

## Case Study

# **Occupational health protection in standardisation experiences as an example of self-regulation**

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Preparation date: May 2014

Document version: final

## **Introduction**

Health safety concerns trigger the debates on responsible development and governance, facing the interplay of scientific uncertainty, risk assessment, and occupational health and safety. This latter field is an important area of European policies for RRI and governance efforts, and it is set to gain more relevance in the future. In this context, the use of validated and broadly recognised standards in assessing and managing risks in the workplace has become a major instrument for dealing with such risks, and it exemplifies prominently the interaction between soft and hard law in science and technology governance framework. Initiatives like this one reflect the international and European approach to adopt non-binding regulatory instruments in science and technology governance (including nanotechnology) for coping with the lack of rules or the uncertainty emerging in the application of existing ones.

## Case summary

The Veneto Region Research Cluster on Nanotechnology, through its ECSIN<sup>1</sup> Laboratory, started in 2012 the development of a standard for occupational health and safety dedicated to firms using nanomaterials in their productive processes. The standard has been developed parallelly to another standardization instrument focusing on consumer safety. The standard is still under development. The elaboration of standard was started in response to expressions of interest of a few Italian certification bodies. The standard draws on existing international experiences and attempts to adapt them to the specific national and regional context, which is characterized by the prevalence of SMEs with less than 15 employees. These small and medium firms are reluctant to engage with established standards like ISO, as they have insufficient financial resources to afford them, as well as the technical capacities and expertise to use instruments like the material safety data sheet by themselves and external support, e.g. by the Chambers of Commerce or other public bodies, is not available for implementation or capacity-building. The standard is being elaborated through these steps: (1) analysis, assessment and synthesis of existing international standards; (2) elaboration of the standard; (3) practical testing for feedback and validation through (ideally) some pilot cases, in order to refine the instrument for each specific industry and to ensure a smooth implementation. The development of the standard on occupational health and safety is currently in stage (2).

The standard aims at integrating freedom and responsibility in conducting a business, by diminishing the (potential) firm's exposure to liability claims too. In sum, the standard translates and connects different motivations and interests, of the Research Cluster and of the certification body drafting the document, as well as of the users - the two latter actors' motivations and interests are anticipated on the basis of previous and informal knowledge, contacts, and experience, including the collaboration in the drafting of the consumer protection standard, as no formal consultation has accompanied the preparation of the standard so far. In sum, the analysis of the documents, the recurring study visits at ECSIN, and the interview of key staff involved in the preparation of the standard highlighted the following major features: (1) the standard on occupational health and safety developed as a "spin-off" of another standard for consumer safety, according to the view that responsibility is to be thought as distributed along the value chain; (2) the effective implementation of the standard requires consistent organizational arrangements; the consumer protection standard is again considered as a model, for instance as it requires the creation of a working group on "responsible management" including staff covering different key roles in the company (e.g consultants, quality supervisor, foreman, production manager, workers' representatives or similar) in order to cover different aspects of the evaluation process and to act as a kind of permanent task-force - this aspect is said to be lacking in ISO 9000 standard; (3) the widespread adoption of the standard requires that it should be kept "as simple as possible" by taking the existing mandatory legal requirements

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<sup>1</sup> European Center for the Sustainable Impact of Nanotechnologies.

(already known by the industry) and integrating them specifically for nanomaterials, as well as by providing instruments for easy application, like a sort of “checklist” inspired by international guidelines, in order to provide meaningful data about its implementation and concrete efficacy; (4) the priority focus of the standard is not providing specific guidance for risk analysis, which is highly dependent on industry sector and even specific materials, but to raise firms’ awareness of nanoproducts safety concerns, to foster their responsible attitude in the management of nano-components in their productive processes, and to build appropriate organizational capacities to meet such challenges.

The collaboration between the ECSIN Lab and the certification bodies is expected to correspond to the following pattern once the standard will be elaborated and issued: (1) the standard will be owned and marketed by the certification authority; (2) ECSIN will act as the technical consultant for its practical implementation and refinement, as well as for its periodic monitoring and revision; (3) ECSIN will also act as a sort of “nano helpdesk”, linking firms with public authorities and other research organizations to accompany them in the practical implementation of the standard following its official adoption; (4) ECSIN will assist users to gain public funding for occupational health measures as an incentive for the standard’s adoption and implementation.

## Lessons for Res-AGorA

As an example of responsible innovation “in the making”, this case study offers multiple entry points to examine private code of conducts, standardisation practice and shared guidelines as example of meta-governance. Such entry points relate to the links between soft and self regulation activities and the broader governance and legal frameworks, as well as to specific configurations of actors’ and to the particular division of labour in responsible management of (nano)technology associated to those configurations. In sum, the case study highlights the following entry points: (1) self-regulation activities and soft law tools like these ones have to present internal and external coherence with legal framework and governance policies, for instance considering liability instances for injuries and damages; (2) soft law instruments connect and translate different motivations and interests of an heterogeneous set of actors in contexts where rules lack or uncertainty emerges from the application of the existing regulations and procedures; (3) such regulatory arrangements can be built on previous contacts, networks, and knowledge (including claims about actors’ interests, motivations and expectations), which operate without *ad hoc* formal consultation procedures; (4) responsibility can be seen both as resulting from defined, formal organizational configurations and procedures disciplined by specific soft and self-regulatory arrangements, but also in the even “softer” terms of an organizational climate and culture, acknowledging the existence of safety concerns and promoting responsible behaviour; (5) responsibility is considered a collective process, in two distinct meanings: (a) responsible management (of nanomaterials) is the result of a collective and collaborative effort, in individual organizations - it requires specific organizational configu-

rations enabling the collaboration of different functions and expertises in the firm - and between organizations - inter-organizational structures like research clusters can support implementation, especially in the case of SMEs; (b) responsible management practices should affect the whole value chain, which, in our case study, has prompted the development of different, specific self-regulatory tools.

# Towards Anticipatory Governance of Responsible Research and Innovation



The objective of the Res-AGorA project is to develop a comprehensive governance framework for responsible research and innovation (RRI). This will be a contribution to the EU ambition of becoming a genuine Innovation Union by 2020 striving for excellent science, a competitive industry and a better society without compromising on sustainability goals as well as ethically acceptable and socially desirable conditions.

The goal of the Res-AGorA project will be achieved through extensive case study research about existing RRI governance across different scientific technological areas, continuous monitoring of RRI trends in 16 European countries, and constructive negotiations and deliberation between key stakeholders. This comprehensive empirical work will be the building blocks of the creation of a governance framework for RRI.

The case study summarised in this document is output of Res-AGorA's extensive empirical programme (Work Package 3).

More information at [www.res-agera.eu](http://www.res-agera.eu)

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## **Acknowledgement**

This project is receiving funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no 321427.



Co-funded by the  
European Union