National Consultative Ethics Committee for Health and Life Sciences

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Ethical issues raised by nanosciences, nanotechnologies and health

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A large number of reports have been published in the last three years on nanosciences and nanotechnologies (see Annex) bearing witness to the fascination, hopes and misgivings raised by recent developments in these disciplines and the profusion of possible applications. CCNE decided to study the subject, not with the aim of making an exhaustive list of all the implications, but to consider specifically the ethical issues that such applications could raise as regards health and respect for human beings.

Nanosciences and nanotechnologies aim to arrive at man-made manipulation of the elementary and universal components of matter, atom by atom, on the scale of a millionth of a millimetre, i.e. the nanometre. Before attempting to single out and define the ethical issues arising out of this approach, CCNE considered the specificity of this scientific domain which is usually referred to as being radically new.

I. <u>Nanoworld, nanosciences and nanotechnologies.</u>

Is the nano prefix a radical paradigm shift or simply a change of scale?

A. The nanometre or the atomic scale.

The scope of nanoworlds is defined as exploration, manipulation and modification of the elementary components of matter, both inanimate and living, at spatial scales ranging from the nanometre to a few hundred nanometres.

But manipulating living and inanimate matter on that scale is not in itself a revolution. For example, the DNA molecule, which only measures a few nanometres, has been manipulated with a great degree of precision for over 40 years by techniques which are in no way related to nanotechnology. A large number of drugs and biological markers have been chemically manufactured for quite some time on that scale and affect the living. In other words, if what defined nanosciences and nanotechnologies was simply the possibility of exploring, manipulating and modifying living and inanimate matter on a nanoscale, this has been going on for quite some time and would not be a novelty.

In fact, two different operating modes are at the origin of the nanoworld:

- a strategy called "top-down" (in fact in this case, from small to very small) which consists in reducing millimetric or micrometric devices to attain the nanometric scale. An often-quoted example is electronic chips whose constantly diminishing size is due to improved silicon engraving techniques. The system miniaturisation process pursues economic or environmental aims by reducing the volume of raw materials needed to construct the systems and the energy expenditure required for them to function.

- Another strategy is called "bottom-up" (meaning from very small to small). These are procedures which manipulate atoms and molecules to construct complex, new and non-natural nanosystems. This approach is made possible by the creation and development of tools with which we can perceive and manipulate matter measuring a millionth of a millimetre.

The ambitions of nanosciences and nanotechnologies are defined by the possibility offered by new instruments — the scanning tunnelling, atomic force and high-resolution electronic microscopes, optical tweezers — to manipulate matter atom by atom.

B. The concept of convergence.

Is the concept of convergence a radical paradigm shift or simply a change in amplitude?

A characteristic which is often put forward as particular to nanosciences and nanotechnologies is the concept of *convergence*, illustrated by the expression NBIC — convergence between *N*anotechnologies, *B*iotechnologies, *I*nformation technology and *C*ognitive sciences — evidencing a radically new approach, the novelty residing in its transdisciplinary nature.

Two points can be made in this respect:

Since the whole universe is made up of atoms, obviously the possibility of manipulating the world on an atomic scale offers possibilities that go well beyond the scope of a particular discipline. But this transdisciplinary ambition is probably not in itself as radically new as it would seem: physics and chemistry are today both specific disciplines in their own right and transdisciplinary activities whose scope of application does not have clear boundary lines. It is the amplitude of this ambition which fascinates, more than its nature.

Although nanotechnologies do offer new scope for intervention, there is often some confusion between the possibility of such action and the notion that these possibilities would necessarily be dependent on the use of nanosciences and nanotechnologies. Two examples among many come to mind. The first is connected to the most ambitious dream of the *NB (Nanotechnologies, Biotechnologies)* of the *NBIC* convergence: the creation of "artificial life". Virology has recently synthesised *de novo* the poliomyelitis virus and the 1918 influenza pandemic virus and there are no obstacles in principle to the creation *de novo* of entirely artificial viruses. Their construction did not require the use of nanosciences and nanotechnologies. The "living" and "self"-replicating nature of viruses is disputable perhaps but synthetic biology seeks to construct "artificial cells". The second example is related to the most ambitious side of NBIC convergence, the *IC* portion (*I*nformation technology and *C*ognitive sciences): man-machine interfaces, in particular the coupling of computers and the human brain. The recent creation of artificial arms responding to the "thoughts" of amputees and the recent creation of a computer driven by the "thoughts" of a tetraplegic individual did not resort to nanosciences and nanotechnology.

In other words, *BIC convergences* already exist that do not necessarily need the *N* for nanotechnology. It is of course highly probable that nanosciences and nanotechnology can make their approach and development radically new. But this differs from the usual notion that nanosciences and nanotechnologies are in themselves the root of such convergence and that the very existence of this convergence depends on the development of these new disciplines. Although, in the long term, they may drastically change the process of convergence, for the moment they are simply a part of it.

C. Between two apparently contradictory concepts: controlled engineering and the emergence of the unpredictable.

Two apparently contradictory approaches co-exist for nanosciences and nanotechnologies:

- On the one hand, the engineer's approach, rearranging, atom by atom, molecule by molecule, following a precise plan and in so doing, trying to control, domesticate and bend to our will what nature has blindly produced. This is a continuation, with new instruments, of the engineer's traditional dream. It is in this spirit that the objective of manufacturing new nanomaterials and molecular factories is being developed.

- On the other hand, working material in order to construct molecular objects capable of self-assembly or replication, giving them properties which will enable them to evolve so that they can adjust to their environment. The plan is "to create the unpredictable in the hope of controlling it when the time comes"[1]. But as we have already said, this is not a problem which is specific to nanosciences and nanotechnologies: synthetic biology raises the same issues.

The fact that these two partially contradictory dreams are more often than not presented as being an integral part of a single nanoscience and nanotechnology project is a factor for confusion between two approaches with widely divergent objectives and states of advancement. The possibilities, already on the drawing board or still the stuff of dreams, are among others:

- manipulating and modifying matter on that scale to manufacture new objects;
- producing molecular "factories";
- producing molecular "factories" capable of self-assembly;
- producing molecular robots capable of self-replication, as entities sharing some of the properties of life forms and so blurring a little further the ever hazier frontier between inanimate and living matter.

[1] J.P. Dupuy

Some of these objects (in the first two categories above) are already within the realm of reality or are being developed, or are even being marketed. The last two categories of applications are still only dreamt of for some, or feared by others.

D. The objectives of nanobiosciences and nanomedicine.

An increasing number of prospective studies report on health issues that could be affected by present and future developments in nanomedicine, in particular diagnostic and therapeutic instruments. Many applications, both *in vitro* and *in vivo*, could be involved:

- In particular the clinically routine production of a genetic map (DNA chips and "lab-on-a-chip"[*]) and the identification of a large number of individual genetic susceptibilities using diagnostic tools and analytical techniques.
- Implanting in a patient multi-parametric biosensors and locally-effective bioactive material.
- Using functional markers for non-invasive medical imagery, agents for the identification of the target of treatment and carriers of a therapeutic device in the field of static and interventional nanoimagery on a molecular, subcellular and cellular scale: "theranostics".
- Designing nanomaterials and nanosystems: bio-mimetic and bio-sensitive systems that can be implanted for tissular engineering and regenerative or restorative medical procedures.
- Producing "man-machine" nanoscale interfaces between the body and a prosthetic device.
- Innovative drug delivery systems and new pharmacological tools at apparently less toxic doses since they are selectively targeted, in particular complex medicinal nanoscale systems: nanocapsules and liposomes containing anti-cancer agents, macromolecular conjugates of antibodies and cytotoxic agents, nanoparticles of tumoral imagery with magnetic properties that can be activated and also macromolecular vectors capable of passing through biological barriers — in particular the blood-brain barrier protecting the central nervous system — or more generally cellular membranes and the nuclear envelope isolating the genome.

II. <u>Do nanosciences and nanotechnologies raise new ethical issues or previously encountered ethical issues in a novel context?</u>

The nanosciences are frequently described as a scientific revolution.

[*] Expression designating biological testing of microsamples using electronic chips.

A. Is this a scientific revolution, or a new representation of the world, or a new template for understanding reality?

For the time being, the nanosciences do not seem to have (yet?) modified our representation of the universe. Nor do they bring a new template revealing or suggesting the existence of an invisible, hidden and unimagined aspect of reality. They postulate that nanoscale manipulation can change the elementary properties of matter, but the existence and the possible effects of such changes are still hypothetical and unknown — possibly subjects for research. The possibility that certain modifications of the site of a component in an entity can change the properties of the components or of the entity itself is not without precedent in many other scientific fields, as is illustrated for example by the Mendeleyev table in chemistry, radioactivity in physics and the genetic code in biology, etc. In these disciplines, the question is not so much: "Can the properties of the elementary components and the entities change?" as "What would be the consequences of such change?". The instruments permitting the development of nanosciences and nanotechnologies, i.e. the scanning tunnelling microscope and the atomic force microscope, for the time being make it possible to manipulate matter as we already knew it. And the level — the atomic level — at which such manipulation takes place is probably not the most elementary level since several branches of physics have been attempting for several decades to work on the subatomic composition and properties of matter.

The nanosciences do not at this time seem to be a new scientific discipline where the world, or indeed ourselves, are revealed as being any different from what we believe them to be.

They could perhaps better be described as representing a discipline which tells us that we now have new possibilities of affecting a world with which we are already familiar. That such action may hold surprises in store for us, or discoveries and new-found knowledge is very likely. But, at this point we are not confronted apparently with a real scientific revolution. It is no more than a technical revolution bearing — perhaps — the promise of a future scientific revolution with the ever-present temptation of becoming fascinated by science fiction.

The situation today can best be described in fact as a technological revolution which could perhaps give rise in future to a scientific revolution, of a discipline describing itself as a science although it is essentially for the time being a remarkable technological step forward. As a result, there is a gap between public perception and what the market has to offer.

III. <u>The ethical issues in this respect are those generally raised by the development of technologies.</u>

Ethics covers here a complex multidisciplinary array of issues ranging from the possible effects on health of nanoparticles used for non medical purposes through to the benefits and risks of nanomedicine and the human sciences. The premature integration into research activities of a potential risk to health requires reflection on the probability of infringement of individual liberties since technical possibilities are almost infinite and nanomaterials are difficult to detect.

A. Possible risks to health

1. The issue of traceability

Nanoparticles are not detected by ordinary methods because of their diminutive size but it would be imprudent to introduce them surreptitiously into the environment and the human body. We already live in a world in which nanomaterials are rife, such a Diesel particles in the air, but releasing new non-degradable nanostructures (see below) into the atmosphere could be a source of danger comparable to asbestos, for instance as regards carbon nanotubes. Obviously, the lack of nanometric-scale metrological tools would further complicate their detection.

The first priority is therefore knowing they are present, which takes precedence over the usefulness or even the significance of their presence. The issue of traceability also arises because of their use against people if nanoparticles were connected to surveillance equipment unbeknown to carriers (for example RFID: Radio Frequency IDentification). The convergence of nanotechnologies with communication sciences functioning through remote connections between sensors and computers clearly raise some ethical issues. Admittedly personal security could benefit from such technologies, supposing those concerned were aware of their presence, but we live in a world where tracers already abound and this could signify a *de facto* annihilation of respect for privacy since a system of personal privacy-violating tracking would be created deliberately. Traceability can therefore be both a beneficial development when it recognises the biological presence of nanoparticles and a source of concern if it is designed to track people themselves. The essential issue is therefore not just the need for traceability but also the supervision and control exercised over those in charge of the tracking process.

2. The issue of biological effects and biodegradability

We do not as yet know the effects that possible pharmacological nanovectors could have on the physiological mechanisms of the human body, in particular the breaking of biological barriers such as the barrier between circulating blood and the brain. The brain is protected from aggression or products carried by the bloodstream. If that barrier is crossed, the effects could be either beneficial or harmful, or even serve to manipulate people. The same can be said of cellular biological barriers and genomic oligonucleotide vectorisation and targeting.

Low biodegradability could cause or aggravate ecological pollution and human toxicity problems. For example, the inclusion of nanoparticles in macrophages, i.e. cells capturing antigens, could be a source of concern if they were not biodegradable.

3. The issue of possible "new properties" of matter undergoing nanometric manipulation

The larger surface to mass ratio of complex nanometric molecular systems compared to bigger structures could have hitherto unknown consequences as regards biological and chemical reactivity; studying possible changes in the behaviour of material of which nothing is known is surely no easy task. Radioactivity was an example of the impossibility of predicting the effects of changes in the behaviour of material before they are identified. Knowledge was retrospective. It was the discovery of these "new properties" of radioactive matter that led to its traceability. As long they had not been discovered, they could neither be traced nor protected against. Unlike radioactive isotopes of atomic elements, nanoparticles only have new properties of a structural nature. Their introduction into micro- or millimetric devices might well be devoid of serious risk apart from those related to production or decay.

4. A minute percentage of the research and development budget is devoted to research on possible damage to health

There seems to be little enthusiasm on the part of biologists, toxicologists, environmentalists and epidemiologists to devote much time to such investigation. Worldwide, in 2005, $10 billion were spent for R&D on nanosciences and nanotechnologies, of which only $40 million were used for researching possible side effects. In other words, only 0.4% of global expenditure was spent on researching risks, including risks to health. In the circumstances the problem is the temptation to start by producing, selling and disseminating, leaving study and understanding until later.

5. The temptation to disconnect words and reality

Views now being expressed present a paradox raising ethical issues: there is much talk of the revolutionary development of nanoscience to treat an abundance of diseases which are still incurable or difficult to manage. But for the time being, only paints, airbag sensors, road surfacing, inkjet print heads, cosmetics, etc. are being marketed by manufacturers. Technicians and scientists are only just beginning to evaluate the possibility and efficacy of anticancer treatment, fighting age-related diseases, treating multiple sclerosis, saving energy, etc. Words may seem all the more disconnected from reality that achievements so far still have only limited medical applications, although rapid development is likely, while posing possible unidentified health risks.

The situation resembles to some extent events at the time of GMO plant development: the words were all about fighting global hunger, but marketing mainly related to the objectives of the large agro-industrial companies in rich countries.

6. An essential ethical problem: the apparent confusion between targeted research and fundamental research

It would appear that nanosciences and nanotechnologies are more concerned with answers and solutions than with the more customary characteristics of research, i.e. the investigation of questions.

a) Producing to understand before producing to sell

Are we producing and distributing applications with the intention of deferring study and understanding until later? Or are we seeking first of all to understand before making any decision, giving due consideration to advantages and drawbacks?

Ethics when they evolve before scientific knowledge is acquired are almost always suspect of normativism. The ethical point of concern is not the possibility of drawing up some kind of risk/benefit ratio which would in any case be difficult to do at this point in the development of nanosciences. A more general reflection is required however on the conditions of knowledge sharing, transparency and codes of conduct. Clearly in this case and more than ever, the issue of the epistemological relationship between ethics and science must be addressed.

In this new area of competency, society must be able to rely on scientists to act entirely responsibly, individually of course, but also at the collective team level which is the true operational level of research. This new material must be investigated in the light of considerations which are not restricted to simple matters of scale. Ethical reflection, bearing on the way in which projects are managed, young researchers are trained and acquired knowledge is transferred to the production sector is a major responsibility incumbent on research institutions and user enterprises. Although the discussion and the development of a code of best practices as regards research and manufacturing nanoproducts may seem premature, it must be recalled that it was within that same context that the principle of secure laboratories and workshops was made mandatory for molecular biologists 30 years ago, through reflection in Asilomar and a moratorium.

b) Insufficient fundamental research, or even more disquieting, research not being published?

Is there a lack of fundamental research or is it that much research remains unpublished because the share of industrial applications is too large (the leading scientific publications require an even spread between tools and products of research)?

1. The issue of knowledge sharing and industrial property rights.

How does one ensure that industrial property rights and economic concerns do not inhibit freedom of publication and the circulation of important information on the nanosciences and nanotechnologies? How can ethical problems be discussed in a context of excessive confidentiality? The recent obligation to register and put on line all therapeutic trial plans and, as regards industrial chemical products, the European directive REACH (Registration, Evaluation, Authorisation for Chemicals, 2006) are models that can be a useful basis for reflection and finding possible solutions to these problems.

2. The issue of sharing objects for research.

Sharing out not just information, but also objects, methods and products of research and technological development is now becoming necessary: there are many examples of coupling the obligation to make products available for scientific study with the protection of industrial property rights. The European institutions are working on possible alternatives to traditional patents and licensing agreements so as to sidestep confidentiality problems for the scientific community and society.

In both cases, the apparent lack of publication and information on the progress of fundamental research in this field raises an ethical issue.

In the final analysis, referring to the principle of precaution as regards nanotechnologies must implicate a call for the development of research. How otherwise would it be possible to protect vulnerable people without knowing anything about the mechanisms which could be a threat to them? It is conceivable for instance that nanomaterials might be particularly toxic at an early age for embryos or fœtuses but relatively harmless for adults. Should then women capable of producing offspring not be allowed to enter manufacturing centres or research laboratories working on nanomaterials? Since at this time there is no clear answer to such questions, perhaps urgent attention should be devoted, much more intensively than is presently the case, to animal exposure in various stages of development, even though the information to be obtained is always difficult to extrapolate to human beings. Animal research is absolutely urgent because the borderline between medical (medicines) and non medical (cosmetics) uses is extremely fine and justifies caution in exposure to nanoparticles. Consent to therapeutic use or to participation in the production of nanomaterials in a situation so fraught with uncertainty cannot be based on precise scientific data. There is therefore a great need to distinguish clearly between what is intrusive (respiratory, digestive and intravenous systems) or potentially intrusive (deep into the dermis?) and what is not intrusive (presence within a non-diffusing nanoparticle product).

The principle of precaution does not consist in doing nothing. It involves constant research and anticipation of potentially harmful effects based on exposure studies.

Knowledge is a prerequisite for the exercise of responsibility. This is the very foundation of the concept of free and informed consent. That is why the foremost ethical recommendation would be to demand the **development of fundamental research before, and not only after, technical application.**

Such research must not be limited to the study of possible side effects. It must anticipate research on toxicity related to the nature of nanomaterials in cellular or animal models. In other words, the ethical attitude to nanosciences and nanotechnologies is not to stand in the way of science but on the contrary to ask for more science, more research, more reflection, more soul-searching covering research, transfer, innovation and industrial applications. And less *a priori* expressions of certainty where only the possibly beneficial effects are highlighted while the possibility of adverse effects is denied.

B. Ethical considerations regarding personal information obtained by using nanoproducts

The risk that human beings be reduced to the sum of their genetic and biochemical parameters is already obvious and will be an even greater danger in the future. The ease with which an observer will be able to access a considerable sum of data will mean that instant identification of a given person with a given profile will be effortless. Patients will become "barcode" subjects and one can readily imagine how such accessibility by not invariably benevolent outside institutions to intimate biological details could cause trouble, further compounded by the risk of health/insurance/employers cross referencing. Billions upon billions of items of data interconnected by atomic scale codification should be the subject of careful thought regarding their purpose before any practical implementation is considered.

Similarly, predictive medicine unattended by concrete solutions or palliative therapies is progressively invading the sphere of medical science. Nanodiagnoses could extend their possibilities to an unprecedented extent; the consequences as regards consent, the use of such data by third parties (insurance companies) should be considered beforehand so as to prevent a situation where people would feel dispossessed of their physical integrity or find themselves in a situation where they constantly need to cope with apparently meaningless information. Military applications are already a reality, alerting us to the extraordinary potential for information that a web of computerisation, nanomaterials and centralised structures can achieve.

C. Ethical considerations regarding non-therapeutic personal alterations using nanoproducts

The transition from nanoprocesses and nanoproducts designed to offer remedial treatment of motor and/or sensory functions to applications intending to amplify the performance of healthy individuals, which specialists refer to by the name of "augmented reality", could lead to abuse. Nanotechnologies could participate for example in the emergence of undetectable "nanoprepared" sportsmen. The secret nature of doping activity of this kind paves the way for human fakes, for frauds which could destroy the meaning of trust. Such activities are already being considered for aggressive — military or consumerist — purposes.

In fact, the ethical issue is the changed relationship between humanity and the world, changed by the possibility of claiming a constantly variable identity, humanity locked into dependence, alienated instead of liberated. The issue is not one of the nature of the human spirit, but of its plasticity when it falls under external control. All these considerations converge on the question of the social acceptability of nanotechnologies, even though, as is rarely the case, ethical debate seems to be taking place before the technology is applied. A climate of uncertainty makes for uneasy discussion which is further complicated by the need to avoid basing communication on excessive and therefore necessarily fallacious metaphors or pure ideology. Information given on the technological developments of the nanosciences, including the identity of those responsible for these developments, must be entirely transparent.

The difficulty is making uncertainty comprehensible without falling into disaster-scenario "grey goo" descriptions or at the other extreme, into scientism at its most careless or traditional. Perhaps nanomaterials and new manufactured nanosystems and their true purpose should be the subject of public debate before they are developed, and risk and biodegradability be included among the major ethical issues for discussion.

This is the quintessence of the principle of precaution. Science opens up new vistas, broadens the concept of analysis, a process which presupposes that such innovation moves into a public forum accessible to everyone. This new culture of exchange with public opinion would require that pertinent training in ethics be on offer for researchers, engineers and economic decision-makers because the paradox is that democracies may be more sensitive to consumer arguments than to the ethics of responsible action and that the discussion on GMOs has locked both hard-line scientists and dogmatic opponents into a stalemate.

What could be more significant is our refusal to add new forms of alienation to a world which already relies increasingly on man-made props and substitutes. As it is, our relationship with the world we live in surrenders a growing share of our freedom to instruments while labouring under the delusion of increased freedom. Our technological relationship with information technology demonstrates that each human being can now be traced, located and summoned, although humans see themselves as the root and origin of the system. Were we to invest naively, without giving a thought to societal issues and without regard for human dignity, in an environment and a medical science producing *a priori* wellbeing and health through nanotechnology, we would paradoxically be banishing and alienating humanity.

IV. <u>Recommendations</u>

1. Ensure the availability of sufficient information on the alarming and ambivalent capacity of molecular man-made nanosystems to pass through biological barriers, in particular between blood and brain. Similarly, information must be forthcoming on the low or non-existent biodegradability which could have major consequences on health except for some specific therapeutic indications.

2. As a matter of urgency, intensify research and development on nanometrology to design more instruments for the detection and identification of nanoparticles, in particular those created specifically for the formation of nano-objects and nanostructures.

3. Underline the disparity between too little development (or publication) of fundamental research and the accelerated production of commercial technological applications. As a result, some essential decisions and choices may be bypassed. More support is urgently required for the development of fundamental research on nanosciences, without prejudice to the freedom of research. Ethical aspects must be evaluated in projects to be financed by national and European organisations and private foundations. Scientists now being trained, in particular future PhDs in nanosciences and nanotechnologies, should be required to include in their doctoral theses a summary of ethical issues relating to their research. In the European research arena and on the global scene, States must implement strategies which include such ethical reflection in the "knowledge triangle": research, education and transfer.

4. Encourage integrated multidisciplinary research to ensure that the design of new nanomaterials and nanosystems is combined with a study of their primary effects on the environment, on health and their positive and negative biological implications. The separation of these approaches into calls for different projects (ANR and European FRDP7) does not guarantee that sufficient research is carried out on risk assessment before such innovations emerge from the confines of research laboratories and go into industrial production. Risk evaluation must include the complete life-cycle of nanoproducts. This requires an upgrading of industrial toxicology using human and technical resources on a par with standard procedures in the field of innovative technology. Industrial financing of research on risks is an ethical priority, even though it may and should be complemented by more extensive investment in public and fundamental research.

5. Give priority to the array of protective measures required for workers in contact with nanomaterials and to the confinement of premises used for their study and production. Give priority to research on adverse effects with particular attention to low-dose toxicity for highly vulnerable populations, in particular workers in contact with nanomaterials who could be exposed despite protective measures. For precautionary reasons, pregnant women should be excluded from such employment. Monitoring of fœtuses and newborns should be prescribed by regulation in the event of professional or accidental exposure. Animal research on the effects of nanoparticles should be greatly intensified, even for nanomaterials devoid of any purely medical application (nanocosmetics).

As regards occupational medicine and the work of site security and hygiene committees, laboratories, research teams and production sites must be required to draw up a code of good practices and to implement special procedures for monitoring the protection and supervision of research and industry personnel engaged in the manufacture of nanometric products.

6. Ensure a climate of trust by reporting regularly and clearly on scientific progress to the research community, both public and private, supported by European regulations for the mandatory registration of all new nanostructures together with their possible consequences on biological reactivity. A European law similar to REACH must be enabled for nanoproducts. European reflection on standards for the protection of intellectual property rights and models for licensing agreements more appropriate to nanotechnologies should also include new knowledge-sharing and research product-sharing procedures designed to increase the attention given to ethical considerations.

7. Encourage networking and information-pooling among the various agencies: Biomedicine, AFSSAPS, AFSA and the *Institut de Veille Sanitaire*. The greatest attention must be given to the respect of relevant principles, such as privacy, informed consent before exposure to these innovations and the protection of personal safety. Industrialists must be required to provide information and clear specific labelling of products containing nanoparticles so that consumers can refuse to use them if they so wish. The collection and transparency of information on the pharmacovigilance of nanomedical products will be achieved by an extension of the scope of competence of existing agencies involved in the supervision of medicines and implanted devices.

8. Develop the dissemination of scientific, technological and industrial cultural material in the field of nanosciences and nanotechnologies. Set up an effective information system for the public and society through the organisation of <u>public</u> contradictory <u>debates</u>. These would be decentralised to regions and be the subject of public reports including the responses given by researchers and industrialists to questions, expectations and fears expressed during the debates. Making publicly available a maximum amount of trustworthy information and not hiding behind the pretext of industrial confidentiality to abstain from doing so, should become a practical obligation.

9. Finally, determined vigilance must be exercised regarding the serious consequences for individual liberties and for respect for human dignity if identification and interconnection capacities were developed without the knowledge of those concerned. Any possibility of military applications being adapted for civilian purposes should be fully and publicly debated with due regard for individual rights before any transfer takes place.

In conclusion, the ethical dimension of the use of nanomaterials can be studied under two headings. On the one hand, the philosophical man-machine problem raised by nanosystems, which remains a threat to the respect for human beings. This important intellectual subject must not however be allowed to overshadow a second and much more urgent question which is the covert intrusion of nanoparticles with more regard for technological performance and commercial profitability than for the perception of potential risks. This second question makes it very necessary to raise awareness so as to avoid outright rejection by society of new techniques more concerned at this point with competing in the race for innovation than with respect for the physical and mental integrity of individuals. Controlling the consequences of scientific and technological progress is the responsibility of society as a whole; it cannot be the sole concern of economic players or associations. We must not allow nanotechnology to supersede nanoscience.

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ANNEX

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