

Memorandum

How can risk governance keep pace with the enabling role of advanced (nano)materials in the green and digital transition?

Lessons learned from risk governance of nanomaterials

November 24. 2022

Summary

European innovation policies are focused on their supportive role to accelerate the green and digital transition in Europe. Advanced materials like nanomaterials are prioritized as one of the Key Enabling Technologies within these policies. Meanwhile the Commission acknowledges in its 2019 Communication on Better Regulation the need “to have regulation that fosters and, at the same time, harnesses innovation to the benefit of the environment, the economy and EU citizens”. The three H2020-projects Gov4Nano, NANORIGO and RiskGONE (shortened as NMBP-13 projects) have gathered meaningful insights about challenges and issues in risk governance of nanomaterials. We regard these insights relevant for efficient and effective risk governance of advanced (nano)materials.

This memorandum reports about these insights and suggests four lines of policy actions to fill gaps regarding knowledge, connection with innovation policies and regarding harmonization and standardization. These actions are considered pivotal for a precautionary approach in the development of safe and sustainable advanced (nano)materials and their applications. Coordination of efforts and enhancing synergies are urgently needed.

The ambition of this document is twofold: 1) to raise awareness that the specific issues regarding safety (and sustainability) of advanced (nano)materials are not automatically covered in projects and activities under the Chemicals Strategy for Sustainability (CSS) 2) to appeal to the European Commission, Member States and other stakeholders (research, industry and NGO’s) to actively support the identified lines of action.

Four main challenges for risk governance of advanced (nano)materials

Our observations largely draw on the past decades of research activities on the risk governance of nanomaterials and extend into the domain of sustainable development. From this perspective we highlight four challenges:

- **Regulation in support of Innovation:** Innovative materials are developed at a much higher pace than adaptation of regulations (the pacing problem). This pacing problem needs to be reduced. Timely insight in regulatory coverage (including regulatory accepted test methods) of innovative materials requires early awareness for potential regulatory issues and regulatory science needs, already at premarket stage (regulatory preparedness)
- **R&D for the specifics of advanced (nano)materials Regulatory Risk Assessment:** knowledge development is needed for identification of regulatory issues, as well as for delivering evidence to address these issues. Feedback mechanisms should be included to guide regulatory research and innovation agendas and programmes
- **Innovations require to go beyond regulatory compliance:** co-creation with value chains and optimizing life cycles of both materials and products is essential to operationalize the concept of Safe-and-Sustainable-by-Design (SSbD); co-creation requires improved connection between regulation and innovation

- Standardization and harmonization on test methods and tools: Timely development of test methods and tools applicable for regulatory purpose, sustaining the OECD’s work as an indispensable contribution to a strong and enforceable EU regulation. The Malta Initiative, a coordinating action of European contributions to OECD on adapting existing and developing new OECD Test Guidelines (TGs) and/or Guidance Documents (GDs) for regulatory requirements for nanomaterials faces discontinuation. This Initiative and their underlying actions could form a strong basis for requirements for advanced materials as well.

In response to these challenges, four lines of action for policy were identified for contemporary risk governance of advanced (nano)materials serving the goals of innovation policies, whilst serving the goals of the CSS as well:

Lines of policy action	Solutions needed	Connection to policy
Premarket identification of regulatory issues and regulatory science needs	Foresight system for early identification of regulatory issues, i.e., operationalization of regulatory preparedness	European Innovation Principle: improved connection between innovation policy and regulatory policy
Regulatory R&D	<ul style="list-style-type: none"> • Addressing specific regulatory issues • (Legally sound) Prove of validity of new and existing test methods • Avoid case-by-case approaches 	Strategic Research and Innovation Plan (SRIP) to the CSS for Sustainability, including tools for SSbD
Regulation connected to innovation	Co-creation between regulators and innovators in innovation programmes; foster awareness raising, training and education for the implementation of SSbD	Synergies between the CSS and Innovation Policies
Validated and standardized tools and methods	Regulatory accepted test methods and test guidelines valid for advanced materials	OECD’s work is an indispensable contribution to a strong and enforceable EU regulation

Each of these lines needs active support from the European Commission, Member States and stakeholders like industry and NGO’s. Together, these four lines of action serve to i) close the gap between regulatory science development in support of innovation policies for advanced (nano)materials; ii) embed regulatory science in the design and production of advanced (nano)materials through co-creation; iii) fully embed specific requirements for advanced (nano)materials in the execution of the SRIP of the European CSS. Coordination of efforts and enhancing synergies are urgently needed.

To our opinion active support from the European Commission, Member States and other stakeholders (e.g., industry, NGO’s) means support in terms of funding, coordination and seeking synergies, to effectuate these lines of action.

Background

Advanced (nano)materials in support of Green Deal goals

Advanced (nano)materials are one of the Key Enabling Technologies identified by the European Commission to support industrial competitiveness in Europe¹. Advanced (nano)materials provide novel or enhanced properties and functions over conventional materials. These properties are required to enable innovations facilitating the achievement of sustainable development goals in many sectors, such as energy, healthcare, transportation, buildings and construction, agriculture, food and food packages and consumer products². These properties also may give rise to less predictable behavior and health effects. Therefore, the challenge for European risk governance for these materials is to keep pace with the development and application of advanced (nano)materials. This alignment is crucial in the broader policy context of the European CSS to reach for safe and sustainable chemicals.

Stimulation of advanced (nano)materials research and innovation³

The [Materials 2030 Manifesto](#), an initiative by European research institutes and industries, stressed the importance of EU's technology leaderships, strategic autonomy and the role of advanced materials. The subsequent [Roadmap](#) and the [Advanced Materials Initiative2030](#) (AMI2030) pushed this Manifesto to further action. The AMI2030 was initiated in response to a lack of a common framework for all Advanced Materials stakeholders to work together. The AMI2030 is foreseen to coordinate and seek synergies through the newly introduced common framework "Materials Commons". The Roadmap identifies and focuses on priority Materials Innovation Markets. Moreover, the approach of SSbD and harmonization of norms and standards is regarded in support of policy.

In parallel, the European Commission has established an [Expert group on Advanced Materials](#), with the mission to strengthen cooperation between Member States, Associated States and the Commission on advanced materials, including nanomaterials. This group will contribute to identification of gaps of current actions and innovation at regional and national level as well as European projects. The group will focus on research and innovation activities relevant to materials, products and chemicals to fulfil the concept of SSbD.

Advanced Materials in the Chemicals Strategy for Sustainability

Advanced materials need to adhere to the goals and actions of the European [CSS](#) (CSS). The CSS and derived actions, like described in the [SRIP](#) consider advanced materials as chemicals. However, the SRIP seems to lack acknowledging that safety evaluation of advanced (nano)materials needs specialized and specific attention. The need for specialized and specific risk attention was recognized by the European Commission in their support for the [European Union Observatory for Nanomaterials](#) at ECHA (EUON), the [EU NanoSafety Cluster](#) and the [Malta Initiative](#). Therefore, actions like mentioned below need dedicated actions for advanced materials:

- 1) Addressing research and innovation needs to achieve the goals of the CSS, as laid down in the recently published [SRIP for Chemicals and Materials](#).
- 2) Addressing precautionary risk management through SSbD and operationalization of the [Safe and Sustainable by Design Framework](#),

¹ https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/key-enabling-technologies_en (accessed November 5, 2022)

² Efforts on the definition of the term "advanced materials" are underway at ISO-level (drafting a definition in the frame of TC229), while OECD has published a working description. However, terminology and the overlap with adjacent notions (like functional materials, or smart materials) is not scope of this document.

³ This overview has been adopted from: https://research-and-innovation.ec.europa.eu/research-area/industry/key-enabling-technologies/advanced-materials-and-chemicals_en (accessed September 27, 2022)

3) Addressing innovation in risk assessment by development of new methods and skills to address chemical safety challenges, as taken on board by the new EU [Partnership for the Assessment of Risks from Chemicals \(PARC\)](#).

Issues and challenges

Issue: Knowledge gaps for safety of Advanced (nano)materials are not automatically covered by CSS actions for regular chemicals

Not only the three H2020-projects [Gov4Nano](#), [NANORIGO](#) and [RiskGONE](#), but also all activities under the [European NanoSafety Cluster](#) (NSC) clearly substantiate the need for nanospecific risk governance and the need for nanospecific research and development to address the goals of the CSS. Especially the physical characteristics (for example like shape and particle size) of advanced (nano)materials will drive their behavior in test systems, whereas in chemicals this merely is driven by their chemical characteristics. In 2017 the NSC again confirmed the need for improved understanding of issues pertaining to the safe use of nanomaterials. A broad array of European projects first identified whether there were significant safety issues relating to nanomaterials. Based upon the evidence generated by these studies, EU projects then moved on to develop strategies for risk assessment and decision making and to identify whether nanomaterials are adequately regulated by current European legislation. These activities were further enhanced in H2020 to develop precautionary approaches like Safe by Design and identification of risk governance needs. However, there remain significant gaps in knowledge and procedures that need to be addressed in order to generate appropriate and proportionate regulation for nanomaterials that is informed by a sound evidence base.

Issue: disconnect between innovation policies and regulation of advanced materials

The [European Innovation Principle](#) promotes smart, future-oriented regulation and policies designed to encourage innovation activities that can deliver socially and environmentally beneficial progress, recognizes that ideally, all activities come together in organizing the development of safe and sustainable advanced materials. One of the specific objectives is to achieve an optimal balance between predictability of the regulatory environment and adaptability to scientific and technological progress.

The [Manifesto](#) developed by industry and European research institutions and gaining acceptance in the Commission virtually omit clear reference to the [CSS](#), [SSbD](#) or the Commission's [Safe Chemicals objectives](#) for 2030. The Manifesto has received a lot of deserved attention and growing support. The actions are coordinated and implemented via the [Advanced Materials Initiative](#) (AMI2030) which has recently released a [roadmap](#). Although topics like SSbD and harmonization & standardization are topics of attention, but the link with the ambitions and goals of the CSS need to be worked out much more pronounced before the Manifesto becomes ingrained in the developing public and private research & Innovation process. First then these kind of innovation initiatives are well connected to the demands for safe and sustainable chemicals as foreseen by the CSS.

Issue: Discontinuation of European coordinated activities for the safety of nanomaterials

During the Horizon2020 programme the development of nanospecific safety knowledge in support of development of regulations meant major financial support from the Commission, with an ambition to bridge many gaps, for example:

- Creating knowledge on nanomaterial safety for health and environment culminating amongst others in the development of the SSbD concept,
- Supporting the development of nanospecific standards (OECD Test Guidelines) for regulatory risk assessment
- Raising and developing an interdisciplinary educated workforce with due attention for societal impact.

This was supported by the NSC as a high-profile platform for the coordination of nanosafety research in Europe. It provides strategic direction for the EU and member states, enhances synergies between running and newly starting projects, preserves the outputs and data from finished projects and promotes Findable, Accessible, Interoperable and Reusable (FAIR) data. The NSC integrates and synthesizes the existing and produced nanosafety knowledge to provide a unified message to stakeholders including academics, regulators, industry and civil society. It has established a well-connected European community of nanosafety experts representing academia, research institutions, regulators and industry.

The NSC was thrived by the projects under the NMBP-program in the cluster Digital, Industry & Space (cluster 4). In Horizon Europe the NMBP-program was not continued, neither was a similar program for advanced materials developed. This discontinuation directly threatens the existence of the internationally renowned NSC, and more broadly of structured coordination and harmonization efforts amongst EU, Member States and stakeholders in the field of nanosafety research.

Challenges

We must strike a balance in dedicated actions (i.e., specifically targeted on new generations of advanced (nano)materials) and integrative actions (aiming at uptake in broader research and innovation communities, the mix of chemical policy goals and sustainable development goals, new risk management paradigms and (digital) infrastructures). The other balancing act is to carefully craft governance arrangements both in and outside research and innovation programs, to guide processes of stakeholder collaboration and value chain interaction by policy learning and political agenda setting.

It is our opinion that each of the lessons and challenges discussed below, provides valuable elements for enabling a green industrial transformation, especially if proper attention is paid to the role of stakeholders and European member states and the power balances between the various actors.

Four main challenges for risk governance of advanced (nano)materials

Our observations with respect to challenges for governance largely draw on the past decades of risk governance of nanomaterials and extend into the domain of sustainable development. From that position we highlight four challenges:

- Regulation in support of Innovation: Innovative materials are developed at a much higher pace than adaptation of regulations (the pacing problem). This pacing problem needs to be reduced. Timely insight in regulatory coverage (including regulatory accepted test methods) of innovative materials requires early awareness for potential regulatory issues and regulatory science needs, already at premarket stage (regulatory preparedness)
- R&D for the specifics of advanced (nano)materials in Regulatory Risk Assessment: knowledge development is needed for identification of regulatory issues, as well as for delivering evidence to address these issues. Feedback mechanisms should be included to guide regulatory research and innovation agendas and programmes
- Innovations require to go beyond regulatory compliance: co-creation with value chains and optimizing life cycles of both materials and products is essential to operationalize the concept of SSbD; co-creation requires improved connection between regulation and innovation
- Standardization and harmonization on test methods and tools: Timely development of test methods and tools applicable for regulatory purpose sustaining the OECD's work as an indispensable contribution to a strong and enforceable EU regulation. New test methods should be developed with an idea of its potential application in a regulatory context and as such should be accompanied by the definition of standard method characteristics such as a standard protocol, validity criteria, reproducibility etc. The "Malta Initiative" (MI) arose during the Maltese EU Council Presidency in 2017, when Germany initially approached the EU Directorate-General for Research and Innovation (DG RTD) to request political and financial

support to develop and amend TGs and GDs to ensure that nano-specific issues for fulfilling regulatory requirements are addressed. The Malta Initiative brings together a group of EU member states, the European Commission (notably the DG RTD, DG ENV, DG GROW and JRC), ECHA, industry and other institutions committed to this aim and welcomes additional international collaborators. This Initiative and their underlying actions could form a strong basis for requirements for advanced materials as well.

Regulation in support of Innovation

Regulation, including Harmonization and Standardization are key for unlocking the full potential of innovations and Key Enabling Technologies like nanotechnology or advanced materials. It is therefore of utmost importance to stimulate those regulations keep pace with innovation as well as to be achievable. This pacing problem can at least be reduced by a) developing mutually related roadmaps for innovation and regulation; b) accelerating innovation in risk assessment c) actively give meaning to co-creation by sorting out regulatory issues together with materials research and development rather than in response to materials research development.

R&D for advanced (nano)materials specific Risk Assessment

There is a clear need for specification of the SRIP into an advanced (nano)materials focused SRIP. First then a supporting Research Agenda focusing on knowledge needs to address the specifics of advanced (nano)materials in the CSS can be compiled and priorities set. Coordination and synergies will be pivotal to align the execution of the SRIP for chemicals and with the specifications for advanced (nano)materials.

Standardization and harmonization

Nanosafety research has learned that existing test methods were not always applicable and test methods for some endpoints were missing, while nanomaterials entered the market and regulations (amended REACH regulation, in force 2020) required information on such endpoints. The [Malta Initiative](#) was launched in 2017 to support the amendment and development of TGs for nanomaterials and especially nanoforms in REACH in response to these regulatory demands. The coordination of European activities in this initiative has led to accelerated progress. Nevertheless, needs in method developments for nanomaterials remain, while new developments in material innovations require further method developments. The experiences of the Malta Initiative show that a coordinated effort leads to successful and efficient TG development. However, its continuation is not secured under Horizon Europe and has become uncertain.

Innovation requires to go beyond regulatory compliance

The scope of the actions discussed so far might raise the question who is going to pay for all this. We think that the ability of regulators to ask the right questions about the appropriateness of assessment approaches and test methods (a form of regulatory preparedness) can go hand in hand with making use of the knowledge generated for assessment purposes by innovators. For both sides the key question is how to account for physical structuring of chemical compounds (functionalizing). Arranging both openness and confidentiality (a [Trusted Environment](#)) for R&D programs is different compared to situations in which materials are already widely embedded in value chains, such as the case of titanium dioxide. Organizing constructive interactions between innovators and regulators therefore provides an opportunity to open debates about risk-based vs. hazard-based norms towards SSbD strategies and R&D agendas. On systemic level this requires a policy mix for chemicals by which the distribution of costs, in concern-based testing for example, is rewarding for the actors involved and regulations work as a driver for innovation rather than a source of norms to comply with.

Four lines of policy actions for safe and sustainable advanced materials

In response to these challenges, four interrelated lines of action for policy were identified for contemporary risk governance of advanced (nano)materials serving the goals of innovation policies as well as the goals of the CSS:

Line of policy action	Solutions needed	Connection to policy
Premarket identification of regulatory issues and regulatory science needs	Foresight system for early identification of regulatory issues, i.e., operationalization of regulatory preparedness	European Innovation Principle: improved connection between innovation policy and regulatory policy
Regulatory R&D	<ul style="list-style-type: none"> Addressing specific regulatory issues (Legally sound) Prove of validity of new and existing test methods Avoiding case-by-case approaches 	SRIP to the CSS, including tools for SSbD
Regulation connected to innovation	Co-creation between regulators and innovators in innovation programmes; foster awareness raising, training and education for the implementation of SSbD	Synergies between the CSS and Innovation Policies
Validated and standardized tools and methods	Regulatory accepted test methods and test guidelines valid for advanced materials	OECD's work is an indispensable contribution to a strong and enforceable EU regulation

Each of these lines needs active support from the European Commission, Member States and stakeholders like research, industry and NGO's. Together, these four actions serve to i) close the gap between regulatory science development in support of innovation policies for in advanced (nano)materials; ii) embedding of regulatory science in the design and production of advanced (nano)materials through co-creation; iii) fully embed specific requirements for advanced (nano)materials in the execution of the SRIP of the European CSS. Coordination of efforts and enhancing synergies are urgently needed.

In our opinion it requires active support from the European Commission, Member States and other stakeholders (e.g., industry, NGO's) in terms of funding, coordination and seeking synergies, to effectuate these lines of action.