## Act for the Protection of Embryos (The Embryo Protection Act)<sup>\*</sup>

## Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz – ESchG)

Of 13<sup>th</sup> December 1990 (BGBI. I p. 2746), last amended by Article 1 of the Law of 21<sup>st</sup> November 2011 (BGBI. I p. 2228)

#### Section 1

## Improper use of reproduction technology

## (1) Whosoever

- 1. transfers to a woman an unfertilised egg cell collected from another woman,
- 2. undertakes to fertilise artificially an egg cell for any purpose other than bringing about a pregnancy in the woman from whom the egg cell was collected,
- 3. undertakes, within one treatment cycle, to transfer more than three embryos to a woman,
- 4. undertakes, by gamete intrafallopian transfer, to fertilise more than three egg cells within one treatment cycle,
- 5. undertakes to fertilise more egg cells from a woman than may be transferred to her within one treatment cycle,
- 6. removes an embryo from a woman before its implantation in the uterus is completed, in order to transfer it to another woman or to use it for a purpose other than its preservation, or
- 7. undertakes to carry out an artificial fertilisation of a woman who is prepared to give up her child permanently after birth to third parties (surrogate mother) or to transfer a human embryo to her.

shall be punished with up to three years' imprisonment or a fine.

- (2) Likewise anyone shall be punished who
- 1. brings about artificially the penetration of a human egg cell by a human sperm cell, or
- 2. inserts a human sperm cell into a human egg cell artificially,

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without intending to bring about a pregnancy in the woman from whom the egg cell was collected.

(3)

- 1. In the cases of subsection 1, numbers 1, 2 and 6, the woman from whom the egg cell or embryo was collected, and likewise the woman to whom the egg cell or embryo will be transferred, and
- 2. in the cases of subsection 1, number 7, the surrogate mother and likewise the person who wishes to permanently take care of the child,

shall not be liable to punishment.

(4) In the cases of subsection 1, number 6, and subsection 2, any attempt shall be punishable.

#### Section 2

## Improper use of human embryos

- (1) Whosoever sells a human embryo created outside the woman's body, or removed from the woman before the completion of implantation in the uterus, or makes it available, or acquires or uses it for a purpose other than its preservation, shall be punished with up to three years' imprisonment or a fine.
- (2) Likewise anyone shall be punished who causes a human embryo to develop further outside the woman's body for any purpose other than the bringing about of a pregnancy.
  - (3) Any attempt shall be punishable.

#### Section 3

## Forbidden sex selection

Whosoever undertakes to fertilise artificially a human egg cell with a sperm cell that is selected for the sex chromosome contained in it, shall be punished with up to one year's imprisonment or a fine. This shall not apply when the selection of a sperm cell is made by a physician in order to preserve the child from developing Duchenne-type muscular dystrophy or a similarly severe sex-linked genetic illness, and the illness threatening the child is recognised as being of appropriate severity by the body responsible according to Land legislation.

## Section 3a

## Pre-implantation genetic diagnosis; Authority to issue ordinances

- (1) Whosoever subjects the cells of an embryo to *in vitro* genetic screening prior to its intrauterine transfer (pre-implantation genetic diagnosis) shall be punished with up to one year's imprisonment or a fine.
- (2) Where the genetic pre-disposition of the woman from whom the egg cell was collected, or that of the man producing the sperm cell, or both, suggest that their offspring will be highly

likely to have a serious genetic illness, it shall not be an offence for anyone who intends to bring about a pregnancy to subject the cells of the embryo to state-of-the-art *in-vitro* genetic screening for this illness prior to intrauterine transfer, if the woman from whom the egg cell was collected gives her written consent.

Nor shall it be an offence for anyone to carry out, with the written consent of the woman from whom the egg cell was collected, pre-implantation genetic diagnosis in an embryo to identify an abnormality that would be highly likely to lead to still-birth or miscarriage.

- (3) Pre-implantation genetic diagnosis as set out in subsection 2 may only be performed
- 1. when the woman has given her informed consent after having been informed and counselled on the medical, psychological and social implications of the genetic screening of the embryonic cells requested by her,
- 2. after an interdisciplinary ethics committee at the approved centres for pre-implantation genetic diagnosis has verified compliance with the requirements of subsection 2 and delivered a favourable opinion and
- 3. by a specifically qualified physician in centres approved for pre-implantation genetic diagnosis that have the diagnostic, medical and technological resources necessary to carry out the procedures involved in pre-implantation genetic diagnosis.

The approved centres shall report, in an anonymised form, the measures carried out within the framework of pre-implantation genetic diagnosis, including the cases dismissed by the ethics committees, to a central body for documentation purposes. The Federal Government shall issue an ordinance with the approval of the *Bundesrat*, to stipulate the details regarding

- 1. the number of and the approval requirements for the centres where pre-implantation genetic diagnosis may be performed, including the qualification of the physicians working there and the period of validity of the approval,
- 2. the establishment, composition, functioning and financing of the ethics committees for pre-implantation genetic diagnosis,
- 3. the establishment, structure and organisation of the central body that will be responsible for documenting the measures performed within the framework of pre-implantation genetic diagnosis,
- 4. the requirements for the reporting of measures performed within the framework of preimplantation genetic diagnosis to the central body and the requirements for documentation.
- (4) Whosoever, in breach of subsection 3 sentence 1, performs pre-implantation genetic diagnosis commits an administrative offence. The administrative offence shall be punishable with a fine of up to fifty-thousand euros.
- (5) No physician shall be under an obligation to perform or take part in a measure as set out in subsection 2.

Non-participation may not lead to any disadvantage for the physician concerned.

(6) The Federal Government shall draw up, every four years, a report on the experience with pre-implantation genetic diagnosis. Based on central documentation and anonymised data, the report shall contain the number of measures performed each year as well as a scientific evaluation.

# Unauthorised fertilisation, unauthorised embryo transfer and artificial fertilisation after death

- (1) Whosoever
- undertakes artificially to fertilise an egg cell without the woman whose egg cell is to be fertilised, and the man whose sperm cell will be used for fertilisation, having given consent,
- 2. undertakes to transfer an embryo to a woman without her consent, or
- 3. knowingly fertilises artificially an egg cell with the sperm of a man after his death

shall be punished with up to three years' imprisonment or a fine.

(2) In the case of subsection 1 number 3, the woman in whom the artificial fertilisation was performed shall not be liable to punishment.

#### Section 5

## Artificial alteration of human germ line cells

- (1) Whosoever artificially alters the genetic information of a human germ line cell shall be punished with up to five years' imprisonment or a fine.
- (2) Likewise anyone shall be punished who uses a human germ cell with artificially altered genetic information for fertilisation.
  - (3) Any attempt shall be punishable.
  - (4) Subsection 1 shall not apply to
- 1. the artificial alteration of the genetic information of a germ cell situated outside the body, if any use of it for fertilisation is ruled out,
- 2. the artificial alteration of the genetic information of any other autologous germ line cell that has been removed from a dead embryo or fetus, a human being or a deceased person, if it is ruled out that
  - a) it will be transferred to an embryo, fetus or human being or
  - b) a germ cell will originate from it,

and likewise

3. vaccinations, radiation, chemotherapeutic or other treatments which are not intended to alter the genetic information of germ line cells.

#### Section 6

## Cloning

- (1) Whosoever causes artificially a human embryo to develop with the same genetic information as another embryo, fetus, human being or deceased person shall be punished with up to five years' imprisonment or a fine.
- (2) Likewise anyone shall be punished who transfers to a woman an embryo as specified in subsection 1.
  - (3) Any attempt shall be punishable.

#### Section 7

## Creation of chimeras and hybrids

- (1) Whosoever undertakes
- 1. to combine embryos with different genetic information to form a cluster of cells, using at least one human embryo,
- 2. to combine a human embryo with a cell that contains genetic information different from the embryo cells and, so combined, is able to differentiate further, or
- 3. by fertilisation of a human egg cell with the sperm of an animal or by fertilisation of an animal's egg cell with human sperm, to engineer an embryo that is able to differentiate,

shall be punished with up to five years' imprisonment or a fine.

- (2) Likewise anyone shall be punished who undertakes
- 1. to transfer an embryo arising out of a procedure defined in subsection 1 to
  - a) a woman or
  - b) an animal

or

2. to transfer a human embryo to an animal.

## Section 8

## **Definition**

- (1) For the purposes of this Act, an embryo shall already mean the human egg cell, fertilised and capable of developing, from the time of fusion of the nuclei, and further, each totipotent cell removed from an embryo that is assumed to be able to divide and to develop into an individual under the appropriate conditions.
- (2) In the first twenty-four hours after nuclear fusion, the fertilised human egg cell shall be held to be capable of development unless it is established before the expiry of this time period that it will not develop beyond the one-cell stage.
- (3) Germ line cells, for the purpose of this Act, shall be all cells that, in one cell-line, lead from the fertilised egg and sperm cells to the resultant human being and, further, the egg cell from the insertion of or penetration by the sperm cell until the completion of fertilisation by fusion of the nuclei.

#### Section 9

## **Medical prerogative**

Only a physician shall be entitled to carry out

- 1. artificial fertilisation,
- 2. pre-implantation genetic diagnosis,
- 3. transfer of a human embryo to a woman,
- 4. preservation of a human embryo or human egg cell which has already been penetrated by a human sperm cell or into which a human sperm cell has been artificially inserted.

#### Section 10

## **Voluntary participation**

No one shall be under an obligation to carry out the measures described in section 9 above or to take part in them.

#### Section 11

## Offences against the medical prerogative

- (1) Whosoever, without being a physician,
- 1. carries out an artificial fertilisation contrary to section 9 number 1,
- 2. carries out pre-implantation genetic diagnosis contrary to section 9 number 2, or
- 3. transfers a human embryo to a woman contrary to section 9 number 3,

shall be punished with up to one year's imprisonment or a fine.

(2) In the case of section 9 number 1, a woman who carries out an artificial insemination on herself, and the man whose sperm is used for artificial insemination shall not be liable to punishment.

#### Section 12

#### **Administrative fines**

- (1) An administrative offence shall be deemed to have been committed by a person who, without being a physician, in violation of section 9 number 4, preserves a human embryo or a human egg cell as described therein.
- (2) The commission of an administrative offence may be punished with a fine not exceeding two thousand five hundred euros.

## Section 13

## **Entry into force**

This Act shall enter into force on 1st January 1991.

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The constitutional rights of the Bundesrat have been observed.

The above Act is herewith signed and will be published in the Federal Law Gazette (*Bundesgesetzblatt*).

Bonn, 13<sup>th</sup> December 1990

The Federal President Weizsäcker

The Federal Chancellor Dr. Helmut Kohl

The Federal Minister of Justice Engelhard

The Federal Minister for Youth, Family and Health Ursula Lehr

The Federal Minister for Research and Technology Riesenhuber