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Declassified[1]
AS/Soc (2022) PV08add
30 January 2023
Asocpv08add_2022

Committee on Social Affairs, Health and Sustainable Development

Minutes

Public hearing on "Deliberate germline editing in human beings", held in Paris, on Friday, 2 December 2022

In the framework of the report currently in preparation on "Deliberate germline editing in human beings" by **Mr Stefan Schennach** (Austria, SOC), the Committee **held** a public hearing with the participation of:

- ✓ **Ms Anne Forus**, Vice-Chairperson of the International Bioethics Committee (UNESCO) and Senior Advisor, Department of Health Legislation & Biotechnology, Norwegian Directorate of Health
- ✓ **Ms Laurence Lwoff**, Head of Human Rights and Biomedicine Division, Human Rights Directorate (Council of Europe)

Ms Sibel Arslan (Switzerland, SOC), third Vice-Chairperson of the Committee, opened the hearing and introduced the guest speakers. She then gave the floor to the rapporteur for a brief introduction.

Mr Schennach briefly presented the latest additions to the revised introductory memorandum and welcomed the expert contributions.

Ms Forus informed members that genome editing enabled scientists to make targeted changes in one or more genes by genetic engineering, for instance to remove mutations that could cause diseases or to introduce desired genetic characteristics. Development of technologies such as CRISPR had given rise to renewed discussions about the ethics of genetic alteration among the research community, governments, international bodies, and wider society. Genome editing technologies had considerable potential for research in the field of biomedicine and improvements in human health. There was strong support for the better understanding of the causes of disease with a view to future treatment. But the application of genome editing technologies to human gametes or embryos raised many ethical, legal, and social considerations, particularly where a modification of the human genome could be passed on to future generations.

Ms Forus then went deeper into the relevant instruments by the Council of Europe and UNESCO. At the Council of Europe, it was the Convention on Human Rights and Biomedicine (1997) that dealt with the issue of genome editing, in particular its Articles 13 and 18. Already at the time of the drafting of the convention, the drafters had foreseen the possibility of interventions on the human genome (as reflected in Article 13). The main concerns behind this provision had been about misuse and abuse, in particular intentional modification of human genome to produce individuals or entire groups endowed with particular characteristics and required qualities (e.g., enhancement). The provision had thus limited genome editing to medical purposes. Moreover, another main concern had been about safety, owing to the unknown risk inherent in the introduction of changes to the genome that would be passed on to descendants. Thus, the provision had prohibited such interventions altogether.

In 2015, DH-BIO[2] had released a statement on genome editing technologies where it stressed the importance of public debate around the issue. It had estimated that the Oviedo Convention provided principles that could be used as references for the debate at international level on the fundamental questions raised by what had been described as recent technological developments (as foreseen by Article 28 of the Convention). As part of its mandate, DH-BIO had then agreed to examine the ethical and legal challenges raised by genome editing technologies that had emerged in the light of the principles laid down in the Oviedo Convention.

In 2018, DH-BIO had released another statement reacting to the news about Chinese twins that had been born by use of genome editing technology. It had stressed that any use of such technologies in human beings should

[1] The minutes were approved and declassified by the Committee on Social Affairs, Health and Sustainable Development at its meeting on 24 January 2023.
[2] On 1 January 2022, the Committee on Bioethics (DH-BIO) became the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO).

be guided by ethics and human rights. Thereafter, DH-BIO had started a process of analysing technical and scientific aspects of genome editing developments and discussing their ethical and human rights implications.

At its plenary meeting in 2021, DH-BIO had agreed that the underlying principles and provisions of Article 13 were still relevant: no modification of the provisions had been deemed necessary. However, clarifications had been needed, in particular on the terms “preventative, diagnostic and therapeutic”, and misinterpretation of the applicability of this provision to “research” had to be avoided.

As regards research, the provisions of Article 13 applied to any intervention that sought to modify the human genome, including research. Moreover, the limitations on permittable purposes (“preventative, diagnostic and therapeutic”) also applied to research. According to Article 13, a permissible intervention which had the aim to modify the human genome was an intervention carried out for medical purposes. Interventions that sought to modify the human genome for the acquisition of knowledge and that were relevant to the permitted purposes could be carried out.

With regard to clarification of the permitted purposes for gene editing, DH-BIO had concluded that for an intervention that modified the human genome to be considered permissible, the intervention had to be for medical purposes and clarified this as “preventative, diagnostic and therapeutic”. An intervention that had a preventative purpose aimed at avoiding the occurrence of disease or disorder. The term “disease” referred to a disease or a disorder defined in accordance with internationally accepted medical standards. An intervention that had a diagnostic purpose had to be understood as intervention undertaken to identify a disease or disorder, or a genetic variant or factor associated with the development of a disease or disorder, as defined. An intervention that was undertaken for therapeutic purpose had to have the aim of controlling symptoms of a disease or disorder, slowing or reversing its progression, or providing a cure by removing the underlying cause.

The added value of these clarifications was, amongst other things, increased understanding of the relevance of the provisions of Article 13, protection of the dignity of the human being, greater certainty enjoyed by researchers who worked with human cells, new treatments being developed within clear limits and the presence of a clear marker in the renewed international debate on heritable genome editing which had to take place at the societal level.

Moving on to UNESCO and the International Bioethics Committee (IBC), Ms Forus pointed out that already in 1997, the drafters of the Universal Declaration on the Human Genome and Human Rights, which had been adopted at the intergovernmental level, had recognised the importance of public debate on the issue. Article 24 laid down, *inter alia*, that the IBC should organise appropriate consultations with the parties concerned, notably vulnerable groups. In 2005, the Universal Declaration on Bioethics and Human Rights had been adopted at the international level. Article 16 underlined the importance that future generations had to be protected. The Declaration also included provisions on benefits and harm, as well as risk assessment and management.

In 2015, the IBC, an advisory body of independent experts from 36 UNESCO member states, had published a report on updating its reflection on the Human Genome and Human Rights with recommendations to states and governments. The experts had called for a temporary ban on editing of human DNA and a wide public debate on genetic modification of human DNA. The report had cautioned against the editing of human genome germlines which introduced hereditary modifications. The report called on states and governments to agree on a moratorium on genome engineering of the human germline, at least for as long as the safety and efficacy of the procedures were not adequately proven as treatments; to renounce the possibility of acting alone in relation to engineering the human genome and to co-operate on establishing a shared global standard for this purpose, built on the principles set out in the Declaration on the Human Genome and Human Rights and the Universal Declaration on Bioethics and Human Rights. The report had also encouraged, through the means of national legislation as well as international regulations, the adoption of rules, procedures, and solutions, which should be as non-controversial as possible, especially with regard to the issues of modifying the human genome and producing and destroying human embryos.

The community of scientists and related regulatory bodies should participate in international fora to share updates in research and information on the efficacy, safety and consequences of new technologies related to the human genome. Moreover, they should renounce the pursuit of spectacular experiments that did not respect fundamental human rights, universal normative ethical standards and other standards with proven efficacy and safety.

With the breaking of the news of the birth of the first gene-edited babies in 2018, UNESCO had cautioned against reckless application of gene editing and had reiterated internationally agreed principles that affirmed the value of human rights and human dignity as the prime concern for any medical research and intervention on human beings and which should be upheld.

In 2021, the IBC had published a new report on the principle of protecting future generations. The report had addressed possible scenarios and ethical challenges to genome editing. Ms Forus held that changes on germ cells that were passed down would have a significant impact on future generations. Modifications on the human genome were likely to have unforeseen and irreversible consequences on individuals and their descendants.

The safety and efficacy of such interventions remained unproven, and possible damage was inheritable. Concerns were also expressed regarding the desire to choose specific traits that were to be transmitted, which could be considered a eugenic drift. Although somatic gene editing did not affect the next generation at the genetic level, social and moral values could nevertheless be affected. For instance, if gene therapies that used such technologies became established and frequent, and if serious diseases that were previously incurable became fully curable, that could change our view of the body and illnesses.

In its recommendations on governance for States and international agencies, the IBC had proposed that genome editing, despite the possibilities that it offered, should be subjected to an effective and monitored framework to prevent drift. The IBC had supported the WHO Human Genome Editing (HGE) Registry that was intended to make information on human genome editing trials publicly accessible. The IBC stressed that the HGE Registry should cover all human genome editing technologies, including base editing, prime editing, editing of mitochondrial DNA and epigenetic editing. Moreover, it had to cover any form of genetic manipulation, including both somatic cells and germline clinical trials. The IBC also supported "Human Genome Editing: A Framework for Governance" that had been drafted by WHO's Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing.

Lastly, in its recommendations for society at large and the international community, the IBC had called for caution with regard to gene editing on the human genome. In particular, germline editing that introduced heritable modifications required specific precautions because it raised serious ethical concerns. The IBC had considered that it was irresponsible to clinically apply gene editing to the human embryo, zygote, or germline. It had also encouraged the international community to take appropriate measures to prevent the premature commercialisation of clinical applications of the technology. Finally, the IBC had recommended that UNESCO should work in synergy with WHO and other UN agencies to implement an international framework and guiding principles for the use of genome editing in research.

Ms Arslan thanked Ms Forus for her presentation and opened the floor for debate.

Ms Lwoff informed members that the outcome of the recent work of CDBIO with regard to genome editing would be added to the explanatory memorandum of the Oviedo convention.

Mr Schennach thanked Ms Forus for her excellent presentation and for underlining the importance of Articles 13, 18.1 and 18.2 of the Oviedo Convention. Indeed, Article 13 allowed genome editing on human beings for diagnostic purposes but stressed that it was not allowed if it could have an impact on future generations. He also warned against seeing genome editing as a possibility to go to the "supermarket" and shop for specific eye colour or other features. Mr Schennach expressed his gratitude to both CDBIO and UNESCO for the important recommendations they had made.

Mr Fridez expressed his concerns about some people launching the search for a perfect child through genome editing. He asked the experts whether this was a problem outside of China as well, or if the legislation in other countries was good enough to avoid this.

Mr Amraoui agreed with the concerns expressed by Mr Fridez. He pointed out that the possibilities of genome editing in research were many and well known, but that little was known about what was going on in laboratories. He wondered if there was any way of finding out.

Ms Forus replied to these questions by stressing the importance of having mechanisms in place to monitor the developments. In this regard, it was important to promote Article 13 of the Oviedo Convention. Moreover, seminars and discussions on genome medicine were held to discuss the possibility of gene editing. International governance and public debate on the topic were of paramount importance. Even in China, what had happened had been a breach of Chinese national law; yet many wanted to get rid of hereditary diseases.

Ms Lwoff further explained that with their desire to have the perfect child, there would always be people who would want to use gene editing. The international legal framework and co-operation between states was essential, but it was impossible to guarantee that there would be no misuse. In China three babies had already been born through the use of gene editing. Those children had probably been under very careful monitoring, which would probably continue throughout their lives. All statements on genome editing referred to public debate at the end but there was little guidance on how the public debate should be held. However, CDBIO had developed a guide on public debate which could be useful in discussing genome editing.

Mr Grin noted that there were some diseases that humans could not cure and wondered if alternatives to gene editing existed that would have less impact on future generations.

Mr Fridez expressed concerns about the ability to choose who would live and who would not live through diagnostics.

Ms Lwoff answered that the problem could not be solved with gene editing. The latter was often misleadingly presented as modifying embryos, but in fact embryos were being destroyed.

Ms Tanguy informed members that this issue had been discussed in the French National Assembly when it had voted on the bioethics law regarding embryo selection.

Ms Forus answered that the IBC report had reflected on the issues raised and the impact on future generations. Going back to the previous question, she explained that the difference of doing an analysis of the embryo was that an embryo was removed if its cells had a gene with an unwanted disease. But with gene editing, the opposite was done. Gene editing might remove the disease from the child to be born, but future generations could also be much more affected than if it was only a "healthy" embryo that was selected. The IBC report had also considered the profiling of embryos and choosing them based on selected profiles. This would lead to discussions about what was a good or bad genetic profile, which in turn would lead to ethical discussion on the right of the child to choose. This was an issue worth reflecting on.

Ms Lwoff added that this issue was at the heart of the Oviedo Convention; it deserved a public debate. This was not a one-off problem, but a problem that could have consequences for the whole human species.

Mr Schennach thanked his colleagues for their comments and the experts for their enlightening replies. The matter discussed was a major question of human rights and ethical issues. Unfortunately, when talking about creating a society for the future, people were also talking about who should live and who should not. That was why it was important to have a public debate on the issue of gene editing.

The Chairperson then **closed** the hearing.

Committee on Social Affairs, Health and Sustainable Development
Commission des questions sociales, de la santé et du développement durable

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Ms / *Mme* Anne Forus, Vice-Chairperson of the International Bioethics Committee (UNESCO) & Senior Advisor, Department of Health Legislation & Biotechnology, Norwegian Directorate of Health / *Vice-présidente du Comité international de bioéthique (UNESCO) & Conseillère principale, Département de législation sur la santé & biotechnologie, Direction de la santé de Norvège*

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