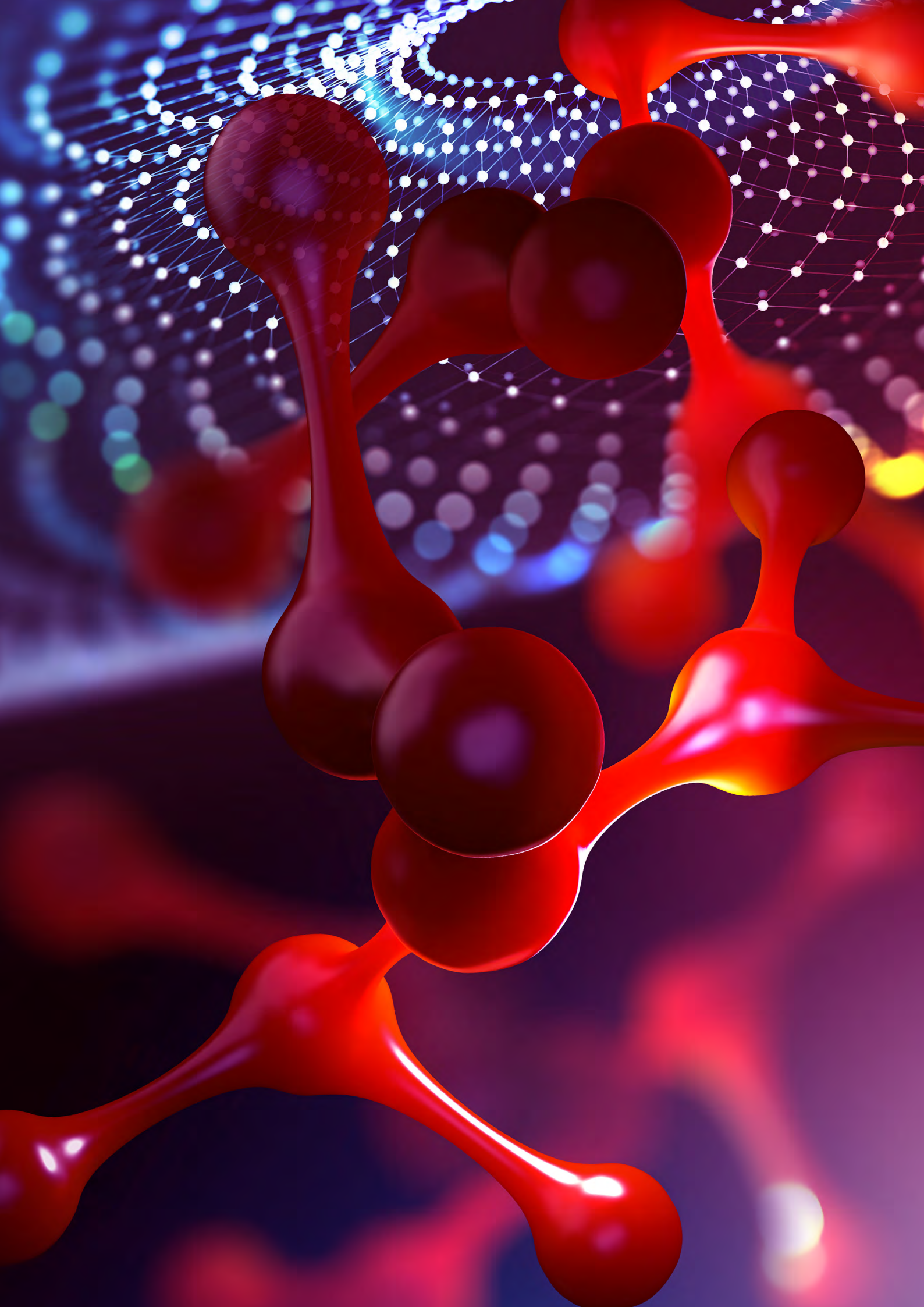
Governance brief 4

SAFE AND SUSTAINABLE DEVELOPMENT STRATEGIES FOR MATERIALS DEVELOPMENT

Gaps and recommendations for Safe and Sustainable by Design implementation in research and innovation



INTRODUCTION

This brief report provides a synthesis of critical gaps and roadblocks, and recommendations on the ways forward in the implementation of Safe and Sustainable by Design (SSbD) approaches for nanomaterials in research and innovation contexts (R&D, manufacturing and production).

The ambition of this document is twofold: to inform future research activities from researchers and innovators, and to provide suggestions for policy and risk governance approaches to promote SSbD implementation.

The brief is an outcome of the research activity on the topic of three European projects, including a specific consultation of regulatory authorities and research and innovation players active in different areas of use and application of nanomaterials, performed through three workshops held in 2021 and 2022 and follow up interactions. Details on the methodology are reported in Gov4Nano deliverable 5.6: Report on case studies for Risk Governance available on **www.gov4nano.eu**.

It is part of a series of initiatives organized by the **Gov4Nano project**, in cooperation with the **RiskGONE** and **NANORIGO** projects, to discuss governance issues with the goal to promote the safety and sustainability of innovation in nanomaterials in Europe. This specific brief has been developed thanks also to cooperation with the **Sbd4Nano project**.

BACKGROUND

The safety and sustainability of chemicals and materials and their applications is a cornerstone of current European policy and industrial strategies. Policy makers and industrial actors are working to identify frameworks and criteria for the practical implementation of the Chemicals Strategy for Sustainability (CSS), and these will increasingly become premium aspects to access funding and contracts. Nanomaterials are now generally seen in the context of innovation toward advanced materials.

Nanomaterials provide an exemplar of initial implementation of SSbD, as they possess new properties and their industrial use creates new opportunities, but they also present unprecedent challenges, risks and uncertainties at economic, safety, environmental and legal level compared to conventional chemicals. There are different definitions and interpretations of the terms safe and sustainable by design, most derived by the work on nanomaterials, such as the one provided by the Chemical Strategy for Sustainability. These working descriptions adapt to the development of knowledge in the field. All these definitions share some aspects:

- The need to design, produce and use substances with lower hazardous characteristics and improved environmental footprint, while maintaining their functionality
- the idea that safety and sustainability would be more effective and less costly for researchers and innovators if it is incorporated earlier within the innovation process and throughout, keeping in mind the entire life cycle[1].

The main areas concerned with SSbD during product development and life cycle are (Caldeira et al, JRC):

1) Re-design phase: material efficiency, minimize the use of hazardous chemicals/materials, design for energy efficiency, use renewable resources, prevent and avoid hazardous emissions, reduce exposure to hazardous substances, design for end-of-life, consider the whole life cycle
2) Safety and sustainability assessment phase: Intrinsic hazards (CLP regulation), risk considerations based on CLP regulation, environmental sustainability based on product environmental footprint (PEF) supported by the eco-design for sustainable products regulation (SPI), socio-economic aspects supported by the corporate sustainability reporting directive

A complementary concept uses the term Safe(r) and Sustainable Innovation Approach (SSIA) as a combination of SSbD and regulatory preparedness (NANoREG, NanoReg2 and other projects[2]). What makes SSIA different from SSbD is that it needs dialogues between industries and regulators starting from the very early stages of innovation and this drives regulatory preparedness and makes SSbD more efficien A Working group at OECD level is dealing with this issue (OECD WPMN, SG SSIA) t.

1 Safe and sustainable by design is a pre-market design approach whereby the objectives of minimising the use of hazardous chemicals, reducing greenhouse gas emissions, and fostering the reuse and recycling of materials in a circular economy are built into product design (Chemicals strategy for sustainability,2020)

2 Examples of existing projects on SbD and SSbD of nanomaterials (which are a "legacy of NanoReg and NanoReg2"), include:

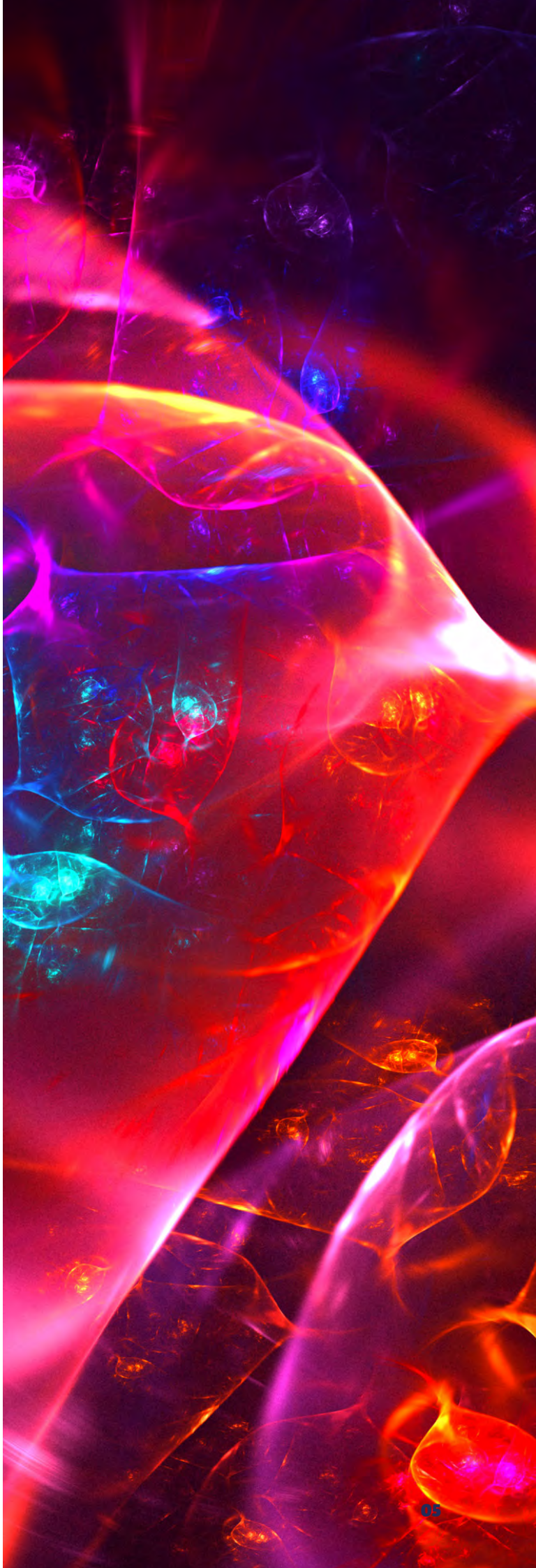
- **Mandala:** Demonstrate the feasibility of a Circular Economy approach for multilayer packaging by validating different ed-of-life scenarios
- **Sunshine:** Develop and implement simple, robust and cost-effective SSbD strategies for advanced multi-component NMs
- **SbD4Nano:** e-infrastructure for SbD performance testing and implementation in the nanotechnology supply chain
- **SAbyNa:** improving the usability of existing databases, test methods, models, frameworks and tools and integrating them into an interactive and user-friendly web-based guidance
- **Diagonal:** New methodologies for long-term nanosafety along the multicomponent nanomaterials and high aspect ratio nanoparticles life cycle
- **AdvancedNano IN:** supporting the implementation of FAIR principles in current nano-EHS databases to facilitate access, retrieval, use, and re-use of (primarily) nano safety data

THE PROBLEM AT STAKE

The European Green Deal policy and its underlying strategies including the EU Chemicals Strategy for Sustainability and the Zero Pollution Action Plan have put higher demands for the development of innovative (advanced nano) materials and, at the same time, have increased the ambitions to address safety and sustainability in terms of 'toxic free environments' and 'zero pollution'.

These demands have added complexity to the already existing challenges concerning SSbD of nanomaterials, including:

- It is a new concept for most stakeholders, and not yet precisely defined, despite a long experience on safety and sustainability in product development
- It requires a holistic approach along the value chain and life cycle, bridging different communities and experiences (e.g., safety, sustainability, innovation)
- It is a complex approach, as it deals with innovative materials and products (and thus with a certain degree of uncertainty and unknowns) and it needs understanding of risks and impacts at different levels (value chain and life cycle)
- It needs to cope with a context of fragmentation of both risk assessment and impact assessment processes, across regulatory domains and application sectors.



GAPS AND ROADBLOCKS

In this context, we identified a set of critical gaps and roadblocks on SSbD here listed in order of the importance given by stakeholders:

COMPLEXITY AND HETEROGENEITY

Most of these innovative materials are multicomponent forms, have heterogeneous morphology, show complex behaviours in humans and environmental compartments (materials and constituents' interaction), are applied in different forms and domains. This challenge concerns both their physico-chemical characterization and the overall risk and impact assessment analysis. In short, the key questions to address are "what they are, where they go, what they do".

CHANGES IN PRODUCTION PROCESSES

The SSbD concept promotes a holistic approach, and sets stringent requirements, affecting the entire value chain and life cycle. But this might require adaptations or changes to existing processes and practices, and thus could represent a major barrier for SSbD implementation.

LACK OF AWARENESS AND GUIDANCE

There is a demand from stakeholders to increase awareness on SSbD, as this is key to motivate and build trust. Stakeholders, innovators in the first place, are asking for more guidance and support on many different aspects, e.g.: how to interpret and apply different legislation and standards, how to produce and use FAIR data, how to understand when a specific product is sufficiently safe and sustainable, how to develop practical SSbD industrial strategies. Work at OECD and European Commission level is ongoing to develop criteria and evaluation procedures for SSbD.

LIMITED COMPETITIVE ADVANTAGES AND ADDITIONAL PRODUCT COSTS

Despite *"sustainable chemicals, products and processes produce confidence in industrial users, private consumers, and customers from the public sector"* [Calderia et al], innovators might have to face increased costs at production level (and thus higher market prices for end-users) and limited competitive advantages in the application of SSbD.
For example, within a project developing bioproducts for packaging solutions in the pharma and food sectors, application of life cycle costing methods showed doubled overall costs for "SSbD" products. In this case, the pros of SSbD were a significant reduction of waste management costs compared to the benchmark, the cons were an increase of the product price for the end user (since externalities such as waste management are not considered in the end-user price).
Benefits of SSbD identified by stakeholders include efficiency in the use of resources, safety at the workplace, regulatory compliance, reputation, positive societal impacts, and other aspects, but these advantages might not easily counter-balance increased costs at production and market level.

OVERLAP WITH EXISTING PRACTICES

There are consolidated practices at industrial level to deal with both safety and sustainability issues. The application of a new and holistic SSbD approach might require changes and adaptation.

DATA FAIRIFICATION

FAIRification of data is key for SSbD but presents a series of barriers for stakeholders, including data IP and privacy concerns, lack of incentives, awareness of FAIR data principles, lack of time and/or resources, lack of skills or tools, concerns about data quality.[3]

3 See the governance brief 2: Implementation of FAIR principles in nanosafety data management

WAY FORWARD

The key to move forward is to establish what research and policy actions should be undertaken to overcome the gaps and roadblocks identified and who should be responsible for their implementation.

We identified the following **ways forward** into research activities on nanomaterials and policy settings on SSbD that goes well beyond improvement in toxicological knowledge:

MASTERING MATERIAL AND PRODUCT DESIGN

The capacity to master the full engineering processes (physico-chemical characterization, materials design and functionalization, processes, and product design), and change and adapt it to safety and sustainability requirements (in a by-design perspective) is crucial, as this influences impacts all along the life cycle.

MASTERING SAFETY AND SUSTAINABILITY ASSESSMENT

There is a need for more efficacy and efficiency in risk and impact analysis tools. This requires investments in areas such as experimental and modelling research, grouping and read-across strategies, safety and sustainability testing and others.

STAKEHOLDER ENGAGEMENT AND TRAINING

Most experts highlighted that engaging all the stakeholders along the value chain and the different groups of stakeholders (academia, public authorities, industry, end users) is important to achieve shared, useful, and reliable results. Stakeholder engagement is crucial also to succeed in the harmonization and standardization of SSbD practices. Training could be a good way to provide the needed skills and knowledge, but also to engage stakeholders and increase their awareness towards both risk and sustainability issues.

CREATE INCENTIVES

Incentives at the policy, regulatory, or market level are needed, at least in the initial phases, to address extra costs related to SSbD.

ALIGN AND INTEGRATE WITH EXISTING PRACTICES

Build approaches taking advantage of existing practices, adapting, and connecting and improving whenever necessary, to limit the burden for SSbD adoption. There is a need to integrate safety approaches (hazard and exposure modelling and assessment, characterization and measurement of exposure, risk management measures, safety testing of products, fate and behaviour methods) with Life Cycle Analysis tools (e.g., LCA, LCC, SLCA), in a value chain perspective.

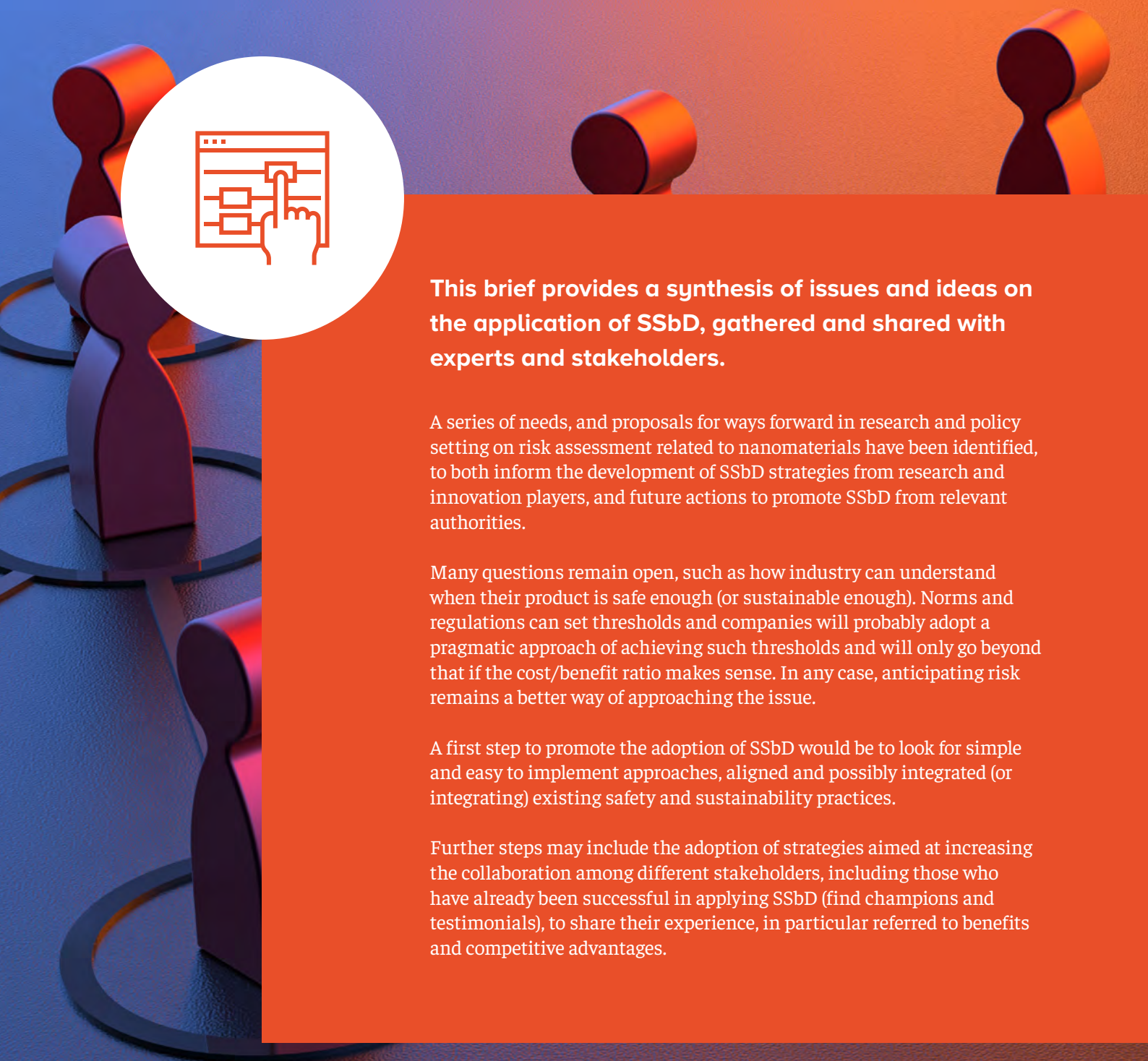
DEVELOP A TRUSTED ENVIRONMENT

A trusted environment facilitates an early dialogue between different stakeholders, in particular industry and regulators, which is crucial to improve products safety and sustainability, but also to share knowledge or expertise, and enhance public perception. A trusted environment could also be the right place to develop an active SSbD supportive community.

GLOBAL COLLABORATION

Broader international research cooperation is a key point to go from individual risk management approaches to global approaches, and advance knowledge in all those fields that have been identified as areas where more research is needed. Collaboration of European projects is ongoing among sisters' projects and projects active on this topic. Global collaboration is fundamental also because in many sectors the value chains are pervasive, covering the entire planet, thus many issues must be addressed at global level.

FINAL REMARKS



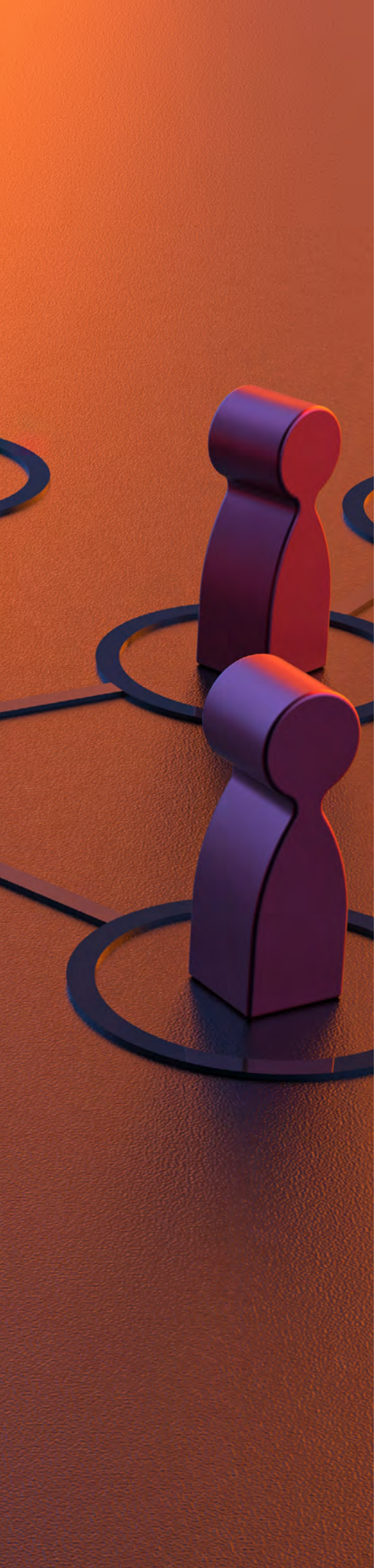
This brief provides a synthesis of issues and ideas on the application of SSbD, gathered and shared with experts and stakeholders.

A series of needs, and proposals for ways forward in research and policy setting on risk assessment related to nanomaterials have been identified, to both inform the development of SSbD strategies from research and innovation players, and future actions to promote SSbD from relevant authorities.

Many questions remain open, such as how industry can understand when their product is safe enough (or sustainable enough). Norms and regulations can set thresholds and companies will probably adopt a pragmatic approach of achieving such thresholds and will only go beyond that if the cost/benefit ratio makes sense. In any case, anticipating risk remains a better way of approaching the issue.

A first step to promote the adoption of SSbD would be to look for simple and easy to implement approaches, aligned and possibly integrated (or integrating) existing safety and sustainability practices.

Further steps may include the adoption of strategies aimed at increasing the collaboration among different stakeholders, including those who have already been successful in applying SSbD (find champions and testimonials), to share their experience, in particular referred to benefits and competitive advantages.



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Brief: Safe and Sustainable Development strategies for materials development

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