

# INTERVENTION ON THE HUMAN GENOME

## RE-EXAMINATION PROCESS OF ARTICLE 13 OF THE OVIEDO CONVENTION

### CONCLUSIONS AND CLARIFICATIONS



Steering Committee for Human Rights  
in the fields of Biomedicine  
and Health (CDBIO)

## **Article 13 – Interventions on the human genome**

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

## **CONCLUSIONS**

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### **Conclusions of the re-examination process of Article 13 of the Convention on Human Rights and Biomedicine**

*In accordance with Article 32 of the Convention on Human Rights and Biomedicine (Oviedo Convention), the Committee on Bioethics (DH-BIO) proceeded to the re-examination of Article 13 of the Oviedo Convention. During its 1st plenary meeting (31 May – 3 June 2022), the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO), which by decision of the Committee of Ministers, starting on 1<sup>st</sup> January 2022, took over the responsibility assigned by Art. 32 of the Oviedo Convention, adopted the conclusions hereafter which were presented for information to the Committee of Ministers at its 1444<sup>th</sup> meeting at Deputies' level (27 September 2022).*

1. In accordance with Article 32 of the Convention on Human Rights and Biomedicine (Oviedo Convention), and as foreseen in the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020 – 2025), the DH-BIO proceeded with the re-examination of Article 13 of the Oviedo Convention.
2. Following the discussion held and on the basis of the comments made by delegations, the DH-BIO concluded that, taking into account the technical and scientific aspects of these developments as well as the ethical issues they raise, it considered that the conditions were not met for a modification of the provisions of Article 13. However, it agreed on the need to provide clarifications, in particular on the terms “preventive, diagnostic and therapeutic” and to avoid misinterpretation of the applicability of this provision to “research”.
3. The DH-BIO entrusted a drafting group with the task of preparing those clarifications in close cooperation with the Secretariat. They were discussed by the CDBIO at its 1<sup>st</sup> plenary meeting, which considered that the clarifications that appear in appendix to these conclusions could usefully complement the explanatory report on the Convention drawn under the authority of the Secretary General of the Council of Europe.

## CLARIFICATIONS

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### **Clarifications as agreed by the CDBIO, in the light of the acquired experience in the implementation of the Oviedo Convention**

In keeping with Article 32 of the Oviedo Convention and as foreseen in the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020 – 2025), the DH-BIO, and later the CDBIO, began re-examining Article 13 of the Oviedo Convention in November 2020. The provisions of Article 13 were discussed, and the following clarifications agreed in the light of the experience gained from implementing the provisions.

#### **Scope with regard to research**

- ▶ The provisions of Article 13 apply to any intervention seeking to modify the human genome. This includes interventions carried out in research as well as in a clinical context.
- ▶ If an intervention seeking to modify the human genome is carried out on an individual or on cells that are to be introduced into an individual in a research context, the standards laid down for the protection of research participants in Article 15 of the Oviedo Convention and the following Articles must be respected.
- ▶ The prohibition of an intervention seeking to introduce a modification in the genome of any descendants has the implication that gametes, embryos or their precursors that have been subjected to such intervention may not be used for the purposes of procreation.
- ▶ The requirement in paragraph 91 of the Explanatory Report on the Oviedo Convention, for approval by the appropriate ethical or regulatory body for research aiming to introduce genetic modifications in spermatozoa or ova which are not for procreation, applies equally to such research on embryos, gametes and their precursors.

#### **Preventive, diagnostic or therapeutic purposes**

- ▶ The Article limits the purposes for which any intervention that seeks to modify the human genome may be carried out, to preventive, diagnostic or therapeutic purposes.
- ▶ An intervention seeking to modify the human genome undertaken for a preventive purpose, will aim at avoiding the occurrence of a disease or disorder. Disease and disorder (also referred to as “ailment” in paragraph. 90 of the Explanatory Report), are defined in accordance with internationally accepted medical standards. An example of such medical standards is provided by the World Health Organisation’s International Statistical Classification of Diseases and related Health Problems (ICD).
- ▶ An intervention seeking to modify the human genome undertaken for diagnostic purposes, will aim at identifying a disease or disorder, or a genetic variant/factor associated with the development of a disease or disorder as defined above.

- ▶ An intervention seeking to modify the human genome undertaken for a therapeutic purpose, will aim at controlling symptoms of a disease or disorder, slowing or reversing its progression, or providing a cure to a disease or disorder, for example by removing its underlying cause.
- ▶ In the context of research, interventions seeking to modify the human genome for the acquisition of knowledge relevant to these permitted purposes may be carried out. Such knowledge may be relevant to the understanding of the biological factors associated with diseases or disorders or their mechanism of action, as well as the development of means to treat, diagnose or prevent the occurrence of such diseases or disorders.