

MACRAMÉ

Advanced Characterisation Methodologies to assess and predict the Health and Environmental Risks of Advanced Materials

Wrap-Up



Integrated Assessment and
Advanced Characterisation
of Neuro-Nanotoxicity

nanoPASS

**MALTA
INITIATIVE**

1ST JOINT ONLINE WORKSHOP: HARMONISATION & STANDARDISATION OF
TEST METHODS FOR NANO- AND ADVANCED MATERIALS

22ND – 23RD NOVEMBER 2023, ONLINE



The MACRAMÉ project has received funding from the European Union's Horizon Europe Research and Innovation programme under grant agreement No. 101092686.

Day 1 – Harmonisation: (Eco)Tox Testing

Review/development of OECD TGs/GDs ... Validation ... in-vivo / in-vitro / NAMs

- TG/GD reviews/developments: harmonisation, validation, acceptance, use
 - Malta Initiative, NanoHarmony
 - iCare Project, MACRAMÉ Project, nanoPASS Project
- NAMs – ‘New Approach Methodologies’ / ‘Non-Animal Methods’
 - Discussion with policy-making and policy-informing organisations
 - What is to be included? – *‘we need a whole range of mechanistic methods ...’*
 - How are NAMs going to be further developed? – *‘the right mix of policy incentives’ and ‘the right mix of contributors’*
 - How are NAMs going to be applied? – *‘it seems that the more NAMs we develop, the fewer NAMs we use ...’*

Day 2 – Standardisation

- VAMAS / CEN / ISO – Committees & their results on nanotechnologies ... and graphene
- Graphene – R&I and its outcomes and impacts in the Graphene Flagship
- Next steps for `graphene` R&I:
 - Ongoing standardisation needs
 - Prioritisation of most relevant materials / forms of `graphene`
 - Safety-testing for market access
 - Increased collaborations with the nanomaterials (safety) community (cf. ACCORDs Project)

Harmonisation & Standardisation of Nanomaterials ... and beyond

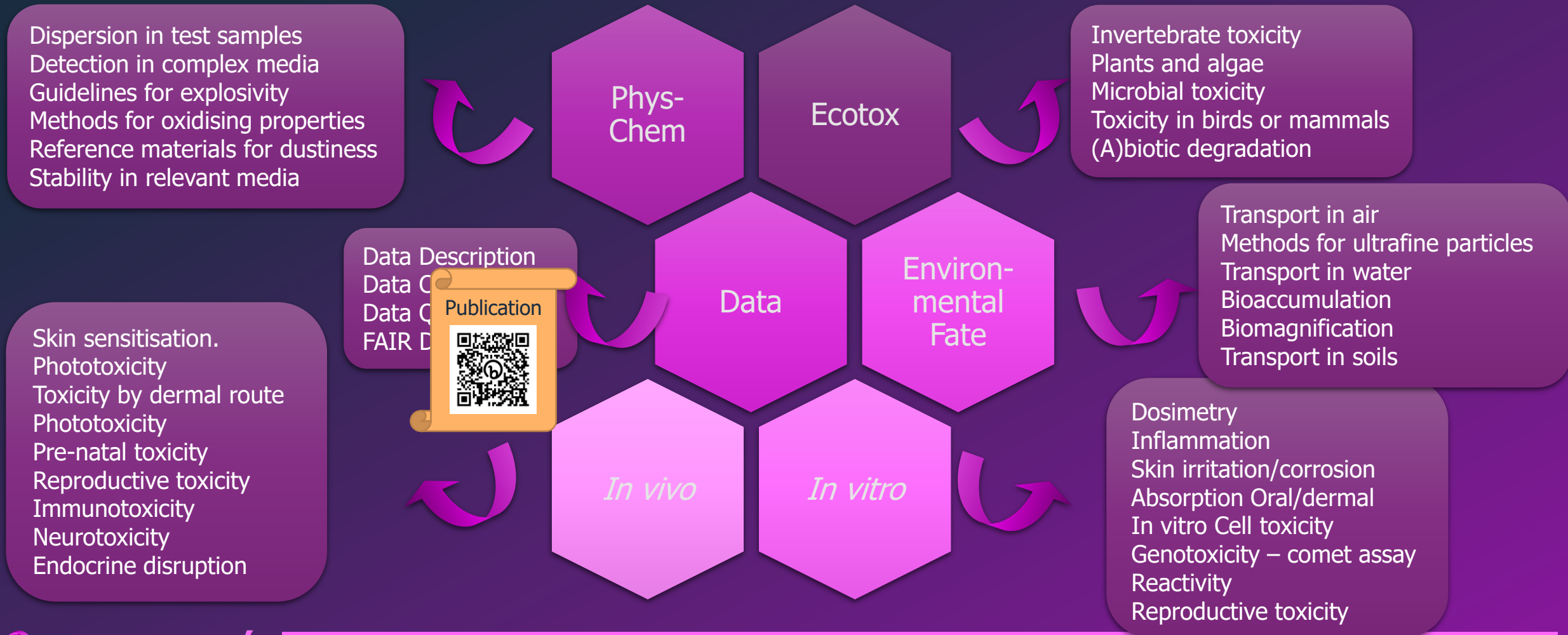
ISO	<u>Terminology</u> Achieved 18 On-going 7	<u>Measurement</u> Achieved 8 On-going 6	<u>Characterisation Graphene</u> Achieved 13 On-going 8	<u>Characterisation (Other)</u> Achieved 27 On-going 2	<u>Exposure and Risk</u> Achieved 23 On-going 11	<u>Performance Evaluation</u> Achieved 3 Ongoing 3
CEN	<u>Terminology</u> Achieved 7 On-going 5	<u>Measurement</u> Achieved 5 On-going -	<u>Characterisation (Other)</u> Achieved 1 On-going 3	<u>Exposure and Risk</u> Achieved 19 On-going 11	<u>Other</u> Achieved 4	
OECD	<u>Physico-chemical Characterisation</u> Achieved 5 On-going 5	<u>Human Toxicology</u> Achieved 5 On-going 5	<u>Environmental Toxicology</u> Achieved 1 On-going 4	<u>Environmental Fate</u> Achieved 1 On-going 3	<u>End of Life</u> Achieved 1 Ongoing 1	

215 Standards!



But we still have gaps

(Nano)Materials Standardisation Gaps



Meeting Announcements

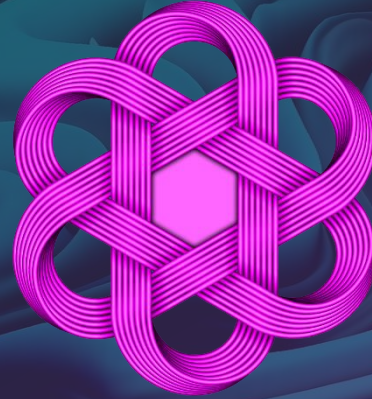


1st MACRAMÉ Regulatory Risk Assessors' Summit:
27th – 28th November 2023, Berlin

'Materials Week 2024':
17th – 21st June 2024, Limassol, Cyprus

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Thank you

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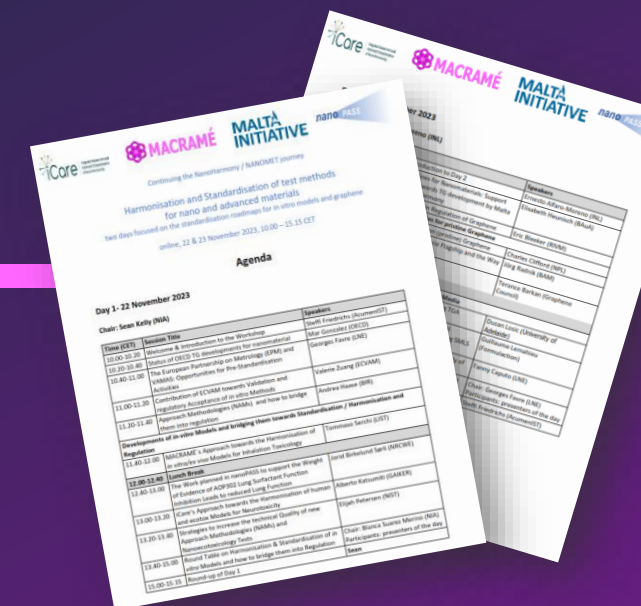


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Workshop Agenda

... best accessed *via* the website: www.macrame-project.eu

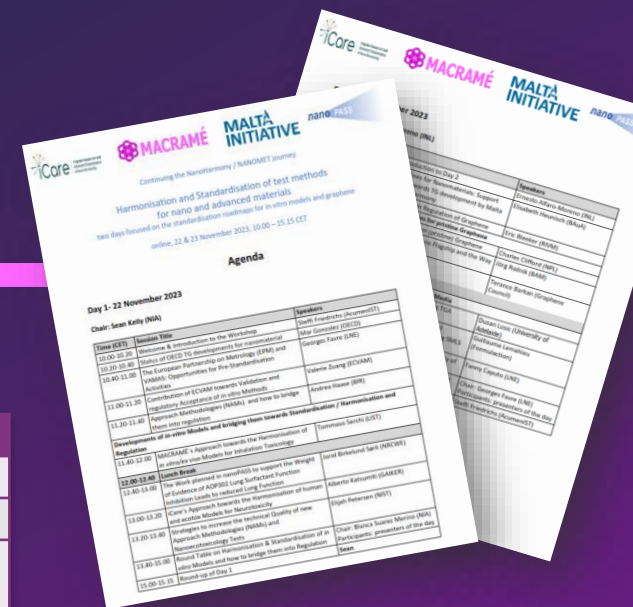
The screenshot shows the MACRAMÉ website interface. At the top, there is a navigation bar with links for 'About the Project', 'The Consortium', 'Press & Public Events', 'MACRAMÉ Events', and 'MACRAMÉ Team Login'. Below the navigation bar, a light blue box contains the following text: 'The 2nd MACRAMÉ Project Meeting will be held ONLINE on the 10th – 11th May 2023. MACRAMÉ Partners are invited to use the link to the Agenda & Documentation (on the right); the relevant password has been provided in the invitation email.' To the right of this box is a dark blue sidebar menu with the following items: 'MACRAMÉ Kick-Off Meeting', '2nd MACRAMÉ Project Meeting', '1st Harmonisation & Standardisation Workshop', '1st Regulatory Risk Assessors' Summit', and '3rd MACRAMÉ Project Meeting'. The main content area features a large white box with the title 'Harmonisation & Standardisation of Test Methods for Nanomaterials and Advanced Materials (ONLINE)'. Below the title, it states 'Continuing the NanoHarmony NANOMET journey: Two Days focused on the Standardisation Roadmaps for *in vitro* Models and Graphene'. The dates are listed as '*** ONLINE *** 22. – 23. November 2023, 10:00 – 15:00 CET'. At the bottom of this white box are two dark blue buttons: 'Announcement & Registration' (with a pencil icon) and 'Agenda & Documentation' (with a document icon). A large pink arrow points from the right towards the 'Agenda & Documentation' button.



Workshop Agenda – Day 1

... best accessed *via* the website: www.macrame-project.eu

Time (CET)	Session Title	Speakers
10.00-10.20	Welcome & Introduction to the Workshop	Steffi Friedrichs (AcumenIST)
10.20-10.40	Status of OECD TG developments for nanomaterial	Mar Gonzalez (OECD)
10.40-11.00	The European Partnership on Metrology (EPM) and VAMAS: Opportunities for Pre-Standardisation Activities	Georges Favre (LNE)
11.00-11.20	Contribution of ECVAM towards Validation and regulatory Acceptance of in vitro Methods	Valerie Zuang (ECVAM)
11.20-11.40	Approach Methodologies (NAMs) – and how to bridge them into regulation	Andrea Haase (BfR)
Developments of in-vitro Models and bridging them towards Standardisation / Harmonisation and Regulation		
11.20-11:40	MACRAMÉ 's Approach towards the Harmonisation of in vitro/ex vivo Models for Inhalation Toxicology	Tommaso Serchi (LIST)
11:40-12.40	Lunch Break	
12.40-13.00	The Work planned in nanoPASS to support the Weight of Evidence of AOP302 Lung Surfactant Function Inhibition Leads to reduced Lung Function	Jorid Birkelund Sørli (NRCWE)
13.00-13.20	iCare's Approach towards the Harmonisation of human and ecotox Models for Neurotoxicity	Alberto Katsumiti (GAIKER)
13.20-13.40	Strategies to increase the technical Quality of new Approach Methodologies (NAMs) and Nanoecotoxicology Tests	Elijah Petersen (NIST)
13.40-15.00	Round Table on Harmonisation & Standardisation of in vitro Models and how to bridge them into Regulation	Chair: Blanca Suarez Merino (NIA) Participants: presenters of the day
15.00-15.15	Round-up of Day 1	Sean



Workshop Agenda – Day 2

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Time (CET)	Session Title	Speakers
10.00-10.10	Welcome & Introduction to Day 2	Ernesto Alfaro-Moreno (INL)
10:10-10.30	OECD Test Guidelines for Nanomaterials: Support and future steps towards TG development by Malta Initiative and NanoHarmony	Elisabeth Heunisch (BAuA)
10.30-10.50	Status and Challenges in Regulation of Graphene	Eric Bleeker (RIVM)
Session on (Pre-)Standardisation Activities for pristine Graphene		
10.50 – 11.10	ISO and VAMAS Activities on (pristine) Graphene	Charles Clifford (NPL)
11.10 – 11.30	Achievements of the Graphene Flagship and the Way forward	Jörg Radnik (BAM)
11.30-11.50	Framework on Characterisation	Terance Barkan (Graphene Council)
11.50-12.30	Lunch Break	
Activities on Determination of Graphene in complex Media		
12.30-12.50	Interlaboratory Study of graphene using TGA	Dusan Losic (University of Adelaide)
12.50 – 13.10	Simultaneous Screening of the Stability and Dosimetry of Nanoparticles Dispersions using SMLS for in vitro Toxicological Studies	Guillaume Lemahieu (Formulaction)
13.10 – 13.30	Approaches to identify and measure the Stability of Graphene in complex Media	Fanny Caputo (LNE)
13.30 - 15.00	Round Table on the Needs for Characterisation and Test Method Developments for Graphene	Chair: Georges Favre (LNE) Participants: presenters of the day
15.00-15.15	Workshop Wrap-Up – Conclusions - Outlook	Steffi Friedrichs (AcumenIST)

