PRISMA

PRISMA PILOTS RRI ROADMAPS:

Archa

CEN workshop background document

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The Company

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 the 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.

RRI commitment

- The RRI PRISMA pilot has been endorsed by the Executive management, and the R&D and quality managers
- Motivation for RRI: address risk and risk perception related to use of nanomaterials all along the life cycle of the product, strengthen product acceptability, address normative and regulatory compliance

Context

- Type of pilot organization: SME
- Country: Italy
- R&I project selected: NanoCube
- Technology: nanotechnologies
- Regulatory regimes relevant for NanoCube: nanomaterials, cosmetics, medical devices
- Type of R&I activities: cooperative research
- Type of business: business to business
- Time to Market (indicative): 3-5 years
- CSR policies: Archa is certified OHSAS 18001 (Occupational Health and Safety Assessment), SA8000 (Social Accountability), UNI EN ISO 14001 (environmental management), UNI EN ISO 9001 (quality management).
- Gender balance and gender policy in R&D: similar composition of R&D personnel in terms of men and women, no relevance of gender & diversity in recruitment criteria and selection of R&D personnel
- RRI Maturity Level: Strategic

Materiality & experimentation

- Key stakeholders: NanoCube research partners, technology developers, nanomaterials producers, dermo-cosmetic and medical devices manufacturers, hospitals, retailers, certification bodies, consumers

- Key ethical, legal and social issues: product efficacy, safety and safe production, risk perception and user acceptability (in particular for nanomaterials), improved quality, affordability, compliance with sustainability norms (workers' rights, supplying of raw materials, reduced environmental impact in processing and production)

- RRI actions selected for the PRISMA pilots [3]: RRI Training, ethical and social analysis, stakeholder dialogue

Validation aspects (key performance indicators)

- The most significant criteria identified with the company to analysis and monitor over time the impacts (in terms of costs & benefits) of the RRI actions on the NanoCube products are[4]:

    - Q1.1: Inspire technological innovation
    - Q2.1: Product acceptability; Q2.2: Product safety;
    - Q3.3: Transparency on product qualities; Q3.4: Customer satisfaction, meeting new consumers' needs or requests; Q3.5: Building legitimacy and gain consumer loyalty on the product;
    - Q.4.4: Safety at the workplace; Q4.5: Risk management
    - Q5.7: Human Resources (use of)

RRI Roadmap

RRI VISION

Create nano-based dermo-cosmetic products, based on ethically acceptable and sustainable production methods and on a safe and more effective use of natural and organic ingredients.

R&I Technologies and products

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.
A key research challenge is the exclusive use of natural ingredients, including the nanocapsules, and processing steps avoiding the use of chemical (synthetic) solvents. The final dermo-cosmetic product is expected to fulfil specific voluntary international certifications for organic and natural cosmetics.
Final products of NanoCube include: a dermo-cosmetic product based on controlled released of bioactive agents, that might be further developed in a medical device (class I) for anti-inflammatory dermal treatments; an electrospinning device/process for nano-capsule production; a medical device for lesion care (class II medical device) using nanowires produced by electrospinning.

Drivers and challenges for RRI

Drivers:

- **Demand for more eco-friendly and organic based dermal products**
- **More efficient use of natural substances**
- **Reduce use of antibiotics**
- **Reduce risks for workers in handling active substances**

Challenges

- **Transparency and open communication to consumers**
- **Ensure workers' and consumers' rights all along the supply chain and product life cycle**
- **Efficacy, reliability and quality vs. conventional detergents**

[3] Further information available in PRISMA deliverable D2.4: Responsible innovation in practice: experiences from industry
[4] For more details on the criteria for impact analysis used in this section, see PRISMA D5.1: Report on conditions for success of RRI uptake by industry

Risks and barriers to be addressed by RRI actions

- **Regulatory uncertainties (e.g. regarding NM classification)**
- **Upscale of production system for nano-capsules**
- **Risks of use of NM into the body**
- **Risk perception on nanotech of professional users and, in particular consumers of green and natural cosmetics**

RRI actions

Reflection & Anticipation:

- **Ethical and social impact analysis** (stakeholder and value inventory, design for values approaches)

Inclusiveness

- **Organize regular dialogue (co-creation) events on product development with stakeholders** in particular developers, producers, certification bodies, distributors of cosmetic products for sharing values, creating positive ethical networks, and improving acceptability of the final product:
    - A first stakeholder dialogue has been held during the Prisma project to shape the contents of this roadmap; others should be organized continue all along the product development phases.
- **Dialogue and cooperation with authorities** to anticipate potential risks and monitor regulatory development, in particular for the nano-capsule production system and the medical device product
- **Developing of a communication strategy, based on scientific evidence, to ensure transparency and quality and credibility of product claim.** Particular attention to the use of nanomaterials. Specific criteria for the strategy include:
    - Distinguishing between natural substances and synthetic substances
    - highlighting improvements in durability and efficacy of the product, and possibility to avoid/reduce the use of conservatives in the cosmetics
    - Providing indication on the safe use of nanomaterials during production, use and disposal (complementing normative requests of cosmetic regulation, requiring including nanomaterials in product labelling)
    - further emphasise in project communication aspects of gender balance in R&I as one of the strengths of the project and the company

Responsiveness:

- **Implementation of risk management systems for nanomaterials**, including use of state-of-the-art practices and standards for characterization, measurement and safety testing of nanomaterials (e.g. OECD test guidelines). Full assessment of potential exposure to nanomaterials during the production of nano-capsules, and regarding the end of life of the product
- Implementation of **computational models, pre-screening techniques and in-vitro approaches for safety assessment of the product** (in the case of medical devices, as alternatives to animal testing).
- **Certification at process and product level to promote safety, ethical acceptability and societal desirability of products**:
    - Fulfill requirements of ethical certification for the dermo-cosmetic products (e.g. COSMOS certification for organic and natural cosmetics products in Europe) and certifications concerning biological farming for production of raw materials (production of the active substance of the dermo-cosmetic)
    - Integrate in existing risk management, quality and social accountability certification at company and supply chain level, best practices for safe handling of nanomaterials in the workplace (e.g. control banding tools), and for end of life management of nano-related products

Roadmap design

The aspects relevant for RRI uptake by the company, covering all the period until the commercialization and use of the product, have been synthetized in an overall diagram, following the visual approach described in the PRISMA exemplar roadmap (Figure 2).

The RRI roadmap developed in PRISMA is a useful starting point for RRI uptake, being suitable for implementation in the context of the NanoCube project. Some short-term actions were already planned by the company, other have been implemented thanks to the cooperation with PRISMA. Some of the RRI tools and approaches emerged by the work of PRISMA will be integrated in usual practices of the company on several R&D projects.
Participation in PRISMA, helped the company to better understood the relevance of societal values to improve the R&D process, and the need of a transparent communication and of cooperation with stakeholders to align R&D products to their needs, expectations and requirements.

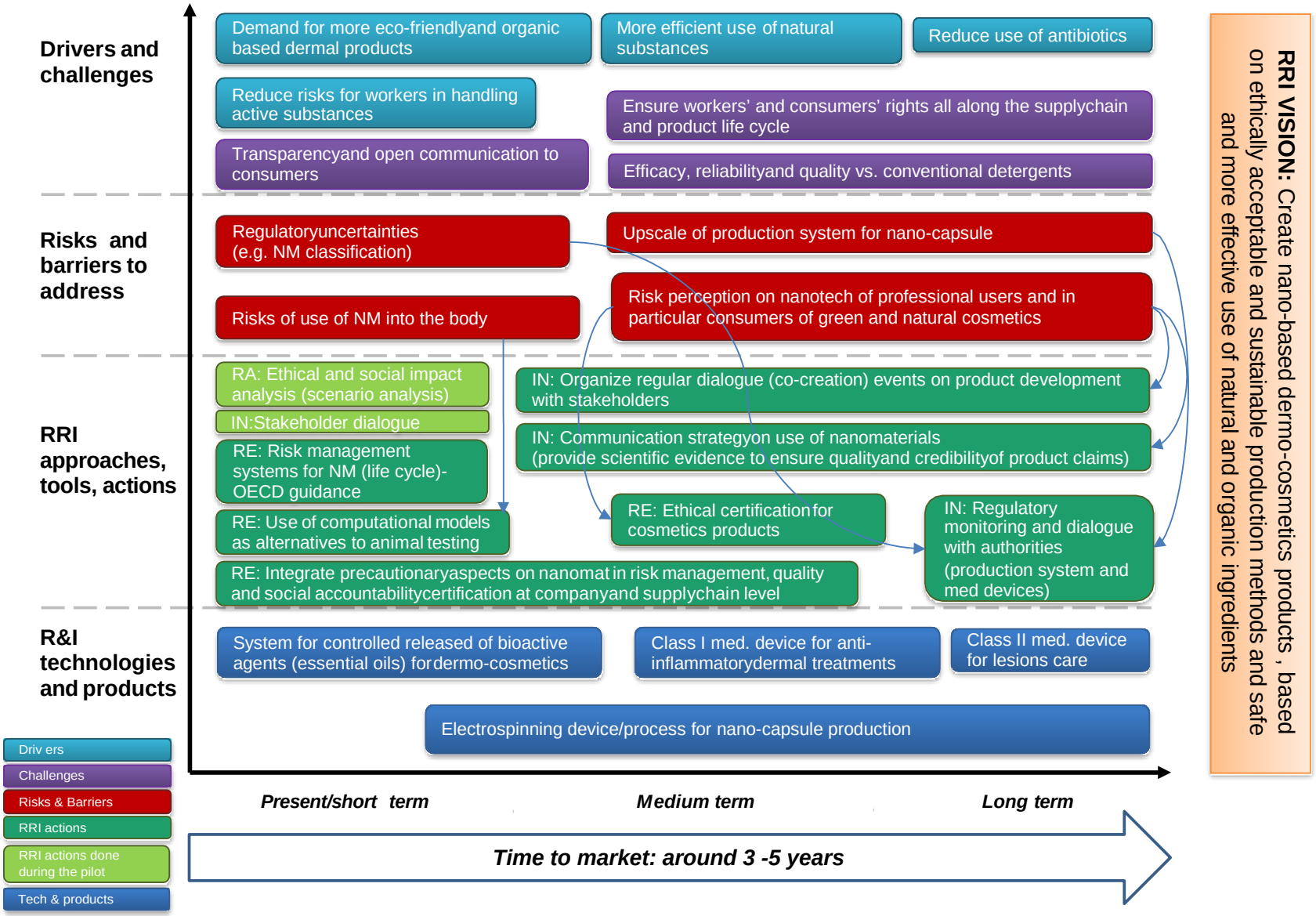

Figure 2: Laboratori Archa, PRISMA RRI roadmap