

LAW, UNCERTAINTY AND EMERGING TECHNOLOGIES

Towards a Constructive Implementation of the Precautionary Principle in the Case of Nanotechnologies

[DERECHO, INCERTIDUMBRE Y TECNOLOGÍAS EMERGENTES

Hacia una implementación constructiva del principio de precaución en el caso de las nanotecnologías]

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Sumario: 1. La novedad de las tecnologías emergentes; 2. El uso ambiguo del principio de precaución, entre riesgo e incerteza; 3. Hacia un significado constructivo del principio de precaución: consecuencias para una visión general de la regulación.

Contents: 1. The novelty of emerging technologies; 2. The ambiguous use of the precautionary principle between risk and uncertainty; 3. Towards a constructive meaning of the precautionary principle: Consequences for a general view of regulation.

1. THE NOVELTY OF EMERGING TECHNOLOGIES

Emerging technologies offer an excellent perspective from which to analyze the shift from government to governance, that frequently occurs today¹. This perspective is particularly obvious with nanotechnologies and various new developments in biotechnologies, such as the so-called synthetic biology. I shall focus here on the case of nanotechnologies.

Nanotechnologies affect many legal domains, including environmental protection, consumer protection, medical law, occupational health and safety, privacy and civil liberties, intellectual property rights, and patent

1. OST F. (2008), *Dalla Piramide alla rete: un nuovo paradigma per la scienza giuridica?*, in M. Vogliotti (a cura di), *Il tramonto della modernità giuridica. Un percorso interdisciplinare*, Giappichelli, Torino, pp. 29-48, p. 42.

law. Nevertheless, analysis of the legal implications of nanotechnologies is just beginning².

The European Commission and European advisory bodies (e.g., the European Group on Ethics of Technology) have suggested that existing laws designed for other purposes should be applied to nanotechnologies³. This, however, has mainly proven to be an untenable approach. It is widely recognized that nanotechnology outcomes are not properly addressed by existing laws. First of all, the scale, novel properties, and hybrid composition of nanoproducts may make them unsuitably covered by existing legislation. Second, nanotechnologies produce effects that are not classifiable in discrete categories such as the mechanical, chemical, or biological ones. For example, nanomedical products cannot be placed into one of the traditional classifications of drugs, devices, or biological products⁴. In addition, nanotechnologies are characterized as “enabling technologies”, since they can pervade any other technological domain, a further reason why they tend to cross and blur the classifications made by existent law.

However, the problems faced in applying existing law to evaluate products and processes involving nanotechnology can hardly be solved by simply enacting new laws, unless some conceptual issues are confronted first. The core issue concerns the risks associated with ingestion, inhalation, and absorption of nanoparticles by the human body and with the dispersion of nanoparticles in the environment. These risks are hard to qualify and quantify as is foreseeing the probabilities of their occurrence.

Let us consider some examples. Chemical substances seem to change their behavior at the nanoscale, invalidating the intended monitoring effect of the distinction between existing substances (which appears in the European Inventory of Existing Commercial Substances) and new substances. REACH (Registration, Evaluation, Approval of Chemicals) is the only EC legislative initiative (Regulation CE n. 1907/2006) intended to solve this

2. BROWNSWORD R. (2008), *Rights, Regulation, and the Technological Revolution*, Oxford University Press, Oxford; VAN CALSTER G. (2008), “Risk Regulation, EU Law and Emerging Technologies: Smother or Smooth?”, *Nanoethics*, 2, n. 1.

3. It should be noted that the European Parliament came to the opposite conclusion, maintaining that a new, ad hoc regulation is needed for nanotechnologies.

4. For issues concerning nanomedicine, see GUERRA G. (2008), “European Regulatory Issues in Nanomedicine”, *Nanoethics*, 2, 1; Dorbeck-Jung (2009). For a wider perspective and with reference to additional EU countries’ legislation, see BOWMAN, D.M. (2008), “Governing Nanotechnologies: Weaving New Regulatory Webs or Patching Up the Old?”, *Nanoethics*, 2, 179-181; LUDLOW, K. (2008), “Nanoregulation. Filtering Out the Small Stuff”, *Nanoethics*, 2, 183-191.

problem⁵. But establishing the criteria for distinguishing existing substances from new ones in the case of nanomaterials involves making some theoretical choices. For example, the molecular identity of a listed substance may be an insufficient criterion to identify a substance at a nanoscale as an existing chemical substance, since scale seems to make a difference in the physical, chemical, and biological properties of a material⁶. Determining the distinct qualities of nanoparticles, therefore, requires the use of complex criteria, based –for instance– on size and an emergent (significant) property, or on size and the significant new use.⁷ In another example, new drug delivery systems provided by nanobiotechnological applications are difficult to fit into the taxonomy of medical devices established by Communitarian law (Directive 93/42/EEC).

With regard to the second issue, we can see that just one of the main advantages made possible by nanotechnologies, i.e. specific therapeutic targeting, could be one of the causes of uncertainty in foreseeing and assessing risks. That uncertainty makes it difficult to provide adequate information for obtaining consent for therapy or performing a clinical trial. It may also affect the individuation of the trade-off between risks and benefits. The highly targeted drug effects promised by nanomedicine might undermine the relatively steady effects required when applying statistical criteria to enroll human subjects for trials as well as foreseeing the outcome.

To sum up, it may be that the very role played by clinical trials should, in a sense, be reconsidered. Criteria for determining the causality nexus in law are traditionally based on ascertained probabilities, which are not assured in nanomedicine. This issue is highly important when professional negligence, medical malpractice liability, and harm assessment are at stake. Early diagnosis may increase a patient's responsibility, but it may also enlarge the physician's responsibility and liability as well as widen the gap between diagnostic capacity and therapeutic capacity. In the domain of a therapeutic relationship, responsibility might tend to shift from physician to patient, because of the possibility of earlier detection of diseases and the availability of the so-called lab-on-chip. The very borders between health

5. BOWMAN, D.M. (2008), *op. cit.*; VAN CALSTER G. (2008), *op. cit.*.

6. See PRESTON, C.J., SHENIM, M.Y., SPROAT, S.J., SWARUP, V.P. (2010), "The Novelty of Nano and the Regulatory Challenge of Newness", *Nanoethics*, 4, pp. 13-26.

7. *Ibidem*.

and illness might start to vanish, especially if we also consider the promise of enhancement of human performance.

Both those who think that emerging technologies such as nanotechnologies should be regulated as much as possible by existing norms that have been created for other purposes and those who maintain the need for a specific regulation must defend their positions by establishing whether (i) there is anything truly new in nanotechnologies affecting legal regulation; (ii) the existing normative framework can be regarded as comprehensive, unambiguous, consistent, and acceptable; and (iii) if it can be complied with⁸.

To rely solely on the existing normative framework might be awkward, since it might be possible for a nanotechnology process or product to be affected by several normative disciplines. This would cause uncertainty or incoherence in applying existing norms. Moreover, sticking to existing law might amplify the drawbacks stemming from differences among domestic regulations and encourage the "lex shopping phenomenon" for firms, users and consumers.

The construction of a regulatory framework for emerging technologies, however, requires two preliminary steps, respectively dealing with clarifying background principles and embracing a specific risk management model. In order to design a regulatory approach to nanotechnologies, it should first be asked if, from the legal point of view, the notion of risk differs from the notion of uncertainty. It seems as if it does differ, which is why the precautionary principle, though questionable in its meaning and implications, has to be applied. Regulators need to know whether nanoproducts are potentially harmful, but they have to regulate even when risks and harm are not quantifiable.

2. THE AMBIGUOUS USE OF THE PRECAUTIONARY PRINCIPLE BETWEEN RISK AND UNCERTAINTY

Uncertainty in assessing the consequences for the environment, health and safety that may be associated with a given process or product represents the main reason for the appeal to the precautionary principle in

8. GRUNWALD, A. (2005), "Nanotechnology. A New Field of Ethical Inquiry", *Science and Engineering Ethics*, 11, p. 189; VAN DE POEL, I. (2008), "How Should We Do Nanoethics? A Network Approach for Discerning ethical Issues in Nanotechnology", *Nanoethics*, 2, pp. 32-33.

the search for a regulatory framework applicable to emerging technologies such as nanotechnologies⁹.

The precautionary principle was recognized for the first time within the *World Charter for Nature* in 1982, restated in 1992 within the Rio Declaration, and then within the Convention on Biodiversity, and the Cartagena Protocol on Biosafety (2000). It has therefore taken the status of a principle of international law and it is applied to a variety of topics, such as sustainable development and the Sanitary and Phytosanitary Measures Agreement (1994) passed by the World Trade Organization. It has also taken on the status of general principle within the EU legal order as well, with regard to environmental and health protection issues.

The precautionary principle has been defined and interpreted in several ways, mainly in terms of a weaker and a stronger meaning. The weaker meaning maintains that the absence of evidence of the harm that may be associated with the use of a substance or with an activity should not be a reason to avoid regulating the matter. The stronger meaning requires preventive measures to be taken if a substance or an activity appears to be damaging to human health or the environment, even if the causal nexus has not been fully shown.

Common to all the definitions of the principle is the inversion of the burden of proof, which depends on those who propose the actions at issue¹⁰.

In recent years, a wide-ranging debate has underscored the shortcomings of the precautionary principle, which has been regarded as ambiguous, unsuitable for the orientation of genuine regulatory options, capable of increasing people's anxiety, and too intertwined with a biased social perception of risk¹¹.

9. This point of view has been explored by the European Commission Communication on the precaution principle (2000) and in the Italian National Bioethics Committee opinion on *Nanosciences and Nanotechnologies* (2006).

10. In the EU legal order, according to the clarification of the EU Commission Communication on the Precautionary Principle, the inversion of the burden of proof does not apply in general but just to those activities and products that require approval before being put on the market. In all the other cases it is up to users and addresses (citizens, consumers' associations, or the government) to show the kind and degree of the harm and the level of risk that can be associated with them. See on this, FEINTUCK, M. (2005), "Precautionary Maybe, but What's the Principle? The Precautionary Principle, the Regulation of Risk, and the Public Domain", *Journal of Law and Society*, 32, 3, p. 386.

11. SUNSTEIN, C.R. (2005), *Laws of Fear. Beyond the Precautionary Principle*, Cambridge University Press, Cambridge (Mass.); MARCHANT, G.E. et. al. (2008), "Risk Management Principles for Nanotechnology", *Nanoethics*, 2, 1; HULL, G. (2007), *Normative Aspects of a "Sub-*

It has often been pointed out that the precautionary principle is geared towards the *status quo* and fails to highlight the opportunity costs. As such, the precautionary type of logic could lead regulators to focus on some events and difficulties related to certain activities, but would not allow consideration of all the options; as a result, regulative decisions would tend to be based on the most negative predictions, rather than on a balanced consideration of all possible consequences¹². In this sense, the precautionary principle is regarded as fostering a tendency to consider the advantages and risks of a given activity or product separately¹³.

For these reasons, this principle is regarded by many scholars as unsuitable to shape policies measures and risk management strategies. According to this perspective, rather than a genuine legal principle, capable of being translated into policies and applied by judges, it can at most be seen as a “mental state”¹⁴. It is, however, possible to find in such a precautionary principle a tool suitable for the fostering of a constructive view of dialogue among the sciences, society, politics, and law, which seems to be a very fertile ground for shaping a regulatory approach to emerging technologies. Some important suggestions in this direction can be found within the communication drafted by the (European Union) Commission on the precautionary principle. This paper aims to clarify the Commission’s approach to the principle, set down the guidelines for its implementation, and avoid references to the precautionary view as a hidden form of protectionism in international commerce within and outside the EU.

From the EU Commission’s point of view, the precautionary principle is to be thought of as a part of a structured approach to risk analysis, which includes three dimensions: risk assessment, risk management, and risk communication. This principle is regarded as particularly relevant for risk management. Within this perspective it is emphasized that (i) the appeal to the precautionary principle does not necessarily involve the introduction of legally binding measures; (ii) the normative decisions stemming from the application of the principle should meet proportionality and non-discrimination and should be based on a cost-benefit analysis that is not solely

stantive” Precautionary Principle, in: Social Science and Research Network (SSRN) available at: [SSRN_ID2023357_code861170.pdf](https://ssrn.com/abstract=ID2023357).

12. MAJONE, G. (2002), “What Price Safety? The Precautionary Principle and its Policy Implications”, *Journal of Common Market Studies*, 40, 1, p. 103.

13. MARCHANT, SYLVESTER and ABBOTT (2008), *op. cit.*.

14. MAJONE (2002), *op. cit.*, pp. 93; 106.

economic but that takes into consideration the opportunity costs as well; and (iii) such decisions should be open to revisions and suitable for a horizontal type of diffusion requiring the responsibility of producing scientific evidence for a wider risk assessment. It is worth noting that the Communication construes and underscores the difference between a prudential approach and the application of the precautionary principle. Whereas the prudential approach is part of risk assessment, application of the precautionary principle is said to be part of the risk management process specifically when scientific uncertainty does not allow a full understanding of the risk itself. Thus, strictly speaking, the distance between a prudential approach and the precautionary principle is based on the distance between risk and uncertain harm¹⁵. As it has also been pointed out by the Expert Group on Science and Governance, “risk, uncertainty, ambiguity, ignorance, indeterminacy... [imply] quite a different strategic and methodological treatment, extending well beyond conventional ‘risk assessment’¹⁶.”

A problem, thus, emerges at this point: on the one hand, the precautionary principle is, according to the Commission, relevant when it is not possible to quantify the risks that may be associated with a given substance, activity, or technology yet on the other hand, the precautionary principle is called upon to frame the *risk* management. The notion of uncertainty is therefore replaced by the idea of risk¹⁷, even though the latter notion has widely been regarded as not useful in the contexts of emerging technologies¹⁸. Cost-benefit analysis looks at costs solely in economic terms,¹⁹ but such costs are not always entirely of an economic nature and are not always comparable. Moreover, the legal policies measure must also protect public interests and individual rights, even if they conflict with specific interests and economic evaluations. Once again, the best available technological model seems to be inadequate in the case of nanotechnologies, due to the lack of information on related risks and because it does not foster the acquisition of new knowledge²⁰.

15. On this distinction, see VAN CALSTER (2008), *op. cit.*

16. Expert Group on Science and Governance, 2007, p. 35.

17. On the importance of the distinction between risk and uncertainty: FEINTUCK (2005), *op. cit.*, p. 390.

18. FERRARI, A. (2010), “Developments in the Debate on Nanoethics: Traditional Approaches and the Need for New Kinds of Analysis”, *Nanoethics*, 4, p. 33.

19. ZIEGLER, A.S. (2006), “Threat to Converging Technologies”, *Annals of New York Academy of Sciences*, p. 342.

20. MARCHANT et al. (2008), *op. cit.*

This illustrates an inherent difficulty which is a characteristic of the precautionary principle: it was conceived to approach contexts that cannot be appropriately confronted through the model of acceptable risk, cost-benefit analysis, or reference to the best available technology²¹. It does not contain in itself the criteria and the tools to automatically fulfill this task. It therefore seems likely that the risk assessment framework will continue to be the dominant framework in this context²².

The shift from uncertainty to risk can lead us to miss the specificity of the precautionary principle. Such specificity is also reflected in some features of the provisions inspired by the principle, such as the need for flexibility, the temporary nature of the legal provisions and their openness to new information.

Given the broad definition of the precautionary principle and the function which has been assigned to it, the regulatory relevance of the precautionary principle seems to depend more on the clarification of the forms of its implementation rather than on its definition.

3. SHIFTING TOWARDS A CONSTRUCTIVE MEANING OF THE PRECAUTIONARY PRINCIPLE: CONSEQUENCES FOR A GENERAL VIEW OF REGULATION

A reasonable interpretation of the precautionary principle, as confirmed by the EU Commission Communication, demands on an understanding of the principle to be considered in risk (*rectius*: uncertainty) analysis that includes risk assessment and risk management²³. Such a perspective has the advantage of integrating analysis and management of risk, with important consequences for the conceptualization of the relationships among social assessment, regulation, and scientific analysis. This view involves the idea that defining risk requires both implicit and explicit ethical, social, and political choices and that applying the precautionary principle requires a preliminary prioritization of the values at stake²⁴. It is thus extremely im-

21. *Ibidem*.

22. Also see on this FERRARI (2010), *op. cit.*, p. 33.

23. DE SADELEER, N. (2006), "The Precautionary Principle in EC Health and Environmental Law", *European Law Journal*, 12, 2, p. 146; FEINTUCK (2005), *op. cit.*, p. 384.

24. SAGOFF, M. (2004), *Price, Principle, and Environment*, Cambridge University Press, Cambridge, p. 28.

portant to determine how the process of defining an acceptable level of risk can become a democratic one.

It follows that a sound understanding of the precautionary principle should not encourage regulators to embrace the strong meaning of the principle to such an extent that such a meaning turns out to be an inhibitory one. To adopt the precautionary principle should not be understood as the definitive word for the problem of uncertainty; rather, it should serve as the starting point for the construction of a system of assessment and management of uncertainty. This is the main reason to opt for a regulatory approach that integrates reactive, proactive, and anticipatory measures.

Regulation should foster a constant acquisition of information about the processes or the products at stake, with two main purposes: the reduction of uncertainty in risk assessment and the gradual construction of the notion of acceptable risk. In addition, public regulation should promote the creation of arenas in which the reflexive understanding of the consequences of technologies and their acceptability is possible.

In the case of nanotechnologies, at least as they are relevant to the domains that have been regarded as particularly worthy of being pursued and developed by the EU approach, regulation should fulfill three basic purposes: (i) promoting specific policy pathways; (ii) fostering the constant *improvement* of achievable safety standards; and (iii) encouraging the uniformity of standards.

Given these aims, the legitimacy of such regulations should not focus on the centralized and formal character of rule-making, but on some procedural advantages, considering both its ability to be open and warrant the joint participation of companies, government and stakeholders in a rule-making program and its suitability for a basis of proper private accountability pathways.

Resorting to excessive or solely “command-and-control” regulation may slow down the development of knowledge, give rise to inefficient regulation, and encourage “lex shopping” by the business community or by consumers. On the contrary, a mix of hard law and soft law, including self-regulation measures, would seem to be a sound alternative²⁵.

25. MARCHANT, SYLVESTER and ABBOTT (2008), *op. cit.* The potential of soft law measures in approaching nanotechnologies has been widely pointed out by the *Foresight Guidelines for Responsible Nanotechnology Development* (Foresight Institute, 2006).

“Soft law” usually refers to legal tools working on the basis of voluntary compliance and not supported by legally institutionalized sanctions. In this sense, “soft law” includes (i) declarations and opinions worked out by governmental and non-governmental organizations or by national, supranational, and international institutions; (ii) technical regulation based on standards or self-regulation, such as codes of conduct or audit systems (voluntary self-regulation) and (iii) private regulations enforced by the government (enforced self-regulation)²⁶.

In order to examine the idea of a regulatory framework characterized in this fashion, any formalistic view of law should be abandoned in favor of a legal view that acknowledges the social sources of legal phenomenon²⁷. A conscious mix of hard and soft law would have the flexibility as well as the dynamic character required to manage the potential side effects of emerging technologies²⁸. A regulatory framework should not limit itself to prohibiting or commanding, but should foster knowledge processes. It should construe arenas for “bidirectional learning”, through which not only the knowledge of consequences and the gradual transformation of uncertainty into risk becomes increasingly possible, but also the suitability of the regulatory measure in question can be evaluated through constant communication between the normative framework, scientific knowledge and the social context. Appealing to self-regulation could facilitate the sharing of responsibilities, taking advantage of information flows, and giving a voice to experts: thus, regulations would gain efficiency²⁹.

In contrast, critiques of soft law underline its lack of certainty and its tendency to erode rationality in legal norms³⁰. In particular, self-regulation could contribute to legal fragmentation by multiplying legal regimes³¹, fos-

26. AYRES, I. and BRAITHWAITE J. (1992), *Responsive Regulation: Transcending the Deregulation Debate*, Oxford University Press, New York, pp. 103 ff.

27. WITTEVEEN, W.J. (2005), “A Self-regulation Paradox: Notes Towards the Social Logic of Regulation”, *Electronic Journal of Comparative Law*, 9, n. 1, <http://www.ejcl.org>.

28. ABBOTT, K.W. et al. (2006), *A Framework Convention for Nanotechnology?*, ‘Environmental Law Reporter’, 36, pp. 10931-10942.

29. OST, F. (2008), *Dalla Piramide alla rete: un nuovo paradigma per la scienza giuridica?*, in M. VOGLIOTTI (a cura di), *Il tramonto della modernità giuridica. Un percorso interdisciplinare*, Giappichelli, Torino, pp. 29-48, p. 44.

30. KLABBERS, J. (1998), “The Undesiderability of Soft Law”, *Nordic Journal of International Law*, 67, pp. 381-391.

31. KLABBERS, J. (1996), “The Redundancy of Soft Law”, *Nordic Journal of International Law*, 65, pp. 167-182.

tering technocratic trends, and moving away from the democratic representation perspective.

When defining a regulatory model, three basic elements should be taken into consideration: (i) the principles embodied by the model; (ii) the technical standards implied by the model; and (iii) the mechanisms of enforcement and the reasonable degree of compliance which can be available or constructed³². The view of law and regulation that is widespread within civil law culture tends to give little relevance to enforcement, and more generally, to the link between norms and social context. In contrast, some theories of regulation, for example, the theory of "responsive regulation"³³, are meant to acknowledge the role of social context and enforcement in shaping regulatory models.

The element of uncertainty and its qualitative distinctiveness from risk may, in my view, justify soft law as a useful subsidiary tool. While some believe it could be a way of diminishing responsibility, soft regulation actually seems to foster the *distribution* of responsibility and to promote stakeholders' participation. The active involvement of businesses and epistemic communities in regulations could increase information as well as normative compliance. For example, businesses are "strategic" addressees of regulation, since they are able to strengthen communication toward other subjects (employees, suppliers, partners, consumers, local or expert communities, and the environment). This approach is coherent with the acknowledgment of the role that private actors play in determining both normative effectiveness and normative efficacy, and underscores the importance of accountability, which concerns both private subjects and public authorities.

If and how much self-regulatory tools may succeed in this aim naturally depends on the success of constructing communication and monitoring mechanisms for the activities of enterprise (quality and purposes of R&D, features of the life-cycle of products, respect for the environment, respect for consumers and employees' rights, and promotion of social needs). It also depends on the choice of the proper form of delegation from governmental power to private entity.

In this sense, it is intriguing to see if regulatory models at some point could overcome the dichotomy between private and public by expressing

32. On the role of the enforcement to determine the quality of regulation: BALDWIN, R. and CAVE, M. (1999), *Understanding Regulation. Theory, Strategy, and Practice*, Oxford University Press, New York, p. 117.

33. AYRES and BRAITHWAITE (1992), *op. cit.*; BALDWIN and CAVE (1999), *op. cit.*

the distinction between state and society in terms of “policontextuality”, i.e., the idea that several social perspectives are reflected in the law, without a distinction among them always being possible³⁴. This could be a way of overcoming the view that allowing room for self-regulation encourages the eclipse of public authority by private interests³⁵. Such a phenomenon has been often explained in a superficial way: according to popular opinion, the spread of private law categories is explained by their proximity to economic interests. This explanation overlooks what seems to be another important reason: the specific proximity of private law categories to social contexts which is becoming a leading factor for determining the success of regulatory models, to the extent that state sovereignty is becoming weaker. The key element for understanding and framing regulatory inputs in light of transnational issues that have arisen as a result of technological development lies in the centrality of the nexus between law and society. This idea has been neglected and even rejected by the formalistic view of law prevailing in the modern age, but must be retrieved to face the challenges posed by globalization and the diffusion of technology.

Soft law, specifically in the sense of self-regulation, may have a significant degree of compliance, since the juris-genesis here tends to rest on the validity associated with the norms. Norms originate because the subjects contributing to their formation and diffusion acknowledge their validity and agree on their purposes. In contrast, in the case of command-and-control regulation, sanction is the key to effectiveness, and a deficit of control of compliance tends to become a structural deficit of enforcement. This is why soft law may be even more effective than legally and formally binding norms³⁶.

34. TEUBNER, G. (1999), *Diritto policontesturale: prospettive giuridiche della pluralizzazione dei mondi sociali*, trad. it. La Città del Sole, Napoli, p. 146.

35. FERRARESE, M.R. (2000), *Le istituzioni della globalizzazione. Diritto e diritti nella società transnazionale*, il Mulino, Bologna, especially ch. III; FERRARESE, M.R. (2006), *Diritto sconfinato. Inventiva giuridica e spazi nel mondo globale*, Laterza, Roma-Bari; GALGANO, F. (2005), *La globalizzazione nello specchio del diritto*, il Mulino, Bologna, ch. IV; ROSSI, G. (2003), *Il conflitto epidemico*, Adelphi, Milano.

36. PARKER, C. (2002), *The Open Corporation. Effective Self-Regulation and Democracy*, Cambridge University Press, Cambridge; AYRES and BRAITHWAITE (1992), *op. cit.*, especially pp. 103-116, where it argues for a regulatory model based on public enforcement of privately promulgated standards, understood as a form of delegation or subcontracting of regulatory functions from the government to the regulated private subjects.

Of course, specific legitimization issues arise in soft law. One of the most frequently used arguments against self-regulation emphasizes its democratic deficit. According to this argument, law stemming from civil society without legislative formalization (or delegation) would seem to lack any democratic legitimization. This could be addressed by stressing that self-regulation must adapt to the legal order (its principles and sources) and can regulate matters in-depth by following a “bottom-up” perspective, seeking for precision but also flexibility, and taking advantage of the role private actors could play in promoting a good quality of regulation and compliance. In a globalized world, self-regulation measures could even claim a democratic character, to the extent that normative measures are based on information sharing and stakeholders’ participation.

Provided, therefore, that the efficacy of the precautionary principle depends on the method of its implementation, soft law measures that may underpin forms of diffuse participation and responsibility, as well as accountability toward risk assessment, communication, and management could be a sound solution. This is the solution that seems to be suggested by the “Code of Conduct for Responsible Nanosciences and Nanotechnologies Research” adopted by the European Commission in 2008 (Resolution 2008/345/CE).

Considering the insufficiency of most traditional risk management models in confronting the uncertainty that characterizes the consequences of emerging technologies for the environment and human health, such an issue does not concern going *beyond* the precautionary principle adhering to it³⁷, but rather to search for the soundest meaning of this principle through coherent and effective regulatory measures.

37. SUNSTEIN, C.R. (2005), *Laws of Fear. Beyond the Precautionary Principle*, Cambridge University Press, Cambridge (Mass.).

Resumen: *El trabajo trata sobre el impacto de las nanotecnologías en la regulación legal y parte de la idea de que las tecnologías emergentes ofrecen una excelente perspectiva desde la cual analizar el paso del gobierno a la gobernanza que es típico de nuestros días.*

Las nanotecnologías afectan a varios aspectos legales, entre ellos la protección medioambiental, la protección de los consumidores, el derecho médico, la salud y seguridad laborales, y las libertades civiles, los derechos de propiedad intelectual y el derecho de patentes.

El trabajo desarrolla tres puntos fundamentales: 1. la aplicabilidad de los productos nanotecnológicos y de los procesos jurídicos actualmente vigentes a otros supuestos; 2. el significado, papel y límites del principio de precaución; 3. el papel del soft law en la gobernanza de las nanotecnologías.

El trabajo parte de un significado constructivo del principio de precaución y de que ese significado sólo se puede clarificar a través de la implementación del principio; la autoregulación y el soft law se ven como una forma adecuada de regulación si están unidos a un hard law, para implementar el principio de precaución y para reducir la incertidumbre que provocan las nuevas tecnologías.

Palabras clave: Nanotecnologías; nanomedicina; derecho y tecnología; principio de precaución; regulación reactiva; soft law; gobernanza de las nanotecnologías.

Abstract: *The paper deals with the impact of nanotechnologies on the view of legal regulation and moves from the idea that emerging technologies offer an excellent perspective from which to analyze the shift from government to governance, that typically occurs nowadays.*

Nanotechnologies affect many legal domains, including environmental protection, consumer protection, medical law, occupational health and safety, privacy and civil liberties, intellectual property rights, and patent law.

Three main issues are addressed in the paper: (1) the applicability to nanotechnology products and processes of the law already in force for other purposes; (2) the meaning, role and limits of the precautionary principle; (3) the role of soft law in the governance of nanotechnologies.

In the paper, a constructive meaning of the precautionary principle is embraced; it is maintained that such meaning can only be clarified through the implementation of the principle; self-regulation and soft law are thought of as a form of regulation suitable, if properly joined with hard law, to implement the precautionary principle and to manage the uncertainty arising from emerging technologies.

Key words: Nanotechnologies; nanomedicine; law and technology; precautionary principle; responsive regulation; soft law; governance of nanotechnologies.

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