

2. Laboratori Archa



NANO

“Thanks to our participation in PRISMA, we better understood the relevance of societal values to improve the R&D process, and the need to cooperate with authorities, certification bodies, distributors, end-user and consumers, to align NanoCube products to their needs, expectations and requirements. We have also been convinced on the importance of a transparent communication toward all stakeholders, to address uncertainties and concerns related to the use of nanomaterials. With this lesson in mind we plan to integrate some of RRI aspects emerged in PRISMA into social responsibility and quality certification procedures of Archa.”

Francesca Braca
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The company and the technology

Laboratori Archa S.r.L (Archa) is a small-to-medium size enterprise (SME), with the mission to provide assistance, technological innovation and know-how to companies to enable them to produce while respecting human health and the environment, preventing risk and complying with moral and ethical principles.

The support spans over all the stages of the innovation process: outlining/definition of the idea, the research and development phases, prototyping, start-up and industrialization.

Archa and its start-up for the industrialization of products, Techa Srl, are involved in PRISMA pilot through the research project NanoCube.

The NanoCube project, coordinated by Archa and Techa (Tuscany region funds POR FESR 2014-2020) develops innovative technologies aimed at producing nanocapsules and nanosystems providing



controlled release of bioactive agents for cosmetic and biomedical applications. Partners include research organizations, cosmetic producers, hospitals, a company developing the production equipment and a private research centre.

The products expected by the project include:

- A dermocosmetic (detergency) product, providing innovative and more effective ways of using a natural active substance for antimicrobial action. The system has manifold advantages: reduce the risks for workers and users in handling and using the active substance, reduce the use of active substances compared to conventional treatments, improve the efficiency of the final product.
The system might be further developed into a class I medical device with anti-inflammatory action. Thanks to its properties, the device could act as a replacement for conventional antibiotics used for derma applications and thus in the long term reduce the need for antibiotics. For both the two products the expected time to market is in the short to medium term.
- A bioactive 3D nanostructured patch for chronic lesions care, using a complex nanostructure surface to improve adherence with skin and nano-capsules for the controlled releases of active substances. The product is expected to improve efficacy of the healing and tissue regeneration processes in case of chronic derma lesions and in the long term to reduce costs correlated to lesion care. The expected time to market is in the medium term.

For all products, a key research challenge is to make use only of natural ingredients, including the nano-capsules, and processing steps without the use of chemical (synthetic) solvents.

Key ethical and social issues are addressed along the R&D pathway. They include: precautionary approach in the risk management of nanomaterials, research ethics (research activities on humans, replacing and reducing animal testing), addressing specific ethical values in product development (in line with demanding ethical certifications for natural and organic cosmetics), address issues of risk perception, and user acceptability in relation with nanotechnologies.

Integration of innovative technologies, such as nanotechnologies, in the sector of natural, organic cosmetics is one of the key challenges of NanoCube.



Working with Laboratori Archa

Activity included a series of meetings in person and by telephone with the staff of the company, organization of a multi-stakeholder dialogue event designed to address the specific ethical and social issues identified by PRISMA⁵, a public workshop to discuss on the application of RRI in NanoCube⁶, and engagement of the pilot in the main activities

organized by the PRISMA project. The main contact person has been the Project Manager of NanoCube at Archa, though meetings and interaction have been conducted also with people working in Management, R&D, quality, CSR, as well as external partners of the NanoCube project.

The company has actively cooperated in all PRISMA pilot activities. It has allowed PRISMA partners to get access to extensive information and to get in contact and engage relevant stakeholders of the NanoCube project. It has cooperated in the participatory events organized during PRISMA. It has provided information to select and measure RRI-KPI for the NanoCube project and taken part in the workshop in Brussels in April 2017 and the Milan stakeholder dialogue in October 2018; has co-operated in filming a video interview and discussed, reviewed and agreed on actions to continue pursuing RRI during the next product development phases (roadmap for RRI implementation in NanoCube).

Advice

There are some particular social and ethical issues that have received particular attention in the course of the pilot and for which specific advice has been developed through discussion with the company and interaction with stakeholders.

Product key (social) values

Reflection with the company and dialogue with stakeholders helped to identify the most relevant values to pursue for NanoCube products. It turned out that Archa and the partners of the NanoCube project should work to address these values in product design, and to provide scientific evidence through testing activities and to identify suitable ways to communicate these values to all actors along the supply chain, and end-users and consumers.

⁵ The agenda of the PRISMA and Nanocube multi-stakeholder workshop is available here: https://www.airi.it/wp-content/uploads/2018/11/Prisma_DialogueInitiative_Archa_Agenda_Fp.pdf

⁶ The workshop “Responsible Innovation in Nanotech applications for healthcare and wellbeing” was held on September 13th, 2018 in Rome, within the NanoInnovation 2018 Conference, with the aim to promote the RRI activities of the two PRISMA pilots dealing with nanotechnologies.





These values include:

- Product efficacy: the added value, beyond existing product benchmarks, provided by the new technology (controlled releases of natural active substances, use of nanostructured surfaces)
- Safety of the product, and nanomaterials in particular: ensuring safe use of nanomaterials all along the product life cycle
- Natural ingredients: product based on the use of natural substances and not using any chemical solvent
- Improvement of quality and shelf life (dermo-cosmetic product)
- Highly efficient lesion care, with no side effects (medical device)
- Efficient and safe production system for nanocapsules
- Accessible/affordable cost of the final product
- Compliance with sustainability and business ethics principles, including in particular respect for workers' rights, ethics in supplying of raw materials, reduced environmental impact in processing and production

Precaution, safety and quality in production

How should safety of nanomaterials be addressed during the development process and all along the life cycle, considering the existing debate (and related uncertainties) in methodologies for testing, classification and future regulatory developments of nanomaterials?

A safe by design approach has been considered in NanoCube and it should be further sustained. This includes a precautionary approach in selection, design and functionalisation of ingredients of the product; consideration of the state of the art practices and standards (beyond normative requirements) for the characterization, measurement and safety testing of nanomaterials.

The computational pre-screening techniques and in-vitro approaches already considered by NanoCube have been identified as valuable to this end. Further insights are needed to ensure a full assessment of potential exposure to nanomaterials during the production of nano-capsules, and regarding the end of life of the product.

Standards and guidance developed by OECD on nanomaterials, use of control banding approaches for safety of NM in occupational settings, expert advice, continuous update on regulatory

developments are among the tools identified to this end.

Interaction and cooperation with authorities to anticipate potential risks and identify suitable ways to minimize them has been also suggested as a key action, in particular in the case of the medical devices (due to the more demanding requests of the regulation).

(Ethical) acceptability and societal desirability of products

How could acceptability of the final product be ensured considering public risk perception of nanotechnologies (in particular cosmetics)? How are the concerns of distributors and certification bodies in using new technologies linked to uncertainties in terms of risks, public concern and regulatory development? And how best to address the scepticism of users and customers of green and natural cosmetics regarding the use of new technologies?

A communication strategy needs to be developed, with a focus on the use of nanomaterials. Product claims should be supported by scientific evidence (testing activities). Specific criteria to take into account for communication along the supply chain and to consumers include:

- Distinguishing between use of ingredients (including nanomaterials) based on natural substances (molecules non modified with respect to the natural molecules) and synthetic substances
- Highlighting improvements in durability and efficacy of the product, achieved thanks to the use of nanotechnologies. In particular underlining any improvement in terms of shelf life (avoiding/reducing the use of conservatives in the cosmetic)
- Providing indication on the safe use of nanomaterials during production, use and disposal (complementing normative requests to include nanomaterials in product labelling)
- Ensuring transparent and sound communication, based on scientific evidence, of information on product characteristics, including use of nanotechnologies.

In order to ensure acceptability of the final products, the communication strategy should be enriched by regular dialogue (co-creation) on the product development with stakeholders, in particular, developers, producers, certification bodies, distributors of the cosmetic products. This dialogue, started



during the PRISMA project, should continue all along the product development phases.

Process and Product certification.

How is RRI embedded in the innovation governance of the company and in the project? What RRI aspects emerging from the project could integrate existing certifications at process and product levels, and become part of the usual approach to innovation management of the company?

Adoption of voluntary certifications on sustainability, social responsibility and ethics is part of the culture of Archa, as well as in that of the other companies involved in NanoCube (producers). For Archa and Techa, this includes adoption of OHSAS 18001 (Occupational Health and Safety Assessment), SA8000 (Social Accountability), UNI EN ISO 14001 (environmental management), UNI EN ISO 9001 (quality management). The cosmetic products of NanoCube are expected to fulfil requirements of the COSMOS certification (certification for organic and natural cosmetics products in Europe), and as well of certifications concerning biological farming for production of raw materials. These certifications provide an added value to address the specific ethical and social issues identified for NanoCube and to pursue an RRI approach.

At the process level, the advice has been to integrate safety procedures for nanomaterials developed within NanoCube in the usual risk management and quality procedures used by the company (in line with the above mentioned certifications). This might include indication for researchers to implement safe by design approaches, procedures for safe handling of nanomaterials in the workplace, indication for end of life management of nano-related products. Control banding tools for safety of nanomaterials (such as the ones in the PRISMA RRI toolkit) might be considered to this end.

The attention to gender balance in any of the R&I activities of the company, as shown by almost equal participation of women and men to projects and consideration of gender aspects in project design and execution, could be further emphasised in project communication.

Adoption of additional certification mechanisms could be considered to further highlight and consolidate the approach toward RRI of the company. An example of standards useful to this purpose are the Guidelines for management and processes development for responsible innovation (UNI/PdR



27:2017). At the product level, the explicit consideration of aspects related to nanomaterials (e.g. application of the precautionary principle in selection of formulations; implementation of best practices for safety, etc.) within existing certification mechanisms could be pursued.

The aspects underlined above are going to be structured and elaborated in a roadmap to integrate RRI into the NanoCube products after the end of PRISMA, and covering all the period until the commercialization and use of the product. The agreement with the company of the final roadmap will be the conclusive step of the pilot.

Final remarks

The cooperation with Archa on RRI implementation has been quite fruitful, also thanks to the experience and attitude on social responsibility of the company. Some of the RRI tools and approaches emerged by the work of PRISMA might in the future be integrated in usual practices of the company on several R&D projects.

The experience with PRISMA supported the company in a better understanding of potential impacts (both risks and benefits) of the NanoCube project. In particular RRI approaches helped to anticipate both Environment, Health and Safety and Ethical, Legal and Social Aspects of nanotechnologies with specific advantages at product level. This included improvements of safety and communication in the use of nanomaterials, fulfilment of certification requirements for natural and organic cosmetics products, alignment with distributors requirements for “premium” products, and better understanding of consumers’ expectations.

However, the PRISMA pilot shows that assessment and implementation of RRI actions, for example the organization of stakeholder dialogues, are resource demanding.

There is a need for a specific expertise on RRI, and thus for people trained in coordinating and conducting RRI actions. It should also be considered that in cooperative projects, some of the partners might lack experience, or willingness, in cooperating and taking part in RRI actions.



Therefore, in most of the cases adequate resources should be made available to put in practice RRI. Considering specific tasks and resources (personnel, financial) for RRI since the early stage of a R&I project is an essential aspect for successful RRI implementation. Depending on the specific situation, this might include getting support from external experts, as it was in the PRISMA project.

