



Strasbourg, 12 June 2013

**DH-BIO/ abr RAP 3**

**COMMITTEE ON BIOETHICS  
(DH-BIO)**

**3<sup>rd</sup> MEETING  
Strasbourg, 28-30 May 2013**

**ABRIDGED REPORT**

## **I. Adoption of the agenda**

1. The Committee on Bioethics (DH-BIO) held its 3<sup>rd</sup> 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 4<sup>th</sup> 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 4<sup>th</sup> 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 4<sup>th</sup> 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 4<sup>th</sup> 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 4<sup>th</sup> 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 5<sup>th</sup> 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 4<sup>th</sup> 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 fetuses: 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 fetuses.
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**



#### **2. 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**



#### **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**



#### **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.

#### **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



#### **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

**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



**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

**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.



**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**



**a. 2014-2015 biennium. Information on the preparation of the CoE activity programme**

**b. Expert study(ies) on emerging technologies**

- Approach and timetable for the launching of the studies



**12. Trafficking in Human Organs**



**13. Relations with other international bodies**

#### 14. Dates of the next meeting

Dates proposed:

4<sup>th</sup> meeting of the DH-BIO: 19-22 November 2013

5<sup>th</sup> meeting of the DH-BIO: May 2014

#### 15. Recommendation 2017 (2013) “Nanotechnology: balancing benefits and risks to public health and the environment”

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*

6. concerning Recommendation 2017 (2013) “Nanotechnology: balancing benefits and risks to public health and the environment”

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.

#### 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 fetuses: 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)

## **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, Appeli 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, Magistrat au sein du bureau du droit des personnes et de la famille à la direction des affaires civiles et du Sceau **apologised/excusée**

**Georgia/Géorgie** – 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, Honorary Chair of the Permanent Working Party of Research Ethics Committees in Germany Inc., Lenaustraße 15, D-50858 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 **apologised/excusée**

**Ireland/Irlande** – Ms Angela O'FLOINN, Dept of Health, Hawking House, Dublin 2

Dr. Siobhán O'SULLIVAN, Chief Bioethics Officer, Dept. of Health, Hawkins House, Dublin 2

**Italy/Italie** — M. le Professeur Adriano BOMPIANI, Université catholique Polyclinique "A. Gemelli", Largo Gemelli 1, 00197 Roma

**Latvia/Lettonie** – Dr.Vents SĪLIS, Assistant Professor at Riga Stradins University, Department of Humanities, Dzirciema street 16, Riga

**Liechtenstein** **apologised/excusé**

**Lithuania/Lituanie** – Dr Eugenijus GEFENAS, Chairman of Lithuanian Bioethics Committee, Associate Professor at Vilnius University, Lithuanian Bioethics Committee, Vilnius str.33, LT-2001 VILNIUS

Ms Jurate SEREPKAITE, Chief specialist, Lithuanian Bioethics Committee, Vilnius str. 33, LT-2001, Vilnius  
**apologised/excusee**

**Luxembourg** – Mr Jean-Paul HARPES, membre du Comité National d'Ethique de la Recherche, 119, Val des Bons Malades, L-2121 Luxembourg  
**apologised/excusee**

Mr Mike SCHWEBAG, Attaché de Gouvernement 1er en rang, Ministère de la Santé, Allée Marconi - Villa Louvigny, 2423 Luxembourg  
**apologised/excusee**

**Malta/Malte** - Mme Mary Anne CIAPPARA, B. Pharm., M. Phil. Pharmacist, Hon. Secretary, Bioethics Consultative Committee, Palazzo Castellania, 15 Merchant Street, VALLETA

**Republic of Moldova/République de Moldova** – Lucia TURCAN, Assistant Professor, PhD., The State University of Medicines and Pharmacy "Nicolae Testemitanu", Clinical Pharmacology Department, Chisinau  
**apologised/excusee**

M. Petru MOSCALIUC, Consultant, Law Department, Ministry of Health

**Monaco** - **apologised/excusee**

**Montenegro/Monténégro** – Dr Omer ADZOVIC, Institute for Childhood Diseases, Medical Centre of Montenegro, Krusevac BB, 81000 PODGORICA

**Netherlands/Pays-Bas** – Mr. Arjan VAN DRIELEN, Ministry of Health, Welfare and Sport, Directorate Public Health, Section Ethics, PO Box 20350, 2500 EJ DEN HAAG

**Norway/Norvège** – Mrs Anne FORUS, Senior Adviser, ph.d, Biotechnology and health legislation department, Division of specialised health care services, Norwegian Directorate of Health, P.O.Box 7000, St Olavs plass, N-0130 Oslo

Camilla Closs WALMANN, Senior Adviser, Department for Biotechnology and Health Law, Norwegian Directorate of Health, P.O.Box 7000 St Olavs plass, N-0130 Oslo

**Poland/Pologne** – Dr Jerzy UMIASTOWSKI, Chairman of the Medical Ethics Committee of the Polish Medical Board, Local Medical Board, Ul. Sniadeckich 33, 80-204 GDANSK

**Portugal** - Prof. Miguel OLIVEIRA DA SILVA, Conselho Nacional de Ética para as Ciências da Vida Av. D. Carlos I, nº 146, 2º Esq, 1200-651, Lisboa

**Romania/Roumanie** – Prof. Dr. Vasile ASTARASTOAE, Institutul de Medicina Legală, Buna Vestire nr. 4, 700455 IASI  
**apologised/excusee**

Mrs Beatrice Gabriela IOAN, Associate Professor, President of the Bioethics Commission of the Romanian College of Physicians, Institutul de Medicina Legală, str. Bunavestire nr. 4, IASI

**Russia/Russie** – Mr Boris YUDIN, Director, Institute of Human Studies, Russian Academy of Sciences, Volkhonka 14, MOSCOW 119992  
**apologised/excusee**

Ms Natalia STEPANOVA, Director, PhD, Russian Committee on Bioethics, Commission of the Russian Federation for UNESCO, Responsible Secretary, Scientific Secretary of the Centre "Bioengineering", RAS, Russian Federation, Moscow. 117312, prospect 60-let Oktyabrya, 7- korp.1, Centre "Bioengineering", RAS

**San Marino/Saint-Marin** - Dr. Luisa BORGIA, Vice-President of the National Ethics Committee, Contrada Le Grazie, n.3, 62029 Tolentino (MC)

**Serbia/Serbie** - Prof. Dr Zvonko MAGIC, Head of the Institute for Medical Research in the MMA (Military Medical Academy), professor of the human genetics at the Medical Faculty and Cochairmen of the National Committee for bioethics of UNESCO Commission of Serbia, Serbian Academy of Sciences and Arts, 11000 Belgrade

**Slovakia/Slovaquie** – Assoc. Prof. Jozef GLASA, MD, PhD, PhD; Institute of Pharmacology and Clinical Pharmacology, Slovak Medical University; National Reference Centre for Management of Chronic Hepatitis; Institute of Medical Ethics and Bioethics n.f.\*; Ethics Committee, Ministry of Health SR; Limbová 12, 83303 Bratislava

**Slovenia/Slovénie** – Urh GROSELJ, MD, MA, University Children's Hospital, University Medical Center Ljubljana, Bohoriceva 20, 1000 Ljubljana

Prof. Joze V. TRONTELJ, Chair, National Medical Ethics Committee, Institute of Clinical Neurophysiology, University Medical Centre, Zaloška 7, SI-1525 LJUBLJANA  
**apologised/excusé**

**Spain/Espagne** – Carlos ALONSO BEDATE, [Centro de Biología Molecular](#), Member of the National Committee for Bioethics, C/ Alberto Aguilera, 21. 28015 Madrid

Prof. Carlos M. ROMEO – CASABONA, Professor of Penal Law, Head, Inter-University Chair in Law and the Human Genome, Avda. de las Universidades 24; 48007 BILBAO

Javier ARIAS-DIAZ, Associate Professor of Surgery, Subdirección de Terapia Celular y Medicina Regenerativa, Instituto de Salud Carlos III, Sinesio Delgado 4, 28029 Madrid

Asier URRUELA MORA, Facultad de Derecho, Universidad de Zaragoza, C/ Pedro Cerbuna, 12, 50009, Zaragoza  
**apologised/excusé**

M<sup>a</sup> Concepción MARTIN ARRIBAS, Subdirección General de Investigación en Terapia Celular y Medicina Regenerativa – Instituto de Salud Carlos III – ISCIII, Avda. Monforte de Lemos 5, 28029 Madrid

**Sweden/Suède** – Mrs Tesi ASCHAN, Legal Adviser, The National Board of Health and Welfare, Socialstyrelsen, 106 30 Stockholm  
**apologised/excusée**

**Switzerland/Suisse** – Dr Martin GÖTZ, Office fédérale de la santé publique, Division Biomédecine, collaborateur scientifique, Seilerstrasse 8, 3003 Bern

**"The Former Yugoslav Republic of Macedonia"/"l'ex-République yougoslave de Macédoine"** – Dr Zudi BILALLI, Head of Sector, Ministry of Health, Vodnjanska BB, 91000 SKOPJE  
**apologised/excusé**

Burim MAKSUTI, lawyer, Junior Desk Officer, Sector for European integration, Ministry of Health 50 Divizija br.6, 1 000 Skopje  
**apologised/excusé**

**Turkey/Turquie** – Prof. Ergun ÖZSUNAY, Professor of Civil, Comparative Law and EU Private law, Istanbul Culture University, Faculty of Law, İstiklal cad. 233/1, Tunca Apt. Daire 7, 34430 ISTANBUL

**Ukraine** - Prof Zoreslava SHKIRYAK-NYZHNYK, Vice-president of Bioethics Committee of National Academy of Medical Sciences, Chief of the Department of Family Health Problems, Academy of Postgraduate Education, Institute of Paediatrics, Obstetrics and Gynaecology, Mayborody str., 8, 04050 KYIV

**United Kingdom/Royaume-Uni** - Dr Mark BALE, Principal administrator, Head of Genetics Branch; Scientific Development & Bioethics Division, Department of Health, Wellington House, Waterloo Road, London Road, London SE1 6LH

INVITED EXPERTS / EXPERTS INVITES
-----------------------------------

Prof. Bernard DUBUISSON, Faculté de droit et de criminologie, Collège Thomas More, Place Montesquieu, 2, 1348 Louvain-la-Neuve

PARTICIPANTS
--------------

**CDCJ** - Mrs Xeni SKORINI, Professeur associé, Faculté de Droit d'Athènes, 6 rue Essopou, GR-14563 ATHENES-Kifissia, GRECE

**CDDH** – Mme Brigitte KONZ, Vice-Présidente du tribunal d'arrondissement de Luxembourg, Cité judiciaire, Bâtiment T.L, B.P. 15, L-2080 Luxembourg **apologised/excused**

**CD-P-TS** – Dr. Guy RAUTMANN, Secretary of the European Committee on Blood Transfusion (CD-P-TS), European Directorate for the Quality of Medicines and HealthCare, Department of Biological Standardisation and OMCL Network **apologised/excused**

**CD-P-TO** – Ms Marta LOPEZ FRAGA, Secretary of the CD-P-TO, Email: marta.lopezfraga@edqm.eu

**PARLIAMENTARY ASSEMBLY/ASSEMBLÉE PARLEMENTAIRE** – Maren LAMBRECHT-FEIGL, Secretary of the Committee on Social Affairs, Health and Sustainable Development, Parliamentary Assembly of the Council of Europe, F-67075 Strasbourg Cedex

Ayşegül ELVERİŞ, Co-Secretary to the Committee on Social Affairs, Health and Sustainable Development, Parliamentary Assembly of the Council of Europe, F-67075 Strasbourg Cedex

OTHER PARTICIPANTS / AUTRES PARTICIPANTS
--

**EUROPEAN COMMISSION/COMMISSION EUROPEENNE** – Mr Lino PAULA, European Research Area, Ethics and Gender Unit, Directorate-General for Research and Innovation, Office SDME 3/14, B-1049 Brussels **apologised/excused**

Dr Jim DRATWA, Head of Ethics and Head of the EGE Secretariat, Member of the Bureau of European Policy Advisers (BEPA), European Commission, Rue de la Loi 200 Wetsraat, BERL 8/358, B-1049 Brussels

**Canada** – Mr. Michael HALUCHA, Policy Analyst, Bioethics and Policy Integration, Department of Health Canada, 11 Holland Avenue, 5<sup>th</sup> Floor, Holland Cross Building, Tower A PL: 3005B, Ottawa, Ontario, Canada K1A 0K9 **apologised/excused**

Dr. Peter MONETTE, Manager of Bioethics, Department of Health Canada, 11 Holland Avenue, 5<sup>th</sup> Floor, Holland Cross Building, Tower A PL: 3005B, Ottawa, Ontario, Canada K1A 0K9 **apologised/excused**

**Holy See/Saint-Siège** – Mgr. Jacques SUAUDEAU, Academie Pontificale pour la Vie, Via della Conciliazione, 3, I – 00193 Rome

**Japan/Japon** – **apologised/excused**

**Mexico/Mexique** – Dr. Manuel H Ruiz de CHÁVEZ, President of the National Academy of Medicine of Mexico, President of The Council of the National Commission of Bioethics, Carretera Picacho-Ajusco No. 154, piso 6°, Col. Jardines de la Montaña. C.P. 14210, Del. Tlalpan, Mexico, D. F.

Alejandro MARTINEZ PERALTA, Chargé d'affaires, a. i., Représentation du Mexique auprès du Conseil de l'Europe

Mme Andrea BARBOSA, Attachée, Mission permanente du Mexique auprès du Conseil de l'Europe, 8, boulevard du Président Edwards, 67000 Strasbourg, France

**USA/Etats-Unis d'Amérique –**

**apologised/excuse**

**UNESCO** – Mrs. Dafna FEINHOLZ KLIP, Section de la bioéthique, Division de l'éthique des sciences et des technologies, UNESCO, 1 rue Miollis, 75732 PARIS CEDEX 15

**apologised/excusee**

**OECD/OCDE** – Dr Jacqueline E M Allan, Senior Policy Analyst (Biotechnology and Nanotechnology) Directorate for Science, Technology and Industry, OECD, 2 rue André-Pascal, 75775 Paris Cedex 16 France

**apologised/excusee**

**World Health Organisation/Organisation Mondiale de la Santé (WHO/OMS)** – Dr Marie-Charlotte BOUËSSEAU, Technical officer, Ethics, Trade, Human Rights and Health Law, WORLD HEALTH ORGANIZATION, 20 Avenue Appia, CH-1211 GENEVA 27

**apologised/excusee**

Dr Stefano CRETIER, Interne, Unité Ethique et santé, OMS/IER/ETH 3158, Avenue Appia 20, 1211 Genève 27

**apologised/excuse**

Dr. Lynn WOODWARD, Volunteer, Department of Ethics, Equity, Trade and Human Rights (IER/ETH), World Health Organization, 20 Avenue Appia, Geneva 1211

**apologised/excuse**

Dr Andreas REIS, Technical Officer, Department of Ethics, Equity, Trade and Human Rights, WHO, 20 Avenue Appia, CH-1211 GENEVA 27

**apologised/excuse**

**Permanent representation of Turkey/Représentation permanente de la Turquie** - Mr Basri YILDIZ, Legal expert

<b>OBSERVERS / OBSERVATEURS</b>
---------------------------------

**Australia** - Samantha ROBERTSON, Executive Director, Research Translation, National Health and Medical Research Council (NHMRC), Postal Address: **National Health and Medical Research Council, GPO Box 1421, Canberra ACT 2601,**

**apologised/excusee**

**Israel/Israël** – Dr Ilana SCHMIDT-HOPFELD, Department of Science Teaching, Weizmann Institute of Science, 200 Herzl St., REHOVOT 76100

**apologised/excusee**

Professeur Michel REVEL, Weizmann Institute, Department of Molecular Genetics, Brasil House, 5 REHOVOT 76100

**apologised/excuse**

**European Science Foundation/Fondation Européenne de la Science (ESF)** – Dr Maria Manuela NOGUEIRA, Senior Science Officer, European Science Foundation, 1 quai Lezay-Marnésia, BP 90015, 67080 Strasbourg cedex, France

Dr Vanessa CAMPO-RUIZ, Science Officer to the Chief Executive, European Science Foundation (ESF), Strasbourg, France

**apologised/excusee**

Prof. Isabel VARELA-NIETO, Instituto Investigaciones Biomédicas "Alberto Sols", Neurobiology of Hearing Group, Arturo Duperier 4, 28029 Madrid

**apologised/excusee**

**KEK – Church and Society Commission of the Conference of European Churches/Commission Eglise et Société de la Conférence des Eglises Européennes** – Pasteur Richard FISCHER, Secrétaire Exécutif de la Commission Eglise et Société de la Conférence des Eglises européennes, 8, rue du Fossé des Treize, 67000 Strasbourg

## **SECRETARIAT**

### **Directorate General Human Rights and Rule of Law Direction Générale Droits de l'Homme et Etat de Droit**

#### **Bioethics Department / Service de la Bioéthique**

Mr Carlos de SOLA, Head of Bioethics Department / Chef du Service de la Bioéthique, Tel: +33 (0) 388 41 24 38, Email : [carlos.desola@coe.int](mailto:carlos.desola@coe.int)

Mrs Laurence LWOFF, Secretary of the DH-BIO / Secrétaire du DH-BIO, Tel: +33 (0) 388 41 22 68, Email: [laurence.lwoff@coe.int](mailto:laurence.lwoff@coe.int)

Mrs Lindsay YOUNGS, Administrator / Administratrice, Tel: +33 (0) 388 41 21 63, email: [lindsay.youngs@coe.int](mailto:lindsay.youngs@coe.int)

Mr Kristof VAN ASSCHE, Administrator / Administrateur, Tel: +33 (0) 390 21 42 09, email: [kristof.vanassche@coe.int](mailto:kristof.vanassche@coe.int)

Ms. Tatiana WINTER, Assistant / Assistante, Tel: +33 (0) 388 41 33 67, Email : [tatiana.winter@coe.int](mailto:tatiana.winter@coe.int)

Ms. Catherine FORNÉ, Assistant / Assistante, Tel: +33 (0) 388 41 22 20, Email: [catherine.forne@coe.int](mailto:catherine.forne@coe.int)

Mlle Cristina MURANO Trainee / Stagiaire

Ms. Agnès NOËL, Trainee / Stagiaire

Ms. Anastasia PAZARIOTIS, Trainee / Stagiaire

Ms. Elena IFRIM, Future Trainee / Future Stagiaire

## **INTERPRETERS / INTERPRETES**

Amanda BEDDOWS  
Corinne McGEORGE  
Shéhérazade HOYER  
Christine TRAPP  
Michael HILL

### **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.