areas and recommend options for actions for decision-makers (identify needs for risk management, research, assessment methods (incl. TGs) and information requirements).
- ***Advanced Materials Case Studies*** (2D and others to: 1) test the strategy and improve it and 2) to develop a number of case studies that should lead to recommendations and the development of specific guidance)

Linking SIA to AdMa activities

Early4Nano to identifies different areas of information:

1) **Application and Market-entry stage**: is the application already on the market or is there an indication on the time to market (e.g. TRL stage), and what is the (anticipated) scale of application (large, medium, niche)?
2) **Safety assessment - Human Health**: are there human health safety issues conceivable that need further attention, for example related to Physical-chemical, hazard, toxicokinetics or exposure? Especially issues that may be specific for AdMa (e.g. new or enhanced properties of the AdMa compared to conventional non-nano/non-advanced materials).
3) **Safety assessment - Environment**: are there environmental safety issues conceivable that need further attention, for example related to PChem, hazard, fate or exposure/environmental release? Especially issues that may be specific for AdMa (e.g. new or enhanced properties of the AdMa compared to conventional non-nano/non-advanced materials).
4) **Applicability of Regulatory Frameworks**: do the (regionally) relevant Regulatory Frameworks provide insight in whether the current regulatory frameworks are expected to address AdMas adequately and are potential risks addressed adequately?
5) **Sustainability**: are there sustainability issues conceivable along the life cycle of the AdMa that need further attention, for example as related to raw materials, environmental footprints, recyclability/reusability? Social aspects with regard to sustainability may be mentioned but are not included in this system.

Case Studies goals:

1. To test the strategy and further refine it for its use in a regulatory context and ensure it is appropriate for addressing:
   a) safety concerns;
   b) sustainability concerns,
   c) regulatory gaps; and/or; issues with the assessment methods.
2. To learn whether a material could present a concern and identifying recommendations for actions for addressing those concerns (e.g. developing guidances and/ or Test guidelines).

- ✓ Playing field AdMa
- ✓ Integrate them into the workflow of chemicals/ draft strategy for AdMa
- ✓ Case studies to refine the draft Strategy + learn from AdMa and take action

- ✓ integrate sustainability into SIA
- ✓ Working descriptions: Sustainable-by-design and sustainability.
- ✓ Learn where early dialogue between innovators & regulators is facilitated (Case Studies)
- ✓ Identify the roles in and conditions for building a TE

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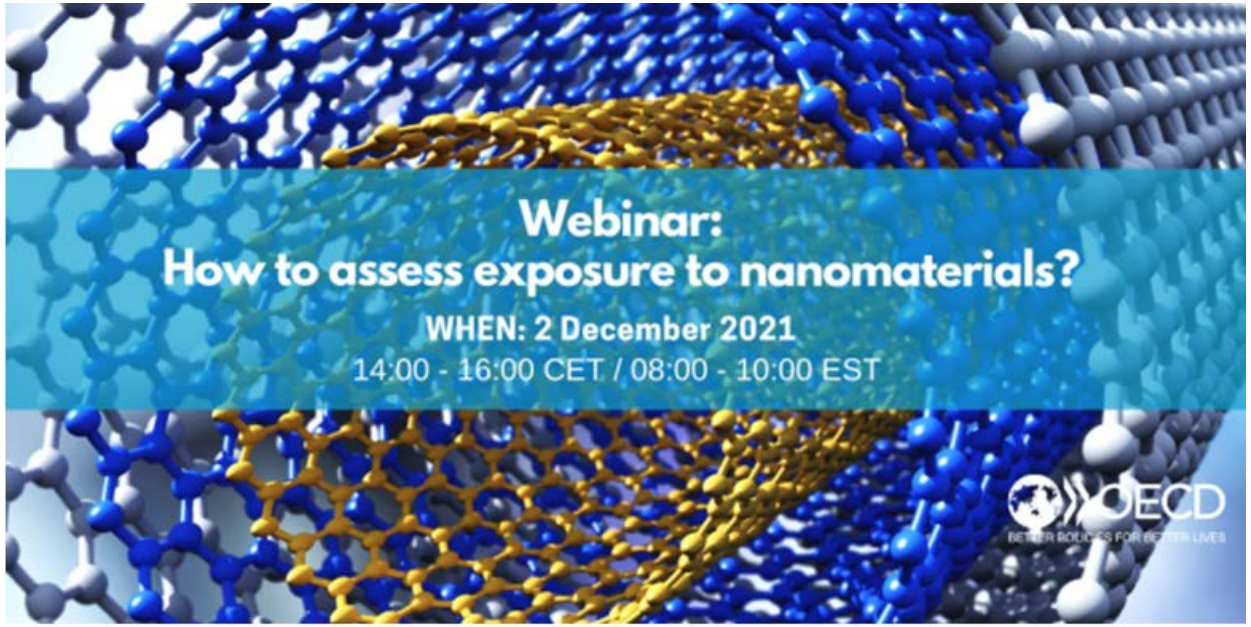
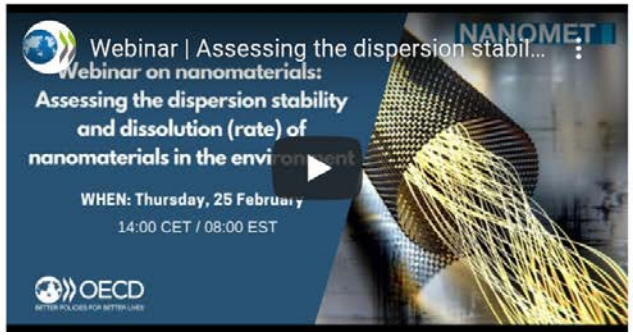
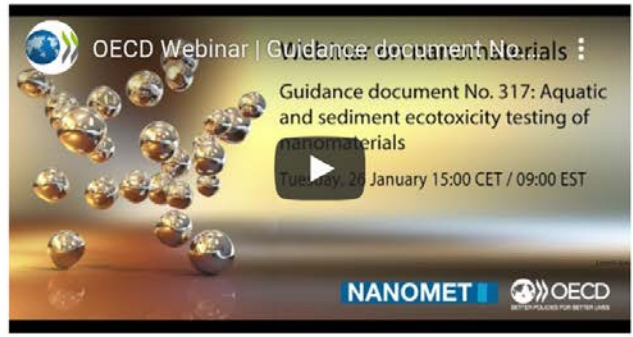


Webinar on assessing the dispersion stability and dissolution rate of nanomaterials in the environment



Webinar on aquatic and sediment ecotoxicity testing of nanomaterials



Thanks