

MACRAMÉ

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

Group 1 – Characterization Items & Standardization

6TH EU-ASIA DIALOGUE ON NANOSAFETY
21ST JUNE 2023, BERLIN



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

MACRAMÉ's central Objectives

- detect, characterise and quantify Advanced Materials (AdMas) during handling and processing along the product life-cycle,
- assess potential impacts on (human) health and the environment in intended or unintended exposure situations (i.e. 'Exposure Points') in the product value-chain,
- advance the wide-spread applicability of the developed test and characterisation methods, by demonstrating their effectiveness and efficiency in the context of existing, market-relevant industrial AdMas containing products, and
- prepare and initiate standardisation, harmonisation and technological & regulatory validation of test- and characterisation-methods.

The MACRAMÉ R&I Approach

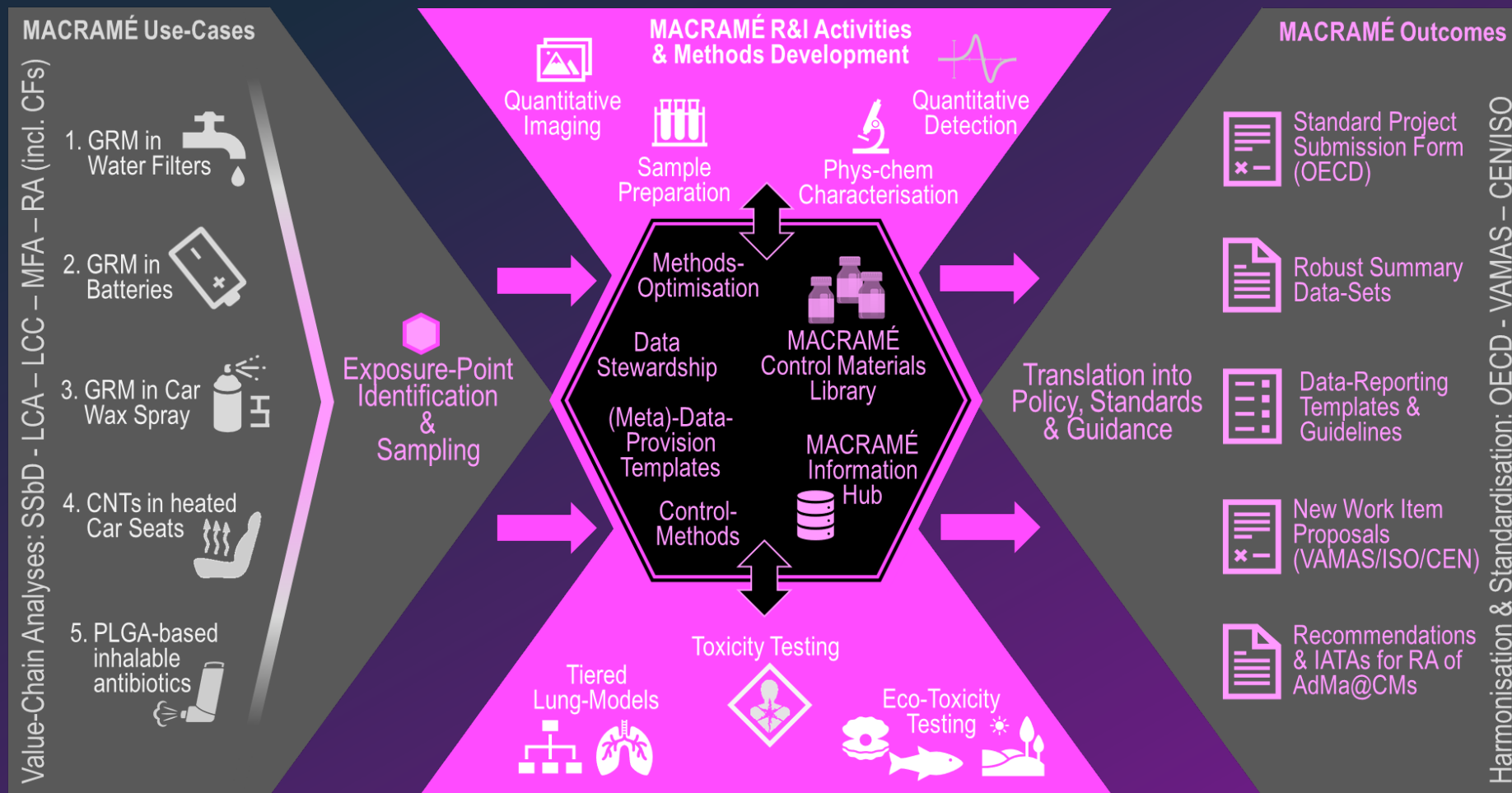


Illustration of the MACRAMÉ R&I Approach (AdMa@CMs: Advanced Materials in complex matrices; CF: Characterisation Factor; GRM: graphene-related material; IATA: integrated approaches to testing and assessment; LCA: Life-Cycle Assessment; LCC: Life-Cycle-Costing; MFA: Material-Flow Analysis; RA: Risk-Assessment; SSbD: Safe-&-Sustainable-by-Design).

Group 1 – Characterization Items & Standardisation

Background: *INISS-Nano* – a 'Network of Networks' (1)

International Network Initiative on Safe and Sustainable Nanotechnologies (INISSNano)

The aim of the initiative is to bring together science, industry and government from all over the world, not duplicating structures but connecting with them (e.g. NSC, ANF, EU-USCoRs).

Such contacts can assist the work of standardization bodies (such as CEN, ISO, ASTM, etc.), of international organizations (e.g. OECD, CEFIC) and of agencies (e.g. ECHA, EFSA, US-EPA, US-FDA, AECEN).

The focus shall be on the collaboration in different fields pertaining to nanotechnology research in general and nanosafety research in particular. This shall include collaboration in terms of, e.g., training, knowledge and data sharing, standardization efforts, test-guidelines development, metrology, commercialisation, ethical aspects, sustainability, and joint research supporting governance and regulatory guidance. The scope can be extended to further joint working items.

The added value of INISS-Nano shall be the collection and analysis of available information worldwide, always in collaboration with existing organizations or working groups (e.g. for definitions and ontologies of nanotechnology; analysing differences between markets; common strategies on transfer of scientific results into policy; regulation; standardization; harmonization of methods, such as risk assessment methodologies).

[*INISS-Nano: revised concept and action*, A. Falk et al. , ZENODO (2022)
<https://doi.org/10.5281/zenodo.6818049>.]

Background: *INISS-Nano* – a 'Network of Networks' (1)

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Background: *INISS-Nano – a 'Network of Networks'* (2)

INISS-Nano will aim at making this knowledge accessible for the stakeholders worldwide and, based on identified gaps and/or bottlenecks, initiate common activities to achieve this goal. Joint activities could be (but shall not be limited to) development of:

- joint funding programs,
- joint research projects and develop common publications,
- reduce/avoid duplication in research and innovation,
- exchange programs for students,
- data sharing,
- sharing laboratory infrastructure,
- expert exchange,
- consultancy services,
- support of the development of harmonised and validated protocols, e.g., for characterization methods, and
- gaining an overview on available certification protocols, to understand the process but also to contribute to this towards harmonization and validation of methods.

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Background: *INISS-Nano* – a 'Network of Networks' (3)

The following four pillars have been identified by the INISS-Nano core group as important action fields that shall be in the focus and actions to be implemented at the start of INISSNano:

1. Harmonization
2. Support industrial understanding
3. Sharing / facilitate sharing of resources / infrastructures
4. International collaboration on ethical and societal aspects of nanotechnology

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Pillar 1 - Harmonization

The harmonization pillar consists of two elements:

1. Standardization efforts, and
2. Transfer of Scientific information into harmonised Guidance and Standards

1. Standardisation Efforts:

INISS-Nano will be aiming at facilitating and boosting cooperation in the field of nanosafety and nanomaterial characterization standardization.

...by implementing the following actions:

- Facilitate and accelerate the development of joint nanosafety and harmonised/prestandardised nano-characterization to enable its standardization, which will eventually benefit the consumer and governmental risks agencies as well as relevant industrial sectors, as this will lead to reliable nanosafety-relevant data.
- Support capacity building in the scientific community to take a bolder role in the development of nanosafety and nano-characterization harmonization to improve the efficiency of knowledge transfer for the creation of standards.

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Pillar 1 – Harmonization: *1. Standardisation Efforts*

[...continues] 1. Standardisation Efforts:

- Enable capacity clustering in a way that a mechanism is installed for scientific collaboration [...].
- Make existing documents and work in progress better known to the various stakeholders, including industrialists [...].
- Further enhancement of research and development collaboration in favour of supporting harmonization and development of new standards by promoting some of the mechanisms already in place [...].
- Support inter-lab assessments initiatives (in particular through the implementation of a dedicated funding programme similar to the ASTM Interlaboratory Study Program) [...].
- Involve the National Metrology Institutes (NMIs) in the process [...].
- Support better coordination and synergy in test guidelines for regulatory systems through enhancement of international collaboration [...].
- Enhance the existing collaboration between international standardization bodies like ISO/TC 229, CEN/TC 352, etc. as well as national standardization bodies in the area of nanosafety and nano-characterization standards [...].

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Pillar 1 – Harmonization: *2. Transfer of Scientific information into harmonised Guidance and Standards*

The establishment of INISS-Nano will relieve the burden and limitation of *ad-hoc* call-specific international collaborations that are newly established on a case-by-case basis, and that may not be able to allow productive, cross-border collaborations to take place.

The proposed INISSNano could become a permanent collaborative space for the exchange of knowledge and ideas across borders and beyond the immediate regulatory requirements of a single jurisdiction, thus supporting the development of a community for sustainable nanotechnology, based on principles and values that are jointly agreed on a global level.

- the vision: harmonization, ...
- ... the way to achieve this: collaboration.

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Pillar 1 – Harmonisation

Core ,problem`:

- VALIDATION needs to precede standardisation (not just for harmonisation/standardisation purposes)

Action

Short-term (until Dec 2023)

Medium-term (until 2025 and beyond)

Pre-standardization / Harmonization efforts (including interaction with the metrology community)

~~Documents to support Regulatory Preparedness in Nanotechnology [lead: tbd]~~

- CF: 'Concept of Regulatory Preparedness' (& other NanoReg (2) papers) → OECD SIA approach + 'early for
- Cf paper by Bleeker et al. (2023): TG review
- >> NOW: document on how o achieve it (lead: TBC)
- Prioritizing and listing the needs of standards by crowd sourcing approaches [lead: Hasan Pouypouy] ??? (possibly cross out)
- Promote already available funding mechanisms (i.e. dedicated annual calls for proposals regarding pre-standardization activities within the new European Partnership on Metrology programme) [lead: Georges Favre]
- → clarify the correct channel

Initiate a collaboration with VAMAS [lead: Georges Favre]

- → INISS-nano was already mentioned at VAMAS, their is interest to be a good vehicle for aforementioned validation work



Contribute to identify and prioritize the needs regarding OECD TG implementation documents [lead: Miguel Banares, Georges Favre, Steffi Friedrichs]

- → take forward, Europe&Asia needs a 'NCL'-like initiative to address nanomateruials (and TG/Standardsa implementation)
- ... linked to:




Work to establish a funded programme to support the organization of inter-laboratory comparisons to validate methods/protocols prior to their standardization (on a similar model to the ASTM programme) [lead: Georges Favre]

- Cf PEPPER-model PPP + 'Nanomesure France Association' (both France)






Pillar 1 – Harmonization: *ACTION PLAN (2)*

Action	
Short-term (until Dec 2023)	Medium-term (until 2025 and beyond)
Standardization	
<ul style="list-style-type: none"> Communicate on standardization programme (available and under development documents upon availability) [lead: Hasan Pouypouy] <ul style="list-style-type: none"> • Done (cf workshop, 16th Feb.) • Produce and disseminate summary reports of CEN/TC 352 and ISO/TC 229 meetings, if permitted [lead: Hasan Pouypouy] <ul style="list-style-type: none"> • ????? • Outreaching international experts [lead: tbd] <ul style="list-style-type: none"> • Carry forward  	<ul style="list-style-type: none"> Contribute to the development of an internationally recognised Standardization Certificates to acknowledge standardization work (in particular for academic experts) [lead: tbd] Contribute to identify and prioritize the needs regarding standardization work in order to optimize resource allocation [lead: tbd] • Becoming liaison of regional and international standardization organization [lead: Hasan Pouypouy] Joint development of standard in the field of: [lead: tbd] <ul style="list-style-type: none"> Characterization and measurement methods Guidelines Protocols



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Pillar 1 – Harmonization: *ACTION PLAN (3)*

Action	
Short-term (until Dec 2023)	Medium-term (until 2025 and beyond)
<h2>Nanometrology</h2>	
<ul style="list-style-type: none"> Promotion and facilitating inter-laboratories comparisons [lead: Georges Favre] ... ongoing Implementation of an European Metrology Network to coordinate effort on metrology to support the Advanced Materials/Nanomaterials topic [lead: Georges Favre] DONE (AdvanceManu EMN)  	<ul style="list-style-type: none"> Collaboration with Regional Metrology Organizations (RMOs like EURAMET, APMP, SIM) and BIPM [lead: Georges Favre] <ul style="list-style-type: none"> DONE: MoU between VAMAS&EURAMET ... plus APMP&VAMAS) To develop collaborative roadmap jointly with regional /international metrology institutes (e.g. BIPM, EURAMET) [lead: Georges Favre, Steffi Friedrichs] 
<h2>Regulations</h2>	
<ul style="list-style-type: none"> Sharing and exchange of experiences and policies regarding nanosafety regulations and laws [lead: tbd] <ul style="list-style-type: none"> OECD WPMN TdT Policy data sharing [lead: tbd] (cf. European Data Portal) 	<ul style="list-style-type: none"> Organizing joint meeting in the field of regulation and laws [lead: tbd] Promoting harmonizing approaches among regional/international regulatory bodies [lead: tbd] (cf.: other parties, such as Parma-event)
<h2>Capacity Building</h2>	
<ul style="list-style-type: none"> Training workshops bilateral and multi-lateral [lead: tbd] ... ongoing Knowledge /data sharing and transfer [lead: tbd] ... ongoing (possible webinars / invite to Project webinars, such as MACRAME) 	<ul style="list-style-type: none"> Tutorial packages [lead: tbd] ... ongoing (cf. EU academy ('tool on how to develop a reference material') link any resulting tutorials to EU academy)



NanoFabNet

international Hub for
sustainable High-Tech Innovation



The NanoFabNet project has received funding from the European Union's Horizon 2020 Research and innovation programme under grant agreement No. 886171.

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I would also like to register for the NanoFabNet newsletter

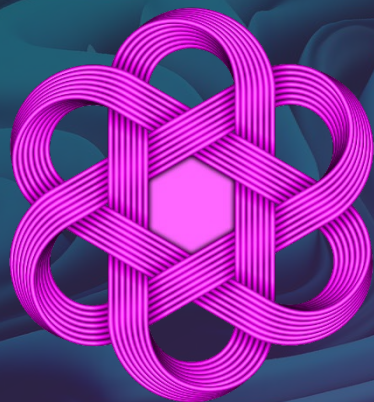
Pre-register

www.nanofabnet.net

The 'DigiMerge' Cluster

Five 'HorizonEurope-2022-Digital-Emerging-01-35 Sister Projects

- [ACCORDs - Green deal inspired correlative imaging-based characterization for safety profiling of 2D materials](#)
- [iCARE - Integrated assessment and Advanced Characterisation of Neuro-Nanotoxicity](#)
- [MACRAMÉ - Advanced Characterisation Methodologies to assess and predict the Health and Environmental Risks of Advanced Materials](#)
- [nanoPASS - Bridging the gaps in nanosafety for animal-free prediction of adverse outcomes](#)
- [POTENTIAL - Optimisation To Enable NanomaTerIAL safety assessment for rapid commercialisation](#)



Thank you

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