A Bill
entitled

AN ACT to provide for the protection of human embryos and other ancillary matters.

BE IT ENACTED by the President, by and with the advice and consent of the House of Representatives, in this present Parliament assembled, and by the authority of the same as follows:-

1. (1) The short title of this Act is the Embryo Protection Act, 2012. Short title and commencement.

(2) This Act shall come into force on such date as the Minister responsible for justice, with the concurrence of the Minister responsible for health, may by notice in the Gazette establish, and different dates may be so established for different provisions and different purposes thereof.

2. In this Act, unless the context otherwise requires:- Interpretation.

"Authority" means the Embryo Protection Authority established by article 3;

"the Council" means the Medical Council established by article 9 of the Health Care Professions Act; Cap. 464.

"embryo" means the fertilisation of a human egg cell by a human sperm cell which is capable of developing and shall further include each totipotent cell removed from an embryo or otherwise produced, that is assumed to be able to divide and to develop as a human being under the appropriate conditions;

"germ line cells" means all egg and sperm cells which may lead to the resultant human being;

"health care professional" shall have the same meaning assigned Cap. 464.

to it by article 2 of the Health Care Professions Act;

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"medical practitioner" means a person licensed under the Health Care Professions Act to practice as a medical practitioner;

"Minister" means the Minister responsible for health;

"prospective parent" means either of two persons of the opposite sex who are united in marriage, or who have attained the age of majority and are in a stable relationship with each other.

Establishment and composition of the Embryo Protection Authority.

3. (1) There shall be a body, to be known as the Embryo Protection Authority, which shall consist of a chairman and such number of other members not being less than four who shall be appointed by the Minister.

(2) A person shall not be qualified to hold office as a member of the Authority if he:

(a) is a Minister or Parliamentary Secretary;

(b) is a member of, or a candidate for election to, the House; or

(c) is a member of a local government authority; or

(d) has a financial or other interest in any enterprise or activity which is likely to affect the discharge of his functions as a member of the Authority.

(3) Subject to the provisions of this article, the office of a member of the Authority shall become vacant -

(a) at the expiration of five years from the date of his appointment or at such earlier time as may be specified in the instrument by which he was appointed; or

(b) if any circumstances arise that, if he were not a member of the Authority, would cause him to be disqualified for appointment as such.

(4) A member of the Authority may be removed from office by the Minister if, in the opinion of the Minister, such member is unfit to continue in office or has become incapable of properly performing his duties as a member, whether arising from infirmity of mind or body or any other cause, or for misbehaviour.

(5) If the office of a member of the Authority is vacant or if a member is for any reason unable to perform the functions of his office, the Minister may appoint another person as a temporary member of the Authority until the member who was unable to perform the functions of his office resumes those functions.

(6) The members of the Authority, in the exercise of their functions, shall act on their own individual judgement and shall not be subject to the direction or control of any person or authority.

Functions and powers of the Authority.

4. (1) The functions and powers of the Authority shall be the following:

(a) to ensure that high standards of ethics are maintained by all medical practitioners, paramedics and other personnel involved in procedures of medically assisted procreation;

(b) to issue licences to clinics that apply for registration and to carry out regular inspections in order to ensure that the standards of best practice are being respected and implemented;

(c) to issue certificates regarding eligibility of the prospective parents for treatments relating to medically assisted procreation;

(d) to keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities regulated by this Act, and advise the Minister, if he so requests, about those matters;

(e) to provide, to such extent as it considers appropriate, advice and information to persons to whom licences apply or prospective parents receiving treatment for the purpose of activities regulated by this Act, or who may wish to do so;

(f) to maintain a statement of the general principles which, in its opinion, should be followed:

(i) in carrying out its activities under this Act; and

(ii) in carrying out its functions in relation to such activities under this Act;

(g) to ensure, in relation to activities under this Act, compliance with:

(i) the obligations and requirements imposed by or under this Act; and

(ii) the codes of practice established under paragraph (a);

(h) to perform such other functions as may, from time to time, be prescribed by regulations made under this Act.

(2) Notwithstanding the provisions of article 7 but subject to the provisions of article 18, the Authority may give for adoption the fertilized egg cells, in the case where, after the fertilization of the egg cells but before the implantation of the fertilized embryos into the womb has taken place, death of the woman ensues or where for any other reason the implantation of the fertilized embryo into the womb cannot take place.

Entitlement to medically assisted procreation procedures.

5. (1) Any prospective parent shall have access to medically assisted procreation procedures:

Provided that these procedures may only be resorted to where there is a reasonable chance of success and the procedures do not entail any known undue risk to the health of the woman or the child.

(2) Any person who provides, or assists in, any medically assisted procreation procedure to a person other than a prospective parent shall be guilty of an offence and shall, on conviction, be liable to a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment:

Provided that where the person is a medical practitioner, who performs the said procedure, the medical practitioner shall be exempt from criminal liability where he shows that he took reasonable care to determine that the person on whom the procedure was performed or attempted was entitled to access to such procedure.

Unlawful procedures.

6. Whosoever –

(a) artificially fertilizes any egg cell for any purpose other than that of bringing about the pregnancy of the woman from whom the cell originated;

(b) intentionally fertilizes more than two egg cells from one woman within one treatment cycle;

(c) does not transfer all embryos produced into a

woman within one treatment cycle;

(d) removes an embryo from a woman before the completion of implantation in the womb in order to transfer the embryo to another woman;

(e) selects or discards an embryo for eugenic purposes;

(f) carries out an artificial fertilization of, or transfers a human embryo into, a woman who is prepared to give up her child permanently after birth (surrogate mother),

shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment:

Provided that -

(i) the woman from whom the egg cell or embryo originated, in respect of the conduct referred to in paragraphs (a) and (d); and, or

(ii) the woman into whom the egg cell or embryo will be transferred, in respect of the conduct referred to in paragraph (f);

shall have the punishment decreased by one or two degrees.

Prohibition of preservation of embryos.

7. All forms of preservation, including cryo-preservation of embryos are prohibited and whosoever contravenes this article shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment:

Provided that where the transfer of the fertilized embryos into the womb is not possible owing to grave and certified *force majeure* not predictable at the moment of fertilization, it shall be lawful to preserve such embryos up to the date of such transfer which shall take place as soon as possible:

Provided further that when there has been a breach of any provision of this Act, the Authority may order the freezing of any embryo to preserve its life.

Improper use of human embryos.

8. (1) Whosoever, other than for the purpose of implantation in a woman as may be authorized by the provisions of this Act disposes of, hands over or acquires a human embryo produced outside the body, or removes such embryo from a woman before the completion of implantation in the womb, shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment.

(2) Whosoever causes a human embryo to develop further outside the body for any purpose other than in order to bring about a pregnancy, shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment.

Improper use etc., of gametes.

9. The use, transfer or the fertilisation of any germ line cells not originating from the prospective parent is prohibited and any person, who contravenes this article shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment:

Provided that where the person is a medical practitioner he shall be exempt from criminal liability where he shows that he took reasonable care to determine that the person from whom the germ line cells originated was a prospective parent within the meaning of this Act.

Prohibition of selection of sex.

10. (1) Whosoever artificially fertilizes a human egg cell with a sperm cell that is selected for the sex chromosome contained in it, shall be guilty of an offence and, on conviction, shall and liable to the punishment of a fine (*multa*) of not less than four thousand euro (€4,000) and not exceeding ten thousand euro (€10,000).

(2) Nothing contained in sub-article (1) shall be understood as preventing the selection of a sperm cell by a medical practitioner in order to preserve the child from falling ill with a sex-linked genetic illness.

Prohibition of cloning.

11. (1) Any intervention seeking to create a human being genetically identical to another embryo, *foetus*, or human being, whether living or dead, is prohibited and for the purpose of this article, the term "genetically identical" means a human being sharing with another the same nuclear gene set.

(2) Whosoever intervenes or participates in any artificial intervention as referred to in sub-article (1) shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment.

(3) Whosoever transfers into a woman an embryo as referred to in sub-article (1) shall be liable to the same punishment laid down in sub-article (2).

Unauthorised fertilisation, embryo transfer, and artificial fertilisation after death.

12. Whosoever -

(a) artificially fertilizes an egg cell without the consent of the woman, whose egg cell is to be fertilized, or without the consent of the man, whose sperm cell will be used for fertilization;

(b) transfers an embryo into a woman without her consent;

(c) knowingly artificially fertilizes an egg cell with the sperm of a man after his death,

(d) knowingly artificially fertilizes an egg cell of a woman after her death,

shall be guilty of an offence and shall, on conviction, be liable to a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-five thousand euro (€25,000):

Provided that the punishment shall be decreased by one or two degrees -

(i) as regards the woman whose egg has been fertilized, in respect of paragraph (c); and

(ii) as regards the man whose sperm was used for fertilisation in respect of paragraph (d).

Prohibition of artificial alteration of human germ line cells.

13. (1) Subject to the provisions of sub-article (3), whosoever shall willfully alter in an artificial way the genetic information of a human germ line cell shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment.

(2) Whosoever knowingly uses a human germ line cell with artificially altered genetic information for fertilization shall be guilty of an offence and shall be liable to the same punishment laid down in sub-article (1).

(3) No offence shall arise, against the medical practitioner carrying out the medically assisted procedure, under sub-article (1) where the alteration of the genetic information of a germ line cell is the unintended consequence of inoculation, radiation or chemotherapeutic or treatment.

Prohibition of formation of chimerae and hybrids.

14. (1) Whosoever-

(a) unites embryos with different genetic material to a cell conglomerate using at least one human embryo; or

(b) joins a human embryo with a cell that contains genetic information different from the embryo cells and induces them to develop further; or

(c) fertilizes a human egg cell with the sperm of an animal or fertilizes an animal's egg cell with the sperm of a man, with the intention of generating an embryo capable of development,

shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) not less than ten thousand euro (€10,000) and not exceeding seventy thousand euro (€70,000) or to imprisonment not exceeding seven years or to both such fine and imprisonment.

(2) Whosoever transfers to a woman or an animal an embryo arising out of a procedure described in sub-article (1) or transfers to an animal a human embryo shall be guilty of an offence and shall be liable to the same punishment laid down in sub-article (1).

Prohibition of experimentation on human embryos.

15. (1) Any experimentation on human embryos is prohibited and whosoever contravenes this sub-article shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) not exceeding seventy thousand euro (€70,000) and to imprisonment not exceeding seven years.

(2) The creation of human embryos for the purpose of research or experimentation or for any other purpose not permitted under this Act is prohibited and whosoever contravenes this sub-article shall be guilty of an offence and shall be liable to the same punishment laid down in sub-article (1).

(3) Clinical interventions on a human embryo are allowed on condition that said interventions pursue an exclusively diagnostic and, or therapeutic purpose related to the embryo and are in the interests of the health and development of the embryo itself:

Provided that no other alternative medical method or procedure is available and the consent of the prospective parents has been given in writing and there is no undue risk to the embryo and to the mother.

Wilful destruction of embryos.

16. (1) Whosoever willfully destroys any embryo shall be guilty of an offence and shall, on conviction, be liable to a fine (*multa*) not exceeding twelve thousand euro (€12,000) or to imprisonment not exceeding two years or to both such fine and imprisonment.

(2) This article shall also apply to any human clone created in breach of article 11.

Application of articles 121D and 248E(3) of the Criminal Code. Cap. 9

17. The provisions of articles 121D and 248E(4) of the Criminal Code shall, *mutatis mutandis*, apply to persons found guilty of an offence under this Act.

Informed consent.

18. (1) The consent of both prospective parents who are to have access to medically assisted procreation procedures is to be expressed jointly in writing in such form, as may be prescribed by regulations under this Act, to, and in the presence of the medical practitioner in charge of the procedure:

Provided that such consent may only be withdrawn in writing by either of the prospective parent before fertilisation.

(2) For the purposes of informed consent and before applying any procedure leading to medically assisted procreation, the medical practitioner in charge of the procedure shall inform in detail and in writing both prospective parents on:

(a) the methods and treatment of any procedure to be employed;

(b) the complications that may arise for the woman and potential offspring;

(c) the probable chances of success of the said procedure;

(d) all the risks involved to both prospective parents and the offspring;

(e) the possible psychological effects as a result of the application of the said procedure to both prospective parents and offspring;

(f) the bioethical issues, including the freezing process involved as referred to in article 4(2); and

(g) where applicable, on the cost of the entire procedure.

(3) The medical practitioner in charge of the procedure shall ensure that the prospective parents receive proper counselling as approved by the Authority prior to the procedure.

Status of child born.

19. Any child born as a result of any medically assisted procreation procedure shall be considered to be the child of the prospective parents who have expressed their consent in writing as provided in article 18 and shall for all intents and purposes of law be deemed to have been naturally born of the same prospective parents without the intervention of any procedure as aforesaid; and notwithstanding the provision of any other law, any such child shall be registered in any act of civil status as the direct descendant of such prospective parents who shall enjoy such rights and bear such duties according to law in respect of such child.

Conscientious objection.

20. (1) A health care professional is under no obligation to participate in any procedure for the application of any technique of medically assisted procreation regulated by this Act when such professional considers such participation objectionable as a matter of conscience and declares his objection beforehand. Such a declaration shall be communicated within three months from the coming into force of this Act to the director of the hospital or medical establishment with whom the health care professional is employed.

(2) The objection declared as provided in sub-article (1) may be revoked or the said objection may be declared even after the lapse of the period referred to in sub-article (1) but in such a case the declaration raising the objection shall only come into effect after the lapse of a month from the date of its communication as provided in sub-article (1).

(3) The objection declared as provided in sub-articles (1) or (2) shall have the effect of exempting the health care professional who makes the declaration from any participation in any procedure or activity specifically and necessarily directed towards the

implementation of the technique or procedure leading to a medically assisted procreation but does not exempt him from providing assistance before or after the said procedure or activity.

Additional penalties.

21. Without prejudice to any punishment as may be prescribed by this Act or by any other law, where the person convicted of an offence under this Act is a medical practitioner or a health care professional, the Court shall order that a copy of the judgment be served upon the competent council under the Health Care Professions Act and on the Minister.

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Licence for premises.

22. (1) Premises may not be used for any activity relating to medically assisted procreation unless they are specifically licensed by the Authority according to the provisions of this Act.

(2) In granting such licence the Authority may attach such conditions to the licence as it deems fit and in particular, but without prejudice to its general power, such conditions as relate, according to each case, to the premises used for such medically assisted procreation, such conditions which, *inter alia,* relate to hygiene, equipment, implements, structure, space and accommodation.

(3) Whosoever commits an offence under this article and, on conviction, shall liable on conviction to a fine (*multa*) not exceeding twelve thousand euro or to imprisonment not exceeding one year or to both such fine and imprisonment.

Power to make regulations.

23. The Minister shall, with the concurrence of the Minister responsible for justice, have power to make regulations to:

(a) prescribe anything which may be prescribed for the implementation and execution of the provisions of this Act;

(b) regulate the licensing of any premises used for the execution of any procedure of medically assisted procreation including the conditions required for a medical practitioner to practice any such procedure in such premises;

(c) lay down any conditions for the execution of such procedures of medically assisted procreation.

Objects and Reasons

The objects of this Bill are to regulate the procedure relating to medically assisted procreation and to protect human embryos.