

Introduction

Addressing the Uncertainties of Nanotechnologies: Some Perspectives for a Future Research Agenda

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Nanotechnology could become the most influential force to take hold of the technology industry since the rise of the Internet. Nanotechnology could increase the speed of memory chips, remove pollution particles in water and air and find cancer cells quicker. Nanotechnology could prove beyond our control, and spell the end of our very existence as human beings. Nanotechnology could alleviate world hunger, clean the environment, cure cancer, guarantee biblical life spans or concoct super-weapons of untold horror. Nanotechnology could be the new asbestos. Nanotechnology could clean up toxic waste on the atomic level. Nanotechnology could change the world from the bottom up. Nanotechnology could become an instrument of terrorism. Nanotechnology could lead to the next industrial revolution. Nanotechnology could transform the food industry. Nanotechnology could repair the ozone layer. Nanotechnology could change everything (UNESCO, *The Ethics and Politics of Nanotechnology*, Paris, 2006).

The above examples suggest that nanotechnologies make radical new opportunities much closer in many fields, while, at the same time, raise new concerns about ethical, social and legal issues. Nanotechnologies, as with other emerging technologies, do not escape the rhetoric of the so called “regime of economics of technoscientific promises” (Wynne et al., *Taking European Knowledge Society Seriously*, Report on Science and Governance, Directorate-General for Research, EC, 2007, p. 24). Indeed, while nanotechnologies seem to be absolutely *new* “when technological elites speak to investors, policy makers or patent offices, and to the public to be enrolled in the new venture” (*ibidem*), at the same time, they are presented as nothing unusual when concerns about health or safety are at stake.

The following pages report the results of the International Conference “*Managing the Uncertainty of Nanotechnologies: challenges to Law, Ethics and Policy Making*”, promoted by the Centre for Environmental Law Decisions and Corporate Ethical Certification (Ciga), that took place in Rovigo, Italy, in May 22-23, 2008. The initial premise of the conference was that nanotechnologies amplify

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both the rapid growth of technoscientific development and the uncertainty about the social impact of added innovation. The conference offered a multidisciplinary perspective about three aspects of this topic that occupies a central role on a global perspective. These aspects were first discussed in three separate panel sessions: the first on “nanotechnologies and regulatory issues”; the second on “nanotechnologies, ethics and public policy”; and the third dedicated to “nanotechnologies, foresight and the broader future-oriented debate”. Due to this differentiation of perspectives, and to the numerous participants from different countries (Australia, Canada, Europe, India, United States), we obtained a “multicoloured silhouette” on this topic. This volume collects the contributions on the developing issues in the regulation and policy making in nanotechnology, while, other contributions on public engagement and ethical, legal and social issues related to risks will be published in the forthcoming volume titled *Technoscience in Progress. Managing the Uncertainty of Nanotechnology*, Amsterdam, IOS Press, eds, S. Arnaldi, A. Lorenzet, F. Russo.

Some of the scientific and technical characteristics of nanoscience and nanotechnologies (N&N) make governance and regulation very difficult. For example, the pervasiveness of nanotechnological development in so many different types of enterprises and fields raises formidable challenges to centralized processes of regulation, which, therefore, gives an important role to voluntary standards and self-regulation. Moreover, the lack of scientific data and suitable assessment methodologies implies that the regulation and policy making process is both crucial and difficult. In fact, there are many different specific and general questions that arise in public discussion. Most of the general considerations that are raised relate to the uncertainty that characterizes not only the scientific debate but also the regulatory one. Also, beside the uncertainty, two other important issues that emerge are the importance of ethical values, and the interaction between laws and different social actors.

Following these considerations, two general problems arise.

First, we cannot cope successfully with “nano” issues using only local or even regional perspectives. The globalisation of the markets, risks and innovations call for a trans-national vision on the impact of regulatory and policy responses. Nevertheless, this does not exclude the pivotal role of public actors in governing nanotechnology. Domestic rules and the implementation of new tools and modes of interaction between law, science, and society can help in designing new global policies which also take into account local priorities.

Secondly, an integrated approach in the social sciences and humanities is a fundamental tool for answering these issues. This is accomplished by using both general and abstract approaches (e.g. learned discussions on regulatory approaches and kinds of regulatory regimes) and through very practical and concrete approaches (e.g. pharmaceutical and cosmetic regulations).

Also, this volume deals with issues related to specific fields and specific regulatory aspects. For instance, the analysis of the biomedical regulatory framework which is concerned with drugs, devices and biological products demonstrates a trend in the EU context in regards to the use of the premarket test

and system of surveillance for biomedical products. The recognition of the Indian policy on health, and the description of the UK pilot model on nanomaterial innovation policy let us understand the impact of local differences on regulatory regimes. Moreover, the interpretation of EC cosmetics regulation in light of the USA and Australian regimes delineates different risk assessment methodologies.

The first part of the present publication addresses general issues on nanotechnology and regulation.

Brownsword (King's College) asks what the fundamental regulatory question in this field is. In his opinion, it is whether there should be a more systematic and dedicated regulatory oversight of the development and use of nanotechnology. Brownsword, also, asks which reasons or purposes should guide such a regulatory response and in which form should regulators intervene. The context of uncertainty that characterizes the field of nanotechnologies does not help to effectively address these issues. On the basis of these premises, the author sketches eight subjects of uncertainty that summarize two principal questions: first, to what extent are we identifying uncertainties that are new and associated distinctively with nanotechnologies; and secondly, to what extent does the responsibility for addressing these uncertainties rest with regulators. Brownsword observes that even if regulators do not have the primary responsibility for addressing some of these uncertainties, they need to have a strategy for dealing with the uncertainty as long as it persists. The author concludes with the following considerations: the uncertainties and difficulties connected to nanotechnologies are similar to the ones of other emerging technologies; the responsibility for resolving these various uncertainties does not lie solely with the regulatory community; there is a gradation of these uncertainties because some are less problematic than others; finally, the uncertainties concerning underlying ethical values, represent the deepest difficulties for the regulatory enterprise.

Pariotti (University of Padova) focuses on the same pivotal question analyzed by Brownsword: do we need special regulations or are existing laws already suitable to the many fields of nanotechnologies? She analyzes this issue by considering if the existing normative framework is sufficiently "comprehensive, unambiguous, locally consistent, acceptable and if it can be complied with". The author underlines that emerging technologies challenge some traditional categories of both legal and scientific knowledge. As for the scientific field, she presents the example of new drug delivery systems and the blurry boundaries between pharmaceuticals and medical devices; more broadly, she refers to specific therapeutic targeting and to the impact that this could have on statistical criteria currently used for clinical trials. This could imply legal consequences in the regulation of drugs and medical devices and, more generally, of clinical trials. Regarding the legal culture, the traditional central role given to hard law and the crucial role of the State in the process of regulation, as well as the private/public dichotomy are challenged by nanotechnological development. Consequently, the issue becomes how to provide a *sound normative framework*. A mix of different legal tools is required. Beside hard law, soft law (including self-regulation) is an important and useful means for legal regulation. Notwithstanding problems

related to legitimacy, the author claims that there is a need to recognize new forms of governance merging domestic, transnational, supranational and international levels. In her view, the precautionary principle can be used in a “constructive” way when the consequences of nanotechnologies’ uses are uncertain. This means to encourage “participation ... in decisions concerning risk assessment and risk management” and “flexibility of regulation” in order to properly monitor regulatory responses, to foster knowledge improvement and to distribute responsibilities between different actors.

The second part of the volume addresses some more specific topics.

The paper written by Dorbeck-Jung (University of Twente) provides some insights into regulatory deficiencies of existing EU medical product regulation that are relevant for certain nanomedical applications. The author conducts an analysis through an observation of the history of regulatory regimes in the biomedical product field and through the investigation of their policy rationales. She found that a comparison between earlier and current borderline product regulation indicates a tendency to stipulate a principal mode of regulation and to integrate components of the regimes related to the other relevant modes of action. Dorbeck-Jung also observes that EU drug regulation pays more attention to pre-marketing and post-marketing controls than the regulations on medical devices, blood products and the donation of cells and tissues. Consequently, she concludes that with regard to the approval of nano-medical products, the Advanced Therapy Medicinal Products (ATMP) Regulation tends to use a central procedure and to pool expertise at the central level. She also stresses that it is not clear whether new nanomedical regulation will move in the direction of tight legislation that leaves no room for soft law.

Srivastava (The Energy and Resources Institute) and Chowdhury (University of Twente) focus on applications in health related sectors in India. In regards to the rapid pace and a strong governmental input in current investments in research and technology in the Indian framework, there is insufficient attention to regulatory and ethical aspects. In the authors’ view, the existing legal tools lack the capacity to respond to the new challenges accompanying research and development in nanotechnologies. Moreover, they underline the lack of coordination between the different governmental bodies involved and the consequential repercussions on enforcement and regulatory certainty. The authors urge the Indian authorities to take up the challenge for a greater general review of local regulations, also, in accordance with the necessity to shape the international direction of the nanotechnologies.

Using cosmetics as a case-study, the article written by van Calster and Bowman (University of Leuven) reviews the readiness of the Australian, European Union and United States regulatory structures to regulate the new nano-science technologies. The article examines the varying regulatory approaches being employed within these three jurisdictions to protect consumers against potential risks posed by one particular class of engineered nanomaterial used in cosmetics products, specifically nanoscale metal oxides. The authors’ aim is to draw upon the insights and conclusions of each of the reviews in a comparative manner so as to enable the reader to review which regulatory regime appears to be the best equipped to deal with the additional challenges posed by these products. Moreover,

the paper investigates the adequacy and effectiveness of the different regulatory regimes for regulating cosmetic products which incorporate insoluble nanoparticles. This class of engineered nanoparticles has been identified as having the potential to cause health concerns under certain circumstances. The authors conclude that cosmetics are more strictly regulated under the *sui generis* system, established by the EU Cosmetics Directive, than compared to the regimes employed in Australia and the USA.

The paper written by Marrani (University of Salerno) explores the intellectual property issues of nanotechnology. She underlines that some problems may arise from nanotechnology's interdisciplinary nature in regard to patenting conditions. This is due to its highly diversified technical-scientific operational field, which involves physics, biology, chemistry, genetics and computer science. The author finds that experts usually do not feel the need of an *ad hoc* patent regime, since most issues of N&N are common to other technologies. However, she thinks that nanotechnology inventions have just highlighted special problems, which need appropriate solutions. The specificity arises not only with respect to patent requisites but also to nanotech patents' legal regime with a view to introduce benefit-sharing mechanisms. The main issues analyzed are the legal framework of nanotechnology patents *vis-à-vis* general rules and *ad hoc* regulations, key patent problems applying to nanotechnology specificity, and proposals for the nanopatent legal regime. Lastly, the author reflects upon the fact that patents could be publicly owned and this would allow the patentee to earn revenue from the patent and make the invention utilization free. Marrani suggests that a specific competence could be consigned, in Italy, to the National Biosafety, Biotechnology and Life Sciences Committee (a consultative body of the Italian Government), in analyzing the characteristics of inventions in disputes.

Nanomedicine, nanocosmetics and patents are just some of the different and multi-faceted areas involved with nanotechnologies. However, this interaction between so many and different fields suggests the necessity of prompt and integrated analysis of all the different actors involved in research and development of nanotechnology. This includes not only regulators and policy makers, but also companies, universities and final users that need to be engaged in the regulation and governance of nanotechnology. Some of these aspects are addressed in the third part.

Weil (Illinois Institute of Technology) addresses the question of why *this* is the right time for voluntary standards of care. She discusses the desirability and the necessity of "building a legal framework of regulation". Moreover, she underlines what is the right time, the importance and the aims for voluntary standards of care, and who should be involved in developing suitable standards of care. Weil states we should not lose any more time. In fact, "the increasingly fast pace of commercialization" stands in front of "the very slow pace of efforts to reduce ignorance of potential harms". She justifies an emphasis on voluntary standards instead of government mandatory standards of care with the following considerations: a) the need for guidance in the virtual absence of government regulation and in the lack of information about risks; b) the "formidable challenge to centralized, systematic

oversight” related to the pervasive character of nanotechnological development; c) the special moral obligation of adherence to an appropriate standard of care that characterizes the nano realm and nano facilities, and the difficulties for regulators to keep up with the rapid pace of technological advance. She argues that an open and inclusive process should be implemented with public engagement “upstream”, involving both insiders, (i.e. members of research and development environments), and outsiders, (i.e. stakeholders and members of the public). Her approach to voluntary standards is informed by two recent projects: a survey aimed to seek information from companies about their workplace safety policies and an ethnographic project in a Nano facility.

Bucci and Stanton-Jean (University of Montreal) focus on challenges related to the widely emerging diffusion of nanomedical diagnostic and therapeutic applications in a Canadian context. This process indicates that important issues need to be addressed, especially dealing with the specific areas of safety, privacy and human identity. The authors give a brief overview of the past policy experiences in biomedicine, with special regard to new reproductive technologies and genetic technologies. They recognize the importance to integrate ethical, legal, social, health and safety issues in policy approaches to emerging technologies. Since initiatives toward a broader policy framework for nanomedicine are still in their infancy in Canada, they discuss three different health services models (the medical model, the public health model and the fundamental rights model) that could inform a future nanomedicine policy framework. They argue that the last model is the most suitable for developing a sound conceptual framework for nanomedicine in Canada.

Magnusson (University College London) compares the different approaches that guide the UK and Finland nanotechnology policies in the so called “mode 2/post-academic society” and their underlying key aspects. Magnusson reports the outcomes of the pilot stage of an empirical research she is conducting, using a qualitative approach. The paper reviews how the promotion and regulation of nanotechnology is addressed in the UK and in Finland, using the two different trends of the democratic approach and of the technocratic approach. The study analyses how the nanotechnology policy-making process is evolving in both countries. In particular, three different aspects are addressed: 1- who takes part in the nanotechnology policy negotiations and how government, industry, academia and society perceive each other; 2- the attitudes of different parties involved in the negotiations toward the cooperation process in regulatory and promotional matters; 3- how the regulatory and promotional negotiations are carried out in terms of openness and secrecy.

Rafolds, Meyer, Morgan, Nightingale, Smith and van Zwanenberg (University of Sussex) consider the appropriate regulation for nanomaterial innovation in light of the uncertainties regarding the environmental impact of materials with novel properties. They also consider the ability of a traditional regulatory framework to cope with materials whose environmental and human safety properties have the potential to change radically in response to only minor physical changes to the material itself. The paper reports on a pilot study undertaken by the same authors for

the UK Royal Commission on Environmental Pollution, that deals with how public policy might purposefully influence and encourage nanomaterial innovation that are either environmentally beneficial or benign, and discourage those that are environmental detrimental. They draw on evolutionary and systemic perspectives on innovation, and explore how these can inform debates about the regulation and broader governance of nanomaterials. There is possibility for current regulatory and governance efforts to be substantially broadened in order to promote technologies and technological trajectories that are environmentally advantageous. In their opinion, the ‘shape’ of the nanomaterials innovation system suggests that there has been a relative neglect of the ‘downstream’ side of the innovation system. They emphasize that the innovation framework typically involves an evolutionary understanding of innovation, and the body of innovation literature also stresses the interactive nature of innovation. Finally, the Authors focus on two main aspects that arise from the observation of the UK nanomaterials innovation system: innovation within the nanomaterial value chain is highly distributed and the UK nanomaterials innovation system has a distinct ‘hour-glass shape’.

Regulators and policy makers, as well as all the other actors engaged in N&N research and development, are involved in a complex process that has been defined, in the European context, as a “collective experimentation”. The European society has been perceived, consequently, as an “experimental laboratory without walls” where “complex and networked technologies especially, experimental conditions, open-endedness and unanticipated new interactions and behavioural demands – new test conditions and questions – continue way out into society’s farther reaches, well beyond formal societal regulatory testing, approval and release” (Wynne et al., *Taking European Knowledge Society Seriously*, cit., p. 63). This collective experimentation involves, of course, the whole planet. In this global context, in which “the scientific object ... is itself ambiguous, and in need of continual collective work to negotiate and, at least, temporarily stabilise its collective meaning” (*ibidem*, p. 17), the contribution of legal discussion and reasoning is necessary for balancing the interests of science and society with the protection and promotion of fundamental rights.