

***NanoSafety
Cluster***



ROADMAP TOWARDS SAFE AND SUSTAINABLE ADVANCED AND INNOVATIVE MATERIALS

(outlook for 2024-2030)



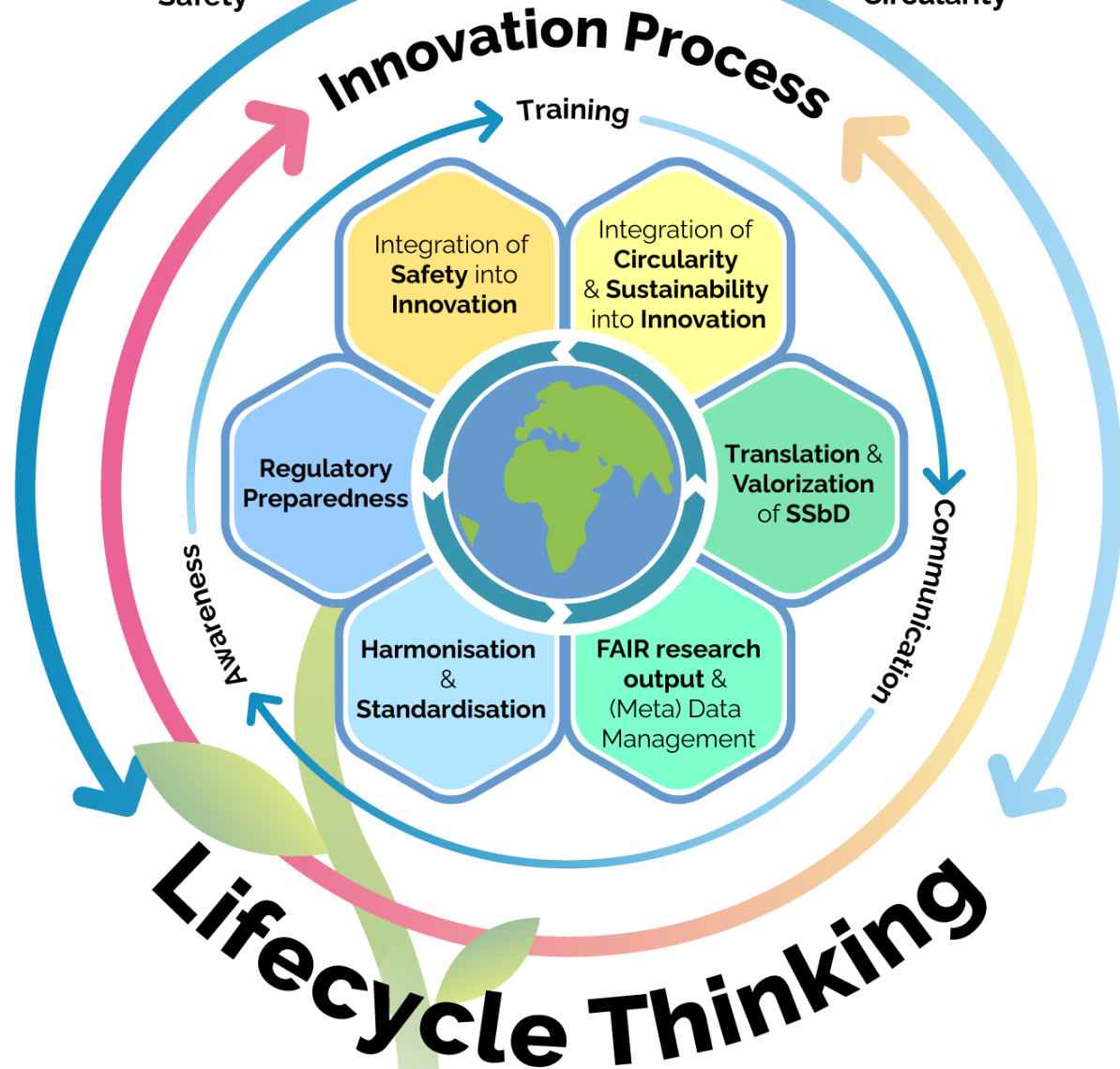
Safety

Sustainability



Circularity

NanoSafety
Cluster



• Introduction

• Presentation Roadmap

- Links to innovation: (safe) & sustainable by design - circular economy - valorisation
- Data Management & FAIR principles
- Validation, harmonization & standardization
- Governance & Regulatory Preparedness
- Communication and awareness training

TODAY'S SPEAKER



Monique Groenewold,
National Institute for Public Health and the
Environment (RIVM)



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Member of the NanoSafety Cluster Coordination team

Chair OECD Working Party on Manufactured Nanomaterials

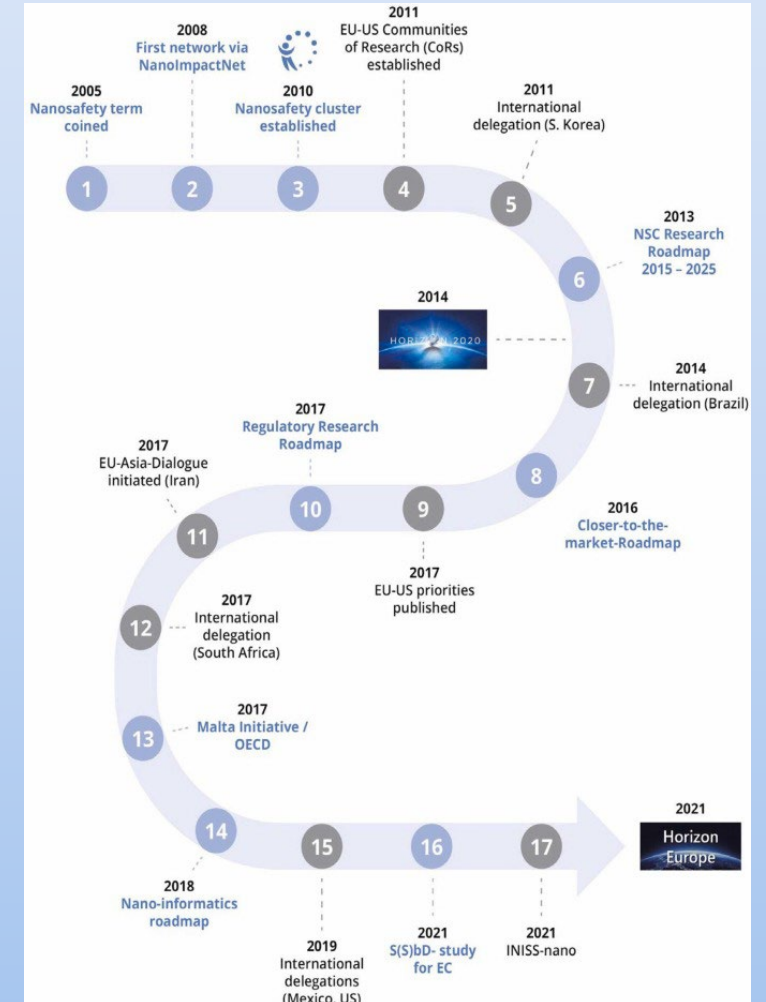


On behalf of the authors of the NSC roadmap

[EU NanoSafety Cluster – The NanoSafety Community](#)

INTRODUCTION AND BACKGROUND

- The EU NanoSafety Cluster – Since 2010
- Maximises the synergies between European-level projects
- Initiative of the European Commission DG-RTD
- Open platform for dialogue and exchange
- Since 2011 EU-US Communities of Research
- Since 2017 EU-Asia Dialogue
- Researchers, regulators, administrators, industry, civil society representatives
- Not limited to partners in European projects



EU NANOSAFETY CLUSTER - ORGANISATION

NSC Working Groups



Education, Training & Communication











Safe and Sustainable by Design (SSbD), Innovation & Regulation



Research Output management, FAIRness & sharing

International Cooperations Enhancing Global Partnerships

Current actions

 Hozo International Collaborations	 EU NanoSafety Delegations	 EU-US Communities of Research
 The Malta initiative	 Regulations, risk governance and standardisation	 Society for Risk Analysis Roundtable with the NSC
 CUSP cluster	 INISS nano	

On-going projects



24

**Contributing
projects and
industrial partners**



30+

**Collaborating
countries
worldwide**



2,000+

**Participating
experts**



Integrity, Responsibility, Professionalism

Performing world class research, with a strong ethical code, pragmatic approach and critical thinking. We strive for continuous, efficient and effective development.



Openness & Collaboration

We promote global collaboration based on openness, share of knowledge, trust and mutual assistance within the nanosafety community.



Creativity & Innovation

Walking the extra mile, finding new connections and relationships and try new approaches to ensure a *safer by design* nanotechnology



Serving Public Interest

All of our actions and approaches are dedicated to serve public interest,

NEW POLICY AMBITIONS: NEW DEMANDS FOR (NANO)MATERIALS SAFETY

The European Green Deal is about **improving the well-being of people**. Making Europe climate-neutral and protecting our natural habitat will be good for people, planet and economy. No one will be left behind.

The EU will:



Become climate-neutral by 2050



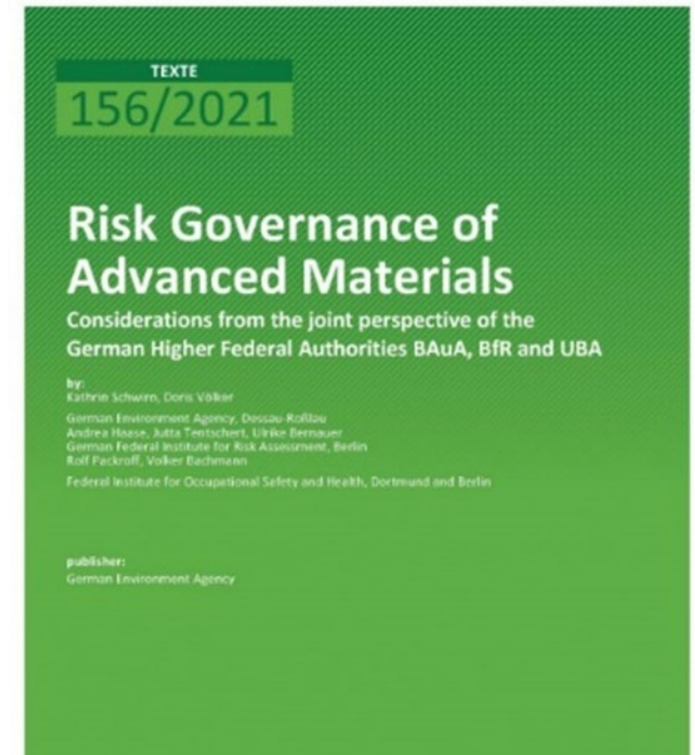
Protect human life, animals and plants, by cutting pollution



Help companies become world leaders in clean products and



Help ensure a just and inclusive transition



European Commission Plan

- On 27 February 2024 the Commission has adopted a Communication on ‘Advanced Materials for Industrial Leadership’
- Sets out a series of actions from research to market uptake to boost the design, development, and use of advanced materials in Europe

create a dynamic,
secure and
inclusive ecosystem
for advanced
materials in Europe

that both ensures
leadership in
research and

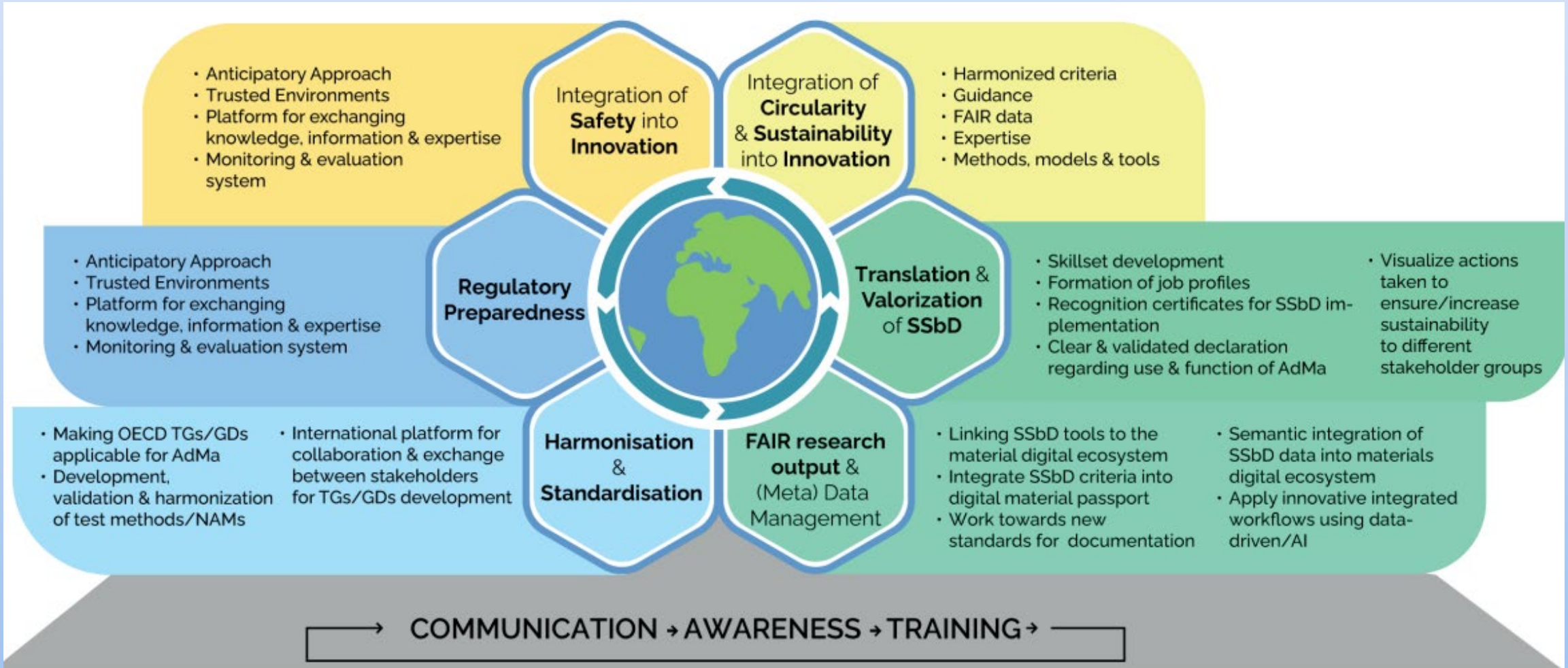
fast-track
innovations to the
single market

WHAT ABOUT SAFETY & SUSTAINABILITY?

- Safety, sustainability and circularity are mentioned as conditional, no actions formulated
- Fast tracks for development and application of admas runs the risk of regulations, validity of test methods, standards, increasingly lagging behind (even more than for nano)
- Technology Council does not take representatives for safety (sustainability, circularity) into account
- Who will be accountable for Chemicals Strategy covering advanced materials?

THE NANOSAFETY CLUSTER ROADMAP

Towards Safe and Sustainable Advanced and Innovative Materials



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FROM NANOMATERIALS TO ADVANCED / INNOVATIVE MATERIALS

- Interest in novel materials has moved beyond nanomaterials
 - functionality derived from properties other than nanoscale size or internal nanostructures
- No agreed definition of advanced materials exists yet
 - a working description (OECD)
 - ongoing process for international agreement (ISO)
- Advanced materials comprise a variety of materials
 - innovative and novel behaviour can be demonstrated
 - temporal or comparative element in the description
 - materials currently perceived as advanced will no longer be so in the future
 - new materials will be added to the list in the future



STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

- Nanomaterials are seen as members of the innovative advanced materials family
- Thus we can use nanomaterials
 - the vast amount of knowledge on their behaviour accumulated (e.g. in NanoSafety Cluster project research)
 - existing safe (and sustainable) by design (S(S)bD) assessment of nanomaterials
 - methods, approaches and roadmaps established
- This can inform and speed up the process towards safe and sustainable innovative advanced materials

UNRESOLVED ASPECTS, EMERGING ISSUES – WHAT IS NEEDED TO BE SUCCESSFUL?

- **New functionalities but also additional complexity in**
 - safety and sustainability assessment
 - differing rates of degradation, solubility, reactivity and associated toxic potencies of the separate and interacting components
 - interactions with biological and environmental systems
- Concerns magnified by current **lack of fundamental research and regulatory guidance** addressing unique properties of newly discovered advanced and innovative materials

HOW TO CLOSE THE GAPS?

- Increase efficiency, predictivity and robustness of toxicity testing
 - Integrated Approaches to Testing and Assessment (IATAs)
 - New Approach Methodologies (NAMs)
- Improve and adapt existing Standard Operating Procedures (SOPs)
- Consider versatility in approaches
(simple when sufficient, advanced where necessary)
- Introduce early in the process sustainability (thinking and) testing

LINKS TO INNOVATION: SBD, SSBD, CIRCULARITY TRANSLATION, VALORISATION OF SSBD



SAFE AND SUSTAINABLE BY DESIGN CHEMICALS AND MATERIALS

A EUROPEAN ASSESSMENT FRAMEWORK



MAKING CHEMICALS AND MATERIALS SAFE
AND SUSTAINABLE TO PROTECT HUMAN
HEALTH AND THE ENVIRONMENT.

INTEGRATION OF SAFETY IN INNOVATION

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

- Frameworks and Approaches for over 10 years of research in EU projects on Safe NM and products, Safe production and end of life
- Methodologies and tools of increase complexity through the innovation process, aiming for negligible risk through an acceptable balance between risk, functionality and costs
- Several examples from EU and other initiatives where running safe and sustainable by design also helps anticipate regulatory requirements



UNRESOLVED ASPECTS, EMERGING ISSUES – WHAT IS NEEDED TO BE SUCCESSFUL?

- Harmonised criteria along the different stages of the life cycle (NanoReg2 example)
- Issues implementing the EU Commission Framework with nanomaterials
- Expertise and training
- Responsibilities regarding actors in the value chain and implementation of SSbD

• **Safety** to human health and the environment is a relative concept whereas absolute values are needed to perform the necessary regulatory risk assessment

- Setting **harmonized criteria** grounded in regulation
- Providing **guidance** on how to implement SbD
- Supplying an **enabling environment** to implement SbD

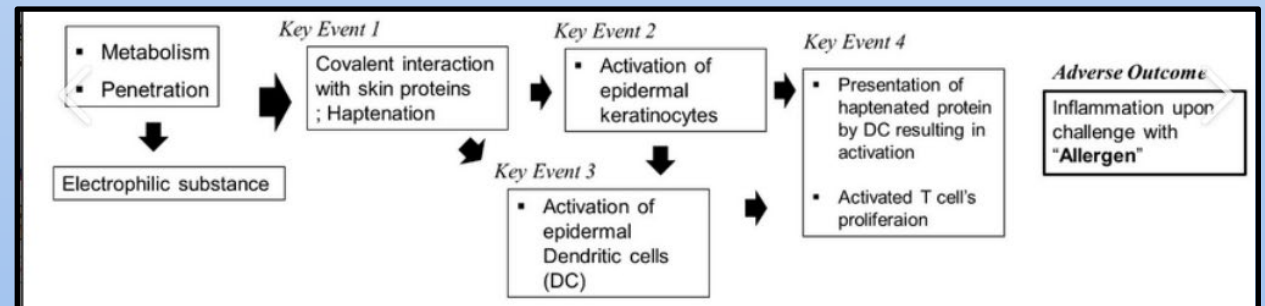
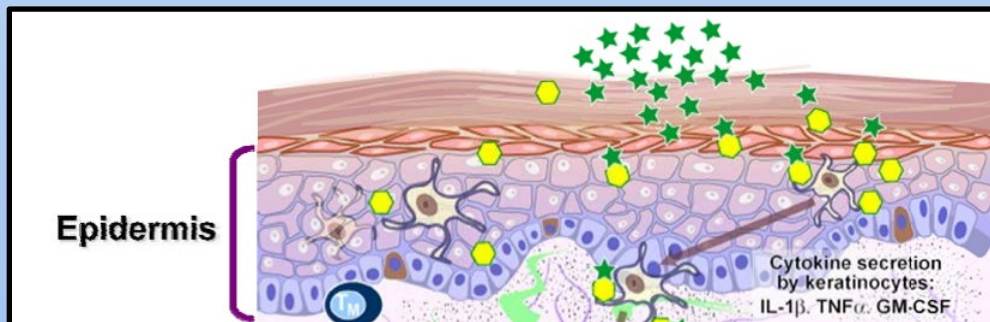
- **Cost efficient test methods**, accepted within the boundaries of regulatory requirements are available
- **Safety** is clearly implemented in sustainability goals



HOW TO CLOSE THE GAPS?

- Establish mutual understanding and promote agreed policies such as procedures on FAIR data policies
- Updates of methodologies and testing approaches (implementation of NAMs) suitable to AdMa mode of action
- Community-based acceptance criteria for trade offs

However.....

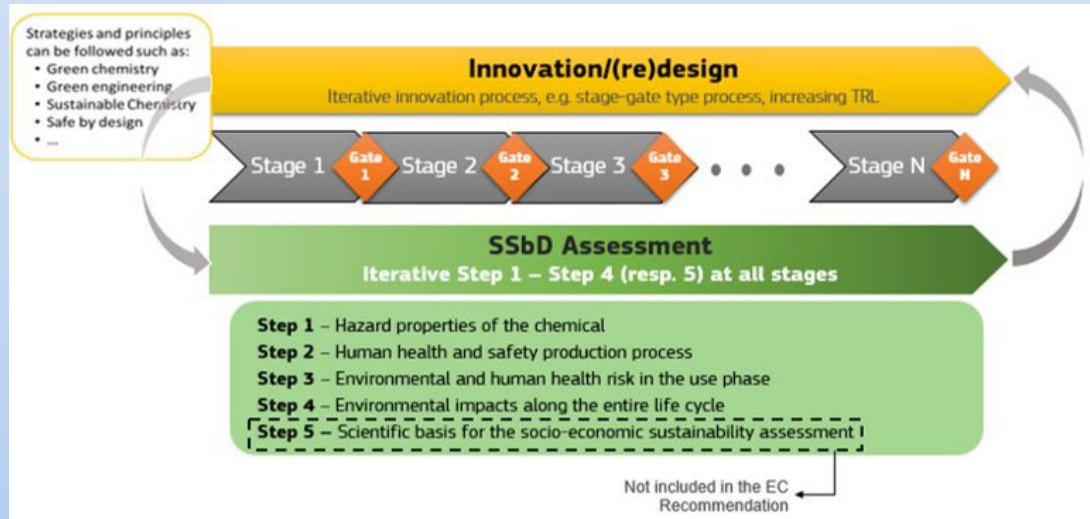
- Before adapting test guidelines: understand the Mode of Action!!



  Cannot continue...

FROM SBD TO SSBD: INTEGRATION OF SUSTAINABILITY IN THE INNOVATION PROCESS

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?



SSbD Chemical, Material & Product

SSbD Production

SSbD Use & End-of-Life



EC JRC SSbD Framework (2022) & Guidance (2024)



Critical Material Act

Ecodesign

DPP

Corporate Sustainability Reporting Directive

UNRESOLVED ASPECTS, EMERGING ISSUES – WHAT IS NEEDED TO BE SUCCESSFUL?



Lack of
sustainability
harmonised
criteria



**JRC Criteria
on-going**



Data
management
and FAIR data
is lacking for
sustainability



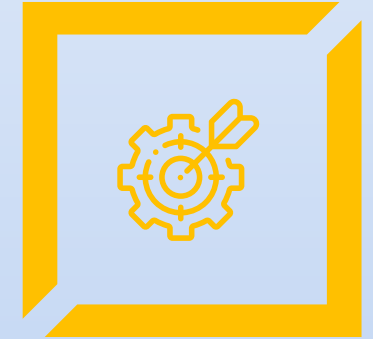
**Data and
ontologies
lacking**



Multi-
disciplinary
expertise



**Required to
address all
sustainability
dimensions**



SSbD
Methods
and tools



**Low tier most
urgently
needed**

Life cycle thinking. Integrative approaches

HOW TO CLOSE THE GAPS?



Governance
Develop acceptable trade-offs



Multi-disciplinary expertise
and training for industry



Incentives
Certification?
Labels?



Develop and apply methods
and tools



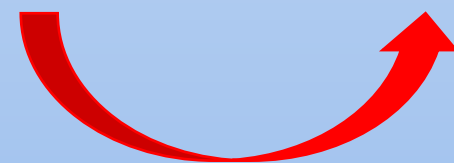
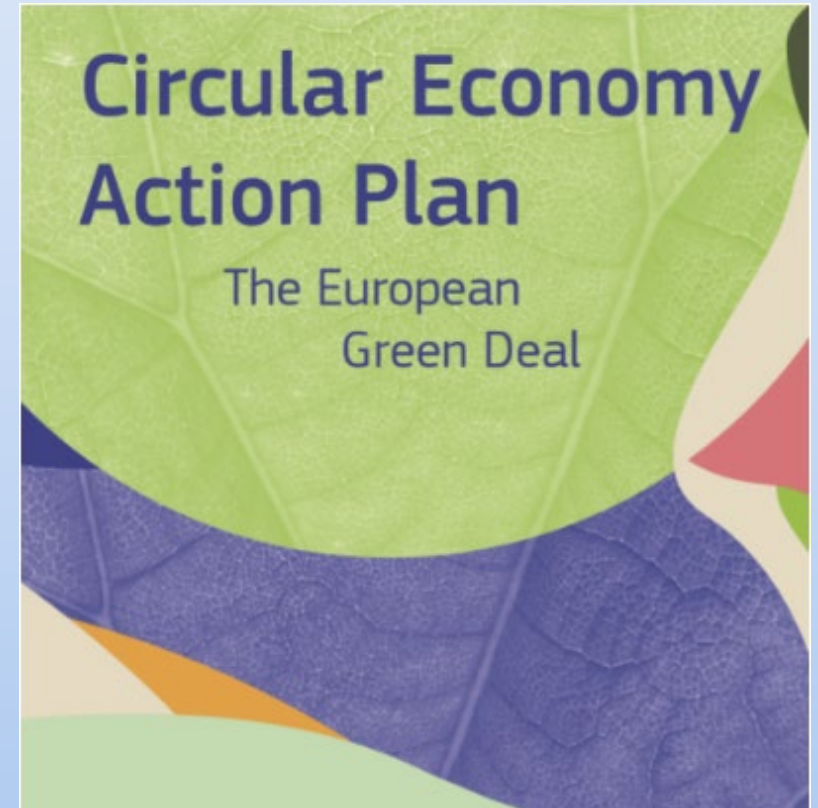
Communications channels
along and across value chain
– creation of an ecosystem

SSbD AS A PREREQUISITE FOR A CIRCULAR ECONOMY

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

The SSbD innovation process aims at delivering products design that contributes to the three principles of the Circular Economy:

- Designing out waste and pollution (including enhancing circularity in a toxic free environment)
- Keeping safe products and materials in use
- Regenerating natural systems, while providing consumers with cost saving opportunities and trustworthy and relevant information at the point of sales



SSbD

UNRESOLVED ASPECTS, EMERGING ISSUES – WHAT IS NEEDED TO BE SUCCESSFUL?

- Unresolved aspects



- Limited guidance to design a sustainable product for Circular Economy
- Not clear how data is collected and stored along the product life cycle

- What is needed to be successful



- Include circular economy metrics: durability, reusability, and recyclability
- Outcome of SSbD need to be meaningful for the B2B and B2C value chains
- Improve guidance for socio-economic assessment on LCC

HOW TO CLOSE THE GAPS?



- Harmonise policies (EcoDesign, Ecolabelling, DPP) into a unique guidance for industry



- Provide an approach to score the circularity of a product developed by the SSbD methodology (e.g., adapt existing indicators from the WBCD or the EMF)



- Adapt the socio-economic assessment with a Life cycle costing (LCC) that focuses on comparative cost analysis with other products being sold on the market



- Complement the PEF with Biodiversity metrics

Move resources from the current Take-Make-Dispose System to implementing circularity

TRANSLATION AND VALORISATION OF SSbD

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

“how much of today’s resources ought to be invested for the benefits of tomorrow?”

- Limited experiences of implementing the SSbD approach
- Knowledge gained and made available in the past 15 years by the NSC community is ready to be further translated and valorised
- Governance Portal, PARC toolbox

SSbD leads to business opportunities while keeping innovation potential and helping implement Green Deal goals

UNRESOLVED ASPECTS, EMERGING ISSUES – WHAT IS NEEDED TO BE SUCCESSFUL?

Next steps to implementation of SSbD



- Good access to SSbD decision support systems including access to data and modelling software
- Consultancy services, up-skilling services, and educational training is available at low cost
- Criteria for SSbD-compliance

DIGITALISATION OF RESEARCH OUTCOME: FAIR PRINCIPLES & DATA MANAGEMENT

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

- **FAIRness (and openness) are key** for breaking up still-existing data and software silos
- Willingness to **share data** has to be paired with the willingness to **reuse data**



Need to make data understandable, reproducible and **build trust** in the provided data and its applicability to guide SSbD



- **Nanosafety has a long history** of providing concepts and tools for data management, (public) sharing and semantic integration

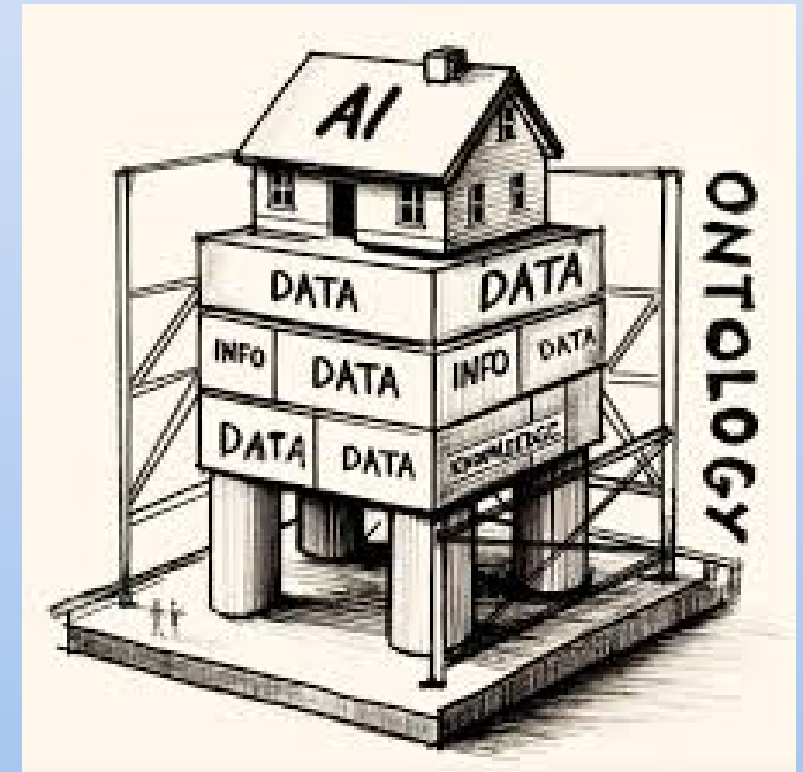
UNRESOLVED ASPECTS, EMERGING ISSUES — WHAT IS NEEDED TO BE SUCCESSFUL?

- Building a mutual understanding
 - the need for rich metadata and minimum information requirements
- Supporting data providers and data users
 - adapting their experimental and computational workflows to these new requirements
 - Combining and mapping of the semantic and technical frameworks of all domains relevant for Safety and Sustainability (functionality, characterisation and modelling, safety, sustainability, economics)
- Involving / training all shareholders for the green and digital transition



HOW TO CLOSE THE GAPS?

- Further progress with the implementation of FAIR
 - improve openness and **curation / quality control standards**
 - in this way, build trust in the existing data
 - Extend FAIRness to **all research outputs** especially focusing on interoperability and **combinability** of models, software and SSbD platforms as well as on **material, sample and data provenance**
- Build the semantic foundation and big-data spaces for AI



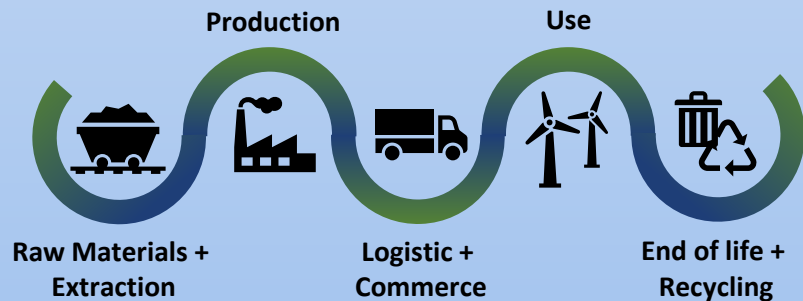
HOW TO CLOSE THE GAPS?

- Support the generation of the European Materials Data Infrastructure
 → **Materials Commons**

- a distributed and federated as well as harmonised and interoperable system of digital resources

4. Develop the 'materials commons' by mid-2025, a European digital infrastructure for advanced materials aimed at accelerating the research and innovation processes

- Provide easy access to performance and SSbD data
 - at different life cycle stages and along the value chain
 - in the form of **digital chemical/material (SSbD) passports**



Digital Product Passport

The ESPR will introduce a Digital Product Passport (DPP), a digital identity card for products, components, and materials, which will store relevant information to support products' sustainability, promote their circularity and strengthen legal compliance.

HARMONISATION / STANDARDISATION

OECD TEST GUIDELINES AND STANDARDS BEING
APPLICABLE TO ADVANCED MATERIALS

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

- OECD Test Guidelines (TGs) and standards need revision to accommodate nano- and advanced materials
- Some progress was made in the last years to develop and amend OECD TGs for nanomaterials
- New (regulatory) requirements/ endpoints are not covered by OECD TGs/ standards
- The need for developing TGs and standards to also accommodate more complex advanced materials (e.g. 2D-materials, carbon-based materials) was identified and developments started



UNRESOLVED ASPECTS, EMERGING ISSUES – WHAT IS NEEDED TO BE SUCCESSFUL?

- Continue the development of TGs for advanced materials
- Constant check on the applicability of TGs towards new materials
- Take into account the developments in regulation and policy
 - e.g. transition towards animal-free testing and testing for SSbD
- More standardised test methods for exposure and sustainability assessment along the life cycle
- A coordinated European effort to support development and validation of test methods

Facilitate timely development of OECD TGs by:

- Training of students and scientists
- Improving the FAIRness of research data
- Close collaboration between industry, regulators, scientists



HOW TO CLOSE THE GAPS?

- Long-term dedicated funding towards development, validation and standardisation of test methods
- Establish an (stakeholder) exchange platform for development of OECD TGs and other standards
- Establish a steering group for the amendment and development of TGs in Europe to support regulation and broader policy goals

- Enable sound regulatory testing
- TGs and standards that reflect the current state of the art
- Minimize the use of animals in safety testing



ESSENTIAL STEPS FOR OECD TGs AND STANDARDS BEING APPLICABLE TO ADVANCED MATERIALS

Identification of gaps: lack of (applicable) standards

Prioritisation of test method developments needs

Scientific development of the test method

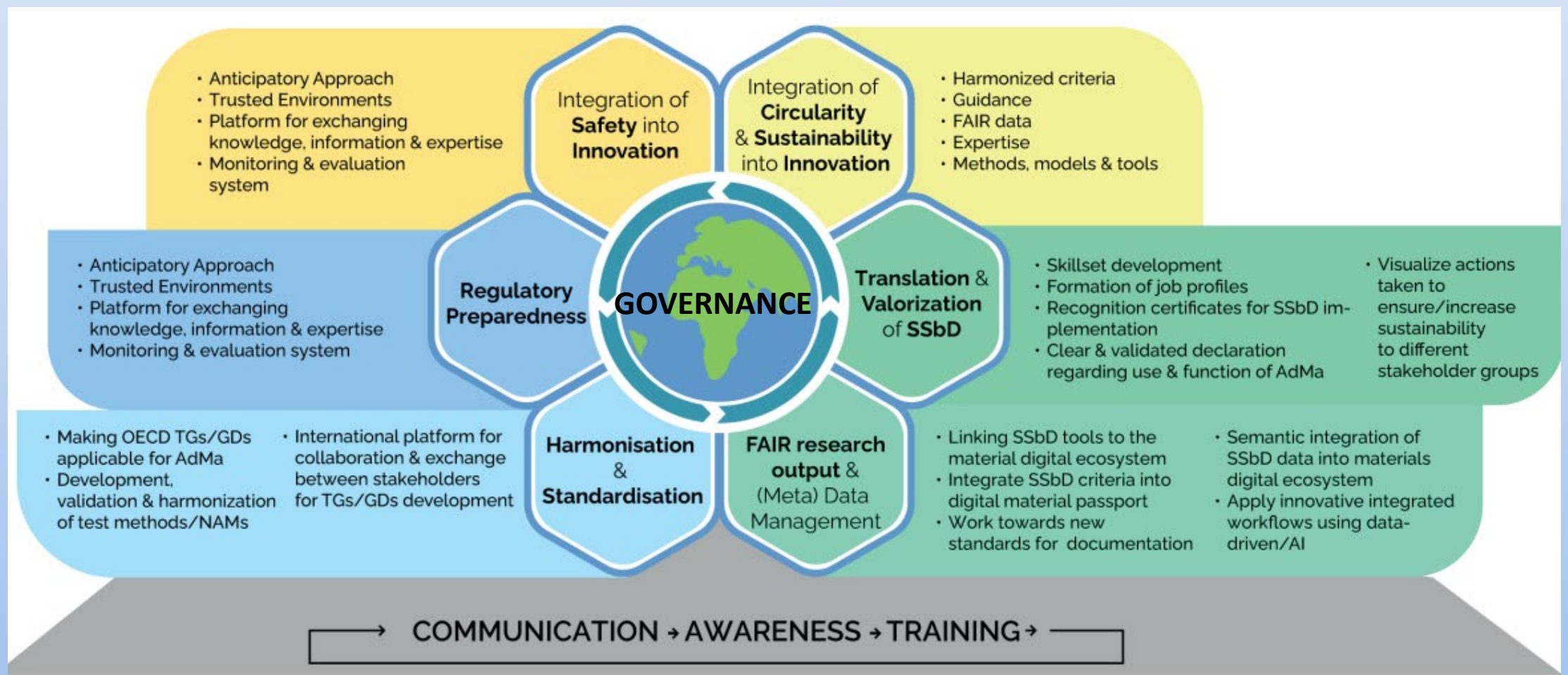
Validation and standardisation of the test method

TGs / standards applicable to advanced materials

GOVERNANCE & REGULATORY PREPAREDNESS

ORGANISATION OF GOVERNANCE - STAKEHOLDER ENGAGEMENT

GOVERNANCE OF SAFE AND SUSTAINABLE ADVANCED AND INNOVATIVE MATERIALS



STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

The current situation...

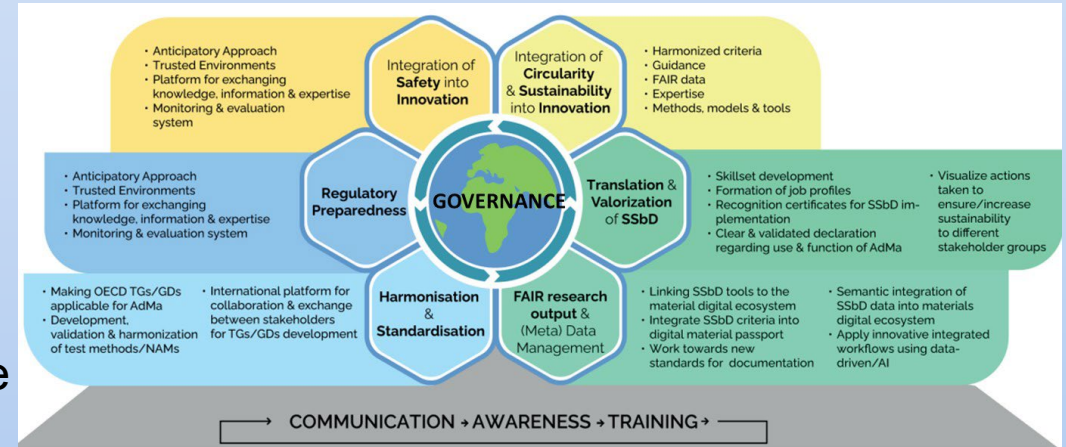


Disconnect between drivers of innovation and

- safety, sustainability and circularity
- technology users, and affected groups



Socio-economic sustainability aspects are positioned as a “complementary option”



UNRESOLVED ASPECTS, EMERGING ISSUES – WHAT IS NEEDED TO BE SUCCESSFUL?

The way forward...



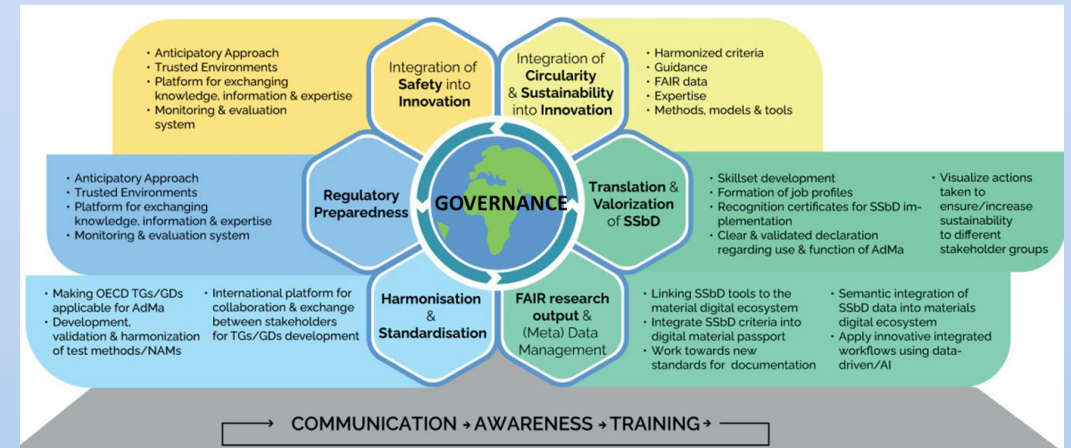
Implement SSbD in industry



Engage stakeholders in innovation in a participatory approach



Integrate the views of all stakeholders to an optimized societal trade-offs



HOW TO CLOSE THE GAPS?

Pursuing these goals ...



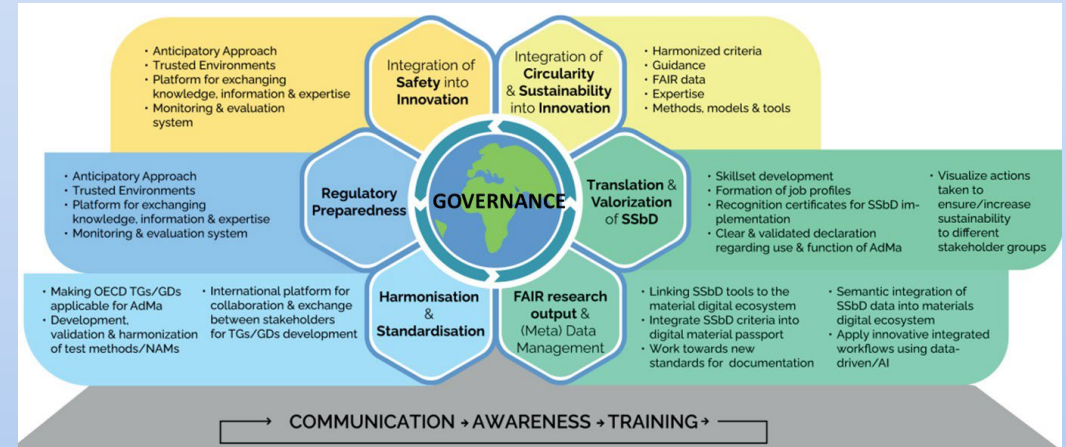
Roll-out Environmental-Social Governance to industrial R&I workflows



Enhanced data reliability



Establish community-agreed rules for explainable AI within SSbD

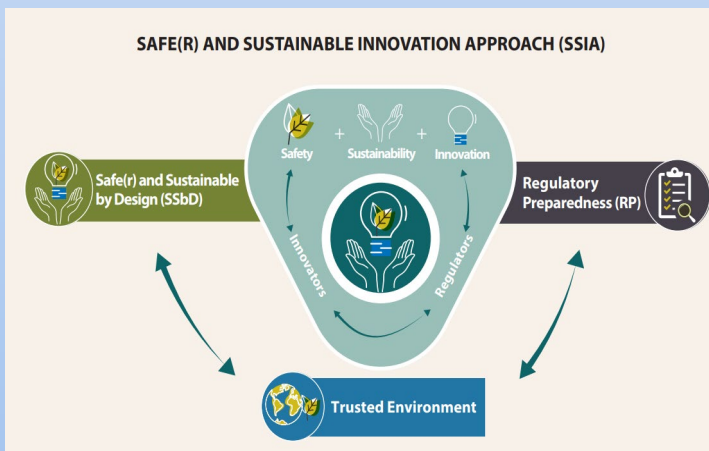


REGULATORY PREPAREDNESS

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

Regulatory Preparedness

- The capacity of regulators, including policymakers **to anticipate** the regulatory challenges posed by emerging technologies particularly to human and environmental safety challenges.
- Reduces uncertainties for innovators and industry on safety and sustainability legislation



WHAT IS SSIA?

The **Safe(r) and Sustainable Innovation Approach (SSIA)** seeks to enhance the ability of all stakeholders to address the safety and sustainability assessment of innovations in a robust yet agile manner. SSIA aims at reducing the time gap between the emergence of technological innovations and the development of suitable risk assessment tools and frameworks. SSIA combines:

- **Safe(r)-and-Sustainable-by-Design (SSbD)** concept, which recommends innovators to integrate safety and sustainability considerations as early as possible into the innovation process.
- **Regulatory Preparedness (RP)** aims to improve the anticipation of regulators in order to facilitate the development of adaptable (safety and sustainability) regulation that can keep up with the pace of knowledge generation and innovation of nanomaterials, nano-enabled products, and advanced materials.

Both **SSbD** and **RP** concepts are supported by a process to share and exchange knowledge, information and views in a **Trusted Environment (TE)**. SSIA thus relies on dialogue between innovators and regulators.

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

Regulatory Preparedness requires:



Regulators become aware of and understand innovations early



Regulators take appropriate action as needed



Appropriate regulatory tools to be modified or developed as needed



Dialogue and knowledge-sharing between regulators, innovators, industry and other stakeholders

UNRESOLVED ASPECTS, EMERGING ISSUES – WHAT IS NEEDED TO BE SUCCESSFUL?

A systematic approach for safety and sustainability governance should include:



Anticipatory approaches

Regulatory challenges need to be anticipated, e.g. by horizon scans and foresight



Trusted environments

To facilitate dialogue for confidential inquiries and information sharing



A platform for exchanging knowledge, information, and expertise

To provide processes and infrastructure for exchange



A monitoring & evaluation (M&E) system

To ensure timely actions are taken

UNRESOLVED ASPECTS, EMERGING ISSUES – WHAT IS NEEDED TO BE SUCCESSFUL?

An anticipatory risk and sustainability governance approach should include:



- Further development and operationalisation of the Early4AdMa system
- An inventory on ongoing activities related to AdMas to connect them (e.g. national governments, OECD, ISO,...)

Building blocks for **trusted environments for dialogue** are:

- A foundation of **trust** and facilitate innovator-regulator dialogue
- Development of a **platform for exchanging knowledge**, information, and expertise
- **Systematically measure the progress** of SSbD operationalization

COMMUNICATION & AWARENESS & TRAINING

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

The current situation...

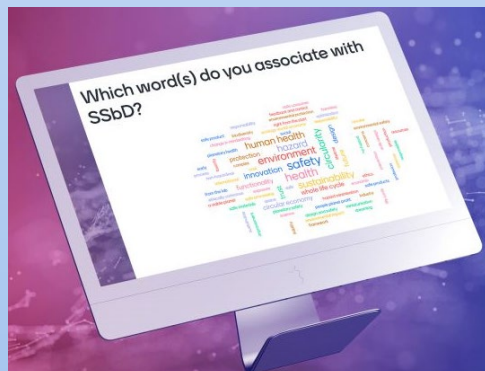
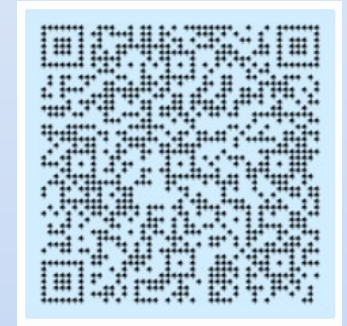
- The **NSC provides an array of teaching materials** established through joint training endeavors.
- This achievement needs to be **broadened to the wider public and transferred to sustainability of advanced materials.**


STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

- **NSC WG A:
Education, Training & Communication**

- **Community-efforts
on different educational levels**

- from pre-graduate to secondary school level, to education of experts in terms of PhD programmes, to continuous professional development of researchers



Welcome - NSC Education Day @ 

Block 1 - Emerging approaches in nanorisk assessment

- ▶ New developments in human hazard assessment - focus on AOP, QSAR, IATA
- ▶ Exposure & life cycle assessment - determination & modeling


Block 2 - Data workshop & e-tools for nano & beyond


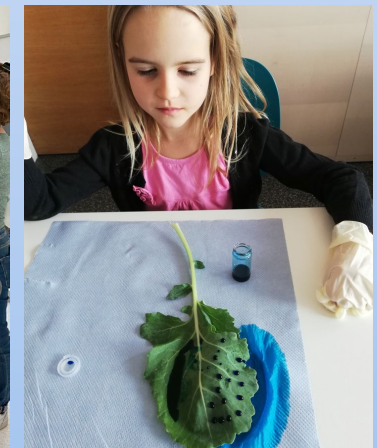
- ▶ Data FAIRness, metadata completeness, scientific quality assurance
- ▶ Spectrum of e-tools along data life cycle

Block 3 - NanoRisk Governance & Safe-by-Design concepts - fit for translation to sustainable development?

- ▶ Features of nanoRGs in development & current NRGC concepts
- ▶ Elements of SbD for sustainable development & Innovation

Martin Himly (PLUS)
Chair WG-A Education, Training, Communication
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 mailing list of WG-A Education, Training, Communication

STATE OF THE ART – WHAT DO WE ALREADY HAVE OR KNOW?

- **Early Career Researchers' Group**
- Long tradition on **interdisciplinary, hands-on Training Schools in Venice**
- **Training side-events** at key conferences
- **Public engagement materials** (posters, videos, games, etc.)



UNRESOLVED ASPECTS, EMERGING ISSUES — WHAT IS NEEDED TO BE SUCCESSFUL?

The way forward...

- Integrate **diverse stakeholder views**
- **Customize SSbD training** based on **sector-specific needs**
- **Connect science to society**
- Campaigning for safety & sustainability **awareness raising** in society



HOW TO CLOSE THE GAPS?

The objectives...

- **Well-curated, interactive, and mutual communication structure**
 - between science, industrial innovation, and open public
- **SSbD implementation in industry**
- **Regained confidence & trust in science**

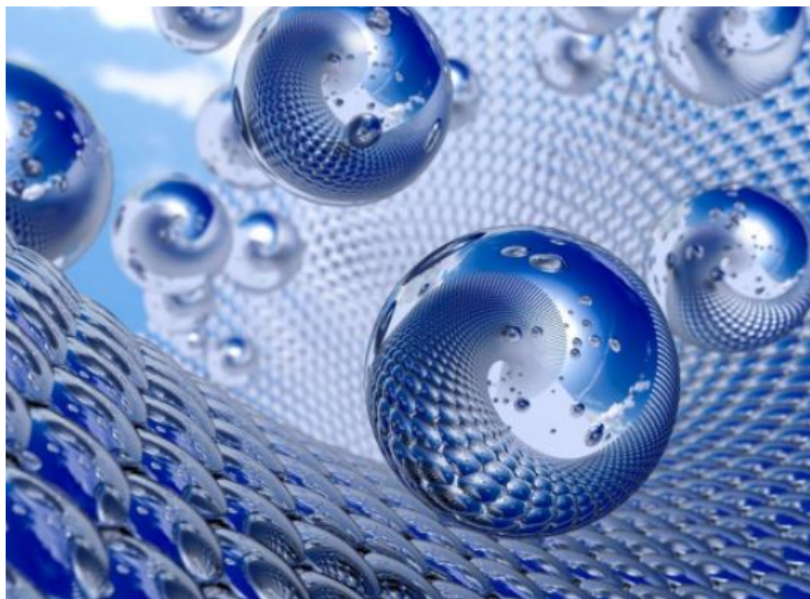


CLOSING REMARKS

- We see a dynamic field in safety and sustainability of nanotechnology and innovative advanced materials
- Researchers and regulatory agencies work together
 - to enhance understanding of the safety & sustainability of advanced materials
 - collaboration with innovators from the design phase is crucial
 - collaboration demands regulatory preparedness and foresight
- Proactive approach enables development of AdMas that are safe and sustainable
- By integrating environmental considerations and safety standards from the outset, the way for the creation of cutting-edge, eco-friendly materials can be paved

businesses can drive positive change and contribute to a more innovative and responsible future by embracing collaboration, regulatory foresight, and a commitment to sustainability

RIVM on Advanced Materials



RIVM on Advanced Materials

Covering scientific and European policy developments on safety and sustainability

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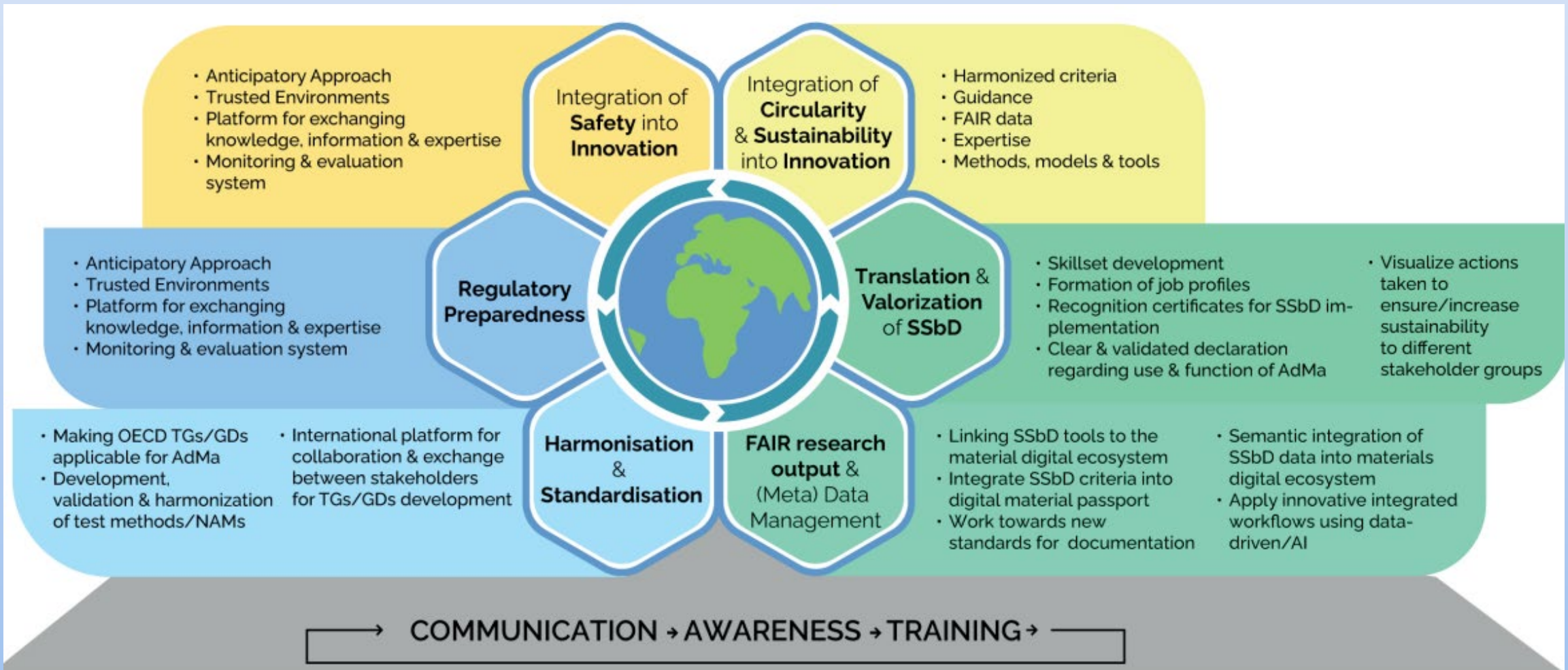
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Towards Safe and Sustainable Advanced and Innovative Materials



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doi.org/10.1016/j.csbj.2024.05.018

