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THE INTERNATIONAL REGULATION OF BIOTECHNOLOGY

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I. Introduction: modern biotechnology from a regulatory perspective

II. Human Rights

III. International Protection of the Environment

IV. International Trade Law

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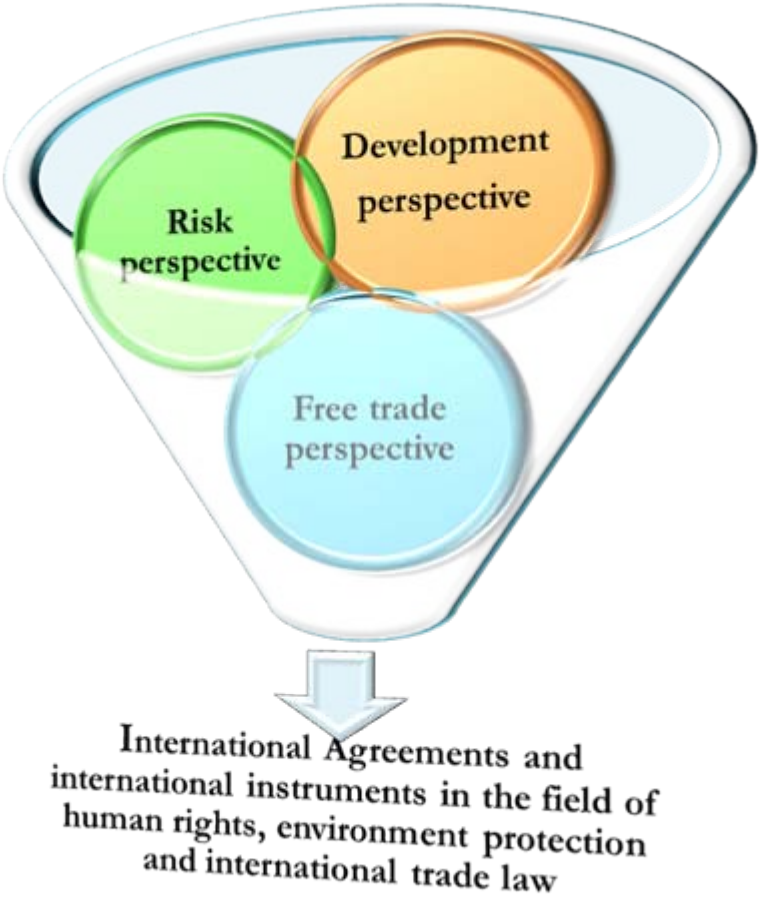
Perception of chances and risks

- benefits for human health
- chances for food supply, agricultural productivity and reduction of pesticides
- risks for the environment
- new scientific knowledge and remaining uncertainties
- societal conflicts over ethical implications of certain techniques
- the possible "instrumentalisation" or "commercialisation" of human life and parts of the human body

Different regulatory concerns



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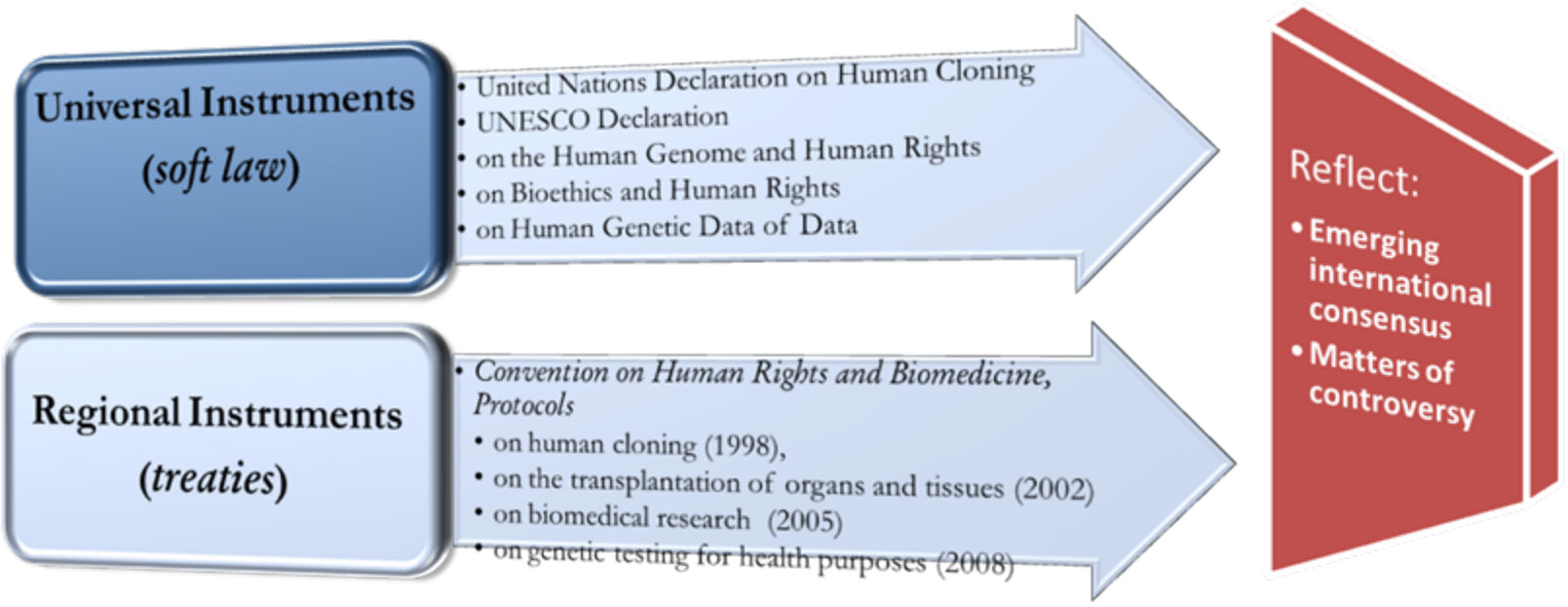
Human Rights



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Human Rights

The emerging international consensus

- right to prior, free and informed consent,
- protection of persons unable to consent,
- right to information and the right not to know,
- prohibition of eugenic or selective practices,
- prohibition of commercial uses of the human body,
- prohibition of the creation of human embryos for research purposes and
- prohibition of "reproductive human cloning"

Matters of controversy

- prohibition of "therapeutic cloning",
- research on embryos *in vitro* and production of embryonic stem celllines and
- patents on inventions involving human embryos and human DNA

International Protection of the Environment

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UN Convention on Biological Diversity

Art. 8 (g) "establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity (…)"

Art. 19 (3): „The Parties shall consider (…) setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

Cartagena Protocol on Biosafety

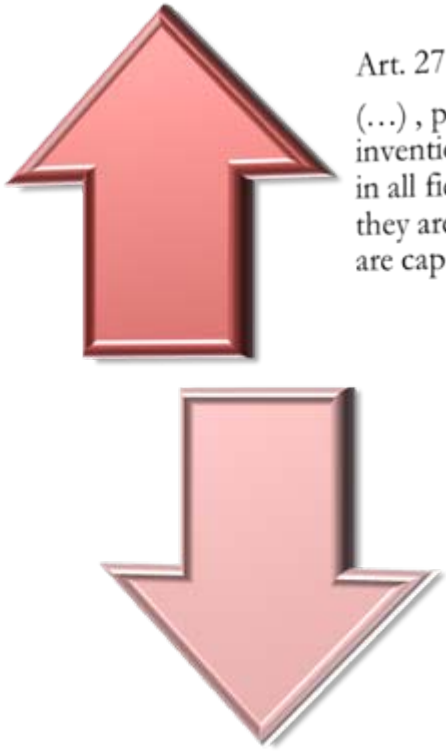
Art. 19 (6): "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import (…), shall not prevent (..)from taking a decision, as appropriate, with regard to the import of the living modified organism (…)"

Art. 26: "The Parties (…), may take into account (…) , socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

International Trade Law

International Trade Law

Patents on biotechnological inventions



Art. 27 (1) TRIPS:

(…) , patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.(…)

Art. 27 (2) TRIPS:

"Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

Deference to democratic choices and societal discourse

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On *in vitro fertilization(IVF) ECHR, Evans v. United Kingdom:* "The Court observes that there is no international consensus with regard to the regulation of IVF treatment or to the use of embryos created by such treatment. (…)

Since the use of IVF treatment gives rise to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments, and since the questions raised by the case touch on areas where there is no clear common ground amongst the Member States, the Court considers that the margin of appreciation to be afforded to the respondent State must be a wide one."