The interlinked SUNSHINE Trusted Environment and Foresight Framework as a tool for detecting emerging trends in AdMa Innovation

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Major industrial sectors such as energy, cosmetics, electronics, construction, food and healthcare are investing in research and technological development of advanced materials (AdMa) such as multi-component nanomaterials (MCNMs). These innovative materials can offer significant technological benefits over existing materials, since the integration of different components in a unique system can lead to improved functionalities, better performance coupled to energy and material savings which contribute to the overarching aims of the European Commission, in the form of the Green Deal, digital circular economy and climate change targets. Nevertheless MCNMs pose significant challenges in terms of regulatory compliance and environmental, health and safety (EHS) concerns, many of which are addressed by the European Research project Sunshine[2], funded under the H2020 programme.

Innovations tend to develop rapidly and in a myriad of directions such that regulators often have difficulties to follow and assess the implications of these innovations, and therefore are not always able to provide timely and adequate regulatory cover. Regulatory Preparedness, ensuring regulations are fit for purpose and ready for implementation, requires that regulators are made aware of upcoming trends and developments by industry. The **Sunshine** project aims to streamline and facilitate that process by developing and testing a Foresight Framework integrated into a Trusted Environment, which will host regulators, innovators, industry and key experts.

The essential first step is to create a forum where actors can freely share, comment, discuss and evaluate sensitive information, in other words a Trusted Environment (TE). The Foresight Framework cannot operate unless it is securely embedded in a TE. Establishing the TE depends on establishing the operational rules which can be accepted by all actors, and which are enshrined contractually in the rules of the TE, and a selection of these rules are shown in Figure 1.

A TE provides some clear opportunities for Industry and Regulators in particular, including:

- Creating a safe space for open discussion
- Raising common issues that could prevent a level playing field in the market
- Gaining visibility at supply chain level to anticipate future investments
- Early and voluntary industry involvement in the setting of new regulation
- Provides aligned communication & dialogue with civil society/NGOs

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- Accelerates the resolution of cross-cutting issues that could slow the market expansion

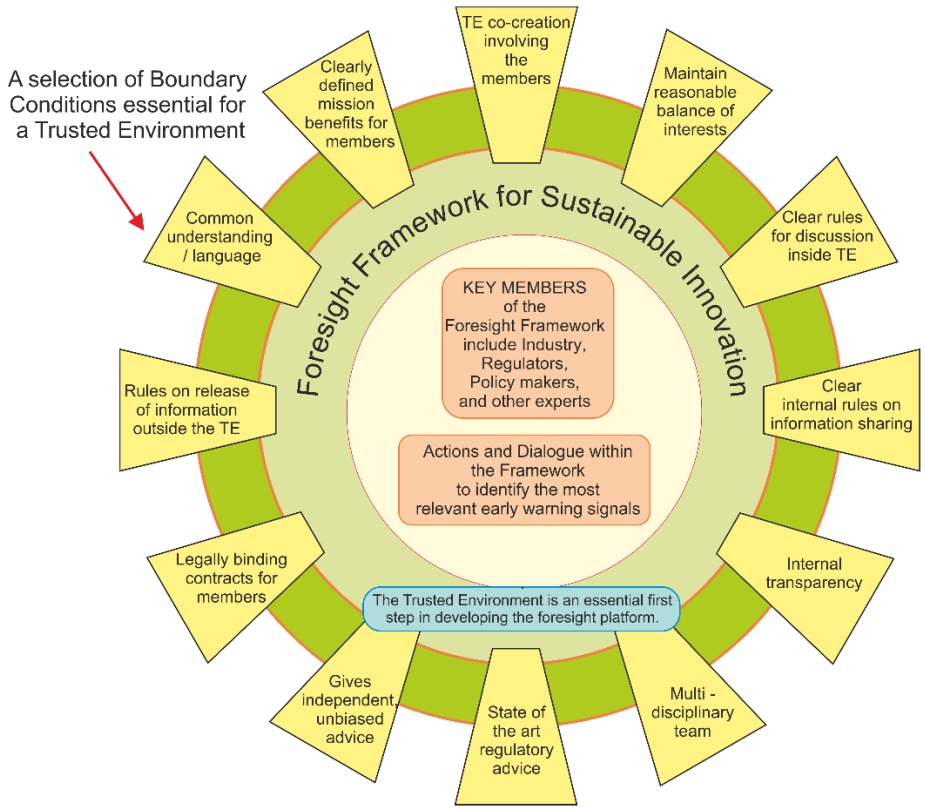

*Figure 1: The linked **Sunshine** Trusted Environment and Foresight Framework currently under development by TEMAS Solutions and RIVM together with partners JRC and Yordas.*

Trust between the members of the TE, and therefore the Foresight Framework is key, and therefore strict adherence to the rules of the **Sunshine** TE is essential. Potential barriers to be avoided include:

- Unclear/no rules on disclosure and management of sensitive information
- Lack of commonly agreed scope and goal
- Lack of mutual interests/benefits
- Perception of a non-inclusive working process
- Opaque decision-making process
- Unbalanced representation of stakeholders' interests along the supply chain

The Foresight Framework, developed and piloted in the **Sunshine** project, comprises a number of steps by which various sources and databases are mined in order to identify weak signals or signs of upcoming industrial innovation and development (see Figure 2). A selection of available sources of relevant information, mostly literature, will be mined by suitable software and a selection made of the indicators of upcoming trends and developments in AdMa which can be of potential interest to regulators. Refined processing will produce at regular intervals throughout a year a set of information which must be scrutinised and evaluated by the experts within the Trusted Environment. This selection of information will be the main output of the Foresight Framework, and will be integrated into the **Sunshine** e-infrastructure, and will support the development of Regulatory Preparedness in the **Sunshine** project.

The creation of a Foresight Framework included in a Trusted Environment will benefit both SSbD and Regulatory Preparedness because when knowledge is openly shared between industry stakeholders and Regulators from the early stages of innovation, the time for Advanced Materials such as MCNMs-based materials and products to reach the market can be substantially reduced, while ensuring high levels of human and environmental safety. A preliminary survey of industry working in the field of nano or advanced materials have expressed interest to be part of a Foresight Framework.

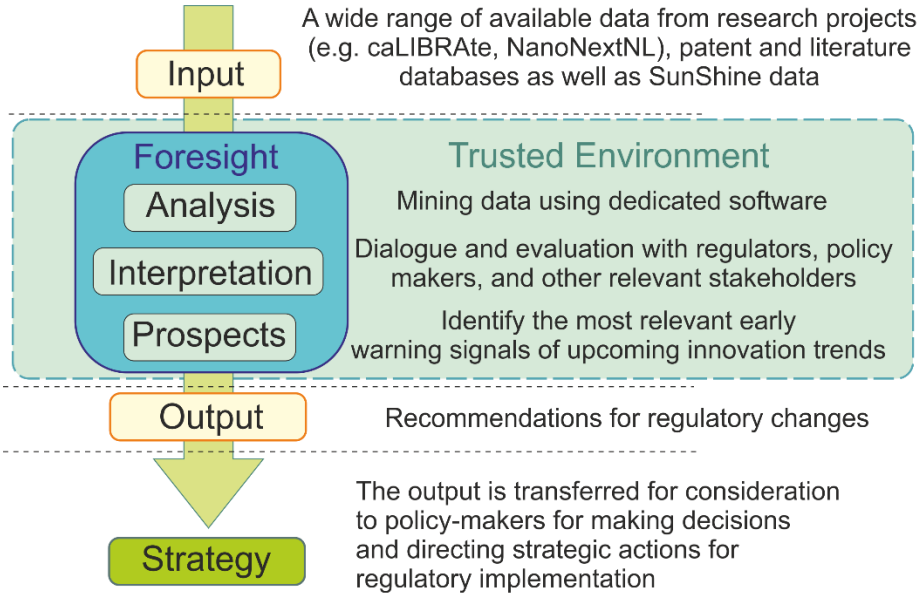

*Figure 2: A simplified overview of the steps in the **Sunshine** Foresight Framework*

Improving the anticipatory capabilities of regulators and (regulatory) risk assessors and to facilitate, where needed, timely adaptation of (safety) legislation, guidance guidelines and standards. Timely clarity on how regulators deal with novel materials such as MCNMs reduces uncertainty for industry about the information needed to comply with a regulation and how testing should be performed.

The implementation of the **Sunshine** Foresight Framework will support Regulatory Preparedness leading to a shorter time to market of MCNMs or MCNMs-enabled products.