MACRAMÉ

Deliverable Report D1.3

Summary Report about the 1st Regulatory Risk Assessors Summit

Project & Programme Information	
Project Acronym	MACRAMÉ
Project Full Name	Advanced Characterisation Methodologies to assess and predict the Health and Environmental Risks of Advanced Materials
Grant Agreement No.	101092686
Work Programme	HORIZON.2.4 - Digital, Industry and Space
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)
Project Start Date	01 December 2022
Duration	36 months

MACRAMÉ has received funding from:

the European Union's Horizon Europe Research and innovation programme under grant agreement No. 101092686.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI

UKRI Innovate UK

Project & Programme Information	
Work Package	WP1
Deliverable Number	3 (D1.3)
Associated Task	Task 1.3
Type [1]	R
Dissemination Level [2]	PU
Version	V1
Actual Submission Date	31.12.2023
Contractual Submission Date	30.11.2023
Lead author (organisation)	BioMS
Contributors	AIST, RIVM, BAuA, GAIKER, TEMASOL
Reviewers	

Version	Date	Changes made	By	Sent to	Purpose
0.1	30.11.2023	Draft version	BioMS	AIST, RIVM, BAuA, GAIKER, TEMASOL	Partner contribution
0.2	15.12.2023	Review	BioMS	all	Review
0.3	20.12.2023	Review	BioMS	AIST	Finalisation
1.0	31.12.2023	Finalisation & Submission	S. Friedrichs (AIST)	EC	Submission
1.1		Update			

[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.

MACRAMÉ has received funding from:
the European Union's Horizon Europe Research and innovation programme under grant agreement No. 101092686.
Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra
Swiss Confederation
Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI
UKRI Innovate UK

Acronyms Listed in this Document	
AdMas	Advanced Materials
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Federal Institute for Occupational Safety and Health)
BfR	Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment)
CE	Conformité Européenne (European conformity)
CEN	Comité Européen de Normalisation (European Committee for Standardization)
CNR	Consiglio Nazionale delle Ricerche (National Research Council)
CNTs	Carbon Nanotubes
CSA	Coordination and Support Action
CSRD	Corporate Sustainability Reporting Directive
DPP	Digital Product Passport
EC	European Commission
EC_{50}	Half maximal Effective Concentration
ECHA	European Chemicals Agency
ESPR	Ecodesign for Sustainable Product Regulation
IP	Intellectual Property
ISO	International Organization for Standardization
JRC	Joint Research Centre
LCA	Life Cycle Assessment
LNE	Laboratoire national de métrologie et d'essais
NAMs	New Approach Methodologies
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PMT	Persistent, Mobile and Toxic
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment)
SME	Small and Medium-sized Enterprise
SSbD	Safe and Sustainable by Design
SSIA	Safe and Sustainable Innovation Approach
UBA	Umweltbundesamt (Federal Environment Agency)

Contents

List of Tables

Executive Summary

The 1st MACRAMÉ Regulatory Risk Assessors Summit took place on the 27th – 28th of November in Berlin. It marked a pivotal event in highlighting challenges, needs, and gaps in the current regulatory frameworks related to risk assessment during the life cycle of Advanced Materials (AdMas) and AdMas-containing products. The summit was structured into three sessions to provide platforms for expert insights, stakeholder perspectives, and interactive discussions. For detailed information about the summit, including the agenda and speaker biographies, please visit the MACRAMÉ website [https://macrame-project.eu/macrame-meetings-workshops/1st-macrame-risk-assessors-summit/].

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 concepts of 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 Small and Medium-sized Enterprises (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 concluded in 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 thorough discussions and analyses. Three breakout groups delved into specific challenges of risk assessment during the life cycle of AdMas-containing products. Each of these groups focused on either occupational, consumer, or environmental safety. The outcomes of these sessions included identified needs, issues, and future recommendations. These were later shared with all participants, fostering a collaborative approach.

Central themes included the evolution of regulatory frameworks, the integration of SSbD with LCA, and the digital product passport (DPP). Needs were identified 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. This Summit resulted in a diverse range of stakeholder recommendations that set the stage for further advancements in the MACRAMÉ project. These discussions will help shape the direction for the upcoming 2nd MACRAMÉ Risk Assessors Summit. Outcomes and recommendations from the MACRAMÉ project will be presented there and the crucial dialogue with essential stakeholders will continue.

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 broader discussions on material safety and sustainability.

1 Introduction

1.1 Purpose and Objective of the Summit

The 1st MACRAMÉ Regulatory Risk Assessors Summit was centred around the critical objective of discussing and addressing the safety of Advanced Materials (AdMas) throughout their product lifecycle. The summit aimed to engage stakeholders from academia, industry, and regulatory bodies in assessing the status of regulatory frameworks for AdMas and identifying areas where these frameworks need enhancement. The meeting aimed specifically to explore the integration of risk assessment with life cycle assessment (LCA) while incorporating sustainability principles within the Safe and Sustainable by Design (SSbD)[3] framework. The summit sought to identify gaps, issues, and potential recommendations in the field, contributing significantly to the overarching goals of the MACRAMÉ Project. This event stimulated a comprehensive understanding of impacts of AdMas, while laying a basis for future advancements in regulatory practices and safety standards for AdMas and AdMas-containing products.

1.2 Summit Framework and Agenda

The 1st MACRAMÉ Regulatory Risk Assessors Summit took place on the 27th and 28th of November 2023 at the Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) in Berlin, Germany.

The summit attracted 43 in-person participants, with a few additional participants listening in *via* an online format. Participation by industry leaders, researchers, network members, and representatives from key regulatory agencies (e.g. BAuA, LNE, BfR, ECHA, EMPA, CNR, RIVM, UBA, OECD, and JRC), highlighted the event's significance in the field of regulatory risk assessment.

The summit was structured into three focused sessions, each designed to cover various dimensions of the risk assessment and LCA of AdMas-containing products. A first session on, 'Expert Insights' explored policy frameworks (e.g. the European Green Deal and the SSbD framework) and brought insides into LCA and its connection to risk assessment. The second session on 'Stakeholder Perspectives' brought diverse viewpoints from regulators, consumers, industry, and researchers, and involved a more detailed panel discussion on AdMas risk assessment along the life cycle. The final session encompassed 'Interactive Breakout Sessions' that targeted specific challenges in occupational, consumer, and environmental safety of AdMas. This structure facilitated a comprehensive understanding and collaborative exploration of AdMas risk assessment.

The detailed agenda and program of the summit are outlined in Table 1 and Table 2 provided in the ANNEX A1.

[3] Safe and Sustainable by Design – website of the European Commission (accessed: 31.12.2023): https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/key-enabling-technologies/chemicals-and-advanced-materials/safe-and-sustainable-design_en.

2 Summary of Content

2.1 Introduction to the 1st Regulatory Risk Assessors Summit

Introduction by the Host - Rolf Packroff (BAuA)

Dr Rolf Packroff, the Scientific Director at BAuA, welcomed the MACRAMÉ community and invited experts at BAuA and opened the Summit with a focus on the evolving landscape of AdMas. Emphasizing the need for regulations to keep pace with innovative advancements in materials, he highlighted the unique challenges posed by AdMas, particularly in terms of occupational health and safety. Rolf Packroff's insights set the stage for the summit, underlining the urgency for research and regulatory adaptation in this rapidly advancing field.

Introduction to the MACRAMÉ Project – Steffi Friedrichs (AIST)

Dr Steffi Friedrichs, as the coordinator of the MACRAMÉ Project, highlighted the importance of expert collaboration to address the challenges of AdMas and introduced the MACRAMÉ project. She underscored the importance to improve and develop methods for the characterisation and testing of AdMas on real, market-relevant products, such as the five use-cases that the MACRAMÉ Project is focussing on. She described how the multidisciplinary project team had to agree on a new terminology to identify and further investigate the possible exposure points for each of the five use-case AdMas in their respective life cycles. Steffi Friedrichs outlined the Project's central objectives, research and innovation strategy, and introduced the agenda and expectations of the Summit.

2.2 Summary of Presentations: Key Topics and Insights

The presentations by leading experts provided profound insights into the sustainable development and governance of Advanced Materials (AdMas). These talks encompassed a range of topics, from the European policy landscape and its impact on AdMas to the intricacies of life cycle assessment and risk assessment. Dr Lya Soeteman-Hernandez (RIVM) provided the broader European policy landscape, the importance of advanced materials for Europe, and lessons learned from governance of nanomaterials, and addressed the integration of the SSbD framework in line with the European Green Deal. Dr Hubert Rauscher (JRC) elaborated on the implementation of the SSbD framework and its policy context. Dr Roland Hischier (Empa) brought a focus on the holistic approach needed for effective LCA, and Prof. Dr Bernd Nowack (Empa) delved into the vital role of characterisation factors in LCA for AdMas. These presentations collectively highlighted the complexity and interdisciplinary nature of managing and accessing AdMas, underlining the need for a comprehensive approach that integrates safety, sustainability, and policy considerations.

2.2.1 The European policy landscape and lessons learned from nano governance for AdMas - Lya Soeteman-Hernandez (RIVM)

Dr Lya Soeteman-Hernandez, an expert in the Safe and Sustainable Innovation Approach (SSIA) from the Dutch National Institute for Public Health and the Environment (RIVM), set the scene for the summit. Her talk was centred on the European policy landscape, particularly in the context of AdMas, and the lessons learned from nano governance.

Key Topics and Insights:

1. European Green Deal and SSbD Framework: The presentation accentuated the significant role of the European Green Deal in enhancing people's well-being and setting policy benchmarks. It focused on the integration of the SSbD framework into product development. This highlighted a shift towards sustainable practices in line with EU policies such as the

Regulation on the registration, evaluation, authorisation and restriction of chemicals (REACH)[4] (REACH) and the Ecodesign for Sustainable Product Regulation (ESPR)[5].

2. Challenges Associated with Advanced Materials: Lya Soeteman-Hernandez outlined specific challenges related to the safety and lifecycle management of AdMas. Key issues discussed included the dispersion and morphological changes of AdMas. Also their (foreseen) key role in propelling the EU towards a safe, sustainable, climate neutral and circular economy was highlighted.

3. Insights from Gov4Nano: Lessons learned on governance from the Gov4Nano project were shared, particularly the pacing and coordination challenges within regulatory frameworks. The presentation underscored the importance of creating better linkages between funding mechanisms and regulation, along with addressing the growing reliance on New Approach Methodologies (NAMs) and existing knowledge gaps. In addition, the presentation described, how considerations were needed for hazard criteria for new endpoints, e.g. in REACH and the regulation of Classification, Labelling and Packaging of substances and mixtures (CLP)[6]. Endpoints include endocrine disruption, immunotoxicity and developmental neurotoxicity, persistent, mobile and toxic (PMT), and persistent, bioaccumulative and toxic (PBT). Harmonisation and standardisation procedures were key to bring both NAMs and the new hazard endpoints to practice. Transregulatory dialogue was essential to bridge the science-policy interphase in an efficient manner.

4. Transition from Nanomaterials to Advanced Materials: The discussion extended beyond nanomaterials to encompass a wider range of advanced materials. It highlighted the necessity for a comprehensive regulatory framework to facilitate this transition, mentioning the establishment of a dedicated steering group for AdMas.

5. SSbD in the Context of the Green Deal: Safe and Sustainable by Design was presented as a crucial element of the Green Deal, essential for preparing industries for future regulatory landscapes. The talk also covered aspects of the Corporate Sustainability Reporting Directive (CSRD)[7], stressing the integration of sustainability into corporate finance reporting.

Overall, the presentation provided a comprehensive overview of the current European policy landscape regarding AdMas, stressing the need for an integrated approach that combines safety and sustainability assessments. These insights laid the basis for subsequent discussions on the governance and regulatory aspects of AdMas.

---

[4] REACH Regulation – website of the European Commission (accessed: 31.12.2023): https://environment.ec.europa.eu/topics/chemicals/reach-regulation_en.

[5] Ecodesign for Sustainable Products Regulation - website of the European Commission (accessed: 31.12.2023): https://commission.europa.eu/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/sustainable-products/ecodesign-sustainable-products-regulation_en.

[6] European Agency for Safety and Health at Work: https://osha.europa.eu/en/themes/dangerous-substances/clp-classification-labelling-and-packaging-of-substances-and-mixtures (website accessed: 31.12.2023).

[7] Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting (Text with EEA relevance): EUR-Lex - 32022L2464 - EN - EUR-Lex (website accessed: 31.12.2023).

2.2.2 Safe and Sustainable-by-Design: Implementing the Framework – Hubert Rauscher (JRC)

Dr Hubert Rauscher, leading expert in Safe and Sustainable Advanced Materials at the European Commission's Joint Research Centre (JRC), shared his expertise on SSbD at the summit. His presentation focused on the implementation of the SSbD framework. This was a critical element in the European policy landscape, especially regarding the sustainable and safe development of AdMas and nanomaterials. Hubert Rauscher's work at the JRC encompassed supporting EU legislation for advanced materials. He contributed significantly to the field through his research and involvement in numerous European projects.

Key Topics and Insights:

1. Policy Context and Framework Development: The presentation provided an overview of the policy context surrounding the SSbD framework, emphasising its role in the European Green Deal. It highlighted the journey from the initial development of the framework to the European Commission's recommendations, showcasing how the Commission recommends applying the SSbD framework to case studies.

2. Framework Structure and Steps: The structure of the SSbD framework was outlined in detail, including its design part and assessment phases. The talk stressed that the SSbD assessment should be conducted at each stage of material development. The underlying assessment included four necessary steps: hazard assessment of the chemical/material, health and safety during production/processing, health and safety during final application, and environmental sustainability along the life cycle.

3. Life Cycle Assessment and SSbD Bootcamp: The presentation showed the importance of incorporating environmental sustainability assessment in the SSbD framework, recommending the use of the Product Environmental Footprint in LCA. The SSbD Bootcamp at the JRC was mentioned as a key training initiative. This highlighted the interdisciplinary approach and the need to merge safety and sustainability perspectives.

4. Expectations and Contributions to the Framework: The talk touched upon the expectations from various sectors, including regulatory, industrial, and academic, towards the application of the SSbD framework. It also discussed how research and innovation could contribute to the framework, linking the European Green Deal with advanced materials and aiming for a green industrial transition.

5. SSbD as a Holistic Approach: The presentation focused on the comprehensive nature of the SSbD framework, illustrating its role in guiding innovation towards a green industrial transition and establishing it as a global standard for safety and sustainability. It stressed the framework's role in enabling comparative assessments of new and existing chemicals and materials.

In conclusion, the presentation offered a comprehensive view of the SSbD framework, detailing its structure, objectives, and the role it plays in aligning with EU policy goals for sustainable and safe materials and chemicals. The talk provided insights into how the framework could foster innovation and guide the development of safer and more sustainable products.

2.2.3 Life Cycle Assessment and Risk Assessment – Roland Hischier (Empa)

Dr Roland Hischier, an environmental scientist from Empa in St. Gallen, delivered a comprehensive presentation on LCA at the summit. With over 25 years of experience in LCA, particularly in areas like nanotechnology, packaging, and electromobility, Dr Hischier brought a wealth of knowledge to the discussion.

Key Topics and Insights:

1. Holistic View for Sustainability: The talk emphasised the need for a holistic approach to sustainability, highlighting LCA as a comprehensive method for assessing environmental and human health impacts. It was pointed out that LCA aided decision-makers by providing a scientific basis for evaluating the overall impacts of products and systems.

2. Scope and Limitations of LCA: Roland Hischier discussed the possibilities and limitations of LCA, noting that it primarily focuses on environmental and health aspects, excluding economic and social factors. He stressed the relative approach of LCA, which required comparable scenarios for effective analysis allowing to compare very different things at the same time.

3. Risk Assessment in LCA: The presentation explored the concept of risk as a function of exposure and hazard. Roland Hischier highlighted the need for comparability in LCA scenarios, using the example of titanium dioxide in paint to illustrate how the application context could affect LCA outcomes.

4. Sustainability Focus: The focus was on assessing the sustainability, being it of materials or of products, with LCA being equated to the ecological sustainability. The importance of adhering to International Organization Standardization (ISO) standards in LCA was mentioned, along with its role as a tool for weak point analysis and legal requirements.

5. Comparative Approach and Challenges: The talk concluded with insights into the challenges of LCA for nanomaterials, emphasising the need for comparable scenarios and consider function-based assessments. The necessity for appropriate data and characterisation factors for accurate LCA of nanomaterials was also discussed.

Roland Hischier's presentation provided an in-depth view of the ins and outs of life cycle assessment in the context of advanced materials, underlining its critical role in achieving sustainable and safe product development.

2.2.4 Characterisation Factors in Life Cycle Assessment - Bernd Nowack (Empa)

Prof. Dr Bernd Nowack, an expert in environmental risk assessment from Empa, delivered further detailed insights on LCA. His extensive experience in environmental risks of engineered nanomaterials and development of SSbD methods informed his talk on the characterisation factors in Life Cycle Assessment.

Key Topics and Insights:

1. Concept of Characterisation Factors in LCA: The presentation began with an introduction to what characterisation factors are in LCA and what their role was in impact assessment; characterisation factors enabled the comparison of diverse environmental impacts, such as contrasting CO_2 emissions with phosphate emissions into water.

2. Challenges with Nanomaterials and Advanced Materials: A significant focus was on the lack of characterisation factors for nanomaterials and AdMas. This gap made it difficult to quantify all impacts of a material, especially those related to environmental release.

3. Modelling the Fate of Nanoparticles: Bernd Nowack discussed the complexities of assessing the release and environmental fate of nanoparticles. He highlighted the use of models like USEtox for chemicals and the importance of understanding factors, such as dissolution, agglomeration, and sedimentation in nanomaterials to enable the use of such release models for nanomaterials.

4. Development of Characterisation Factors in MACRAMÉ: The presentation included insights into how MACRAMÉ contributes to the development of characterisation factors. This

involved creating a decision tree to identify when such factors are necessary, as well as analysing various releases, product life cycles, and energy intensities in AdMa production.

5. Case Studies and Practical Applications: Bernd Nowack presented case studies, including one on microplastics, to demonstrate the application of characterisation factors in real-world scenarios. He mentioned the use of worst-case scenarios in modelling, highlighting that actual impacts might be lower than predicted.

In conclusion, Bernd Nowack's presentation shed light on the crucial role of characterisation factors in the LCA of nanomaterials and advanced materials. He provided a clear understanding of the challenges and the ongoing efforts to develop these factors, which are essential for accurate environmental impact assessments.

2.3 Short Talks: Major Points and Perspectives

Regulators View - Camelia Constantin (ECHA)

Dr Camelia Constantin from the European Chemicals Agency (ECHA) shared the challenges of potentially regulating AdMas under the current legal framework. Her presentation underscored the limitations within the REACH regulation: ECHA did not have a legal mandate to regulate AdMas, since currently only individual substances are subject of registration under REACH. She highlighted the difficulty in fitting AdMas into the hazard assessment framework and the uncertainty of existing REACH rules for risk assessment regarding their applicability for AdMas. Camelia Constantin acknowledged the potential of the SSbD approach to better link risk assessment and LCA for AdMas, despite ECHA currently having no formal mandate for SSbD. Her talk provided a critical perspective on the regulatory challenges and the need for adaptable frameworks to address the unique properties of AdMas.

Large Industry View - Xavier Chaucherie (SARPI – VEOLIA)

Xavier Chaucherie from SARPI-VEOLIA Group brought attention to the challenges faced by the hazardous waste industry concerning AdMas. He mentioned the lack of information and traceability regarding AdMas in hazardous waste, highlighting the need for internal method development and complex analytical tools for tracking nanoparticles. Xavier Chaucherie underscored the necessity for harmonized methods for physico-chemical characterisation and quantification of AdMas. He pointed out the industry's lack of focus on AdMas, due to the absence of characterisation factors and stressed the criticality of sampling as a long-standing issue in defining emission factors. This talk provided valuable insights into the practical challenges and requirements for managing AdMas in the hazardous waste industry, especially in the context of recycling and environmental safety.

SMEs' View - Daniel Müller (MyBiotech)

Dr Daniel Müller, CEO and Co-founder of MyBiotech GmbH, brought a unique perspective from the biotechnology and pharmaceutical industry to the summit. His presentation focused on the challenges and innovations in formulation development, particularly involving AdMas such as nanomaterials, nanoemulsions, liposomes, and polymeric nanoparticles. Daniel Müller emphasised the importance of sustainability in biotech and pharma product development, especially using bottom-up technology. He highlighted the major challenge of risk assessment in the context of different product types, including oral and inhalation products. This also includes the complexities involved in ensuring compliance on Good Manufacturing Practice (GMP) throughout the development and manufacturing processes. Daniel Müller also discussed the necessity of internal processes to establish reporting of potential risk assessment by workers, underscoring the importance of risk assessment from the design phase of drug formulation. His insights provided a comprehensive view of the intricacies involved in developing formulations for drugs and navigating the challenges associated with risk assessment in the biotech and pharma sectors.

Consumers' View - Blanca Suarez-Merino (TEMASOL)

Dr Blanca Suarez-Merino, Regulatory Affairs Director at the Nanotechnology Industries Association and Cofounder of TEMAS Solution GmbH, addressed the consumer perspective on risks associated with AdMas. Her presentation highlighted concerns about food contamination with microplastics and the increasing consumer awareness of such environmental risks. Blanca Suarez-Merino discussed the need for transparency in the product lifecycle, proposing the implementation of digital product passports (DPP) to provide comprehensive information. She noted that current eco-labels tend to focus more on the product rather than its entire lifecycle. Blanca Suarez-Merino suggested extending such approaches to AdMas, emphasising the evolving consumer perception of risks, the utility of eco-labels in delivering sustainability information, and the potential role of the CE mark in safety assessment; a CE mark indicated that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. Her talk provided insights into how consumer awareness and demand for information could drive more sustainable practices in the production and use of AdMas.

Researchers' View - Natalia Konchakova (Helmholtz-Zentrum Hereon)

Dr Natalia Konchakova, a senior scientist at Helmholtz-Zentrum Hereon, highlighted the development and application of digital tools in the context of risk assessment and LCA for AdMas. She discussed the VIPCOAT[8] project, i.e. the Virtual open Innovation Platform for active protective COATings guided by modelling and optimization. The project focused on active protective coatings and the challenges in managing released nanoparticles from these coatings. Natalia Konchakova emphasised the need for interoperable data exchange and the creation of an open innovation environment, where collaborative decision-making is facilitated through B2B2B (business-to-business-to-business) conditions. Her presentation also covered the importance of creating platforms that support interoperability pipelines for machine-readable data, linking external data sources, and the potential benefits of a digital materials and product passport for AdMas. Natalia also informed about a new EU Coordination and

[8] VIPCOAT project: (a) https://cordis.europa.eu/project/id/952903 (website accessed: 31.12.2023), (b) https://ms.hereon.de/vipcoat/ (website accessed: 31.12.2023).

support action (CSA) project DigiPass[9], which would focus on harmonisation of advanced materials ecosystem to support the digital maturity of European materials development communities. The project was anticipated to start in April 2024 with a main objective to enhance communication and cooperation among AdMas developing communities. The aim was to facilitate creation and utilisation of digital materials and the product passport along the distribution value chain. The importance of risk assessment, LCA and SSbD criteria for the co-innovation process was clearly indicated in the talk. In the presentation approaches were suggested that could enhance collaborative innovation and transparency in the development and production of new materials and products.

2.4 Summary of the Panel Discussion: Stakeholder Views on Risk Assessment in the Context of Life Cycle Assessment

Moderated by Dr Steffi Friedrichs (AIST), the panel brought together the experts presenting to discuss the multifaceted challenges in assessing and managing the risks of AdMas within the LCA framework.

- **Regulatory Complexity of AdMas:** Camelia Constantin from ECHA highlighted the regulatory challenges in classifying AdMas, which often appeared as mixtures or specific forms of substances. The absence of a clear legal mandate for regulating AdMas as a distinct category was underscored, emphasising the need for consistent and comprehensive terminology.
- **Safe and Sustainable by Design Integration**: The panel discussed the integration of SSbD with LCA, exploring the necessity for innovation hubs and collaborative platforms that aimed to bring diverse expertise together. The potential of SSbD as an operational tool for co-creation among stakeholders was also highlighted.
- **Data Management and Digital Tools:** The discussion delved into the importance of data integration, particularly in complex fields like battery technology. The role of digitalization in enhancing transparency and the need for secure data management, especially customer data, were discussed. The panel highlighted the importance of trust-building before digitalization.
- **Consumer Engagement and Transparency:** The panel considered various consumer interests in product information, recognising regional differences in consumer awareness and concerns. The potential for the DPP to provide detailed product lifecycle information was explored.
- **Stakeholder Involvement and Collaborative Innovation:** The discussion acknowledged the importance of involving diverse stakeholders, including trade unions and customer organisations, in the innovation process. The panel emphasised the need for a uniform approach to translating complex information for consumers and other stakeholders.
- **Challenges in Battery Recycling and Recovery:** The panel discussed the specific challenges in recycling and recovering materials from batteries, highlighting the importance of knowledge exchange and collaborative research in this area.

[9] Call Topic for the successful DigiPass Proposal: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-cl4-2023-resilience-01-39 (website accessed: 31.12.2023).

- **Digitalisation vs. Trust Building:** There was a debate about the priority between digitalisation and trust-building in the innovation process, with a consensus on the need for a stepwise approach that incorporates both.
- **Flexibility in LCA Approach:** The panel discussed the need for more flexibility and harmonization in LCA approaches, particularly regarding the standardisation of LCA factors and methodologies.
- **Inclusion of Other Disciplines in SSbD:** The discussion touched upon the potential benefits of incorporating insights from other disciplines, such as ethics and law, into the SSbD process. This points out the need for a multidisciplinary approach in SSbD.
- **Future Directions for AdMas Assessment:** The panellists explored the need for developing new, more sustainable AdMas to potentially replace established, possibly hazardous materials. This included the development of new methods, incorporating feedback from large industries, and establishing comprehensive criteria and key performance indicators for decision-making processes.

Overall, the panel discussion illustrated the complexities and diverse viewpoints in the field of AdMas, calling for a collaborative, innovative, and holistic approach to risk assessment and life cycle management.

2.5 Summary of Breakout Sessions: Discussions and Outcomes

2.5.1 Breakout Session: Occupational Safety

The Breakout Session on 'Occupational Safety' at the 1st MACRAMÉ Regulatory Risk Assessors Summit was led by Dr Elisabeth Heunisch from the Federal Institute for Occupational Safety and Health (BAuA). The session focused on occupational safety in the context of AdMas, particularly emphasizing hazard management during the production and end-of-life stages.

- **Occupational Safety at Production:** The session highlighted the need for effective testing strategies and guidance for AdMas, discussing the integration of Adverse Outcome Pathways (AOPs) and the validation of test methods. The importance of accurate exposure models and dose metrics in assessing occupational hazards was a key focus.
- **Challenges in Hazard Assessment**: Methodological challenges in assessing the hazards of AdMas were discussed, including the need for models and methods applicable throughout the material's lifecycle.
- **Lifecycle Information and Exposure Limits:** Discussion on Occupational Exposure Limits (OELs) and Derived No-Effect Levels (DNLs) underlined the need for consistent safety information throughout the product lifecycle.
- **Occupational Safety at End-of-Life (Waste/Recycling):** The session addressed the need for guidance and awareness in sectors like waste treatment and recycling, focusing on the unique hazards posed by AdMas and nanomaterials.
- **Regulatory and Awareness Challenges:** The importance of unified regulatory approaches and raising safety awareness in various sectors but also within key groups such as SMEs and academic institutions, was highlighted.
- **Data Gaps and Digital Solutions:** The session identified data gaps, especially in environmental safety assessment, and discussed the potential of digital solutions like the DPP to address these gaps.

In summary, the 'Occupational Safety' Session highlighted the importance of comprehensive hazard and exposure assessment and management for AdMas, particularly during production

and end-of-life stages. The discussions emphasized collaborative efforts in developing methodologies, enhancing regulatory frameworks, and improving information sharing for occupational safety in the context of AdMas.

2.5.2 Breakout Session: Consumer Safety

The 'Consumer Safety' Session at the 1st MACRAMÉ Regulatory Risk Assessors Summit was led by Dr Blanca Suarez-Merino (TEMASOL). Participants delved into the complex landscape of consumer safety concerning AdMas, acknowledging the existence of different "classes" of consumers in this context. This session focused on the diverse perspectives and needs of these consumer groups, ranging from primary producers of chemicals to secondary buyers such as large manufacturing companies.

- **Diverse Consumer Classes:** The session recognised the varying levels of consumers in the AdMas chain, from industrial users to end consumers, each with unique safety and sustainability concerns.
- **Anticipating Consumer Safety Questions:** Emphasising the need for primary producers to proactively address potential inquiries from their industrial consumers, the session highlighted case studies, such as carbon nanotubes' use in car tires. These examples demonstrated the necessity for industries to conduct experiments and provide comprehensive safety data.
- **Regulatory Compliance and Industry Proactivity:** Discussions also covered the necessity for industries to anticipate regulatory demands and incorporate relevant safety data into compliance processes, such as those required for REACH registration.
- **Challenges in Data Management and Standardisation:** The session explored the complexities of managing databases while protecting intellectual property and the significant investment required in data generation. The role of standardised methods in ensuring product safety was also discussed, both for industry-driven (ISO/European Committee for Standardization (CEN)) and regulatory-driven (OECD) demands.
- **Sustainability and Consumer Demand:** The session accentuated the importance of industries aligning their practices with both regulatory requirements and consumer expectations, especially in light of increasing consumer demand for sustainable and safe products.

In summary, the 'Consumer Safety' Session at the Summit highlighted the multifaceted nature of consumer safety in the AdMas sector, stressing the importance for industries to understand and respond to the varying needs and expectations of different consumer classes. This approach was crucial for ensuring product safety, regulatory compliance, and market competitiveness in the evolving landscape of AdMas.

2.5.3 Breakout Session: Environmental Safety

Dr Alberto Katsumiti (GAIKER) led the Breakout Session on 'Environmental Safety' at the 1st MACRAMÉ Regulatory Risk Assessors Summit. Here the focus was on the safety assessment challenges of AdMas. The session delved into various aspects of AdMas, from their transformation along the lifecycle to the applicability of existing knowledge about nanomaterials.

- **AdMas Definition and Transformation:** The session underscored the complexity in defining AdMas and discussed the transformation of materials from traditional forms to AdMas. Participants debated the assessment of AdMas transformations throughout their lifecycle.

- **Safety Assessment Challenges and Needs**: Key challenges identified included the definition of AdMas, with discussions around their dimensional characteristics and compositions. The need for models, realistic exposure data, and understanding environmental media interactions was highlighted. Issues like the release of fragments and the form of released materials were also discussed.
- **Knowledge Transfer from Nanomaterials:** The session explored whether existing knowledge on nanomaterials could be translated to AdMas. The consensus was case-dependent, acknowledging that while some known principles might apply, AdMas presented unique challenges as well.
- **Regulatory and Methodological Gaps:** Participants identified gaps in regulation and methodology, questioning the adequacy of current methods for environmental safety assessment of AdMas. The challenges in testing AdMas for risk assessment, including tracking transformation and extrapolating laboratory data to real environments, were discussed.
- **Data Gaps and Digital Solutions:** The most critical data gaps identified were in lifecycle data, EC_{50} values (half maximal effective concentration of a substance that elicits a 50% maximal response in a biological system), and fate kinetics description. The potential of the DPP as a solution to data integrity and trust issues along the value chain was suggested.
- **Regulatory Perspectives and Recommendations:** The session acknowledged the complexity of AdMas regulation, noting the limitations of current frameworks focused on individual substances. The need for recommendations to support future regulatory approaches for AdMas, considering their mixture-like nature, was emphasised.
- **Responsibility and Collaboration in Data Management:** The importance of determining responsibility for filling data gaps was discussed, with a focus on the role of the value chain and collaborative efforts in data management.

In summary, the 'Environmental Breakout' Session highlighted the need for a comprehensive approach to risk assessment of AdMas, considering their unique properties and lifecycle. The session emphasised the importance of developing new methodologies, enhancing regulatory frameworks, and fostering collaboration to address the challenges in assessing and managing the environmental safety of AdMas.

2.6 Closing of the Summit

During the wrap-up of the 1st MACRAMÉ Regulatory Risk Assessors Summit by Dr Friedrichs, she reminded the audience of the European Commission's comment on 1st day of the Summit:

> *'MACRAMÉ is fully in line with the EU's policies […] it is very much ahead of many projects […]'*
>
> *[quote from one of the speakers at the 1st NACRAMÉ Regulatory Risk Assessors Summit]*

She concluded by outlining the next steps, including the Project plans to work on the challenges identified during this 1st Regulatory Risk Assessors Summit, and follow up on its achievements at a 2nd Regulatory Risk Assessors Summit, underlining its significance in furthering discussions on AdMas.

3 Outcomes from the Summit

The 1st MACRAMÉ Regulatory Risk Assessors Summit brought together a diverse group of stakeholders in the field of AdMas. The forum enabled an exchange of unique perspectives and expertise. This diversity and balance led to a rich tapestry of recommendations and identified a number of needs and gaps that will now be further elaborated by the Project, with a view to either tackling them from within the MACRAMÉ Project and/or wider stakeholder community or recommending the most adequate approaches to the relevant responsible stakeholders.

The collective insights, tailored to various stakeholder groups, reinforced the need for a co-creational and holistic approach in the AdMas sector. This approach recognises the distinct challenges and requirements of each group, while highlighting the critical importance of collaborative efforts and shared knowledge for the field's advancement and responsible management.

3.1 Key Outcomes from the Summit:

3.1.1 Regulatory Relevance

- **Adapting Policy Frameworks:** A consensus emerged on the need for dynamic and flexible regulatory frameworks that could keep pace with the evolving nature of AdMas.
- **Standardising Terminology:** A call was made to standardise terminologies across disciplines, enhancing clarity in stakeholder communication and aiding in effective policy development.
- **Harmonising Assessment Methods:** The need for consistent and standardised assessment methods throughout the lifecycle of AdMas was highlighted to ensure effective management and risk assessment.

3.1.2 Collaboration in the Value Chain:

- **Integrating SSbD and LCA:** The importance of merging SSbD with LCA methodologies was underscored to gain a comprehensive understanding of material impacts.
- **Fostering Collaborative Innovation:** The establishment of innovation hubs was identified as crucial to bring together diverse expertise for AdMas development and to address various needs for different consumer classes.
- **Enhancing Traceability and Transparency:** The advancement of traceability methods and the implementation of transparent data solutions like the DPP to improve AdMas data management was an important point of the discussion.

3.1.3 Building (Consumers') Trust in the Value Chain:

- **Encouraging Sustainable Consumer Choices:** The role of consumers in demanding sustainable and less harmful material alternatives was emphasised, reflecting a shift towards more responsible consumption.
- **Assuring Data Integrity:** Developing robust systems for validating and comparing data accurately was seen as essential for material assessments.
- **Building Trust Across the Value Chain:** Establishing trust was recognised as a key factor for successful collaborative ventures and data sharing.

3.1.4 Research & Innovation Needs:

- **Promoting Interdisciplinary Research:** There was strong support for the development of new methodologies that incorporate cross-disciplinary insights.
- **Addressing Environmental Safety Gaps:** The urgency of filling data gaps, particularly in environmental impact assessments of AdMas was highlighted.
- **Driving Material Innovation:** There was a strong call to innovate and develop new materials that are not only economically viable, but that could also serve as (more) sustainable and safer alternatives to potentially hazardous materials.

In conclusion, the summit offered a comprehensive overview of the current state of risk assessment in the context of life cycle assessment of AdMas-containing products. This elucidated critical gaps, needs, challenges, and recommendations.

4 Outlook

The 1st MACRAMÉ Regulatory Risk Assessors Summit and the Harmonization & Standardisation Workshop (held online on 22nd-23rd November 2023), both held in Project Month M12, have highlighted key challenges, needs, gaps, and recommendations in the risk assessment during the life cycle of AdMas-containing products. According to the MACRAMÉ Engagement Roadmap (D1.4, delivered in M10), these activities mark the transition from the first 'Connect & Inform' phase to the second 'Collect & Integrate' phase of the MACRAMÉ Project. This second phase will focus on assimilating the accumulated insights into the project's ongoing activities by supporting its development of test guidelines and standards, as well addressing (part of) the challenges, gaps, and needs identified during the summit. Together with the results of the "Need Assessment Report of Regulatory & Policy Frameworks" (D1.2), scheduled for Project Month 24, the insights from the Harmonisation & Standardisation Workshop and the Summit will contribute to Milestone M5.2: Draft Recommendations on Future Needs for Test Guidelines & Standards Developments, expected by Project Month 24. This shows the close collaborations within the different WPs enabling to translate identified gaps into research questions and/or recommendations for the future. The discussions of the draft recommendations at the 2nd Regulatory Risk Assessors Summit (scheduled for mid 2025) in the last phase 'Rollout & Transfer' of the project will further finetune "Recommendations on Future Needs for TG and Standards Developments" that will be reported in Deliverable D5.4 scheduled for Project Month 36. The publication of the results in a perspective paper will mark a significant milestone in the development of methods and tools. This perspective paper will aim to support regulators in the risk assessment of AdMas containing products during their life cycle.

5 Dissemination

To enhance the reach and impact of the event, the MACRAMÉ Project's summit materials are being disseminated publicly. The agenda, a description of the Summit, speaker biographies, and selected presentations are accessible on the MACRAMÉ website [https://macrame-project.eu/macrame-meetings-workshops/1st-macrame-risk-assessors-summit]. Additional content, including password-protected presentations and a short summary of the summit's outcomes, will be distributed to participants. Public materials are available for reference and can be appropriately acknowledged as per the usage policy, ensuring widespread information sharing while respecting intellectual property.

ANNEX A1 – Agenda of the 1st MACRAMÉ Regulatory Risk Assessors Summit

Table 1: 27th November 2023: Keynote Speeches, Expert Presentations, and Stakeholder Discussions.

12:00 – 13:00	**Registration & Light Lunch**	
13:00 – 13:15	**Welcome** – Elisabeth Heunisch, Rolf Packroff (BAuA)	
13:15 – 13:30	**Introduction to MACRAMÉ and the Summit** – Steffi Friedrichs (AIST)	
Session 1: Policy framework of Green Deal, SSbD, and LCA Chair: Eric Bleeker (RIVM)		
13:30 – 13:50	**The European policy landscape and lessons learned from nano governance for AdMas** Lya Soeteman-Hernandez (RIVM)	
13:50 – 14:10	**Implementation of the SSbD framework** Hubert Rauscher (JRC)	
14:10 – 14:40	**Life Cycle Assessment and Risk Assessment** Roland Hischier (Empa)	
14:40 – 15:00	**Characterisation Factors in Life Cycle Assessment** Bernd Nowack (Empa)	
15:00 – 15:30	Coffee Break	
Session 2: Stakeholder views on Risk Assessment in the context of the Life Cycle of AdMas Chair: Kathleen Spring (BioMS)		
15:30 – 15:40	**Regulators View** Camelia Constantin (ECHA)	
15:40 – 15:50	**Large Industries'** Xavier Chaucherie (SARPI – VEOLIA)	
15:50 – 16:00	**SMEs' View** Daniel Müller (MyBiotech)	
16:00 – 16:10	**Consumers' View** Blanca Suarez-Merino (TEMASOL)	
16:10 – 16:20	**Researchers' View** Natalia Konchakova (Hereon)	
16:20 – 17:30	**Panel discussion** Stakeholder views on risk assessment in the context of Life Cycle Assessment	
	Participants: Steffi Friedrichs (AIST) Lya Soeteman-Hernandez (RIVM) Hubert Rauscher (JRC) Roland Hischier (Empa) Bernd Nowack (Empa)	 Camelia Constantin (ECHA) Xavier Chaucherie (SARPI – VEOLIA) Daniel Müller (MyBiotech) Blanca Suarez-Merino (TEMASOL) Peter Klein (Fraunhofer ITWM)
17:30 – 17:35	**Wrap up of Day 1**	
from 17:35	**Networking with Snacks and Drinks**	

Table 2: 28th November 2023: Interactive Breakout Sessions and Conclusive Reporting

8:30 – 8:45	**Welcome & Introduction**
Session 3: Specific Challenges of Risk Assessment during the Life Cycle of AdMas-containing products Chair: Klaus-Michael Weltring (BioMS)	
08:45 – 09:00	**Introduction Breakout Sessions**
09:00 – 11:00	**Breakout Session on Life-Cycle-based challenges addressing:** 1. Occupational safety (BAuA) 2. Consumer safety (TEMASOL) 3. Environmental safety (GAIKER)
11:00 – 11:30	**Coffee Break**
11:30 – 12:30	**Reporting from Breakout Sessions and capturing future recommendations** Klaus-Michael Weltring (BioMS) Elisabeth Heunisch (BAuA) Blanca Suarez-Merino (TEMASOL) Alberto Katsumiti (GAIKER)
12:30 – 13:00	**Closing**
13:00 – 15:00	**Lunch and Networking, Departure**