



United Nations Educational, Scientific and Cultural Organization  
Organisation des Nations Unies pour l'éducation, la science et la culture

Distribution: limited

SHS/EST/05/CONF.203/5  
Paris, 6 April 2005  
Original: English / French

**First Intergovernmental Meeting of Experts  
Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics**

UNESCO Headquarters, 4-6 April 2005  
(Room XI, Fontenoy building)

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**Final Report**

Division of Ethics of Science and Technology

## **I. INTRODUCTION**

1. In accordance with the Timetable for the elaboration of the declaration, approved by the Executive Board at its 169th Session (169 EX/Dec. 3.6.2), and in application of 170 EX/Decision 3.5.1 adopted by the Executive Board at its 170th Session, the first intergovernmental meeting of experts (Category II) aimed at finalizing a draft declaration on universal norms on bioethics took place at UNESCO Headquarters in Paris, from 4 to 6 April 2005.

2. Government experts from the following 75 Member States participated in the meeting with the right to vote: Afghanistan, Algeria, Andorra, Angola, Argentina, Australia, Austria, Belgium, Benin, Bolivia, Brazil, Burkina Faso, Canada, Chile, China (People's Republic of), Cyprus, Colombia, Costa Rica, Croatia, Czech Republic, Ecuador, Egypt, El Salvador, Finland, France, Gabon, Germany, Greece, Grenada, Guatemala, Honduras, , Iceland, India, Indonesia, Italy, Japan, Kazakhstan, Kenya, Lebanon, Libyan Arab Jamahiriya, Lithuania, Luxembourg, Madagascar, Malawi, Mexico, Monaco, Niger, Norway, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Saint Lucia, Saint Vincent and the Grenadines, Saudi Arabia, Senegal, Slovakia, South Africa, Switzerland, Syrian Arab Republic, The Netherlands, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, United Republic of Tanzania, United States of America, Uruguay, Venezuela and Yemen.

3. Palestine and the Holy See participated in the meeting as observers. The Council of Europe, the World Trade Organization (WTO), the Organization for Economic Cooperation and Development (OECD) also sent representatives as observers and the following international non-governmental organizations also attended as observers: the World Medical Association (WMA), the International Social Science Council (ISSC), the World Academy of Biomedical Technologies (WABT), the World Federation of Scientific Workers (WFSW). Mrs Michèle S. Jean, Chairperson of the International Bioethics Committee (IBC), attended the meeting as a resource person. The list of participants (SHS/EST/05/CONF.203/INF.3) is contained in Annex I of this report.

4. Before the meeting began, a minute of silence was observed in tribute to His Holiness Pope John-Paul II, deceased on Saturday 2 April 2005 and to His Serene Highness Prince Rainier III of Monaco, deceased on 6 April 2005. The meeting was opened by Mr Koïchiro Matsuura, Director-General of UNESCO, who briefly recalled the origins of the mandate entrusted by the General Conference at its 32nd session. The Director-General expressed his thanks to IBC, which had finalized the preliminary draft declaration in just one year. He underlined the transparent and participatory nature of the elaboration process which, following numerous consultations with all the actors concerned, had given rise to a text that provided a consensual basis for the work under way. The Director-General highlighted the connection between the first meeting and the second meeting, to be held in June 2005, thus leaving time for the internal consultations on the text needed to be able to complete the negotiations in June. The opening address of the Director-General is contained in Annex II.

5. After electing its Chairperson, H. E. Mr Pablo Sader (Uruguay), Ambassador of Uruguay to UNESCO, by consensus, the meeting then adopted its Agenda (SHS/EST/05/CONF.203/1), contained in Annex III, and its Rules of Procedure (SHS/EST/03/CONF.203/2).

6. In accordance with Article 4 of the Rules of Procedure, the meeting elected the members of its Bureau as follows:

Chairperson: Mr Pablo Sader (Uruguay);

Vice-Chairpersons: Mr Glenn Rivard (Canada);  
Mr Umar Anggara Jenie (Indonesia);  
Mrs Rima Vaitkiene (Lithuania);  
Mr Ali Belhani (Tunisia)

Rapporteur: Mr Bindi Ouoba (Burkina Faso).

7. Having formed the Bureau, the Chairperson reminded the participants that this first meeting was part of a larger process that would be continued with the second meeting of government experts in June. The purpose of this first meeting was to give participants the opportunity to express different points of view, to identify major points of divergence and to determine those areas of the text where consensus seemed already to have been reached. While oral amendments would be accepted, States were asked to present their amendments in writing if possible to facilitate the work. The Chairperson also pointed out that the task of the Drafting Group, which was to be established in accordance with item 9 of the Agenda, would be one of drafting and not of negotiating.

## **II. PRELIMINARY PRESENTATION BY THE SECRETARIAT CONCERNING THE OBJECTIVES OF THE MEETING AND THE WORKING DOCUMENTS AND PRESENTATION OF THE PRELIMINARY DRAFT OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS**

8. Under item 6 of the Agenda, Mr Henk ten Have, Director of the Division of Ethics of Science and Technology, briefly presented the aims of the meeting and the working documents. He recalled that two meetings of government experts had been organized several months apart. This first meeting would allow for points of consensus and points of disagreement to be established in order to prepare the way for the second meeting in June and the finalization of a consensual draft declaration. The preliminary draft declaration drawn up by IBC was included in the documents provided to the participants of the meeting. Mr ten Have pointed out that as the Director-General would be presenting a report on the elaboration of the declaration to the Executive Board at its 171st session two weeks after the present meeting, document 171 EX/13 which included the preliminary draft in an annex had been made available to all delegates in the six official languages of the Organization. The Draft Agenda (SHS/EST/05/CONF.203/1 (Prov.)), the Provisional Rules of Procedure of the meeting (SHS/EST/05/CONF.203/2 (PROV.)) and the Explanatory Memorandum on the Elaboration of the Preliminary Draft (SHS/EST/05/CONF.203/4) were also included in the documentation distributed to the participants.

9. Under item 7 of the Agenda, the Chairperson of the meeting invited Mrs Michèle S. Jean, Chairperson of IBC, to present the preliminary draft declaration on universal norms on bioethics (SHS/EST/05/CONF.203/3). Mrs Jean briefly recalled the different drafting phases and pointed out that following the meetings in January 2005 with the Intergovernmental Bioethics Committee (IGBC), certain articles of the Preliminary Draft had been re-examined. The presentation by Mrs Jean is contained in Annex IV.

### **III. DISCUSSION ON THE PRELIMINARY DRAFT OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS (PREAMBLE AND OPERATIVE PART)**

10. Under Item 8 of the Agenda, the delegations presented their observations and comments on the preliminary draft declaration. At the suggestion of the Bureau, the delegates proceeded first of all with a presentation of general comments on the Preliminary Draft and an examination of the section on “General Provisions”, and began an examination of the text article by article.

#### **General comments**

11. A number of speakers congratulated IBC for the work accomplished and for the quality of the preliminary draft. Considering the text to be well-balanced and having noted that clear improvements had been made following the consultations, particularly with IGBC, they felt that the preliminary draft constituted a solid basis for the work of the meeting. Nevertheless, some delegations expressed strong reservations with regard to the text of the preliminary draft, which did not necessarily reflect all the observations expressed by some States during the consultation process, especially developing countries.

12. The discussions dealt first of all with the scope of the declaration. Some participants said that the field of application of bioethics had been considerably extended in recent years; these participants also said that, although bioethics originally referred to ethical issues arising in the field of medicine and life sciences, over the past ten years it had gradually encompassed ethical issues associated with the environment and the biosphere; it had acquired a particularly strong social dimension, notably in developing countries.

13. Whilst this present broad field of application of bioethics was not questioned, divergences appeared with regard to the nature of the bioethical issues that should fall within the field of application of the declaration. Some wished to limit the scope of the declaration to bioethical issues related to medicine and the life sciences, at the same time expressing the wish that the text acknowledge the link between the human being and the biosphere. Others felt that the social dimension of bioethics should be at the heart of the future declaration, the principles of which should apply not only to so-called “emerging” issues, i.e. those linked to advances in science and the new technologies, but also to “persistent” issues, i.e. those linked to development, poverty, public health, access to treatment and health care, etc.

14. General comments were also expressed with regard to whom the declaration was intended, as this did not appear to be clearly defined. All agreed that the future declaration should aim to become a reference text in the field of bioethics for all the stakeholders concerned. There was a general agreement that the declaration was addressed in the first place to States. A distinction should be made with the other actors in order to define those responsible for and those who benefit from the principles set forth in the declaration.

15. Some speakers commented on the language used in the preliminary draft. With regard to the use of the words “shall” and “should”, some delegates considered that the non-binding nature of the declaration called for the use of this verb in the conditional form, since the text contained no formulation of an obligatory nature. Other delegates felt that the use of “shall” in a declaration only indicated the moral commitment of States without contesting the non-binding nature of the text. Others felt that if the provision dealt with an obligation or a right already defined in other international instruments adopted by States, the use of “shall” should be favoured, whereas, if a new obligation seemed to emerge, the use of the word “should” would allow for the nature of the declaration – where no new obligations can be created - to be respected.

16. Some delegations supported the deletion of the phrase “any decision or practice” which was considered too broad and imprecise. It was suggested that the provisions be reformulated and that the principles be stated in an impersonal manner. Other delegations supported retaining the original draft text and highlighted the importance of keeping the notion of “practice” throughout the text. As to questions of semantics, the delegates also wished to have a certain harmonization of the terms used, in particular with regard to the use of ‘human being’ or ‘human person’.

### **Section on “General Provisions” (Articles 1 to 3)**

17. Several States proposed amendments of a textual nature and of substance to this section. Nevertheless, the discussions showed that the examination of the provisions of this section were closely tied to the general discussions on the scope of the declaration. Divergent points of view were expressed with regard to the definition of bioethics and to the use of this term in the framework of the declaration and with regard to the field of application of the declaration. The meeting therefore wished to have a detailed discussion on the different perspectives of bioethics and on the way in which they could be reflected in the text.

18. Concerning more particularly Article 1 on the Use of Terms, speakers were unanimous in considering that working definitions for the purpose of the declaration were called for, rather than a theoretical definition of bioethics. Some even preferred to speak of a “description” of bioethics. Participants were reminded that the declaration should be a practical application and in no way constitute an academic document. For some, the definition of bioethics should reflect the different concepts of bioethics expressed during the general debates. Others, faced with the difficulty of reaching an agreement on the definition, felt that these different perspectives should be brought out in the text and suggested that a definition of bioethics should not be sought.

19. Article 2 concerning the scope would need to be revised taking account of the debates being held on the field of application of the declaration. Some delegates also insisted that this provision clearly state to whom the declaration is addressed, making a distinction between the States and the other actors concerned, in accordance with the discussions held on the recipients of the text.

### **Section on “Principles” (Articles 4 to 10)**

20. An exchange of views then took place on Articles 4 to 10 on the section on “Principles” and a number of proposed amendments were presented by States.

21. With regard to Article 4, all speakers recognized the importance of affirming human dignity, human rights and fundamental freedoms as a basic principle in the field of bioethics. Some delegates wished to include mention of the respect for human life, considering this to be the basis of human dignity and human rights. With regard to paragraph b) on the primacy of the human person, the discussion focused on the balance to be found between the interests of the individual and the interests of society. Some recalled that in accordance with Article 29 on the interrelation and complementarity of the principles, the primacy of the human person is bounded by the principles of justice and solidarity. Whilst some considered that the word “sole” constituted a balance in the formulation used, others preferred to delete the reference to society and to limit it to science. Several delegates emphasized the necessity of consistency in using terms like “human being” or “human person”. Some delegations expressed their preference for the use of the term “rights of the person” rather than “human rights” as used in the French version of Article 4. Nevertheless, they felt that this was a question of semantics that went beyond the mandate of the meeting.

22. Article 5 concerning equality, justice and equity was considered to be an Article of capital importance; particularly for developing countries. In this respect, some delegates insisted on the need to avoid double standards and to that end wished to add a reference to the right to health and access to essential medicines both in the developed and the developing countries. Others felt that that reference would be more appropriate in Articles 13 and 14 concerning social responsibility and sharing of benefits.

23. With regard to Article 6 on benefit and harm, some felt it was necessary to explain precisely that, in keeping with its origin, that principle applies to medicine and the life sciences. Others wished to introduce the idea of direct and indirect benefit to encompass all possible cases, for example drug research. Still others highlighted the importance of making explicit mention not only of persons but also of human groups as beneficiaries.

24. With regard to Article 7 on respect for cultural diversity and pluralism, everyone recognized the importance of that provision, in particular in a declaration drawn up in the framework of UNESCO. To make the text easier to read, some advocated the deletion of the list defining cultural diversity, while others on the contrary preferred to maintain it in order to make clear the factors that make up cultural diversity. In addition, some delegates wished to revise the last sentence of that provision, as it seemed to imply an opposition between respect for cultural diversity and respect for human rights, whereas respect for cultural diversity necessarily implies for human rights. Lastly, several delegates raised the issue of the position of that Article which could be grouped with Articles 6, 12 and 13, all of which deal with principles that apply to relations among human beings.

25. With regard to Article 8 on non-discrimination and non-stigmatization, emphasis was placed on the protection both of individuals and families, groups or communities. Some delegates called for the reintegration of the list of grounds for discrimination contained in the previous version of the text in order to reinforce the principle. Furthermore, some insisted on making reference to situations of discrimination and stigmatization already existing in society so that this principle could also be applied to such situations. It was also proposed to clarify terminology, and to replace the terms “no one” and “individual” with “person”.

26. Article 10 concerning consent was considered by all as a key article of the declaration and gave rise to several questions. Some felt that that principles derived from the principle on autonomy and individual responsibility set out in Article 9 which seemed to be acceptable as it stood. Concerning the conditions for consent, some delegates wished to make explicit reference to domestic law, while others laid emphasis on Article 30 which already includes such a clause applicable to all the articles of the declaration. Comments were also made concerning exceptions to this principle. Some felt that in dealing only with people without capacity to consent, paragraph c) was too limited and preferred an explicit reference to mentally disabled people. The need to include specific high standards for the protection of persons not able to consent was also stressed. Similarly specific cases of emergency situations and collective consent could be dealt with explicitly. It was also proposed that wording on the options of withdrawing consent should be added. Others pointed out that a unanimous agreement existed on the general scope of the declaration which should set forth principles without entering into detail on the exceptions; these being already covered in a general manner by Article 30.

#### IV. WORK OF THE DRAFTING GROUP

27. In accordance with the Agenda, a drafting group was established. In order to ensure a fair geographical distribution, it was decided that the drafting group be composed of two Member States per region, leaving it open for other States to participate in the debates. The Member States of the drafting group were: Brazil, Croatia, France, India, Japan, Kenya, Lithuania, Mexico, Saudi Arabia, Senegal, Syria and the United States of America. The following States also participated in the drafting group as observers: Belgium, Bolivia, Burkina Faso, Canada, Germany, Luxembourg, The Netherlands and the United Kingdom.

28. The Group elected Mr Ousman Diop-Blondin, Representative of Senegal, Chairperson and Mr Christophe Valia-Kollery, Representative of France, Vice-Chairperson.

29. The task of the drafting group decided by the meeting in plenary consisted of revising the preliminary draft declaration on the basis of proposed written amendments presented by States and in the light of the debates held in plenary. The mandate was technical: on issues where consensus emerged, the group was to formulate a consensual proposal, on others, where disagreement persisted, alternative formulations could be proposed.

30. The drafting group met once, on Tuesday 5 April, after the afternoon plenary session. Nevertheless, given the content of the debates during the first two days, the group faced difficulties in carrying out its technical drafting task, because it became apparent that discussions of substance were still necessary. The group felt that to fulfil its mandate, it was preferable that the plenary meet again so that further in-depth discussions could be pursued, notably on the issue of the scope of the declaration.

#### V. RECOMMENDATIONS

31. The States represented at the first intergovernmental meeting of experts aimed at finalizing a draft declaration on universal norms on bioethics on the basis of the Preliminary Draft of the International Bioethics Committee:

1. *Recognize* the complexity of the subject dealt with and the value of the exchanges held during this first meeting and *note* that it is necessary for further discussions to be held among Member States on fundamental issues such as the scope of the future declaration, its recipients and the definition of bioethics;
2. *Aware* of the crucial role that the government experts play in the process of elaborating the declaration, *confirm* their willingness to engage in a constructive process of negotiation on the different positions expressed;
3. *Invite* the Chairperson of the meeting to encourage and to lead open-ended intersessional consultations between States on diverging views in order to prepare and facilitate the work of the second intergovernmental meeting of experts in June 2005 and, on these occasions, to play the role of facilitator between the different parties;
4. *Consider* it essential to have additional time at the June 2005 meeting, with the availability of documents and interpretation in all official languages of the Organization, to be able to attempt to finalize a draft declaration for the 33rd

session of the General Conference in October 2005 and *express* their concern as to the availability of all material resources necessary for the conduct of their work under the best possible conditions.

5. *Thank* the Government of Italy for its generous financial offer with regard to the funding of the interpretation of the remaining official languages.
6. *Request* the Chairperson of the meeting to bring the above to the attention of the Director-General and of the Chair of the Executive Board.

## **VI. ADOPTION OF THE REPORT AND CLOSURE OF THE MEETING**

32. The Rapporteur, Mr Bindi Ouoba (Burkina Faso), presented his draft report and highlighted the major lines of the discussions held in plenary and in the drafting group. He stated that the report would be finalized in the light of the final discussions of the last plenary session. Some delegations presented proposals for amendments and these have been taken into account in the finalization of the report.