Parliamentary Assembly
Assemblée parlementaire
https://pace.coe.int

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

**Doc. 13117**
29 January 2013

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

**Report**[1]
Committee on Social Affairs, Health and Sustainable Development
Rapporteur: Mr Valeriy SUDARENKOV, Russian Federation, Socialist Group

*Summary*

Nanotechnology – the manipulation of matter on an atomic and molecular scale – and its myriad applications have the potential for enormous benefits (in particular in the field of "nanomedicine"), but also for serious harm. As with most emerging technologies, many risks, both to public health and to the environment, are as yet poorly understood. However, commercial applications of nanotechnology are already in widespread use. Regulations have struggled to keep up with the pace of scientific innovation.

The Council of Europe, as the only pan-European body with a human rights protection mandate, should set legal standards on nanotechnology based on the precautionary principle which will protect 800 million Europeans from risk of serious harm, but which will not hinder nanotechnology's potential beneficial use. The Assembly should thus recommend that the Committee of Ministers work out appropriate guidelines on balancing benefits and risks to public health and the environment in the field of nanotechnology that can be used as a model for regulatory standards worldwide, starting with a feasibility study to be entrusted to the Council of Europe's Committee on Bioethics (DH-BIO).

1. Reference to committee: Doc. 12372, Reference 3718 of 8 October 2010.

**Contents** **Page**

A. Draft recommendation ..... 3
B. Explanatory memorandum by Mr Sudarenkov, rapporteur ..... 5
1. Introduction ..... 5
2. Definition and potential of nanotechnology ..... 5
3. Nanotechnology and bioethics ..... 6
4. Balancing potential risks and benefits ..... 6
5. Conclusions and recommendations ..... 6

## A. Draft recommendation[2]

1. Nanotechnology is the manipulation of matter on an atomic and molecular scale. Nanomaterials involve structures having dimensions of nanometres (nm), that is one billionth (or $10^{-9}$) of a metre, typically between 1 and 100 nanometres in size. At such dimensions, materials can show significantly different physical, biological and/or chemical properties from materials at bigger dimensions, which opens up a range of new possibilities for technology.

2. Nanotechnology and its myriad applications have the potential for enormous benefits (in particular in the field of "nanomedicine"), but also for serious harm. As with most emerging technologies, many risks, both to public health and to the environment, are as yet poorly understood. However, commercial applications of nanotechnology are already in widespread use. Regulations have struggled to keep up with the pace of scientific innovation.

3. For years, the Parliamentary Assembly and the Committee of Ministers of the Council of Europe have been advocating the need for a culture of precaution incorporating the precautionary principle into scientific and technological processes, with due regard for freedom of research and innovation. In 2005, the Heads of State and Government of the Council of Europe gave undertakings in the Final Declaration of the 3rd Summit of the Council of Europe "to ensure security for our citizens in the full respect of human rights and fundamental freedoms" and to meet, in this context, "the challenges attendant on scientific and technical progress".

4. The Assembly believes that, in keeping with these undertakings, the Council of Europe, as the only pan-European body with a human rights protection mandate, should set legal standards on nanotechnology based on scientific knowledge and the precautionary principle, which will protect 800 million Europeans from risk of serious harm, while encouraging nanotechnology's potential beneficial use.

5. The Assembly thus recommends that the Committee of Ministers work out guidelines on balancing benefits and risks to public health and the environment in the field of nanotechnology which:

5.1. respect the precautionary principle while taking into account freedom of research and encouraging innovation;

5.2. allow for consistent application 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;

5.3. seek to harmonise regulatory frameworks, including of risk assessment and risk management methods, protection of researchers and workers in the nanotech industry, consumer and patient protection and education (including labelling requirements taking into account informed consent imperatives), as well as of reporting and registration requirements, in order to lay down a common standard;

5.4. are negotiated in an open and transparent process, involving multiple stakeholders (national governments, international organisations, the Parliamentary Assembly, civil society, experts and scientists) in the framework of a dialogue which transcends the Council of Europe area;

5.5. can be used as a model for regulatory standards worldwide;

5.6. could first take the form of a Committee of Ministers recommendation, but could also be transformed into a binding legal instrument if the majority of member States so wish, for example in the form of an additional protocol to the 1997 Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164, "Oviedo Convention");

5.7. aspire to create an international interdisciplinary centre to be the world's knowledge base in the field of nanosafety in the near future;

5.8. will be able to promote the development of an assessment system of ethical rules, advertising materials and consumer expectations, regarding research projects and consumer products in the nanotechnology field impacting on human beings and the environment.

2. Draft recommendation adopted unanimously by the committee on 19 November 2012.

6. The Assembly recommends that the Council of Europe's Committee on Bioethics (DH-BIO) be entrusted with a feasibility study on the elaboration of possible standards in this area, based on paragraph 5 of the present recommendation, as a first step in the start of negotiations on the topic with a multiple stakeholder approach.

## B. Explanatory memorandum by Mr Sudarenkov, rapporteur[3]

### 1. Introduction

1. In October 2010, Mr Marquet (Monaco, ALDE) and other parliamentarians – amongst them your rapporteur – tabled a motion for a resolution on "Nanotechnologies, a new danger to the environment?" (Doc. 12372), with a view to recommending that the Council of Europe's member States take measures aimed at harmonising the use of nanotechnologies in order to guarantee in particular health security and ensure environmental protection.

2. This motion was referred to the (then) Committee on Environment, Agriculture and Local and Regional Affairs for report and to the (then) Social, Health and Family Affairs Committee for opinion. I was appointed rapporteur for the lead committee in February 2011, with Mr Paul Flynn (United Kingdom, SOC) being appointed rapporteur for opinion. Both committees immediately started work on the subject, leading to an exchange of views with an expert consultant, Ms Ilise Feitshans, in the Social Committee in September 2011 and a discussion on a preliminary draft report in the Environment Committee in October 2011.

3. In January 2012, the two committees were merged with the Committee on Economic Affairs and Development to become the new Committee on Social Affairs, Health and Sustainable Development. At the end of May 2012, Ms Feitshans delivered an expert paper on which the rapporteur has based this report, which she kindly updated with a chapter on nanotechnology and bioethics at the end of September 2012. The rapporteur has chosen to reproduce this expert paper as a committee information document and to summarise its findings in this explanatory memorandum – but the conclusions and recommendations are the rapporteur's own.

### 2. Definition and potential of nanotechnology

4. Nanotechnology is the manipulation of matter on an atomic and molecular scale. Nanomaterials involve structures having dimensions of nanometres (nm), that is one billionth (or $10^{-9}$) of a metre, typically between 1 and 100 nanometres in size. At such dimensions, materials can show significantly different physical, biological and/or chemical properties from materials at bigger dimensions, which opens up a range of new possibilities for technology.

5. Nanotechnology already has myriad applications and the potential for more: since materials behave so differently at nanoscale, structures and devices can be engineered that would have been unthinkable a few decades ago. Some nanomaterials are already being mass-produced and incorporated into consumer products, ranging from titanium dioxide and zinc oxide in sunscreens and cosmetics, over silver in food packaging, clothing, disinfectants and household appliances to carbon nanotubes, for example in tennis rackets. However, the developing field of "nanomedicine", which uses both the scale of nanomaterials (able to penetrate, for example, the skin barrier or even the brain barrier, which bigger molecules cannot) and/or their different properties at nanoscale, holds the promise of enormous benefits in both detection and treatment of some of the greatest contemporary killers of mankind, including cancer and heart disease.

6. As with most emerging technologies, nanotechnology also carries the risk of serious harm, both to human health and to eco-systems in the environment. Many of these risks are as yet poorly understood. However, studies have already demonstrated that nano-silver applied to textiles does wash out. The anti-bacterial properties of nano-silver considered beneficial in hospital sheets (and, more frivolously, in tennis socks) can wreck havoc when washed away in the waste water stream, as they have the capacity to destroy bacteria which are critical components of natural eco-systems, farms and waste-treatment processes. Even more worryingly, some carbon nanotubes seem to have the capacity of provoking similar tissue damage in the lungs as asbestos, and it appears that nanoscale titanium dioxide (used, for example, in sunscreens) can create oxidative stress in cells. Ms Feitshans cites the special report of the German Advisory Council on the Environment (SRU) in this respect: "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 …"[4]

---

3. This explanatory memorandum was prepared on the basis of a report by Ms Ilise Levy Feitshans, JD and ScM, visiting scientist at the University of Lausanne (Switzerland); see document AS/Soc/Inf (2013) 03: www.assembly.coe.int/CommitteeDocs/2013/Asocdocinf03_2013.pdf.

4. See document AS/Soc/Inf (2013) 03, paragraph 8.

### 3. Nanotechnology and bioethics

7. In the eyes of the expert consultant, Ms Feitshans, "[n]anotechnology poses the greatest bioethical issue of informed consent for the 21st century, for Europe and for the rest of the world".[5] The reason for this assertion is that in her view the state of the art is such that there are more questions than answers at this stage when it comes to risk assessment (and thus also risk disclosure).

8. Informed consent is a crucial concept in bioethics. A whole chapter is devoted to the issue of free and informed consent in the 1997 Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164, "Oviedo Convention"). It is the linchpin of consumer protection (in the area of biomedicine/nanomedicine–patient protection), and also of corporate liability.

9. Both of the key facets of informed consent – disclosure of risks to inform the consumer and acceptance of risks, or consent to conditions despite stated known risks – cannot be addressed in the field of nanotechnology given the present state of the art, due to the dearth of information about unknown and unquantified risks, in particular from cumulative exposures. Traditional labelling requirements are thus not workable in this context, unless set against the background of a solid (European, if not international) 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.

### 4. Balancing potential risks and benefits

10. Regulations have indeed struggled to keep up with the pace of scientific innovation in the field of nanotechnology. For the time being, most jurisdictions are either using existing regulations (which, of course, leave wide gaps, due to the extremely small scale and/or the specific nature of nanomaterials), or "adding on" to them in an effort to close these gaps. Thus, in the European Union, for example, a multitude of regulations apply to nanotechnology. Efforts are currently being made by many to devise more novel, comprehensive and consistent nanotechnology regulations, from nation States (United States, China, South Africa, India) to international organisations (Organisation for Economic Cooperation and Development (OECD), World Health Organisation (WHO)), associations (International Standards Organisation (ISO)) and non-governmental organisations (NGOs). [6]

11. Unfortunately, there seems to be far too little communication between the different stakeholders and even less effort at harmonisation. The result is a cacophony, and a current legislative environment which either tends to stifle innovation or is short on risk control. It is my impression that most jurisdictions are currently not erring on the side of caution, in an attempt to stimulate technological development and reap economic rewards in the process. The resultant lack of application of the precautionary principle may yet prove to be dangerously short-sighted, as it has the potential to cause enormous harm both to human health and to the environment.

12. It is thus clear that there is a need to create a common standard to properly balance potential risks and benefits of nanotechnology by harmonising the legislative base with the precautionary principle in mind. What is also needed is not just communication and debate between the different stakeholders in achieving this goal, but also an informed public debate, including consumer and patient information and education (including labelling requirements taking into account informed consent imperatives). The Council of Europe, with its unique human rights mandate and convention-based standard setting, as well as its expertise in the bioethics field, may be able to achieve such transparent harmonisation where other stakeholders with a narrower mandate have so far failed.

### 5. Conclusions and recommendations

13. The expert consultant, Ms Feitshans, offered her own conclusions and recommendations, based on the idea that laws can foster and incubate new industries while monitoring the situation through funding and incentive systems, to control emerging risks. I agree with her on this (and most other) point(s): 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.

---

5. Ibid., paragraph 37.
6. For the complete list: ibid., paragraph 12.

14. This is because the Committee of Ministers and the Parliamentary Assembly agree that it is necessary to advocate "a culture of precaution incorporating the precautionary principle into scientific research processes, with due regard for freedom of research and innovation".[7] In this context, the Committee of Ministers recalled in 2008 the undertakings given by the Heads of State and Government of the Council of Europe in the Final Declaration of the 3rd Summit of the Council of Europe to "ensure security for our citizens in the full respect of human rights and fundamental freedoms" and to meet, in this context, "the challenges attendant on scientific and technical progress".[8]

15. In the context of the current knowledge (and lack of it) on the potential hazard nanotechnologies present both to human health and the environment, it thus seems evident to me that the precautionary principle needs to be applied in this field. Unfortunately, it appears that the nanotechnology industry is developing at a pace at which regulatory development and application is not keeping up. The massive use – already today – in everyday consumer products, as described by Ms Feitshans, of certain nanoparticles with known toxicity (for example nano-silver in everything from clothing to food packaging) or with a potential – as yet poorly understood – for considerable harm to human health (such as nano-sized titanium oxide in sunscreens) may turn out in hindsight to have been a poor application of the precautionary principle. Obviously, researchers and workers in the nanotech industry are in the front line here. But end-consumers may also suffer. Do we really need another asbestos,[9] a prime example of poor (or lacking) application of the precautionary principle?

16. I believe that the Council of Europe, as the only pan-European body with a human rights protection mandate, is well placed to work out guidelines on nanotechnology based on the precautionary principle which will protect 800 million Europeans from risk of serious harm, but which will not hinder the technology's potential beneficial use. These guidelines could first take the form of recommendations (such as a Committee of Ministers recommendation), but could also be transformed into a binding legal instrument if the majority of member States so wish, for example in the form of an additional protocol to the Oviedo Convention. The Council of Europe's Committee on Bioethics (DH-BIO) could be the body to be entrusted with a feasibility study on the elaboration of possible standards in this area as a first step in the start of negotiations on the topic with a multiple stakeholder approach.

17. The guidelines should be designed with a view to obtaining a clear and consistent text applicable 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. The guidelines should seek to harmonise regulatory frameworks, including of risk assessment and risk management methods, protection of researchers and workers in the nanotech industry, consumer protection and education (including labelling requirements where appropriate), as well as of reporting and registration requirements, in order to lay down a common standard.

18. The process of negotiation of these guidelines should be as open and transparent as possible, involving multiple stakeholders (national governments, national parliaments, international organisations, the Parliamentary Assembly, civil society, experts and scientists) in the framework of a dialogue transcending the Council of Europe area, leading to the creation of an international interdisciplinary centre to be the world's knowledge base in the field of nanosafety in the near future. I believe that such regional guidelines would have the potential of imposing themselves as the regulatory standard worldwide, thus protecting the human rights of every person to health and to a healthy environment.

---

7. See Assembly Recommendation 1787 (2007) on the precautionary principle and responsible risk management, and the Committee of Ministers' reply thereto (Doc. 11491), in particular paragraph 4 of the latter.
8. Ibid., paragraph 2.
9. Indeed, some carbon nanotubes already mass-marketed, much appreciated by industry for their strength, flexibility, and other properties, are feared to be very similar to asbestos fibres in their effect on human tissues (for example lung tissues).