Opinion of the CDDH on Recommendation 2017 (2013) of the Parliamentary Assembly – "Nanotechnology: balancing benefits and risks to public health and the environment"

CDDH : 78th meeting – 25/28 June 2013 CDDH(2013)R78

1. The Steering Committee for Human Rights (CDDH) takes note with interest of this recommendation. It notes, however, that the categorisation "nanomaterial", which relates to the particle size, neither implies a specific risk, nor necessarily means that the material actually has new hazard properties. Any regulatory framework must therefore be flexible in its approach.

2. It also endorses all comments prepared by the Committee on Bioethics (DH-BIO)[1], as they appear below:

DH-BIO Comments

1. The Committee of Ministers agreed to communicate to the Committee on Bioethics (DH-BIO) for information and possible comments Recommendation 2017 (2013) – Nanotechnology: balancing benefits and risks to public health and the environment.

2. The DH-BIO examined the Recommendation at its 3rd plenary meeting (28-30 May 2013) and adopted this opinion.

3. In its recommendation, the Assembly underlined "the potential for enormous benefits (in particular in the field of "nanomedicine")", but also "the potential for serious harm" that nanotechnology and its applications may have. To address those issues, the Assembly proposes "as a first step" the preparation of a feasibility study with a view to "the elaboration of possible standards in this area".

4. The DH-BIO notes that the proposals of the Parliamentary Assembly cover fields such as the environment, going beyond its field of competence.

5. The DH-BIO recalls that the role of progress in sciences and technologies in the biological and medical field in the improvement of human health and quality of life is widely acknowledged in the work of the Council of Europe. But the implications for human beings of a misuse of such knowledge and technologies are also stressed and, as stated in the preamble of the Convention on Human Rights and Biomedicine, the need to use this progress for the benefit of present and future generations.

6. The objective of the work carried out by the DH-BIO is to protect human dignity and individual rights in the field of biomedicine, in particular with respect to new scientific and technological advances. To that end, it follows developments in the biomedical field to assess the ethical challenges.

7. It is in this context that the DH-BIO proposed to examine in 2014-2015 ethical challenges raised by emerging technologies, including nanotechnology. The DH-BIO thus proposed the preparation of studies to analyse the implications for human rights

[1] 3rd meeting of the DH-BIO, 28-30 May 2013; see abridged report DH-BIO/ abr RAP 3, Appendix III.

of these technologies and their applications in the biomedical field with a view to the drafting a possible white paper. This project proposed for the 2014-2015 biennium would contribute to providing a basis for a possible standard-setting initiative of the Council of Europe in the field of emerging technologies, in particular nanotechnology.

8. Furthermore, the applications of nanotechnology outside the field of biomedicine may have indirect effects on human health. Their bioethical implications could be identified in the studies considered.

Recommendation 2017 (2013)[1]
Provisional 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 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;

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 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, without prejudice to the continued support, even in financial terms, to ongoing research projects aimed at determining potential risks of nanomaterials;
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.
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. 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 of standardisation and/or legislation.