Parliamentary Assembly
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COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Recommendation 2017 (2013)[1]
Final version

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

Parliamentary Assembly

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 nm 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 to all nanomaterials under regulation across borders and regardless of their origins (synthetic, natural, accidental, manufactured, engineered), functional uses or biological fate;

5.3. seek to harmonise regulatory frameworks, including in the areas 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 reporting and registration requirements, in order to lay down a common standard;

1. *Assembly debate* on 26 April 2013 (18th Sitting) (see Doc. 13117, report of the Committee on Social Affairs, Health and Sustainable Development, rapporteur: Mr Sudarenkov). *Text adopted by the Assembly* on 26 April 2013 (18th Sitting).

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 geographical area of the Council of Europe;

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

5.6. 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 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. allow for the creation of an international, interdisciplinary centre to be the world's knowledge base in the field of nanosafety in the near future, without prejudice to the continued support, even in financial terms, for ongoing research projects aimed at determining potential risks of nanomaterials;

5.8. 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.

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 multi-stakeholder approach. This study should include, in any case, ongoing scientific research at international level to learn about the risks of nanotechnological material. Thus, the scientific community will be actively involved in the drafting of any proposal for standardisation and/or legislation.