Parliamentary Assembly
Assemblée parlementaire
http://assembly.coe.int

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Doc. 13141
14 March 2013

Ethics in science and technology

Report[1]
Committee on Culture, Science, Education and Media
Rapporteur: Mr Jan KAŹMIERCZAK, Poland, Group of the European People's Party

Summary

The responsibility of scientists to consider the ethical dimension of their work emerged as a public issue with the development and use of the first atom bomb during the Second World War. Since then, growing global inter-connectedness and commercial pressures have driven technological change faster than ever, making the forecast and assessment of its long-term consequences increasingly difficult, and generating increasing numbers of pressing ethical dilemmas for scientists and policy makers alike.

Some of these ask how far we should go in changing the human body – gene technology and cloning, biomedical engineering and human enhancement, neuroscience and modifying the brain, or the moral status of the embryo. Some raise concerns about the long-term effects of new technologies on human health – for example, the proliferation of electro-magnetic fields and new chemicals in the environment, nanotechnology or genetically modified organisms. Some look at the wider consequences of technological advance – should there be limits on the development of new weapons, the private exploration of space, or climate change geo-engineering? Ultimately, a deeper philosophical question emerges: what exactly is mankind's relationship to nature, and how far should scientists be permitted to go in altering it?

The Committee on Culture, Science, Education and Media reviews the various initiatives at national, European and global level to bring ethical thinking to bear on the aims and methods of scientific endeavour, as well as its consequences and side-effects. It proposes new fora for such thinking, and suggests that parliaments and the public should become more involved in the debate. Finally, the European Union and UNESCO are invited to join forces with the Council of Europe to draft – and periodically review – a basic set of ethical principles to be applied to all fields of science and technology.

1. Reference to committee: Doc. 11886, Reference 3557 of 29 May 2009.

Contents **Page**

A. Draft resolution[2]

1. The Parliamentary Assembly observes that within the context of growing global economic competition, the political and economic pressures on science and technology to provide innovation and make economic success faster and easier can collide with ethical concerns and could lead to a lowering of the standards needed to prevent the hazards of scientific and technological research and fully protect human dignity. At the same time, the increasing complexity of science and technology through their growing convergence and interdependence, and the way they interact with the society, are making it difficult to accurately foresee and assess their long-term consequences.

2. Therefore, the Assembly holds that more concerted ethical consideration should be given – at national, supraregional and global level – to the goals and purposes pursued by science and technology, to the instruments and methods they employ, to their possible consequences and side-effects, and to the overall system of rules and behaviour within which they operate.

3. The Assembly believes that setting up a permanent ethical reflection globally would make it possible to address ethical issues as a "moving target", rather than fixing an "ethical code", and enable a periodic re-questioning of even basic assumptions, such as the definition of "human identity" or "human dignity".

4. The Assembly welcomes the initiative of the United Nations to set up a global committee with a view to engaging an ongoing ethical reflection and to explore the possibilities of drafting and periodically reviewing a set of fundamental ethical principles based on the Universal Declaration of Human Rights. It believes that the Council of Europe could and should contribute to this process.

5. In this respect, the Assembly recommends that the Secretary General of the Council of Europe consider establishing a flexible and informal structure of ethical reflection, through co-operation between relevant Assembly committees and members of relevant expert committees, including the Committee on Bioethics (DH-BIO), with a view to identifying emerging ethical issues and main ethical principles that could guide political and legal action in Europe.

6. To reinforce the common European framework of ethics in science and technology, the Assembly recommends that member States which have not yet done so sign and ratify the 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") and its protocols and fully engage in the work of the Committee on Bioethics.

7. Furthermore, the Assembly recommends that the Council of Europe member States:

7.1. extend ethical reflection and assessment to all fields of research, using the experience gained in the field of bioethics;

7.2. entrust the competent bodies to draft guidelines outlining general ethical principles to be applied in all areas of scientific research, and more detailed national codes on research ethics to be applied to specific fields, including social sciences and humanities;

7.3. consider ethical reflection and assessment of scientific research and technological development as a priority and allocate adequate administrative support and funding to the advisory and monitoring institutions, while guaranteeing their independence;

7.4. where necessary, reform existing procedures and structures to harmonise ethical rules and streamline monitoring procedures;

7.5. where necessary, review and reform existing rules in the evaluation system of professional achievements of scientists to eliminate elements in this evaluation system which could potentially reward non-ethical behaviour (such as violations of the rights of intellectual property, plagiarism, spoofing of scientific data, "artificial multiplying" of scientific achievements, for example by means of "dismembered" publishing of results);

7.6. encourage the setting up of more research ethics committees at the level of universities, hospitals and other medical establishments in order to enhance the understanding and application of ethical principles and related legislation among students and researchers;

2. Draft resolution adopted unanimously by the committee on 23 January 2013.

7.7. endeavour to ensure that courses in all scientific disciplines include obligatory modules on ethical reflection in science and technology;

7.8. increase the capacity of researchers and scientists to deal with ethical issues in their work through awareness-raising and dedicated education;

7.9. introduce in the secondary education curricula opportunities to initiate deeper critical thinking on some fundamental issues related to science and technology, including the definition of human and its place in relation to nature;

7.10. facilitate wide public debates on ethical issues emerging from scientific research and the development of new technologies.

8. Referring to its Resolution 1870 (2012) on the need for independent and credible expert assessments, the Assembly recommends that all Council of Europe member States reconsider the existing protocols and control mechanisms concerning independent scientific and technical assessments of risks to human health and the environment, and improve them as appropriate, in particular to:

8.1. prevent new processes from being implemented and new products from being commercialised without sufficient guarantees concerning their safety for human health and the environment;

8.2. prevent conflicts of interest and ensure the highest reliability of results, *inter alia* by measures allowing sufficient lapses of time for the assessment of long-term risks;

8.3. ensure the highest transparency and independence of scientific and technical assessment, *inter alia* by introducing an assessment traceability system and by setting up a public fund to finance "sensitive" expert assessments.

9. The Assembly calls on national parliaments to develop their own scientific and technological capacity assessment and increase the involvement of the public in political decision-making as regards scientific and technological choices and regulation. The parliaments are also invited to take an active part in the European Parliamentary Technology Assessment (EPTA) network.

10. The Assembly invites the European Union and UNESCO to co-operate with the Council of Europe to reinforce the common European framework of ethics in science and technology and, to this end:

10.1. create European and regional platforms to regularly exchange experiences and best practice covering all fields of science and technology, using the experience of the Forum of National Ethics Committees (NEC Forum) and the meetings of the Council of Europe Committee on Bioethics;

10.2. draft and periodically review a set of fundamental ethical principles to be applied to all fields of science and technology;

10.3. provide further guidance to help member States harmonise ethical rules and monitoring procedures, building on the positive impact of ethical requirements under the European Commission's Seventh Framework Programme for Research, Technological Development and Demonstration Activities (2007-2013) (FP7).

B. Explanatory memorandum by Mr Kaźmierczak, rapporteur

1. Terms of reference and preparation of the report

1. On 30 April 2009, Ms de Melo and 27 colleagues tabled a motion for a resolution on "The ethics of science", which was referred to the committee for report on 29 May 2009. The committee appointed Ms de Melo rapporteur. An outline report was discussed by the committee in Istanbul on 10 May 2010. I was appointed rapporteur in replacement of Ms de Melo on 4 October 2010 and submitted to the committee a revised outline report which was discussed on 13 April 2011. Following this discussion, a questionnaire was sent to the national parliaments through the agency of the European Centre for Parliamentary Research and Documentation (ECPRD) and Professor Armin Grunwald, Director of the Office of Technology Assessment at the German Bundestag, was commissioned to prepare a background report.

2. On 5 March 2012 in Paris, the committee held a joint hearing on this issue in co-operation with UNESCO and discussed the background report prepared by Professor Grunwald, with the participation of Ms Irina Bokova, Director General of UNESCO, and the following experts: Professor Grunwald, Mr John Crowley, Head of the Ethics of Science and Technology Section, UNESCO, Dr Jacques Bordé, former Director of Research at the French National Scientific Research Centre (CNRS) and Counsellor to its Committee of Science Ethics (COMETS), Ms Dafna Feinholz, Team Leader for Bioethics in the UNESCO Sector for Social and Human Sciences, Professor Jan Hartman, Chair of the Committee for Good Academic Practices at the Polish Ministry of Science, Ms Monique Atlan, journalist and producer at France 2, and Mr Roger-Pol Droit, philosopher and member of the National Consultative Ethics Committee (CCNE), France, authors of the book "Humain" (ed. Flammarion, 2012), and Professor Michèle Guillaume-Hofnung, Vice-President of the Academy of Ethics, France.

3. On 28 June 2012 in Strasbourg, the committee held an exchange of views with Professor Rafael Capurro, President of the International Center for Information Ethics (ICIE) and former member (2000-2010) of the European Group on Ethics in Science and New Technologies (EGE), Mr Carlos de Sola, Head of the Bioethics Department, Directorate of Human Rights, Directorate General I – Human Rights and Rule of Law, Council of Europe, and Ms Laurence Lwoff, Secretary of the Committee on Bioethics (DH-BIO), Directorate of Human Rights, Directorate General I – Human Rights and Rule of Law, Council of Europe.

4. I wish to thank Professor Grunwald and all experts who took part in the two hearings for their valuable contribution to this report.

2. Objectives of the report

5. Science and technology play a crucial role in the development of modern societies. New knowledge and innovative technologies are main driving forces of progress in many areas, such as welfare, the economy, competitiveness, health, security and sustainable development. However, as history has shown, scientific research and its outcomes, in particular new technology, are ambivalent with regard to ethical norms and values.

6. The debate on ethics in science and technology, and in particular on the responsibility of scientists, went beyond restricted circles after the development and use of the first atom bomb at the end of the Second World War. It developed more broadly in the 1960s with the increasing awareness of unintended side effects of technology, primarily its effects on the environment. Today, ethical attention is directed at science and its applications in many fields, such as gene technology and biotechnology, biomedical engineering, molecular biology and stem cell research, neurosciences, use of nanotechnologies in medical treatment or various forms of human enhancement.

7. The debate focuses on possible impacts and consequences of scientific research and technological developments for human beings and society, and it opens up some fundamental questions of what is human, or the place of man in nature and man's relationship to nature. While it has long been a matter of controversy whether science has any morally relevant content at all, it has become clear that science and technology are subject to human responsibility and call for ethical reflection at national, supraregional and global level.

8. Some scientists perceive ethics as an obstacle to their work, as it may lead to limitations and restrictions, and working in a prohibitive setting. However, the opposite view is probably the most accurate. Ethics is an intrinsic part of scientific integrity. Science is based on rational argumentation, and ethical reflection is also bound to good arguments. Ethics and science therefore share the common conviction that the quality of arguments is decisive.

9. Scientific and technological advancement generally increase possibilities for human action. Whatever has been inaccessible to human intervention, whatever has had to be accepted as something natural (which cannot be influenced) or as fate, is increasingly becoming an object of human influence. This interpretation of scientific progress represents a legacy of the European Enlightenment.

10. However, fundamental ethical questions derive from uncertainties, unintended side effects, risks to human health and the environment, misuse of knowledge and technology, and the loss of a general sense of direction and purpose. The opportunity to choose from a number of options has been converted over time into pressure to make a choice. With humanity's increasing empowerment for action, its responsibility also increases, requiring a capacity to cope with a wider scope of its freedom by means of taking responsible decisions.[3]

11. Owing to this ambivalent situation, science and technology have been over the past few decades accompanied by debates in society, and the world of science, on the issues of risks and opportunities, potential successes and side effects, degree of control and responsibility. Approaches such as technology assessment, science and engineering ethics and value sensitive design have been developed. Several scientific, medical and engineering bodies have committed themselves to social and moral responsibility and implemented codes of conduct.

12. However, what should concretely follow from an ethical consideration is often a subject of controversy. Decisions are made by democratic institutions, not by ethical judgment. We are confronted with diverging opinions about the level of acceptable risks, the desirability of technical intervention into the body, pre-implantation diagnostics and eugenics, the use of animals, in particular primates, for experiments, the moral status of the embryo, the commercial pressures on science, the relationship between our responsibility for future generations and the needs of today, and so forth.

13. Ethics in science and technology have to deal with these controversies, which have become even more complex as a result of increasing globalisation and intercultural exchange. Neither a universal moral or regulatory framework for science nor a global governance of science is available. This report will therefore examine, in particular, the following issues:

– the present situation regarding ethics in science and technology, its institutionalisation, recent developments and current issues, with a focus on the situation in Europe;

– risk factors and obstacles that could hamper compliance with ethical frameworks concerning science and technology;

– consideration of a common foundation for an ethical framework for scientific and technological development;

– considerations for political and institutional measures which could contribute to a stronger role of ethics in the governance of science and technology, and in particular possibilities for the Council of Europe to address the current situation.

3. Classification of ethical issues in science and technology

14. Science and technology exhibit ethical aspects, namely with regard to: 1) the goals and purposes they pursue; 2) the instruments they employ; 3) the consequences and side effects they produce; and 4) the system of rules and behaviour within which they operate.

15. In order to provide a sense of direction for science and technology, there needs to be a number of ideas concerning desired future developments and the goals and visions of future research and its applications. In many cases, the aims of science and technology are not problematic. Visions like the development of therapies for illnesses such as Alzheimer's disease, the provision of new facilities to support people with disabilities or

3. As argued by the philosopher Hans Jonas in his book "The Imperative of Responsibility" (1984).

the protection of society against natural hazards will gain considerable social acceptance and ethical support. In other areas, however, there are ethical conflicts and controversies. The visions concerning human space flight, for example, are controversial in nature, as in many cases are research goals for new and more powerful weapons. In the field of "converging technologies" it is disputable whether human performance should be enhanced and whether research should be carried out to achieve this. These questions challenge the policy of acquiring knowledge: What knowledge do we want to have in the future and what do we not want to have? These questions will obviously be subject to ethical analysis and deliberation.

16. Instruments, measures, and scientific practices, especially research, may give rise to ethical questions. Examples are the moral legitimacy of experiments on animals or of practices making human beings, embryos, or stem cells subjects of research. Other examples are experiments with genetically modified organisms or plants, especially their release outside laboratories and, in earlier years, the experimental testing of nuclear weapons. The collection and use of personal and genetic data, as may be the case with biobanks, can also give raise to serious ethical concerns over the right to respect for one's private life.

17. Since the 1960s, the unintended and adverse effects of scientific and technical innovations have been considerable, and some have assumed dramatic proportions: accidents occurring at technical facilities (Chernobyl, Bhopal), threats to the natural environment (air and water pollution, ozone holes, climate change), negative health effects, as in the case of asbestos, and social and cultural side effects (for example labour market problems caused by productivity gains). The growing complexity of science and technology and their close links with many areas of society are increasing the difficulties to foresee and assess the consequences of new developments and to prevent hazards. This applies in particular to new cross-cutting technologies such as nanotechnology and other fields of new and emerging science and technology (NEST).

18. A fourth dimension concerns the science system as such, its rules and principles, its "workflow" and the behaviour and conduct of scientists and researchers. Ethical reflection in this respect points out the responsibility of scientists and researchers as professionals responsible for safeguarding the quality of scientific and technological output and for observing overarching regulatory and ethical principles. It covers the issues of non-discrimination, intellectual property rights and correct behaviour within the science system, but also regarding its societal contexts, including the dialogue with society and an open attitude to participatory procedures. Moreover, certain rules in the evaluation systems of professional achievements and scientific career could further affect the ethical behaviour of scientists. Some potentially dangerous rules could incite and reward non-ethical behaviour, such as violations of the rights of intellectual property, plagiarism, spoofing of scientific data and "artificial multiplying" of scientific achievements, for example by means of "dismembered" publishing of results. These elements, if they exist, ought to be recognised and eliminated. These issues primarily have to be observed at an individual level, but adequate measures also have to be implemented at the level of rules, regulation and structures. Codes of conduct, self-regulation through peer review or other types of rules of good scientific practice are instruments that can be used to meet these expectations and challenges.

19. There is also room for philosophical and ethical reflection beyond these areas. Ongoing debates address questions such as for the future of mankind, the very nature of scientific and technological advance and changing relations between mankind, technology and nature.

4. The European landscape of institutions and activities relating to ethics in science and technology

20. Europe displays a very rich and varied landscape of ethics in science and technology that is developed at various levels and reflects different cultural and legal traditions. Councils, committees and commissions debate ethical issues in various fields and publish a considerable number of studies on a range of subjects. Specialists dealing with ethics at universities, colleges and research institutes are involved in further developing the theoretical basis of this vast and growing subject. This section covers, however, only a small selection of activities.

4.1. The Council of Europe

21. The Council of Europe was a pioneer in the field of bioethics from 1985 and into the1990s, preceding the adoption of the Convention on Human Rights and Biomedicine ("Oviedo Convention")[4] in 1997 and its successive protocols, which influenced several European Union Directives and the Universal Declaration on Bioethics and Human Rights (UNESCO, 2005).

22. The Oviedo Convention entered into force on 1 December 1999. To date, it has been ratified by 29 member States of the Council of Europe, including Switzerland and France – two countries that have a well-established pharmaceutical industry and advanced biomedical research.

23. The convention puts emphasis on the primacy of the human being (Article 2): "The interests and welfare of the human being shall prevail over the sole interest of society or science." Equitable access to health care of appropriate quality is also regarded as a fundamental right (Article 3). With regard to the responsible and proper behaviour of scientists, the Council of Europe does not set up its own values and principles but refers to professional standards (Article 4): "Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards." Of central importance for the convention's structure and content is the obligation to obtain informed consent (Article 5): "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it." Accordingly, particular emphasis is placed not only on the protection of persons not able to give their consent and of individuals with a mental disorder, but also on the issue of research on people unable to give their consent. Other issues covered by the convention include: research on the human genome, predictive genetic tests, research on human embryos, and organ and tissue removal from living donors for transplantation purposes.

24. Over the last decade, the Council of Europe has continued its debate on specific issues concerning biomedicine in more detail and has drawn up additional protocols to the Oviedo Convention concerning:

– Prohibition of Cloning Human Beings (ETS No. 168)

– Transplantation of Organs and Tissues of Human Origin (ETS No. 186)

– Biomedical Research (CETS No. 195)

– Genetic Testing for Health Purposes (CETS No. 203).

25. The Council of Europe also supports co-operation between national ethics committees, and set up the European Conference of National Ethics Committees (COMETH), the purpose of which is to promote co-operation between national ethics committees, to help countries wishing to do so to set up and run a national ethics committee, and to promote a pluralist public debate on ethical issues raised by progress in the fields of biology, medicine and public health.

26. The Council of Europe's Committee on Bioethics (DH-BIO) is currently working on the following issues: biomedical research, biobanks and data protection; genetics and use of predictive health data; end of life decision-making process considering the different stakeholders; transplantation of organs and tissues of human origin and the fight against organ trafficking; the situation in the member States with regard to prenatal sex selection; protection of persons with mental disorders with regard to involuntary placement and involuntary treatment. Future themes considered include access to medical files, neurosciences and enhancement, applications of brain imaging.

4.2. The European Union

27. Building on the pioneering work of the Council of Europe, several European Union Directives[5] make explicit reference to the Oviedo Convention. Reference is also made to it in the preamble to the Charter of Fundamental Rights of the European Union.

28. In 1991, the European Commission set up the European Group on Ethics in Science and New Technologies (EGE) and (re)formulated its mandate for the period 2011-2015: The task of the EGE is to advise the Commission on ethical questions relating to sciences and new technologies, either at the request of the Commission or on its own initiative. The European Parliament and the European Council may draw the Commission's attention to questions which they consider to be of major ethical importance.

4. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164), also known as the "Convention on Human Rights and Biomedicine" or the "Oviedo Convention". For more information: http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm.

5. EU Directive 98/79/CE on *in vitro* diagnostic medical devices; EU Directive 2004/23/CE towards standards of quality and safety for human tissues and cells in Europe; EU Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation; Regulation (EC) No. 1394/2007 on advanced therapy medicinal products.

29. The EGE has considered legal and ethical aspects and issued recommendations (opinions) in a number of diverse fields, such as synthetic biology, clinical research in developing countries, patenting stem cells, animal cloning for food supply, ethical aspects of modern agriculture, nanomedicine and genetic testing at the workplace. It is important to note that EGE opinions contain critical reflections rather than moral judgments of what should be right or wrong.

30. Moreover, the European Union Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, adopted in 2008 on the initiative of the European Parliament, goes beyond the challenge of scientific integrity and addresses issues concerning the social and ethical responsibility of researchers and scientists.

31. Similarly, the European Commission's Seventh Framework Programme for Research, Technological Development and Demonstration Activities (2007-2013) (FP7)[6] states that "[all] the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles" (Article 6.1) and excludes the following fields of research for ethical reasons (Article 6.2):

– research activity aiming at human cloning for reproductive purposes;

– research activity intended to modify the genetic heritage of human beings which could make such changes heritable (research related to cancer treatment of the gonads can be financed);

– research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

32. The FP7 includes research on a large variety of ethical issues, such as human enhancement, synthetic biology and nano-safety as well as issues related to sustainable development, equity and access to the benefits of new and emerging science and technology. Projects running under the FP7 have to observe specific ethical guidelines.

33. The European Parliament addresses ethical issues of new and emerging science and technology via its Scientific and Technological Options Assessment unit (STOA). Recent or ongoing projects concern synthetic biology ("Making Perfect Life"), nano-safety, human enhancement and privacy issues.

4.3. European research organisations

34. The European Research Council (ERC) has drafted its own guidelines, which not only focus on the instrumental dimension of science and research but also consider the "potential loss" of important values.

35. The European Science Foundation (ESF) has 38 years of experience in co-ordinating science and research networking programmes with a high level of expertise in science management. With peer review guidelines, it promotes the proper behaviour of scientists and researchers as individuals with mutual respect and responsibility for independent research and education. However, the dimension of the societal consequences of future research is not addressed as such, and the responsibility for future generations has been so far restricted to the supervision of young scientists and scholars.

36. Responsible Research and Innovation (RRI) is a fairly new element in science governance, reflecting the diagnosis that available approaches to shaping science and technology still do not meet all the high expectations. The hope behind the responsible innovation movement is that new – or further developed – approaches (for example the Value Sensitive Design approach) could considerably complement existing approaches, such as technology assessment and ethics of science.

5. National level: legislation, monitoring and institutional framework related to ethics in science and technology

37. This chapter is based on the information document AS/Cult/Inf (2013) 02[7] with replies from the 33 Council of Europe member States to the questionnaire that I addressed to them through the agency of the European Centre for Parliamentary Research and Documentation.

6. ftp://ftp.cordis.europa.eu/pub/fp7/docs/guidelines-annex5ict.pdf.
7. Document available at the following address: http://assembly.coe.int/Main.asp?link=/CommitteeDocs/ComDocMenuCultEN.htm.

5.1. Legislation and guidelines

38. The level of regulation and accompanying mechanisms for its implementation are very diverse across Europe, but in general all countries have adopted laws and regulations in one or more of the following areas: a) medical and health research; b) biotechnology, including GMOs; c) other sciences and technology; d) animal testing; e) social sciences and humanities; and f) general provisions (codes) to regulate research, the work of scientists and scientific integrity, including provisions for research within higher education.

39. Some national constitutions contain relevant provisions, namely concerning the promotion of freedom of scientific research (Italy, Montenegro, Poland, "the former Yugoslav Republic of Macedonia"), the protection of human dignity with regard to the application of biology and medicine (Montenegro) and the requirement of voluntary consent for scientific experiments (Bulgaria, Poland).

40. National research programmes represent the principal research planning and co-ordination instrument and, through integration in the European Research Area, are in principle linked to the strategic objectives and ethical requirements under the European Commission's Seventh Framework Programme for Research.

41. Moreover, ratification of the Oviedo Convention and its protocols, transposition of European Union directives and the European Charter for Researchers were good incentives to advance legislation which reflects ethical concerns and principles at the national level.

42. A good example is the "Code of ethics for scientific research" in Belgium,[8] adopted in 2008, outlining general ethical principles to be applied in all areas of scientific research. The code was jointly drafted by prominent experts from the Academies of Science, Medicine and Fine Arts under the auspices of the Federal Public Planning Service Science Policy. Another example is the "Code of Ethics of Estonian Scientists"[9] drafted by the Estonian Academy of Sciences to highlight the moral dimension of science and the social responsibility of scientists. Several other countries such as Finland,[10] Hungary, Latvia, the Netherlands and Norway[11] have also undertaken similar initiatives. In some countries, such as Poland, a "code of ethics" doesn't formally exist but in national law it is effectively replaced by other suitable regulations and documents. However, most countries lack overarching general guidelines to be applied in all areas of research.

5.2. Institutions and monitoring procedures

43. Many European countries have ethics councils and committees for different purposes, with different remits and in different institutional settings.[12] The majority have ethics committees that are established at universities and/or hospitals to review and approve clinical trials. Frequently, they dispose of ethical codes to govern their activity. In some countries, there is a central ethics committee to co-ordinate the work of local ethics committees.

44. Most countries have national bioethics committees with mandates that vary from ethical review of research projects to an advisory role to political decision-makers (president, parliament, government). These bodies issue opinions on emerging ethical issues in connection to biomedicine, for example on transplants, assisted reproduction, cloning, protection of patients, privacy rights and data collection, use of animals in research, and even on wider topics such as biodiversity and release of GMOs. Those national bioethics committees took part in the European and international dialogue on bioethics through the European Conference of National Ethics Committee (COMETH) initiated by the Council of Europe, and more recently the Forum of National Ethics Committee (NEC Forum) funded by the European Commission.

---

8. Belgium, see website: www.belspo.be/belspo/organisation/publ/Eth_code_fr.stm.
9. Estonia, see website: www.akadeemia.ee/_repository/File/ALUSDOKUD/Code-ethics.pdf.
10. Finland: Guidelines on ethical review in the humanities and social and behavioral sciences, see website: www.tenk.fi/en/ethical-review-human-sciences.
11. Norway: Guidelines for research ethics in science and technology: www.etikkom.no/Documents/English-publications/Guidelines%20for%20research%20ethics%20in%20science%20and%20technology%20(2008).pdf.
and Guidelines for research ethics in social sciences, law and humanities: www.etikkom.no/Documents/English-publications/Guidelines%20for%20research%20ethics%20in%20the%20social%20sciences,%20law%20and%20the%20humanities%20(2006).pdf.
12. Fuchs (2005), National Ethics Councils: www.ethikrat.org/_english/publications/Fuchs_International_Ethics_Councils.pdf.

45. For example, Switzerland has established two ethics committees at the federal level, one for ethical questions affecting human beings, mainly in the field of medicine (Swiss National Advisory Commission on Medical Ethics), the other for ethical issues not affecting humans (Swiss Ethics Committee on Non-Human Biotechnology).

46. In France, the National Consultative Ethics Committee for Life Sciences and Health (CCNE) was set up in 1983 and is one of the oldest ethics committees. Its focus is on ethical issues of modern biomedicine, understanding responsibility in a broad social sense. With the adoption of the Law on Bioethics in 2004, the CCNE gained the status of an independent authority and expanded its mandate. Germany established an Ethics Council (Deutscher Ethikrat) at the federal level in 2001. It is autonomous in determining the issues to be dealt with. Its remit is to advise the government and trigger public debate.

47. Committees on research ethics were established within hospitals and universities in Poland from the 1980s onwards. Research ethics obtained legal recognition under the Medical Professions Act of 1996, in particular to supervise clinical trials. Ethics committees based at the Academy of Sciences, the Academy of Arts and Sciences and the State Committee for Research promote good conduct in science.

48. Norway has a national system for research ethics composed of specialised but co-ordinated national committees for research ethics, which cover different research areas such as medical and health research, sciences and technology, social sciences and humanities. They share a common secretariat. In addition, there are seven regional committees for medical and health research, the National Board of Health Supervision, the National Data Inspectorate and the National Commission for Investigation of Scientific Misconduct.

49. The parliamentary offices of technology assessment (EPTA) are also increasingly involved in debating ethics in science and technology. For example, in recent years, the Office of Technology Assessment at the German Bundestag has commissioned studies on biobanks, synthetic biology, brain research, geo- and climate engineering and cognitive enhancement. In Greece[13] for example, national parliament also has a specific monitoring role, in addition to drafting studies and holding public debates.

50. Finland displays a very good model of self-regulation within the research community. Organisations that conduct scientific research are primarily responsible for promoting good scientific practice and dealing with alleged misconduct and fraud in science. The National Advisory Board on Research Ethics, which includes representatives from major scientific fields and key supervising authorities, has drafted guidelines[14] which contain procedures for handling alleged violations of good scientific practice and which cover all fields of science. The research community is broadly committed to these guidelines as well as to additional ethical norms for each field specifically.

6. Risk factors and obstacles

51. In spite of the fact that ethics in science and technology have been well developed over the past decades and have been implemented in many institutional forms there are questions about their real impact and concerns about the many threats to the effective respect of ethical principles and standards. These threats are mainly related to societal surroundings and influencing factors, including the political, economic, institutional and social conditions within which science and technology operate. In this respect, the following elements are of major importance: 1) increased scientific competition at the global level; 2) global mobility of researchers; 3) measurement of excellence via the Institute for Scientific Information (ISI citation system); 4) economic pressures on science; and 5) lack of ethical transparency in private research.

52. Competition among scientists and scientific institutions all over the world has increased dramatically over the past two decades. The use of the Internet as a global medium of comparison and exchange, the increased mobility not only of knowledge but also of people, the emergence of a system of globally recognised scientific journals, the institutionalisation of international evaluation regimes and the expectation that good scientists should be visible at the international level and be global players changed radically the functioning of science. While in earlier times only highly specialised disciplines such as Theoretical Physics formed an international community, today all disciplines are expected to act globally. Ratings and rankings of scientific institutions receive high awareness in science policy in spite of severe methodological problems and critique. Competition is about hiring excellent researchers and attracting promising students and the best PhD students.

13. Greece: Parliamentary Special Permanent Committee on Research and Technology.
14. Finland: Guidelines on good scientific practice and procedures for handling misconduct and fraud in science, www.tenk.fi/en/resposible-conduct-research-guidelines.

In this context, ethical guidelines and regulations are often regarded as an obstacle to research, slowing down scientific progress and causing additional bureaucracy (for example if research projects must be approved by an ethics committee). University presidents and managers of research institutions, therefore, may be tempted to sidestep ethical requirements in practice, although these are needed to meet Corporate Social Responsibility (CSR) expectations.

53. Today, mobility of researchers at the global level is much higher than in the past. While this is a welcome development in many respects it has impact on the role of ethical reflection. Since there is no universal framework for ethical assessment of science or ethical behaviour of scientists, different ethical models are to be applied when moving from one region, or even from one country to another. Scientists could therefore look for best locations not only with regard to resources but also with regard to low ethical standards. Developing countries sometimes have no or very low standards and this situation can be misused, for example by pharmaceutical industry research. This well-known fact undermines the power of ethical reasoning and calls for international agreements about ethical standards.

54. A revival of "excellence" in the traditional sense, relying only on inner-scientific criteria and neglecting ethical issues, can be observed by looking at the increased importance of publication indicators and publications in assessments and evaluations of the journal of the Institute for Scientific Information (ISI). The strong emphasis on excellence and the choice of specific indicators to measure it could affect scientists' engagement in ethical reflection and their willingness to take over social responsibility actively.

55. Indeed, the increasing importance of the ISI citation and impact factor system favour decontextualised and globalised science while context-related research, dedicated to specific problem-solving and including ethical reflection, is disadvantaged. Thus there is a (perhaps unintended) tendency to bring science back to being a more separated, perhaps isolated and more autonomous activity, following its own rules and hunting for impacts in the ISI system rather than taking care of the "real world", for example by taking ethical and social responsibility seriously.

56. Ethics in science as a reflective activity is not appreciated in this system of excellence. Scientists might assume that engaging in ethics would consume time and creativity resources which they should, following the incentives of excellence and evaluation regimes, better spend on publishing ISI papers (and this is also related with the competition issue mentioned above). In particular, this holds true for scientific careers, which are increasingly dominated by quantitative criteria of excellence such as the citation index. The force and pressure to become visible in this system is a serious obstacle to the willingness to engage in ethical debates. The risk of highly specialised researchers becoming narrow-minded, in their own "virtual world" ruled by incentives and forces of purely inner-scientific excellence has increased considerably in recent years.

57. Economic globalisation leads to growing economic competition at the global level. The industrialised countries put much more emphasis on the role of science as part of the national and regional innovation systems, expecting that research and development could strongly contribute to sustaining or increasing their competitiveness in order to maintain economic success, employment, and welfare. Some countries, like Germany, increased research funding even in the time of the economic crisis. Consequently, the focus was shifted to more application-oriented research, technology transfer and innovation management. The political and economic pressure on science to provide innovation can collide with ethical concern and could lead to a lowering of standards in order to make innovation and economic success easier.

58. A considerable and, in many countries, dominant part of scientific research and development is taking place in the private sector. Private research has to observe the law, but is not bound to publicly declared codes of conduct, to recommendations of ethics committees or to ethical guidelines of research associations. Ethical questions are here confronted with strategic analysis of the management, with interest in return on investment and with financial and economic concern. There is no public space for debating ethical questions because of the private nature of the research. The main risk is that private research is conducted which might have an enormous impact on future society but without any prior ethical reflection. The boundaries between science and the economy are increasingly blurred in some fields. This is particularly the case in the field of biotechnology where university professors are often also founders and owners of companies directly transforming knowledge into new products and services.

59. In this respect, reference can be made to Assembly Resolution 1870 (2012) on the need for independent and credible expert assessments, which cautioned against economic interests and lack of full and transparent scientific information and assessment which have led in the past to many health-care scandals (contaminated blood, use of growth hormones, asbestos, controversy over GMO testing, controversy over thresholds for

electromagnetic fields in the mobile phone industry, etc.). This resolution calls for a legal framework to reinforce credibility of expert assessments and to guarantee a transparent and pluralist expert debate prior to determining standards and sealing approvals to commercialise products.

60. However much care is taken in prior assessments, the risk of errors will remain. Therefore it is essential that adequate mechanisms be established to monitor the effects of products after their commercialisation is authorised and to intervene rapidly when they prove to entail higher risks than those initially foreseen. Recent examples of chemical and pharmaceutical products which allegedly may provoke serious health diseases[15] testify to the difficulties of ensuring relevant unbiased and clear information of users and consumers, and the effective protection of general interest and public health against significant economic interests.

61. The growing number of liability cases against scientists who are providing expertise and/or scientific forecast is a rather worrying trend and has been increasingly reported in the media. In November 2012, a French psychiatrist was accused of failing to correctly diagnose and medically follow up a schizophrenic patient who in a fit of delirium murdered his grand-mother's companion. Another striking example of a very severe court judgment against four seismologists and two engineers for failing to accurately predict the 2009 earthquake in Aquila in Italy also raises a number of important questions: Can a scientist be held liable for not being able to predict with certainty what is difficult to accurately predict in nature or in human behaviour? What is the interface between scientific expertise and forecast, public communication and public decision-making to prevent or minimise risks?

62. In conclusion, it becomes clear that: 1) the many activities of science and technology ethics cover only parts of the entire research; 2) increased and global competition within science and technology, together with the increasing mobility of researchers, threaten the possible impact of insular ethical regulation; 3) the pressure towards scientific excellence in relation with quantitative measures such as the ISI system endanger the role of ethics; 4) economic pressure changes the nature of scientific research, pushing it more towards commercial thinking, and raises the issue of scientific liability.

7. Towards a universal framework of science and technology ethics?

63. The institutions dealing with ethics in science and technology are confronted with moral controversies and partially diverging assessments and judgments. The moral plurality of modern society is also reflected in ethical reasoning about scientific research and progress, as different philosophical, religious and cultural traditions influence ethical positions. This can be observed even within Europe.

64. While the continental tradition is dominated by deontological philosophy, with Immanuel Kant as probably the most influential author with far-ranging consequences for ethical positions, the Anglo-Saxon tradition relies on the utilitarian ethics developed by Jeremy Bentham and John Stuart Mill. In spite of the fact that both traditions frequently produce concurrent results in concrete applications, there is a deep philosophical gap sometimes leading to practical divergence, in particular in the field of biomedicine.

65. Moreover, many different religious and cultural, including non-religious, traditions coexist in Europe. Some of the major controversial issues of ethics in science and technology are closely related to religious beliefs. For example, the moral status of the embryo regularly gives rise to debate about the permissibility of using embryos in research. The Catholic Church holds a very strict position on this issue. In other fields, such as nuclear power and nuclear waste disposal, the Protestant Churches in some countries have expressed a firm negative opinion.

66. The global level is even more complex. Cultural and religious diversity does not only express itself in diverse regulations but it strongly underlines some fundamental questions. For example, European and Asian traditions each have a very different understanding of human relation to nature; they display different images of nature and evolution that consequently lead to some very different views on the extent of human responsibility. Thus, in South Korea, for example, the willingness to allow biomedical research in ethically sensitive areas is much stronger than in most European countries.

15. Some examples include: third and fourth generation contraceptive pills, Aspartame as a sugar substitute in food and beverages, the Mediator drug for treatment of diabetes, Ritalin and other psychotropic medication for children with attention deficit hyperactivity disorder (ADHD), etc.

67. Furthermore, notions such as “human life”, “person” and “dignity” will be understood in different ways, resulting in diverging opinions whether priority should be given to individual interests over the interests of the community. Different trust in scientific advancements can be noted between many European countries and the United States, which has an impact on certain positions concerning the permissibility of research. The role of the Precautionary Principle is also regarded differently across the Atlantic.

68. Given these divergences and incompatibilities, it might seem a senseless endeavour to ask for a universal framework for science and technology ethics. Instead, given the rapid evolvement of science and technology, an ongoing process of ethical reflection and international dialogue would be required, which may have as an outcome an agreed set of principles in the form of a “declaration” (ethos), using the example of the Oviedo Convention in Europe or the Universal Declaration on Bioethics and Human Rights (UNESCO).

69. Setting up a permanent ethical reflection globally – which has already been formalised in Europe through the EGE in co-operation with a network of national ethics committees – would make it possible to address ethical issues as a “moving target” rather than fixing an “ethical code”. This approach to ethics in science and technology would enable, at the global level, a periodic re-questioning of even basic assumptions, such as the definition of “human identity” or “human dignity”.

8. Conclusions

70. Science is not autonomous, but is instead “science in society”. This implies that science and technology have an ethical and moral responsibility. Ethical reflection is reasoning about orientation and justification using the means of a discursive process. In this sense, ethics in science and technology should not be assimilated to a prohibitive factor, but understood as the basis of a constructive, reasoned dialogue aimed at guiding scientific and technological progress for the good of humankind. Scientists, politicians, industry and other relevant stakeholders, citizens, philosophers and others who are involved in ethical thinking should take part in this dialogue.

71. Ethical reflection influences critical thinking, which represents the essence of democracy. Deeper reflection is therefore needed on science and its purpose, considering also moral and cultural plurality in Europe and worldwide. Advances in science and technology that lie ahead for the 21st century will be inevitably of a greater magnitude than those accomplished in the past. Science and technology will affect the Earth, life and humans, by providing humans with a capacity to alter life and the fundamental phenomena of our planet.

72. Moreover, science and technology today progress at a much faster speed than the capacity of individuals and society to psychologically adapt to it. As science and technology accelerate, there is an ever stronger need to anticipate their evolution far in advance, since the questions raised by them are so fundamental: What is human and what is human identity? How to define human dignity? What is humankind’s place within, and relationship to, nature? Should humankind be preserved (in its natural form) or transformed?

73. Ethical reflection on science and technology must therefore not be limited to academic circles. There needs to be a close link to governance via scientific academies, funding agencies and scientific associations, but also political institutions such as parliaments and governments, and of course the general public. In this respect, I have made a number of proposals in the draft resolution to invite member States to strengthen existing legislation, monitoring procedures and advisory structures, and to engage in a wide public debate in order to extend and deepen ethical reflection and assessment to all fields of research and to involve to a greater extent the scientific community, private enterprises and the general public in this process.

74. In particular, research ethics committees should be more widely established at the level of universities, hospitals and other medical establishments, in order to enhance the understanding and application of ethical principles and related legislation among students and researchers. In most countries, scientists and research personnel do not receive enough education and training on research ethics and they are not fully aware of all requirements.

75. Capacity building – in particular through education – is crucial. University education in all scientific disciplines should include obligatory modules on the ethics of science across the world. The capacity of researchers and scientists to deal with ethical issues in their work should be improved by awareness-raising and dedicated education. Courses to educate teachers in ethics could be introduced. Curricula in secondary education should also initiate deeper critical thinking on some fundamental issues related to science and

technology, including the definition of human and its place in relation to nature. Reference should be made in this context to the educational tool developed by the Council of Europe to promote debate among young people on bioethical issues.

76. More dialogue among stakeholders[16] as well as public debate[17] on ethical issues emerging from scientific research and development of technologies is advocated locally, nationally and at European level. For example, European and regional platforms could be created to regularly exchange experiences, along the lines of the Forum of National Ethics Committees or meetings of the Council of Europe Committee on Bioethics (DH-BIO) (formerly the Steering Committee on Bioethics (CDBI)).

77. Moreover, greater harmonisation of ethical rules and monitoring procedures is needed at national and also European level, particularly in the biomedical field, where complex rules and procedures, as well as numerous monitoring and advisory bodies co-exist.

78. Ethical reflection and assessment should be encouraged in all fields of research, using the example and experience gained in bioethics. General guidelines outlining overarching ethical principles to be applied in all areas of scientific research should be drafted and co-ordinated at national and European level.

79. Governments and parliaments need to give political priority to this issue and facilitate adequate administrative and funding support to monitoring and advisory institutions, guaranteeing their independence and effective functioning, so that the implementation of ethical principles can be improved in practice. European support is also needed, including stronger requirements, building on the positive impact of ethical requirements under the European Commission's Seventh Framework Programme for Research.

80. Based on the experience of UNESCO in drafting the Universal Declaration on Bioethics and Human Rights, a committee could be established at United Nations level to engage an ongoing ethical reflection and to explore the possibilities of drafting and periodically reviewing a set of fundamental ethical principles based on the Universal Declaration of Human Rights. Experience could be drawn from the existing models in Europe and from the work of COMEST (World Commission on the Ethics of Scientific Knowledge and Technology).

81. Within the Council of Europe, the Parliamentary Assembly provided valuable political guidance and reflection to the work of the Committee on Bioethics, through joint debates which aimed to identify emerging ethical issues and main ethical principles that could guide political and legal action. A flexible and "light" structure could therefore be envisaged to continue such co-operation in the future, by periodically organising joint hearings and debates between relevant Assembly committees and experts (members of the Committee on Bioethics and others).

16. Proposal from Estonia: discussion on institutional set up and monitoring, co-ordination, membership of advisory or monitoring committees, broadening of mandates, concrete implications for various guidelines, etc.
17. Reflecting the principles of pluralism, tolerance, participation and constructive dialogue.