

Act on Regulation of Human Cloning Techniques

(Act No. 146 of December 6, 2000)

(Purpose)

Article 1 The purpose of this Act is, in light of the risk that certain techniques including the Cloning Techniques (hereinafter referred to as the "Cloning Techniques, etc.") among the techniques for manipulating Embryos or Germ Cells of a human or an Animal could, depending on the way they are applied, create an individual with the same gene structure as a certain individual (hereinafter referred to as a "Human Clone Individual") or an individual which cannot be clearly classified as a human or an Animal (hereinafter referred to as an "Hybrid Individual"), or artificially create other similar individuals, and have a serious influence on the preservation of human dignity, safety for human life and body, and maintenance of public order (hereinafter referred to as the "Preservation of Human Dignity, etc."), to prevent creation of Human Clone Individuals and Hybrid Individuals and to regulate artificial creation of individuals similar to them by means of prohibiting transfer of Embryos produced by the Cloning Techniques or Specified Fusion/Aggregation Techniques among Cloning Techniques, etc. into a human or Animal uterus, regulating production, receipt by assignment and import of Embryos created by Cloning Techniques, etc., and taking other measures for securing appropriate handling of the relevant Embryos, thereby ensuring the development of science and technology in harmony with society and citizens lives.

(Definitions)

Article 2 (1) In this Act, the meanings of the terms listed in the following items are as prescribed respectively in those items:

- (i) Embryo--A cell (except for a Germ Cell) or a cell group which has the potential to grow into an individual through the process of development in utero of a human or an Animal and remains at a stage prior to placental formation;
- (ii) Germ Cell--A sperm (including a spermatid and a spermatocyte whose number of chromosomes is equal to the number of chromosomes of the sperm; the same applies hereinafter) and an Unfertilized Egg;
- (iii) Unfertilized Egg--An unfertilized ovum and oocyte (limited to an oocyte whose number of chromosomes is equal to the number of chromosomes of the ovum);
- (iv) Somatic Cell--A cell (except for a Germ Cell) taken from an individual (including a dead individual) or a Fetus (including a dead Fetus) belonging to

- the class Mammalia, or a cell produced by division of the relevant cell, excluding an Embryo or a cell constituting an Embryo;
- (v) Embryonic Cell--A cell taken from an Embryo or a cell produced by division of the relevant cell, excluding an Embryo;
 - (vi) Human Fertilized Embryo--An Embryo produced by fertilization between a human Sperm and a human Unfertilized Egg (including each Embryo which is produced successively by single or multiple splitting of the relevant Embryo and is not a Human Split Embryo);
 - (vii) Fetus--A cell group lying in utero of a human or an Animal which has the potential to grow into an individual through the process of development in utero and has begun formation of a placenta, and which is to include the placenta and other appendages;
 - (viii) Human Split Embryo--An Embryo produced by splitting ex utero of a Human Fertilized Embryo or a Human Embryonic Nuclear Transfer Embryo;
 - (ix) Human Embryonic Nuclear Transfer Embryo--An Embryo produced by Fusion between a Human Enucleated Egg and a Human Fertilized Embryo or Human Split Embryo at the one-cell stage or an Embryonic Cell with a cell nucleus of a Human Fertilized Embryo, Human Split Embryo or Human-Human Chimeric Embryo;
 - (x) Human Somatic Cell Nuclear Transfer Embryo--An Embryo produced by Fusion between a Human Enucleated Egg and a human Somatic Cell with a cell nucleus (including each Embryo produced successively by single or multiple splitting of the relevant Embryo);
 - (xi) Cloning Techniques--The techniques for producing a Human Somatic Nuclear Transfer Embryo;
 - (xii) Human-Human Chimeric Embryo--Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of the relevant Embryo):
 - (a) an Embryo produced as a result of aggregation of two or more of Human Fertilized Embryos, Human Split Embryos, Human Embryonic Nuclear Transfer Embryos or Human Somatic Cell Nuclear Transfer Embryos (including an Embryo produced as a result of aggregation of the relevant Embryo and either a Human Somatic Cell or an Embryonic Cell of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo or Human Somatic Cell Nuclear Transfer Embryo);
 - (b) an Embryo produced as a result of aggregation of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo, or Human Somatic Cell Nuclear Transfer Embryo and either a human Somatic Cell or an Embryonic Cell of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo or

- Human Somatic Cell Nuclear Transfer Embryo;
- (xiii) Human-Animal Hybrid Embryo--Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of the relevant Embryo):
 - (a) an Embryo produced by fertilization between a human Germ Cell and an Animal Germ Cell;
 - (b) an Embryo produced by Fusion between a human or Animal Enucleated Egg and an Embryo at the one-cell stage described in (a) or an Embryonic Cell with a cell nucleus of an Embryo described in (a);
 - (xiv) Human-Animal Clone Embryo--Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of the relevant Embryo):
 - (a) an Embryo produced by Fusion between an Animal Enucleated Egg and either a human Somatic Cell or a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo or Human Somatic Cell Nuclear Transfer Embryo at the one-cell stage or an Embryonic Cell with a cell nucleus of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo, Human Somatic Cell Nuclear Transfer Embryo or Human-Human Chimeric Embryo;
 - (b) an Embryo produced by Fusion between a Human Enucleated Egg and an Embryo at the one-cell stage described in (a) or an Embryonic Cell with a cell nucleus of an Embryo described in (a);
 - (xv) Human-Animal Chimeric Embryo--Any of the following Embryos which is not a Human-Human Chimeric Embryo, Animal Embryo or Animal-Human Chimeric Embryo (including each Embryo produced successively by single or multiple splitting of the relevant Embryo):
 - (a) an Embryo produced as a result of aggregation of two or more Embryos (including an Embryo produced as a result of aggregation of the relevant Embryo and Somatic or Embryonic Cell);
 - (b) an Embryo produced as a result of aggregation of an Embryo and a Somatic or Embryonic Cell;
 - (c) an Embryo produced by Fusion between an Embryonic Cell with a cell nucleus of an Embryo listed in (a) or (b) and a human or Animal Enucleated Egg;
 - (xvi) Specified Fusion/Aggregation Techniques--Techniques to produce a Human-Animal Hybrid Embryo, Human-Animal Clone Embryo or Human-Animal Chimeric Embryo;
 - (xvii) Animal--An individual except for a Human belonging to the class Mammalia;
 - (xviii) Animal Embryo--Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of the relevant Embryo):

- (a) an Embryo produced by fertilization between an Animal sperm and an Animal Unfertilized Egg;
 - (b) an Embryo produced by Fusion between an Animal Enucleated Egg and either an Animal Somatic Cell or an Embryo at the one-cell stage described in (a) or an Embryonic Cell with a cell nucleus of an Embryo described in (a);
 - (c) an Embryo produced as a result of aggregation of two or more Embryos listed in (a) or (b) (including an Embryo produced as a result of aggregation of the relevant Embryo and either an Animal Somatic Cell or an Embryonic Cell of an Embryo listed in (a) or (b));
 - (d) an Embryo produced as a result of aggregation of an Embryo listed in (a) or (b) and either an Animal Somatic Cell or an Embryonic Cell of an Embryo listed in (a) or (b);
- (xix) Animal-Human Clone Embryo--Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of the relevant Embryo):
- (a) an Embryo produced by Fusion between a Human Enucleated Egg and either an Animal Somatic Cell or an Animal Embryo at the one-cell stage or an Embryonic Cell with a cell nucleus of an Animal Embryo;
 - (b) an Embryo produced by Fusion between an Animal Enucleated Egg and either an Embryo at the one-cell stage described in (a) or an Embryonic Cell with a cell nucleus of an Embryo described in (a);
- (xx) Animal-Human Chimeric Embryo--Any of the following Embryos (including each Embryo produced successively by single or multiple splitting of the relevant Embryo):
- (a) an Embryo produced as a result of aggregation of two or more Animal-Human Clone Embryos (including an Embryo produced as a result of aggregation of the relevant Embryo and a Somatic or Embryonic Cell);
 - (b) an Embryo produced as a result of aggregation of one or more Animal-Human Clone Embryos and one or more Animal Embryos or Somatic or Embryonic Cells;
 - (c) an Embryo produced as a result of aggregation of one or more Animal Embryos and Human Somatic Cells or Embryonic Cells of a Human Fertilized Embryo, Human Split Embryo, Human Embryonic Nuclear Transfer Embryo, Human Somatic Cell Nuclear Transfer Embryo, Human-Human Chimeric Embryo, Human-Animal Hybrid Embryo, Human-Animal Clone Embryo, Human-Animal Chimeric Embryo or Animal-Human Clone Embryo (including an Embryo produced as a result of aggregation of the relevant Embryo and either an Animal Somatic Cell or an Embryonic Cell of an Animal Embryo);
 - (d) an Embryo produced by Fusion between a Human or Animal Enucleated

- Egg and an Embryonic Cell with a cell nucleus of an Embryo listed in (a) through (c);
- (xxi) Fusion--Production of a single cell through combination of more than one cell without fertilization, which includes transfer of the nucleus of a single cell to another enucleated cell
- (xxii) Enucleation--Removal of the nucleus from a cell or destruction of the nucleus of a cell
- (xxiii) Human Enucleated Egg--An enucleated human Unfertilized Egg or an enucleated Human Fertilized Embryo or Human Split Embryo at the one-cell stage
- (xxiv) Animal Enucleated Egg--An enucleated Animal Unfertilized Egg or an enucleated Animal Embryo at the one-cell stage
- (2) With regard to application of the provisions shown in Column A of the following table, an Embryo or cell shown in Column B of the same table is regarded as an Embryo or cell shown in Column C of the same table which is mentioned in the relevant provisions.

Column A	Column B	Column C
Article 2(1)(viii)	Human Split Embryo	Human Fertilized Embryo
Article 2(1)(ix)	Human Embryonic Nuclear Transfer Embryo	Human Fertilized Embryo
Article 2(1)(x)	Human Somatic Cell Nuclear Transfer Embryo at the one-cell stage, or Embryonic Cell of a Human Somatic Cell Nuclear Transfer Embryo	Human Somatic Cell
Article 2(1)(xii)(a) and (b)	Embryonic Cell of a Human-Human Chimeric Embryo	Embryonic Cell of a Human Somatic Cell Nuclear Transfer Embryo
Article 2(1)(xiii)(b)	Human-Animal Hybrid Embryo	Embryo described in (a)
Article 2(1)(xiv)(a)	Human-Animal Clone Embryo	Human Somatic Cell Nuclear Transfer Embryo
Article 2(1)(xiv)(b)	Human-Animal Clone Embryo	Embryo described in (a)

Article 2(1)(xviii)(b) i i i)	Animal Embryo	Embryo described in (a)
Article 2(1)(xviii)(c) and (d))	Embryonic Cell of an Animal Embryo	Embryonic Cell of an Embryo described in (a)
Article 2(1)(xix)(a))	Animal-Human Clone Embryo	Animal Embryo
Article 2(1)(xix)(b) i)	Animal-Human Clone Embryo	Embryo described in (a)
Article 2(1)(xx)(c) i i)	Embryonic Cell of an Animal-Human Chimeric Embryo	Embryonic Cell of an Animal Embryo
Article 2(1)(xxiii) i i i)	Human Embryonic Nuclear Transfer Embryo or Human Somatic Cell Nuclear Transfer Embryo	Human Fertilized Embryo
Article 2(1)(xxiv) i v)	Human-Animal Hybrid Embryo, Human-Animal Clone Embryo or Animal-Human Clone Embryo	Animal Embryo

(Prohibited acts)

Article 3 No person must transfer a Human Somatic Cell Nuclear Transfer Embryo, Human-Animal Hybrid Embryo, Human-Animal Clone Embryo or Human-Animal Chimeric Embryo into a human or Animal uterus.

(Guidelines)

Article 4 (1) The Minister of Education, Culture, Sports, Science and Technology (hereinafter referred to as the "Minister") must, in light of the risk that a Human Split Embryo, Human Embryonic Nuclear Transfer Embryo, Human Somatic Cell Nuclear Transfer Embryo, Human-Human Chimeric Embryo, Human-Animal Hybrid Embryo, Human-Animal Clone Embryo, Human-Animal Chimeric Embryo, Animal-Human Clone Embryo or Animal-Human Chimeric Embryo (hereinafter referred to as a "Specified Embryo") could,

when transferred into a human or Animal uterus, develop into a Human Clone Individual or Hybrid Individual or an individual that has an equivalent effect on the Preservation of Human Dignity, etc., establish guidelines on the handling of Specified Embryos (hereinafter referred to as the "Guidelines") while taking into consideration scientific knowledge related to the clarification of the phenomenon of life, in order to secure appropriate production, receipt by assignment or import and subsequent handling of Specified Embryos (hereinafter referred to as the "Handling of Specified Embryos").

(2) The Guidelines are to prescribe the following matters:

(i) matters concerning the requirement of consent by the donor of the Embryos or cells necessary for production of a Specified Embryo and other requirements for allowable production of Specified Embryos

(ii) beyond what is listed in the preceding item, matters concerning the requirements for allowable Handling of Specified Embryos

(iii) beyond what is listed in the preceding two items, procedures and other matters to be considered in the Handling of Specified Embryos

(3) When the Minister intends to establish or change the Guidelines, that minister must consult the heads of the relevant administrative organs and hear the opinions of the Council for Science and Technology Policy in advance.

(4) When the Minister establishes or changes the Guidelines, the minister must announce the relevant establishment or change without delay.

(Compliance obligation)

Article 5 The Handling of Specified Embryos must be conducted in accordance with the Guidelines.

(Notification of production, receipt by assignment or import of Specified Embryo)

Article 6 (1) A person who intends to produce, receive by assignment or import a Specified Embryo must notify the following matters to the Minister pursuant to the provisions of an Order of the Ministry of Education, Culture, Sports, Science and Technology (hereinafter referred to as an "Order of MEXT"):

(i) the name and domicile and, in the case of a juridical person, the name of its representative

(ii) the type of the Embryo to be produced, to be received by assignment, or to be imported

(iii) the purpose of production, receipt by assignment or import and, in the case of production, its method

(iv) the scheduled date of production, receipt by assignment or import

(v) the method of the handling after the production, receipt by assignment or import

(vi) beyond what is listed in the preceding items, matters specified by an Order of MEXT

- (2) If a person who has made the notification under the preceding paragraph intends to change any matters pertaining to the notification, that person must notify such change to the Minister pursuant to the provisions of an Order of MEXT.

(Order to change or abolish the plan)

Article 7 (1) Where the notification under paragraph (1) or (2) of the preceding Article has been made, if the Minister finds that the Handling of the Specified Embryo pertaining to the notification does not conform to the Guidelines, the minister may, within sixty days from the date of acceptance of the notification, order the person who has made the notification to change or abolish the plan concerning the method of the relevant Handling of the Specified Embryo or to take other necessary measures.

- (2) If the Minister finds that the contents of the matters pertaining to the notification under paragraph (1) or (2) of the preceding Article are reasonable, the minister may shorten the period prescribed in the preceding paragraph. In this case, the Minister must give notice of the shortened period to the person who has made the notification, without delay.

(Limitation on execution)

Article 8 A person who has made the notification under Article 6, paragraph (1) or (2) must not produce, receive by assignment or import the Specified Embryo pertaining to the notification, or change any matters pertaining to the notification until sixty days (if the notice under the second sentence of paragraph (2) of the preceding Article has been served, the period pertaining to the notice) have passed from the date of acceptance of the notification.

(Notification of production of Specified Embryo by chance cause)

Article 9 A person who has made the notification under Article 6, paragraph (1) must, in the case the Specified Embryo pertaining to the notification has produced a different type of Specified Embryo by a chance cause, promptly notify the following matters to the Minister pursuant to the provisions of an Order of MEXT; provided, however, that this does not apply to the case where the relevant produced Specified Embryo is immediately disposed of:

- (i) the name and domicile and, in the case of a juridical person, the name of its representative;
- (ii) the type of the produced Embryo;
- (iii) the date of the production;
- (iv) beyond what is listed in the preceding three items, matters specified by an

Order of MEXT.

(Record)

Article 10 (1) A person who has made the notification under Article 6, paragraph (1) or the preceding Article must make a record of the following matters with regard to the Specified Embryo pertaining to the notification, pursuant to an Order of MEXT:

(i) the type of the Embryo which has been produced, received by assignment or imported;

(ii) the date of production, receipt by assignment or import;

(iii) the process of the handling after production, receipt by assignment or import;

(iv) beyond what is listed in the preceding three items, matters specified by an Order of MEXT.

(2) The record prescribed in the preceding paragraph must be preserved pursuant to the provisions of an Order of MEXT.

(Notification of assignment of Specified Embryo)

Article 11 A person who has made the notification under Article 6, paragraph (1) or Article 9 must, in the case that person has assigned, exported, destroyed or disposed of the Specified Embryo pertaining to the notification, notify the following matters to the Minister without delay, pursuant to the provisions of an Order of MEXT:

(i) the name and domicile and, in the case of a juridical person, the name of its representative;

(ii) the type of the Embryo which has been assigned, exported, destroyed or disposed of;

(iii) the date of the assignment, export, destruction or disposal and, in the case of destruction or disposal, the manner of destruction or disposal;

(iv) beyond what is listed in the preceding three items, matters specified by an Order of MEXT.

(Order to take measures with regard to the Handling of Specified Embryo)

Article 12 If the Minister finds that the Handling of a Specified Embryo by a person who has made the notification under Article 6, paragraph (1) or Article 9 does not conform to the Guidelines, the minister may order the person who has made the notification to discontinue or improve the method of the Handling of the Specified Embryo or to take other necessary measures.

(Protection of personal information)

Article 13 A person who has made the notification under Article 6, paragraph (1)

or Article 9 must endeavor to take necessary measures for the prevention of disclosure of Personal Information (information about an individual, which can identify the specific individual by name, date of birth or other description contained in the information (including information that can be compared with other information and thereby identify the specific individual); hereinafter the same applies in this Article) of the donor of the Embryos or cells used for producing the Specified Embryo pertaining to the notification, and for the proper management of the Personal Information.

(Collection of report)

Article 14 The Minister may, within the limit necessary for enforcement of this Act, ask a person who has made the notification under Article 6, paragraph (1) or Article 9 to report on the state of the Handling of the Specified Embryo pertaining to the notification and of other necessary matters.

(Entry and Inspection)

Article 15 (1) The Minister may, within the limit necessary for enforcement of this Act, have officials of the ministry enter the office or research facility of a person who has made the notification under Article 6, paragraph (1) or Article 9, inspect documents and other necessary materials of the relevant person, and ask questions of the persons concerned.

(2) When an official enters the office or research facility pursuant to the provisions of the preceding paragraph, that person must carry a certificate for identification and produce it upon request of the persons concerned.

(3) The authority under paragraph (1) must not be construed as that approved for the purpose of criminal investigation.

(Penal Provisions)

Article 16 A person who has violated the provisions of Article 3 is punished by imprisonment for not more than ten years or a fine of not more than ten million yen, or both.

Article 17 A person who falls under any of the following items is punished by imprisonment for not more than one year or a fine of not more than one million yen:

(i) a person who has, without making the notification under Article 6, paragraph (1) or by making false notification, produced, received by assignment or imported a Specified Embryo;

(ii) a person who has, without making the notification under Article 6, paragraph (2) or by making false notification, changed the matters prescribed in the same paragraph;

- (iii) a person who has violated the order prescribed in Article 7, paragraph (1);
- (iv) a person who has violated the order prescribed in Article 12.

Article 18 A person who has violated the provisions of Article 8 is punished by imprisonment for not more than six months or a fine of not more than five hundred thousand yen.

Article 19 A person who falls under any of the following items is punished by a fine of not more than five hundred thousand yen:

- (i) a person who has failed to make the notification under Article 9 or has made false notification;
- (ii) a person who has failed to make the record under Article 10, paragraph (1) or has made a false record;
- (iii) a person who has violated the provisions of Article 10, paragraph (2);
- (iv) a person who has failed to make the notification under Article 11 or has made false notification;
- (v) a person who has failed to make the report under Article 14 or has made a false report;
- (vi) a person who has defied, obstructed or evaded the entry or inspection, or has failed to make a statement or has made a false statement in response to the question under Article 15, paragraph (1).

Article 20 When the representative of a juridical person, or an agent, employee or other worker of a juridical person or individual has committed an act in violation of the provisions from Article 16 through the preceding Article with regard to the business of the relevant juridical person or individual, not only the offender is punished but also the relevant juridical person or individual is punished by the fine prescribed in the respective Articles.

Supplementary Provisions

(Effective Date)

Article 1 This Act comes into effect as of the day on which six months from the date of promulgation have elapsed; provided, however, that the following provisions come into effect as of the date described in each item:

- (i) the provisions of Article 4, paragraph (3) of this Act and Article 3 of the Supplementary Provisions--the date of promulgation;
- (ii) the provisions of Article 4, paragraphs (1), (2) and (4), from Articles 5 through 15, from Articles 17 through 19 and Article 20 (limited to the portion pertaining to Articles 17 through 19) of this Act--the day specified by a Cabinet Order within a period not exceeding one year from the date of

promulgation,

(Review)

Article 2 Within three years of enforcement of this Act, the Government is to review the provisions of this Act based on the results of study by the Council for Science and Technology Policy and others on how Human Fertilized Embryos should be handled as the emerging potential of human life, while taking into consideration the state of enforcement of this Act and changes in the circumstances surrounding the Cloning Techniques, etc., and take necessary measures based on the results of the review.

(Transitional measures)

Article 3 With regard to application of the provisions of Article 4, paragraph (3), during the period from the date of promulgation of this Act until the day before the effective date (January 6, 2001) of the Act for Partial Revision of the Cabinet Act (Act No. 88 of 1999), the term "Minister of Education, Culture, Sports, Science and Technology" in the same paragraph is deemed to be replaced with "Prime Minister," and the term "Council for Science and Technology Policy" is deemed to be replaced with "Council for Science and Technology" .

(Partial amendment of the Act for Punishment of Organized Crimes, Control of Crime Proceeds and Other Matters)

Article 4 A part of the Act on Punishment of Organized Crimes and Control of Crime Proceeds (Act No. 136 of 1999) is amended as follows.

The following item is added to the appended table:

(lxi) an offense prescribed in Article 16 (Transfer of a Human Somatic Clone Embryo or other Specified Embryo into a human or Animal uterus) of the Act on Regulation of Human Cloning Techniques (Act No. 146 of 2000)