Nanomaterials and the environmental risk: is there some room left for ethics and law?

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SUMMARY

How legitimate may be the concern posed by the nanotechnologies for health and environment,this effort for reaching a better knowledge of the biotoxicity of nanomaterials is not enough. As Pr. Didier Sicard noted, we believe that the ethical reflection should not be the good conscience that may help science in getting rid of social fears. But the ethical reflection is there also to discuss taboo issues in the perspective of a better societal understanding.

Key-words: Nanotechnology, Science, Technology, Environment, Legislation, Social control over science, Risk, Risks and benefits, Health hazards, International Cooperation, Health policy, Precautionary principle, Europe, European union, United States, France, Debates.

RÉSUMÉ

LES NANOMATÉRIAUX ET LE RISQUE ENVIRONNEMENTAL. QUELLE PLACE POUR L'ÉTHIQUE ET LE DROIT ?

Quelle que soit la légitimité des préoccupations posées par les nanotechnologies en matière de risque pour la santé et l'environnement, une meilleure connaissance de la toxicité des nanomatériaux n'est pas suffisante. Toutefois, comme le Pr D. Sicard l'a relevé, nous ne pensons pas que la réflexion éthique doit se contenter d'être la bonne conscience qui aide la science à se débarasser des peurs sociales car la réflexion éthique est aussi là pour discuter des questions tabous dans la perspective d'une meilleure compréhension sociale.

Mots-clés : *Nanotechnologie, Science, Technologie, Environnement, Législation, Contrôle social de la science, Risque, Risque bénéfice, Risque pour la santé, Coopération internationale, Politique de santé, Principe de précaution, Europe, Union européenne, États-Unis, France, Débat.*

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INTRODUCTION

No doubt that nanotechnology is offering new scientific perspectives and new industrial applications that may be used to solve backside effects of existing technologies or to extend our control on communication, energy… However, we should not be so presumptuous to ignore our limits.The recent experience of nuclear energy or genetic engineering delivers us a message. It is no more possible to engage into at risk industrial activities without being able to set up an appropriate societal reflection on risk acceptability and on our capacity of controlling such risk.

I. A SOCIETAL APPROACH OF THE RISK

In its informative brochure on "The Ethics and Politics of Nanotechnology"[1], UNESCO states that "the most pressing near-term issues related to nanotechnology are toxicity and exposure to humans and the environment. This is more properly a safety and health issue-not an ethical or political issue".

I would like to express my deep disagreement to this approach for two reasons.

First, the question of the fear we may have concerning the implications of nanotechnology on our health and environment is not simply a rationale technical issue about toxicity and exposure. It is a more global concern about how meaningful are such risks for our life project and the vision we have of the importance of technoscience for our society.

Second, and this time the UNESCO document acknowledges the limits of "risk management"[2], it would be illusory to think that technical standards and codes of good practices may solve the societal concern raised by the development of nanotechnology. Ethics and law have certainly to take part in this debate to incorporate as much as possible its social, cultural and anthropological components in order to facilitate public discussion but merely to bring society and science to common trust.

And that would be the true meaning of bioethics: building a bridge to the future[3].

A. Should we fear the impact of nanomaterials on health and the environment?

The world known Belgian singer, Jacques Brel, in his last interview was asked about the fact he liked to take risks. His reply was that the whole life was a lethal risk[4]. If we may agree that risks are consubstantial to human life, we may also remind that the social acceptability for risks may differ according to different cultures, social or economical contexts. A struggle for life will incite the stake holders to consider taking wider risks while a sustainable development may imply to reduce the risks.

The way we live with industrial risks is also deeply related with those different interactions.

Since the XVI century Renaissance time, the conjunction of arts, religion and politics have supported in Western countries the stream which gave birth to industrial revolution, democracy, free market and individual autonomy.

This positive approach based on rationality and progress collapsed with the Second World War after we took conscience that misuses of science and medicine could lead to massive destruction of population and even, with the nuclear bomb, to the destruction of our planet. More recently, this awareness extended to types of risks in relation with regular human activities such as biochemical industries and genetic engineering. From Minamata (Japan, 1932-1966)[5] to Seveso (Italia, 1976)[6], Bhopal (India, 1984)[7], Chernobyl

1. UNESCO, the Ethics and Politics of Nanotechnology, UNESCO, Paris, 2006.
2. "While ("risk management" has the benefit to accurately stating the risks…of newly created substances, materials and devices, it does not address any wider issues of the ethical or political meaning of this risk", UNESCO, the Ethics and Politics of Nanotechnology, UNESCO, Paris, 2006, p.14.
3. Van Rensselaer Potter, Bioethics; Bridge to the Future, Prentice Hall, Clifford (New-Jersey), 1971.
4. Jacques Brel, interview to the Belgian television RTBF, Knokke, 1971, *beemp3.com/download. php?file=1045621&song=Brel+Parle+(Interview+1971+%C0+Knokke)*.
5. Timothy S. George. Mina Mata: Pollution and the Struggle for Democracy in Postwar Japan. Cambridge, Mass.: Harvard University Press, 2001.
6. A. Ballarin-Denti, S. Facchetti, A. Ballarin Denti, Chemistry, Man and Environment: The Seveso Accident 20 Years on : Monitoring, Epidemiology and Remediation : Proceedings of the Meeting Held in Milan, Italy, 21-22 October 1996.
7. Amnesty International, Clouds of injustice, Bhopal disaster, 20 years on, London, 2004.

(Ukraine, 1986)[8], AZF, (France, 2001)[9], and Fukushima (Japan, 2011) we have now experienced a long series of industrial accidents which have resulted in a complete reversal of social acceptability of new scientific applications. This is the reason why before sorting and evaluating the types of risks concerned we have now to deal with the question in which kind of society we would like to live?

1) What benefice are we expecting from new industrial risks? For what kind of society? What kind of humans?

Perhaps the originating point of this discussion is the lecture by the famous physicist Richard Feynman called "There's plenty of room at the bottom"[10] in which this Nobel laureate laid out with bravado all the possible ways in which miniaturization, computer and information technologies and physics can be used to explore the sub-microscopic world . Forty years later, not only many engineers and scientists are still excited by these predictions but also policy makers have found in nanotechnology a new way for industrial development. This has raised a high competition between economies, the new ones trying to emerge and the old ones tempting to maintain their industrial capacity[11]. We may understand that they have different interests and that the request for a safer environment imposed by public opinion in western countries may face an argument for a right to access economical development and consumption society for the emerging economies. At the global level the nanotechnology issue is certainly an important element of the contemporary debate of how far and for what purpose we should develop our technoscientific economy.

Another reflection at the global level concerns the sociological and anthropological implications of nanotechnology. Will the extend of their applications lead to easiest social control and to "big brother" society? The temptation would be great to use them for fighting new types of criminality such as international terrorism but also to elaborate programs to control the expenditure of pandemics… Will the incorporation of nanomaterial in our clothes, our food and drugs and in our every day products make our biology and our body, including our brain, more relying on artefacts? Could it affect our anthropology?

Finally, at a more focused level, we will find that nanotechnology are presenting real advantages or at least potential benefits (for example it would allow to prepare individually targeted drugs that would limit the adverse effects of existing drugs or it could help us to provide people with easiest access to communication or better using the energy resources) and then we will have to prepare ourselves to this future by adopting specific policies.

In all cases, we will have to identify the risks and to develop a system for evaluating them with the capacity to move from experimental research to large scale industrial applications.

2) What kind of risks? How to evaluate the risks?

Two main reasons explain the specific attention we should pay to the risk implication of nanotechnologies. First, the nanoscopic scale creates a complete change in our understanding of physical law. We are loosing one's points of reference. For example carbonic nanotubes are a hundred times more resistant than steel while they are six time lighter. Second, nanotechnological applications are already there and are part of various products we are commonly using: cellular telephones, micro-ships, cosmetics, glasses, socks, food-packing, paintings… And most of these new products were elaborated without any knowledge of potential implications on health and the environment. So a lot of questions are raised regarding the types of risks and the way we could evaluate them.

a) Identifying the risks

We may identify the following group of questions:

– Is there a significant risk for the population to be exposed to nanoproducts and what would be the effects of this exposure on human health?

– Can nanomaterials be released in the environment? In which form and quantity? What may be the effects of this release?

8. WHO, Health effects of the Chernobyl accident: an overview, Fact sheet N° 303, April 2006, Geneva
9. L. Bonnaud, E. Martinais, Les leçons d'AZF, La Documentation française, Paris 2008.
10. By this now famous sentence Richard Feynman announced in 1959 during a conference at the Caltech what he believed was the future exploration of the nanoworld.

Although incomplete the scientific data may already be worrying. Nanoparticles can cross the biological barriers separating the air which is in our lungs from the blood which flews in our arteries, our blood from our brain and the mother's blood from the fetus 'one. As nanoparticles can also penetrate the nucleus of a cell, carbonic nanotubes have been classified for their capacity to induce genetic mutations as potentially carcinogenic.

Concerning their transformation and degradation mechanisms, we still know very little about the way they behave in different media such as air, soil, water or in living organisms (humans, animals, plants). The question is then: is there any risk created by a potential bioaccumulation? Moreover, we have to take into consideration their high capacity of translocation[12].

b) Risks and governance

Policy makers are particularly aware of the importance of controlling the risk issue as a necessity for developing nanotechnology industry and many countries have supported initiatives to analyse these risks.

In France different scientific institutions have reported on the risks of nanotechnologies[13] and other countries may also be quoted for their national reports[14].

But the research process on the risk issue is not limited to the countries which developed nanotechnologies. So, it became very quickly a matter of international concern as we may note from the initiatives of the European Commission, OECD, the United Nations organizations as well as the informal International Dialogue Conferences on nanotechnologies.

This rapid involvement of many international organizations in the relatively new field of nanotechnologies might appear as an important change in the governance of scientific applications. But for some think thanks this perception of the so called global approach of nanotechnologies is illusory. They observed that this concern came quite late after hundreds of nanoproducts have already been developed. Furthermore, the contributions of so many institutions each having a specific mandate and with no global coordination makes the process very slow and less than global. Finally, the expression "governance" is a politically correct term used to elude the real ethical and political issues, the lack of socio-economic, environmental and health impact studies.

B. How may ethics and law take part in balancing risks and benefits?

In publishing its 2003 report the Canadian think thank ETC warned us that the most powerful nanotechnologies are emerging in a space which has no rule or policy to govern them and a former chair of the French National Bioethics Committee reminded us that the ethical reflection should not be the good conscience that may help science in getting rid of social fears.

Consequently it is our view that the ethical reflection is there to point out all the risks with the idea that publicly discussing the risks is the only way to build trust between nanotechnologies and society.

1) A Reflection that must point out all the risks

At the beginning of the years 2000 there was an international consensus, regarding health and environmental issues of new materials, that "the most urgent ethical issues are the possible health and environmental risks of nanoparticles due to a substantial gap in all national and transnational regulations". Policy makers are now aware that the promotion of nanotechnologies will largely depend on a reliable system for preventing the risks. And this policy implies to define what is a nanotechnology, to identify the nanoproducts and the risks and to set up appropriate regulation mechanisms to control them. Although different strategies may be discussed to reach these

11. In 2001 The Us Government Launched The National Nanotechnology Initiative For Which The National Science Foundation Has Become A Leader In Funding. Following This Initial Surge Of Research Money In The Us, Several Other Nations Have Begun Funding Nanotechnology: Japan, The European Union Among Which France And The U-K, And More Recently China, Iran, Brazil And Israel.
12. F. Marano, Les Problèmes Poses Par L'évaluation Des Risques Des Nanoparticules Sur La Santé, Dossier Nanotechnologies Et Santé Publique, Actualité Et Dossier En Santé Publique, N°64, Septembre 2008, P. 35.
13. Rapport Office Parlementaire D'évaluation Des Choix Scientifiques Et Technologiques (Opecst), Nanosciences Et Progrès Médical (2004) Www.Senat.Fr/Rap/R03-293/R03-293.Html ; Rapport Du Comité De La Prévention Et De La Précaution, Nanotechnologies, Nanoparticules : Quels Dangers, Quels Risques ? (May 2006) Www.Ecologie.Gouv.Fr/Img/Pdf/Nanotechnologies_Juin_2006.Pdf_;
14. Agence française de sécurité de l'environnement et du travail (AFSSET), Les nanomatériaux, effets sur la santé de l'homme et sur l'environnement (July 2008) www.afsset.fr/upload/ bibliotheque/367611898456453755693572842048/nanomateriaux.pdf

objectives, no doubt that risks control is an essential step of the ethical and legal reflection on nanotechnology. But this step has clearly to take into account that both "the new opportunities expected from nanotechnologies and the new health and environmental risks go hand in hand. For this reason, there is an urgent need to define new standards for testing the safety of these products and their abrasion and to make these standards the basis for new regulations". Contrary to the asbestos contamination scandal, we should not wait years and years to incorporate into our regulations the knowledge that we may obtain about toxicity of nanoparticles. It is why research on long term effect should no more be neglected.

2) An objective: building trust between new technoscience and society

But this effort for reaching a better knowledge of the biotoxicity of nanomaterials is not enough. As Didier Sicard, we believe that the ethical reflection is there also to discuss taboo issues, not to create unjustified fears but to ease social understanding and, in some way, acceptability of new techniques.

For example, we should not ignore the impact of nanotechnologies on food and agriculture. Combining nanotechnologies, biotechnologies and industrial property may lead to some radical changes in food production and distribution. Especially, industrial secrecy should not be used to keep confidential information that would be successful to assess risks.

Because some products based on nanoparticles or nanostructured composites are already on the market and many more are in the pipeline, there is an urgent need to define new standards for testing the safety of these products and their abrasion. In addition, there is an urgent need for the much-too-long-neglected research in nanoparticle toxicolology, as well as in methods for making nanoparticles safe by surface treatment or encapsulation. The need for transparency is therefore essential to build a new trust between science and society.

II. THE PRECAUTIONARY PRINCIPLE AS A DYNAMIC RULE TO ANTICIPATE AND MANAGE THE RISK

The present remarks about the urgent need to define standards for evaluating the risks raised by the development of nanomaterials may justify the idea that there is a legal gap in this new technological field.

The question is nevertheless more complex because the lack of specific regulations may be compensated by the existence of strong general principles, such as the precautionary principle which can be used as a dynamic rule to develop policy making. However, although we are not building nano regulations on sand, we still face to major choices such as: should we impose a moratorium on some nanotechnologies? Should we adopt specific regulation for the others?

A. How the risk induced from nanomaterials fit with the precautionary principle?

The precautionary principle is a moral and political principle which states that if an action or policy might cause severe or irreversible harm to the public or to the environment, in the absence of a scientific consensus that harm would not ensue, the burden of proof falls on those who would advocate taking the action.. The principle implies that there is a responsibility to intervene and protect the public from exposure to harm where scientific investigation discovers a plausible risk in the course of having screened for other suspected causes.

The precautionary principle may be formulated in different ways but all definitions of the principle have two key elements and imply policy action to transpose them to the scientific applications concerned.

1) The key elements of the precautionary principle are:

a) an expression of a need by decision-makers to anticipate harm before it occurs. Within this element lies an implicit reversal of the burden of proof: under the precautionary principle it is the responsibility of an activity proponent to establish that the proposed activity will not **(or is very unlikely to) result in significant harm.**

b) the establishment of an obligation, if the level of harm may be high, for action to prevent or minimize such harm even when the absence of scientific certainty makes it difficult to predict the likelihood of harm occurring, or the level of harm should it occur. The need for control measures increases with both the level of possible harm and the degree of uncertainty.

The numerous reports and initiatives adopted in the early years of the XXI century show that those key elements are broadly considered as appropriate in the field of nanotechnology and environment. Nevertheless, the awareness that the precautionary principle should be applied does not bring a clear view of how policy makers would like to do it.

2) The necessity to consider uncertain risks

a) At the national and European level

Obviously, the potential consequences on human health and the environment of using nanomaterials is a matter of applying the precautionary principle and the reading of national and European reports in this field gives a good example of such potential risk. The French Agency for the Safety of Environment and Work observed that new nanoproducts arrive on the market without any application of preventive measures and the Committee for prevention and precaution recommended specific actions. Different ethics committees also proposed to promote a research ethics in this field. Similar efforts have been made in other countries and the European Commission has developed since 2004 a specific "safe, integrated and responsible" strategy for nanosciences and nanotechnologies. Following this initiative, the Scientific Committee on Emerging and Newly Identified Risks has adopted an opinion on the evaluation of risks in the field of nanotechnology which concluded that the existing methods used in toxicology and ecotoxicology are not fully appropriate to detect and evaluate the effects of nanoparticules. This explains the increasing financial effort in supporting research on security of nanomaterials in the 7th EC Framework program on Research and technology (PCRD). In February 2008, the European Commission released a Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research.

b) At the international level

Numerous international organisations have approached in various ways the issue such as WHO, FAO, IOMC, UNIDO, UNEP, WIPO and OECD. This resulted in a fragmented technical approach which is a clear incentive for a federative international action. The UN Interagency coordinating office is aware of this and as far as Member States will support such initiative, an International Dialogue may develop on nanotechnologies with the participation of the European Union which policy strongly favours such action since the 26th September 2008 conclusions of the European Council.

It is our view that the globalisation of the development of nanomaterials should not paralyse the application of the precautionary principle. So, as a first step, we should rely on national and European regulations. This approach already implies to make some political choices.

B. What kind of policy?

Countries wishing to benefit from and to support the development of the nano industry have no real choice.

Since hundreds of new products are already on the market and hundred of others are just coming, it is a matter of economical survival in the big international competition to regulate nanomaterials.

And they have to do it taking into account the experience of regulating GMOs which did not succeeded in incorporating the public opinion view. Policy makers have then reached on some points of agreement regarding the approach to elaborate regulations. But, they are still controversial issues on the scope of such regulation.

1) Points of agreement

a) Developing our knowledge of the risk

There is a broad consensus to agree that the most pressing near-term issues related to nanotechnology are toxicity and exposure to humans and environment and that there are strong needs to develop research in these fields. To date, there have been a handful of studies about these risks and only buckyballs have been seriously studied among "engineered" nanoparticles, a completely new class of particles. As we mentioned above this has generated awareness on the necessity to develop further specific research. Financial efforts have been made both at national level (Nanosafe 1 and 2 – 12,5 millions euros – in France and 40 millions dollars in 2006 for the USA) and European level (the

7th Framework Program on Research and Development) to support research and different expert committees were assigned with the task to define the content and methodology of such research. For example, the European Union proposed a list of 12 recommendations which consists, among others, to develop a new nomenclature and new measuring instruments for nanomaterials, to collect data and perform analysis on new nanoparticles, to develop standardized – risk assessment methods, guidelines and standards for production, strive for the elimination or minimization of the release into the environment and create institutions to monitor the development of nanotechnology.

In the USA, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and the National Institute of Occupational Safety and Health have also begun to inquire into the need to change the existing process to evaluate nanotechnology. Both the EU and the USA are now on the way to possess systems through which hazard and exposure risks of nanotechnology might be assessed.

b) Supporting transparency and debate

The debate on new biotechnological applications and GMOs has particularly point out the role of the market economy, on one hand, and of the public opinion, on the other hand, in defining public policy.

Although limited information were publicly available before 2005, the case of nanotechnology may represent a further step in being one of the first where scientists themselves are no longer capable of autonomously directing scientific research due to the growth of external pressures, not only commercial, but from civil society and State actors as well.

To prevent or minimize the fear about the risks of nanotechnology, transparency has become a leitmotiv of any public policy but, beyond the risk issue, what is at stake is also a clear debate on social priorities in the field of nanotechnology.

Faced to the potential risks of nanotechnology, public authorities have mandated ethics committees and experts groups to report on that point. They have also organised dialogue with the citizens' groups. One of the first initiatives is the citizens' conference organised in June 2004 by the Danish Board of Technology. We may also quote the NanoJury which was set up in 2005 in the U-K or the 2006 Nanoforum followed by the "Grenelle de l'environnement" in France. Three round tables in 2007 produced 14 "cahier d'acteurs" with the view of the different groups which participated in the discussion. The European Commission has also set up a yearly "Safety for Success Dialogue". But many private initiative conducted by NGOs has merged .In 2007 a coalition of 47 organisations has launched a declaration of "Principles for Nanotechnologies and Nanomaterials Overnight".

The information of the public is crucial to prevent misunderstandings about the risk issue and to facilitate the social acceptability of a balanced regulation. However, it would be a mistake to believe that the public concern is only on transparency about risks. It is something much more complex involving sociocultural and even anthropological insights. The nanotechnology revolution may lead to a transgression of several major sociocultural references as the GMOs did with the homogenisation of feeding models. As the French Parliamentary Office for Technology Assessment underlined in its 2007 report, the frontier between fundamental science and its applications does not exist any more in the field of nanotechnology. There are up to now little consideration regarding the ethics of economy. Managing the risk issue through a system of traceability could lead to a strict social control on individuals. It also creates some fear that the individual could be radically transformed corporally and psychologically using nanomaterials.

c) Regulating

The transparency and safety arguments naturally support the idea that at least nanoproducts should be submitted to regulations in order to control the existence and safety of new products.

A pragmatic attitude also considers that the existing domestic and European regulations applying to the safety of new products and to the protection of workers and consumers may serve as references for such regulation and that nanotechnology are not facing a legal vacuum. But some divergences appeared concerning how far existing regulations may be used as a concrete model for nanotechnology. Furthermore, some radicals called for a moratorium and even a ban on nanotechnology.

2) Controversial issues

They clearly point out the two existing approaches on the precautionary principle.

a) Should we impose a moratorium on nano-technology?

Considering that "Nanomaterials could well be the 21st century's asbestos," some NGO's have adopted radical views concerning nanoproducts.

For example, Friends of the Earth (FoE), a group of environmental activist organisations called for moratorium of nanomaterials containing products. Their spokesman explained that some of the biggest names in cosmetics are rapidly introducing nanomaterials into their products and onto the faces and hands of millions of people, despite a growing body of evidence indicating nanomaterials can be at risk while at the same time the UK's Royal Society had recommended to perform a safety testing before launching it as consumer.

An FoE latest report "nanotoxicity and health issue" said that over 720 products containing nanomaterials are being released for public consumption without adequate safety testing. It stresses that nanoproducts are currently in a regulatory vacuum as there are no laws that monitors it.

In 2006 six US NGOs have requested the FDA to withdraw from the market all cosmetics containing nanoparticles while in Germany some people feel faint avec using "Magic Nano" spray.

Other NGOs criticise nanotechnology as a new feature in their fight against the technoscientific development. They claim that nanotechnology will increase social control of the individuals and their bodies will produce artificial organisms and mental manipulation. They fear it would lead in a loose of control over artificial items that would be able to self replicate.

However, most of those in charge with expressing ethical opinions on the development of nanotechnology considered that currently there are no nanotechnological objects capable of self-replication and that this so called ethical issue constitutes a distraction because "it forces the discussion of ethical and social issues to revolve around the risks of possible future research rather than real system for research oversight and regulation which exists today". A similar distraction is created by discussions of 'post-humanism' because the issue of performance enhancing is already there with drugs in sport and information that we carry on our body.

If we exclude the prohibitive approach and do not regard nanotechnology as a totally unregulated area, the only serious question which remains is to know if the present regulations are sufficiently adequate to deal with the concrete issues posed by the development of nanoproducts.

b) Should we adopt specific regulation?

The view that nanotechnology needs a specific regulation is mainly supported by private foundations and NGO's mainly in the US with the idea that the best solution would be to elaborate an international instrument. Pragmatic reasons incite governments to favour a less specific approach that would consist to adapt the existing regulations to the specificity of nanoproducts. A first and main reason is the fear that developing a specific regulation would increase the bureaucratic and administrative constraints on this new industry. It would therefore stigmatise the promising field of the nanotechnology at a time more research are demanded. A second reason is that the present regulations deal with activities and goods without any distinction according to the techniques employed. They are only two exceptions: nuclear energy and genetic engineering but the experience the governments faced in these two areas is evidence that they do not want to adopt the same approach for nanotechnology.

For the European Commission, "the existing EU legislation covers in broad extend the risks raised by nanomaterials". The Commission refers, in particular, to the framework directive 89/391/CEE concerning the protection of the safety and health of workers, the directives 91/414/EC on plant protection products and 98/8/EC on biocides, the directive 2008/1/EC on Integrated Pollution Prevention and Control, the so-called Seveso II directive (96/82/EC), the framework directive on water (2000/60/EC) and the Reach (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation adopted in 2006 (EC/1907/2006).

Although they are no provisions in REACH referring specifically to nanomaterials, it is considered that this regulation includes nanomaterials through its broad definition of the term "substance" ("substance: a chemical element and its compounds in the natural state or obtained by any manufacturing process, including only additive necessary to preserve its ability and any impurity from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition"). Consequently, since 1st June 2008, new

substances at the nanoscale have to be registered before manufacturing or importing if they concern quantities of 1 tonne per year (by exception, restrictions on the manufacturing, placing on the market and use of dangerous substances are not submitted to tonnage triggers). Technical information should also be transmitted and when 10 tonnes of substances are manufactured or imported, a report should be annexed on the safety of the substance. In any case, the European Chemical Agency may ask any further information. We should remind that the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has produced two opinions in relation to risk assessment of nanomaterials, respectively in March 2006 and in June 2007 from which it derives that current risk assessment procedures may require modification for nanomaterials both regarding test methods and hazard identification and exposure assessment.

Regarding classification and labelling, the Commission and Member States have decided that "nanomaterials having specific properties may require a different classification and labelling compared to the bulk material, also when the nanoform is derived from a bulk substance".

However, several stakeholders have raised the concern that 1 tonne threshold for registration may exclude registration of many substance at nanoscale and may lead to a lack of information. With respect to substance identification, it is also discussed at which point nanomaterials with different kind of surface modifications should be seen as belonging to the same substance or whether they should be considered as separate substance.

National initiatives are therefore possible in Europe as far as they would respect the principle of free circulation of goods. In France, the present article 37 of the so-called Grenelle 1 draft law introduces a compulsory registration for manufactured or imported nanomaterials. (« L'utilisation des substances à l'état nanoparticulaire ou d'organismes contenant des nanoparticules ou issues de nanotechnologies fera l'objet d'un débat public organisé au plan national avant fin 2009. L'État se donne pour objectif que, dans un délai de deux ans qui suit la promulgation de la présente loi, la fabrication, l'importation ou la mise sur le marché de substances à l'état nanoparticulaire ou d'organismes contenant des nanoparticules ou issues de nanotechnologies fasse l'objet d'une déclaration obligatoire, relative notamment aux quantités et aux usages, à l'autorité administrative ainsi qu'une information du public et des consommateurs. Une méthodologie d'évaluation des risques et des bénéfices liés à ces substances et produits sera élaborée. L'État veillera à ce que l'information due aux salariés par les employeurs soit améliorée sur les risques et les mesures à prendre pour assurer leur protection »). Similar initiatives but on a voluntary basis have also been taken in the USA and in the U-K.

CONCLUSION

The consciousness we have about the different risks which our health and environment are facing as a consequence of human development in a context of ongoing globalization may be a good incentive to adopt an integrative policy for nanomaterials which takes into account not only the scientific and economic view but also a global ethical, legal and social approach.

Let we conclude by quoting Blaise Pascal:

> "The visible extent of the world surpasses us visibly; but, since we surpass small things, we believe ourselves capable of possessing them, and yet it requires no less capacity to reach nothingness as it takes to reach everything". ■