NANO2ALL is an initiative funded by the European Union's Horizon 2020 Research and Innovation programme under the Grant Agreement Number 685931. It supports the establishment of Responsible Research and Innovation (RRI) policy and governance on nanotechnologies. NANO2ALL also aims to identify RRI practices, with a focus on societal engagement in nanotechnology research and innovation (R&I) across Europe and beyond, with the purpose to share knowledge, experience and recommendations with other nanotechnology stakeholders and motivate a wider application of such mechanisms in Europe.

RRI is an approach that anticipates and assesses potential implications and societal expectations, with regard to R&I, with the aim to foster the design of inclusive and sustainable R&I\(^1\). As a dimension of RRI, societal engagement implies interactions between relevant stakeholders (companies, research organisations, policymakers, civil society organisations, consumers, affected citizens and others) in order to align research, development and innovation with the values, expectations and needs of the society. Such interactions can take various shapes, such as brainstorming, scenario workshops, user committees, online forums, dialogues, informal / formal meetings, or other formats.

The activities of NANO2ALL include the collection and showcasing of best practices of implementation of RRI by governments, civil society or the industry. One of these practices is the NANOCUBE project to which this report is dedicated. NANOCUBE is a project which was coordinated by the companies ARCHA and TECHA for the development of dermo-cosmetics and biomedical applications based on the use of nanomaterials. The H2020 RRI-PRISMA project supported ARCHA and TECHA to integrate principles of RRI in the development of NANOCUBE, addressing ethical and social implications arising with the development and use of nanomaterials in cosmetics, especially citizen concerns on the risks for human health, issues of risk perception from both the public and professional stakeholders, and questions as to the added value and efficacy of these materials.\(^2\) Addressing these questions throughout the process of product development is deemed to be essential for businesses aspiring to integrate aspects of RRI into their R&D. This is to the benefit of the industry, to ensure

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acceptability of the final product, as well to address existing legal requirements for the integration of nanomaterials in cosmetics. This report briefly defines the RRI concept in the context of NANOCUBE, describes the stakeholder engagement process as it was implemented within NANOCUBE and presents recommendations towards other actors interested to implement similar activities. The report was developed based on Deliverable D2.4 of the PRISMA project, desk research and a short interview with Andrea Porcari of Airi (Italy), partner of PRISMA.

RRI at ARCHA SRL and NANOCUBE

ARCHA SRL is an innovative SME which operates in Italy and performs applied research to “provide assistance, technological innovation and know-how to companies to enable them to produce while respecting man and the environment, and to work in compliance with moral and ethical principles”4. The fact that RRI is embedded in the mission of ARCHA is further demonstrated by the fact that it implements in its research and innovation processes different certification procedures, regarding in particular health and safety at the workplace, social accountability, environmental and quality management. The participation of equal number of women and men in product design and development, and the incorporation of the gender dimension in all phases of R&D are also a cornerstone of ARCHA activities.

In the case of NANOCUBE of ARCHA and TECHA (a subsidiary of ARCHA) the role of PRISMA was to provide advice towards fostering RRI in the entire product development process, ensuring in particular that the precautionary approach and the principle of “safe by design” are applied. The broader purpose of the cooperation with PRISMA, has been to integrate societal values in the final product. Such values are related to the efficacy of the product compared with existing products, safety, improved quality, affordability, safe production and compliance with sustainability norms also as regards the supply of raw materials. Additionally, the aim has been to address the concerns of societal actors about the risks posed by nanomaterials and overall about the perceived uncertainty.

Stakeholder engagement at NANOCUBE

In the context of the cooperation of ARCHA with PRISMA on the NANOCUBE project, a Stakeholder Dialogue was carried out. The Dialogue was a one-off event that took place in Pisa (Italy) in June 2018. The event brought together actors from the entire R&D chain. The purpose was to “understand how to ensure a responsible development of nanomaterials along the R&I value chain, considering safety, quality and desirability of final products and understand how to define methods and procedures for a safe use of nanomaterials in cosmetics and medical devices”5.

In the preparations for the event the agenda and a flyer were distributed to the participants. The day was structured in a first part with plenary lectures, and a second part to discuss RRI aspects of Nanocube, based on a draft “RRI roadmap” for uptake of RRI within Nanocube prepared by PRISMA.

The themes discussed in Part A “Nanotechnologies for dermo-cosmetic applications” were, first, nanotechnology and nanomaterials, and in particular the following topics: a) responsible research in nanomaterials, b) nanotechnology in cosmetics and in biomedical products: opportunities, barriers and prospects; second, dermatology, cosmetics and innovation, and in particular a) Innovative models of risk evaluation for the safety of consumers, b) prospects and market and consumer expectations; third, regulations and certifications and in particular: a) Regulation and standards in nanotechnologies, b) Expectations of

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3 Porcari A. (2018), as above
5 Porcari A., email exchanges with the writer of the report
product distributors and consumer on product quality in the world of cosmetics, c) Guidelines for responsible innovation for nanotech companies. **Themes discussed in Part B** “How to promote responsible development of nanomaterials in the supply chain of cosmetic products and medical devices: quality, compliance and certification, and communication aspects” were, **first**, The Project Nanocube, **second**, Introduction to work tables, and, **third**, the discussion table: an “RRI roadmap" for the NanoCube project.

So, the event revolved around these themes and topics, whereby some of the participants did presentations and others provided inputs during the discussion. In Part B the discussion took place in the format of the World Café, in round tables where participants were asked to provide input to the RRI roadmap for Nanocube and in particular to the social, ethical and legal aspects of nanotechnology for cosmetics and to how these aspects could be addressed by quality, certification, and communication approaches. One of the organisers from Airi was the moderator, facilitating the dialogue.

The participants in the event were around 20 and were representing the entire value chain, from the research, development stages of R&I, to producers, retailers, hospitals (for biomedical applications), certification bodies and experts in legal and ethical aspects of both nanotechnology and cosmetic research. The participants were selected based on an initial mapping of the innovation ecosystem around Nanocube, with most of them already in the network of the organisers, including partners of the Nanocube project.

Following the dialogue, a report was drafted including the presentations and the input from the World Café discussions and was circulated to the participants for review. In substantial terms, the outcomes and insights from the dialogue were integrated directly in the R&D processes of the technology developer. One of the key benefits of the dialogue was that it brought together all the key stakeholders thus allowing the company to explain the use of nanotechnologies with natural substances, and the overall safety aspects of the product. This explanation was addressed as well to the certification body for organic cosmetics that participated in the event and which took notice of the processes and assurances provided by the company, making potentially the certification process less cumbersome (this process has not been concluded yet). For the technology developer the challenge was to communicate as clearly as possible the safety assurance procedures it has put in place. The fact that the process became more transparent was particularly beneficial for and welcomed by all the participants.

**Lessons learnt and recommendations**

Based on the experience of the dialogue, the organisers identified as major challenges the need to motivate people to participate, the identification of specific topics and the allocation of resources. It was evaluated as a long and time-consuming process. The feedback they received from the company was particularly positive, as they were interested in the legal and ethical aspects of nanomaterials R&I.

Key recommendations to organize similar events include:

- Prepare the event carefully to identify a focused topic and the relevant stakeholders in the innovation ecosystem of the project/product concerned.
- Dedicate enough time and resources on the preparation, management and follow-up of the event.
- Address sensitive issues (such as the reluctance of companies to disclose information about new products or processes) by creating a trusted environment and ensuring confidentiality.