Year 2006

COLLECTION OF LAWS
OF THE CZECH REPUBLIC

PROFILE OF THE REGULATION:

Title of the Regulation:
Act on Research on Human Embryonic Stem Cells and Related Activities and on Amendment to Some Related Acts

Citation: **227/2006 Coll.** *Part:* 75/2006 Coll.
On Page (from-to): 2850-2861 *Distributed on:* 29 May 2006
Type of the Regulation: Act *Authors:* Parliament
Date of Passing: 26 April 2006 *Date of Effect:* 1 June 2006
Validity: YES *Remarks:*
Key Words in Register:
(will be added only after the end of the year according to the subject index of the Collection of Laws edition)
Issued under:
This regulation amends:
Act No.140/1961 Coll.; Act No.20/1966 Coll.; Act No. 634/2004 Coll.; Act No. 130/2002 Coll.; Act No. 160/1992 Coll.; Act No. 94/1963 Coll.
This regulation repeals:
Reference to the draft bill and explanatory report on the Chamber of Deputies Web Site, Parliamentary Draft No. 1071/0

Text of the Regulation:

227

ACT

of 26 April 2006

on research on human embryonic stem cells and related activities and on amendment to some related acts

The Parliament passed the following Act of the Czech Republic:

PART ONE

PRINCIPLES OF HANDLING HUMAN EMBRYONIC STEM CELLS

CHAPTER I

GENERAL PROVISIONS

Section 1

Scope

The Act shall lay down

a) conditions for research on human embryonic stem cells,

b) permitting the research on human embryonic stem cells,

c) conditions for conducting activities related to human embryonic stem cell research,

d) scope of competences of administrative and advisory bodies in defined areas,

e) control over human embryonic stem cell research and related activities,

f) registration of the human embryonic stem cell lines and conditions for maintaining their registry,

g) sanctions for violating the Act.

Section 2

Definition of Terms

For the purposes of this Act the used terms are defined as follows:

a) “research on human embryonic stem cells” a systematic and creative activity undertaken in order to acquire new knowledge or its application, conducted on human embryonic stem cell lines,

b) “human embryonic stem cells” all the pluripotential stem cells that are descended from human pre-implantation embryos created outside a human body,

c) “lines of the human embryonic stem cells“ (hereinafter referred to as the “lines“) all the human embryonic stem cells that are kept in cultures or are, in relation to them, stored cryopreserved,

d) “human embryo” totipotential cell or their groupings that is able to develop into a human individual,

e) “redundant human embryo” a human embryo created through the method of artificial insemination outside of a human body for the purposes of assisted reproduction, but later not used for these purposes,

f) “related activities” import, export and transit, as well as acquisition of human embryonic stem cells and their lines; these activities do not constitute research,

g) “lines registry” list of basic identification data established for the purposes of identification and monitoring of the origin of human embryonic stem cell lines,

h) “registration” process of registration into the stem cell lines registry,

i) “import of human embryonic stem cells” (hereinafter referred to as the “import”) entry of human embryonic stem cells into the territory of the Czech Republic,

j) “export of human embryonic stem cells” (hereinafter referred to as the “export”) exit of human embryonic stem cells out of the territory of the Czech Republic.

CHAPTER II

CONDITIONS FOR RESEARCH ON HUMAN EMBRYONIC STEM CELLS AND PERMITTING THIS RESEARCH

Section 3

Conditions for research on human embryonic stem cells

(1) Research on human embryonic stem cells may be conducted only on the basis of a permission issued by the Ministry of Education, Youth and Sport (hereinafter referred to as the “Ministry”). This research may be conducted only on workplaces listed in the permission for research on human embryonic stem cells.

(2) Research on human embryonic stem cells may conducted only

a) on imported lines, provided that they were obtained from human embryos in such a way that does not object to the Czech legislation or legislation of the country of origin; their import was permitted by the Ministry and the only reason for their import into the Czech Republic is their usage for research purposes under this Act; or

b) on the lines obtained from redundant human embryos in the Czech health care institutions providing assisted reproduction under a separate regulation[1)] (hereinafter referred to as the “centre for assisted reproduction”).

(3) Such manipulations with human embryonic stem cells must be prevented within the research which could lead to creation of a new human individual (reproductive cloning).

(4) Both lines and human embryos intended for obtaining human embryonic stem cells must be protected against theft or using them for activities being inconsistent with the regulations.

Section 4

Conditions for issuing permission for research on human embryonic stem cells

(1) Research on human embryonic stem cells may be conducted only on the basis of a permission issued by the Ministry; each of these permissions should be marked with its number.

(2) The Ministry shall issue the permission for research on human embryonic stem cells only if it is proved that

a) research serves to obtain basic scientific knowledge or enlarge medical knowledge in development of diagnostic, preventive or therapeutic methods applicable to humans,

b) according to the current level of scientific and technological knowledge, research solves issues that cannot be solved only on in-vitro models with animal cells or in experiments in animals,

c) expected scientific benefits cannot be reached by other methods,

d) professional level of research is guaranteed, especially through professional publication activity, patents and/or patent applications and annual reports,

e) the research project is ethically acceptable, and

f) other conditions under Sections 3 and 5 are met.

Section 5

Application for permission to conduct research on human embryonic stem cells

(1) Application for permission to conduct research may be filed only in writing in a documentary form or by electronic document signed by advanced electronic signature[2)]. The applicant may be only a legal entity with its registered office in the Czech Republic, or a legal entity with its registered office, central headquarters or main place of business on the territory of another European Union member state[3)], having its organisational unit situated on the territory of the Czech Republic, whose main business activity is research; this fact is specified in the applicant's foundation deed, deed of association, statutes or any other foundation document required by law or is laid down by a separate regulation if the applicant is established under it.

(2) The applicant shall provide following data in the application for permission to conduct research:

a) business firm or a name, registered office and identification number of the applicant, and addresses specifying the workplaces where research will be conducted,

b) name, or names and surnames, and permanent or residence addresses of persons executing the function of the applicant's statutory body or its member,

c) detailed description of research activities, with defined research goals and methods.

(3) The applicant shall support his/her application for permission to conduct research by

a) documents on any previous research work by the applicant in research and development areas being utilisable for research on human embryonic stem cells,

b) a document proving integrity of persons executing function of the applicant's statutory body or its member under Section 7,

c) documents certifying meeting of conditions as laid down in Section 4 (2).

(4) After receiving the application, the Ministry shall without undue delay ask the Research and Development Council[4)] (hereinafter referred to as the "Council") for its expert opinion, which the Council shall deliver on the basis of the application examination by the Bioethics Committee. The Council shall send this expert opinion to the Ministry within 8 weeks of receiving the request.

(5) In the event that the application for permission to conduct research or notification of changes in its scope under Section 6 (4) is directly connected with medical treatment, the Ministry shall ask also the Ministry of Health to deliver its expert opinion. The Ministry of Health shall send this expert opinion within 8 weeks of receiving the request.

(6) The expert opinion of the Council or the Ministry of Health, as the case may be, shall explicitly recommend or not recommend granting of permission, with explanation of the reasons leading to such recommendation or rejection. The opinion shall assess whether the application meets the conditions as laid down in Section 4 (2) in all professional and ethical aspects.

(7) If the Ministry in its decision departs from the expert opinions produced by the Council or the Ministry of Health under paragraph 5, or disagrees with such opinion, it shall give the reasons in its decision.

Section 6

Issue of permission to conduct research on human embryonic stem cells

(1) The permission to conduct research on human embryonic stem cells shall be issued for a period of 6 years; for a particular research activity only described in the application in detail. The Ministry shall decide within 3 month of receiving the last expert opinion under Section 5 (4) to (6); if the expert opinion of the Council or the Ministry of Health, as the case may be, recommends explicitly granting the permission and the applicant meets other conditions as laid down in this Act, the Ministry shall issue the research permission.

(2) In the permission, the Ministry shall give

a) business firm or a name, registered office and identification number of the applicant,

b) name, or names and surnames, and permanent or residence addresses of persons executing the function of the applicant's statutory body or its member,

c) addresses of workplaces, where this research may be conducted,

d) description or definition of research activity being permitted,

e) date till when the research is permitted, and

f) research permission number.

3) The legal entity authorised to conduct research under this Act may ask for prolongation of the research permission. The permission may be prolonged only once, by another 4 years. The Ministry shall decide on the prolongation within 3 month of receiving the request. The request for prolongation of the research permission may not be submitted earlier than 18 months before expiration of its term, but not later than 12 months before this date.

(4) The legal entity authorised to conduct research under this Act shall deliver to the Ministry without undue delay the application for permission to change the scope of research, particularly any change in research targets and methods. Upon this information, the Ministry may change or revoke its decision on permission. For this purpose the Ministry may ask the Council for a new opinion and the Council shall send it to the Ministry within 8 weeks of receiving the request. The Ministry shall decide within 3 months of receiving the expert opinion of the Council under Section 5 (4) and (5). The application for change in the research permission may be filed 12 months before expiration of its term at the latest.

(5) The legal entity authorised to conduct research under this Act shall notify the Ministry without undue delay of any premature termination of this research.

(6) The Ministry shall decide on revocation of the research permission under this Act in the event that the legal entity authorised to conduct research ceased to meet the conditions under Sections 3 to 6, or committed an administrative offence under Section 16 (1) in the last two years. In its decision on revocation of the permission to conduct research on human embryonic stem cells the Ministry shall also give the date when the research is to be terminated.

Section 7

Proving integrity

(1) For the purposes of this Act "a person of integrity" means a person, who was not lawfully convicted of a premeditated or negligent criminal act committed in connection with conducting the activity under this Act, unless deemed to have never been convinced.

(2) Any citizen of the Czech Republic shall prove his/her integrity by extract from the Penal Register[5)], which must not be not older than 3 months.

(3) Any citizen of the EU member state shall prove his/her integrity by extract from the criminal record or equivalent document issued by a competent court or administrative body of this state or the last member state of residence. If this state is not issuing extracts from criminal records or equivalent documents, the person executing the function of the applicant's statutory body or its member shall submit the statement of integrity in accordance with a separate regulation [6)] made before a notary public or body of the member state of his/her citizenship, or before a notary public or body of the last member state of residence. These documents must not be older than 3 months and must be submitted together with a sworn translation into the Czech language. The document referred to in this paragraph may be substituted by a certificate of recognition of acquired qualification if proving also the observance of the integrity requirement under paragraphs 1 to 4.

(4) The citizen of a state other than the states referred to in paragraphs 2 or 3 shall prove his/her integrity by extract from the criminal record and corresponding documents issued by the state of his/her citizenship, or states where he/she has been residing for a continuous period longer than 3 months in the last 3 years; these documents must not be older than 3 month and must be submitted together with a sworn translation into the Czech language.

CHAPTER III

RELATED ACTIVITIES

Section 8

Obtaining human embryonic stem cells for research purposes from redundant human embryos

(1) Obtaining human embryonic stem cells for research purposes from redundant embryos is possible if

a) the woman and man, from whom this redundant embryo was obtained, and the donor of embryonic cells[1)] gave their written consents in accordance with Section 9,

b) this redundant human embryo was provided by a centre for assisted reproduction.

(2) Human embryos for obtaining human embryonic stem cells for research purposes may be only supplied to a legal entity conducting research as permitted under this Act.

(3) Only those redundant human embryos may be used for obtaining human embryonic stem cells for research purposes which are not older than 7 days; the age of embryo does not include the period of its cryopreservation.

Section 9

Written consent with using a redundant human embryo for obtaining human embryonic stem cells

(1) The written consent under Section 8 (1) (a) may be given only if it is evident that the human embryo is redundant, and at the same time earlier than it is used for obtaining human embryonic stem cells. Prior to giving their consent under the first sentence, the persons under Section 8 (1) (a) must be informed in an understandable and sufficient way, both orally and in writing, for what purpose the redundant human embryo is to be used.

(2) In addition, the written consent under Section 8 (1) (a) shall contain an express consent to use the redundant human embryo for creation of human embryonic stem cells for research purposes and a statement that they were informed about the purpose, for what the redundant embryo would be used. At the same time, the written consent should contain the name, or names and surnames, permanent addresses and signatures of persons under the first sentence, date of the signature and business firm or a name and registered office of the centre for assisted reproduction, where they were informed. Written consent under this paragraph shall be kept by the centre for assisted reproduction for a period of at least 30 years since it was given.

(3) Data contained in the written consent under Section 8 (1) (a) shall be protected according to a separate regulation[7)].

(4) Written consent under Section 8 (1) (a) may be withdrawn in writing by each one individually, even without giving any reason, within 3 months from the date when it was given, provided the embryo has not been already used for obtaining human embryonic stem cells.

(5) No reward shall be paid to persons referred to in Section 8 (1) (a) for their consent to use a redundant embryo for obtaining human embryonic stem cells for research purposes.

(6) All costs associated with acquiring the consent to use a redundant embryo for obtaining human embryonic stem cells shall be reimbursed to the centre for assisted reproduction by the legal entity authorised to conduct research under this Act, who intends to use these cells for obtaining the human embryonic stem cells.

Section 10

Import of human embryonic stem cells for research purposes

(1) Human embryonic stem cells for research purposes may be imported into the Czech Republic only in the form of their lines. Such import of lines shall be subject to the permission of the Ministry. The imported lines may not become a source of infectious contamination.

(2) The permission to import human embryonic stem cells shall be granted by the Ministry to a legal entity asking for permission to conduct research on human embryonic stem cells or to whom permission was granted to conduct research under this Act; and if at the same time

other conditions under paragraphs 3 to 6 are met.

(3) The permission to import human embryonic stem cells may be applied for 9 months before expiration of the research permission at the latest.

(4) The import of human embryonic stem cells shall be permitted by the Ministry only if it is necessary for meeting the needs of research and development or international co-operation in research and development. In the permission, the Ministry shall lay down the period of validity which must not be longer than 1 year and must not exceed the period of validity of the permission to conduct research on human embryonic stem cells.

(5) In his/her application for import permission, the applicant shall specify

a) business firm or a name, registered office and identification number of a legal entity importing the lines,

b) names of countries where the line is registered, including registration numbers and names of registries, and countries of origin,

c) when importing lines for research already in progress, the identification number of the research permission, and name and registered offices of a legal entity conducting the research,

d) brief reasons for the application.

(6) The applicant shall include with his/her application for import permission following documents:

a) an official certification submitted together with a sworn translation into the Czech language and issued by a competent body of the country of origin, stating that the imported lines cannot become the source of infectious contamination,

b) an official certification submitted together with a sworn translation into the Czech language and issued by a competent body of the country of origin, stating that the lines were obtained in conformity with the laws of the country of origin.

(7) The Ministry shall decide on the application for import permission within 3 months of receiving it. In the event of an application filed in the moment when the legal entity under paragraph 2 is only applying for the research permission, the import permission may not be issued before the decision on research permission comes into legal force.

Section 11

Export and transit of human embryonic stem cells for research purposes

(1) Export may be performed only by a legal entity with a valid permission to conduct research under this Act.

(2) The legal entity under paragraph 1 shall announce to the Ministry in writing seven days before export at the latest

a) registration number of the line assigned by the Ministry under this Act,

b) date when the line leaves the territory of the Czech Republic,

c) name and address of the line's consignee.

(3) Only lines registered on the territory of the Czech Republic, which have already undergone research, may be exported purely for the purpose of additional research.

(4) The Ministry shall without undue delay enter the data on export of lines into the registry.

(5) The carrier must announce the transit of lines to the Ministry in writing 7 days before the day when the lines will be transported to the territory of the Czech Republic at the latest. Besides a unique identification of the carrier, the notification of transit shall mention the route along which the lines will move on the territory of the Czech Republic and the day, when the lines leave the territory of the Czech Republic. The lines transit shall not be entered into the registry.

(6) The transit under paragraph 5 may last not more than 3 days.

(7) The exportation of embryos is prohibited.

CHAPTER IV

ADMINISTRATION OF RESEARCH ON HUMAN EMBRYONIC STEM CELLS

Section 12

The Ministry

While administering research on human embryonic stem cells, the Ministry shall:

a) issue, change or revoke permissions to conduct research on human embryonic stem cells and to import human embryonic stem cells under this Act,

b) secure the role of administrator and operator of the lines registry,

c) exercise control over research workplaces; within this activity it shall monitor whether the research on human embryonic stem cells is not conducted inconsistent with law and impose sanctions for administrative offences under Sections 15 to 17, and

d) maintain the registry of lines; this registry being the public administration information system[8)].

Section 13

Registry of lines

(1) The research on human embryonic stem cells may only be conducted on lines registered by the Ministry. The lines originated by separation from the already registered ones are subject to registration as well.

(2) The registry of lines shall contain following data

a) identification and address of the workplace, where the line was created,

b) identification and address of the workplace, where the line is being used for research,

c) business firm or a name, registered office and identification number of the legal entity using this line,

d) country of origin,

e) research permission number,

f) identification numbers or other registration numbers of lines in foreign registries, if assigned, or another unique identification of the line,

g) date of import for imported lines,

h) for lines created in the Czech Republic, business firm or a name and registered office of the centre for assisted reproduction supplying the embryo from which the line was created,

i) date of issue of registration certificate,

j) for expiring lines their expiration dates.

(3) Data contained in the registry of the Ministry are open to public use, through remote access as well; upon request, the Ministry shall issue an extract from the registry.

(4) The application for registration of lines shall be filed to the Ministry by a legal entity authorised to conduct research on human embryonic stem cells under this Act, who has created these lines or will conduct research on these lines, within 30 working days of their creation date. The application shall contain data specified in paragraph 2 (a) to (h). The Ministry shall decide on the registration of lines within 4 weeks of receiving the application; if the applicant meets conditions for registration of lines under this Act, the Ministry shall make the registration.

(5) If the application for registration is incomplete or contains incorrect data, the Ministry shall return it to the applicant within 4 weeks of receiving it, with specification of defects and invitation for their removal within a given deadline. If the application defects are not removed within a given deadline, the Ministry shall suspend the proceedings.

(6) For imported lines, data under paragraph 2 (a) to (g) shall be supplied to the registry by the legal entity authorised to conduct research on human embryonic stem cells, for the research of whom the lines are being imported, within 10 working days of acquiring the lines.

(7) The Ministry shall be notified by the legal entity conducting research on human embryonic stem cells of any changes in data on lines and of completion of data on lines being registered under paragraph 1 within 10 working days of their occurrence.

Section 14

Control over research on human embryonic stem cells and related activities

(1) The Ministry shall be authorised to carry out inspections, even unannounced, of workplaces conducting research in biology and medicine with the aim to monitor how the conditions of research are met, particularly whether it has been permitted, and with the aim to monitor the use of embryos for human embryonic stem cells and prevent any unpermitted research on human embryonic stem cells.

(2) The control under paragraph 1 shall be exercised by the Ministry through authorised employees (hereinafter referred to as the "inspectors"). The inspectors shall prove their identity with a letter of authorisation. The Ministry shall lay down the sample letter of authorisation by decree. In addition to rights and duties stipulated by a separate regulation[9)] , the inspectors shall be authorised to access containers and other storage facilities, which serve or may serve for storing embryos intended to be used for human embryonic stem cells and for storing lines, and shall be authorised to take samples.

(3) A statutory body or members of a statutory body of the legal entity conducting research on human embryonic stem cells shall be obliged to provide the inspectors carrying out the inspection under paragraph 1 with all required documents concerning the research and other documents find necessary by the inspectors for explaining circumstances, under what the research is conducted.

(4) The Ministry shall issue the protocol on inspection findings within 20 working days after the end of inspection.

(5) The control activity of the Ministry shall be governed by a separate regulation[9)], unless otherwise stipulated by this Act.

(6) For control over research-related activities under Section 2 (f) the provisions of paragraphs 1 to 5 shall apply analogously.

CHAPTER V

ADMINISTRATIVE OFFENCES

Section 15

Offences

(1) An individual shall commit an offence by

a) conducting research on human embryonic stem cells inconsistent with Section 3(1) or (2), or

b) importing human embryonic stem cells inconsistent with Section 10, or exporting or transiting them inconsistent with Section 11.

(2) A fine up to CZK 20.000 may be imposed for the offence under paragraph 1.

Section 16

Administrative offences of a legal entity

(1) A legal entity shall commit an administrative offence by

a) conducting research on human embryonic stem cells inconsistent with Section 3 (1) or (2) or violating conditions laid down in the permission issued under Sections 4 to 7,

b) importing human embryonic stem cells inconsistent with Section 10, or importing or transiting them inconsistent with Section 11,

c) providing incorrect data in the application for permission to import human embryonic stem cells under Section 10 or in the notification of their export or transit under Section 11 or when registering the lines under Sections 13 or 19,

d) failing, as an entity authorised to conduct research on human embryonic stem cells, for the research of whom these lines are imported, to notify the Ministry of changes in registered data under Section 13 (7),

e) failing, as an entity authorised to conduct research under this Act, to apply for permission to change the scope of research or its premature termination under Section 6 (4), or by

f) conducting research on lines, which were not registered under this Act.

(2) A legal entity authorised to act as a centre for assisted reproduction shall commit an administrative offence by

a) providing a human embryo for obtaining human embryonic stem cells for research purposes without a written consent under Section 8 (1) (a),

b) providing a human embryo for obtaining human embryonic stem cells for research purposes inconsistent with Section 8 (3),

c) providing a human embryo for obtaining human embryonic stem cells for research other than permitted,

d) offering a reward for the written consent to use the human embryonic stem cells,

e) failing to inform persons referred to in Section 8 (1) (a) on the use of a redundant embryo under Section 9 (1) and (2), or

f) failing to keep the written consent under Section 8 (1) (a) for a period of at least 30 years since its giving.

(3) A fine up to CZK 2.000.000 shall be imposed for an administrative offence under paragraph 1 (a) and (b) and paragraph 2 (a) to (c); a fine up to CZK 1.000.000 shall be imposed for an administrative offence under paragraph 2 (d); and a fine up to CZK 500.000 shall be imposed for an administrative offence under paragraph 1 (c) to (f) and paragraph 2 (e) and (f).

Section 17

Joint provisions to administrative offences

(1) A legal entity shall not be held responsible for an administrative offence if it furnishes a proof that it used its best efforts to prevent the violation of a legal obligation.

(2) The seriousness of the committed administrative offence shall be taken into account in determining the level of the fine to be imposed on a legal entity, particularly the way it was committed, its consequences and circumstances of its commitment.

(3) The responsibility of a legal entity for an administrative offence shall cease to exist if the administrative body fails to institute proceedings on it within 1 year from the date it learnt about it, but within 3 years from the date it was committed at the latest.

(4) In the first instance, the administrative offences under this Act shall be dealt with by the Ministry.

(5) Fines shall be collected and recovered by the Ministry. Fines shall become income to the state budget

CHAPTER VI

JOINT AND TEMPORARY PROVISIONS

Section 18

(1) Unless otherwise stipulated herein, the Rules of Administrative Procedure shall apply to proceedings under this Act.

(2) Applications for research and import permissions may be filed 2 months after the coming into force of this Act at the earliest.

(3) In the event that a woman, and if married also her husband, and the donor are not alive or are not known, the redundant embryos may be used for obtaining human embryonic stem cells for research if other conditions provided by law are met. The consent under Section 8 (1) (a) is not required.

Section 19

Registration of lines originating before the coming into force of this Act

(1) The lines created or imported before the coming into force of this Act are considered to be imported or created in compliance with this Act if registered by 31 December 2008. It is possible to continue the already started research on these lines without permission of the Ministry till 31 December 2008 on condition that this research is conducted within the framework of a research plan, project or grant project under a separate regulation[10)].

(2) The application for registration of lines under paragraph 1 shall contain

a) business firm or a name, registered office and identification number of a legal entity in the Czech Republic, where the lines are used,

b) a country of origin of the authorised health care institution, where the collection took place,

c) purpose of the research,

d) identification or registration numbers in foreign registries, if assigned, or another unique identification of an embryo.

(3) The application for registration of lines shall be filed to the Ministry by a legal entity authorised to conduct research on human embryonic stem cells under this Act. The application shall contain data specified in paragraph 2. The Ministry shall decide on the registration of lines within 4 weeks of receiving the application; if the applicant meets conditions for registration of lines under this Act, the Ministry shall make the registration.

(4) If the application for registration is incomplete or contains incorrect data, the Ministry shall return it to the applicant within 4 weeks of receiving it, with specification of defects and invitation for their removal within a given deadline. If the application defects are not removed within a given deadline, the Ministry shall suspend the proceedings.

PART TWO

Amendment to the Penal Code

Section 20

In Act No. 140/1961 Coll., the Penal Code, as amended by Act No. 120/1962 Coll., Act No. 53/1963 Coll., Act No. 56/1965 Coll., Act No. 81/1966 Coll., Act No. 148/1969 Coll., Act No. 45/1973 Coll., Act No. 43/1980 Coll., Act No. 10/1989 Coll., Act No. 159/1989 Coll., Act No. 47/1990 Coll., Act No. 84/1990 Coll., Act No. 175/1990 Coll., Act No. 457/1990 Coll., Act No. 545/1990 Coll., Act No. 490/1991 Coll., Act No. 557/1991 Coll., Ruling of the Constitutional Court of the Czechoslovak Federative Republic published in Volume 93/1992 Coll., Act No. 290/1993 Coll., Act No. 38/1994 Coll., Act No. 91/1994 Coll., Act No. 152/1995 Coll., Act No. 19/1997 Coll., Act No. 103/1997 Coll., Act No. 253/1997 Coll., Act No. 92/1998 Coll., Act No. 112/1998 Coll., Act No. 148/1998 Coll., Act No. 167/1998 Coll., Act No. 96/1999 Coll., Act No. 191/1999 Coll., Act No. 210/1999 Coll., Act No. 223/1999 Coll., Act No. 238/1999 Coll., Act No. 305/1999 Coll., Act No. 327/1999 Coll., Act No. 360/1999 Coll., Act No. 29/2000 Coll., Act No. 101/2000 Coll., Act No. 105/2000 Coll., Act No. 121/2000 Coll., Act No. 405/2000 Coll., Act No. 120/2001 Coll., Act No. 139/2001 Coll., Act No. 144/2001 Coll., Act No. 256/2001 Coll., Act No. 265/2001 Coll., Act No. 3/2002 Coll., Act No. 134/2002 Coll., Act No. 285/2002 Coll., Act No. 482/2002 Coll., Act No. 218/2003 Coll., Act No. 276/2003 Coll., Act No. 362/2003 Coll., Act No. 52/2004 Coll., Act No. 91/2004 Coll., Act No. 537/2004 Coll., Act No. 587/2004 Coll., Act No. 692/2004 Coll., Act No. 411/2005 Coll., Act No. 413/2005 Coll., Act No. 70/2006 Coll., Act No. 115/2006 Coll. and Act No. 135/2006 Coll., after Section 209a there is inserted the new Section 209b, worded as follows:

"Section 209b

Prohibited manipulation of human embryo and human genome

(1) Who

a) performs interventions leading to creation of a human embryo for purposes other than implantation into a woman’s body,

b) uses a human embryo or larger number of human embryonic stem cells or their lines for research inconsistent with a separate regulation,

c) imports or exports a human embryo or larger number of human embryonic stem cells or their lines inconsistent with a separate regulation,

d) implants the created human embryo into the uterus of another animal species,

e) implants a human genome into the cells of another animal species or vice versa, or

f) manipulates the human embryonic stem cells during their research in a way leading to creation of a new human individual (reproductive cloning),

shall be punished by imprisonment up to three years or ban on activity.

(2) The offender shall be punished by imprisonment for one to three years or by ban on activity or by money penalty,

a) if he/she commits the act under paragraph 1 as a member of an organised group,

b) if he/she commits this act repeatedly, or

c) if he/she obtains an advantage of large extent through this act for himself/herself or another person.

(3) The offender shall be punished by imprisonment for three to eight years or forfeiture of property,

a) if he/she commits the act under paragraph 1 as a member of an organised group operating in several states, or

b) if he/she obtains an advantage of large extent through this act for himself/herself or another person.".

PART THREE

Amendment to Act No. 20/1966 Coll.

Section 21

Act No. 20/1966 Coll., on Public Health Care, as amended by Act No. 210/1990 Coll., Act No. 425/1990 Coll., Act No. 548/1991 Coll., Act No. 550/1991 Coll., Act No. 590/1992 Coll., Act No. 15/1993 Coll., Act No. 161/1993 Coll., Act No. 307/1993 Coll., Act No. 60/1995 Coll., Act No. 206/1996 Coll., Act No. 14/1997 Coll., Act No. 79/1997 Coll., Act No. 110/1997 Coll., Act No. 83/1998 Coll., Act No. 167/1998 Coll., Act No. 71/2000 Coll., Act No. 123/2000 Coll., Act No. 132/2000 Coll., Act No. 149/2000 Coll., Act No. 258/2000 Coll., Act No. 164/2001 Coll., Act No. 260/2001 Coll., Act No. 285/2002 Coll., Act No. 290/2002 Coll., Act No. 320/2002 Coll., Act No. 130/2003 Coll., Act No. 274/2003 Coll., Act No. 37/2004 Coll., Act No. 53/2004 Coll., Act No. 121/2004 Coll., Act No. 156/2004 Coll., Act No. 422/2004 Coll., Act No. 436/2004 Coll., Act No. 379/2005 Coll., Act No. 381/2005 Coll. and Act No. 109/2006 Coll., is hereby amended as follows:

1. After Section 27c new Sections 27d to 27h shall be added, including footnotes 6a and 6b, worded as follows:

"Section 27d

(1) The assisted reproduction shall mean techniques and methods of manipulation with gametes or embryos, including their storage, with a view to treat both male and female infertility. These techniques and methods are

a) collection of gametes,

b) artificial insemination of a woman, by

1. fertilisation of a woman’s egg with a man’s sperm outside a woman’s body,

2. transfer of embryo into a woman's genital tract, or
3. introduction of gametes into a woman's genital tract.

(2) Genetic examinations of embryos are permitted only in defined indications in order to exclude risks of serious genetically conditioned diseases and defects with embryos before they are implanted into the cavity of the uterus.

(3) The assisted reproduction under paragraph 1 (b) may be practised on the basis of a written application of a woman and man who are going to undergo this treatment together (hereinafter referred to as the "infertile couple"), if for medical reasons it is not very probable or totally excluded that the woman gets pregnant naturally or if there exists a demonstrable risk of transfer of genetically conditioned diseases or defects. The application shall contain the man's consent to artificial insemination of the woman; such consent to be repeated before each artificial insemination procedure. The application must not be older than 24 months; it is part of the woman's medical records.

(4) No woman and man in family relationship, which excludes contracting marriage under a separate regulation[6a)], may be considered an infertile couple for the purposes of treatment under paragraph 1 (b).

Section 27e

(1) Assisted reproduction under Section 27d (1) (b) may be practised in woman of fertile age (hereinafter referred to as the "female recipient"), if her health state does not prevent the assisted reproduction procedure. The physician performing the assisted reproduction procedure shall be held responsible for examining the health state of the female recipient.

(2) The donor of gametes for assisted reproduction purposes shall mean a person forming the infertile couple. Any adult woman in the age from 18 to 35 years may donate her eggs for the assisted reproduction purposes. Any adult man in the age from 18 to 40 years may donate his sperm for the assisted reproduction purposes. It is not permitted to fertilise the eggs with sperm of a man who is known to be in direct family link or a sibling, uncle, cousin or a child born to a cousin of the woman, whose egg is used for the assisted reproduction method, or the female recipient.

(3) The donor shall be obliged to undergo necessary examinations, including genetic examinations, in order to assess his/her health ability to take part in the assisted reproduction procedure. The physician, who decided on the possibility to use gametes for the assisted reproduction methods, shall be held responsible for assessing the health ability of the donor. The donor neither female recipient must be legally incapacitated or with a limited capacity to enter into legal acts.

(4) The physician collecting the gametes and the physician performing the artificial insemination are obliged to inform the persons undergoing this treatment in advance on the character of this treatment, all potential health risks and on all other factors related to the assisted reproduction.

(5) The assisted reproduction treatment may only be performed after a prior consent of the person who will undergo this treatment. While giving his/her consent with the assisted

reproduction treatment, the donor also gives the consent to use his/her gametes for artificial insemination and to obtain the embryonic stem cells from the redundant embryo originating from his/her gametes for research under a separate regulation governing the research on human embryonic stem cells[6b)]. The physician specified in paragraph 1 or 3 shall enter this consent into the medical records of the person giving this consent; the statement of consent shall be signed both by the physician and the person, who gave it.

(6) At assisted reproduction only as many eggs of the female recipient shall be fertilised and implanted into her genital tract as is necessary according to the present level of medical knowledge for the pregnancy to be probably induced with success.

(7) Gametes and embryos created for the assisted reproduction purposes may be used only for artificial insemination. If not all embryos created in favour of the infertile couple were used in the process of artificial insemination of the female recipient, it is possible to store them and use for the next infertility treatment of this couple; this is not the case if the infertile couple declares that it is not going to use the embryos for any additional artificial insemination and gives

a) its consent under a separate regulation[6b)] governing the research on human embryonic stem cells to obtain the embryonic stem cells from the redundant embryo for research under this separate regulation, or

b) its consent to use the redundant embryo for artificial insemination of another woman.

The attending physician shall enter this consent into the medical records of the female recipient; the statement of consent shall be signed both by the attending physician and the infertile couple.

(8) No financial or other reward is attached to donation of gametes and embryos and delivery of gametes and embryos to the operator of the health care institution, where the assisted reproduction is provided. The donor shall be entitled to compensation of expenses effectively spent in relation to the collection. These expenses shall be reimbursed to the donor by operator of the health care institution where the collection was performed upon his/her request. The operator of the health care institution may ask the female recipient undergoing the artificial inseminated or operator of the health care institution, to which the gametes or embryos were supplied, to reimburse these expenses. The operator of the health care institution, which took over the gametes or embryos for assisted reproduction and reimbursed the expenses under the previous sentence, may ask the female recipient undergoing the artificial insemination to reimburse these expenses.

(9) The health care institution providing the assisted reproduction shall be obliged to maintain the anonymity of both the donor and infertile couple, and the donor and child born of assisted reproduction. To maintain the anonymity of the donor and infertile couple and of the donor and child shall be also the liability of each medical worker who learnt this fact.

(10) Upon request of

a) a woman or man from the infertile couple prior to the beginning of the artificial insemination procedure, or

b) a legal representative of a child born of assisted reproduction or adult person born of assisted reproduction,

the physician of the health care institution, where the health ability of a potential donor was assessed, shall furnish information on findings having a direct impact on development of the health state of a child or person born of assisted reproduction, particularly information on any discovered genetic endowment or dispositions.

Section 27f

(1) The health care institution, where the health qualification of a potential donor was assessed, shall be obliged to pass on data on the donor's health state to the health care institution performing the artificial insemination. The health care institution, where the artificial insemination was performed, shall be obliged to store these data for at least 30 years since the use of gametes.

(2) The health care institution may practise the techniques and methods of assisted reproduction only on the basis of a consent granted by the Ministry of Health. The Ministry of Health shall grant the consent following a request of the health care institution, if the health care institution meets the technical and material demands on facilities and proves that techniques and methods of assisted reproduction will be practised by physicians with specialised branch of vocational training under Section 27h.

Section 27g

(1) It is not permitted to use the assisted reproduction techniques for the purpose of choosing a future child's sex, with the exception of cases when the assisted reproduction techniques may be used to prevent serious Mendel-type sex-related genetically conditioned diseases that

a) are incompatible with the postnatal development of a child,

b) significantly shorten the life,

c) cause early disablement or other serious health consequences, or

d) are untreatable given our present level of knowledge.

(2) Selection of a future child's sex in cases under paragraph 1 shall be recommended by a physician with specialised vocational training in medical genetics, in conjunction with a physician with specialised vocational training in gynaecology and obstetrics.

Section 27h

The Ministry of Health shall lay down by decree

a) reasons for genetic examinations of an embryo aimed at discovering the genetically conditioned diseases of foetus or likelihood of their occurrence,

b) list of diseases, defects and other health states disqualifying the donor,

c) list of specialised branches of medical education of doctors, who may practise the techniques and methods of assisted reproduction,

d) material and technical demands on facilities of a health care institution providing the techniques and methods of assisted reproduction.

6a) Act No. 94/1963 Coll., on Family, as subsequently amended.

6b) Act No. 227/2006 Coll., on Research on Human Embryonic Stem Cells and Related Activities and on Amendment to Some Related Acts.".

2. In Section 27a (1) the words "Medical interventions into reproductive abilities of individuals, castration" shall be replaced by the word "Castration".

3. In Section 70, a comma shall replace the full stop at the end of paragraph 2 and a new point (c) shall be added as follows:

"c) grant its consent to practising the techniques and methods of assisted reproduction".

4. In Annex a new point 14 shall be added, worded as follows:

"14. National registry of assisted reproduction

The registry shall process personal data necessary for identification of a woman, who has undergone the artificial insemination procedure (personal insurance number or another identification data under this Act), personal history of a woman, who has undergone the artificial insemination procedure, data related to her health state and diagnostic data related to the artificial insemination procedure; data on health state of a man, who has undergone the procedure of collection of gametes for the purpose of insemination; data necessary for identification of the operator of the health care institution that provided the assisted reproduction.

These personal data shall be anonymised after 20 years of the data entry."

PART FOUR

Amendment to Act on Administrative Fees

Section 22

In Annex to Act No. 634/2004 Coll., on Administrative Fees, after item 102 a new item 102A shall be added, including footnote 61a, worded as follows:

"**Item 102A**

Acceptance of an application

a)	for permission[61a)] to conduct research on human embryonic stem cells	CZK 500
b)	for permission [61a)] to import human embryonic stem cell lines	CZK 500
c)	for registration[61a)] of a human embryonic stem cell line	CZK 500

61a) Act No. 227/2006 Coll. on Research on Human Embryonic Stem Cells and Related Activities and on Amendment to Some Related Acts."

PART FIVE

Amendment to Act No. 130/2002 Coll.

Section 23

Act No. 130/2002 Coll., on Research and Development Support from Public Funds and on Amendment to Some Related Acts (Research and Development Support Act), as amended by Act No. 41/2004 Coll., Act No. 215/2004 Coll., Act No. 342/2005 Coll., Act No. 413/2005 Coll. and Act No. 81/2006 Coll., is hereby amended as follows:

1. In Section 35, a comma shall replace the full stop at the end of paragraph 2 and a new point (i) shall be added as follows:

"i) deliver opinions to applications for permission to conduct research on human embryonic stem cells or applications concerning changes in this permission, or applications for permission to import human embryonic stem cells, as the case may be, upon proposal prepared by its advisory body, the Bioethics Committee.".

2. In Section 35, new paragraphs 7 and 8 shall be added as follows:

"(7) The Research and Development Council shall establish the Bioethics Committee as its technical advisory body preparing supporting materials for fulfilling the tasks of the Research and Development Council connected with bioethical aspects in research and development, particularly draft opinions of the Research and Development Council to applications for permission to conduct research on human embryonic stem cells or applications concerning changes in this permission, or applications for permission to import the human embryonic stem cells, as the case may be. The Chairman of the Bioethics Committee shall be a member of the Research and Development Council.

(8) The membership in advisory bodies of the Research and Development Council does not constitute any labour relations towards the Czech Republic. The amounts of remuneration received for functions executed in the above bodies shall be determined by the Chairman of the Research and Development Council".

Section 24

Temporary provision to Amendment to Act No. 130/2002 Coll.

The Council shall establish the Bioethics Committee as its advisory body and approve its Statutes and Rules of Procedure within 2 months after the coming into force of this Act. In the Statutes, the Council shall regulate particularly the way of solving the conflict of interest issues to guarantee independency in delivering draft opinions to applications for permission to conduct research on human embryonic stem cells or applications for changes in this permission.

PART SIX

Amendment to Act No. 160/1992 Coll.

Section 25

In the third paragraph of Section 10 of Act No. 160/1992 Coll., on Health Care Provided by Non-public Health Care Institutions, as amended by Act No. 258/2000 Coll., Act No. 285/2002 Coll., Act No. 96/2004 Coll., and Act No. 121/2004 Coll., after point (c) a new point (d) shall be added, worded as follows:

"d)
consent of the Ministry of Health to practise techniques and methods of assisted reproduction, if practising of methods and techniques of assisted reproduction is concerned,".

Points (d) to (i) shall be renumbered (e) to (j).

PART SEVEN

Amendment to the Family Act

Section 26

Act No. 94/1963 Coll., on Family, as amended by Act No. 132/1982 Coll., Act No. 234/1992 Coll., Act No. 72/1995 Coll., Act No. 91/1998 Coll., Act No. 360/1999 Coll., Act No. 301/2000 Coll., Act No. 109/2002 Coll., Act No. 320/2002 Coll., Act No. 321/2002 Coll., Act No. 315/2004 Coll., Act No. 383/2005 Coll. and Act No. 112/2006 Coll., is hereby amended as follows:

1. In Section 54, paragraph 3 shall be added, including footnote 7b, which shall read as follows:

"(3) If a child is conceived through artificial insemination of a woman in assisted reproduction under a separate regulation[7b)], the man who gave his consent to artificial insemination of the woman under this separate regulation shall be considered the child’s father, unless proven that the woman became pregnant in other way.

7b) Act No. 20/1966 Coll., on Public Health Care, as amended by Act No. 227/2006 Coll.".

Footnote 7b, including reference, shall be renumbered 7c.

2. In the third paragraph of Section 61 the words "Section 57 (2) and Section 59 (1)" shall be replaced by words "Section 57 (2), Section 58 (2) and Section 59 (1)".

PART EIGHT

EFFECTIVENESS

Section 27

This Act shall enter into effect on 1 June 2006.

Per procurationem **Kasal** m.p.

Klaus m.p.

Paroubek m.p.

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1) Section 27 et seq. of Act No. 20/1966 Coll., on Public Health Care, as amended by Act No. 227/2006 Coll.

2) Act No. 227/2000 Coll., on Electronic Signature and on Amendment to Some Other Acts (Electronic Signature Act), as subsequently amended.

3) Article 48 of Treaty establishing the European Community.

4) Section 35 of Act No. 130/2002 Coll., on Research and Development Support from Public Funds and on Amendment to Some Related Acts (Research and Development Support Act), as amended by Act No. 227/2006 Coll.

5) Section 11 of Act No. 269/1994 Coll., on Penal Register, as amended by Act No. 126/2003 Coll.

6) Section 6 (1) (c) of Act No. 455/1991 Coll., on Trade and Entrepreneurial Activities (Trade Licensing Act).

7) Act No. 101/2000 Coll., on Personal Data Protection and on Amendment to Some Acts, as subsequently amended.

8) Act No. 365/2000 Coll., on Public Administration Information Systems and on Amendment to Some Other Acts, as amended by Act No. 517/2002 Coll.

9) Act No. 552/1991 Coll., on State Control, as subsequently amended.

10) Act No. 130/2002 Coll., as subsequently amended.