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Gene editing techniques in humans

The European legal framework

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Convention on Human Rights and Biomedicine (1997) ("Oviedo Convention")

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**"



- 1. Limitation of purposes:** genome-editing techniques can only be used for medical purposes (preventive, diagnostic or therapeutic purposes)
- 2. Prohibition of modifications that are transmissible to the descendants**



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➤ Genetic interventions on **somatic cells**



➤ Genetic interventions on **germ cells**
(embryos and reproductive cells)





Explanatory Report to the Oviedo Convention

Two concerns:

1. Germline modification “may endanger not only the individual but the species itself”

2. It could be misused to intentionally modify the human genome “so as to produce individuals or entire groups endowed with particular characteristics and required qualities”

What is the way forward?



1. There is an urgent need to identify an adequate **governance model** for gene editing technologies at the global level. This governance should be guided by an ethics based on the *common good* and take into account broad social contexts, values and current concerns about the long-term impact on the human species, rather than narrowly focusing on the immediate potential risks and side-effects of the technique.

What is the way forward?



2. Considering that the use of this technology concerns the **whole of humanity**, and not only the scientific community, self-regulation by scientists does not appear to be a satisfactory governance model.

Scientists should certainly be involved in the regulatory process in this field, but they have neither the necessary independence, nor the democratic legitimacy to determine *alone* whether or under what conditions gene editing techniques should be authorized.

What is the way forward?



3. The **international community** has a central role to play in the standard-setting process in this field. The United Nations, or some of its specialized agencies (eg. UNESCO, WHO) could offer the necessary intergovernmental platform for developing common standards on gene editing techniques at the global level.