INTRODUCTORY DOCUMENT
WORKSHOP: SUNSHINE FORESIGHT FRAMEWORK
Monday, November 20th 14.30h -16h

The SUNSHINE Foresight workshop will be used to gather the opinions of participants, through a number of questions asked using Mentimeter. These questions are designed to provide feedback on the foresight framework (foresight process in a trusted environment), supporting the e-infrastructure of the SUNSHINE project. The following section gives you background details on the trusted environment and the foresight process. The final section lists the questions.

Background

Regulatory preparedness (RP) aims to improve the anticipation of regulators 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. RP empowers regulators and policy makers to better anticipate and adapt governance to keep up with the pace of knowledge generation and innovation (i.e., modify and/or develop regulatory tools for risk assessment/risk management decisions). This requires that regulators become aware of and understand innovations sufficiently early to take appropriate action, and that appropriate regulatory tools are modified or developed as needed[1,2].
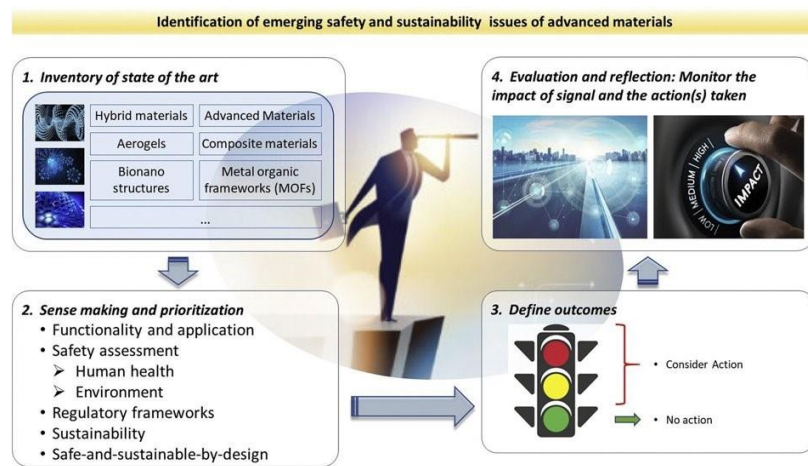

Figure 1: Identification of emerging safety and sustainability issues of advanced materials: Proposal for a systematic approach. Adapted from Peijnenburg et al. 2021; https://doi.org/10.1016/j.impact.2021.100342

Relevance of the SUNSHINE Foresight Framework

The H2020 SUNSHINE project SIA (Safe Innovation Approach) E-infrastructure aims to foster dialogue, collaboration and information exchange between various stakeholders and provide the tools and data needed for RP and to develop Safe and Sustainable by Design (SSbD) strategies for materials, products and processes focusing on multicomponent nanomaterials (MCNMs), though the approach is also applicable to non-nano AdMa.

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[1] https://www.oecd.org/chemicalsafety/safer-and-sustainable-innovation-approach/brochure-safer-and-sustainable-innovation-approach.pdf
[2] https://one.oecd.org/document/env/jm/mono(2020)36/REV1/en/pdf
[3] The European Green Deal (europa.eu)

An integral part of the E-infrastructure is the **SUNSHINE Foresight Framework**. This comprehensive framework will enable Regulators, Industry and other stakeholders to participate in a structured dialogue within a trusted environment to identify early warning signals of upcoming trends and challenges in industry as well as planned policy developments, in a beneficial symbiotic way that will drive forward responsible innovation as a cornerstone to the Green Deal[3].

Why a SUNSHINE Foresight Framework?
There are challenges in gathering key players like regulators, policy makers and industry to discuss freely and openly major issues to advance European development of advanced (nano) materials. Getting the right information, in a timely manner, on these developing materials will accelerate their innovation agenda. A foresight process in a trusted environment will enable experts to share upcoming risks to the benefits of a wider audience gathering policy and industry stakeholders on advanced (nano) materials.

The SUNSHINE Foresight Framework Goals:
A Foresight framework describing a <u>system</u> to:
- Proactively avoid the occurrence of potential **unexpected safety and sustainability risks** of advanced (nano)materials.
- Identify **emerging safety and sustainability issues and/or early warnings** of advanced nanomaterials.
- Enable the dialogue by creating transparency, trust and mutual interest, in order to share information in **a trusted environment**.
- Structure the dialogue by creating **process steps**, towards the identification of early warnings.

By achieving these goals, the SUNSHINE foresight framework will **enable**:
- Regulators to:
  - have focal points to consider for future regulations.
  - get advanced warning of industrial trends.
- Industry to get advanced knowledge of potential new or/and upcoming regulations.

Background on Trusted Environment
Trusted environments were introduced in the NanoReg2 project as part of the Safe Innovation Approach[4], which includes Safe by Design (SbD)[5] (the precursor to Safe and Sustainable by Design) and Regulatory Preparedness (RP)[6] (Fig 1). In such a context trusted environments represent a "safe" platform (physical or virtual) where regulators and industry can openly share ideas without issues such as intellectual property rights and non-disclosure agreements coming into place. A follow up effort on trusted environments was pursued by TEMASOL under the Gov4Nano Initiative (https://www.gov4nano.eu/) and it is currently being

[4] Soeteman-Hernandez LG, Apostolova MD, Bekker C, Dekkers S, Grafström RC, Groenewold M, Handzhiyski Y, Herbeck-Engel P, Hoehener K, Karagkiozaki V, Kelly S, Kraegeloh A, Logothetidis L, Micheletti C, Nymark P, Oomen A, Oosterwijk T, Rodriguez-LLopis I, Sabella S, Sanchez-Jimenez A, Sips AJAM, Suarez- Merino B, Tavernaro I, van Engelen J, Wijnhoven SWP, Noorlander CW. Safe Innovation Approach: Towards an agile system for dealing with innovations Materials
[5] Kraegeloh A, Suarez-Merino B, Sluijters T, Micheletti C Implementation of Safe-by-Design for Nanomaterial Development and Safe Innovation: Why We Need a Comprehensive Approach   Nanomaterials 8(4)
[6] OECD 2020 Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products Series on the Safety of Manufactured Nanomaterials No. 96

further developed in the OECD Safe and Sustainable Innovation Approach Steering Group[7] under the leadership of RIVM with the contribution of BIAC (Business at OECD) and the H2020 SUNSHINE EU project (https://www.h2020SUNSHINE.eu/)[8].

Figure 2: Trusted Environments in the context of the Safe and Sustainable Innovation Approach[9]

Background on Foresight

The EU project NANoREG resulted in a proposal for a foresight system for new nanomaterials (NMs) and nano-enabled products, presented by Micheletti and Sips (2016)[10]. This foresight system proposes a platform, dedicated to regulators, allowing the assessment of the possible adverse impacts of potential new applications of NMs. The platform identifies Target Applications (TAs) for a preliminary risk assessment approach that includes the definition of qualitative risk hypotheses.

Th EU project Calibrate developed a Risk governance framework to screen apparent and perceived risks and trends. In particular, this project developed the nano-risk radar which is purely a content-based technology to rank a given sets of documents according to their potential to generate impact as measured by the future number of citations of the article.

In the early awareness and action (Early4AdMa) system[11], Tier 1 consists of Scanning the field and AdMa selection through a Screening assessment consisting of: i) NESSI (Novelty, Exposure, Severity, Scope, Immediacy; a methodology developed by BfR), ii) sustainability and iii) Applicability of regulatory frameworks. As input for the foresight, work from the Graphene Flagship, JRC[12] and UBA[13] can be used as inspiration. Tier 2 consists of the Preliminary warning description by collecting additional information to be discussed by experts. The additional information includes i) Application and Market-entry stage; ii) Safety assessment, iii) Human Health, iv) Safety assessment – Environment; v) Applicability of Regulatory

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[7] one.oecd.org/document/env/jm/mono(2020)36/REV1/en/pdf

[8] Durand and Baker. SUNSHINE Trusted Environment and Foresight Platform for Sustainable Innovation. 8th International Conference on Environmental, Health and Safety issues related Nanomaterials, nanoSAFE'23 and NanoSafety Cluster joint conference June 5-9, 2023 – Maison Minatec, Grenoble, France

[9] https://www.oecd.org/chemicalsafety/safer-and-sustainable-innovation-approach/brochure-safer-and-sustainable-innovation-approach.pdf

[10] (PDF) NANoREG Foresight (System) Platform Christian Michelettiecsin.it/wp-content/uploads/2017/10/NANoREG-Foresight... · 2017. 10. 20. · NANoREG Foresight (System) Platform Christian - DOKUMEN.TIPS

[11] Early4AdMa brochure | RIVM

[12] Farcal et al. 2023; https://doi.org/10.12688/f1000research.127810.1

[13] Advanced materials: Overview of the field and screening criteria for relevance assessment | Umweltbundesamt

Frameworks; vi) Sustainability; vi) Assessment of warning and prioritisation between warnings, vii) Early warning and proposal for follow-up action: outcomes are defined and communicated to decision makers, policy makers and regulators, and viii) Reflection and evaluation: evaluation and monitoring of the impact of the warning and the action(s) taken.
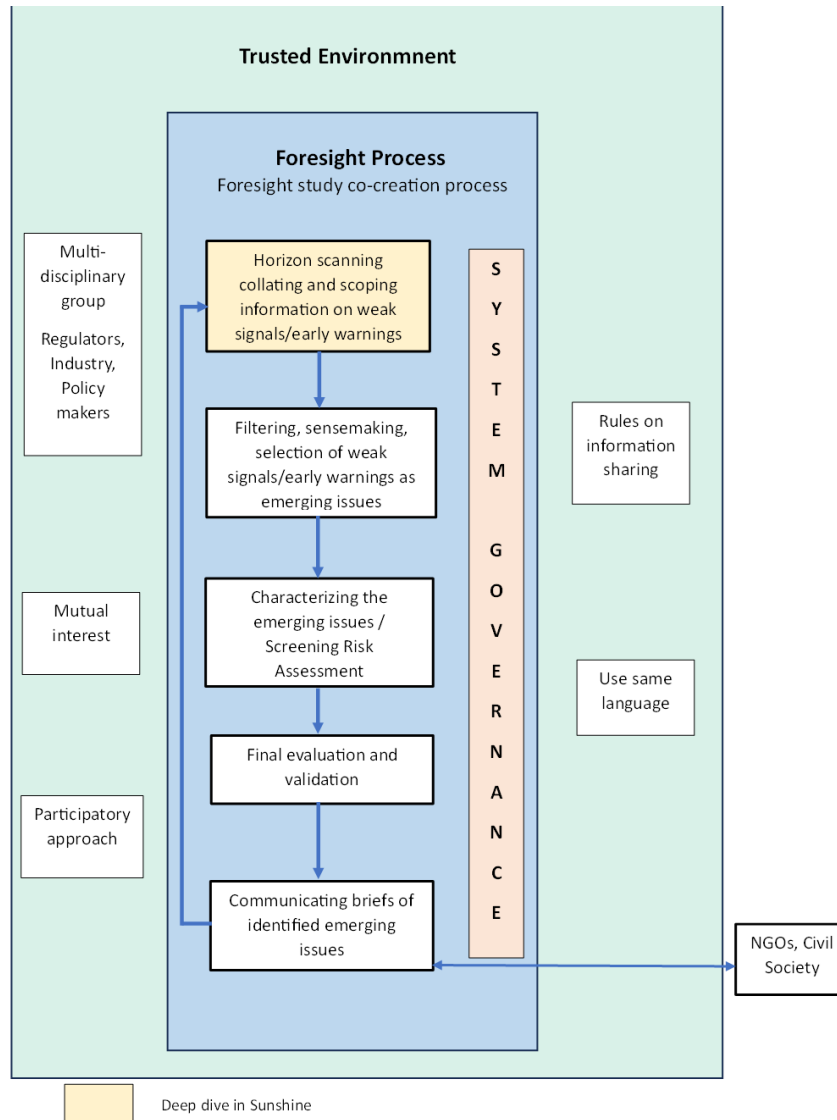
Key elements of the SUNSHINE Foresight Framework

Figure 3: SUNSHINE Foresight Framework (for discussion)

Governance of the SUNSHINE Foresight Framework system
Establishing effective governance will ensure that each participant is engaged in a co-creation process facilitated by a trusted environment. Additionally, the roles and the groups created in the governance structure are key to guaranteeing the efficient execution of the system process. The governance system could include:

- A small secretariat with responsibility for the coordination of the activities of system process. The secretariat's tasks would include the organisation of meetings, preparation of materials and templates and the gathering of the information.
- The secretariat would also have the responsibility for developing or coordinating the external communication (e.g., briefs and reports) related to the emerging issues.
- Additionally, the secretariat would have a key role in creating, maintaining, or growing and managing the trusted environment. For example, the secretariat would ensure the rules of information sharing, are endorsed and applied by the participants.
- The secretariat, in combination with an oversight body, would be responsible for ensuring that members of the Foresight Platform adhere to the rules of the Trusted Environment.
- A pool of experts with representative from the industry and regulators, and potentially other stakeholders. This working group would contribute to the system process steps by providing input on the collation of early warning signals, the filtering/ranking and the characterization of the selected emerging issues. Several task forces can be created if multiple specific topics needs to be handled separately.

An external review committee would provide an opinion on the list of potential emerging issues, selected by the above pool of experts, to ensure no key elements are missing.

Questions requiring input from the participants during the workshop

In order to facilitate a good flow of information and ideas from the participants, we are sharing the questions for which we want input in advance of the Workshop.

About the Foresight System (system process in a trusted environment) – break-out

The questions below will be adapted to the profile of each of the break-out groups.

1/ What are your thoughts on the Foresight System presented in the Workshop?

2/ Are there, in your opinion, elements missing from the Foresight System? If yes, what would you include or adapt?

3/More specifically, regarding the step *horizon scanning and collating early warning signals*:

- 3.a/What are the sources of information we should not ignore?
- 3.b/Are you aware of any tools or methodologies that could be used? (e.g., nano risk radar developed in the Calibrate project). If yes, which ones?

About the system process and the multistakeholder dialogue - plenary

4/Do you agree with the statement that for implementing this foresight framework a transparent dialogue and sharing of information is needed?

5/Are there gaps/aspects/specific points in this framework which would prevent us from creating a transparent dialogue? If yes, which gaps?

About the foresight system outcome as an enabler to accelerate innovation - plenary

6/Which community of regulators and industrial representatives should get the results and how should they be communicated?

7/Do you agree with the statement that the outcomes of foresight framework discussions will accelerate policy development on MCNMs/advanced materials?

8/What steps should be taken to ensure that we have a mechanism in place to inform the policy makers, regulators and industry about the relevance and importance of the early warnings identified by the foresight framework?