



Workplace exposure to engineered nanomaterials: The Italian path for the definition of occupational health and safety policies

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ARTICLE INFO

Article history:

Received 31 October 2012

Received in revised form 13 January 2014

Accepted 29 January 2014

Keywords:

Occupational health and safety

Nanotechnologies

Stakeholders engagement

Legislative framework

Emerging risk

Participatory decision-making process

ABSTRACT

This study explores the way the publication of a National White Book on health and safety risks that affect workers in jobs involving Nanotechnologies and Nanomaterials influenced the key Italian stakeholders attitude toward this issue and identifies the standpoints and priorities shared among researchers and stakeholders to develop a policy framework to address this issue.

The study not only highlights some important assumptions (*i.e.* the acknowledgment by the key stakeholders of the need for actions and the identification of objectives which can gain a wide consensus) for the establishment of a policy community that sustains the development of a policymaking process on the issue but, through the interaction between stakeholders and OSH researchers, it also identifies some in nuce proposals that represent the starting point for policy interventions aimed at meeting the needs of both stakeholders and scientific community.

Results obtained in terms of clarification of interests at stake, identification of potential areas of consensus and level of key national actors' engagement achieved, show the potentialities of adopting a knowledge based and inclusive approach to policy-making to address the issue of prevention and management of health and safety risks related to technological innovation within a framework of scientific uncertainty.

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1. Introduction

Nanotechnologies bridge a number of scientific disciplines and help add additional value to products. The development of nanotechnologies has spanned over different industrial sectors, including electronics, chemical, pharmaceutical, cosmetic and medical industry, energy, construction and transportation [1,2].

Estimates suggest that the market for products incorporating nanotechnologies will reach 3000 billion USD in products by 2020, with up to 6 million people including, researchers and workers, involved in a nanotechnology domain [3].

This scenario, makes dealing with nanotechnologies and nanomaterials (NT&NMs) into a crucial issue, not only for consumers, but also for workers' health and safety, as some harmful effects of nanomaterials have been observed with *in vivo* and/or *in vitro* studies [4,5].

Particularly with regard to workers' health, the importance to properly tackle risks related to nanotechnologies is due to their specific exposure conditions (in terms of level, modality and duration of exposure) throughout the life

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cycle of Engineered Nanomaterials (ENMs), from research through scale-up, manufacturing, product development, transport, to recycling and waste management [6]. The need of an occupational health and safety policy framework has therefore become very urgent, in order to promote the safe and responsible development of nanotechnologies.

Nevertheless, it is not easy to address this issue, since nanotechnologies are relatively new and there is still no comprehensive knowledge of risks associated with the potential exposure to them, and consequently, how these risks can be prevented and managed [7,8].

As a result of this scenario, the sustainable development of NT&NMs entails a crucial challenge: the need to maximize the protection of human health and safety against unpredicted risks related to NT&NMs and, at the same time, to avoid affecting the predicted benefits of their development and use more than what is reasonable and necessary [9].

However at present, a fully satisfactory response to this need has not yet been found. In fact, NT&NMs are in most cases, regulated only according to current norms and laws. Nevertheless the development of a specific regulatory framework, or even the integration of the existing regulatory framework, are widely called upon. For instance, the European Commission (EC) recommends the application and adaptation of the regulatory framework set up for Chemicals by the REACH directive [10].

The debate on different regulatory approaches is still open both at institutional level and among stakeholders and studies on this issue have been promoted in Europe as well as in United States [11,12]. In general, the scientific uncertainty involved in evaluating potentially harmful properties of ENMs complicates and hampers the implementation of proper regulative measures by legislators [13].

In fact, the lack of certain data on risk assessment and management calls for the development of a regulatory framework under pinned by the adoption of the precautionary principle [14,15]. However, it has to be considered that applying the precautionary principle appropriately is a difficult task because it leaves room for the risk of enacting compulsory regulations based on insufficient information [16].

Since the adoption *tout court* of the precautionary principle needs a *full reverse burden of proof* that is not scientifically viable, a proper application of this principle requires, on one side, the development of a regulation that is able to capture and balance the plurality of social values and interests involved and, on the other side, the integration of this regulation within a wider policies framework aiming to increase knowledge availability and promote a transparent, responsible and socially accepted use and development of this technological innovation [17–19].

According to these needs, as pointed out, among the others, by EC, the participation in decision-making processes of all stakeholders involved in or concerned by NT&NMs seems to be the most suitable way to address the issue of governing the development of NT&NMs [20]. The adoption of the participative approach is generally considered to be the best method with which to increase the quality of decisions and to resolve conflicts among competitive interests

where risk's boundaries are unknown and interests and value judgments are potentially different [21–23].

So far for nanotechnology, various attempts have been made, and are still being made, to promote open and transparent policy deliberations and extensive public discourse [24–27]. Nevertheless, even if these engagement exercises aim to influence policy making, research suggests that, until now, they have had little discernible impact on this regard [28].

An effort to develop further practices of stakeholders' engagement is therefore needed to make the most of the added value that can be gained from adopting a participatory approach to have an effective governance of technological innovation. As suggested by studies on public participation, one way forward should be to move up as much as possible from the public consultation level to the effective and active engagement of key stakeholders in the policy making process [29].

According to this need, the former Italian Institute for Occupational Health and Safety (ISPESL), whose function was transferred to INAIL in 2010 by Italian law, has conducted the study presented here which aims to give a contribution to a better understanding of the prospect for public engagement in policy making both on technological innovation in general and on the specific case of NT&NMs related risks governance.

This study is a follow-up of the “White Book on the exposure to engineered nanomaterials and their effects on workers' health and safety” published in 2010 by INAIL in collaboration with “NanOSH Italia”, a National network involving *Occupational Health and Safety* (OHS) researchers in the field of nanomaterials to address one of the key emerging priorities for research on OHS identified in Italy [30,31]. The White Book provides a state of the art review, including an analysis of the key issues for the development of relevant research, with the intent of streamlining the dissemination and sharing of available scientific knowledge.

This study engaged with Italian social partners, public authorities and representatives of research institutions in a process addressed to share available knowledge provided by the White Book and, in the light of such knowledge explore are their standpoints and priorities and identify if any shared policy options are available.

2. Materials and methods

The study was conducted in two steps. In the first step, a stakeholder analysis was conducted and a list of key Italian stakeholders was developed, taking into consideration the need to represent all different interests concerned with occupational health issues related to NT&NMs exposure. Afterwards, the identified stakeholders were grouped in three reference groups.

Stakeholders having a third party interest, with regard to the issues addressed in the study, were gathered together in the group that was named **Institutions & Associations**. This included both public institutions endowed with decision-making power over policies affecting the development of NT&NMs and the protection of workers' health, as well as Italian OHS Professional Associations that have a professional concern in facing the OHS issues

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