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Nanotechnologies and Health: Juridical and Philosophical Implications

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Nanotechnologies and Health: Juridical and Philosophical Implications

Abstract: Although their applications have not yet extended widely due to their incipient state, nano-technologies and nano-medicines may be presumed to be at the origin of the next great technological revolution, foreseeably contributing to a new stage with respect to evolutions in mankind's progress. Their possibilities are truly immense in enormously varied spheres, but the risks and uncertainties they engender are enormous too. Because access and use of the unceasingly increasing mega-quantity of information they generate will place further strain on the protection of personal life, privacy, the exercise of freedom, as well as the safeguarding of other fundamental principles and rights.
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I. Beyond a doubt, in the past decade the rise in nanotechnologies has been incessant. The possibilities that emerge from the convergence of the various disciplines involved are obviously enormous. But the challenges raised in various fields are daunting as well.

We consequently see the emergence of inevitable questions, such as: what might be the effects of nanoparticles on states of health and the environment? What grade of toxicity and what level of health risk might nanomaterials generate?

On the other hand, what effects might these nanoproducts have if they are introduced into the food chain? And, due to their microsize, will these new ultra-fine particles be able to cross cellular membranes like the skin, e.g., ordinarily protecting the organism against external aggressions?[1]

Also, from the labor aspect, unavoidable questions arise too, like those involving ways of detecting these nanoparticles and how to protect workers from them. With respect to the economic dimension, the repercussions will also be quite varied. For example, the downsizing of products developed will considerably lower manufacturing costs, as well as distribution and sale estimates. But that process will have consequences in the developing countries that are the main suppliers of minerals and metals as raw materials.

From another perspective, both the access and use of an enormous mass of information – that is constantly increasing – via microprocessors, will be able to place at risk the respect and

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[1] Andrew D., Maynard-Eileen D. Kuempel "Airborne Nanostructured particles and occupationel health" in **Journal of Nanoparticle Research**, 2005, 7, pp. 587-614.

protection of fundamental rights relating to private life, in reference to aspects of intimacy or privacy, unless that information mass be subjected to a certain control.

Therefore it is hardly surprising that from 2004 on the European Commission has repeatedly called for a "frank (approach) to the potential risks to public health, security, the environment or consumers in general, generating the data necessary for evaluating those risks, and integrating the risk evaluation into every stage of the lifecycle of products produced by nanotechnologies"[2]. The same might be said of UNESCO and its manifest interest in encouraging a process of prospective reflection on the course of recent developments in new technologies and, particularly, in nanotechnologies[3].

Along these lines, the European Commission has promoted 'a public consultation' (2008) on the project of a code of conduct for responsible investigation in the domain of nanociences and nanotechnologies. This Code will be founded on respect for the Charter of fundamental human rights of the European Union, on the European Convention on the Rights of Man, the European Convention on Human Rights and Biomedicine signed in Oviedo, and the Aarhus Convention concerning access to information, public participation and respect for the environment.

The expected form will involve a recommendation from the European Commission and will invite Member States, industry and universities, as well as other economic and social agents, to follow determined criteria, in particular three basic principles: "precaution, inclusiveness and integrity"[4].

Basing ourselves on these references, It is easy to see the obvious need and desirability of addressing the applications and implications of nanotechnologies from a bioethical perspective. There is really a lot at stake. And the balanced and interdisciplinary reflection of the human, social and juridical sciences cannot remain on the margins or insensible to the challenges coming from these new technologies.

Only in this way will it be possible to avoid, on the one hand, the utopian dreams, optimistic in character but unreal and negligent, that some propose, with unforseeable long term effects[5]. And, too, on the other hand, we will be armed with data, analysis and rational

[2] Hervé-Fournereau, N., "La sécurité sanitaire et écologique vis-à-vis des nanomateriaux" in **Cahiers Droit, Science et Technologies,** 2008, p. 59.
[3] Cf. **The Ethics and Politics of Nanotechnology**, or "L´éthique et les orientations de la nanotechnologie" UNESCO 2006, in Henk A.M.J. ten Have (Ed.), **Nanotechnologies, éthique et politique**, Paris, UNESCO, 2008, p. 32.
[4] Hervé-Fournereau, N., "La sécurité sanitaire et écologique vis-à-vis des nanomateriaux" in **Cahiers Droit, Science et Technologies,** 2008, p. 82.
[5] G. Hottois , **Entre symboles st Technoscience**, Editions Champ Vallon, 1996, p. 99.

arguments against the possible apocalyptical nightmare sometimes accompanying speech and debate on the future of nanotechnologies.

And in fact the challenges of nanotechnologies do not just concern the fields of health or the environment. They are also challenges impregnated with a cultural, ethical and anthropological character – broadly speaking. Additionally, as Weill moreover warns, they appear as strategic in the economic, and even military, spheres[6]. Nor are they in any way alien to political, juridical and social dimensions, taking into account the international dimension of the markets – i.e., their global character[7].

Once again, as happened with the Human Genome Project, at the request of Dr. J. Watson, simultaneous reflection during the investigation and application process (but, not a posteriori as had occurred until then with other scientific projects) on the various ethical, juridical and social implications (ELSI), becomes unavoidable[8]. And inaugurating access to an open domain, not restricted to the most interested agents, cannot be postponed.

This is also the proposal that is most readily agreed to, as J.P. Dupuy affirms, openly defending a process of reflection in real time on the changes and transformations originating in scientific and technical exchange. Because it makes no sense to hope to know the results and react later.

On the contrary, this is to be done precisely in order to advance at the same speed as its development and, if possible, "anticipate its projection by means of impact studies and a permanent monitoring, no less interdisciplinary than that characterizing nanociences[9].

Only in this way will we realize the need to integrate the treatment of nanomaterials into the laws of health and environmental risk, for it adds up to an unavoidable exigency, as we shall see now.

II. If we now approach nanotechnologies more concretely from a juridical point of view, the first thing that should be noted is that present-day regulations seem inadequate because they are insufficient. Various organizations work to regulate and provide answers to the questions emerging in the development and application of nanotechnologies.

This is the case e.g. for European programmes like Nanosafe, Nanoderm or Shape Risk. In this respect, AFNOR (French Association for Standardization), CEN (European Committee

[6] Gaffet, E., **Cahiers Droit, Science et technologie,** 2008, p. 21, Hullman, A., **The economic development of nanotechnology. An indicator based in analysis.** Comisión Europea, DG Research, 2006.
[7] Weill, C., Ibídem, p. 42.
[8] Blázquez-Ruiz, F. J., **Derechos Humanos y Proyecto Genoma**, Granada, Comares, 1999.
[9] "Pour une évaluation normative du programme nanotechnologique" 19/12/2003. Cf. Hervé Fournereau, N., Ibídem, p. 71.

for Standardization), as well as the ISO (for International Organization for Standardization) try to elaborate standards concerning nanotechnology and nanopartícles.

In fact, a high degree of uncertainty really does exist on the derivative risks related to the use of nanotechnologies. This uncertainty, sometimes generating fear, leads us to think that we are faced with conditions and circumstances that justify a thorough application of the precautionary principle.

In this way we will be able to closely follow the development of nanotechnologies, classifying and orienting them, simultaneously specifying both their positive and negative aspects.

Because today, obvious lacunae exist with respect to the treatment of potential nanotechnological risks. These lacunae are due to the relative newness of these nanofabricated materials; this has brought about a certain temporary unbalance between the juridical understanding of the risks and, on the other hand, the latters' scientific evaluation.

Echoing this concern, the European Parliament has proposed incorporating specific provisions referring to nanoparticles – in the Reach regulation, with a view to ensuring an "adequate evaluation of the latters' security"[10].

In this respect, it helps to realize that the production of standards regarding laws governing health and environmental risks is to a good degree "sophisticated" – to such a point that we can say with Hervé-Fournereau that "its family tree resembles an ancient labyrinth"[11].

In this sense, since 2004, numerous European and internationally-based information sources, recognize the potentiality for health and environmental risks, while insisting on urgently intensifying investigations. These studies have repeatedly pointed out the absence of relevant scientific data, such as: census and characterization of materials, sectors of the population exposed to risk, deficits in methodologies as well as standardized and validated measurement tools, etc.[12] The few published studies that examine the interactions of nanoparticles at cellular levels, invite caution.

In 2004 – in fact – the European Commission organized a workshop on the risks of nanotechnologies. They considered five possible scenarios concerning health and environmental impacts. Concretely, they consist in: laissez-faire, establishing a moratorium,

[10] Recommendation for the 2nd reading relative to the common position of the Council in view of adopting the regulation of the European Parliament (EP) and of the Council concerning the registering, evaluation and authorization of chemical substances, as well as restrictions applicable to substances (Reach), reporter Guido Sacconi, Amendment 24 (Considering 104 bis (new)) A6-0352/2006 13/10/2006.
[11] Hervé-Fournereau, N., Ibídem, p. 59.
[12] Hervé-Fournereau, N., Ibídem, p. 66.

resorting to voluntary approaches, the adoption of specifically targeted legislation and the progressive adaptation of existing legislation.

Among such possibilities, the Commission clearly showed its preference for resorting "to existing regulations, as much as possible". And it voiced its frontal opposition to the possibility of applying a clear and explicit moratorium, considering that option "dangerously counter-productive[13].

As we indicated before, in this respect, the proposal to apply the juridical precautionary principle as a regulating criterion seems more than reasonable – in terms of responsibility. In fact, the precautionary principle included in the European Union Treaty of Maastrich was later ratified in the Treaty of Amsterdam, and later in the Treaty of Nice.

These texts, amounting to pillars of EU jurisprudence with respect to environmental protection, subsequently resulted in jurisprudence – both European and national – extending its reach "to health risks".

Nevertheless the standards existing – until the moment when responsibility and reparation regarding health and environmental damage be regulated - are obviously paltry and, hence, insufficient. Consequently, for technical reasons, it is difficult to impute responsibilities in cases of damage[14].

III. Undoubtedly, once further information is available on the risks of nanoparticles, it will be that much easier for both health professionals and patients to make decisions. That decision-making process, accepting the risk-benefit tradeoff at the time of confronting a diagnosis or a therapeutic treatment in which nanoparticles are included, will be carried out in the same way "as that currently practiced with all implemented diagnostic and therapeutic procedures that have the scientific community's acceptance[15].

Nevertheless, it should be pointed out that there is a glaring difference, not only as to the difference but also the disproportion, existing between nanotechnological investment and budgets assigned for analyzing security and health risks. Hence it will not be easy to simultaneously realize a precise determination of the benefits and risks of nanomaterials. Both of which, it should be pointed out, are potential.

[13] Nanotechnologies Workshop, a preliminary risk analysis on the basis of a workshop, 1º and 2/3/2004, Bruxelles. http://ec.europ.eu/health/ph_risk_en.htm.
[14] Weil, C., Ibidem, p. 52.
[15] Buisán, L., "Sobre la toxicidad de las nanopartículas en el ámbito de la nanomedicina" in Casado, M., Coord. **Bioética y Nanotecnologías,** Civitas-Thomson-Reuters, 2010, p. 205.

On the other hand, studies and directed tests to minimize the risks of nanomaterials throughout their life cycle will require the cooperation of multidisciplinary investigations, that, still, in certain cases will make use of size scales superior to those of nanometry[16].

Doubtlessly protecting people exposed to the potential risks of nanomaterials requires information adapted to such risks in accordance with laws on access to information and the principle of transparency. This demand for public information is encountered regularly in all recent texts on environmental and health law.

In this sense the European Commission recognizes that it is "imperative that the development of nanotechnologies be open, traceable and controlable, in conformity with democratic principles". But it additionally insists on the need to open channels of information to society, while it invites Member States "to adopt an overture, a frank rapprochement and a dynamic dialogue with respect to R&D policies on nanotechnology, with a view "to gaining the interest and confidence of the greater public"[17].

In this respect, we should bear in mind that an increasingly visible and established tendency exists, consisting in allocating and shifting a part of the financing of basic theoretical investigation towards applied investigation, to the detriment of a more fundamentals based education. As Schumer proposes, it would be advisable to include ethical contents and proposals/scenarios in scientists' academic formation, so as to avoid falling into the practice of investigations considered to be "ethically neutral"[18].

A practice that can in some sense erode and devalue – in this case by omission – exercise of the responsibility principle, which, as is well known, constitues the fundamental principle of the normative order in both ethical reflection and law.

And consequently, as we indicated earlier, this may affect access to sensitive, valuable information, related to personal aspects, meaning of a private character and intimate, which may eventually lead to a possible infringement on fundamental rights.

So, after all, it is not surprising that a good part of public opinion voices an ever increasing demand for "the establishment of guarantees safeguarding citizens against technological invasions of their privacy"[19].

[16] Weil, C., Ibídem, p. 41.
[17] Ibidem, p. 81.
[18] Schumer, J., Ibídem, p. 101.
[19] Pérez-Luño, A.E., "El derecho a la intimidad en el ámbito de la biomedicina" in Martínez, N., Coord., **Biotecnología, derecho y dignidad humana**, Granada, Cátedra Derecho y Genoma, Ed. Comares, 2003, pp. 261-287.

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