

NANOREG Foresight System to monitor innovations in new nanomaterials and their application

Deliverable 6.01

Introduction

Nanotechnology is developing at a rapid pace, and researchers and industry are exploring and placing on the market new nanomaterials and new products. For example, organic nanomaterials are increasingly used in novel applications, but the scientific work to assess safety of these nanomaterials is still trailing. At the same time, regulatory development is slowly addressing the safety issues that nano-innovation are posing. The net result is that risks, concerns and uncertainties of new technologies are often considered only at a late stage, often just before market introduction. Their implications are not made to bear upon the design and development of new research, products and services. Therefore, despite huge private and public investments, innovation may fail due to lack of timely concern for safety, as well as for ethical and societal factors.

To avoid the failing of nanotechnology due to societal worries (as happened for example for GMO or Carbon Capture and Storage technology), governance of nanotechnology innovation is necessary. Governance is a concept that can be defined as a system that allows the development, steering and control of research, development, and application of a technology. Governance is a proactive process, learning from both the past and the future, and it is inclusive.

There is a strong effort at European and global level to avoid failure of nanotechnology innovation and take to the society the benefits of this technology. NANOREG contributed to this effort by developing an innovation monitoring proposal to assess potential impacts on safety and regulatory process of future nanomaterials and nanomaterial-based products.

Methodology

Safe-by-Design and Safe Innovation approaches can support the inclusion of safety in the industry innovation process from the beginning, building at the same time a dialogue with regulators. However, for effective governance it is not sufficient to look at what's on the innovation pipeline right now, but it is necessary to start thinking also to what is on the horizon and will be on the market 10 years from now.

The NANOREG Foresight System (ForeNANO) was developed to monitor nanotechnology progress and future applications, and it is mainly focused to regulators supporting them in the process of safety evaluation of foreseen nanomaterials' applications and the regulatory implications. However, industry can benefit from the use of the system to focus the development of a specific safer use, or think about risk mitigation measures. Also financial institution can identify prospective applications to fund on the basis of the system results.

Main Results

ForeNANO integrates two well-known methodologies, already applied in other fields: Horizon Scanning (HS) and Screening Risk Assessment (SRA). HS aims at identifying potential future nanomaterials applications of concern for regulators; applications are identified through the collection and evaluation of information taken from different sources (e.g. peer-reviewed literature, market report, experts, newsletters), and ranked on the basis of socio-economic criteria. A concern can be for a nanomaterial, for an industrial sector, or for a specific application. The selected applications are included in a list of Target Applications. The potential impacts of Target Applications are then assessed in the SRA, by identifying

a set of likely risk hypotheses. Risk hypotheses are an explication of the relationships between exposure scenarios (foreseen nanomaterials uses, exposure pathways, and potentially exposed population) and the expected adverse effects (i.e. hazard profile), along the whole life cycle of the nanomaterial in relation to the specific application/s.

The expected results of the NANoREG foresight system are the early assessment of safety implications of innovations of concern (Target Applications), the identification of data gaps for regulatory safety assessment, and the regulatory implications in terms of current regulation and needed regulation and guidelines. The integration of socio-economic assessment in the results is left to decision makers, as it is implicitly exerted at the beginning of the procedure in the dialogue with stakeholders, and explicitly after the results of ForeNANo are delivered. The application of ForeNANo has to be supported by tools (e.g. exposure estimation models, grouping approaches, read across schemes) and expert judgement. Expert opinions are needed in different phases of the procedure, to collect and interpret information and conclusions. The ForeNANo results elaborated by decision makers will contribute to the governance of nanotechnology innovation.

Horizon Scanning

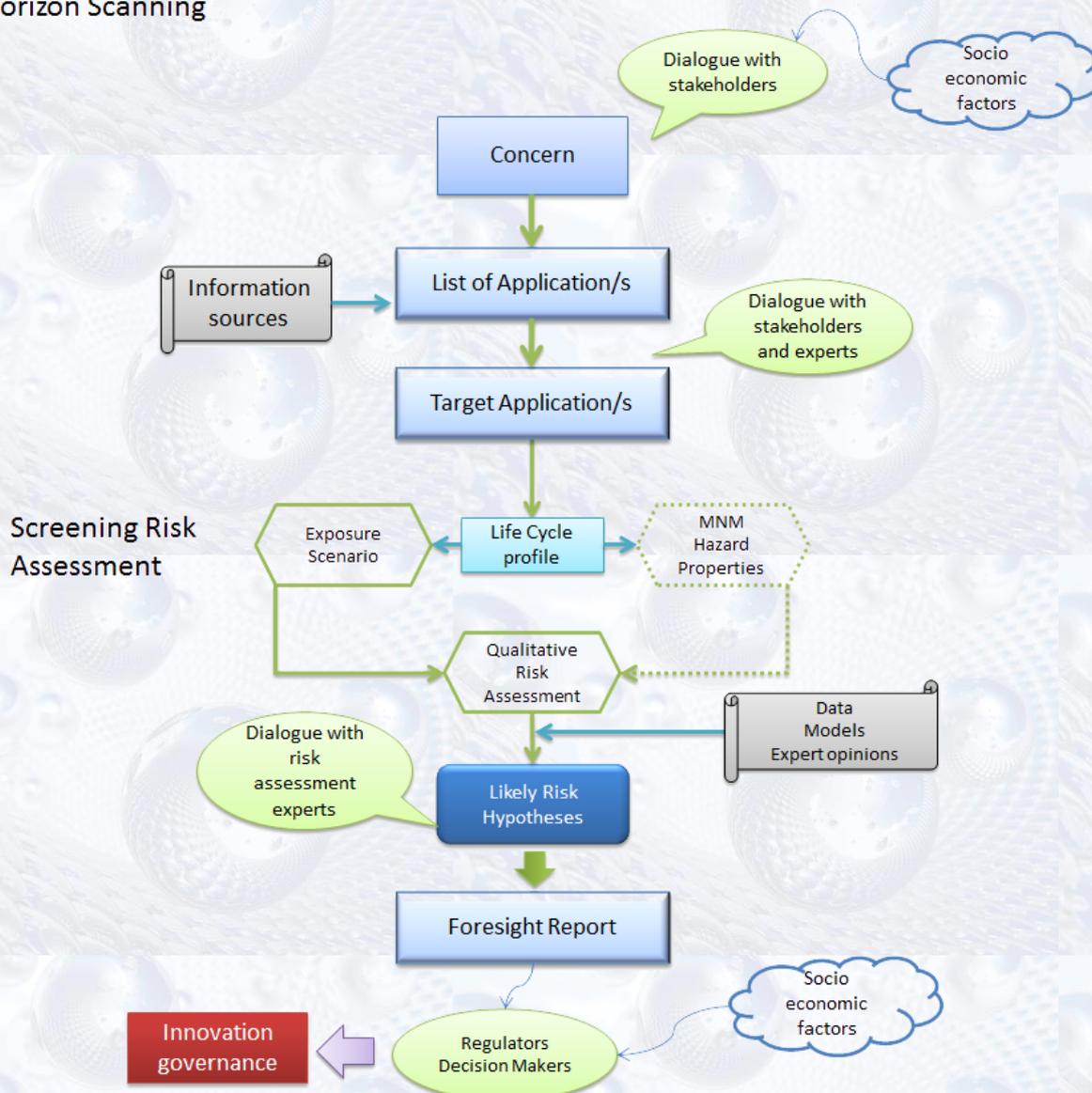


Figure: NANoREG Foresight System simplified workflow

For more details about NANoREG please visit the official website www.nanoreg.eu.

