COMMITTEE ON BIOETHICS

(DH-BIO)

3rd MEETING
Strasbourg, 28-30 May 2013

ABRIDGED REPORT
I. Adoption of the agenda

1. The Committee on Bioethics (DH-BIO) held its 3rd meeting in Strasbourg from 28 to 30 May 2013. The agenda of the meeting and the list of participants appear in Appendix I and Appendix II to this abridged report.

II. Chart of signatures and ratifications of the Convention on Human Rights and Biomedicine, the Protocol on the Prohibition of Cloning Human Beings, the Protocol concerning Transplantation of Organs and Tissues of Human Origin, the Protocol concerning Biomedical Research and the Protocol concerning Genetic Testing for Health Purposes

2. The DH-BIO was informed that on 12 February 2013, Montenegro ratified the Additional Protocol to the Convention on Human Rights and Biomedicine regarding Biomedical Research. The same day, Montenegro signed and ratified the Additional Protocol concerning Genetic Testing for Health Purposes.

III. Developments in the field of bioethics

3. The DH-BIO took note of the developments in the field of bioethics within the member states, as well as in international organisations. It was also informed of the relevant developments in other Council of Europe bodies.

IV. The decision-making process regarding medical treatment in end-of-life situations

4. The DH-BIO was informed about the results of the public consultation organised from February to April 2013 on the working document elaborated by the Drafting Group on the decision-making process regarding medical treatment in end-of-life situations.

5. The Committee entrusted the Drafting Group with the task of preparing a revised version of the guide on the decision-making process regarding medical treatment in end-of-life situations in the light of the comments received during the public consultation.

6. The revised draft will be examined by the DH-BIO at its 4th plenary meeting (26-28 November 2013) with a view to its approval and, where appropriate, its launching during the Austrian Chairmanship of the Committee of Ministers (first semester 2014).

V. Predictivity, genetic testing and insurance

7. The Committee examined the outline prepared by the Secretariat in consultation with experts having participated in the previous Working Party.

8. The Committee approved the main lines of the structure of the draft text. Comments were made on the content of the provisions included in the draft.

9. Following the discussion, delegations were invited to send their comments in written form by 18 June 2013.

10. The Secretariat was entrusted with the task of preparing a revised draft in the light of the comments made by the delegations and in consultation with experts having participated in the previous Working Party.

11. The revised draft will be submitted to the DH-BIO at its 4th meeting (26-28 November 2013). The Committee would then be asked to take a decision on the advisability of preparing a legal instrument.

VI. Genetic testing for health purposes: information document on genetic testing, in particular its nature and possible implications of its results

12. The Committee was informed that the information document had been translated into 17 non official languages thanks to the help and support of the European Society of Human Genetics
(ESHG) and EuroGentest. The Chair will send a message to the ESHG and EuroGentest to thank them.

13. Delegations were invited to:

- send their suggestions for translation into other non-official languages, including where appropriate non-European languages;
- indicate the names of organisations/institutions to which the information document could be sent directly for dissemination;
- send information on the dissemination and use of this information document at national level.

VII. Re-examination of Recommendation (2006) 4 on research on biological materials of human origin

14. The Committee examined the draft revised Recommendation prepared by the Drafting Group. Delegations made comments on the general approach proposed by the Drafting Group as well as the changes suggested in the different chapters.

15. The DH-BIO agreed to consult the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD) on the issues identified by the Drafting Group, in particular in relation to Article 3 - Identifiability of biological materials.

16. Delegations were invited to send their comments in written form by 24 June 2013.

17. The Drafting Group was entrusted with the task of preparing a revised draft and, where appropriate, draft elements for the explanatory memorandum in the light of the comments made by delegations.

18. The revised draft will be submitted to the DH-BIO at its 4th meeting (26-28 November 2013) with a view to a decision on a possible public consultation on a working document.

VIII. Additional Protocol on the protection of the dignity and fundamental rights of persons with mental disorders with regard to involuntary treatment and placement

19. The Chair recalled the different steps which had led to the decision by the Committee to prepare an Additional Protocol on the protection of the dignity and fundamental rights of persons with mental disorders with regard to involuntary treatment and placement. She stressed the importance for the Drafting Group to receive comments from delegations on the outline of fundamental principles prepared by the Secretariat.

20. Delegations which have not already done so were invited to send their possible comments by 10 June 2013 so that they can be considered by the Drafting Group at its meeting on 19-20 June 2013.

21. It was agreed that experts with clinical expertise/experience in psychiatry and/or in policy development in this field proposed by delegations could be invited to participate in the work of the Drafting Group in order to complement where appropriate, the expertise within the Group. Such an invitation could also be made on an ad hoc basis to address specific issues. The invitation would be made by the Chair of the Drafting Group in agreement with the Chair of the DH-BIO.

IX. Prenatal sex selection

22. The Secretariat presented a summary of the replies to the questionnaire on prenatal sex selection sent by 37 member states and two non-member states. The DH-BIO then held a preliminary exchange of views on the issue and the next step to be considered.

23. Delegations were then invited to reflect on the possible action(s) that could be undertaken, including, as suggested in the mandate given by the Committee of Ministers, the preparation of possible guidelines and good practices and send their proposal(s) by 15 September 2013.
Delegations should keep in mind the evolution of technologies such as non-invasive prenatal testing and cell sorting, when considering possible action. They should specify for each proposal the reasons supporting it and the nature of the action proposed.

24. Suggestions from delegations will be examined at the 4th plenary meeting (26-28 November 2013) with a view to a decision on (a) possible activity(ies).

X. **Cooperation programme (DEBRA)**

25. The Secretariat informed the DH-BIO that no requests had been submitted for organising cooperation activities in 2013.

26. It was recalled that any request from a member state to organise an activity in 2014 should be submitted to the Secretariat at the latest by 10 November 2013.

27. Delegations were invited to give more consideration to the possibility for the DEBRA programme to contribute to promoting and facilitating the ratification by member states of adopted legal instruments, in particular the Additional Protocol concerning Genetic Testing for Health Purposes.

XI. **Future activities and working methods of the DH-BIO**

28. The DH-BIO was informed about the timetable for the preparation of the 2014-2015 programme of activities.

29. The Committee agreed with the approach proposed by the Bureau for the carrying out of the expert studies as well as the proposed steps and calendar proposed for the work.

XII. **Trafficking in human organs**

30. The Committee was informed about progress in the work of the European Committee on Crime Problems (CDPC) towards finalising the draft explanatory report to the Convention against Trafficking in Human Organs, which was foreseen at the meeting taking place at the same time as that of the DH-BIO.

31. The draft Convention and its explanatory report would then be submitted to the Committee of Ministers who should forward them to the Parliamentary Assembly for its opinion.

XIII. **Dates of the next meetings**

32. The DH-BIO agreed to hold its 4th plenary meeting in Strasbourg on 26-28 November 2013. It also provisionally noted the dates of 13-15 May 2014 (alternative 20-22 May 2014) for its 5th plenary meeting (to be confirmed) to be held in Strasbourg.

33. The Bureau had agreed to meet on 3 and 4 October 2013 in Paris. A joint meeting with the Drafting Group on biobanks would be organised on 3 October 2013 in order to finalise the revised draft Recommendation to be presented to the DH-BIO at its 4th meeting.

XIV. **Recommendation 2017 (2013) of the Parliamentary Assembly (PACE) - “Nanotechnology: balancing benefits and risks to public health and the environment**

34. The Committee adopted the opinion (which appears in Appendix III to this abridged report) on Recommendation 2017 (2013) of the PACE, elaborated on the basis of a draft prepared by the Bureau.

XV. **Other business**

**Male circumcision and Article 6 of the Convention on Human Rights and Biomedicine**

35. The Committee took note of the Secretary General's request to delegations for the purpose of obtaining written information on the way in which the issue of male circumcision is dealt with
under national law. It was noted that this was not a request for interpretation, even unofficial, on the part of the Committee of the provisions of the Convention on Human Rights and Biomedicine on this issue.

36. Delegations were invited to send written information on the legal situation of the issue in their respective countries by 30 September 2013.

Cooperation with National Ethics Committees

37. Delegations held a preliminary exchange of views on possible closer cooperation of the Committee with national ethics committees.

38. A number of delegations expressed doubts about creating a new body in this field.

39. Delegations were invited to send written comments and possible proposals by 15 September 2013. Such proposals should also take into account existing initiatives taken in particular by the European Commission involving National Ethics Committees, i.e. the NEC Forum which concerns NEC from states which are EU members and candidates.

Industrial use of material derived from human embryos or foetuses: ethical and legal issues – Informal exchange of views at the request of the delegation of Hungary

40. The Committee heard a presentation by Mr Szabó, Deputy Commissioner on Fundamental Rights, responsible for the protection of the interests of future generations in Hungary, on the ethical and legal issues raised by the industrial use of material derived from human embryos or foetuses.

41. The Committee thanked Mr Szabó and held a brief exchange of views. Several delegations underlined the diversity and complexity of the issues raised. The Chair concluded that delegations needed more time to examine these questions appropriately.

Co-operation with other committees

Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)

42. The DH-BIO took note of the work in progress, in particular the questionnaire concerning Recommendation R(97)5 on the protection of medical data, and reports under preparation on nanotechnology and biometrics. It was also informed about the draft terms of reference of the ad hoc Committee on data protection which would be entrusted with the modernisation of the Convention for the protection of individuals with regard to automatic processing of personal data (ETS No. 108). Under these terms of reference, the DH-BIO would be invited to nominate a representative to participate in the work of this committee.

European Committee on Organ Transplantation (CD-P-TO)

43. The DH-BIO was informed about the finalisation by the CD-P-TO of a draft Resolution on the utilisation of kidneys from living donors for transplantation in the light of individual comments made by delegations of the DH-BIO.

44. Furthermore, the CD-P-TO planned to forward a comment concerning the draft guide on medical treatment in end-of-life situations.

Drafting Group on the Human Rights of Older Persons (CDDH-AGE)

45. The DH-BIO was informed of the progress of work by the Drafting Group in the preparation of a draft Recommendation on the human rights of older persons in the light, in particular, of the remarks made by delegations of the DH-BIO.
APPENDIX I

Agenda

Items for information, without decision required by the DH-BIO, are indicated by the following symbol:

1. Adoption of the agenda

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<th>Essential documents</th>
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<td>DH-BIO(2013) OJ1 Prov2</td>
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3. Developments in the field of bioethics

a. Developments in the field of bioethics in member states and other states

Delegations, including observers, are invited to send information in writing.

b. Developments in the field of bioethics in international organisations

c. Developments in the field of bioethics in other Council of Europe bodies

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4. Decision-making process regarding medical treatment in end-of-life situations

Information on replies received following the public consultation on the Working document on decision-making process regarding medical treatment in end-of-life situations.

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5. Predictivity, genetic testing and insurance

- Examination of a preliminary outline of a possible legal instrument on Predictivity, genetic testing and insurance, as prepared by the Secretariat in consultation with experts, with a view to a decision on the preparation of a possible legal (binding or non-binding) instrument.

- Decision on the follow-up

Essential documents

| DH-BIO(2013)11 | Preliminary outline for a possible legal instrument on Predictivity, Genetic Testing and Insurance |

Useful documents

| DH-BIO(2012)29 | Predictivity, genetic testing and insurance: Main issues for further possible work |
| DH-BIO(2012)14REV | Compilation of replies received during the consultation process |
| DH-BIO/INF(2012)9 | User guide to the compilation of replies received during the consultation process |
| DH-BIO/INF(2012)1 | Consultation document on predictivity, genetic testing and insurance |

6. Genetic testing for health purposes: information document on genetic testing in particular their nature and possible implications of their results

Information on progress made in the dissemination of the leaflet in the language of the member states

Essential document

| DH-BIO(2013)11 | Translations of the Leaflet on Genetic testing for health purposes. |
| Proposals made by delegations for dissemination of the Leaflet on Genetic Tests for Health Purposes |
7. **Re-examination of Recommendation (2006) 4 on research on biological materials of human origin**

- Examination of the preliminary draft revised Recommendation, prepared by the Drafting group on Biobanks
- Decision on the follow-up

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8. **Additional Protocol on the protection of the dignity and fundamental rights of persons with mental disorders with regard to involuntary treatment and placement**

First meeting of the drafting group to be held on 19-20 June 2013

| **DH-BIO(2013)14REV** | Proposals from delegations of experts who could participate in the elaboration of the future additional Protocol to the Convention on Human Rights and Biomedicine on protection of persons with mental disorder |

9. **Prenatal Sex Selection**

- Presentation of the replies from the DH-BIO delegations to the Questionnaire on Prenatal Sex Selection.
- Discussion on the follow-up to be considered with a view to a decision on the possible drafting of guidelines.

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10. **Cooperation programme (DEBRA)**

Delegations wishing to organise DEBRA activities in 2014 are invited to send their written request by **10 November 2013 at the latest.**
11. Future activities and working methods of the DH-BIO


b. Expert study(ies) on emerging technologies
   - Approach and timetable for the launching of the studies

Useful documents

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<tr>
<td>DH-BIO/BUR RAP(2013)1</td>
<td>Meeting report of the DH-BIO Bureau (Paris, 18-19 April 2013). See points 27-29</td>
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<tr>
<td>DH-BIO(2012)11</td>
<td>Document prepared by Mrs Isabelle Erny on access to medical file</td>
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<tr>
<td>CDBI(2011)9</td>
<td>Document on neurosciences elaborated by Dr Doris Wolfslehner</td>
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<td>CDBI(2011)22</td>
<td>Information collected in member states on neuro-imaging enhancement</td>
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<td>CDBI(2011)10</td>
<td>Background paper on clinical ethics committees elaborated by Prof. Eugenijus Gefenas</td>
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<td>CDBI(2011)20</td>
<td>Information collected on clinical ethics committees in member states</td>
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<td>CDBI(2011)3</td>
<td>Future activities and working methods: Decisions taken by the CDBI</td>
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<td>RES(2011)24</td>
<td>Resolution Res(2011)24 on committees and subordinate bodies, their terms of reference and working methods</td>
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12. Trafficking in Human Organs

Essential documents

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<tr>
<td>CDPC(2013)4 FINAL</td>
<td>Draft Council of Europe Convention against Trafficking in Human Organs</td>
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<td>CDPC(2013)5REV2</td>
<td>Draft explanatory report</td>
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13. Relations with other international bodies

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<td>DH-BIO(2013)10</td>
<td>Relations with other international organisations: list of meetings</td>
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14. Dates of the next meeting

Dates proposed:

4th meeting of the DH-BIO: 19-22 November 2013
5th meeting of the DH-BIO: May 2014

In reply to the decision of the Committee of Ministers concerning Recommendation 2017 (2013) “Nanotechnology: balancing benefits and risks to public health and the environment” (please see below), a draft comment will be presented by the Bureau for discussion and adoption during the plenary meeting.

Ministers’ Deputies
1170 Meeting, 7 May 2013

The deputies


a. agreed to communicate it to the European Committee for Social Cohesion (CDCS), to the Committee on Bioethics (DH-BIO) and to the Steering Committee for Human Rights (CDDH) for information and possible comments by 12 July 2013;

b. in the light of possible comments, invited their Rapporteur Group on Social and Health Questions (GR-SOC) to prepare a draft reply for adoption at one of their forthcoming meetings.

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**Useful document**


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**16. Other business**

a. Male circumcision and Article 6 of the Convention on Human Right and Biomedicine
   Informal exchange of views

b. Cooperation with National Ethics Committees

c. Industrial use of material derived from human embryos or foetuses: ethical and legal issues
   Informal exchange of views at the request of the delegation of Hungary

d. Cooperation with other Committees
   i) Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)
   ii) European Committee on Organ Transplantation (CD-P-TO)
   iii) European Committee on Blood Transfusion (CD-P-TS)
   iv) Drafting Group on the Human Rights of Older Persons (CDDH-Age)
**Essential documents**

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<td>Meeting report of the DH-BIO Bureau (Paris, 18-19 April 2013). See points 36-37</td>
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<td>c.</td>
<td>d.ii</td>
<td>Draft Resolution on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system</td>
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<td>d.ii</td>
<td>PA/PH/TO (11) 3 4 R</td>
<td>Draft Resolution on the development and optimisation of live kidney donation programmes</td>
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<td>d.ii</td>
<td>DH-BIO(2013)2</td>
<td>Comments made by DH-BIO delegations on the draft Resolution on utilisation of kidneys from living donors for transplantation</td>
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<td>d.ii</td>
<td>PA/PH/TO (12) 96 DEF</td>
<td>Final Report of the 10th Meeting of the European Committee (Partial Agreement) on Organ Transplantation (CD-P-TO), (11-12 October 2012)</td>
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<td>d.iv</td>
<td>CDDH-AGE(2013)R3</td>
<td>Draft meeting report (15-17 April 2013, see draft revised Recommendation in appendix)</td>
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<td>d.iv</td>
<td>DH-BIO(2013)12</td>
<td>Comments made by delegations on draft Recommendation on the human rights of older persons</td>
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<td>d.iv</td>
<td>CDDH-AGE(2013)1</td>
<td>Draft Recommendation CM/Rec(20...)… of the Committee of Ministers to member states on the promotion of the human rights of older persons</td>
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**DOCUMENTS FOR POSSIBLE UPDATE BY DELEGATIONS:**

Delegations are invited to provide where appropriate updated information to be inserted in the following documents:

- Legislative on nuclear transfer and their relationship with Article 18.2 of the Convention
  - CDBI(2007)15REV12 | Legislative developments on nuclear transfer and their relationship with Article 18.2 of the Convention |
- Background document on preimplantation and prenatal genetic testing
  - CDBI/INF(2010)6 | Background document on preimplantation and prenatal genetic testing |

**USEFUL DOCUMENTS FOR SEVERAL ITEMS:**

- DH-BIO/RAP2 | Report of the 2nd meeting of the DH-BIO (Strasbourg, 4-6 December 2012) |

**GENERAL INFORMATION DOCUMENTS:**

- DH-BIO-INF(2013)3 | Information document on the DH-BIO |
- DH-BIO-INF(2012)3REV | Texts of the Council of Europe on bioethical matters, Volume I |
- DH-BIO-INF(2012)3REV | Texts of the Council of Europe on bioethical matters, Volume II |
- Please click on the respective link to open the Convention | Convention on Human Rights and Biomedicine (ETS 164) |
- | Explanatory Report to the Convention on Human Rights and Biomedicine |
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<td>Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS 186)</td>
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<td>Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research (CETS 195)</td>
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<td>Additional Protocol concerning Genetic Testing for Health Purposes (CETS 203)</td>
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APPENDIX II

List of participants

MEMBER STATES / ETATS MEMBRES

Albania/Albanie - apologised/excusé

Andorra/Andorre – Mr Pere PASTOR VILANOVA, Juge, Cour Suprême de Justice, Avda de Tarragona, AD 500 Andorra la Vella

Armenia/Arménie – Mr Igor MADOYAN, Phd, President of National Center of Bioethics, n.24, ave Sayat-Nova, apt. 14, entrance 1, 0001 YEREVAN

Austria/Autriche – Dr. Doris WOLFSLEHNER, Head of the division “Bioethics” at the Federal Chancellery of the Republic of Austria, Ballhausplatz 2, 1014 Wien

Dr Renate FALLY-KAUSEK, Medical Officer, Federal Ministry for Health, Department III/6, Radetzkystrasse 2, A-1030 WIEN

Dr. Peter BARTH, Oberstaatsanwalt, Abteilungsleiter-Stellvertreter in der Zivilrechtssektion, 1070 Wien, Museumstraße 7

Azerbaijan/Azerbaïdjan – apologised/excusée

Belgium/Belgique – Mme Régine WILMOTTE, Juriste au sein de la direction générale des Etablissements de Soins du Service public fédéral « Santé publique », Place Victor Horta 40, boîte 10, 1060 Bruxelles

Bosnia and Herzegovina/Bosnie-Herzégovine – Dr. Serifa GODINJAK, Head of Department for European Integration and International Cooperation, Sector for Health Ministry of Civil Affairs Trg BiH 1, 71000 Sarajevo

Bulgaria/Bulgarie – Ms Sylvia TOMOVA, Ministry of Health, Legal Directorate, Chief Legal Advisor, Place St Nedelia 5, Sofia 1000

Croatia/Croatie - Dr. Vanja NIKOLAC, Head of Service, Service for blood, tissues and cells inspection, Inspection Sector, Ministry of Health, Ksaver 200a, 10 000 Zagreb

Cyprus/Chypre – Mrs Rena PETRIDOU-VRAHIMI, Attorney of the Republic of Cyprus, Office of the Attorney General of the Republic of Cyprus, Appelli Street n° 1, 1403 NICOSIA

Czech Republic/République Tchèque – Pr. Pavel MARTASEK, Professor of Medicine, Expert on Genetics, Dept. of Pediatrics, Center for Applied Genomics, 1st School of Medicine, Charles University, Ke Karlovu 2, Building D/2nd floor, 128 08 PRAGUE 2

Denmark/Danemark - Anna Skat NIELSEN, Special Advisor, Center for Hospital Policy, The Ministry of the Interior and Health, 10-12 Slotsholmsgade, DK-1216 Copenhagen K

Estonia/Estonie – Prof Hele EVERAUS, Head of the Clinic, Haematology and Oncology Clinic, Tartu University, Tartu University Hospital, Puusepa 8, 51014 Tartu

Finland/Finlande – Jaakko HALTTUNEN, Counsellor, Ministry for Foreign Affairs, Legal Service, Unit for Human Rights Courts and Conventions, PO Box 441, FI-00023 Government

Ms. TÖRRÖNEN Anneli, Ministry of Social Affairs and Health, P.O. Box 33, FI- 00023 Government

France - Mme Isabelle ERNY, Attachée principale d'administration centrale, Ministère de la Santé, Direction Générale de la Santé, Secrétariat Général, Division droit, éthique et appui juridique, 14 avenue Duquesne, 75350 PARIS 07 SP
Mme Caroline AZAR, Ministère de la Justice, Direction des Affaires Civiles et du Sceau, 13, Place Vendôme, F-75001 PARIS

M. Emmanuel JAUFFRET, Sous-direction des droits de l'homme, Direction des affaires juridiques

Dr Jacques MONTAGUT, Directeur de l'IFREARES, 20 route de Revel, 31400 TOULOUSE

Mme Sandrine BOURDIN, Magistrate au sein du bureau du droit des personnes et de la famille à la direction des affaires civiles et du Sceau

Georgia/Georgie – Dr Givi JAVASHVILI, Head of Family Medicine Department, State Medical Academy of Georgia, Chairman of the National Council on Bioethics, 29 I. Chachavadze Avenue, 0179 TBILISI

Germany/Allemagne – Andrea MITTELSTÄDT, Federal Ministry of Justice, Division III B 2, Mohrenstraße 37, D-10117 Berlin

Prof. Elmar DOPPELFELD (Président de l'Union des Comités d'Ethique), Ottostraße 12, D-50859 Köln

Prof. Thomas HEINEMANN, Philosophical-Theological University of Vallendar (PTHV), Pallottistraße 3, 56179 Vallendar

Dr. Ingo HÄRTEL, Federal Ministry of Health, Division 313, Friedrichstraße 108, D-10117 Berlin

Dr. Daniela von BUBNOFF, Federal Ministry of Education and Research, Division 612, Friedrichstraße 130 B, D-10117 Berlin

Greece/Grèce – Dr Stamatia GARANIS-PAPADATOS, Lecturer, National School of Public Health, 196 Alexandras Avenue, 11521 Athens

Hungary/Hongrie - Dr Dorottya MOGYOROSI, MD JD, head-counsellor professional, Secretariat of Minister of State of Health, Ministry of National Resources, Arany János u. 6-8., 1051 Budapest

Marcel SZABÓ, Deputy Commissioner for Fundamental Rights, responsible for the protection of the interests of future generations, Office of the Commissioner for Fundamental Rights, 22 Nádor street, H-1051 Budapest

Iceland/Islande – Mrs Laufey Helga GUDMUNDSDOTTIR, Specialist, Department of Protection of Rights, Ministry of Welfare

Gudridur THORSTEINSDOTTIR, Head of Department, Department of Protection of Rights, Ministry of Welfare, Hafnarhusinu vid Tryggvagotu, IS-150

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APPENDIX III

Comments from the Committee on Bioethics (DH-BIO) on Recommendation 2017 (2013) of the Parliamentary Assembly – “Nanotechnology: balancing benefits and risks to public health and the environment” adopted on 29 May 2013

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.

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

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”.

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.

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

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.

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 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.

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.