MACRAMÉ

Deliverable Report D5.2

Report on Stakeholder Involvement & Knowledge Transfer in the first 18 months

Project & Programme Information	
Project Acronym	MACRAMÉ
Project Full Name	Advanced Characterisation Methodologies to assess and predict the Health and Environmental Risks of Advanced Materials
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Call and Topic Name	HORIZON-CL4-2022-DIGITAL-EMERGING-01-35 - Advanced characterisation methodologies to assess and predict the health and environmental risks of nanomaterials
Instrument	Horizon Europe – Research and Innovation Action (RIA)
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Deliverable Report Information	
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[1] R= Document, report (excluding the periodic and final reports); DEM = Demonstrator, pilot, prototype, plan designs; DEC = Websites, patents filing, press & media actions, videos, etc.; DATA =Data sets, microdata, etc.; DMP = Data management plan; ETHICS = Deliverables related to ethics issues; SECURITY = Deliverables related to security issues; OTHER = Software, technical diagram, algorithms, models, etc.

[2] PU = Public, fully open, e.g. web (Deliverables flagged as public will be automatically published in CORDIS project's page); SEN = Sensitive, limited under the conditions of the Grant Agreement; Classified R-UE/EU-R = EU RESTRICTED under the Commission Decision No2015/444; Classified C-UE/EU-C = EU CONFIDENTIAL under the Commission Decision No2015/444; Classified S-UE/EU-S = EU SECRET under the Commission Decision No2015/444

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Acronyms Listed in this Document	
AdMa	Advanced Material
AOP	Adverse Outcome Pathway
BIPM	International Bureau of Weights and Measures
CEN	European Committee for Standardization
CODATA	Committee on Data of the International Science Council
CRO	Contract Research Organisation
EC	European Commission
ECVAM	EU Reference Laboratory for alternatives to animal testing
EURAMET	European Association of National Metrology Institutes
GRM	Graphene-related Material
GR2M	Graphene and Related two-Dimensional (2D) Materials
H&S	Harmonisation and Standardisation
ISO	International Organization for Standardization
NAM	New Approach Method/Methodology
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
RAS	Risk Assessor Summit
SME	Small & Medium Enterprise
SOP	Standard Operating Procedure
TG	OECD Test Guideline
VAMAS	Versailles Project on Advanced Materials and Standards
WP	Work Package

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Executive Summary

This deliverable report gives an overview of the stakeholder engagement and knowledge transfer on harmonisation and standardisation (H&S) activities for advanced materials undertaken in the first 18 months of the MACRAMÉ Project. Key events delivered by the MACRAMÉ consortium include an online workshop on H&S on 22. – 23. November 2023, its first Risk Assessors Summit in Berlin on 27. – 28. November 2023 (reported on in MACRAMÉ deliverable report D1.3) and two webinars (on 9. - 11. April 2024) within this period.

The workshop and the webinars also served as an opportunity to collaborate with our sister projects, as the workshop was co-organised with the nanoPASS and iCare projects, Webinar 1 was co-organised with the EU MetrINo project and the NanoMesureFrance Association and Webinar 2 was co-organised with nanoPASS.

In terms of internal knowledge transfer for MACRAMÉ researchers, one training event on harmonisation and OECD Test Guideline (TG) development was organised back-to-back with the first Project meeting. Furthermore, the MACRAMÉ H&S roadmaps (D5.1) were prepared and discussed as a collective project effort, building on the different expertise of the consortium partners.

1 Introduction

Task 5.2 is responsible for organising the stakeholder exchange and improvement of knowledge on H&S activities and processes in MACRAMÉ. The exchange and the improvement of knowledge is aimed both internally at consortium partners as well as towards external stakeholders.

The internal exchange and knowledge transfer aim to improve the knowledge base of Project partners on H&S activities and associated process, as well as initiating a discussion on how to advance the methods developed and optimised in MACRAMÉ into standards or OECD documents, either guidance documents (GD) or test guidelines (TG). To cover these aspects, MACRAMÉ can build on the expertise of various partners who have longstanding involvement in the activities of OECD, CEN, ISO and other (pre-)standardisation bodies (e.g. VAMAS, CODATA) and on the NanoHarmony training materials on OECD TG development.

The exchange with external stakeholders and general knowledge improvement has the aim to get an overview of ongoing harmonisation and standardisation efforts in the field of nano- and advanced materials (AdMas) and offer possibilities for training on H&S and regulatory testing in order to attract new experts to engage with these crucial activities. For external stakeholder engagement and knowledge transfer, MACRAMÉ uses various channels to reach a broad spectrum of stakeholders. In the organisation of events MACRAMÉ cooperates with its sister projects, to use input from various projects and to increase the number of participants. The main stakeholders MACRAMÉ is targeting are:

- *Scientists* – who are developing new methods and approaches for chemical safety and sustainability or developing new materials that may require development of new testing methods;
- *Regulators* – who are interested in incorporating new methods into regulatory frameworks;
- *Industry / CROs / SMEs* – who need to use TGs to comply with regulations;
- *Standardisation bodies and pre-standardisation initiatives* (e.g. VAMAS) – who are developing new standards for nano and advanced materials and are hosting inter-laboratory comparisons to support standards development;
- *OECD / ECVAM representatives* – to have the opportunity to learn about new methods being developed that could be used in future TGs.

Within the first half of the Project, MACRAMÉ organised one online workshop on H&S and two webinars on early MACRAMÉ outputs. The workshop provided an overview of ongoing harmonisation and standardisation projects in the field of nano- and AdMas and included expert discussions on current needs and issues in the form of two round tables. The two webinars aimed at (1) improving the knowledge on standardisation and validation processes in general and (2) giving an introduction to adverse outcome pathways (AOPs) as a tool to incorporate NAMs into regulatory testing, respectively. MACRAMÉ furthermore organised its first Risk Assessors Summit at BAuA Berlin on challenges in addressing sustainability in the Life Cycle Assessment of products including AdMas.

2 Internal Knowledge Transfer

The internal exchange and knowledge transfer aims to ensure that MACRAMÉ researchers have the skills necessary to drive the advancement of MACRAMÉ methods into standards and OECD documents and to improve the knowledge of Project partners on H&S activities in

general and their understanding of the corresponding landscape. Towards this end, a training session on the development of OECD TGs, based on the NanoHarmony training, was given back-to-back with the first MACRAMÉ Project meeting (the Project Kick-Off Meeting, held on the 28. – 28. February 2023 in Brussels)[3]. Furthermore, the preparation of the H&S roadmaps that indicate how MACRAMÉ methods in five fields can be transferred into standards and OECD documents were a collaborative effort, with input from many Project partners. First discussions on the H&S roadmaps were initiated during the first Project meeting and were further developed over the following 12 months, with final discussions during the third Project meeting (held at EMPA in St. Gallen, 12. – 13. December 2023). The roadmaps are described in MACRAMÉ deliverable report D5.1[4] and will be disseminated towards different stakeholders during the forthcoming 18 months.

3 Stakeholder Engagement and Knowledge Transfer *via* public Events

3.1 1st Joint Workshop: Harmonisation & Standardisation of Test Methods for Nanomaterials and Advanced Materials (ONLINE)

MACRAMÉ organised its **1st online H&S Workshop** on 22th to 23th November 2023 in cooperation with the Malta Initiative[5] and the nanoPASS[6] and iCare[7] projects. The aim of the workshop was to continue the successful stakeholder exchange established by the coordination and support action projects NanoHarmony[8] and NANOMET[9] on OECD TG development for nanomaterials and to broaden the scope to standardisation and AdMas.

The workshop was widely advertised *via* a range of channels such as the MACRAMÉ webpage and newsletter, the NanoSafety Cluster (NSC) and NanoHarmony newsletters, at various presentations (e.g. during OECD WPMN, and NanoSafe2023), and through the social networks of MACRAMÉ partners.

The workshop focused on two topics:

1. Development of *in vitro* models and bridging them towards standardisation/ harmonisation and regulation; and
2. Development of standards for characterisation of Graphene and Related two-Dimensional (2D) Materials (GR2M), regulatory challenges and the way forward.

Both days started with general presentations on H&S of nanoscale and advanced materials. On day 1, the status of development of OECD TGs for nanomaterials was presented, followed by presentations on pre-standardisation/ validation opportunities via the European Partnership on Metrology, VAMAS and ECVAM. Day 2 started with a presentation on how the Malta

[3] MACRAMÉ Kick-Off Meeting: https://macrame-project.eu/we-are-kicking-off-the-development-of-new-characterisation-methodologies-for-advanced-materials/ (website accessed: 01. July 2024)

[4] MACRAMÉ deliverable report D5.1: MACRAMÉ Harmonisation & Standardisation Roadmap Summary Report for MACRAMÉ Methods and Models (website accessed: 01. July 2024)

[5] Malta Initiative: https://malta-initiative.org/about/ (website accessed: 01. July 2024)

[6] nanoPASS: https://cordis.europa.eu/project/id/101092741 (website accessed: 01. July 2024)

[7] iCARE: https://cordis.europa.eu/project/id/101092971 (website accessed: 01. July 2024)

[8] NanoHarmony: https://cordis.europa.eu/project/id/885931 (website accessed: 01. July 2024)

[9] NANOMET: https://cordis.europa.eu/project/id/887268 (website accessed: 01. July 2024)

Initiative and NanoHarmony support TG development for nanomaterials and future steps including a priority list for making OECD TGs applicable to nano and advanced materials.

Day 1 continued with presentations of developments towards harmonised/ standardised *in vitro* approaches within the projects MACRAMÉ, iCare and nanoPASS. These were followed by a presentation on "Strategies to increase the technical quality of NAMs and nanoecotoxicology tests". The day was concluded with a vivid exchange in the form of a round table on harmonisation and standardisation of *in vitro* models and how to bridge them into regulation (see the workshop agenda in ANNEX A1).

The round table participants agreed that validation is key in making NAMs applicable for regulation. Research projects are instrumental in supporting validation and standardisation of *in vitro* and *in silico* test methods. Dedicated calls for harmonisation efforts as well as for validation studies seem to be a good trigger to support this. However, current funding is research and innovation (R&I) focussed, and is thus mainly going into development of new methods rather than into validation of existing NAMs, which would require an additional funding stream. An additional challenge is that validation is often not perceived as research, as scientists are trained to focus on innovation and development of new ideas and approaches, that can be more easily published. This leads to a large number of proposed NAMs, that are not validated or standardised and are thus not applicable for use in regulation. A further incentive could be changes in regulation (see animal free testing for cosmetics) and a stronger focus on research impacts / translation of research into practice.

The validation of NAMs is challenging as apart from maturity and reproducibility the scope and relevance (applicability domain) of test methods need to be determined. A further challenge for the validation of NAMs is the lack of nanomaterial references with known properties, and this becomes even more difficult for AdMas where consensus has yet to be reached even on their definition and representative examples are not yet available.

The application of NAMs in regulation is furthermore hindered by a missing exchange between regulators and developers of test methods and a limited understanding on how to use NAMs for regulatory testing. Exchange between regulators and developers of test methods is needed from early on and continuously during the development and documentation of the NAM to ensure that it is fit for purpose for regulatory use. Parish et al., (2020) proposed that NAMs could be used for *prioritisation* of chemicals of interest, *hazard screening* to evaluate chemicals for their potential hazards, as determined by their intended use, and for *risk assessment as* a quantitative evaluation that incorporates hazard, exposure and dose into the final determination on a chemical's safety to a particular population. Developers need to learn how methods are used for regulatory purposes and regulators need training and guidance on NAMs and how they can be applied with increasing certainty for decision making. One-test-one-endpoint approach is not the aim. NAMs need to be included in testing strategies (e.g. into tiered/ defined approaches, and in AOPs) and can support grouping/read across.

Key quotes from the round table of the first day that highlight the challenges include:

- *"It has been instrumental to have all these projects developing data. There is a before and an after Malta Initiative […]"* [Mar Gonzalez, OECD]
- *"We deal with an uncertainty to the power of two."* [Blanca Suarez-Merino, TEMASOL]
- "*The more NAMs we develop the less we use."* [Tommaso Serchi, LIST]

Day 2 continued with presentations on testing of Graphene and Related two-Dimensional (2D) Materials (GR2M), starting with the status and challenges in regulation of GR2Ms. The day continued with a session on (pre-)standardisation activities for pristine graphene covering

presentations on ISO and VAMAS activities, the Graphene Flagship[10] and the Graphene Council[11]. Building on these, activities towards the determination of graphene in complex media were presented and a Mentimeter session organised to identify the priorities to be considered based on inputs from the participants. The day was concluded with a round table discussion on the needs for characterisation and test method development for graphene (and 2D materials generally).

The round table participants agreed that further development of protocols and standards to characterise GR2M is needed. For this we need to distinguish between standards for quality control and safety assessment / regulation. In the field of quality control more standards considering in-line techniques need to be developed. To support safety assessment of GR2M exchange between manufactures and regulators is needed. The field of GR2M is dominated by SMEs. They need support in fulfilling regulatory requirements. To support the development of standards, funding for projects dedicated to validation of already existing methods is needed.

> *"The same hurdles we had a few years ago for nanomaterials now apply for graphene. Look over the EU plate and work with other communities."*
>
> [Steffi Friedrichs, AIST]

All information on the 1st MACRAMÉ H&S Workshop, including the recordings, is accessible via the MACRAMÉ webpage. The workshop was a success both in terms of continuing the regular stakeholder exchange on advancement in TG and standard development of nano and advanced materials, as well as being a vehicle for collecting inputs for the developments and standardisation roadmaps envisioned in MACRAMÉ.

3.2 1st MACRAMÉ Risk Assessors Summit

A detailed description of the Risk Assessors Summit can be found in MACRAMÉ deliverable D1.3.[12] The following text is an excerpt from *D1.3: Summary Report about the 1st Regulatory Risk Assessors Summit*:

The 1st MACRAMÉ Regulatory Risk Assessors Summit at BAuA in Berlin, which took place on the 27th – 28th of November, marked a pivotal event in highlighting challenges, needs, and gaps in the regulatory frameworks important for the risk assessment during the life cycle of Advanced Materials (AdMas) and AdMas-containing products. The summit was structured into three sessions to provide a platform for expert insights, stakeholder perspectives, and interactive discussions.

[10] Graphene Flagship: https://graphene-flagship.eu/

[11] Graphene Council: https://www.thegraphenecouncil.org/

[12] 1st MACRAMÉ Regulatory Risk Assessors Summit: https://macrame-project.eu/crucial-recommendations/ (website accessed: 01. July 2024)

Session 1: Expert Insights

This session established the foundational context for the summit discussions, concentrating on the current policy frameworks. Key highlights included the European Green Deal, lessons learned from EU-funded projects like Gov4Nano, and an in-depth look into the Safe and Sustainable by Design (SSbD) Framework and into Life Cycle Assessment (LCA). These presentations laid out a comprehensive picture of the evolving policy environment concerning AdMas.

Session 2: Stakeholder Perspectives

Diverse viewpoints were showcased in this session, featuring short talks from regulators, representatives of large industries and SMEs, researchers, and consumers. Each speaker shared their unique perspective on risk assessment in the AdMas and AdMas-containing product lifecycle context, spotlighting the various challenges faced by each group. This session also included a panel discussion that amalgamated insights from the previous expert talks with the various stakeholder viewpoints, enriching the depth of the discourse.

Session 3: Interactive Breakout Sessions

The final session was marked by its interactive nature, with breakout groups delving into specific challenges of risk assessment during the life cycle of AdMas-containing products. These groups focused on occupational, consumer, and environmental safety, engaged in thorough discussions and analyses. The outcomes of these sessions, including identified needs, issues, and future recommendations, were later shared with all participants, fostering a collaborative approach.

Central themes included the evolution of regulatory frameworks, the integration of SSbD with LCA, the digital product passport (DPP), and the need for unified terminology and testing methodologies for risk assessment. Emphasizing collaborative innovation, the summit underscored the importance of transparent data management and adaptable LCA methodologies. The outcomes from this Summit, including a diverse range of stakeholder recommendations, set the stage for further advances in the MACRAMÉ Project including helping to shape the standardisation roadmaps. These discussions will be instrumental in shaping the direction for the upcoming 2nd MACRAMÉ Risk Assessors Summit, continuing the crucial dialogue on the sustainable and responsible development of AdMas and AdMas-containing products.

In summary, the 1st MACRAMÉ Regulatory Risk Assessors Summit was carefully structured to ensure a holistic and inclusive exploration of the multifaceted challenges in the risk assessment and lifecycle management of AdMas. The event's diverse agenda and the expertise of its participants underscored its critical role in driving forward the discourse on material safety and sustainability.

3.3 Webinar I: Standardisation and Validation made simple

MACRAMÉ organised its first webinar entitled "Standardisation & Validation made simple" in collaboration with MetrINo and the NanoMesureFrance association on the 9. April 2024.

The main objective was to share information to help the participants understand the role of metrology and standardisation as a means to address the regulatory requirements for advanced materials and nanomedicines.

The slides and full recording are available on the MACRAMÉ webpage.

This was an opportunity to explain various concepts and key terms related to method validation (e.g. trueness, accuracy, bias, precision), the tools to be deployed (e.g. reference materials,

inter-laboratory comparison) to advance progress on the translation of NAMs from research labs to use in regulatory decision making, and summarised the current best practices and databases in the field. The landscape has been explained to increase the participant understanding of the complementarity between the different bodies and initiatives (e.g. BIPM, VAMAS, EURAMET, CEN, ISO, OCED) and examples were given (nanomedicine, nanoparticle concentration, cellulose nanocrystals, and graphene, bilayer graphene & graphene nanoplatelets) to highlight some success stories and show how these successes had been achieved. The coordination between VAMAS, ISO, and CEN was particularly emphasised to highlight VAMAS's prominent role in hosting the inter-laboratory comparisons needed to validate methods and the Standard Operating Procedures (SOPs) that underpin them before formal standardisation / validation processes can be undertaken.

3.4 Webinar II: AOPs: A tool to include NAMs into regulatory testing

MACRAMÉ organised its second Webinar on "AOPs: A tool to include NAMs into regulatory testing?" in collaboration with nanoPASS on the 11. April 2024.

Regulatory safety testing of chemicals and materials is still mainly focused on animal testing. A huge number of NAMs to potentially replace or reduce animal testing have been scientifically developed within the last years. Their regulatory use, however, is still limited. A possible way to include NAMs into regulatory testing may be found in the AOP framework.

The webinar therefore informed participants on what AOPs are, how they can be developed and established, and the role of the OECD in formalising and standardising AOPs. nanoPASS furthermore presented on the development of the AOP for Pulmonary Fibrosis (the first nanomaterial-relevant AOP endorsed by the OECD) and an AOP for acute lung toxicity. These presentations were complemented by a presentation on the applicability of AOPs in (regulatory) hazard assessment.

During the discussion and Q&A session the challenges of implementing NAMs into regulatory hazard assessment were discussed. The main hurdles described were, on the one hand, on the limited validation of NAMs, and on the other hand, that to cover a toxicological endpoint multiple NAMs/AOPs need to be combined into an integrated/ defined approach, that also needs to be validated. NAMs can be currently successfully applied to show an adverse outcome/effect, whereas the evidence for no effect is more challenging.

> *"It's everybody's job now to move the 'maybe' to a 'yes' regarding the acceptance of NAMs into regulatory risk assessment."*
>
> [Sean Kelly, Nanotechnology Industries Association, and Qasim Chaudry, University of Chester]

The slides and full recording are available on the MACRAMÉ webpage.

3.5 Summary of stakeholder involvement and knowledge transfer in the first 18 months of MACRAMÉ

MACRAMÉ was successful in securing a broad engagement of different stakeholders by offering a mix of online and physical meetings. We used our events to share information by presentations as well as offering different discussion formats as for example round tables and break out group discussions. Table 1: Overview of registrants for MACRAMÉ events during months 1-18, sorted by stakeholder groups gives an overview of registrants at the MACRAMÉ events during the first 18 months, sorted by stakeholder groups.

Table 1: Overview of registrants for MACRAMÉ events during months 1-18, sorted by stakeholder groups

Event	Academic	Industry	Regulator	Policy Maker	Service Provider*	Other**	total
H&S Workshop	64	30	23	5	26	5	153
Risk Assessors Summit	10	3	15	1	24	1	54
1st Webinar	28	16	13		21	4	82
2nd Webinar	27	20	18	2	19	5	91

*e.g. CROs or consultancy company

**e.g. NGOs, general public, science reporter

The fraction of the different stakeholder groups varies, dependent on the event. The Workshop for example has a large number of participants from the academic field. The fact of having a significant proportion of representatives from the academic world at the Workshop is good, as it increases the chances of attracting additional experts from this research ecosystem to contribute to these discussions on the harmonisation of methods. The Risk Assessors Summit, by contrast, had a larger percentage of regulators participating, as it had a focus on regulatory aspects.

The events were also used for collaboration and exchange with the MACRAMÉ sister projects iCare and NanoPASS and have improved the exchange between the projects.

4 Outlook

MACRAMÉ will continue its activities on stakeholder engagement and knowledge transfer in the remaining duration of the Project. Towards this end MACRAMÉ will give two training sessions during the MaterialsWeek 2024 on 19th June 2024 on "How to expand the use of your test method? – Validation is key towards standardisation" and "Standardisation needs for regulatory testing of graphene and related 2D materials".

MACRAMÉ is planning to continue the annual online H&S Workshop in November 2024 and 2025. The next Workshop is scheduled for 18th-19th November 2024. The two days will be focused on NAMs validation and uptake into regulatory practice, and imaging and testing of complex samples along the lifecycle. The collaboration with sister projects is foreseen. nanoPASS and iCare already confirmed their interest. We are additionally aiming for at least one webinar in September/ October 2024 targeting Life Cycle Assessment and sustainability.

MACRAMÉ will also start disseminating its H&S roadmaps by presenting them to various stakeholders, to collect feedback and bring them to the attention of the respective standardisation bodies. The first events targeted are the MaterialsWeek 2024 and the next OECD WPMN meeting, both taking place in June 2024.

5 Bibliography

S.T. Parish *et al.*. An evaluation framework for new approach methodologies (NAMs) for human health safety assessment; Regulatory Toxicology and Pharmacology 112 (2020) 104592; https://doi.org/10.1016/j.yrtph.2020.104592.

ANNEX A1 – Agendas Joint online Workshop and Webinars

Table 2: Agenda Joint online Workshop: Harmonisation & Standardisation of Test Methods for Nano- and Advanced Materials

Day 1- 22 November 2023

Chair: Sean Kelly (NIA); Technical Chair: Nikolina Latkovic (NIA)

Time (CET)	Session Title	Speakers
10.00-10.20	Welcome and introduction to the workshop	Steffi Friedrichs (AcumenIST)
10.20-10.40	Status of OECD TG developments for nanomaterials	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	Q&A	all
Developments of *in-vitro* models and bridging them towards standardisation/ harmonisation and regulation		
11.40-12.00	MACRAMÉ´s approach towards harmonisation of in-vitro/ex-vivo models for inhalation toxicology	Tommaso Serchi (LIST)
12.00-12.40	**Lunch Break**	
Developments of *in-vitro* models and bridging them towards standardisation/ harmonisation and regulation		
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 approach towards 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 and standardisation of in-vitro models and how to bridge them into regulation	Moderator: Blanca Suarez Merino (NIA) Participants: presenters of the day
15.00-15.15	Round-up of Day 1	Sean Kelly (NIA)

Day 2 - 23 November 2023

Chair: Ernesto Alfaro-Moreno (INL); Technical Chair: Sean Kelly (NIA)

Time (CET)	Session Title	Speakers
10.00-10.10	Welcome and 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	Moderator: Georges Favre (LNE) Participants: presenters of the day
15.00-15.15	Workshop round-up, conclusions, outlook	Steffi Friedrichs (AcumenIST)

Table 3: Agenda Webinar 1: Standardisation and Validation made simple

9th April 2024

Moderator: Elisabeth Heunisch (BAuA) (technical) support: Steffi Friedrichs (AIST)

Time (CET)	Topic	Speaker
2:00 – 2:10	Welcome	Elisabeth Heunish (BAuA)
2:10 – 2:40	PART A – Basics (including Q&A session)	Georges Favre (LNE)
2:30 – 3:00	PART B – Landscape & Opportunities (including Q&A session)	Caterina Minelli (NPL)
3:00 – 3:30	PART C - An exemplar journey from need to standard (including Q&A session)	Caterina Minelli (NPL)
3:30 – 4:00	PART D - Examples for advanced materials - What's the alternative for less mature cases? (including Q&A session)	Georges Favre (LNE)

Table 3:

Table 4: Agenda Webinar 2: AOPs: A Tool to include NAMs into regulatory Testing?

11th April 2024

Moderator: Steffi Friedrichs (AIST) (technical) support: Elisabeth Heunisch (BAuA)

Time (CET)	Topic	Speaker
2:00 – 2:10	Welcome by MACRAMÉ and nanoPASS	Steffi Friedrichs (AIST)
2:10 – 2:30	Overview of AOPs and their development	Nathalie Delrue (OECD)
2:30 – 2:50	What is next for AOP173/AOP33?	Sabina Halappanavar (Health Canada)
2:50 – 3:10	An AOP for acute lung toxicity including a NAM	Jorid Birkelund Sørli (NRCWE)
3:10 – 3:30	Applicability of AOPs in (regulatory) hazard assessment	Qasim Chaudhry (University of Chester)
3:30 – 3:55	Q & A and Discussions	Blanca Suarez Merino (NIA)
3:55 – 4:00	Closing the meeting	Sean Kelly (NIA)