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**Extraordinary Session of the
International Bioethics Committee of UNESCO (IBC)**
“TOWARDS A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS”
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REPORT

*Mr Leonardo De Castro
Rapporteur*

Division of Ethics of Science and Technology

I. INTRODUCTION

1. At its thirty-second session in October 2003, the General Conference of UNESCO invited the Director-General “to continue preparatory work on a declaration on universal norms on bioethics, by holding immediate consultations with Member States, the other international organizations concerned and relevant national bodies, and to submit a draft declaration to it at its 33rd session” (32/C Res. 24).

2. The Director-General, Mr Koïchiro Matsuura, entrusted to the International Bioethics Committee (IBC) the first stage of the process of drawing up the declaration and, aware of the importance of bringing together the main actors in this vast undertaking, the task of organizing an extraordinary session entitled “Towards a Declaration on Universal Norms on Bioethics”, held at UNESCO Headquarters in Paris from 27 to 29 April 2004. The extraordinary session was attended by more than 200 participants from over 70 countries.

3. The aim of the session was to hold consultations with the actors concerned, initiating a debate on the scope and structure of the future declaration. The session was thus organized into hearings of representatives of three different groups – intergovernmental organizations, international non-governmental organizations and national bioethics committees – followed by a question-and-answer session with IBC members and the audience. All organizations and institutions were invited to submit written contributions in advance, based on an outline structured around groups of questions, to provide IBC with a comprehensive overview of all the ideas and opinions expressed. The hearings afforded an opportunity to clarify the views expressed in the written contributions.

4. In the absence of Mr Alexander McCall Smith, Rapporteur of IBC, Mr Leonardo De Castro agreed to act as Rapporteur of the extraordinary session of IBC, in accordance with Article 16.1 of the Rules of Procedure of IBC which stipulates that “if the Rapporteur is unable to exercise his/her functions during a whole session of the Committee or part thereof, his/her duties shall be carried out by a Vice-Chairperson, following the French alphabetical order”.

II. OPENING OF THE EXTRAORDINARY SESSION OF THE IBC⁽¹⁾

5. In his opening address, the Director-General, recalling the experience gained by UNESCO in setting standards in the field of bioethics through the Universal Declaration on the Human Genome and Human Rights (1997) and the recently adopted International Declaration on Human Genetic Data (2003), said that the future declaration on universal norms on bioethics would be drawn up to ensure respect for human dignity, human rights and fundamental freedoms and in a spirit of cultural pluralism inherent in bioethics. To that end, it seemed logical to entrust the first stage of the drafting process to IBC, which had always adopted an empirical approach in its debates, by raising practical issues rooted in a cultural context and seeking common solutions. The Director-General also stated that the consultations of the actors concerned were invaluable and essential, since the new text would come into being and be further developed with the expertise of all concerned. Finally, he thanked the members of the IBC Bureau for their personal involvement in the undertaking, which would, without a doubt, help to restore society’s confidence in science.

6. Ms Michèle S. Jean, Chairperson of IBC, reported on the IBC’s work since its tenth session (Paris, 12-14 May 2003), in particular the meeting of the Bureau of IBC and the joint meeting with the Bureau of the Intergovernmental Bioethics Committee (IGBC) (Rome, Italy, 18-19 December 2003), at which mechanisms for cooperation and linkage between the two Committees in various areas – capacity-building and education on bioethics in particular, and

1 The addresses delivered during the extraordinary session of IBC are reproduced in the Proceedings of the session.

forms of cooperation on the drafting of the future declaration had been examined. In that respect, the Bureaux had stressed the importance of consultations at every level throughout the drafting process. Consultations on the scope and structure of the future declaration had already taken place in various forms, with United Nations agencies and other intergovernmental organizations, with an initial exchange of views at the second meeting of the United Nations Inter-Agency Committee on Bioethics (Geneva, 25 and 26 November 2003), with the Chairpersons of European national bioethics committees at a meeting held in collaboration with the European Commission (Rome, 19 December 2003), and with Member States through the written consultation launched in January 2004. After introducing the new Committee members, she briefly outlined the work of the extraordinary session. In conclusion, she expressed her conviction that, whatever the outcome of the new project, the reflection and debate generated by the drafting of the text must already be considered a success.

III. PRESENTATIONS ON THE PROCESS OF DRAWING UP THE FUTURE DECLARATION AND THE INITIAL RESULTS OF THE WRITTEN CONSULTATION OF UNESCO MEMBER STATES

7. Mr Henk ten Have, Director of the Division of Ethics of Science and Technology and Secretary-General of IBC, gave a broad outline of the process envisaged for drawing up the future declaration. He recalled that it was on the basis of technical and legal studies conducted by IBC (see the 2003 Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics) that the General Conference had invited the Director-General to draw up the declaration in question.

8. The timetable for drawing up the declaration, established in consultation with the IBC and IGBC Bureaux, consists of three key stages: extensive consultations from the outset on the scope and structure of the declaration, in written form with Member States, in the form of hearings with intergovernmental and non-governmental organizations and national bioethics committees, and in the form of conferences with national experts; the actual drafting by IBC, supported by consultations; and finalization of the text at meetings of governmental experts.

9. The Chairperson of IBC then gave the preliminary results of the consultation launched on 20 January 2004 with UNESCO Member States, Associate Member States and Permanent Observer Missions in the form of a questionnaire designed in consultation with the Bureau of IBC. As at 22 April 2004 the Secretariat had received some 60 official replies from Member States.

10. Those replies generally appeared to favour the drafting of a text that was broad in scope and not limited to humankind. The large majority of States were in favour of a structure comprising a preamble followed by sections. Among the fundamental principles most often cited by States were respect for human dignity, confidentiality, consent and transparency, some States also mentioned others, such as the right to life, the rights of the child, equity and tolerance. The vast majority of the replies suggested that the declaration should make reference to specific subjects as far as possible, although opinion was divided on certain subjects, such as abortion, euthanasia, intellectual property rights and behavioural research. Nonetheless, it was highlighted in the general commentaries that, even if specific subjects were mentioned, the declaration ought to be one of general principles that could be the object of a large consensus and which could be applied to new scientific advances in future.

IV. HEARINGS OF INTERGOVERNMENTAL ORGANIZATIONS⁽²⁾

11. Mr Patrick Robinson, Vice-Chairperson of IBC, chaired the meeting devoted to the hearing of representatives of intergovernmental organizations, repositories of a wealth of experience and versed in already rich international bioethics debates, each in its particular sphere of competence. The following intergovernmental organizations accepted the invitation to make oral presentations: Arab League Educational, Cultural and Scientific Organization (ALECSO), Council of Europe, European Commission, Office of the High Commissioner for Human Rights, Organisation for Economic Co-operation and Development (OECD), United Nations Food and Agriculture Organization (FAO), United Nations University (UNU) and World Intellectual Property Organization (WIPO). The United Nations Office of Legal Affairs was also represented.

12. Some speakers focused on the status of the new declaration, which was intended as a benchmark for bioethics at all levels: decision-makers, scientists, the private sector and the ordinary citizen. In the corpus of international law the future declaration would, by its very nature, constitute a quite formal, non-binding standard. However, it would acquire its authority by virtue of the quality of its drafting and the principles it enshrined. To that end, some speakers called for the exclusion of excessively controversial subjects for which consensus seemed difficult, while others warned against a quest for systematic unanimity that might well lead to the adoption of excessively general principles. Should the challenge be accepted and the declaration acquire indisputable force, it could be envisaged that it might lead to other instruments on specific subjects.

13. As to the question of whether the declaration should be limited or not to humankind, some contributors deemed it impossible to dissociate human beings from their environment (plants and animals). On the other hand, others felt that the field of application should be oriented towards the human being. It was suggested that the declaration should first of all address ethical issues relating to human beings, but that it should also, if desired, address ethical questions concerning the relationship between human beings and other living organisms. For example, it could reaffirm in the preamble that human beings form part of biodiversity and that their well-being and development are intimately linked to the ecosystem in which they live.

14. Regarding the structure of the declaration, all participants wanted the text to consist of a preamble and clear, precise sections. Solidarity, international cooperation and public awareness-raising were among the key themes as potential subjects of sections. It was suggested, moreover, that a distinction should be made between descriptive provisions, which would include issues on which no single point of view could be established and follow a pluralist approach taking the diversity of cultures, practices and thought into account, and prescriptive provisions, which would address those questions on which consensus on a common position had been reached and would establish an ethical framework to which there could be no exceptions.

15. As regards the content of the declaration, some speakers stressed the need to determine the way in which bioethics issues should be addressed: for instance, the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine approached bioethics from a human-rights perspective. In any event, human dignity should be forcefully reaffirmed and should be the basic underlying principle of the declaration. Other principles, such as cultural diversity and the protection of fundamental freedoms, should be cross-cutting and underpin the wording of the entire text.

2 The oral presentations of the extraordinary session of IBC are reproduced in the Proceedings of the session.

16. Mr Robinson thanked all the participants for their contributions and reiterated that consultation with intergovernmental organizations would continue throughout the drafting process, notably by the United Nations Inter-Agency Committee on Bioethics, which would hold its second meeting on 23 and 24 June 2004 at UNESCO Headquarters, affording an opportunity to hold further exchanges on the scope and content of the draft declaration.

V. HEARINGS OF NATIONAL BIOETHICS COMMITTEES

17. Ms Jean chaired the meeting devoted to the hearings of the representatives of national bioethics committees and similar bodies, which are national bioethics stakeholders and policy intermediaries. The following national bioethics committees gave oral presentations: National Consultative Bioethics Committee of Côte d'Ivoire, National Bioethics Committee for Medicine of Croatia, National Bioethics Committee of Egypt, President's Council on Bioethics of the United States of America, National Bioethics Committee of the Academy of Sciences of the Russian Federation, National Consultative Ethics Committee of France, Bioethics Committee of the Council of Science and Technology of Japan, National Bioethics Committee of Mexico, National Council of Ethics for Life Sciences of Portugal, Korean Bioethics Association, National Bioethics Committee of the Democratic Republic of the Congo, National Bioethics Committee of the Dominican Republic, the Nuffield Council on Bioethics of the United Kingdom and National Medical Ethics Committee of Tunisia. More than 15 other national bioethics committees and similar bodies also took part in that meeting.

18. With regard to the title of the declaration, several speakers called for the adjective "universal" to be placed before "declaration" and for the term "principles" to be used rather than "norms". This point was also raised at the hearings of other groups.

19. All speakers considered the drafting of this new declaration to afford an opportunity to reflect on a common ethical framework for the life sciences that should become a benchmark for all: for States as well as for researchers, doctors, the scientific community, patients and families, decision-makers, citizens and the media alike. Moreover, it should contribute to a better awareness of the ethical issues raised by scientific advances and their application. Some participants hoped that the declaration would become as authoritative in the field of science and technology as the Universal Declaration on Human Rights (1948) had become.

20. It was emphasized that an instrument of a universal nature should necessarily be drafted on the basis of respect for cultural diversity. In that respect, a pluralist approach was recommended which would imply both unification – namely a single, shared position on a given subject – and harmonization – namely guiding principles of a more general nature, applied with a national margin of discretion while respecting a minimal threshold of compatibility.

21. With regard to the scope of the future declaration, like the intergovernmental organizations, some speakers considered that while the concept of bioethics related broadly to all living beings, the declaration should nonetheless focus on human beings, since the pertinent issue of the day is the protection of human beings in the face of scientific and technical advances. Others maintained that what was at stake in life sciences not only included but transcended human beings, who represented just one link in the far greater whole, namely the biosphere. Indeed, the interdependence between human beings and their environment and human influence on the biosphere could not be disregarded. Yet others wanted the declaration to deal mainly with human beings and other directly related matters, such as genetically modified organisms and xenotransplantation, while stressing the need to take account of existing international instruments on these subjects and to use a very general approach owing to the risk of conflict of competence with other international organizations.

22. With regard to the structure of the text, the declaration should consist of a preamble that revealed its spirit and key issues by placing it in an international philosophical, cultural and legal context. In particular, other relevant international instruments should be mentioned, as should the connection between those instruments and the declaration. Moreover, in the interest of clear interpretation, some speakers also called for an explanatory note reflecting the debates and discussions held.

23. As to the content of the declaration, all the speakers unanimously recognized that it should be general and should not seek to resolve specific issues. Some thought that the declaration should be designed as a means of interpreting the basic principles of bioethics. In that regard, the problem of differing interpretations of the principles, based on cultural context, was raised. Concepts did exist to which different communities attached different values depending on their tradition or way of life – for instance, human dignity, individual, family and even community consent, doctor-patient relations, the value of individual freedom and the freedom of any given community. Some speakers suggested that the validity of these principles among all of the world's communities should be investigated in advance, and that an attempt should be made to clarify as far as possible the definition and meaning of terms generally held to be established and accepted.

24. Nonetheless, several speakers stated that, although the fundamental principles affirmed in the declaration should be general and broad in application, it might be appropriate in a particular context to make reference to a principle's practical applications. Others suggested that, if circumstances so require, UNESCO might, following on from the declaration, consider other international instruments in the future and instigate or support the establishment of regional instruments to address specific issues. In any event, it was proposed that specific controversial subjects should either be excluded, listed in an appendix or possibly covered by the explanatory note setting out the various positions.

25. Some participants wished that the principles would be ranked in order of priority with respect for human dignity as the central theme of the declaration. Others drew a distinction between absolute and intangible principles, from which no exemption would be possible, and relative principles in which there might be room for manoeuvre depending on the cultural context.

26. Themes such as international cooperation, solidarity, benefit-sharing and, above all, education and equal access to health care, which were key concerns for developing countries, should necessarily figure in a declaration purporting to be universally applicable. Furthermore, in the context of North-South relations in the field of life sciences, there was good reason for the declaration to cover international and transnational research, taking into account current practices relating, for instance, to the donation of human organs, an issue that developing countries faced. Some participants expressed the view that States should be urged to make every effort to conclude bilateral and multilateral agreements in order to build capacities in developing countries and encourage the sharing of scientific knowledge and expertise in all scientific fields.

27. In regard to the implementation of the declaration, participants stressed the importance of including provisions to the subject and of incorporating public awareness-raising and education in particular, as experience had shown that laws and regulations were effectively applied only when supported by education, training and information initiatives at every level. Mechanisms to follow the application of the declaration and facilitate international coordination of the various existing legal instruments on bioethics were also discussed. In that connection the setting up of regional networks should be encouraged.

28. Finally, the participants all hoped that the consultations would continue throughout the drafting process, since such exchanges and discussions in themselves helped to promote bioethical reflection.

V. HEARINGS OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS

29. Ms Nouzha Guessous-Idrissi, Vice-Chairperson of the IBC, chaired the meeting devoted to the hearings of representatives of non-governmental organizations, representatives of civil society and of vulnerable individuals and groups. The following non-governmental organizations were invited to make oral presentations: World Medical Association (WMA), World Association of Children's Friends (AMADE) (apologies received), International Council for Science (ICSU), Development Alternatives with Women for a New Era (DAWN) (apologies received), Disabled Peoples International (DPI), International Federation of Human Rights Leagues (FIDH) (absent), Human Genome Organization (HUGO) and International Association of Bioethics (IAB). Approximately 15 other non-governmental organizations took part in the session.

30. Some participants addressed the issue of the aim of the declaration, specifically regarding whether it should be a document designed exclusively for transposition into domestic law, or one which also had an educational and pedagogic purpose. Most participants were in favour of an ethically-inspired rather than purely legal document, which would serve to promote the positive side of science and technology and encourage related activities, while remaining very practically-oriented in order to facilitate its incorporation into national laws.

31. In regard to the scope of the declaration, the majority of participants called for a text that was broad in scope and placed humankind in its environmental context, although it was mentioned that human beings should be the primary concern and that both their unique character and diversity should be reaffirmed.

32. As human dignity was inherent to humankind and the source of human rights, it should not be affirmed as a principle, but should underpin the instrument as a whole, and respect for such dignity should be acknowledged in the declaration as being capable of contributing to the promotion of scientific progress and the relief of human suffering. In that connection, it was suggested that the right to the recognition of dignity, as affirmed in the Universal Declaration of Human Rights (1948), should also be stated in the future declaration.

33. All speakers were in favour of broadly applicable principles, and some also expressed the view that more weight should be given to community and social principles, thereby giving social ethics pride of place over individual ethics. It was also felt that the future declaration should respond to the concerns of developing countries and, consequently, must address certain cross-cutting themes of particular importance to those countries, such as access to health care, benefit-sharing and justice. Furthermore, procedural principles and mechanisms relating to technology transfers, free access to data, the establishment of ethics committees and others, such as the principle of responsibility or transparency should be included.

34. The notion of disability and how this could best be addressed in the declaration were also discussed. Some participants believed that it is not disability itself that is at the heart of the problem, but, rather, the way in which it is addressed by society. It was considered that the subject should be either clearly mentioned in the text where appropriate, possibly even covered by particular provisions, or addressed in greater detail in an explanatory note.

35. In regard to women's issues, emphasis was placed on certain situations, notably in developing countries, which made women vulnerable. In that connection, reproductive technologies were mentioned and the speakers felt that priority should be given to the ethical questions raised by sex education and abortion, which were still fundamental issues that affected women's health in most developing countries.

36. Ms Guessous-Idrissi thanked all the participants for their constructive contributions and assured them that consultations would continue throughout the drafting process.

VII. CLOSURE AND CONCLUSIONS OF THE IBC EXTRAORDINARY SESSION

37. At the end of the IBC extraordinary session, the Chairperson thanked all the participants and summed up the discussions. With regard to the objectives and scope of the future declaration, it had emerged from the discussions that human beings should be the very cornerstone of the declaration. Regarding its structure and content, the declaration should be centred on the fundamental principles of bioethics – not only affirmed and established principles but emerging principles as well. International cooperation, benefit-sharing, solidarity, education and awareness-raising are extremely important themes, particularly for developing countries, and should be incorporated in the declaration in the context of respect for cultural diversity.

38. Mr ten Have thanked the Chairperson of IBC, the Bureau, the Committee members, all the participants and the assembly, who had, for three days, engaged in constructive discussions on the scope and structure of the declaration in a spirit of dialogue and mutual respect – both indispensable to bioethical reflection. He announced that, at its 169th session on 28 April 2004, the Executive Board of UNESCO had approved the timetable for drawing up the future declaration submitted by the Director-General (available on the Internet: www.unesco.org/bioethics), and pointed out that the timetable already allowed for broad consultation at every level and for meetings of governmental experts.