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## Committee on Social Affairs, Health and Sustainable Development

# Nanotechnology: balancing benefits and risks to public health and the environment

Rapporteur: Mr Valeriy SUDARENKOV, Russian Federation, SOC

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### I. Nanotechnology's revolutionary changes in commerce will transform daily life throughout the Council of Europe member states

1. Nanotechnology has been heralded as a "revolution" in science, for two reasons: first, because of its revolutionary view of the way in which chemicals and elements, such as gold and silver, behave, compared to traditional scientific understanding of their properties. Second, the impact of these new discoveries, as applied to commerce, can transform the daily life of consumer products ranging from sun tan lotions and cosmetics, food packaging and paints and coatings for cars, housing and fabrics, medicine and thousands of industrial processes.[1] Beneficial consumer use of nanotechnologies, already in the stream of commerce, improves coatings on inks and paints in everything from food packaging to cars.

2. Additionally, "Nanomedicine" offers the promise of diagnosis and treatment at the molecular level in order to detect and treat presymptomatic disease,[2] or to rebuild neurons in Alzheimer's and Parkinson's disease. There is a possibility that severe complications such as stroke or heart attack may be avoided by means of prophylactic treatment of people at risk, and bone regeneration may keep many people active who never expected rehabilitation. Miniaturisation of diagnostic equipment can also reduce the amount of sampling materials required for testing and medical surveillance.

3. Miraculous developments, that sound like science fiction to those people who eagerly anticipate these medical products, combined with the emerging commercial impact of nanotechnology applications to consumer products will reshape civil society - permanently. Thus, everyone within the jurisdiction of the Council of Europe is an end-user of nanotechnology, even without realising that nanotechnology has touched daily life.

***Definition***

4. "Nanotechnology" is the science of studying phenomena and the manipulation of materials at atomic, molecular and macromolecular scale. Use of the prefix "nano" in this context refers to a nanometre (nm). A nanometer is one-billionth of a meter. A sheet of paper is about 100,000 nanometers thick; a single gold atom is about a third of a nanometer in diameter. Dimensions between

[1] www.nanocube.ch.
[2] Patrick Hunziker "Nanomedicine: The Use of Nano-Scale Science for the Benefit of the Patient" European Foundation for Clinical Nanomedicine (CLINAM) Basel, Switzerland 2010.

approximately 1 and 100 nanometers are known as the "nanoscale".[3] Unusual physical, chemical, and biological properties can emerge in materials at the nanoscale. These properties may differ in important ways from the properties of bulk materials and single atoms or molecules. Theoretically, engineered or manufactured nanomaterials have greater strength and elasticity or have different electrical properties compared to material presently used in commerce. Naturally occurring nanomaterials, such as volcanic ash, also have industrial uses. "Accidental" nanoparticles may not occur in nature but may be an unintended bi-product of activities in daily life. A key policy decision must be made under law, to determine whether all of these types of "nanomaterials" will be regulated under law, based on their size and without regard to their origin.

5. Unfortunately, the role of each of these categories of "nanomaterials" and their interaction with biological processes is poorly understood at this time. Often, but not always, the properties of substances at the nanoscale differ significantly from those on a larger scale. For example, gold is inert in daily life but combustible at the nanoscale. The question whether these differences in chemical properties at the so-called "nanoscale" have any impact on industrial productivity or pose any risk to public health is therefore very important. But, the technology is so new that little is known regarding the potential dangers.

### A. Global scientific consensus: unknown risks exist

6. Scientists and governments agree that the application of nanotechnology to commerce poses important potential risks to human health and the environment, but the risks are unknown. Examples of high level respected reports that express this concern include: the Swiss Federation (Precautionary Matrix 2008),[4] the Royal Commission on Environmental Pollution (UK 2008),[5] the German Governmental Science Commission, ("SRU"),[6] Public testimony sought by USA National Institute for Occupational Safety and Health (NIOSH, Feb 2011),[7] the OECD working group (since 2007),[8] the World Health Organization (WHO),[9] and the World Trade Organization (WTO) several industrial groups, and various non-governmental organisations.

[3] www.nano.gov.

[4] Swiss National Science Foundation, Opportunities and Risks of Nanomaterials Implementation Plan of the National Research Programme NRP 64 Berne, 6 October 2009; see also Swiss Precautionary Matrix, and documents explaining and justifying its use, available in English from the Federal Office of Public Health.

[5] Chairman: Sir John Lawton CBE, FRS Royal Commission on Environmental Pollution, Twenty-seventh report: Novel Materials in the Environment: The case of nanotechnology. Presented to Parliament by Command of Her Majesty November 2008.

[6] SRU, German Advisory Council on Environment, Special Report "Precautionary strategies for managing nanomaterials" Sept 2011. The German Advisory Council on the Environment (SRU) is empowered by the German government to make "recommendations for a responsible and precautionary development of this new technology".

[7] See: Legal basis and justification: Niosh recommendations preventing risk from carbon nanotubes and nanofibers "post-hearing comments Niosh current intelligence bulletin: occupational exposure to carbon nanotubes and nanofibers Docket NO. NIOSH-161 Revised 18 February 2011; Testimony on behalf of ISRA (International Safety Resources Association) Before NIOSH, USA. Comments prepared by Ilise L Feitshans JD and ScM, Geneva, Switzerland. Testimony presented by Jay Feitshans, Science Policy Analyst; ISRA Draft Document for Public Review and Comment NIOSH Current Intelligence Bulletin: Occupational Exposure to Carbon Nanotubes and Nanofibers, Docket Number NIOSH-161-A.

[8] The OECD Working Party for Manufactured Nanomaterials (WPMN) "OECD Emission Assessment for Identification of Sources of release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance", ENV/JM/MONO (2009)16, http://www.oecd.org/dataoecd/15/60/43289645.pdf. "OECD Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials" OECD ENV/JM/MONO(2009)6, 2009. www.oecd.org/dataoecd/36/36/42594202.pdf.
"OECD Comparison of Guidance on selection of skin protective equipment and respirators for use in the workplace: manufactured nanomaterials", OECD ENV/JM/MONO(2009) 17, 2009. www.oecd.org/dataoecd/15/56/43289781.pdf.

[9] WHO Guidelines on "Protecting Workers from Potential Risks of Manufactured Nanomaterials" (WHO/NANOH), (Background paper) 2011. WHO's Stated Purpose: "These Guidelines aim to facilitate improvements in occupational health and safety of workers potentially exposed to nanomaterials in a broad range of manufacturing and social environments. The guidelines will incorporate elements of risk assessment and risk management and contextual issues. They will provide recommendations to improve occupational safety and protect the health of workers using nanomaterials in all countries and especially in low and medium-income countries."

7. One example the Swiss National Science Foundation has stated, “Physically confining materials at the nanoscale alters the behaviour (sic) of electrons within them, which in turn can change the way they conduct electricity and heat, and interact with electromagnetic radiation. Moreover, materials engineered at the nanoscale can enter into places that are inaccessible to larger materials,… These behaviours (sic) also have potential consequences on the abilities of synthetic nanomaterials to cause harm in novel ways.”

8. Qualitative data to protect exposed people and the greater ecological system that surrounds the human environment lags behind industrial use, research and application of nanotechnology to consumer products. In its Special Report “Precautionary strategies for managing nanomaterials” the German Advisory Council on the Environment (SRU) urged responsible development. "The possible consequences of this use have not been sufficiently studied. There is a danger of a widening gap between the technological development and the knowledge about risks.… **The SRU holds the view that the regulation of nanomaterials is in urgent need of reform and calls for more transparency with regard to the use of nanomaterials in consumer products."**[10]

9. This view is consistent with the Report of the Royal Commission on Environmental Pollution of the UK, (2008) which expressed concern that "novel" materials using nanotechnologies could hold catastrophic consequences and a "nightmare scenario" comparable to thalidomide, despite the best of intentions, but at the same time cautioned against any ban or moratoria on nanomaterials.[11]

10. In response to these emerging science policy issues, a plethora of drafts about nanotechnology are floating around the web and in legislatures around the world: the Organisation for Economic Cooperation and Development, (OECD), the World Health Organisation (WHO),[12] the European Union, USA,[13] China, South Africa, India, the International Standards Organisation (ISO),[14] SICAM, NATO, trade associations, and non-governmental organisations have proposed laws for nanotechnology. Around the world jurisdictions at the state, national and local level, including places as small as Cambridge, Massachussetts in the USA, have drafted nanotechnology regulations and laws, often with several different agencies competing for regulatory turf.

[10] SRU, 1 September 2011: More precaution in the management of nanomaterials.

[11] Royal Commission on Environmental Pollution, UK 2008 paragraph 1.37 "As we have noted, history is replete with instances where such assumptions were shown to be flawed too late to avoid serious consequences. The second approach assumes that the state of the science is up to the job of detecting problems unambiguously and at an early enough stage to prevent widespread damage, which we have not found to be the case here. The third view would deny citizens and consumers the real lifestyle and health benefits that technologies based on novel materials might provide. "

[12] For stakeholder comments, See: The Work, Health and Survival Project, (“WHS”) including: International Safety Resources Association (ISRA), Fullerton California, Earth Focus Foundation, Geneva, Switzerland; Digital 2000 Productions, Stafford, Texas, USA; Donald H. Ewert, IH, VP-Field Services nanoTox, Inc.; Keith Robson, CEO, AssuredNano, Dr Gustav Gob and International Sustainable Energy Organization (ISEO) Geneva, Switzerland, Comments presented by: Ilise L Feitshans JD and ScM "WHS Stakeholder Comments RE: WHO Guidelines on "Protecting Workers from Potential Risks of Manufactured Nanomaterials" (WHO/NANOH), (Background paper) 2011", WHS Geneva, Switzerland 30 March 2012.

[13] Over twelve major federal agencies have regulations pertaining to nanotechnology in the USA, but these rules are not well co-ordinated. The US Environmental Protection Agency (EPA) has accepted jurisdiction of nanoparticles under the Clean Water Act, the Toxic Substances Control Act (TSCA) and in a voluntary "stewardship programme”. The Food and Drug Administration (FDA) has issued guidance and proposed rules regarding medical devices that apply nanotechnology to nanomedicine, but intellectual property is governed by the Patent and Trademark Officer (PTO) and workplace exposures are governed by the Occupational Safety and Health Administration (US DOL OSHA), the National Institute for Occupational Safety and Health (US DHHS CDC NIOSH) and the Occupational Safety and Health Review Commission (OSHRC). See: Ilise Feitshans: “Designing an effective OSHA compliance program” (Westlaw.com, hard copy west thomson Reuters, updated annually).

[14] International Standards Organization (ISO) Technical Committee (TC) 229, in conjunction with the International Electrotechnical Commission (IEC) TC 113, that directs activities on nanotechnologies standards at international level. Note that although influential, ISO is not a government agency or an international organisation with sovereignty.

11. There are many systems in development phase but few efforts towards harmonisation. Hundreds, if not thousands, of proposed nanotechnology laws and regulations are under consideration, in addition to the existing laws that already claim jurisdiction over the use, production and disposal of products that apply nanotechnologies. The full list of relevant laws is too long to print here even as an appendix, but a summary compiled by the Rapporteur is available from the Secretariat.[15]

### B. The regulatory dilemma: how can the benefits of nanotechnology be realised, while minimising the risk of harm?

12. Striking a balance between research and development of toxic nanomaterials despite unknown risks is a clear and consistent theme of background papers about regulation of nanomaterials, throughout the world. Law and science have partnered together in the past to solve major public health issues, ranging from the asbestos threat to industry to averting the threat of a nuclear holocaust. Such precedents are the hallmark of expensive "big science" legislation in the twentieth century, which funded important advances in human progress despite unquantified but undisputed risk.

13. The SRU report provides a prudent benchmark for international human rights laws encouraging public health risk management and environmental protection of "novel" applications of nanotechnologies. The report wisely stated: "The objective is to allow for innovation but also to identify and reduce risks at an early stage."

14. By applying this mantra, the Council of Europe can take action to ensure that international human rights to health are protected while balancing the vital economic interest among member states for competing with existing programmes to advance nanotechnologies. Nanotechnology's revolution for commerce can also revolutionise public health; but to do so requires forethought in legislative drafting followed by harmonisation of the divergent, sometimes overlapping laws regarding nanotechnology, within Council of Europe member nations and around the world.

15. There is a clear role for the Council of Europe in three regards:

As noted, plenty of laws exist already, but there are gaps in significant areas where the Council of Europe can act in order to cultivate a culture of innovation while protecting human rights to health:

1. Defining nanotechnology and its related terminology clearly and consistently under law in the 47 member states;
2. Harmonisation of existing and emerging laws at local, national and international levels, in order to prevent needless duplication and resolve conflicts regarding definitions, jurisdiction and substantive requirements that may be at odds with each other despite a common overarching goal of promoting commerce and protecting public health;
3. Consumer education including education of industries who are end-users and consumers of nanotechnology products (i.e. ink with nanometer protective coatings in packaging) and workers and their families who are exposed to raw products.

16. The goal of these activities should be a clear and persuasive defence of the human right to health for workers, consumers, industrial users of nanotechnology and for all stakeholders. Thus there is a possible role for the Committee of Ministers. First, there should be a Study Commission, charged with the mission to evaluate political and legal aspects to determine whether there should be a Convention regarding "nanotechnology and human rights/health“. The Commission should also consider whether a Protocol to an existing Council of Europe Convention such as the Oviedo Convention on Biomedicine and Human Rights (open to ratification by non-member states, like the Cybercrime Convention which binds the USA) may be appropriate. This goal can be achieved through open dialogue and transparent legislative process that can serve as a model for the rest of the world both in form and in substance.

[15] Valeriy Sudarenkov “Nanotechnologies, a new danger to the environment?”, Preliminary draft report AS/ENA (2011) 35, 22 September 2011, Council of Europe.

### C. Nanotechnology's role in shaping civil society

17. **Nano-consumer products are here!** How big is a Nano? Nanotechnology is predicted to be 3 trillion US dollars of US GDP by 2015, according to Murashov and Howard.[16] The Rapporteur believes the European Union has invested 5,1 billion Euros through its Framework Programmes.[17] China's annual nanotechnology conference and expo demonstrates that Asia too, wants to be a major player - investing and exporting products that apply nanotechnology.[18]

18. Every nation has a nanotechnology policy; low and medium income nations without leading industries provide a clean slate for development of nanotechnologies without the economic disruptions caused by displacement of existing industries in the industrialised nations. Brazil, South Africa, South Korea, China, Sri Lanka, India and Thailand all have breakthrough nanotechnology programmes. By contrast to older industries, such as manufacturing in the so-called "rust belt" where outdated equipment has been abandoned without providing new tools or new jobs for the people left behind, nanotechnology attracts new investment despite a failing global economy.

19. The glitzy customer appeal of "nano" products is underscored by the unexpected success of NANO MANIA - which became the subject of rapid and lucrative trading online when the Swiss grocery store chain, "MIGROS" distributed free toys called "nanomania". It is no surprise therefore that the Swiss "nanocube" website testifies to the rapid increase in consumer products containing nanoparticles. Their trivia quiz begins with the interactive question, "42 consumer products in this photo rely on nanotechnologies. Can you find them?".[19] The answers range from bicycle tyres to the lining of a refrigerator, and a wide variety of products inside it.

## II. Benefits of nanotechnologies for the environment and human health

20. Nanotechnology holds the promise of meeting global challenges of the twenty-first century regarding providing alternative energy, protecting the human right to clean water, ensuring wildlife protection, clean-up of brownfields, and reducing the global disease burden.

[16] Vladimi Murashov and John Howard, “Essential features for proactive risk management in : nature nanotechnology” Vol 4, www.nature.com/naturenanotechnology, Aug 2009 Macmillan Publishers. “Nanotechnology is predicted to improve many aspects of human life. By 2015, it is estimated to represent $3.1 trillion in manufactured goods. Data is emerging that exposure to nanomaterials may pose a health risk to workers. If the economic promise of nanotechnology is to be achieved, ways need to be found to protect nanotechnology workers now". The authors also noted: “There is a significant time lag between the emergence of any new technology and the generation of sufficient risk assessment information to be able to conduct a thorough quantitative risk assessment and to write a traditional regulatory occupational risk management standard […] In the case of nanotechnology, the remarkable variability of nanomaterial compositions, the new properties of these nanomaterials and the introduction of new manufacturing processes bring extra challenges to the process of adopting either mandatory or voluntary risk management approaches”.

[17] Valeriy Sudarenkov “Nanotechnologies, a new danger to the environment?”, Preliminary draft report AS/ENA (2011) 35, 22 September 2011, Council of Europe, citing European Commission, “Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: On the progress made under the Seventh European Framework Programme for Research,” Commission of the European Communities, 2009, p. 43. Hellsten, E., (DG Environment, European Commission), “Environment and Health Aspects of Nanomaterials – An EU Policy Perspective,” presentation to the Nanotech Northern Europe 2008 conference, Copenhagen.

[18] Ilise L Feitshans, "China in the WTO: The Future of Regulation Protecting the Safety and Health of Workers Using Nanotechnology" unpublished paper, Geneva School of Diplomacy 2010. Discussion of CHINANANO 2009: annual conference in Beijing, China, September 2009, sponsored by the National Center for Nanoscience and Technology, Peoples Republic of China.

[19] www.nanocube.ch.

21. **Cheap and clean energy** [20]

Prototype solar panels incorporating nanotechnology are more efficient than standard designs when converting sunlight into electricity. Nanotechnology is in use in batteries, nanomaterials may improve hydrogen storage materials and catalysts for fuel cells. By creating more surface area and lighter storage units, nanotechnology can enhance energy generation, conversion and storage for: fuel cell, solar cell, thermo-to-electric, biomass energy, hydrogen storage, secondary batteries, super-capacitors, and thermal storage fluids.

22. **Protecting the human right to clean water**

Nanotechnology offers[21] inexpensive water purification due to rapid, low cost impurity detection. Magnetic interactions using ultra small rust can help remove arsenic from drinking water. Nanotechnology may also improve air and water quality monitoring, by developing more sensitive detection devices that can measure a broad range of pollutants and toxic agents simultaneously. Rapid detection allows for swift response, thereby minimising damage and reducing remediation costs. According to the Rapporteur, "nanoporous membranes that filter pathogens and other undesirable material are now commercially available. Some scientists propose to remediate ground water pollution by using nanoparticles of iron as a chemical reductant.[22] Nano-engineered membranes could be used for more energy-efficient water purification processes (desalination by reverse osmosis) (sic)".

23. **Clean-up of brownfields**

Antimicrobial properties of nano-silver may clean up oil spills and hazardous chemicals.

24. **Pollution reduction and environmental progress**[23]

Lighter cars and machinery that require less fuel; alternative fuel and energy sources; and materials that detect and clean up environmental contaminants all seem possible. The University College of Dublin (UCD) Center for Bio-Nano Interactions (CBNI) studies the impact of nanoparticles dispersed in environmental milieu, where decaying plant and animal matter becomes natural organic matter, typically composed of polysaccharides, interact with nanoparticles, and examines how this interaction affects organic stability, dispersability, environmental fate and behaviour.

25. **Reducing the global disease burden**

Improvements in health care through enhanced diagnosis and treatment will increase personal well-being worldwide, as discussed below.

26. **Mitigating economic crisis**

Investment in nanotechnology will stimulate economic growth that otherwise might not exist during the economic crisis. This will in turn support development of ancillary industries, such as marketing for new products, recycling and disposal of waste and litigation regarding: intellectual property and liability.

## III. Nanotechnology and risk

27. The risks associated with current consumer and industrial uses remain unknown and therefore unquantified. CBNI has begun research regarding plants, animals, and micro-organisms in order to understand the potential impact of nanoparticles upon ecosystems.

[20] www. nano.gov.
[21] www.nano.gov.
[22] UNEP http://www.unep.org/yearbook/2007/PDF/7_Emerging_Challenges72dpi.pdf.
[23] www.nano.gov.

## A. Nanotechnology and human health

28. **Nanomedicine**:

Instead of the large and costly "packaging" associated with capsules and pills, application of nanotechnology to medicine will allow probes and pharmaceuticals to move into tissues by traversing cell membranes, thereby disrupting the disease process. This will enable doctors to diagnose, treat and cure diseases and illnesses that were previously considered untreatable. So too, lighter and stronger medical implants could be created using nanotechnology. For example, nanoelectronic systems might detect and process information leading to the development of artificial retina or cochlea.[24] Pharmaceuticals reformulated with nanoparticles have greater absorption, and, applying nanotechnology, opticians can use new coatings for eyeglasses to make them scratch resistant.[25]

29. Although human exposure to nanoparticles remains miniscule, it is believed the consequences of these small exposures may be great. No one knows exactly how nanoparticles interact with biological systems, or with each other. Consequently, the same dazzling feature of nanotechnology that makes possible crossing the semi-impermeable membrane of cells for nanomedicine also may unleash negative results that cannot be contained. For this reason, the EU laboratories of "QNano" are studying the so-called "fate" and behaviour of nanoparticles that interact with biological processes. The Rapporteur noted, "2004 reports from two academies in the UK emphasised the importance of the life cycle of the enhanced material from “cradle-to-grave” or Life Cycle Assessment-LCA analysis."[26] This approach is consistent with sound industrial hygiene practice and accepted methods for ecological protection.[27]

30. **Friend or foe?**

The same ability to traverse the cell wall or to cling to the protein corona at the exterior of the cell membrane in order to heal also has some scientists worried about the ability of unwanted nanoparticles to do the same thing: disrupt the ongoing biological process in humans or the larger ecosystem. Uncontrolled mass doses of toxic nanoparticles could have catastrophic effects, thus inadvertently causing harm. Working with NIOSH, the Organisation for Economic Cooperation and Development (OECD) in November 2007 established the OECD Working Party on Manufactured Nanomaterials; their collaboration established a NIOSH-led project to raise awareness about - and harmonise approaches for - exposure measurement and risk mitigation when using nanomaterials.[28] In 2010, NIOSH asked for public comment:

***“Whether the hazard identification, risk estimation, and discussion of health effects for carbon nanotubes and nanofibers are a reasonable reflection of the current understanding of the evidence in the scientific literature” [29]*** in the hope of learning more about filters, barriers best practices and the bio-nano interactions that can stop or cause illness and injury in the workplace.

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[24] Valeriy Sudarenkov “Nanotechnologies, a new danger to the environment?” Preliminary draft report AS/ENA (2011) 35, 22 September 2011, Council of Europe, citing The Royal Society & The Royal Academy of Engineering report, July 2004 “Nanoscience and nanotechnologies: opportunities and uncertainties”.

[25] www. Nano.gov.

[26] Valeriy Sudarenkov, “Nanotechnologies, a new danger to the environment?” Preliminary draft report AS/ENA (2011)35, 22 September 2011, Council of Europe, citing The Royal Society & The Royal Academy of Engineering report, July 2004 “Nanoscience and nanotechnologies: opportunities and uncertainties” page 32. The LCA is the systematic analysis of the resource usages (for example, energy, water, raw materials) and emissions over the complete supply chain from the ‘cradle’ of primary resources to the ‘grave’ of recycling or disposal.

[27] Mark Hoover and Morgan Cox, “A Life-Cycle Approach to Development and Application of Air Sampling Methods and Instrumentation” Figure 4.1, Radioactive Air Sampling Methods , edited by Mark L. Maiello and Mark D. Hoover, “the cycle begins with evaluation of a mission or performance requirement, (real or emerging); proceeds through research ADN development, prototype testing, production control testing, training, and acceptance of a method and the associated instrumentation to accomplish the mission; continues with initial calibration, functional checks, and accumulation and review of operational experience to conduct the mission in a scientifically defensible manner, proceeds through maintenance and recalibration and through periodic performance testing to ensure the method is still working; and eventually ends with either the ultimate completion of the mission or the replacement of the method by more effective methods”.

[28] OECD Workshop on Exposure Assessment & Exposure Mitigation and NIOSH October 2008 Frankfurt, Germany

[29] Ilise L Feitshans Review and Comment NIOSH Current Intelligence Bulletin: Occupational Exposure to Carbon Nanotubes and Nanofibers [PDF - 804KB] Docket Number NIOSH-161 “Legal basis and justification: Niosh recommendations preventing risk from carbon nanotubes and nanofibers” prepared in response to the question

31. New research on the movement of nanoparticles asks whether air pollution that includes nanoparticles can cause changes in heart rhythm or blood pressure, leading to episodes of heart attack or respiratory distress. Research about air pollution suggests that cells and organs may demonstrate toxic responses even to apparently non-toxic substances when they are exposed to a sufficient dose at the nanoscale.[30] This notion is intuitively logical, although empirically hard to prove.

32. **The question whether the type or source of nanoparticle interactions makes a difference under law** is one area, however, where regulators must make a policy decision whether all nanoparticles (regardless whether natural, synthetic, manufactured, engineered or accidental) and the context in which they come into contact with humans should be treated the same way under law. The source of nanoparticles that cause harm could allow some types of nanoparticles to be exempted or held to a higher standard. If so, methods must be built into the law to tease apart the types of nanoparticles, unless the law makes a policy decision to deliberately examine only the context and effects. Methods for determining which types of nanoparticles make an important difference from the standpoint of liability, unless legislators determine that a duty exists to protect against all types of nanoparticles.

33. Evidence of occupational exposure leading to damage of the lung from the application of nanotechnology in China has already appeared in the scientific literature.[31] Claims that seven Chinese factory workers developed severe lung damage from inhaling nanoparticles are stoking the debate over the environmental - health effects of nanotechnology. A paper published in the European Respiratory Journal claims to be the first to document cases of ill health caused by nanoparticles in humans.[32] The study described seven women, aged 18–47 years, who worked in an unidentified printing factory in China; two of them later died. They had pleural granulomas — ball-like collections of immune cells in the lining of the lung that form when the immune system is unable to remove a foreign body. They also had excessive, discoloured fluid in the lung lining. Particles around 30 nanometres in diameter were found in lung fluid and tissue in the lung.

### B. Impact on the environment and non-human species

34. Significant gaps in our knowledge about the environmental fate and toxicity of nanoparticles after they have been used for a targeted purpose have raised grave concern among researchers and policymakers. No one knows the effect of nanoparticles on animals, plants or micro-organisms once the particles come into contact with cell membranes or the proteins that surround the cell. Do they bind to them, or are there some types of particles that will cluster by themselves or be repelled by the organism?[33] According to the Rapporteur, "Various impacts were observed on crustaceans and fish in several studies: alterations of embryonic development in zebrafish (Danio rerio), alterations in the respiratory capacity of rainbow trout exposed to single wall carbon nanotubes, mortality events in amphibians exposed to high concentrations of carbon nanotubes with double walls." [34]

presented by the National Institute for Occupational Safety Health: on behalf of the International Safety resources Association, February 2011.

[30] The Royal Society & The Royal Academy of Engineering report, July 2004 “Nanoscience and nanotechnologies: opportunities and uncertainties” pages 39, 40. http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf.

[31] See message from Andrew Cutz, Date: Friday, 21 Aug 2009, Lung damage in Chinese factory workers sparks health fears.

[32] Y. Song, X. Li and X. Du Eur. Respir. J. 34, 559–567; 2009 Song, Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma, Eu J Resp, doi 10.118309031936. 00178308, 2009 http://erj.ersjournals.com/content/34/3/559.full.pdf.

[33] Stark, W. J., Nanoparticles in Biological Systems. *Angewandte Chemie International Edition 2011*, 50, 1242-1258 and Walczyk, D., Bombelli, F.B., Monopoli, M.P., Lynch, I., Dawson, K.A. , What the cell "sees" in bionanoscience. J. Am. Chem. Soc. 2010, 132, 5761-5768.

[34] Sudarenkov, citing *Ministère de l’écologie, du développement durable, des transports et du logement « Développement et régulation des nanotechnologies » 28 septembre 2009 (mis à jour le 21 janvier 2010).*

35. Current data suggests that the biological behaviour of nanoparticles and the subsequent effects of that behaviour involves a biological interface, but the natural process itself remains poorly understood. Thus, sound information describing this scientific phenomenon is limited; therefore few conclusions can be drawn to guide regulatory activities using robust evidence, at this time.

## IV. Nanotechnology and bioethics

36. Are there bioethical issues of health policy regarding the widespread application of nanotechnologies in commerce in Europe in the 21st century ?

37. Short Answer: Nanotechnology poses the greatest bioethical issue of informed consent for the 21st Century, for Europe and for the rest of the world. The state of the art is such that sound regulators of health-policy issues have more questions than reasonable people or responsible scientists can clearly answer at this stage. This preliminary discussion therefore outlines key areas for further research, but underscores that any conclusion about the content of the requisite disclosure that are the building blocks of informed consent is premature.

### A. Statement of the problem: disclosure of risk information when no information exists

38. Disclosure of risk information is a fundamental tenet of informed consent, but we don't know what we don't know in nanotechnology. Informed consent is the linchpin of protecting consumer health, public health in the use of traditional and nanomedicines, and protecting the life of businesses engaged in commerce using applications of nanotechnology, because it protects disclosing entities from potential liability.

39. Traditional informed consent principles in regulations such as REACH PIC requires product providers to disclose information concerning risk to consumers so that people or corporations using or purchasing a product can make informed choices about those products before purchasing or using them. In exchange for this disclosure, however, consumers are then presumed to have understood and accepted the risks of potential harm associated with the product, thereby insulating the provider of the goods or services from liability in the event of harm.

40. One key bioethical issue of informed consent involves the consumer or user's ability to understand the information disclosed. Another bioethical issue concerns whether the disclosure is adequate to enable people or corporate consumers to reasonably accept and manage risks after making choices based on the information given. Additional issues concern the quality of the data about risk, such as whether it is reliable, replicable by other researchers or otherwise applying methods accepted in the scientific community and therefore valid by consensus if not under a specific regulatory authority. The role of scientific precautionary principles is key to unlocking the right to meaningful informed consent, once there is solid baseline data.

41. Both of these key facets of informed consent:

1. disclosure of risks to inform the consumer or end-user and
2. acceptance of risks, or consent to conditions despite stated known risks, based on reliable, replicable accepted data in order to limit potential corporate liability (or health professional personal liability) cannot be addressed about nanotechnology given the present state of the art., due to the dearth of information about unknown and unquantified risks from cumulative exposures.

42. Key questions raised by parliamentarians in this area concern:

- consumer protection (in particular in the area of biomedicine/ nanomedicine – patient protection), and nanosafety;
- corporate liability;
- other ethics issues raised by the European Group on Ethics (EGE) of the European Union in its opinion on nanotechnology.

### B. Scope of the problem: Uninformed use of nanotechnology applications in commerce

43. An excellent example of the nanotechnology in daily use is found on the website from the Swiss government, nanocube.ch. Its interactive photos identify over fifty household items using nanotechnology and therefore representing potential exposure to engineered or manufactured nanoparticles in daily life, from refrigerator linings (in the house or in transport of food from producer to grocery store) to bicycle tires and cosmetics. The plethora of these products on the market since 2005, and the likelihood that nanoproducts will exceed three trillion US dollars of GDP by 2015 means that it is too late to declare a moratorium, and that even the scientific precautionary principles to be implemented for risk management protecting public health lag behind exposures in the workplace, in the community and the environment.

44. Because nanotechnology often requires use of well-established toxic and hazardous materials such as titanium dioxide in a format where it exhibits novel properties, no-one can declare that any application of nanotechnology is completely safe, even though quantifying the risks is premature. Therefore, in order for the bioethical dilemma of informed consent to be resolved, both the methods of control of harms and the protections for benefits must be made clear before genuine choice can be realised. Thus, unregulated or unbridled use of nanotechnology in civil society deprives consumers of their ability to make choices based on informed consent, and at the same time runs the risk of threatening bankruptcy or other harm to industries that market, purchase, supply or are end-users for nanotechnology products, in the event that a catastrophic long-term effect transpires.

45. This same lack of information and regulatory harness deprives consumers of the benefits of good products because: lack of regulatory protection means that producers must “go bare” without any immunity form false claims. Therefore producers may not bring important and useful nanotechnology products to market, because of fear of potential liability even if harm is not real but is perceived by the general public. And, the absence of a regulatory framework means that European citizens and taxpayers are also unprotected, running the risk that harms from nanotechnology that cannot be traced to their root cause will cost the public purse and increase the overall expensive disease burden in society.

46. **Consumers: Product labels with warning give rise to implicit informed consent**

#### *1. Goods*

REACH is just one everyday example of a vast network of protective regulations that play an important role in informed consent. The open question regarding the scope of REACH jurisdiction regarding nanotechnology in general looms even larger when confronted with the question which risks are sufficiently understood to be required to be disclosed.

### *2. Foods*

Food is a particularly sensitive area for informed consent issues because knowing more about food and becoming increasingly aware of what we put into our bodies is part of a greater global movement towards improved individual health. Therefore, the last decade of the twentieth century gave rise to extensive requirements for labelling and measuring the quantities of particular ingredients, in foods especially but not limited to flavour and colour additives and preservatives. The use of nanotechnology in packaging as well as food production, however, confounds the consumer movement to more informed food choices to protect personal and public health. So little is known about nanoparticles in food, or about the ability of nanoparticles to migrate into food during transport or via packaging, that it is not clear what a label could state as a warning of risk or danger.

47. **Medicine: The traditional battleground and home court for informed consent**

Thousands of doctoral dissertations and legal careers have been financed by the fundamental medico-legal principle of informed consent, which ensures that people have an understanding of the risks that they face even when seeking better health or a cure for disease. In medical contexts, informed consent is specifically requested and authorised in order to allow patients to undergo medical procedures despite known and reasonably quantified risks, even if the risk is quite great. This occurs, for example, when a patient undertakes an experimental treatment, a very dangerous operation when there are few alternatives to surgery, or embarks upon a course of treatment with toxic substances, such as chemotherapy for end-stage cancer. In these instances, the patient gives a signed release from liability for undesirable outcomes. Another reason for informed consent in the medical context involves information that has been or will be disclosed for particular purposes. This form of informed consent releases the caretaker of the data from liability for the disclosure of information, or in the case of the HIV/AIDS pandemic, a release from the potential psychological harm caused due to the so-called “emotional freight” of learning one’s own HIV status.

48. These applications of the principles of informed consent give freedom from recrimination to the person who discloses the confidential information, or the provider of a treatment, only because it is also presumed that the recipient of the information has the underlying understanding of the information disclosed in order to accept it with a comprehension of the attendant consequences. Thus, if there is no reliable scientific data to communicate regarding risk, the patient cannot make an informed choice, and therefore, it is impossible, without good data, to request or provide informed consent.

49. ***Nanomedicine***

Nanomedicine will revolutionize public health by reducing the cost of the “delivery package” for pharmaceuticals, which will replace drug size of contemporary pills and capsules with a comparatively miniscule cost, using nanoparticles that travel between cell walls or can enter the cell itself. The ability of nanoparticles to traverse cell walls is important, but no one knows yet when it will be a blessing or a curse. As noted by Buerki-Thurnherr, von Mandach and Wick, (“knocking at the door of the unborn child: engineered nanoparticles at the human placental barrier”, Swiss Medical Weekly 5 April 2012), “Although these novel characteristics drive the development of numerous applications in many fields of technology and medicine, they may also have unforeseen effects if particles come into contact with cells and tissues of the human body. In fact, nanoparticles have a relatively marked propensity to cross cell membranes. Biological barriers such as the blood-brain barrier that are hardly amenable to larger particles or drugs can be penetrated by certain nanomatérials”.

50. ***Nanoparticles in Traditional Medicines***

Nanotechnology also influences the reduced cost of freight in traditional medical models using pill and capsule delivery systems. Therefore, it can be expected that some nanoparticles will be used in drug packaging. From a legal standpoint regarding products liability and from a regulatory standpoint, it is not clear whether the new nanotechnology applications for pre-existing pharmaceuticals will be covered by the existing legal apparatus for traditional drugs.

51. **Workplace exposures: building on the bedrock of worker right to know**

It is well established that workers have a so-called "Right to know" about toxic or hazardous substances to which they have been or will be exposed in the workplace. This application of the precautionary principle is the bedrock of international law (ILO Convention 155 and the UN GHS, an international system for harmonising the data disclosed in transport of toxic or hazardous chemicals). Furthermore, right to know is addressed in many national laws ensuring occupational safety and health.

52. The right to know under law is typically a two-tiered formula for risk management and public health protection. It typically requires:

1. disclosure about risks using a standardized safety data sheet form and
2. training regarding the best practices for safer handling of the regulated substance

The right to know, like all other forms of informed consent, requires a baseline of reliable data in order for the disclosure of data to be meaningful.

***a. laboratories and research***

Employers and workers alike want to know what to do about unquantified risk in the nanotechnology laboratory setting. The question of reproductive health also arises as science reveals more data suggesting that nanoparticles can traverse the placenta, thus posing risks that are special to the situation of pregnant workers. This question will raise bioethical issues of fairness, access to information and care and prevention of discrimination.

***b. general employment***

The labelling requirements for safety data sheets remain unclear, therefore it is also difficult to state how to protect workers who are not involved in the production of, for example, carbon nanotubes, but are end-users of nanotechnology applications in their work.

53. **Environment: The meaning of warnings on labels for manufacturers and end users**

The same concepts that impact health of individuals in the workplace impact the entire society at large when transporting or dumping dangerous products. Therefore further research is required to examine the bioethical issues for nanotechnology/

a. impacts on the environment that require labelling (i.e. pesticide model);
b. potentially hazardous waste;
c. additional stakeholder concerns.

**C. Proposed Strategy**

54. Nanotechnology poses a vital bioethical dilemma for the 21st century, in Europe and throughout the world. This dilemma involves the trade off to be made by consumers concerning benefits and long-term risks of using products created by the newest applications of nanotechnology because: so little is known about the cumulative effects of exposures even though there is an abundance of nanotechnology-related products in the marketplace

55. Labelling is a key vehicle for informing consumers so they can make choices, thereby resolving the bioethical dilemma of informed consent. Labels disclosing risks are a traditional form of regulation designed to inform purchasers, workers who are handling a given substance, corporate downstream users and the general public about dangers. Once informed, the same labelling regulations operate to insulate producers and suppliers from potential liability. Labels typically contain pertinent information about ingredients so that consumers and end–users can make conscious trade-offs when purchasing and using a given product. Unfortunately, too little is known to determine what labelling regarding nanotechnology applications to daily products is appropriate at this time.

56. Precautionary principles that are ordinarily operationalised by labelling therefore can't help us know what we are buying, eating, breathing or touching, or will absorb into our bodies by accident, from the standpoint of known risks about nanoparticles at this time. The best approach is to engage in the development of a regulatory framework that will facilitate examining nanotechnology applications from the standpoint of their functionality in the context of their use, so that risk can be managed in light of their expected benefits and potential harm. Keeping alive the promises of the Council of Europe about the application of scientific precautionary principles therefore requires creating a framework that will demand and review data once the baseline data has been established.

## V. Regulation of nanotechnologies

### A. Role for the Council of Europe

57. The Council of Europe Committee of Ministers has a vital role regarding two fundamental policy questions to resolve, which will shape the future of nanotechnology laws:

1. How to define nanotechnology, nanoparticles and "other nano things" that should be regulated, if at all, under law and

2. Whether to follow a so-called "list" approach or instead to craft a flexible umbrella of criteria regarding nanotechnology developments and risks.

58. One definition that has gained currency worldwide comes from the USA federal government's project National nanotechnology initiative, (NNI) found at the website, nano.gov: "Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications." The functional component of this respected and often-repeated definition embraces nanotechnology as "Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modelling, and manipulating matter at this length scale."[35]

59. Most draft laws fail to define key terms, including but not limited to: nanotechnology, nanoscience, nanoscale, nanomedicine, nanoelectronic, "manufactured nanoparticles" (as distinguished from engineered nanoparticles, natural accidental or synthetic nanoparticles) neurotransmission of nanoparticles, nanotube, nanoinformatics, nanoethics, "protein-nanoparticle interactions", "nanoporous membranes" nanotoxicity, nanobiotechnology, nanofabrication, nanosafety and "human nanotoxicology".

### B. Legislative Approaches

60. Key legislative drafting techniques can create a practical and flexible response to these issues. The relevant principles of drafting laws traverse across disciplines, across subject matter and across the boundaries of various jurisdictions.

61. One narrow approach would be to define these terms, using a list based on existing state of the art technology. This approach is quick for the users, especially civil servants involved in enforcement of precautions, but is seductively easy without allowing for changes in the list if it omits a problem that is important, includes by coincidence an application that was not intended for regulation but fits the list description. Worst of all, lists are quickly outdated. New developments, whether good or bad, cannot be included on a list; the list is rigid. For example, the definition "100 nanometers or less" sounds great for putting nanoparticles on the regulatory list. Consensus for the use of this term as a reference appears in many texts. Scientists like it because it sounds empirical. The bright line dividing what is under regulation and what is exempted is nice, too – civil servants like it, because the inspectors and enforcers "know who is in who is out." But, what about the problem nanoparticles at 103 nanometers? What about harmless coatings that are less than 100 nanometers, but need no regulation at all? What about the car, the tyre, the toy, or the entire "company" named "Nano", whose size will inevitably exceed the 100 nanometre criterion for regulation? Do the owners of these products in commerce have the right to use the word "nano" in their trade mark and advertising, without any regulation, even though the general public mistakenly believes that these products are subject to regulation because of

[35] www.Nano.gov.

the use of "nano" in the product name? Last but not least, any numbers based-criterion is easily reduced to a "Numbers game". Engineered nanoparticles will be either too big or too small for the numerical parameters under law, depending on whether the owner of the product wants to be included or exempted from regulation. ***Where should the legislature or regulators draw the line to exclude so that one law does not swallow everything?***

62. Lists therefore are deceptively simple: lists look easy but are a foe to progress! Things change, but the list stays the same, unless a committee of experts is convened with the power to change it.

63. The alternative approach that has been successful throughout the late twentieth century is to create flexible criteria under law. For example, the WHO Constitution is a shining example of an international legal text whose definition is flexible and has withstood the test of time. No one could have anticipated HIV or AIDS at the time of its writing in 1948, but everyone in the world expected WHO to pro-actively attack the problem from the outset of the HIV epidemic in the 1980s, and then praised WHO programmes without questioning the agency's underlying jurisdiction to do the work. Its criteria are designed to take into account several variables, and can be applied to situations that were not expected when the laws were written. Critics of the painstaking wordsmithing required for a criteria-based approach exclaim that it "Sounds complicated!" (sic). But, the beauty of a criteria based-approach is that it is ***flexible.*** When supported with defensible robust data or sound reasoning, the system it puts into place can add or delete items from the regulatory agenda as needed. This creates the inevitable important escape hatch needed for all delegated authority, specifically: the subject of enforcement or regulation can be released from "under the law" when application of the criteria under law proves that regulation is inappropriate or makes no sense. Yet, new problems can be captured without waiting for a committee of experts to convene with consensus that the problem should be "on the list".

### C. Criteria for a regulatory template: "safety by design"

64. For the first steps towards developing meaningful criteria that can embrace unanticipated developments - whether unexpected benefits or catastrophic problems - researchers should work with law and health policy analysts in order to develop a preliminary framework for classification of nanomaterials based on the details of their bio-nano interface and its stability, evolution and degradation rather than one based solely on underlying physico-chemical properties. The template for regulation should offer criteria that will take into account: potential for bioaccumulation, potential for degradation, and relevant direct toxicities, and negative impacts from perturbed signalling pathways. Such criteria for a framework can also embrace the potential for nanomaterials to modulate protein activity, with a view to encouraging desired outcomes.

65. An excellent example of potential criteria that would accomplish the goals of risk management protecting public health while fostering new nanotechnology applications by industry involves study of the bio-nano interactions among cells and proteins that surround them. The ways in which different proteins bind to and dissociate from nanoparticles are critical parameters determining their interaction with receptors, and biological responses generally. The biological outcome may also be different depending on the relative exchange rates of protein with nanoparticles and cellular receptors, respectively.[36] In addition, the particle-bound protein may have altered exchange rates with a cellular receptor. It is clear that, in *understanding* how particles will interact with cells, these issues are fundamental. Additionally, the corona may not immediately reach equilibrium when exposed to a biological fluid, and will evolve as the nanoparticle encounters new milieu, for example, when particles redistribute from one compartment or organ to another.

[36] Rivera Gil, P., Oberdörster, G., Elder, A., Puntes, V., Parak, W.J., Correlating Physico-Chemical with Toxicological Properties of Nanoparticles: The Present and the Future. ACS Nano 2010, 4, 5527-5531. Also: Kendall, M., Ding, P., Kendall, K., Particle and nanoparticle interactions with fibrinogen: the importance of aggregation in nanotoxicology. Nanotoxicology 2011, 5, 55-65.

### D. To define Nano, or not to define?

66. Although data is inadequate, hard policy choices must be made to promote nanotechnologies, to cultivate a culture of innovation and provide monitoring for the new developments to protect public health, all at the same time. Some believe that given the dearth of robust empirical data, member states should apply the precautionary principle by banning nanotechnology in order to protect researchers, consumers, and the environment. Other stakeholders oppose this view, stating that existing regulatory frameworks are sufficient. Taking the middle ground, the European Commission report "Regulatory Aspects of Nanomaterials" published in June 2008 concluded that the EU legislative framework "covers in principle the potential health, safety and environmental risks in relation to nanomaterials", but recognised that regulations may be modified as scientific knowledge becomes refined.[37]

67. The question whether to embrace a "List" approach, with the attendant costs of employing experts on a regular cycle to revise the list as appropriate, and the notion of having flexible criteria instead, shares one major working assumption: the need to define nanotechnology and related terms under law. The heretical question posed by Andrew Maynard[38] is, "should the law attempt to define nanomaterials at all?"

### E. Policy considerations for nanotechnologies: dialogue among stakeholders

68. Industry is not a monolith. In some respects, industries are as much of a consumer of nanomaterials as any individual - with concomitant consumer concerns**.**

69. Manufacturers of some products are at the same time end-users of other materials. For this reason, the Global Harmonisation of Chemical Safety (GHS) was established. The same principles should apply across industries manufacturing or applying nanotechnologies, because global trade is an admixture of many different streams of commerce. In order for the industries who are also consumers to understand what they are handling, purchasing or selling across the world, manufacturers and midstream users should publish details of the methodologies they have used, similar to the Safety Data Sheets (SDS) required for toxic and hazardous substances in the workplace under GHS.

70. Governments have issued action plans, such as the Swiss nanotechnology strategy for 2015 that was passed by the federal legislature in April 2012. There is a need for cross-cutting government action, involving many different administrative agencies, particularly in the area of health policy research.

71. The Rapporteur recommended the development of a public, open database of peer-reviewed results of toxicology tests on nanoparticles, which could be used to share information and identify gaps in research. Since several major competing databases already exist, the question is: how to coordinate all of these competing institutions using procedures that can faithfully and accurately archive and retrieve data from competing data sources?

72. QNano is an interdisciplinary centre funded under the EU Seventh Framework to research the toxicity, epidemiology, persistence and bioaccumulation of manufactured nanoparticles and nanotubes, their exposure pathways, to develop methodologies for monitoring them in the built and natural environment. The centre interacts with regulators. It also is a centre for advice on the potential health, safety and environmental impacts of nanomaterials. QNano provides a vibrant infrastructure for coordinating and synthesising the work of over 15 European labs and research institutions.[39] QNano's core aim is the creation of a 'neutral' scientific and technical space in which all stakeholder groups can engage, develop, and share scientific best practices in the field. QNano synthesizes resources from across Europe to develop efficient, transparent and effective processes so that users and stakeholders

[37] According to Mr Sudarenkov, "This position has been challenged by a non-binding resolution adopted in April 2009 by the European Parliament, following a detailed report on nanomaterials presented by the European Parliament's Environment Committee. The resolution asks for tighter controls on nanotechnologies, in particular with respect to legislation on chemicals, food, waste, air and water, workers protection" Valeriy Sudarenkov "Nanotechnologies, a new danger to the environment?" Preliminary draft report AS/ENA (2011) 35, 22 September 2011, Council of Europe.

[38] Andrew Maynard "Don't Define Nanomaterials" (Nature 475, 31 July 2011). In reply, also in NATURE, 29 August 2011, Herman Stamm wrote: "But such a definition is urgently needed, especially for particulate nanomaterials".

[39] http://www.qnano-ri.eu/.

can have access to data in the context of a best-practice ethos. While encouraging evidence-based dialogue among researchers, QNano also pro-actively promotes the highest quality research and practices with consistency throughout the continent. QNano maintains a network bringing together epidemiology, toxicology, studies of exposure pathways and measurement of nanoparticles; medical applications and maintains a database of publicly funded research.

## VI. Conclusions and recommendations

73. Laws can foster and incubate NEW industries while monitoring the situation through funding and incentive systems, to control emerging risks. Forethought beats afterthought!

**Recommendation 1**

74. There is an important role for the Council of Europe to play at this stage of the development of embryonic laws and regulations governing nanotechnology.

Within the context of committee work, deliberations and diplomatic relations there are many drafts and many claims of jurisdiction over nanomaterials. There is no shortage of text, but it seems that people are spending more time writing draft laws than they spend reading the laws and drafts that already exist. Therefore, key tasks for the Council of Europe include:

A. Defining OR regulating nanotechnology in its 47 member states
This task should be designed with a view to clear and consistent text across borders, across the origins of nanomaterials (synthetic, natural, accidental, manufactured, engineered) and across the functional uses and biological fate of the nanomaterials under regulation;

B. Plenty of laws exist already but there are GAPS in two major areas:

1. Harmonisation and
2. Consumer education

These are areas where the Human Rights mandate within the Council of Europe's umbrella can shine to make an important contribution to the nanotechnology law and health policy discourse.

**Recommendation 2**

75. Possible role for Committee of Ministers: There should be a ***Study Commission on Law and Health Policy of Nanotechnology.*** The Commission's mandate should seek key law and health policy experts in nanotechnology from a variety of nations for evaluating economic political scientific and legal aspects of the issues discussed here. In particular, public comments should be available to the rapporteur of the Study Commission:

- gathering fresh information and
- promoting transparency within the nanotechnology regulatory process

The Study Commission should be authorised to determine:

A. A clear answer to the question: should there be a Convention developed on a "nanotechnology and human rights / health“ or possibly a Protocol to an existing Council of Europe Convention such as the Oviedo Convention on Biomedicine and Human Rights? (open to ratification by non-member states, like the Cybercrime Convention which binds the USA).

B. Proposed report - Is a Council of Europe-level recommendation or binding legal instrument recommended? Definitions: which criteria to apply for "defining nano"? Precautionary principle, how respected, what limits? What should be the role of the Council of Europe's Parliamentary Assembly? How best to participate in global discourse, with a view to favouring harmonisation.